Acute Care Services Committee

-- Tentative Agenda --

Tuesday; September 4, 2007

10:00 a.m. – The McKimmon Center – Raleigh, NC

I. Welcome and Announcements — Michael Tarwater, Chairman

II. Approval of Minutes from the May 14, 2007 Meeting — Committee Members

III. Issues related to Acute Care Beds — Victoria McClanahan

A. Review of Revised AC Bed Need Projections (*Using Corrected Growth Factor Data*)
B. Update on Data Discrepancy Correction Process
C. Consideration of AC Beds Petition and Agency Report:
Cape Fear Valley Health System
D. Other Issues Related to Acute Care Beds
E. Development of Recommendation to the SHCC regarding Acute Care Beds

IV. Issues related to Operating Rooms — Ms. McClanahan

A. Consideration of OR Petitions 1-5 and Agency Report:
OR Petition 1: Franklin Regional Medical Center
OR Petition 2: Park Ridge Hospital
OR Petition 3: Pitt County Memorial Hospital
OR Petition 4: Randolph Hospital
OR Petition 5: Rex Hospital
B. Consideration of OR Petitions 6 and 7 and Agency Report:
OR Petition 6: Mecklenburg Foot and Ankle Associates and Diabetic Foot Clinic, P.C.
OR Petition 7: Raleigh Orthopaedic Clinic
C. Review of OR Comments (Not related to Petitions)
D. Development of Recommendation to the SHCC regarding Operating Rooms

V. Issues related to Other Acute Care Services — Committee Members

A. No Petitions or Comments were received regarding this Chapter
B. Development of Recommendation to the SHCC regarding Other ACS

VI. Issues related to Inpatient Rehabilitation Bed Need Projections — Committee Members

A. No Petitions or Comments were received regarding this Chapter
B. Development of Recommendation to the SHCC regarding Inpat. Rehab. Beds

VII. Adjournment — Mr. Tarwater

Revised Acute Care Bed Need Projections

Tables 5A and 5B

Revised as of 7.19.07

Supersedes Table 5A published in the Proposed 2008 SMFP

Corrected Table 5A: Acute Care Bed Need Projections

(2006 Utilization Data from "Solucient" as compiled by the Cecil G. Sheps Center for Health Services Research)

Projection based on Growth Factor at 0.47% per year for the next 6 years. Target Occupancy Factors: ADC less than 100 = 150%, ADC of 100-200 = 140%, and ADC greater than 200 = 133%

A	B	C	D	E	F	G	H	I	J	K
Fac #	Facility Name	County	Licensed AC Beds	Adjustments for LOSs & Prev. Need	"Solucient" 2006 Acute Care Days	6 Years Growth at 0.47% annually	2012 Projected Average Daily Census (ADC)	2012 Beds Adjusted for Target Occ	Projected 2012 Deficit (-) = Surplus	2012 Need Determination
H0272	Alamance Regional Medical Center, Inc.	Alamance	182	0	40,888	42,055	115	161	-21	0
H0274	Frye Reg. Med. Ctr.-Alexander Campus	Alexander	25	0	0	0	0	0	-25	0
H0108	Alleghany Memorial Hospital	Alleghany	41	0	2,602	2,676	7	11	-30	0
H0082	Anson Community Hospital	Anson	52	0	5,962	6,132	17	25	-27	0
H0099	Ashe Memorial Hospital, Inc	Ashe	76	0	5,507	5,664	16	23	-53	0
H0037	Charles A. Cannon, Jr. Memorial Hospital, Inc	Avery	40	0	6,505	6,691	18	27	-13	0
H0002	Pungo District Hospital Corporation	Beaufort	39	0	2,289	2,354	6	10	-29	
H0188	Beaufort County Hospital	Beaufort	120	0	11,416	11,742	32	48	-72	
	Totals for Beaufort County		159	0						0
H0268	Bertie Memorial Hospital	Bertie	6	0	1,470	1,512	4	6	0	0
H0154	Bladen County Hospital	Bladen	48	0	4,534	4,663	13	19	-29	0
H0250	Brunswick Community Hospital	Brunswick	60	14	12,197	12,545	34	52	-22	
H0150	J. Arthur Dosher Memorial Hospital	Brunswick	36	0	4,577	4,708	13	19	-17	
	Totals for Brunswick County:		96	14						0
H0036	Mission Hospitals, Inc	Buncombe	673	0	176,440	181,474	497	661	-12	0
H0062	Grace Hospital, Inc.	Burke	182	-20	20,897	21,493	59	88	-74	
H0091	Valdese General Hospital, Inc.	Burke	131	0	12,439	12,794	35	53	-78	
	Totals for Burke County:		313	-20						0
H0031	NorthEast Medical Center	Cabarrus	447	0	92,686	95,331	261	347	-100	0
H0061	Caldwell Memorial Hospital, Inc	Caldwell	110	0	15,986	16,442	45	68	-42	0
H0222	Carteret General Hospital	Carteret	135	0	26,046	26,789	73	110	-25	0
H0053	Frye Regional Medical Center	Catawba	209	0	49,159	50,562	139	194	-15	0
H0223	Catawba Valley Medical Center	Catawba	200	0	35,928	36,953	101	142	-58	0
	Totals for Catawba County		409	0						0
H0007	Chatham Hospital, Inc.	Chatham	68	-43	2,638	2,713	7	11	-14	0
H0239	Murphy Medical Center, Inc	Cherokee	57	0	8,400	8,640	24	36	-21	0
H0063	Chowan Hospital	Chowan	49	0	6,968	7,167	20	29	-20	0
H0113	Kings Mountain Hospital	Cleveland	72	0	9,145	9,406	26	39	-33	
H0236	Crawley Memorial Hospital, Inc	Cleveland	60	0	21	22	0	0	-60	
H0024	Cleveland Regional Medical Center	Cleveland	241	0	44,056	45,313	124	174	-67	
	Totals for Cleveland County		373	0						0

Revised as of 7.19.07
Supersedes Table 5A published in the Proposed 2008 SMFP

Corrected Table 5A: Acute Care Bed Need Projections

(2006 Utilization Data from "Solucient" as compiled by the Cecil G. Sheps Center for Health Services Research)

Projection based on Growth Factor at 0.47% per year for the next 6 years. Target Occupancy Factors: ADC less than 100 = 150%, ADC of 100-200 = 140%, and ADC greater than 200 = 133%

A	B	C	D	E	F	G	H	I	J	K
Line #	Facility Name	County	Licensed Acute Beds	Adjustments for CON's & Prev. Need	"Solucient" 2006 Acute Care Days	6 Years Growth at 0.47% annually	2012 Projected Average Daily Census (ADC)	2012 Beds Adjusted for Target Occ	Projected 2012 Deficit (-) or Surplus	2012 Need Determination
H0045	Columbus County Hospital, Inc	Columbus	154	0	24,905	25,616	70	105	-49	0
H0201	Craven Regional Medical Center	Craven	270	37	75,750	77,911	213	284	-23	0
H0213	Cape Fear Valley Medical Center	Cumberland	397	134	134,128	137,955	378	503	-28	0
H0273	The Outer Banks Hospital, Inc.	Dare	19	2	3,862	3,972	11	16	-5	0
H0027	Lexington Memorial Hospital	Davidson	94	0	13,188	13,564	37	56	-38	
H0112	Thomasville Medical Center	Davidson	123	0	13,907	14,304	39	59	-64	
	Totals for Davidson County		217	0						0
H0171	Davie County Hospital	Davie	81	0	1,486	1,528	4	6	-75	0
H0166	Duplin General Hospital, Inc	Duplin	61	0	9,776	10,055	28	41	-20	0
H0233	Durham Regional Hospital	Durham	316	0	62,567	64,352	176	247	-69	
H0015	Duke University Hospital	Durham	924	0	236,215	242,955	666	885	-39	
	Totals for Durham Regional and Duke		1240	0					-108	0
H0075	North Carolina Specialty Hospital, LLC	Durham	18	0	3,163	3,253	9	13	-5	
	Totals for Durham County		1258	0						0
H0258	Heritage Hospital	Edgecombe	101	0	14,036	14,436	40	59	-42	0
H0209	**Forsyth Medical Center**	**Forsyth**	**637**	**114**	**204,918**	210,765	**577**	**768**	**17**	
H0229	**Medical Park Hospital, Inc.**	**Forsyth**	**136**	**-114**	**5,608**	5,768	**16**	**24**	**2**	
	Totals for Forsyth and Medical Park:		773	0					19	
H0011	North Carolina Baptist Hospitals	Forsyth	738	51	204,620	210,459	577	767	-22	
N/A	Remainder of 2006 SMFP Need Determination	Forsyth		39	0	0	0	0	0	
N/A	2007 SMFP Need Determination	Forsyth		26	0	0	0	0	0	
	Totals for Forsyth County:		1511	116						0
H0261	Franklin Regional Medical Center	Franklin	70	0	13,335	13,715	38	56	-14	0
H0105	Gaston Memorial Hospital	Gaston	372	0	92,548	95,189	261	347	-25	0
H0098	Granville Medical Center	Granville	62	0	7,072	7,274	20	30	-32	0
H0052	High Point Regional Health System	Guilford	291	0	69,036	71,006	195	272	-19	0
H0159	Moses Cone Health System	Guilford	818	-59	194,847	200,407	549	730	-29	
N/A	2007 SMFP Need Determination	Guilford		34						
	Totals for Guilford County		1109	-25						
H0004	Our Community Hospital, Inc.	Halifax	20	0	189	194	1	1	-19	
H0230	Halifax Regional Medical Center, Inc.	Halifax	186	0	31,797	32,704	90	134	-52	
	Totals for Halifax County		206	0						0

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Supersedes Table 5A published in the Proposed 2008 SMFP

Corrected Table 5A: Acute Care Bed Need Projections

(2006 Utilization Data from "Solucient" as compiled by the Cecil G. Sheps Center for Health Services Research)

Projection based on Growth Factor at 0.47% per year for the next 6 years. Target Occupancy Factors: ADC less than 100 = 150%, ADC of 100-200 = 140%, and ADC greater than 200 = 133%

A	B	C	D	E	F	G	H	I	J	K
Fac #	Facility Name	County	Licensed Acute Beds	Adjustments for CONs & Pres. Need	"Solucient" 2006 Acute Care Days	6 Years Growth at 0.47% annually	2012 Projected Average Daily Census (ADC)	2012 Beds Adjusted for Target Occ	Projected 2012 Deficit (-) = Surplus)	2012 Need Determination
H0224	**Betsy Johnson Regional Hospital**	**Harnett**	**101**	**0**	**27,957**	28,755	**79**	**118**	**17**	
N/A	Harnett Health System Central Campus	Harnett	0	50	0	0	0	0	0	
	Totals for Betsy Johnson and Harnett Health Syst:		**101**	**50**					**17**	
H0080	Good Hope Hospital, Inc. (closed effective 4/11/06)	Harnett	0	34	705	725	2	3	-31	
	Totals for Harnett County		101	84						0
H0025	Haywood Regional Medical Center	Haywood	170	0	19,998	20,569	56	85	-85	0
H0019	Park Ridge Hospital	Henderson	62	0	14,288	14,696	40	60	-2	
H0161	Margaret R. Pardee Memorial Hospital	Henderson	201	0	27,504	28,289	78	116	-85	
	Totals for Henderson County		263	11						0
H0001	Roanoke-Chowan Hospital	Hertford	86	0	15,940	16,395	45	67	-19	0
H0259	Lake Norman Regional Medical Center	Iredell	105	18	28,474	29,286	80	120	-3	
H0248	Davis Regional Medical Center	Iredell	120	-18	17,519	18,019	49	74	-28	
	Totals for Lake Norman and Davis Regional:		**225**	**0**					**-31**	0
H0164	Iredell Memorial Hospital, Incorporated	Iredell	199	0	42,880	44,104	121	169	-30	
	Totals for Iredell County:		424	0						0
H0087	Harris Regional Hospital, Inc.	Jackson	86	0	17,774	18,281	50	75	-11	0
H0151	Johnston Memorial Hospital	Johnston	155	24	38,110	39,197	107	150	-29	0
H0243	Central Carolina Hospital	Lee	127	0	19,468	20,023	55	82	-45	0
H0043	Lenoir Memorial Hospital, Inc.	Lenoir	218	0	45,366	46,660	128	179	-39	0
H0225	Carolinas Medical Center - Lincoln	Lincoln	101	0	14,065	14,466	40	59	-42	0
H0193	Highlands-Cashiers Hospital, Inc.	Macon	24	0	1,074	1,105	3	5	-19	
H0034	Angel Medical Center, Inc.	Macon	59	0	4,754	4,890	13	20	-39	
	Totals for Macon County:		83	0						0
H0078	Martin General Hospital	Martin	49	0	7,685	7,904	22	32	-17	0
H0097	The McDowell Hospital	McDowell	65	0	7,389	7,600	21	31	-34	0
H0071	**Carolinas Medical Center / Ctr. for MH**	**Mecklenburg**	**795**	**0**	**227,068**	233,547	**640**	**851**	**56**	
H0042	Carolinas Medical Center - Mercy & Pineville	Mecklenburg	294	0	54,807	56,371	154	216	-78	
H0255	Carolinas Medical Center - University	Mecklenburg	130	0	20,570	21,157	58	87	-43	
	Totals for CMC, CMC Mer Pine & CMC Univ.:		**1219**	**0**					**-65**	
H0010	**Presbyterian Hospital**	**Mecklenburg**	**463**	**76**	**149,608**	153,877	**422**	**561**	**22**	
H0282	**Presbyterian Hospital Huntersville**	**Mecklenburg**	**50**	**0**	**13,808**	14,202	**39**	**58**	**8**	
H0270	**Presbyterian Hospital Matthews**	**Mecklenburg**	**102**	**0**	**25,644**	26,376	**72**	**108**	**6**	
H0251	Presbyterian Orthopaedic Hospital	Mecklenburg	140	-76	13,001	13,372	37	55	-9	
	Totals for Presbyterian, Huntersville, Matthews & Ortho:		755	0					**27**	
	Totals for Mecklenburg County		1974	0						27

Revised as of 7.19.07

Supersedes Table 5A published in the Proposed 2008 SMFP

Corrected Table 5A: Acute Care Bed Need Projections

(2006 Utilization Data from "Solucient" as compiled by the Cecil G. Sheps Center for Health Services Research)

Projection based on Growth factor at 0.47% per year for the next 6 years. Target Occupancy Factors: ADC less than 100 = 150%, ADC of 100-200 = 140%, and ADC greater than 200 = 133%

A	B	C	D	E	F	G	H	I	J	K
Fac. #	Facility Name	County	Licensed AC Beds	Adjustments for CONs & Prev. Need	"Solucient" 2006 Acute Care Days	6 Years Growth at 0.47% annually	2012 Projected Average Daily Census (ADC)	2012 Beds Adjusted for Target Occ	Projected 2012 Deficit (-/+ = Surplus)	2012 Need Determination
H0169	Spruce Pine Community Hospital	Mitchell	85	-39	6,158	6,334	17	26	-20	0
H0003	FirstHealth Montgomery Memorial Hospital	Montgomery	37	0	1,989	2,046	6	8	-29	0
H0100	FirstHealth Moore Reg. Hosp. & Pinehurst Treat	Moore	297	23	74,037	76,150	209	277	-43	0
H0228	Nash General Hospital	Nash	270	0	58,039	59,695	164	229	-41	0
H0221	New Hanover Regional Medical Center	New Hanover	647	0	152,173	156,515	429	570	-77	0
H0048	Onslow Memorial Hospital	Onslow	162	0	33,454	34,409	94	141	-21	0
H0157	University of North Carolina Hospitals	Orange	602	91	176,345	181,377	497	661	-32	0
H0054	Albemarle Hospital	Pasquotank	182	0	32,548	33,477	92	138	-44	0
H0115	Pender Memorial Hospital, Inc	Pender	43	0	4,279	4,401	12	18	-25	0
H0066	Person Memorial Hospital	Person	50	0	8,731	8,980	25	37	-13	0
H0104	Pitt County Memorial Hospital	Pitt	628	106	189,924	195,343	535	712	-22	0
H0079	St. Luke's Hospital	Polk	45	0	3,352	3,448	9	14	-31	0
H0013	Randolph Hospital, Inc	Randolph	145	0	23,577	24,250	66	100	-45	0
H0265	**Sandhills Regional Medical Center**	**Richmond**	**54**	**0**	**13,559**	13,946	**38**	**57**	**3**	
H0158	FirstHealth Richmond Memorial Hospital	Richmond	99	0	14,150	14,554	40	60	-39	
N/A	2007 SMFP Need Determination	Richmond		6						
	Totals for Richmond County		153	6						0
H0064	Southeastern Regional Medical Center	Robeson	292	0	62,340	64,119	176	246	-46	0
H0072	Morehead Memorial Hospital	Rockingham	108	0	22,897	23,550	65	97	-11	
H0023	Annie Penn Hospital	Rockingham	110	0	17,778	18,285	50	75	-35	
	Totals for Rockingham County:		218	0						0
H0040	Rowan Regional Medical Center	Rowan	223	0	36,768	37,817	104	145	-78	0
H0039	Rutherford Hospital, Inc.	Rutherford	129	0	17,895	18,406	50	76	-53	0
H0067	Sampson Regional Medical Center	Sampson	116	0	19,921	20,489	56	84	-32	0
H0107	Scotland Memorial Hospital	Scotland	97	21	25,732	26,466	73	109	-9	0
H0008	Stanly Regional Medical Center	Stanly	97	0	16,932	17,415	48	72	-25	0
H0165	Stokes-Reynolds Memorial Hospital, Inc	Stokes	53	0	1,649	1,696	5	7	-46	0
H0049	Hugh Chatham Memorial Hospital, Inc.	Surry	81	0	14,800	15,222	42	63	-18	
H0184	Northern Hospital of Surry County	Surry	100	0	17,144	17,633	48	72	-28	
	Totals for Surry County:		181	0						0
H0069	Swain County Hospital	Swain	48	0	1,874	1,927	5	8	-40	0
H0111	Transylvania Community Hospital and Bridgeway	Transylvania	44	-2	6,113	6,287	17	26	-16	0
H0050	Carolinas Medical Center - Union	Union	157	0	33,398	34,351	94	141	-16	0
H0267	**Maria Parham Hospital**	**Vance**	**91**	**0**	**21,651**	22,269	**61**	**92**	1	0

Revised as of 7.19.07

Supersedes Table 5A published in the Proposed 2008 SMFP

Corrected Table 5A: Acute Care Bed Need Projections

(2006 Utilization Data from "Solucient" as compiled by the Cecil G. Sheps Center for Health Services Research)

Projection based on Growth Factor at 0.47% per year for the next 6 years. Target Occupancy Factors: ADC less than 100 = 150%, ADC of 100-200 = 140%, and ADC greater than 200 = 133%

A	B	C	D	E	F	G	H	I	J	K
Lic. #	Facility Name	County	Licensed AC Beds	Adjustments for CONs & Prev. Need	"Solucient" 2006 Acute Care Days	6 Years Growth at 0.47% annually	2012 Projected Average Daily Census (ADC)	2012 Beds Adjusted for Target Occ.	Projected 2012 Deficit (-) - Surplus)	2012 Need Determination
H0199	**WakeMed Raleigh Campus**	**Wake**	**515**	**60**	**166,249**	170,993	**468**	**623**	**48**	
H0276	WakeMed Cary Hospital (Now Lic. Separately)	Wake	114	42	35,260	36,266	99	149	-7	
	Totals for WakeMed Raleigh & WakeMed Cary:	**Wake**	629	102					**41**	
H0065	Rex Hospital	Wake	388	45	100,098	102,954	282	375	-58	
H0238	Duke Health Raleigh Hospital	Wake	186	0	22,268	22,903	63	94	-82	
	Totals for Wake County:		1203	147						41
H0006	Washington County Hospital, Inc.	Washington	49	0	2,458	2,528	7	10	-39	0
H0077	Watauga Medical Center, Inc.	Watauga	117	0	23,519	24,190	66	99	-18	
H0160	Blowing Rock Hospital	Watauga	28	0	774	796	2	3	-25	
	Totals for Watauga County:		145	0						0
H0257	Wayne Memorial Hospital, Inc.	Wayne	255	0	59,606	61,307	168	235	-20	0
H0153	Wilkes Regional Medical Center	Wilkes	120	0	21,502	22,116	61	91	-29	0
H0210	Wilson Medical Center	Wilson	294	0	35,131	36,133	99	148	-146	0
H0155	Hoots Memorial Hospital, Inc	Yadkin	22	0	679	698	2	3	-19	0

Revised as of 7.19.07
Supersedes Table 5B published in the Proposed 2008 SMFP

Corrected Table 5B: Acute Care Bed Need Determinations

(Proposed for Certificate of Need Review Commencing in 2008)

It is determined that the counties listed in the table below need additional Acute Care Beds as specified:

Service Area	Acute Care Bed Need Determination *	Certificate of Need Application Due Date **	Certificate of Need Beginning Review Date
Mecklenburg County	27	To Be Determined	To Be Determined
Wake County	41	To Be Determined	To Be Determined
It is determined that there is no need for additional Acute Care Beds anywhere else in the State and no other reviews are scheduled.			

* Need Determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application Due Dates are absolute deadlines. The filing deadline is 5:30 p.m. on the Application Due Date. The filing deadline is absolute (see Chapter 3).

Acute Care Bed Petition Materials Related to Cape Fear Valley Health System Petition:

- Agency Report
- Cape Fear Valley Health System-Petition and Related Comments

AGENCY REPORT

Acute Care Beds Petition: Cape Fear Valley Health System

Petitioner

Cape Fear Valley Health System
1638 Owen Drive
Fayetteville, North Carolina 28304

Request

The Petition requests an adjusted need determination in the 2008 State Medical Facilities Plan for 20 additional acute care beds in Cumberland County.

Background Information

The standard methodology which projects need for acute care beds is based on the total number of acute inpatient days of care provided by each hospital, as obtained from the Thomson database by the Cecil G. Sheps Center for Health Services Research. The number of days of care is advanced by six years based on a growth rate representing the average annual historical percentage change for the State over the past four years (i.e., three intervals of change). The projected midnight average daily census for the target year is then "adjusted" by target occupancy factors (which increase as the Average Daily Census increases). "Surpluses" or "Deficits" are determined by comparing the projected bed need to the current inventory of licensed plus pending acute care beds.

In deference to the standard methodology, Chapter 2 of the Plan allows persons to petition for an adjusted need determination in consideration of "...unique or special attributes of a particular geographic area or institution...," if they believe their needs are not appropriately addressed by the standard methodology.

Analysis/Implications

The Petitioner provides documentation of the impact that the 2005 Base Realignment And Closure (BRAC) will have on Cumberland County. As a result of BRAC, Cumberland County is expected to grow by approximately 23,000 people in the next four years. The Petitioner outlines on the next page how many additional acute care beds are expected to be needed in 2012 to accommodate the BRAC population.

Table 2: BRAC Related Incremental Acute Care Bed Need

BRAC Related Incremental Acute Care Bed Need			
	Military Dependents	Civilians, Civilian Dependents, and Indirect	Total
Total Projected to Reside in Cumberland County in 2011	5,956	13,638	19,594
Cumberland County Population Growth Factor for 2011 - 2012	0.62%	0.62%	
Total Projected to Reside in Cumberland County in 2012	5,993	13,723	19,715
Patient day Use-Rate for Cumberland County	494	494	
Projected Census [((Population/1000) x Use-Rate) / 365]	8	19	27
Projected Bed Need at 75 Percent Occupancy (1.33 Target Occupancy Factor > 200 Beds)	11	25	34
Estimated out-migration (includes Womack)	50%	40%	
Cumberland County Bed Need	5	15	20

Sources: Cumberland County projected population statistics (used to calculate growth rate) - North Carolina State Demographics Website. Patient days for Cumberland County (used to calculate use-rate) - Solucient. Target occupancy factor, SMFP

First, military personnel were excluded from the analysis since they are primarily served by Womack Army Medical Center ("Womack") at Fort Bragg. Then, to be consistent with the bed need projections in the proposed SMFP, the projected 2011 BRAC population of military dependents, civilians, civilian dependents and indirect population was adjusted for the overall population growth projected by the North Carolina State Data Center to occur in Cumberland County between 2011 and 2012.

The estimated inpatient census resulting from the BRAC population was calculated using the 2012 BRAC population (without military personnel) and the Cumberland County patient day use-rate. The Cumberland County patient day use-rate was calculated by dividing total 2006 Solucient patient days for Cumberland County by the 2006 county population estimate from the North Carolina State Data Center. The bed need was calculated by multiplying the census by the target occupancy factor of 1.33 for hospitals with over 200 beds, per the acute care need determination methodology.

Finally, in order to be conservative, the total projected bed need was reduced due to anticipated out-migration from Cumberland County. Out-migration includes the population served by Womack. For military dependents, 50 percent of the patients are expected to out-migrate since this population will have some access to Womack. Forty percent of the civilians, civilian dependents and indirect population are assumed to out-migrate. The out-migration is assumed to be significantly higher than the 15 percent out-migration experienced for overall Cumberland County residents, since military dependents and retired military are more likely to access other military treatment facilities and Veteran Affairs hospitals. As noted in Table 2, the BRAC population is expected to require 20 beds in Cumberland County.

The Agency accepts the Petitioner's conclusion that accommodating the BRAC population in Cumberland County will require 20 additional beds by 2012. However, according to the *corrected Proposed 2008 State Medical Facilities Plan, by the standard methodology, Cumberland County is projected to have a surplus of 28 acute care beds in 2012. Therefore, subtracting the 20 beds needed to accommodate the BRAC population from Cape Fear Valley Health System's projected **surplus** of 28 beds reduces the surplus to eight beds.

*the Acute Care Growth Factor published in the Proposed 2008 SMFP was corrected to .47%

The Petitioner acknowledges that the standard methodology results in a surplus of acute care beds for Cumberland County in 2012. However, the Petitioner submits that using Cumberland County 2003, 2004, 2005, and 2006 acute care patient days to calculate the Growth Factor results in a bed need for Cumberland County. The Agency supports the standard methodology for projecting need for acute care beds and does not recommend adjusting the Growth Factor for Cumberland County.

Agency Recommendation

In consideration of the projected surplus of 28 beds in Cumberland County by the standard methodology, the Agency recommends that the Petitioner's request for an adjusted need determination for 20 additional acute care beds be denied.

Petition for Adjustment to Need Determination for Acute Care Beds in Cumberland County

DFS Health Planning
RECEIVED

AUG [illegible] 2007

Medical Facilities
Planning Section

August 1, 2007

PETITION FOR ADJUSTMENT TO NEED DETERMINATION FOR ACUTE CARE BEDS FOR CUMBERLAND COUNTY

Petitioner:

Cape Fear Valley Health System
1638 Owen Drive
Fayetteville, North Carolina 28304

Joyce P. Korzen
Interim President and Chief Executive Officer
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910-609-4000

DFS Health Planning
RECEIVED
AUG 2007
Medical Facilities
Planning Section

I. Requested Change

Cumberland County Hospital System, Inc. d/b/a Cape Fear Valley Medical Center ("CFVMC" or the "Petitioner") is petitioning for an adjustment to need determination for the proposed 2008 State Medical Facilities Plan ("SMFP"). CFVMC is requesting that the acute care bed need for 2012 for Cumberland County, proposed in Chapter 5 of the draft SMFP, be adjusted from 0 to 20 beds to support the unique population surge that is anticipated with the 2005 Base Realignment And Closure ("BRAC"), which became law on November 8, 2005. The realignment is required by law to occur by 2011 and is unrelated to current military deployments and offenses in the Middle East.

As described in more detail below, in addition to its normal growth, Cumberland County population is expected to grow by almost 23,000 people in the next four years as a result of BRAC. The SMFP acute care methodology, on the other hand, projects bed need based on current hospital utilization projected forward six years using the average statewide growth of patient days during the last four fiscal years. Since the growth rate is based on historical utilization, the acute care bed need methodology in the SMFP does not accommodate unusual population growth. In fact, the acute care plan methodology does not directly use population in

the need assessment. Consequently, this methodology will not address the unique circumstances faced in Cumberland County.

The Petitioner is not requesting a modification to the methodology for bed need determination in the SMFP. Rather, this request is for an adjustment to need for the BRAC population growth. This Petition is premised on the very type of "unique or special attributes of a particular geographic area..."[1] contemplated by the State Health Coordinating Council ("SHCC") when it considers resource allocations outside of the standard methodology in the SMFP. CFVMC respectfully requests that the SHCC considers Cumberland County's unique situation and grants this request.

II. Reasons for Proposed Adjustment

The BRAC

Cumberland County is the site of the largest military installation in the world. Fort Bragg is adjacent to the city of Fayetteville and brings 175,000 employees and dependents and an economic impact of nearly $4 billion annually to the community. Cumberland County is a metropolitan area with an estimated population of over 308,000 residents in 2007.

Cumberland County and the surrounding population is expected to grow abruptly and substantially due to BRAC. With the base realignment at Fort Bragg and Pope Air Force Bases, base military and civilian personnel and their families are expected to grow by over **18,000** people by 2011 (see "Population Impact of the BRAC" section below for specific projections). When the indirect impact of population relocating to support the base personnel and their families is considered, the estimated total population impact of the base personnel changes will

[1] See Proposed 2008 SMFP, p. 9 which defines the appropriate circumstances for Petitions for Adjustment to Need.

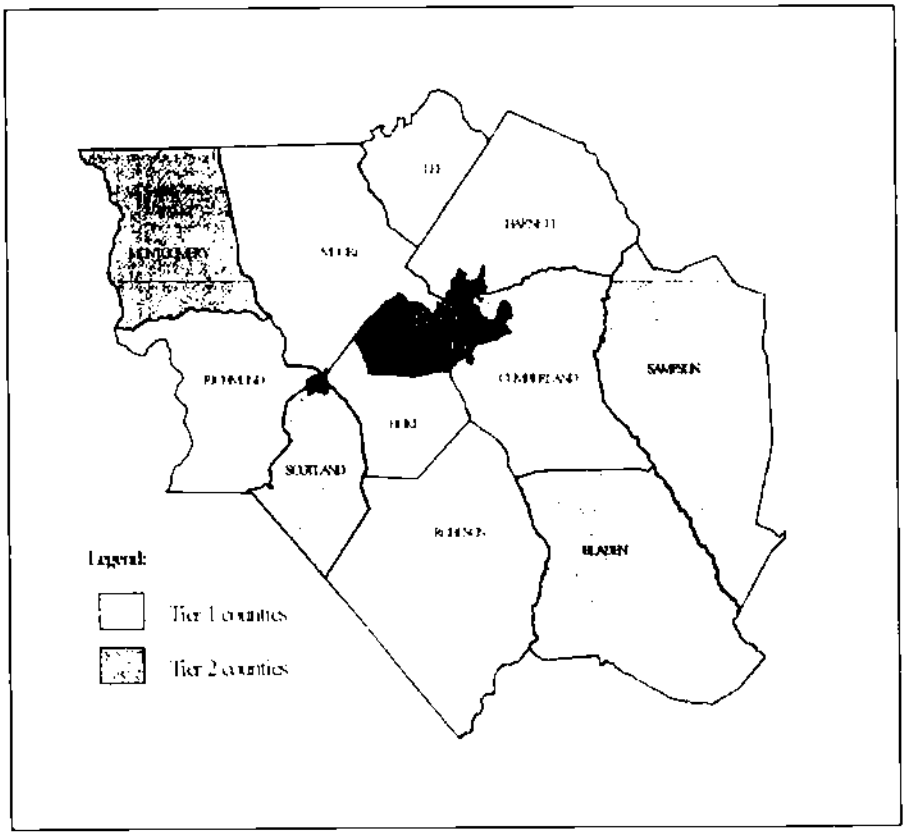
grow to more than **36,000** residents during the same time period. The majority of this growth is expected to occur in Cumberland County.

The realignment includes the relocation of two large headquarters to Fort Bragg: 1) Forces Command (FORSCOM), a four-star headquarters, and 2) the U.S. Army Reserve Command. These high command changes are also expected to result in the relocation of military contractors which are not accounted for in the **36,000** population impact noted above. Military contractors are almost exclusively retired military, an older population that consumes more healtheare services and will tend to remain in the community - a population quite different from the younger and more transient base troops.

The BRAC impact is anticipated to be so significant that 11 area counties came together last year to form the BRAC Regional Task Force. The Task Force has received over $6 million in grants which it is using to develop a growth management plan, train dislocated workers and assist in transforming the workforce in the area. The plan will address 11 specific need areas, including local and regional health care needs. The BRAC has defined two levels of counties which will be impacted by the BRAC. Tier 1 counties (highlighted on the map below), of which Cumberland is a part, are defined as counties that will suffer significant adverse consequence from the impact of BRAC actions and other growth at Ft. Bragg. Tier 2 counties (noted also on the map below) will be included for planning purposes, but are anticipated to absorb less of the population change.

Although the geographic area impacted by BRAC will span multiple counties, the scope of this petition is limited to Cumberland County. The map below shows Cumberland and the surrounding counties as well as the location of Ft. Bragg.

Figure 1: Map of Cumberland and the Surrounding Counties



Source: BRAC RTF website

Population Impact of the BRAC

The projected population impact of the BRAC is shown in the table below. The Center for Urban and Regional Studies at the University of North Carolina at Chapel Hill (the "Center") issued a Preliminary Community Impact Assessment on May 17, 2007. The study estimated the *direct* population increases for military and civilian personnel to be **6,366** and when their families are included to **18,169** by 2011. When a conservative multiplier of 1.0 (the Center suggested a multiplier between 1.0 and 2.0) is applied to allow for *indirect* population increases for such factors as increased jobs that provide services to the new personnel, the impact by 2011 totals **36,338**. The population impact in Cumberland County, as noted in the table below, is projected to be **22,902**.

The total population of Cumberland County, excluding the impact of the BRAC, is currently projected to grow to 314,202 by 2011 (a 1.9 percent increase from the July 2007 estimate of 308,255). Consequently, the BRAC will represent a 7.3 percent ***additional*** increase in the population over the four-year period.

Table 1: Estimated Change in Population from 2006 to 2011 Due to BRAC

County	Military Personnel	Civilian Personnel	Estimated Military Family Members	Estimated Civilian Family Members	Estimated Civilian Family Members	Indirect Population Multiplier (1.0)	Total	Percentage Increase
Bladen	4	29	7	57	97	97	194	190
Cumberland (off base)	3,308	729	5,956	1,458	11,451	11,451	22,902	19,594
Harnett	527	217	949	434	2,127	2,127	4,253	3,726
Hoke	435	110	783	220	1,548	1,548	3,096	2,661
Lee	44	89	79	178	390	390	780	736
Montgomery	3	24	5	46	78	78	157	154
Moore	140	212	252	423	1,027	1,027	2,054	1,914
Richmond	156	47	281	95	579	579	1,158	1,002
Robeson	10	162	18	325	515	515	1,030	1,020
Sampson	7	55	13	110	185	185	369	362
Scotland	10	48	18	96	172	172	344	334
Total	4,644	1,722	8,361	3,442	18,169	18,169	36,338	31,694

Source: Estimated change in military personnel, civilian base personnel, military dependents, and civilian family members developed by the Center for Urban and Regional Studies at the University of North Carolina at Chapel Hill. Additionally, the Center suggested an additional multiplier of 1.0 to 2.0 to account for the indirect population impact for increased jobs that provide services to new personnel.

Moreover, estimates of the Fort Bragg population growth continue to increase, particularly when government contractors are included. As noted in the July 27, 2007 newspaper article attached, Fort Bragg currently estimates that the base will grow by about 12,000 soldiers, contactors and government employees alone (numbers exclude family members and indirect population growth). While CFVMC did not incorporate these higher estimates in its assessment of bed need, the fact, as noted in the article, that Congress is set to provide $37 million in funding for the relocation of troops and others indicates that the growth is real and imminent.

Impact on Demand for Health Care Services

The impact of the BRAC on acute care bed need in Cumberland County is estimated to be approximately 20 additional beds. The method for determining the need is noted in Table 2 and the narrative below.

Table 2: BRAC Related Incremental Acute Care Bed Need

BRAC Related Incremental Acute Care Bed Need	Military Dependents	Civilian Dependent and Indirect	Total
Total Projected to Reside in Cumberland County in 2011	5,956	13,638	19,594
Cumberland County Population Growth Factor for 2011 - 2012	0.62%	0.62%	
Total Projected to Reside in Cumberland County in 2012	5,993	13,723	19,715
Patient day Use-Rate for Cumberland County	.494	.494	
Projected Census ((Population/1000) x Use-Rate) / 365)	8	19	27
Projected Bed Need at 75 Percent Occupancy (1.33 Target Occupancy Factor x 200 Beds)	11	25	34
Estimated out migration (includes Womack)	50%	40%	
Cumberland County Bed Need	5	15	20

Sources: Cumberland County projected population statistics (used to calculate growth rate) - North Carolina State Demographics Website. Patient days for Cumberland County (used to calculate use-rate) - Solucient. Target occupancy factor, SMFP

First, military personnel were excluded from the analysis since they are primarily served by Womack Army Medical Center ("Womack") at Fort Bragg. Then, to be consistent with the bed need projections in the proposed SMFP, the projected 2011 BRAC population of military dependents, civilians, civilian dependents and indirect population was adjusted for the overall population growth projected by the North Carolina State Data Center to occur in Cumberland County between 2011 and 2012.

The estimated inpatient census resulting from the BRAC population was calculated using the 2012 BRAC population (without military personnel) and the Cumberland County patient day use-rate. The Cumberland County patient day use-rate was calculated by dividing total 2006 Solucient patient days for Cumberland County by the 2006 county population estimate from the North Carolina State Data Center. The bed need was calculated by multiplying the census by the target occupancy factor of 1.33 for hospitals with over 200 beds, per the acute care need determination methodology.

Finally, in order to be conservative, the total projected bed need was reduced due to anticipated out-migration from Cumberland County. Out-migration includes the population served by Womack. For military dependents, 50 percent of the patients are expected to out-

migrate since this population will have some access to Womack. Forty percent of the civilians, civilian dependents and indirect population are assumed to out-migrate. The out-migration is assumed to be significantly higher than the 15 percent out-migration experienced for overall Cumberland County residents, since military dependents and retired military are more likely to access other military treatment facilities and Veteran Affairs hospitals. As noted in Table 2, the BRAC population is expected to require 20 beds in Cumberland County.

Occupancy of Current Providers

The service area, Cumberland County, has one acute care hospital, CFVMC, which currently operates at capacity.[2] CFVMC is struggling to keep up with current patient demand for healthcare services. The hospital's Emergency Department continues to be back-logged with patients waiting for beds and CFVMC is currently seeking a temporary increase in beds. The hospital has 397 licensed beds, with approval to construct and convert an additional 112 beds, for a total of 509 licensed beds.[3] Table 3 below summarizes the history of Cape Fear's Utilization over the last several years.

Table 3: Cape Fear Valley Medical Center Historical Utilization

Cape Fear Valley Medical Center Historical Utilization					
	Years Ended September 30				Annualized Year to Date
	2003	2004	2005	2006	June 30, 2007
Licensed Beds	383	394	407	394	397
Admissions	23,250	23,617	25,734	26,475	27,045
Patient Days	115,870	124,246	130,664	134,742	139,655
ALOS	4.98	5.3	5.1	5.1	5.2
ADC	317	340	358	369	383
Percent Occ	82.9%	86.4%	88.0%	93.7%	96.4%
ER Visits	70,649	82,910	93,316	94,343	99,559

Sources: Hospital License Renewal Applications and CFVMC records

[2] Highsmith-Rainey Hospital is an LTCH located in Cumberland County, which will have 66 beds in 2011. Use-rates used in calculating the patient census impact of the BRAC population do not include LTCH patients.
[3] The 2007 SMFP includes a 22-bed need allocation for Cumberland County, for which CFVMC plans to apply. If approved, CFVMC will have 531 acute care beds.

As noted in Table 3 above, current occupancy levels are significantly higher than the target occupancy rates for hospitals with greater than 200 beds (75.2 percent) in the SMFP. Further, even with an additional 134 beds (under construction and in the 2007 SMFP), the current census alone results in over a 72 percent occupancy rate. Of course, pent-up demand and normal population growth is expected to result in much higher occupancy rates.

Additionally, Womack, Fort Bragg's on-base hospital, is not expected to serve significant inpatient needs of the BRAC population over and above the out-migration contemplated in the estimate in Table 2 above. Currently, Womack operates a 165-bed facility which serves TriCare beneficiaries. As stated by Womack's Commander in the attached letter, the hospital is already running at capacity and has had to limit the number of TriCare patients served, even without the BRAC. The U.S. Army does not plan to expand the hospital to accommodate the BRAC troop growth. The Commander further states that Womack fully supports the efforts of civilian health care systems to accommodate the BRAC.

It is important to note that approximately 20,000 Fort Bragg troops are currently deployed. When these troops return, the demand for health care services at Womack as well as other area hospitals will be further increased.

Cumberland County Acute Care Bed Need Determination in Proposed SMFP

As demonstrated above, the BRAC population will clearly require additional bed capacity in Cumberland County. This need may appear to be inconsistent with the 18-bed surplus for Cumberland County in the proposed SMFP. However, this surplus results from the use of a statewide growth factor (the average growth rate of state wide patient days over the last four years) projected forward by six years (to 2012) . The proposed SMFP uses a statewide growth

factor of 0.82 percent, about half of the growth factor in the 2007 plan (1.58 percent). This resulted in substantially lower 2012 patient days for Cumberland County. Conversely, patient days have grown in Cumberland County at a significantly higher rate than the statewide growth rate. Table 4 shows the bed need calculation using the prescribed methodology in the SMFP if patient days of Cumberland County facilities are used to calculate the growth rate. The result is a bed need rather than a surplus for 2012.

Table 4: Cumberland County Projected Acute Care Bed Need (excluding BRAC impact)

Cumberland County Projected Acute Care Bed Need (excluding BRAC impact)			
	Inpatient Acute Care Days	Difference from Prior Year	Percent Change from Prior Year
2003	129,216		
2004	124,246	(4,970)	-3.8%
2005	130,664	6,418	5.2%
2006	134,742	4,078	3.1%
Average			1.5%
Six-year Compound Growth Factor			1.0922
Projected 2012 Patient Days			147,159
Average Daily Census (PDays/365)			403
Target Occupancy Factor (>200 beds)			1.33
2012 Bed Need (ADC x 1.33)			536
Current Bed Inventory			531

Sources: CFVMC 2004-2007 Hospital License Renewal Applications and Highsmith Rainey 2004 Hospital License Renewal Application
Acute care bed need methodology, SMFP
Note 1: In 2004, Highsmith Rainey became an LTCH. Therefore, its days were excluded from the patient day total beginning in 2004

III. Statement of Adverse Effects

Without the requested adjustment to bed need, future residents of Cumberland County associated with the BRAC will have limited access to health services. These citizens will be forced to delay or forgo health services, and/or seek acute care services outside of Cumberland County. While many hospital services can be expanded by extending hours, acute care beds are not flexible and an insufficient inventory will have a direct, negative impact on health care accessibility, efficiency and quality in Cumberland County.

IV. Alternatives Considered

Three alternatives were considered and determined not to be feasible prior to submitting to this petition:

- Status Quo
- Postpone including incremental beds in the SMFP to a future year, and
- Request a change in the need methodology.

Status Quo

The first alternative, to maintain the status quo, and absorb the impact of the increased demand for services by existing health care providers, is not feasible because both CFVMC and Womack have capacity constraints. A decision to do nothing would, in fact, force some citizens to postpone, forgo and/or seek acute care services outside of the service area. The ultimate result would be to reduce the availability, accessibility and quality of health care services for Cumberland County residents.

Postpone Including Incremental Beds in the SMFP

The second alternative considered was to postpone including the incremental beds to support the BRAC to a future year. This alternative is not feasible due to the lead time required to build and open new acute care beds. The population surge will be fully realized by 2011 and the SMFP projects bed need for the year 2012. Further, should CFVMC be awarded the CON to build/open the beds, it would be substantially more cost effective to include the additional beds in its current construction project. By adding additional floors to the existing project, costs associated with the beds will be minimized.

Request a Change in the Need Methodology

The third alternative considered by the Petitioner was to request a change in the need methodology. However, based on discussions with the Division of Health Service Regulation

staff, the unique situation of the BRAC is not easily addressed through changes in need methodology, but more appropriately through an adjustment to need petition.

IV. No Duplication of Existing Services

Since the proposed adjustment of 20 acute care beds in Cumberland County is intended to serve the unique, incremental population resulting from the BRAC, the population will not be included in historical statewide patient day trends used to determine the acute care bed need in the proposed SMFP.

As previously noted, the two area hospitals that would be expected to provide acute care services to this population, Womack and CFVMC, currently operate at capacity. While additional beds are under construction at CFVMC, the beds will only serve to alleviate current capacity constraints and will be insufficient to accommodate the additional patients anticipated from the rapid increase in population associated with the BRAC.

V. Summary

CFVMC requests that the acute care bed need for 2012 for Cumberland County, proposed in Chapter 5 of the SMFP, be adjusted from 0 to 20 beds to support the unique population surge that is anticipated with the BRAC.

CFVMC is proud to provide services to a growing population that serves a unique role to the United States of America and the world. The expected growth is not speculative – it is based on legislated base realignments that must occur by law by 2011. The Petitioner asks that you consider our unique circumstances and assist in continuing to meet the health care needs of this important population.

Attachments (2)

Published on Friday, July 27, 2007

Bragg in line for $37 million

By Henry Cuningham
Military editor

The U.S. House is expected to vote next week on a bill that would give Fort Bragg more than $37 million to prepare for adding troops at the post.

The House Appropriations Committee voted Wednesday to include the money in the 2008 Defense Appropriations bill.

Fort Bragg will add about 12,000 soldiers, contractors and government employees in coming years due to a variety of initiatives, Col. David Fox, Fort Bragg's garrison commander, said Thursday during a meeting of the BRAC Regional Task Force.

The troops are coming because of base realignment, Army growth and reorganization, and the return of U.S. forces from European bases to the United States.

"I am pleased to announce this important funding for Global Rebasing Funding," said Rep. Robin Hayes, a Concord Republican and member of the House Armed Services Committee.

"Making sure our service members are adequately taken care of during this transition period for the rebasing and realignment of our nation's armed forces is vital."

The committee proposed adding more than $1.25 billion to the Army's budget for upkeep and restoration of infrastructure.

The money will go to fix barracks and child-care facilities and to enhance community services through the United States, Europe and South Korea.

The changes at Fort Bragg could result in 35,000 to 45,000 people, including family members, coming to Fort Bragg and surrounding communities, Fox said. That's an increase from earlier estimates of the community growth under just the BRAC initiatives.

Under the bill, Fort Bragg would receive money for:

- Right-Size Community Services: $584,000. This funding would go to enhance programs such as child-care services, family counseling, youth centers and youth sports programs.
- Facility Sustainment, Restoration, and Modernization: $33.9 million. The funding is used for upkeep and maintenance on the Army post, including projects such as fixing leaks, broken windows, keeping heat and air-conditioning systems running, doing road improvements and other projects.
- Funding for Army Community Services Mobilization and Deployment Support: $708,000. The program provides active-duty, Reserve and National Guard units with pre- and post-deployment mobilization briefings, Family Readiness Group assistance, information and referral services, resource materials, and also Operation R.E.A.D.Y. (Resources for Education About Deployment and Youth) training. Training modules provide practical instruction on readiness. Materials are designed to support unit commanders in preparing service members, civilian employees and their families for military operations.
- Family Readiness Support Assistance for U.S. Army Special Operations Command: $2.17 million. The funding will provide administrative assistance specifically in support of USASOC's family readiness programs and activities.

Military editor Henry Cuningham can be reached at cuninghamh@fayobserver.com or 486-3585.

DEPARTMENT OF THE ARMY
WOMACK ARMY MEDICAL CENTER
FORT BRAGG, NORTH CAROLINA 28310-5000

REPLY TO
ATTENTION OF

July 27, 2007

Office of the Commander

North Carolina State Health Coordinating Council
Medical Facilities Planning Section
Division of Facility Services
2714 Mail Service Center
Raleigh, NC 27699

Subject: BRAC Population Growth and Medical Services

Dear Council Members:

I am writing in my capacity as Commander of Womack Army Medical Center, Fort Bragg's on-base hospital. Womack Army Medical Center ("Womack") provides healthcare services to over 180,000 TriCare beneficiaries including active duty service members, military dependents and retirees.

The Base Realignment and Closure (BRAC) most recently approved by the President mandates the relocation of a number of units to Fort Bragg, including two large headquarters units: U.S. Army Forces Command, a four-star headquarters, and the US Army Reserve Command, a three-star headquarters. The realignment will have significant impact on health care services in the area, requiring enhanced medical treatment capabilities in the military and civilian systems. It is likely that BRAC will produce a net population growth of over 15,000 Soldiers, civilian personnel, and dependents.

Womack provides a variety of services, including cardiology, hematology/ oncology, family medicine, obstetrics, gynecology, psychiatric, orthopedic, pulmonary, vascular, pediatric, neonatology, and surgical services, among others, to TriCare beneficiaries. However, our 165-bed facility has limited capacity; we have had to limit the number of TriCare patients we serve even without BRAC. The U.S. Army has no current plans to expand our capacity.

I understand that regional or community hospitals in our area will be impacted by the significant growth in patient population. The Womack Health Care system routinely refers and transfers people to these facilities when clinically necessary. We greatly appreciate what they do to help our fine service members and beneficiaries. To the extent that civilian health care systems in the area seek approval from the State Health Coordinating Council to meet the demands of BRAC growth, Womack fully supports their efforts.

Sincerely,

Terry J. Walters COL MC

Terry J. Walters
Colonel, U.S. Army
Commander

Attachment 14
SHCC
Acute Care

Presentation to the North Carolina State Health Coordinating Council Regarding The Petition for Adjustment to Need Determination for Acute Care Beds in Cumberland County Associated With BRAC Population Changes

DFS Health Planning
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Medical Facilities Planning Section

Members of the Council, Ladies and Gentlemen.

My name is Dr. Eugene Wright and I am the Vice President and Medical Director for Primary Care and Specialty Network at Cape Fear Valley Health System in Fayetteville, NC. I am here today, on behalf of Cape Fear Valley Health System, to submit an adjustment to need petition for 20 additional acute care beds to support our medical community's unique needs resulting from the Base Realignment And Closure (otherwise known as BRAC), which became law November 8, 2005. As a result of the BRAC, Cumberland County is expected to grow by almost 23,000 people in the next four years, in addition to its normal population growth. The bed need methodology in the State Medical Facilities Plan does not accommodate unusual population growth such as this since it is based on historical state-wide patient day growth rates. We are not requesting a modification to the methodology, but we are requesting an adjustment to the need for BRAC population growth.

The realignment includes the relocation of two large headquarters to Fort Bragg - Forces Command, a four-star headquarters, and the US Army Reserve Command. The BRAC impact is anticipated to be so significant that 11 area counties came together last year to form the BRAC Regional Task Force. The Task Force has received a $6 million grant which it is using to develop a growth management plan, train dislocated workers and assist in transforming the workforce in the area. The plan will address 11 specific need areas, including local and regional health care needs. Although the geographic area impacted by BRAC will span multiple counties, the scope of our petition is limited to Cumberland County.

The Center for Urban and Regional Studies at the University of North Carolina at Chapel Hill issued a Preliminary Community Impact Assessment on May 17, 2007. The study estimates the direct population increases in Cumberland County for military and civilian personnel and their family members to be over 11,000 by 2011. When indirect population increases for such factors as increased jobs that provide services to the new personnel are considered, the impact by 2011 is almost 23,000 for Cumberland County.

The impact of the BRAC population growth on acute care need in Cumberland County is estimated to be 20 beds. The method for developing this estimate is detailed in our petition. Briefly, the bed need was calculated using the projected census generated by the non-military 2012 BRAC population and the Cumberland County 2006 patient day use-rate. In order to be conservative, the total projected bed need was reduced in anticipation of out-migration to other counties and military facilities.

It is important to note we are the only acute care provider in Cumberland County, and we are currently operating at capacity. As of June 30, we are running at over 96 percent occupancy, which is triggering back-logs of patients in our emergency department who are waiting for beds. Even when the additional beds that are under construction or in the 2007 State Medical Facilities Plan are considered, our current census alone would result in an occupancy rate of over 72 percent.

Additionally, Womack, Fort Bragg's 165-bed on-base hospital, is running at capacity. According to Womack's commander, the hospital does not plan to expand to accommodate the BRAC growth.

It is clear that, without the requested adjustment to bed need, future residents of Cumberland County associated with the BRAC will have limited access to health services. These citizens will be forced to delay or forgo health services, and or seek acute care services outside of Cumberland County. While many hospital services can be expanded by extending hours, acute care beds are not flexible, and an insufficient inventory will have a direct, negative impact on health care accessibility, efficiency and quality in Cumberland County.

In closing, I would like to leave you with the following messages:

- Cape Fear Valley Health System is proud to provide services to a growing population that serves a unique role to the United States of America and the world.
- The expected growth is not speculative – it is based on legislated base realignments that must occur by law by 2011.
- In order to support this population surge, we are petitioning a 20-bed adjustment to the need determination in the proposed 2008 State Medical Facilities Plan.
- We ask that you consider our unique circumstances and assist us in continuing to meet the health care needs of this diverse population.

Larry Miller, with Cape Fear Valley, and Kathy Barger, with Kennedy Covington, are here with me today. We will be happy to address any questions that you may have.

Operating Room Petition Materials Related to Petitions 1-5:

- Agency Report
- OR Petition 1: Franklin Regional Medical Center- Petition and Related Comments
- OR Petition 2: Park Ridge Hospital- Petition and Related Comments
- OR Petition 3: Pitt County Memorial Hospital- Petition and Related Comments
- OR Petition 4: Randolph Hospital- Petition and Related Comments
- OR Petition 5: Rex Hospital- Petition and Related Comments

AGENCY REPORT

OR Petition 1: Franklin Regional Medical Center
OR Petition 2: Park Ridge Hospital
OR Petition 3: Pitt County Memorial Hospital
OR Petition 4: Randolph Hospital
OR Petition 5: Rex Hospital

Petitioners

OR Petition 1:
Bryan Gwyn
Chief Executive Officer
Franklin Regional Medical Center
100 Hospital Drive
PO Box 609
Louisburg, NC 27459

OR Petition 2:
Jimm Bunch
Chief Executive Officer
Park Ridge Hospital
PO Box 1569, Naples Road
Fletcher, NC 28732-1569

OR Petition 3:
Pitt County Memorial Hospital
2100 Stantonsburg Road
P.O. Box 6028
Greenville, NC 27838-6028

OR Petition 4:
Randolph Hospital
364 White Oak Street
Asheboro, NC 27203

OR Petition 5:
Rex Hospital
4420 Lake Boone Trail
Raleigh, NC 27607

Request

OR Petition 1: The Petition requests an adjusted need determination in the 2008 State Medical Facilities Plan for one additional Operating Room in Franklin County.

OR Petition 2: The Petition requests an adjusted need determination in the 2008 State Medical Facilities Plan for one additional Surgical Operating Room in Henderson County.

OR Petition 3: The Petition requests an adjusted need determination in the 2008 State Medical Facilities Plan for six additional Operating Rooms in the Pitt-Greene operating Service Area

OR Petition 4: The Petition requests an adjusted need determination in the 2008 State Medical Facilities Plan for one additional Operating Room in Randolph County.

OR Petition 5: The Petition requests an adjusted need determination in the 2008 State Medical Facilities Plan for four additional Operating Rooms in Wake County.

Background Information

The Operating Room Need Methodology is based on reported surgical cases by type, i.e., inpatient cases and ambulatory/outpatient cases. The methodology incorporates a number of assumptions including: average case times for inpatient and for ambulatory procedures; average hours of operation; average days of operation per year; and anticipated percentage availability. These assumptions are intended to establish a baseline for projection of future operating room need. By their nature, "averages" do not match each individual facility's circumstances, but should be representative of general practices. The methodology also includes a "Growth Factor," linked to each service area's projected population change between the "data year" and the "target year" for need projections (*i.e., over a four-year period*).

During the spring of 2007, an Operating Room Methodology Work Group met four times and reviewed the methodology for projecting Operating Room need. One of the Work Group meetings included presentations made by interested parties who provided suggestions and recommendations on proposed changes to the methodology as well as their perspective on the adequacy of the methodology. The Work Group developed a set of recommendations at the last meeting. One of the Work Group's recommendations, to exclude facilities with chronically under utilized OR's from operating room need projections, was incorporated into the Proposed 2008 State Medical Facilities Plan.

In deference to the standard methodology, Chapter 2 of the Plan allows persons to petition for an adjusted need determination in consideration of "...unique or special attributes of a particular geographic area or institution...," if they believe their needs are not appropriately addressed by the standard methodology.

Analysis/Implications

To provide background, the operating room inventory, projected need and Year 2010 projected surplus or deficit for the Franklin, Randolph, Pitt-Greene and Wake County Operating Room (OR) Service Areas (from Table 6B of the Proposed 2008 SMFP) is shown below:

County	Inpatient OR's	Ambulatory OR's	Shared OR's	Dedicated C-Section OR's (Excluded)	Trauma/Burn OR's (Excluded)	CON, Settlement, Previous Need Adjustments	Adjusted Planning Inventory	Year 2010 Projected Surplus or (Deficit)
Franklin	0	0	3	0	0	0	3	(.25)
Henderson	0	0	16	0	0	0	16	2.02
Randolph	1	0	5	-1	0	0	5	.21
Pitt	3	8	22	0	-1	0	32	(.25)
Wake	9	16	67	-5	-1	4	90	.79

As the above table shows, the petitioners are located in different areas of the State and differ in the size of their operating room inventories. While some of the issues the petitioners raise are specific to a particular hospital, the Agency has discerned several themes common to the petitions.

First, based on current data, each petitioner's service area is close to triggering a need determination. Franklin County and the Pitt-Greene Multi-County Service Area both have projected deficits of .25 OR's. Randolph County and Wake County have small surpluses, of .21 and .79 OR's, respectively. Henderson County, with a surplus of 2.02 OR's, is not as close to triggering a need as the other service areas. However, as the table below shows, each of the Petitioner's current operating room utilization rates is high.

Hospital	05-06 IP Cases	05-06 OP Cases	05-06 Total Cases	05-06 Total Hours	Total OR's	Standard Hours per OR per Year	Capacity Hours (Rooms*1872 hours)	05-06 %Utilization
Rex	9255	18222	27477	55098	31	1872	58032	95%
Franklin Regional	1001	1716	2717	5577	3	1872	5616	99%
Park Ridge	1348	4536	5884	10848	6	1872	11232	97%
Randolph Hospital	1249	3208	4457	8559	5	1872	9360	91%
Pitt-Greene County OR Service Area	9617	18544	28161	56667	32	1872	59904	95%

The Agency recognizes the petitioners' current high utilization of their operating rooms and appreciates their efforts to increase efficiency.

Secondly, each of the petitioners has provided as rationale for their request the need for some adjustment or adjustments to the Operating Room Methodology, which will contribute to or result in a need determination for their service area.

- Franklin Regional has noted that if small hospitals were allowed to "round up" to 1 OR from .2 OR's then there would be a need determination for 1 OR in Franklin County.
- Franklin Regional and Pitt County Memorial have proposed changing the Growth Factor for their service areas.
- Randolph Hospital and Pitt County Memorial have proposed changing the assumptions used in the OR Methodology, as follows:

OPERATING ROOM METHODOLOGY ASSUMPTIONS			
	Current	Randolph Hospital (Proposed)	Pitt County Memorial (Proposed)
HOURS/DAY	**9**	8	9
DAYS/YEAR	**260**	253	260
% UTILIZATION	**80%**	80%	75%
INPATIENT CASE TIME	**3 Hours/Case**	3 Hours/Case	3 Hours/Case
OUTPATIENT CASE TIME	**1.5 Hours/Case**	1.5 Hours/Case	2 Hours/Case (PCMH ambulatory surgery cases)

- Rex Hospital has proposed allocating operating rooms based on an individual facility's utilization, rather than on the operating room service area's utilization. This would result in Rex Hospital and Raleigh Women's Health generating a projected need for 2.79 OR's and .85 OR's, respectively.

  Similarly, Park Ridge Hospital's request is based on high utilization of their operating rooms. Park Ridge Hospital asks that three OR's, which are "not in use" and located at Margaret R. Pardee Hospital, be excluded from the inventory of OR's in Henderson County. Excluding these OR's would result in need for one OR in Henderson County. However, underutilized OR's were addressed by the Operating Room Work Group and facilities with chronically underutilized OR's were excluded from need projections in the Proposed 2008 SMFP. In addition, review of the CON Application for the operating rooms "not in use" at Margaret R. Pardee Hospital showed that the hospital is allowed one more year to reach utilization projections.

The Agency recognizes the logic of the arguments made by the petitioners. However, the Agency supports the current Operating Room Methodology and anticipates that every hospital could potentially contend that the methodology should be adjusted to better meet their needs. In addition, only one of the Operating Room Work Group's

recommendations was incorporated into the Proposed 2008 SMFP. Additional recommendations, expected to refine and improve the Operating Room Methodology, are to be incorporated into future SMFP's.

Third, Franklin Regional and Randolph Hospital provide data related to the ratio of OR's to population as a rationale for their requests. As the Agency has noted in the past, this is not a valid comparison for the requested adjustments. Differences across the state in the ratio of OR's to population came about because the State has not always regulated operating rooms. Additionally, while the current Operating Room Methodology does not include calculating the ratio of OR's to population, the Methodology uses both operating room inventory and projected population as factors in projecting need.

In addition to these common themes, Pitt County Memorial notes in their petition that they will have added over 100 new beds by 2010. Pitt County Memorial asserts that additional OR's are needed to support these additional beds. However, Pitt County Memorial did not provide enough information or data showing the impact of adding beds without OR's. Therefore, the Agency was unable to analyze and fully understand this rationale for requesting additional OR's.

Agency Recommendation

The Agency believes that it is premature to make an adjusted need determination at this time and recommends that the petitions be denied. The Agency encourages the petitioners to continue to work with existing resources to maximize the efficient utilization of current surgical operating room capacity.

OR Petition 1

PETITION

North Carolina State Health Coordinating Council

Submitted to:
Michael C. Tarwater, Chair
Acute Care Services Committee
c/o Medical Facilities Planning Section
Division of Facility Services
2714 Mail Service Center
Raleigh, NC 27699-2714

DFS Health Planning
RECEIVED

Medical Facilities
Planning Section

Submitted by:
Brian Gwyn
Chief Executive Officer
Franklin Regional Medical Center
100 Hospital Drive
PO Box 609
Louisburg, NC 27549

Franklin Regional Medical Center ("FRMC") is a 70 bed general acute care hospital in Louisburg (Franklin County). FRMC has three shared inpatient/outpatient operating rooms located at the main hospital facility and is the sole provider of surgical services in Franklin County.

Requested Change

FRMC requests a special need adjustment for one additional operating room in Franklin County for the *2008 State Medical Facilities Plan*. The *Proposed 2008 SMFP* indicates a deficit of 0.25 operating rooms in Franklin County, which is less than the 0.5 operating room deficit required to trigger a need. However, FRMC believes that there is an urgent and immediate need for additional operating room capacity in the county.

Reason for Request

FRMC appreciates the work that has been done to revise the need methodology for operating rooms, both by the Acute Care Services Committee as well as the OR Work Group. FRMC understands that such a task is a complex, time consuming process. The changes that have been suggested thus far, some of which have been adopted for the *Proposed 2008 SMFP*, will undoubtedly increase access to surgical services across the state. However, as is often the case with statewide methodologies, there are counties and providers that exist as outliers.

In these counties, the standard methodology does not accurately determine need. FRMC believes that exceptional and unique conditions exist that demand an expansion of operating room capacity in Franklin County.

It is also important to note that a change to the methodology suggested earlier in the year by a SHCC member, Dr. Dana Copeland, would have generated a need for an operating room in Franklin County, if the change would have been adopted. Specifically, Dr. Copeland recognized that the required threshold of a 0.5 operating room deficit in order to generate a need determination has a much greater impact on counties with fewer operating rooms, such as Franklin. Among other suggestions, Dr. Copeland proposed that counties with fewer than five operating rooms (such as Franklin) generate a need determination at a deficit of 0.2 operating rooms. FRMC understands that this change in the statewide methodology was not adopted; however, because Dr. Copeland suggested the change, FRMC believes that there is at least a general understanding of the imbalance that exists for counties with fewer operating rooms.

The following factors further support the need for an additional operating room in Franklin County.

1. Historical growth in volume supports an additional operating room

Surgery volumes at FRMC, the sole provider of surgical services in Franklin County, have grown at a compound annual growth rate (CAGR) of 9.4 percent since 2003. This includes one year of a slight decline in 2005, when FRMC was impacted by a major operating room renovation project and the loss of some surgeons. Nonetheless, from 2003 to 2006, FRMC's surgery volume grew by more than 600 cases, or 31 percent. Projected to 2010, the year for which need determinations in the *2008 SMFP* are projected, FRMC will experience surgical volumes of approximately 3,897 cases.

Historical and Projected Surgeries based on 9.4% CAGR

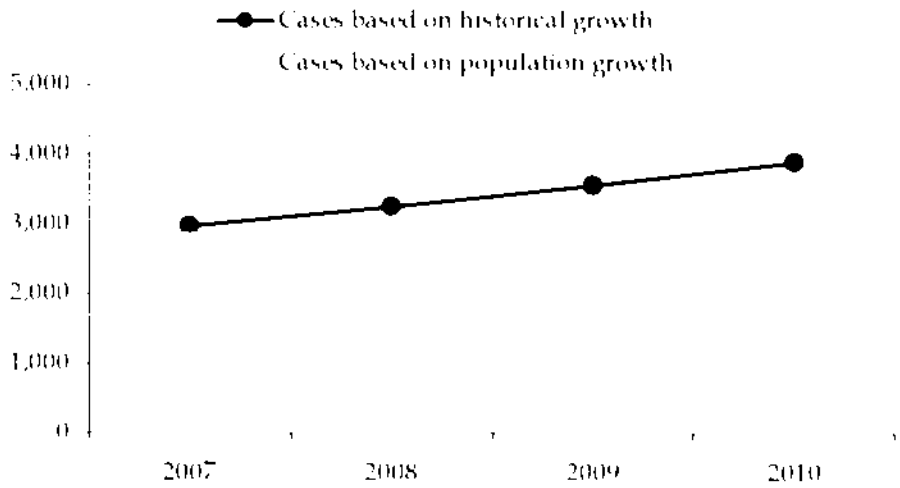
	2003	*2004*	*2005*	*2006*	*2007**	*2008**	*2009**	*2010**
Inpatient	347	383	828	1,001	1,095	1,199	1,312	1,436
Outpatient	1,726	1,865	1,206	1,716	1,878	2,055	2,249	2,461
Total	2,073	2,248	2,034	2,717	2,973	3,254	3,561	3,897

Note: 2007*-2010* are projected based on 2003-2006 CAGR of 9.4% applied to inpatient and outpatient surgeries.

Based on the projected 1,436 inpatient surgical cases and the 2,461 ambulatory surgical cases, FRMC's projected total operating hours for 2010 are 7,999 (1,436 x 3 hours per inpatient case + 2,461 x 1.5 hours per outpatient case = 7,999 hours[1]). Dividing this number by the SMFP's standard hours per operating room per year, 1,872, yields a need for 4.27 rooms in 2010. **Thus, based on actual surgery growth, Franklin County has a need for at least one additional operating room by 2010 given the county's current inventory of only three rooms.**

2. Surgical growth has surpassed population growth in Franklin County

As shown in the chart below, when projected at the historical rate of growth, surgical volumes will far exceed the growth projected by the population growth rate for Franklin County in the *Proposed 2008 SMFP*.



Franklin County's total population is projected to grow at compound annual growth rate of 1.4 percent from 2006 to 2010. This growth rate is well below the 9.4 percent historical growth in surgeries.

For Franklin County, the impact of a surgical growth rate that is higher than the population growth is exacerbated by the following coexisting factors:

a. **Franklin County's operating room need is the highest in the state when compared to its current capacity.** Within the state, no other county has a higher ratio of *Proposed 2008 SMFP* projected operating room deficit to current operating rooms as demonstrated in the table below. In other words, Franklin County is the most disadvantaged

[1] Total hours do not foot because of rounding in inpatient and outpatient surgical volumes.

county with an operating room deficit, because it has the fewest number of existing operating rooms to handle the excess volume. For example, the Pitt-Greene service area also shows a deficit of 0.25 ORs. However, that service area has 32 existing operating rooms; thus, the projected deficit (i.e. operating rooms being utilized over the volume threshold) for the Pitt-Greene service area can be more easily accommodated among the 32 ORs than the three ORs in Franklin County.

Ratio of Operating Room Deficit to Current Operating Rooms

County	*Proj. OR Deficit*	*Adj. Planning Inventory ORs*	*OR Need to OR Inventory Ratio*
Franklin	**0.25**	**3.00**	**0.083**
Columbus	0.34	5.00	0.068
Cleveland	0.46	9.00	0.051
Johnston	0.07	7.00	0.010
Pitt-Greene	0.25	32.00	0.008
Moore-Hoke	0.22	27.00	0.008
Union	0.01	8.00	0.001
New Hanover	0.01	41.00	0.000

Note: Only includes counties where the *Proposed 2008 SMHP* has identified some amount of OR deficit.

As noted above, Dr. Dana Copeland recognized this problem and proposed a modification of the operating room methodology at the February 8, 2007 Operating Room Work Group meeting that would address the relationship between need and current inventory of ORs. This petition would address the problem for Franklin County, which faces the greatest disadvantage in OR capacity.

b. **Franklin County has one of the lowest ratios of operating rooms to population in the state.** Within North Carolina in 2006, the number of operating rooms per 100,000 people varies drastically, ranging from a low of 3.5 rooms per 100,000 in Chatham County to a high of 30.7 per 100,000 in Orange County. There are many reasons for this variation, including: increased patient in-migration at tertiary and academic medical centers; the range of acute care services offered within the county; the number of surgeons and the variety of specialties and sub-specialties they represent, among others. Franklin County, with only three operating rooms for a population of 55,316 in 2006, has a ratio of

just 5.4 rooms per 100,000 people, as demonstrated in the table below. In fact, Franklin County has the largest population of any county with three or fewer operating rooms.[2]

Ratio of Operating Rooms to Population in All NC

Rank	*County*	*OR Inventory per 100K persons in 2006 Prov Pop*	*Adj. Planning Inventory ORs*	*Proj. OR Surplus (Deficit)*
1	Chatham	3.466	2	(1.74)
2	Randolph	3.608	5	(0.21)
3	Pender	4.105	2	(1.70)
4	Johnston	4.618	7	0.07
5	Union	4.649	8	0.01
6	Davie	5.020	2	(1.93)
7	Yadkin	5.290	2	(1.75)
8	**Franklin**	**5.423**	**3**	**0.25**
9	Alexander	5.510	2	(2.00)

Note: In rank order, the next highest county with any projected OR deficit, Columbus, is ranked 32nd in OR Inventory per 1,000,000 persons.

c. **Unlike counties with large surpluses of operating rooms, Franklin County does not have sufficient capacity for growth at a rate higher than that projected by the *SMFP*.** Because the need methodology in the *Proposed 2008 SMFP* is based primarily on population growth, counties whose surgical volumes are growing at a rate faster than the population growth are at a distinct disadvantage over other counties. For example, Pender County, which actually has a lower operating room to population ratio than Franklin County, has a projected growth rate of 13.26 percent from 2006 to 2010 as detailed in the *SMFP* for a compound annual population growth of three percent. In comparison, its compound annual growth rate in surgical cases from 2003 to 2006 has been negative 31 percent.[3] Unlike Franklin, which has experienced surgical growth at a much higher rate than its population growth, Pender County's surgical procedures are projected to grow at a higher rate in the *SMFP* than the county has actually experienced over the last few years. Thus, the same methodology that provides a distinct

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[2] Chatham County has a larger population, but is excluded from this statement because it is served with a critical care hospital with only 25 beds

[3] Source: *2005-Proposed 2008 SMFP's*

advantage to counties like Pender puts Franklin County at a disadvantage.

d. **FRMC needs additional capacity in order to attract and retain surgeons.** The realities of providing health care in rural counties are much different than those in urban areas. Although Franklin County is considered part of the Triangle and is growing rapidly, the county faces challenges when recruiting physicians, including surgeons. As explained above, in 2005, FRMC renovated and expanded its operating rooms, which resulted in at least one operating room being offline for most of the year. During the same year, FRMC lost a general surgery group, which included three surgeons, as well as a two-member ophthalmology group. While FRMC has been able to replace these physicians and is currently recruiting more surgeons, one of the chief concerns expressed by potential surgeons is the lack of sufficient operating room capacity in the county. The allocation of an additional operating room would dramatically improve FRMC's ability to attract surgeons to care for Franklin County patients.

e. **Franklin County's physician base limits its ability to achieve high operating room utilization.** Like many rural counties, Franklin County has a limited number of surgeons and proceduralists. Doctors in the community work in small physician groups where responsibilities cannot be shared as easily as in larger groups, and thus less time can be devoted to high utilization of operating rooms. In addition, physicians in Franklin County often have offices in the Raleigh area, an hour's drive away, which can prevent them from performing surgeries throughout the day. In fact, only one surgeon on FRMC's medical staff practices exclusively in Louisburg. All the others have offices in other parts of the county or in other counties, and most practice at other hospitals in the area as well. As a result, FRMC has difficulty utilizing its operating rooms for nine hours per day, as assumed in the statewide methodology. This situation limits the medical center's ability to achieve the high utilization rates that are required to generate the need for additional operating room capacity.

f. **FRMC's highest rate of growth has been in inpatient surgery**. Unlike the current trend driving higher outpatient growth in much of the state, Franklin County has experienced a compound annual growth rate of 42.4 percent in inpatient surgery since 2003, compared with its overall growth of 9.4 percent. Because these cases are generally more complex and take longer to perform, this high rate of growth in inpatient procedures is much more difficult to accommodate with limited

capacity and the limited surgeon availability as described above. As the growth in inpatient surgery performed at FRMC continues, compounded by the population growth in the county, FRMC will have difficulty scheduling timely inpatient procedures. Moreover, this growth in inpatient surgeries will continue to curtail the ability of surgeons to perform outpatient procedures as the operating rooms are being utilized for more serious cases. Thus, FRMC needs additional capacity in order to satisfy the demand for inpatient procedures and continue to offer sufficient access to outpatient cases.

Impact of Request/Implications if Petition is Not Approved

The proposed special need petition will allocate a single additional operating room in Franklin County. Unlike other counties in the state with large surpluses of operating rooms, Franklin County, with only three operating rooms, has a projected deficit of 0.25 rooms in 2007, based on the application of the population growth rate to its 2006 volume. FRMC, the sole provider of surgical services in the county, has an actual surgery growth rate that is much higher than the population growth rate. As demonstrated in this petition, Franklin County already demonstrates a need for an additional operating room considering the projected volumes for 2010. We believe that the proposed petition demonstrates a more compelling case than found in similar petitions approved in recent years. Without additional operating room capacity, the hospital will not be able to sustain its growth and residents of Franklin County will be forced to seek surgical services elsewhere.

We appreciate your careful consideration of this petition. Please let us know if we can assist the Acute Care Services Committee in your review of this petition.

Thank you.

Raleigh PH
8-1-07
OR

North Carolina State Health Coordinating Council

Public Hearing on the *Proposed 2008 State Medical Facilities Plan*

August 1, 2007

DFS Health Planning
RECEIVED
AUG 01 2007
Medical Facilities
Planning Section

Presented on behalf of: Franklin Regional Medical Center

Good afternoon. I am Bonnie Little, Director of Business Development at Franklin Regional Medical Center and I am here today on behalf of our petition requesting a special need adjustment in the *Proposed 2008 State Medical Facilities Plan*. Specifically, we are requesting the allocation of one additional operating room in Franklin County in next year's Plan. The written petition describes the statistical need for an additional operating room; however, I wanted to speak today in this public setting about why an additional operating room could provide substantial benefits for Franklin County residents. On behalf of the medical center and all the residents of Franklin

County, I would also like to express our appreciation for the SHCC members' willingness to attend these public hearings.

As you know, the current methodology to determine operating room need dictates that until there is a deficit of at least 0.5 operating rooms in a given county, no need will be generated. According to the *Proposed 2008 SMFP,* there will be a deficit of 0.25 operating rooms in Franklin County in 2010. Using the statewide methodology, there will be no additional operating room allocated to Franklin County in the 2008 Plan because the deficit has not yet reached 0.5.

Franklin Regional Medical Center is the only provider of surgical services in Franklin County, and currently has only three operating rooms—that's three OR's to serve a population of more than 55,000. In the past

several years, Franklin has experienced growth in its surgical volume above and beyond the population growth rate used in the OR methodology—in fact, surgery volumes have grown at several times the population growth rate. As volume continues to grow and operating room capacity remains the same, a deficit of 0.25 ORs has a greater impact than it might in another community with greater current capacity. It is important to understand what a "deficit" of OR's really is. It means that providers in the county are projected to operate above the volume thresholds established in the *SMFP*. For counties like Franklin, which have fewer operating rooms to begin with, the challenge of operating above capacity is greater than in other counties. Let me explain this using an example. The Pitt-Greene service area is also projected to have a deficit of 0.25 operating rooms. However, there are 32 operating rooms in this service area. As such, it is much easier to compensate for a

deficit, spreading the "excess capacity" volume among 32 operating rooms. In Franklin County, the additional volume has a significant impact on the three operating rooms.

I want to take a moment to point out that one of the suggestions brought to the OR Work Group this spring would have resulted in a methodology change and a need determination for Franklin County. This suggestion was meant to address the issue I have been explaining. Specifically, Dr. Dana Copeland proposed a tier-ing of the OR service areas, so that areas with fewer OR's would generate a need with a lower deficit. *I believe Dr. Copeland suggested that counties with fewer than five OR's, like Franklin, would generate a need at a 0.2 deficit – which, in this case, would have resulted in a need in Franklin County.* I think it's important to consider that even though the OR Workgroup did not adopt this recommendation for

the statewide methodology, the rationale behind it is sound and supports our petition.

Another important point to understand is how the surgeons provide care at Franklin Regional. As is the case in many rural communities in this state, the surgeons at Franklin tend to be "commuter surgeons;" in fact, only one of our surgeons is based exclusively in Louisburg—the rest commute into town to perform surgery, round on patients and take office visits. After their scheduled time in town, they leave to go to Raleigh or elsewhere to care for the rest of their patients. Because of this, if we need additional OR capacity, we can't just extend the operating hours into the evening and ask surgeons to come back to town for more cases. To put it simply, the lack of sufficient OR capacity means it is difficult to recruit surgeons to provide care to patients in their community hospital.

In addition, most of our surgeons work in small practices, and as a result have greater responsibilities in their offices and spend more time on call, so their availability for surgery is limited. Because these surgeons have multiple obligations, it is not feasible to schedule surgeries in the late afternoon or evening. So as you can see, limited surgeon availability further increases Franklin's limited OR capacity and makes it difficult to operate above capacity to meet the surgical needs of Franklin County residents.

There are several other statistical reasons that we'll be providing in our petition, but I didn't want to take your time today reading off a list of numbers and percentages.

We believe there is a clear and present need for an additional operating room in Franklin County and

appreciate your careful consideration of this petition. Please let us know if we can assist the Acute Care Services Committee in your review.

Thank you.

OR Petition 2

PETITION

TO: Medical Facilities Planning Section
State Health Coordinating Council
NC Division of Health Service Regulation
701 Barbour Drive
P.O. Box 29530
Raleigh, NC 27626-0530

PETITIONER: Jimm Bunch
Chief Executive Officer
Park Ridge Hospital
PO Box 1569, Naples Road
Fletcher, NC 28732-1569
(828) 681-2101

DATE: August 3, 2007

RE: Petition for Adjusted Need Determination for One Surgical Operating Room in Henderson County

Overview

Park Ridge Hospital, located in Henderson County, provides a comprehensive range of healthcare services in a high growth service area. The hospital maintains high inpatient occupancy of its 62 licensed acute care beds and has experienced tremendous growth in surgery and emergency department visits. Park Ridge Hospital is a member of the Adventist Health System, the largest not-for-profit Protestant health care organization in the United States, served almost four million patients last year.

The Operating Room Methodology in the Proposed 2008 State Plan does not address the unique circumstances and needs of the service area. Park Ridge Hospital's high utilization of its six licensed operating rooms requires that cases be scheduled beyond eight hours per day. There is a pressing need to add operating room capacity to serve both inpatients and outpatients; however, the opportunities to add future surgery capacity have been blocked by a neighboring hospital. In 2002, Margaret R. Pardee Memorial Hospital obtained CON approval

to add four operating rooms for a total of ten licensed operating rooms. Now, five years later, the hospital staffs and utilizes only seven of these ten operating rooms. While Pardee has financially struggled in recent years, Park Ridge Hospital has maintained a consistent trend of financial stability and prudent investments in facility expansion. A special adjustment to the OR need determination is justified for Henderson County to compensate for the chronically under-utilized and un-staffed operating rooms at Margaret R. Pardee Memorial Hospital.

Requested Change

Park Ridge Hospital requests an adjusted need determination for one additional operating room allocated to Henderson County. This request relates to the unique circumstance that the Adjusted Planning Inventory (Table 6B, Columns S) for Henderson County includes three unstaffed operating rooms at Pardee that should be excluded from the adjusted planning inventory because these rooms are unavailable to patients and surgeons.

Justification for Requested Adjustment

Park Ridge Hospital provides compelling justification for the requested adjusted need determination.

1) Unlike every other NC hospital of similar size, Margaret R. Pardee Memorial Hospital has three operating rooms reported as "not-in-use". However, these three unused operating rooms remain in the Operating Room Methodology and prevent the OR need methodology from properly functioning. The State Health Coordinating Council has already recommended that the methodology be modified to exclude operating rooms in chronically underutilized facilities from step 5 ("determination of need") in the operating room methodology. This change to the methodology is already reflected in the Proposed 2008 Plan. However, this mechanism has not been applied to Margaret R. Pardee Memorial

Hospital, which added four operating rooms (based on a 2001 CON application) for a current total of ten licensed operating rooms. While Pardee reports total surgery utilization that exceeds 40% of its total licensed capacity, it lacks staffing for three operating rooms as seen in Pardee's 2007 License Renewal Application in Exhibit 1. These Pardee operating rooms, which are licensed but listed as not-in-use, should be considered as chronically underutilized in this unique circumstance.

Patients do not have reasonable access to surgical capacity in Henderson County. Pardee has licensed operating rooms that are un-staffed and out of service; meanwhile Park Ridge Hospital's operating rooms are fully booked. Park Ridge Hospital staffs all six operating rooms a minimum of eight hours per day five days per week. Two operating rooms are routinely scheduled for extended hours for elective cases; one room is utilized until 5 PM and the other until 7 PM. In addition, the hospital maintains on-call coverage for emergency surgery

2) The 2006 DFS patient origin data for all NC hospitals and ambulatory surgery centers shows that 1,389 inpatients (36 percent) and 4,642 ambulatory patients (43 percent) that reside in Henderson County left their home county to obtain surgery at other facilities.

	Henderson Residents Inpatient Surgery	%
Henderson County Hospitals*	2440	64%
Other NC Hospitals**	1389	36%
Totals	3829	100%

	Henderson Residents Ambulatory Surgery	%
Henderson County Hospitals*	6158	57%
Other NC Hospitals and ASCs***	4642	43%
Totals	10800	100%

	Henderson Residents Inpatient and Ambulatory Surgery Combined	%
Henderson County Hospitals*	8598	59%
Other NC Hospitals and ASCs***	6031	41%
	14629	100%

*Henderson County hospitals include Margeret R. Pardee Memorial Hospital and Park Ridge Hospital
**Other NC hospitals include all licensed NC hospitals that submitted inpatient and/or ambulatory surgery patient origin data
***ASCs include all licensed Ambulatory Surgery Centers that submitted ambulatory patient origin data
All data are self reported based on 2007 License Renewal Applications

Park Ridge Hospital asserts that a disproportionate number of surgery patients left Henderson County because of restricted access to operating rooms in their home county. The combined high volume of inpatient and ambulatory surgery cases at Park Ridge contributes to scheduling delays.

3) Park Ridge Hospital has already obtained CON approval to add a dedicated C-section operating room and to reconfigure its existing surgery suite that includes the present six (6) licensed operating rooms. This ongoing project, when completed, will definitely be of great benefit to improving patient satisfaction and safety for C-section patients. However, this project will not adequately respond to the overall current and future surgery demand at Park Ridge Hospital. The following table shows the Park Ridge surgery projections and regulatory performance standards for the hospital following the addition of the dedicated C-section room:

	PRH C-Section Procedures Performed in One Dedicated C Section Room	PRH Surgery Cases Performed in Six Licensed Operating Rooms	PRH Average Cases per Day for the Shared Operating Room*	Regulatory Standards for Shared Operating Rooms (cases / room / day)	Percentages Exceeding the Performance Standard
2009-2010	**213**	**6,135**	**3.93**	**3.2**	**123%**
2010-2011	**221**	**6,366**	**4.08**	**3.2**	**128%**
2011-2012	**230**	**6,605**	**4.23**	**3.2**	**132%**

The above statistics prove that Park Ridge Hospital's six licensed operating rooms will be utilized at **123% to 132%** of the regulatory performance standards even after the dedicated C-section operating room is in service. (These statistics and projections have been analyzed by the CON Section and determined to be based on reasonable assumptions.) Recent historical surgery volume is reflected in Park Ridge's 2007 Licensure Renewal Application. See Ex. 2, p. 8.

4) Park Ridge Hospital also provides historical data for Pardee Hospital, in response to questions raised by a SHCC member at the August 1, 2007 public hearing

	Pardee C-Section Procedures Performed in Dedicated C-Section Room	Pardee Surgery Cases Performed in Licensed Operating Rooms	Pardee Average Cases per Day for the TEN (10) APPROVED / LICENSED Shared Operating Room*	Pardee Average Cases per Day for the SEVEN (7) STAFFED Shared Operating Rooms	Regulatory Standards for Shared Operating Rooms (cases / room / day)	Licensed Rooms Percentages of the Performance Standard (based on 10 ORs)	Staffed Rooms Percentage of the Performance Standard (based on 7 ORs)
2004-2005	**0**	**6,678**	**2.57**	**3.67**	**3.2**	**80%**	**114.7%**
2005-2006	**0**	**6,667**	**2.56**	**3.66**	**3.2**	**80%**	**114.5%**

Pardee completed the project to add four licensed operating rooms during the 2005-06 reporting period. As seen above, Pardee's surgery volume has not increased from the previous year. Using Pardee's staffed beds – which is the

true capacity for Henderson County residents needing surgery – it is clear that there is no additional surgery capacity at either Park Ridge or Pardee. Park Ridge has no information regarding future years' surgery utilization for Pardee Hospital.

Adverse Effects if the Changes Are Not Made

Over time, patients and surgeons have increasingly chosen Park Ridge Hospital which contributes to the shortage of operating room time at the facility. The extended hours of elective surgery is only an interim measure and does not remedy the scheduling back log. Without the requested change, several adverse effects are predicted:

1. Diminished patient satisfaction due to scheduling delays
2. Greater difficulty in recruiting and retaining surgical nurses
3. Increased number of patients leaving Henderson County to obtain surgery

Patients and surgeons often complain about late day / early evening surgery times because the patient has to forego food and drink for an extended period of time. Also, late day ambulatory surgery cases often result in extended recovery periods or an overnight stay that possibly could have been avoided had the procedure been performed in the morning hours.

It is already difficult to recruit surgical nurses. Excessive utilization in too few operating rooms creates more stress for the nursing staff. How long can Park Ridge Hospital maintain positive morale and excellent staff by asking them to work longer hours in the fully booked operating rooms?

In 2006 over 40% of Henderson County's surgical patients left their home county to obtain surgery. This is a hardship for patients and families. In future years, even more patients will be compelled to obtain surgery in other counties.

Alternatives Considered

Park Ridge Hospital has discussed scheduling elective surgery on the weekends but anesthesia coverage would be difficult to arrange and the change in work schedules would probably cause staff turnover. At this time, it is cost prohibitive to staff the operating rooms for weekend elective cases.

Park Ridge Hospital rejects the alternative of maintaining the status quo. Even with the current CON approved project, the addition of one C-section room will not add sufficient surgical capacity for 2009 and later years. As an interim measure, Park Ridge will continue to offer extended hours for elective surgery on weekdays. This arrangement is less than ideal in terms of patient satisfaction.

Park Ridge Hospital chose to petition for an adjusted need determination for one operating room based on the needs of the community. The previously approved surgery renovation project at Park Ridge could simply be modified for an additional operating room. This approach is the most reasonable and cost effective alternative.

Evidence That the Proposed Change Will Not Result in Unnecessary Duplication of Health Resources

The three unstaffed operating rooms at Pardee Hospital are expensive examples of under-utilized healthcare resources. It is highly unusual to have CON regulated healthcare services that are constructed but not staffed and made fully operational.

The purpose of this petition is to seek an adjusted need determination for one additional operating room based on the unique circumstances in Henderson County. The requested change does not represent unnecessary duplication of resources because the unstaffed operating rooms at Pardee are simply inaccessible and should be excluded from the methodology. Similar exclusions

from the 2008 OR methodology are made for chronically under-utilized operating rooms in other facilities.

If given the opportunity, Park Ridge Hospital is committed to pursue and develop an additional full service operating room that will be staffed and made available to the community immediately upon completion of the project. Based on its current high utilization, the requested adjusted need determination for one operating room will not represent unnecessary duplication of healthcare resources specifically at Park Ridge Hospital.

Conclusion

Park Ridge Hospital is an acute care facility that has provided superior medical care with Christian compassion since 1910. Patients and surgeons increasingly choose Park Ridge Hospital over other facilities. As a small community hospital, Park Ridge Hospital has experienced tremendous growth in surgery utilization and should not be unfairly constrained. Approval of our petition for an adjusted need determination for one operating room is entirely justified by the unique circumstances in Henderson County.

Thank you for your consideration of our petition.

Exhibits

1. Pardee's 2007 License Renewal Application
2. Park Ridge's 2007 License Renewal Application

North Carolina Department of Health and Human Services
Division of Facility Services
Acute and Home Care Licensure and Certification Section
1205 Umstead Drive, 2712 Mail Service Center
Raleigh, North Carolina 27699-2712
Telephone: (919) 855-4620 Fax: (919) 715-3073

For Official Use Only
License # H0161 Medicare # 340017
Computer 943324
PC Date

License Fee: **$3,325.00**

EXHIBIT
/

2007
HOSPITAL LICENSE
RENEWAL APPLICATION

Legal Identity of Applicant: **Henderson County Hospital Corporation**
(Full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service.)

Doing Business As
(d/b/a) name(s) under which the facility or services are advertised or presented to the public:

PRIMARY: **Margaret R. Pardee Memorial Hospital**
Other: Pardee Hospital; Pardee Memorial Hospital
Other: Pardee Memorial Hospital

Facility Mailing Address: 800 North Justice Street
Hendersonville, NC 28791-3518

Facility Site Address: 800 North Justice Street
Hendersonville, NC 28791-3518
County: Henderson
Telephone: (828)696-1000
Fax: (828)696-1128

Administrator/Director: JON SCHURMEIER
Title: PRESIDENT/CEO
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Chief Executive Officer: Jon Schurmeier **Title:** President/CEO
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Name of the person to contact for any questions regarding this form:

Name: Michael J. Hansen **Telephone:** 828-696-1194

E-Mail: mike.hansen@pardeehospital.org

12 27 06
3,325.00
00067042

"The N.C. Department of Health and Human Services does not discriminate on the basis of race, color, national origin, religion, age or disability in employment or the provision of services."

All responses should pertain to **October 1, 2005 through September 30, 2006**. If otherwise, indicate the actual reporting period used on Page 3 of this document.

Type of Health Care Facilities under the Hospital License

List Name(s) of facilities:	Address:	Type of Business / Service:
Margaret R. Pardee Memorial Hospital	800 N Justice Street	Acute Care
Margaret R. Pardee Psych Unit	800 N Justice Street	Psych

Please attach a separate sheet for additional listings

Ownership Disclosure (Please fill in any blanks and make changes where necessary.)

1. What is the name of the legal entity with ownership responsibility and liability?

   Owner: Henderson County Hospital Corporation
   Federal Employer ID# 562084959
   Street/Box: 800 North Justice Street
   City: Hendersonville State: NC Zip: 28791-3518
   Telephone: (828)696-1000 Fax: (828)696-1128
   CEO: Jon Schurmeier, President/CEO

   Is your facility part of a Health System? ___Yes X No
   If 'Yes', name of Health System*: _____
   * ***(please attach a list of NC facilities that are part of your Health System)***
   If 'Yes', name of CEO: _____

   a. Legal entity is: ___ For Profit X Not For Profit

   b. Legal entity is: X Corporation ___ LLP ___ Partnership
   ___ Proprietorship ___ LLC ___ Government Unit

   c. Does the above entity (partnership, corporation, etc.) LEASE the building from which services are offered? X Yes ___ No

   If "YES", name of building owner:
   Henderson County

2. Is the business operated under a management contract? ___Yes X No

   If 'Yes', name and address of the management company.
   Name: _____
   Street/Box: _____
   City: _____ State: _____ Zip: _____
   Telephone: (____) _____

Ownership Disclosure *continued. . . .*

3. Vice President of Nursing and Patient Care Services:
   Sally Davenport, R.N. M.S.N.

4. Director of Planning: N/A

Facility Data

A. Reporting Period All responses should pertain to the period **October 1, 2005 to September 30, 2006**. If otherwise, please indicate reporting period: _____

B. General Information (Please fill in any blanks and make changes where necessary.)

a. Admissions to Licensed Acute Care Beds: **include responses to "a – r" on page 4; exclude responses to "2-9" on page 4; and exclude normal newborn bassinets.**	7209	
b. Discharges from Licensed Acute Care Beds: **include responses to "a – r" on page 4; exclude responses to "2-9" on page 4; and exclude normal newborn bassinets.**	7212	
c. Average Daily Census: **include responses to "a – r" on page 4; exclude responses to "2-9" on page 4; and exclude normal newborn bassinets.**	77	
d. Was there a permanent change in the total number of licensed beds during the reporting period?	Yes	No X
If 'Yes', what is the current number of licensed beds?		
If 'Yes', please state reason(s) (such as additions, alterations, or conversions) which may have affected the change in bed complement:		
e. Observations: Number of patients in observation status and not admitted as inpatients, excluding Emergency Department patients.	2364	

C. Designation and Accreditation

1. Are you a designated trauma center? ____ Yes X No
2. Are you a critical access hospital (CAH)? ____ Yes X No
3. Are you a long term care hospital (LTCH)? ____ Yes X No
4. If this facility is accredited by JCAHO or AOA, specify the accrediting body JCAHO and indicate the date of the last survey 12 / 16 / 04

D. Beds by Service (Inpatient – Do Not Include Observation Beds or Days of Care)

[Please provide a Beds by Service (p. 4) for each hospital campus (*see G.S. 131E-176(2c)*)]

Please indicate below the number of beds usually assigned (set up and staffed for use) to each of the following services and the number of census inpatient days of care rendered in each unit. NOTE: If your facility has a designated unit(s) for chemical dependency treatment and/or detoxification, please complete the patient origin sheet pertaining to Psychiatric and Substance Abuse Services. If your facility has a Nursing Facility unit and/or Adult Care Bed unit please complete the supplemental packet for Skilled Nursing Facility beds.

Licensed Acute Care (provide details below) *Campus* Margaret R. Pardee Memorial Hospital	**Licensed Beds as of September 30, 2006**	**Staffed Beds as of September 30, 2006**	**Annual Census Inpt. Days of Care**
Intensive Care Units			
a. Burn *			*
b. Cardiac			
c. Cardiovascular Surgery			
d. Medical/Surgical	13	8	1634
e. Neonatal Beds Level IV ** (Not Normal Newborn)			**
f. Pediatric			
g. Respiratory Pulmonary			
h. Other (List)			
Other Units			
i. Gynecology			
j. Medical/Surgical ***	154	107	*** 24577
k. Neonatal Level III ** (Not Normal Newborn)			**
l. Neonatal Level II ** (Not Normal Newborn)			**
m. Obstetric (including LDRP)	14	14	1525
n. Oncology			
o. Orthopedics			
p. Pediatric	12	12	363
q. Other (List)			
1. Total General Acute Care Beds (a through r)	193 ~~201~~	141	28099
2. Comprehensive In-Patient Rehabilitation	0		
3. Inpatient Hospice	0		
4. Detoxification	8 ~~0~~	8	381
5. Substance Abuse / Chemical Dependency Treatment	0		
6. Psychiatry	21	21	6512
7. Nursing Facility	0		
8. Adult Care (Home for the Aged)	0		
9. Other	0		
10. Totals (1 through 9)	**222**	170	34992

* Please report only Census Days of Care of DRG's 504, 505, 506, 507, 508, 509, 510 and 511.

** Per C.O.N. rule definition. Refer to Section .1400 entitled Neonatal Services. (10A NCAC 14C)

*** Exclude swing-bed days. (See swing-bed information next page)

D. Beds by Service (Inpatient) *continued*

Number of Swing Beds *	0
Number of Skilled Nursing days in Swing Beds	0
Number of unlicensed observation beds	0

* means a hospital designated **as a swing-bed hospital** by CMS (Centers for Medicare and Medicaid Services)

E. Reimbursement Source (For "Inpatient Days," show Acute Inpatient Days only, excluding normal newborns.)

Payer Source	Inpatient Days of Care	Emergency Cases	Outpatient Cases	Same Day Surgery Cases
Charity Care**	169	122	798	39
Commercial Ins. [1]	4137	5624	28053	2978
Medicaid (including HMO)	2835	5806	6516	617
Medicare (including HMO)	18451	9655	46696	3517
Private Pay / Self Pay	1580	7701	4179	170
Other Gov't. [2]	534	611	3167	278
Bad Debt				
All other	393	1039	1086	116
TOTAL	28099	30558	90495	7715

** Charity Care Definition: Health care services that never were expected to result in cash inflows. Charity care results from a provider's policy to provide health care services free of charge to individuals who meet certain financial criteria

[1] Commercial Insurance includes all forms of managed care except Medicaid and Medicare HMO's

[2] Other Government includes Tricare and VA insurance programs

[3] Cases which originate from the Emergency Department

F. Services and Facilities

1. Obstetrics	Enter Number
a. Live births (Vaginal Deliveries)	382
b. Live births (Cesarean Section)	156
c. Stillbirths	2

d. Delivery Rooms - Delivery Only (not Cesarean Section)	
e. Delivery Rooms - Labor and Delivery, Recovery	
f. Delivery Rooms – LDRP (include Item "n" on Page 4)	7
g. Normal newborn bassinets (Level I Neonatal Services) Do not include with totals under the section entitled Beds by Service (Inpatient)	10

2. Abortion Services Number of procedures per Year 0

3. **Emergency Department Services** (cases equal visits to ED)

Number of cases/year: 30558

Does this include fast track/urgent care ? X Yes ____ No.

If "Yes," how many of these are urgent care? 0

	Hours of Operation		Hrs with physician on duty in ER suite	
	From	To	From	To
Monday	24 hours a	day	24 hours	a day
Tuesday	↓		↓	
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

4. **Medical Air Transport**: Owned or leased air ambulance service:

a. Does the facility operate an air ambulance service? __ Yes X No
b. If "Yes", complete the following chart.

Type of Aircraft	Number of Aircraft	Number Owned	Number Leased	Number of Transports
Rotary				
Fixed Wing				

5. **Pathology and Medical Lab** (Check whether or not service is provided)

a. Blood Bank/Transfusion Services X Yes __ No
b. Histopathology Laboratory X Yes __ No
c. HIV Laboratory Testing __ Yes X No
Number during month of September 2005
HIV Serology _____
HIV Culture _____
d. Organ Bank __ Yes X No
e. Pap Smear Screening __ Yes X No

6. **Transplantation Services** - Number of transplants

Type	Number	Type	Number
a. Bone Marrow-Allogenic	0	i. Kidney/Liver	0
b. Bone Marrow-Autologous	0	j. Liver	0
c. Cornea	0	k. Lung	0
d. Heart	0	l. Pancreas	0
e. Heart/Lung	0	m. Pancreas/Kidney	0
f. Heart/Liver	0	n. Pancreas/Liver	0
g. Heart/Kidney	0	o. Other	0
h. Kidney	0		0

Do you perform living donor transplants ? ____ Yes X No.

7. **Specialized Cardiac Services** (for questions, call 855-3865 [Medical Facilities Planning])

(a) Cardiac Catheterization	Diagnostic Cardiac Catheterization ICD-9 37.21, 37.22, 37.23, 37.25	Interventional Cardiac Catheterization- ICD-9 36.01, 36.02, 36.05, 36.06, 36.07, 36.09; 35.52, 35.71, 35.96	Electro-physiology 37.26, 37.27, 37.34, 37.70, 37.71, 37.72, 37.73, 37.74, 37.75, 37.76, 37.77, 37.79, 37.80, 37.81, 37.82, 37.83, 37.85, 37.86, 37.87, 37.89, 37.94, 37.95, 37.96, 37.97, 37.98, 37.99, 00.50, 00.51, 00.52, 00.53, 00.54
1. Number of Units of Equipment	1		
2. Total Annual Number of Cases*	193		
3. Of Total in #2, Number of Patients Age 14 & under	0		
4. Of Total in #2, Number of Cases Performed in Mobile Unit**	0		

* One case is defined to be one visit or trip by a patient to an operating room or catheterization laboratory for a single or multiple procedures or catheterizations. Count each visit once regardless of the number of diagnostic, interventional, and/or EP procedures performed within that visit.

** Please report name of mobile vendor: N/A

Number of operating hours per week on site: N/A

(b) Open Heart Surgery (utilizing heart/lung bypass machines)	
1. Number of Dedicated Open Heart Surgery Operating Rooms	
2. Number of Heart-Lung Bypass Machines	
3. Total Annual Number of Procedures	
4. Of total in #3, Number of Procedures on Patients Age 14 & under	

8. Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases

a) Surgical Operating Rooms and Cases

[1] Please report *Surgical Operating Rooms* built to meet the specifications and standards for operating rooms required by the Construction Section of the Division of Facility Services, and which are fully equipped to perform surgical procedures. These surgical operating rooms include rooms located in Obstetrics and surgical suites. Please report the number of cases performed in these rooms during the reporting period. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was in the operating room.

NOTE: If this License includes more than one campus, please submit the Cumulative Totals **and** COPY this sheet and Submit a duplicate of this page for each campus.

(**Campus** – *If multiple sites*: _____)

Type of Room [A]	Number of Rooms [B]	Of the Rooms in Column [B], the number "Not in Use" [C]	Inpatient Cases [D]	Ambulatory Cases [E]
Dedicated Open Heart Surgery (from 7b)	0	0	0	
Dedicated C-Section	0	0	0	
Other Dedicated Inpatient Surgery	0	0	0	
Dedicated Ambulatory Surgery	0	0		0
Shared - Inpatient / Ambulatory Surgery	10	3	2258	4409
Total of Surgical Operating Rooms & Cases *(Columns [D] & [E] should equal Totals in 8(d))*	10	3	2258	4409

[2] Does this facility have **additional** surgical operating rooms (i.e., **not** listed above) **that are being developed** pursuant to a Certificate of Need or pursuant to the exemption provided in Senate Bill 714? _____ Yes __X__ No

If "Yes," please list the **Types of Rooms** and **Number of Rooms** being developed:

_____

b) Gastrointestinal Endoscopy Rooms and Cases

[1] Report the number of *Gastrointestinal Endoscopy Rooms* and the number of cases performed in these rooms during the reporting period. (***NOTE***: **Other procedure rooms** should be included in **Section 9** on **Page 10** of this application.) Count each patient as one case regardless of the number of gastrointestinal procedures performed while patient was in the GI endoscopy room. For GI Endoscopy Rooms, please also report the Total Number of GI Procedures performed.

Type of Room [A]	Number Of Rooms [B]	Of the Rooms in Column [B], the number "Not in Use" [C]	Inpatient Cases [D]	Ambulatory Cases [E]	Total Number of Procedures [F]
Gastrointestinal Endoscopy Rooms & Cases	3	0	GI: 682	GI: 4156	GI: 4838
			Non GI: 7	Non GI: 139	Non GI: 146

[2] Does this facility have **additional** Gastrointestinal Endoscopy Rooms (i.e., **not** listed above) **that are being developed** pursuant to a Certificate of Need or pursuant to the exemption provided in Senate Bill 714? _____ Yes __X__ No

If "Yes," please list the **Number of Rooms** being developed:

_____

8. Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases *continued*

c) Average Room Availability and Average Case Times:

Type of Room	"Resource Hours" * *(Average Hours per Room per Day Routinely Scheduled for Use)*	Average "Case Time" ** in Minutes for Inpatient Cases	Average "Case Time" ** in Minutes for Ambulatory Cases
Surgical Operating Rooms	58	120	90
Gastrointestinal Endoscopy Rooms	24	20	20

* **"Resource Hours"** = Average number of hours per Room per Day routinely scheduled to be available for performance of procedures. (**Example**: 2 rooms @ 8 hours per day plus 2 rooms @ 10 hours per day equals 36 hours per day; divided by 4 rooms equals an average of 9 hours / per room / per day.)

** **"Case Time"** = **Time from Room Set-up Start to Room Clean-up Finish.** Definition 2.4 from the "Procedural Times Glossary" of the AACD, as approved by ASA, ACS, and AORN. *NOTE. This definition includes all of the time for which a given procedure requires an OR/PR. It allows for the different duration of Room Set-up and Room Clean-up Times that occur because of the varying supply and equipment needs for a particular procedure. For purposes of scheduling and efficiency analysis, this definition is ideal because it includes all of the time that an OR/PR must be reserved for a given procedure.*

d) Surgical Specialty - Of the cases in **Surgical Operating Rooms** (Item 8.a.[1]), enter the number of cases by surgical specialty area in the chart below:

Specialty Area	Inpatient Cases	Ambulatory Cases
Cesarean Sections	156	
Cystoscopy		
Endoscopy (all endo types performed in Surgical Operating Room)	10	51
General	726	1283
Gynecology	165	321
Neurosurgery		30
Open Heart		
Ophthalmology	5	640
Oral Surgery		68
Orthopedics	1013	1414
Otolaryngology	35	207
Plastic Surgery	79	302
Podiatry	1	7
Thoracic (other than open heart)		
Urology	68	86
Other (Specify)		
Total Surgical Operating Room Cases *(Totals should equal totals 8.a[1], columns D & E)*	2258	4409

9. Non-Gastrointestinal Procedure Rooms and Cases

Please report only rooms or cases not reported in 8a or 8b: Other rooms not equipped or meeting all the specifications for an operating room, dedicated to the performance of procedures other than gastrointestinal endoscopy. (Do not list a room for more than one use). **Please note: Any procedures performed in these rooms should not be billed as having occurred in an operating room or reported in 8 as procedures performed in an operating room. Cases**: Count each patient as one case regardless of the number of procedures performed while patient was in the room.

Use	Number of Rooms	Inpatient Cases	Ambulatory Cases
Cast Procedures			
Cystoscopy	1	66	257
Endoscopies *(other than GI Endoscopies)* unless they were performed in a surgical operating room			
Lithotripsy			
Special Procedures/Angiography (neuro & vascular but not including cardiac cath.)			
Sutures			
YAG Laser			
Other (Specify)			
Totals	1	66	257

10a. Diagnostic Imaging and Lithotripsy Data

Indicate the number of machines/instruments and the number of the following types of procedures performed during the 12-month reporting period at your facility. For Hospitals that operate medical equipment at multiple sites, please provide a separate page for each site.

Imaging							
Fixed Equipment (Exclude Research & Policy AC-3 Units)	Number of Units	No. of Procedures: Inpatient	No. of Procedures: Outpatient	Total	No. of MRI Procedures *: With Contrast or Sedation	No. of MRI Procedures *: Without Contrast or Sedation	Total
CT Scanner	3	4389	13987	18376			
MRI	2	509	6306	6815	4714	2101	6815
Open MRI Scanners included in row above	0						
Mammogram	1	3	10922	10925			
Other radiographic & fluoroscopic (See Note Below)	8	12744	30964	43708			
Mobile Equipment Identify Vendor/Owner in space ( ) below:	Number of Units	No. of Procedures: Inpatient	No. of Procedures: Outpatient	Total	No. of MRI Procedures: With Contrast or Sedation	No. of MRI Procedures: Without Contrast or Sedation	Total
MRI #1 ( )	0	0	0	0	0	0	0
MRI #2 ( )	0	0	0	0	0	0	0
CT Scan ( )	0	0	0	0			
Nuclear Medicine Fixed Equipment	Number of Units	No. of Procedures: Inpatient	No. of Procedures: Outpatient	Total			
Dedicated PET Scanner	0	0	0	0			
Coincidence Camera	0	0	0	0			
SPECT	2	0	0	0			
Gamma Camera Combined	1	567	3544	4111			
Mobile Equipment Identify Vendor/Owner in space () below:	Number of Units	No. of Procedures: Inpatient	No. of Procedures: Outpatient	Total			
Dedicated PET Scanner (Alliance Imag	1	0	113	113			
Coincidence Camera ( )	0	0	0	0			
SPECT ( )	0	0	0	0			
Gamma Camera ( )	0	0	0	0			
Policy AC-3 or Research Equipment	Number of Units	No. of Procedures: Inpatient	No. of Procedures: Outpatient	Total	No. of Procedures **: Clinical	No. of Procedures **: Research	Total
MRI pursuant to Policy AC-3:	0	0	0	0	0	0	0
Other Human Research MRI Scanner	0	0	0	0	0	0	0
PET pursuant to Policy AC-3	0	0	0	0	0	0	0
Other Human Research PET Scanner	0	0	0	0	0	0	0
Lithotripsy (Identify Vendor/Owner in space ( ) below:)	Number of Units	No. of Procedures: Inpatient	No. of Procedures: Outpatient	Total			
Fixed ( )	0	0	0	0			
Mobile (Lithotriptors, inc)	1	0	98	98			

Note: Totals of MRI inpatients and outpatients should equal MRI totals with and without contrast or sedation

Note: Totals of MRI inpatients and outpatients should equal MRI totals for clinical and research procedures

MRI procedure is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom. ***NOTE***: Please Report ALL Angiography procedures on page 10, in Table 9 under Special Procedures/Angiography Rooms.

PET procedure is defined as a single discrete PET scan of a patient (single CPT coded procedure), not counting other radiopharmaceutical or supply charge codes.

10b. MRI Procedures by CPT Codes

MRI Procedures by CPT Code		
CPT Code	CPT Description	Number of Procedures
70336	MRI Temporomandibular Joint(s)	
70540	MRI Orbit/Face/Neck w/o	1
70542	MRI Orbit/Face/Neck with contrast	
70543	MRI Orbit/Face/Neck w/o & with	20
70544	MRA Head w/o	118
70545	MRA Head with contrast	
70546	MRA Head w/o & with	
70547	MRA Neck w/o	1
70548	MRA Neck with contrast	1
70549	MRA Neck w/o & with	57
70551	MRI Brain w/o	163
70552	MRI Brain with contrast	2
70553	MRI Brain w/o & with	1019
7055A	IAC Screening	
71550	MRI Chest w/o	4
71551	MRI Chest with contrast	
71552	MRI Chest w/o & with	5
71555	MRA Chest with OR without contrast	2
72126	Cervical Spine Infusion only	
72141	MRI Cervical Spine w/o	617
72142	MRI Cervical Spine with contrast	1
72156	MRI Cervical Spine w/o & with	38
72146	MRI Thoracic Spine w/o	189
72147	MRI Thoracic Spine with contrast	
72157	MRI Thoracic Spine w/o & with	35
72148	MRI Lumbar Spine w/o	1271
72149	MRI Lumbar Spine with contrast	2
72158	MRI Lumbar Spine w/o & with	326
72159	MRA Spinal Canal w/o OR with contrast	
72195	MRI Pelvis w/o	189
72196	MRI Pelvis with contrast	
72197	MRI Pelvis w/o & with	31
72198	MRA Pelvis w/o OR with Contrast	13
73218	MRI Upper Ext. other than joint w/o	21
73219	MRI Upper Ext, other than joint with contrast	
73220	MRI Upper Ext. other than joint w/o & with	11
73221	MRI Upper Ext any joint w/o	786
73222	MRI Upper Ext any joint with contrast	100
73223	MRI Upper Ext any joint w/o & with	8
73225	MRA Upper Ext w/o OR with contrast	
	Subtotal	5031

10b. MRI Procedures by CPT Codes *continued*. . . . .

MRI Procedures by CPT Code		
CPT Code	CPT Description	Number of Procedures
73718	MRI Lower Ext other than joint w/o	102
73719	MRI Lower Ext other than joint with contrast	1
73720	MRI Lower Ext other than joint w/o & with	58
73721	MRI Lower Ext any joint w/o	1204
73722	MRI Lower Ext any joint with contrast	4
73723	MRI Lower Ext any joint w/o & with	11
73725	MRA Lower Ext w/o OR with contrast	14
74181	MRI Abdomen w/o	139
74182	MRI Abdomen with contrast	
74183	MRI Abdomen w/o & with	72
74185	MRA Abdomen w/o OR with contrast	56
75552	MRI Cardiac Morphology w/o	
75553	MRI Cardiac Morphology with contrast	
75554	MRI Cardiac Function Complete	
75555	MRI Cardiac Function Limited	
75556	MRI Cardiac Velocity Flow Mapping	
76093	MRI Breast, unilateral w/o and/or with contrast	2
76094	MRI Breast, bilateral w/o and/or with contrast	78
76125	Cineradiography to complement exam	
76375	MRI 3-D Reconstruction	41
76390	MRI Spectroscopy	2
76393	MRI Guidance for needle placement	
76394	MRI Guidance for tissue ablation	
76400	MRI Bone Marrow blood supply	
7649A	MR functional imaging	
7649D	MRI infant spine comp w/ & w/o contrast	
7649E	Spine (infants) w/o infusion	
7649H	MR functional imaging	
N/A	Clinical Research Scans	
	Total Number of Procedures	6815

11. Radiation Oncology Treatment Data

CPT Code	Description	Number of Procedures	ESTVs/ Procedures Under ACR	Total ACR ESTVs	
	Simple Treatment Delivery:				
77401	Radiation treatment delivery		1.00		
77402	Radiation treatment delivery (<=5 MeV)		1.00		
77403	Radiation treatment delivery (6-10 MeV)	65	1.00		
77404	Radiation treatment delivery (11-19 MeV)	9	1.00		
77406	Radiation treatment delivery (>=20 MeV)		1.00		
	Intermediate Treatment Delivery:				
77407	Radiation treatment delivery (<=5 MeV)		1.00		
77408	Radiation treatment delivery (6-10 MeV)	8	1.00		
77409	Radiation treatment delivery (11-19 MeV)		1.00		
77411	Radiation treatment delivery (>=20 MeV)		1.00		
	Complex Treatment Delivery:				
77412	Radiation treatment delivery (<=5 MeV)		1.00		
77413	Radiation treatment delivery (6-10 MeV)	2343	1.00		
77414	Radiation treatment delivery (11-19 MeV)	3340	1.00		
77416	Radiation treatment delivery (>= 20 MeV)		1.00		
	Sub-Total	5765			

For the increased time required for special techniques, ESTV values are indicated below:

77417	Additional field check radiographs	1048	.50		
77418	Intensity modulated radiation treatment (IMRT)delivery	302	1.00		
77432	Stereotactic radiosurg. treatment mgmt Linear Accelerator		3.00		
77432	Stereotactic radiosurg. Treatment mgmt. Gamma Knife		3.00		
	Total body irradiation		2.50		
	Hemibody irradiation		2.00		
	Intraoperative radiation therapy (conducted by bringing the anesthetized patient down to the linac)		10.00		
	Neutron and proton radiation therapy		2.00		
	Limb salvage irradiation		1.00		
	Pediatric Patient under anesthesia		1.50		
	Sub-Total	1350			
	TOTALS:	7115			

Note: For special techniques, list procedures under both the treatment delivery and the special techniques sections

12. Radiation Oncology Treatment Data *continued*

a.	Number of unduplicated patients who receive a course of radiation oncology treatments (patients shall be counted more than once if they receive additional courses of treatment)	291
b.	Total number of Linear Accelerator(s)	1
c.	Number of Linear Accelerators configured for stereotactic radiosurgery	0

12. Telemedicine

a. Does your facility utilize telemedicine to have images read at another facility? yes

b. Does your facility read telemedicine images? yes

13. Additional Services:

a) **Check if Service(s) is provided:**

	Check		Check
1. Cardiac Rehab Program (Outpatient)	X	5. Rehabilitation Outpatient Unit	X
2. Chemotherapy	X	6. Podiatric Services	X
3. Clinical Psychology Services	X	7. Genetic Counseling Service	
4. Dental Services	X	8. Acute Dialysis	

Number of Acute Dialysis Stations 0

b) **Hospice Inpatient Unit Data:**
Hospital-based hospice units with licensed hospice beds. List each county served and report **all patients by county of residence**. Use each patient's age on the admission day to the Licensed Hospice Inpatient Facility. **For age categories count each inpatient client only once.**

County of Residence	Age 0-17	Age 18-40	Age 41-59	Age 60-64	Age 65-74	Age 75-84	Age 85+	Total Patients Served	Total Days of Care	Deaths
Out of State										
Total All Ages										

13. Additional Services: *continued*

c) **Mental Health and Substance Abuse**

1. If psychiatric care has a different name than the hospital, please indicate:

   _____

2. If address is different than the hospital, please indicate:

   _____

3. Director of the above services.

   Bridget Barron

Indicate the program/unit location in the **Service Categories** chart below. If it is in the hospital, include the room number. If it is located at another site, include the building name, program/unit name and address.

Service Categories: All applicants must complete the following table for all mental health services which are to be provided by the facility. If the service is not offered, leave the spaces blank.

Rule 10A NCAC 27G Licensure Rules For Mental Health Facilities	Location of Services	Beds Assigned by Age				
		0-12	13-17	Subtotal 0-17	18 & up	Total Beds
.1100 Partial hospitalization for individuals who are acutely mentally ill.						
.1200 Psychosocial rehabilitation facilities for individuals with severe and persistent mental illness						
.1300 Residential treatment facilities for children and adolescents who are emotionally disturbed or have a mental illness						
.1400 Day treatment for children and adolescents with emotional or behavioral disturbances						
.1500 Intensive residential treatment facilities for children & adolescents who are emotionally disturbed or who have a mental illness						

Rule 10A NCAC 13B Licensure Rules For Hospitals	Location of Services	Beds Assigned by Age				
		0-12	13-17	Subtotal 0-17	18 & up	Total Beds
.5200 Dedicated inpatient unit for individuals who have mental disorders	Hospital				21	21

Room#'s 301,302,303,304,305,306,307,308,309
310,311,312,314

13. Additional Services: *continued*

c) Mental Health and Substance Abuse *continued*

Rule 10A NCAC 27G Licensure Rules for Substance Abuse Facilities	Location of Services	Beds Assigned by Age				
		0-12	13-17	Subtotal 0-17	18 & up	Total Beds
.3100 Nonhospital medical detoxification for individuals who are substance abusers						
.3200 Social setting detoxification for substance abusers						
.3300 Outpatient detoxification for substance abusers						
.3400 Residential treatment/ rehabilitation for individuals with substance abuse disorders						
.3500 Outpatient facilities for individuals with substance abuse disorders						
.3600 Outpatient narcotic addiction treatment						
.3700 Day treatment facilities for individuals with substance abuse disorders						

Rule 10A NCAC 13B Licensure Rules For Hospitals	Location of Services	Beds Assigned by Age				
		0-12	13-17	Subtotal 0-17	18 & up	Total Beds
.5200 Dedicated inpatient hospital unit for individuals who have substance abuse disorders (specify type) # of Treatment beds ___ # of Medical Detox beds 8	2nd Floor Hospital				8	8

Bed #'s 241,242,243,244,245,246,247,248

Patient Origin -General Acute Care Inpatient Services

Facility County: Henderson

In an effort to document patterns of utilization of General Acute Care Inpatient Services in North Carolina hospitals, please provide the county of residence for each patient admitted to your facility.

County	No. of Admissions	County	No. of Admissions	County	No. of Admissions
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham	1	74. Pitt	
3. Alleghany	1	39. Granville		75. Polk	359
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood	67	80. Rowan	1
9. Bladen		45. Henderson	5934	81. Rutherford	103
10. Brunswick	1	46. Hertford		82. Sampson	
11. Buncombe	169	47. Hoke		83. Scotland	
12. Burke	2	48. Hyde		84. Stanly	1
13. Cabarrus		49. Iredell	1	85. Stokes	2
14. Caldwell	2	50. Jackson	23	86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	310
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	1
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee	4	56. Macon	6	92. Wake	5
21. Chowan		57. Madison	9	93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland	8	59. McDowell	4	95. Watauga	6
24. Columbus		60. Mecklenburg	6	96. Wayne	
25. Craven	1	61. Mitchell		97. Wilkes	2
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	1
29. Davidson		65. New Hanover	2		
30. Davie	1	66. Northampton		101. Georgia	10
31. Duplin		67. Onslow		102. South Carolina	61
32. Durham	1	68. Orange		103. Tennessee	6
33. Edgecombe		69. Pamlico		104. Virginia	7
34. Forsyth		70. Pasquotank		105. Other States	87
35. Franklin		71. Pender		106. Other	
36. Gaston	4	72. Perquimans		**Total No. of Patients**	7209

Patient Origin – Inpatient Surgical Cases – Excluding GI Endoscopy Cases (*In Dedicated Inpatient or Shared Operating Rooms*)

Facility County: Henderson

In an effort to document patterns of "Inpatient" utilization of Surgical Operating Rooms in North Carolina hospitals, please provide the county of residence for each inpatient surgical patient served in your facility. Count each inpatient "once" regardless of the number of surgical procedures performed while the patient was in the operating room. However, each admission as an inpatient operating room patient should be reported separately.

The "Total" from this chart should match the "Total" reported in the **Inpatient Cases** "Column D" in the Table under 8(a), page 8.

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham		74. Pitt	
3. Alleghany		39. Granville		75. Polk	154
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood	15	80. Rowan	
9. Bladen		45. Henderson	1740	81. Rutherford	55
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe	61	47. Hoke		83. Scotland	
12. Burke	1	48. Hyde		84. Stanly	1
13. Cabarrus		49. Iredell		85. Stokes	1
14. Caldwell	1	50. Jackson	2	86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	140
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee		56. Macon		92. Wake	2
21. Chowan		57. Madison	4	93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland	3	59. McDowell	3	95. Watauga	
24. Columbus		60. Mecklenburg	2	96. Wayne	
25. Craven	1	61. Mitchell		97. Wilkes	
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	2
31. Duplin		67. Onslow		102. South Carolina	36
32. Durham	1	68. Orange		103. Tennessee	
33. Edgecombe		69. Pamlico		104. Virginia	3
34. Forsyth		70. Pasquotank		105. Other States	28
35. Franklin		71. Pender		106. Other	
36. Gaston	2	72. Perquimans		**Total No. of Patients**	2258

Patient Origin – Ambulatory Surgical Cases – Excluding GI Endoscopy Cases (*In Dedicated Ambulatory or Shared Operating Rooms*)

Facility County: Henderson

In an effort to document patterns of "Ambulatory" utilization of Surgical Operating Rooms in North Carolina hospitals, please provide the county of residence for each ambulatory surgery patient served in your facility. Count each ambulatory patient "once" regardless of the number of procedures performed while the patient was in the operating room. However, each admission as an ambulatory operating room patient should be reported separately.

The "Total" from this chart should match the "Total" reported in the **Ambulatory Cases**, "Column E" in the Table under 8(a), page 8.

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham		74. Pitt	
3. Alleghany		39. Granville		75. Polk	192
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood	18	80. Rowan	
9. Bladen		45. Henderson	3672	81. Rutherford	42
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe	123	47. Hoke		83. Scotland	
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell		85. Stokes	
14. Caldwell		50. Jackson	2	86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	287
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee	3	56. Macon	3	92. Wake	
21. Chowan		57. Madison		93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland		59. McDowell	5	95. Watauga	
24. Columbus		60. Mecklenburg		96. Wayne	
25. Craven		61. Mitchell	3	97. Wilkes	
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	4
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	5
31. Duplin		67. Onslow		102. South Carolina	31
32. Durham		68. Orange		103. Tennessee	1
33. Edgecombe		69. Pamlico		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other States	18
35. Franklin		71. Pender		106. Other	
36. Gaston		72. Perquimans		**Total No. of Patients**	4409

Patient Origin – Gastrointestinal Endoscopy (GI) Cases – *(Performed In Gastrointestinal Endoscopy Rooms)*

Facility County: Henderson

In an effort to document patterns of utilization of Gastrointestinal Endoscopy Rooms in North Carolina hospitals, please provide the county of residence for each GI Endoscopy patient served in your facility. Count each patient "once" regardless of the number of procedures performed while the patient was in the Gastrointestinal Endoscopy Room. However, each admission as a GI Endoscopy Room patient should be reported separately.

The "Total" from this chart should match the Combined Total reported as **Gastrointestinal Endoscopy Cases**, "Column D" plus "Column E" in the Table under 8(b), page 8.

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham		74. Pitt	
3. Alleghany	1	39. Granville		75. Polk	272
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood	1	80. Rowan	1
9. Bladen		45. Henderson	4206	81. Rutherford	109
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe	106	47. Hoke		83. Scotland	
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell		85. Stokes	
14. Caldwell		50. Jackson	2	86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	230
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee	3	56. Macon		92. Wake	1
21. Chowan		57. Madison		93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland	1	59. McDowell		95. Watauga	
24. Columbus		60. Mecklenburg	2	96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	
26. Cumberland		62. Montgomery	4	98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	4
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	2
31. Duplin		67. Onslow		102. South Carolina	19
32. Durham		68. Orange		103. Tennessee	3
33. Edgecombe		69. Pamlico		104. Virginia	1
34. Forsyth		70. Pasquotank		105. Other States	15
35. Franklin		71. Pender		106. Other	
36. Gaston	1	72. Perquimans		**Total No. of Patients**	4984

All responses should pertain to October 1, 2005 through September 30, 2006 If otherwise, indicate the actual reporting period used on Page 3 of this document

Patient Origin - Psychiatric and Substance Abuse Alamance through Johnston

Facility County: Henderson

Complete the following table below for inpatient Days of Care reported under Section .5200

County of Patient Origin	Psychiatric Treatment Days of Care			Substance Abuse Treatment Days of Care			Detoxification Days of Care		
	Age 0-17	Age 18+	Totals	Age 0-17	Age 18+	Totals	Age 0-17	Age 18+	Totals
Alamance									
Alexander									
Alleghany									
Anson									
Ashe									
Avery		1	1						
Beaufort									
Bertie									
Bladen									
Brunswick									
Buncombe		123	123					11	11
Burke		1	1						
Cabarrus									
Caldwell									
Camden									
Carteret									
Caswell									
Catawba		1	1						
Chatham									
Cherokee		9	9					1	1
Chowan									
Clay									
Cleveland		1	1						
Columbus									
Craven									
Cumberland									
Currituck									
Dare									
Davidson									
Davie									
Duplin									
Durham									
Edgecombe									
Forsyth									
Franklin									
Gaston									
Gates									
Graham		3	3						
Granville									
Greene									
Guilford									
Halifax									
Harnett		1	1						
Haywood		17	17					2	2
Henderson		547	547					50	50
Hertford									
Hoke									
Hyde									
Iredell									
Jackson		10	10					1	1
Johnston									

** Note: See counties. Jones through Yancey (including Out-of-State) on next page

All responses should pertain to **October 1, 2005 through September 30, 2006** If otherwise, indicate the actual reporting period used on Page 3 of this document

Patient Origin - Psychiatric and Substance Abuse Jones through Yancey (including Out-of-State)

Facility County: Henderson

(Continued from previous page)

County of Patient Origin	Psychiatric Treatment Days of Care			Substance Abuse Treatment Days of Care			Detoxification Days of Care		
	Age 0-17	Age 18+	Totals	Age 0-17	Age 18+	Totals	Age 0-17	Age 18+	Totals
Jones									
Lee									
Lenoir									
Lincoln									
Macon		15	15					1	1
Madison		17	17					2	2
Martin									
McDowell		1	1						
Mecklenburg									
Mitchell		5	5					1	1
Montgomery									
Moore									
Nash									
New Hanover									
Northampton		2	2						
Onslow									
Orange									
Pamlico									
Pasquotank									
Pender									
Perquimans									
Person									
Pitt									
Polk		43	43					4	4
Randolph									
Richmond									
Robeson									
Rockingham									
Rowan									
Rutherford		22	22					2	2
Sampson									
Scotland									
Stanly									
Stokes									
Surry									
Swain		4	4						
Transylvania		61	61					6	6
Tyrrell									
Union		1	1						
Vance									
Wake									
Warren									
Washington									
Watauga		2	2						
Wayne									
Wilkes									
Wilson									
Yadkin									
Yancey		8	8					1	1
Out of State		34	34					3	3
TOTALS			930						85

** Note: See counties Alamance through Johnston on previous page

Patient Origin - MRI Services

Facility County: Henderson

In an effort to document patterns of utilization of MRI Services in North Carolina, hospitals are asked to provide county of residence for each patient served in your facility. Patients served include patients receiving MRI procedures reported in Table **10a** of this application (**page 11**).

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham	1	74. Pitt	
3. Alleghany		39. Granville		75. Polk	312
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford	1	77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	1
8. Bertie		44. Haywood	20	80. Rowan	
9. Bladen		45. Henderson	4970	81. Rutherford	78
10. Brunswick	1	46. Hertford		82. Sampson	
11. Buncombe	134	47. Hoke		83. Scotland	
12. Burke	1	48. Hyde		84. Stanly	
13. Cabarrus	1	49. Iredell	2	85. Stokes	
14. Caldwell	2	50. Jackson	6	86. Surry	
15. Camden		51. Johnston	1	87. Swain	1
16. Carteret		52. Jones		88. Transylvania	243
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee	2	56. Macon	3	92. Wake	3
21. Chowan		57. Madison	8	93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland	6	59. McDowell	3	95. Watauga	
24. Columbus		60. Mecklenburg	3	96. Wayne	1
25. Craven		61. Mitchell	1	97. Wilkes	1
26. Cumberland	1	62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	3
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	6
31. Duplin		67. Onslow		102. South Carolina	34
32. Durham	1	68. Orange	1	103. Tennessee	3
33. Edgecombe		69. Pamlico		104. Virginia	4
34. Forsyth		70. Pasquotank		105. Other States	44
35. Franklin		71. Pender		106. Other	1
36. Gaston	3	72. Perquimans		**Total No. of Patients**	5907

Mobile Services: **True** _____ **or False** X

Patient Origin - Radiation Oncology Treatment

Facility County: Henderson

In an effort to document patterns of utilization of Radiation Oncology Treatment in North Carolina, hospitals are asked to provide county of residence for each patient served in your facility. This data should only reflect the number of patients, not number of treatments. Patients reported should be patients receiving [linac] procedures listed in **Section 11** of this application. **Please count each patient only once.**

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham		74. Pitt	
3. Alleghany		39. Granville		75. Polk	40
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford	1	77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood		80. Rowan	
9. Bladen		45. Henderson	179	81. Rutherford	9
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe	16	47. Hoke		83. Scotland	
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell	1	85. Stokes	
14. Caldwell		50. Jackson	3	86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	20
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee		56. Macon		92. Wake	
21. Chowan		57. Madison		93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland		59. McDowell		95. Watauga	
24. Columbus		60. Mecklenburg		96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	1
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	
31. Duplin		67. Onslow		102. South Carolina	11
32. Durham		68. Orange		103. Tennessee	
33. Edgecombe		69. Pamlico		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other States	9
35. Franklin		71. Pender		106. Other	1
36. Gaston		72. Perquimans		**Total No. of Patients**	291

Patient Origin – PET Scanner

Facility County: Henderson

In an effort to document patterns of utilization of PET Scanner in North Carolina, hospitals are asked to provide county of residence for each patient served in your facility. This data should only reflect the number of patients, not number of scans and should not include other radiopharmaceutical or supply charge codes. **Please count each patient only once.**

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham		74. Pitt	
3. Alleghany		39. Granville		75. Polk	7
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood		80. Rowan	
9. Bladen		45. Henderson	75	81. Rutherford	4
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe	3	47. Hoke		83. Scotland	
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell		85. Stokes	
14. Caldwell		50. Jackson		86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	6
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee		56. Macon		92. Wake	
21. Chowan		57. Madison		93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland		59. McDowell		95. Watauga	
24. Columbus		60. Mecklenburg		96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	
31. Duplin		67. Onslow		102. South Carolina	3
32. Durham		68. Orange		103. Tennessee	
33. Edgecombe		69. Pamlico		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other States	3
35. Franklin		71. Pender		106. Other	
36. Gaston		72. Perquimans		**Total No. of Patients**	101

This application must be completed and submitted with ONE COPY to the Acute and Home Care Licensure and Certification Section, Division of Facility Services prior to the issuance of a 2007 hospital license.

AUTHENTICATING SIGNATURE: The undersigned submits application for the year 2007 in accordance with Article 5, Chapter 131E of the General Statutes of North Carolina, and subject to the rules and codes adopted thereunder by the North Carolina Medical Care Commission (10A NCAC 13B), and certifies the accuracy of this information.

Signature: _____ **Date:** 12/14/06

PRINT NAME OF APPROVING OFFICIAL L. Jon Schurmeier

Please be advised, the license fee must accompany the completed application and be submitted to the Acute and Home Care Licensure and Certification Section, Division of Facility Services, prior to the issuance of a hospital license.

North Carolina Department of Health and Human Services
Division of Facility Services
Acute and Home Care Licensure and Certification Section
1205 Umstead Drive, 2712 Mail Service Center
Raleigh, North Carolina 27699-2712
Telephone: (919) 855-4620 Fax (919) 715-3073

For Official Use Only
License # H0019 Medicare # 340023
Computer 043388
PC Date 11/14/06

License Fee: $1,737.50

EXHIBIT
2

2007
HOSPITAL LICENSE
RENEWAL APPLICATION

Legal Identity of Applicant: **Fletcher Hospital, Incorporated**
(Full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service)

Doing Business As
(d/b/a) name(s) under which the facility or services are advertised or presented to the public:

PRIMARY: **Park Ridge Hospital**
Other:
Other:

Facility Mailing Address: P O Box 1569
Fletcher, NC 28732

Facility Site Address: ~~Naples Rd~~ ~~Fletcher, NC 28732~~ 100 Hospital Drive Hendersonville, NC 28792

County: Henderson
Telephone: (828)684-8501
Fax: (828)687-0729

Administrator/Director: ~~Michael U. Schulz~~ Jimm Bunch
Title: Administrator
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Chief Executive Officer: Jimm Bunch **Title:** President & CEO
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Name of the person to contact for any questions regarding this form:

Name: Myriam L. Schulze **Telephone:** 828-681-2102

E-Mail: myriam.schulze@ahss.org

FEES PAID
Date 11 / 14 / 06
Amount $ 1,737.50
Check 237656 Cash Other

"The N.C. Department of Health and Human Services does not discriminate on the basis of race, color, national origin, religion, age, or disability in employment or the provision of services."

Type of Health Care Facilities under the Hospital License

List Name(s) of facilities:	Address:	Type of Business / Service:

Please attach a separate sheet for additional listings

Ownership Disclosure (Please fill in any blanks and make changes where necessary.)

1. What is the name of the legal entity with ownership responsibility and liability?

Owner: Fletcher Hospital, Incorporated
Federal Employer ID#: 56-0543246
Street/Box: P O Box 1569
City: Fletcher State: NC Zip: 28732
Telephone: (828)684-8501 Fax: (828)687-0729
CEO: Michael H. Schultz

Is your facility part of a Health System? X Yes ___No
If 'Yes', name of Health System*: Adventist Health System
* ***(please attach a list of NC facilities that are part of your Health System)***
If 'Yes', name of CEO: Donald Jernigan, Ph.D.

a. Legal entity is: ___ For Profit X Not For Profit

b. Legal entity is: X Corporation ___ LLP ___ Partnership
___ Proprietorship ___ LLC ___ Government Unit

c. Does the above entity (partnership, corporation, etc.) LEASE the building from which services are offered? ___ Yes X No

If "YES", name of building owner:

2. Is the business operated under a management contract? ___Yes X No

If 'Yes', name and address of the management company.
Name:
Street/Box:
City: State: Zip:
Telephone: (___) _____

Ownership Disclosure *continued. . . .*

3. Vice President of Nursing and Patient Care Services:
   Karen Owensby, RN, MSN, Vice President of Clinical Services

4. Director of Planning: Bruce Bergherm, Vice President of Business Development

Facility Data

A. Reporting Period All responses should pertain to the period **October 1, 2005 to September 30, 2006**. If otherwise, please indicate reporting period: _____

B. General Information (Please fill in any blanks and make changes where necessary.)

a. Admissions to Licensed Acute Care Beds: **include responses to "a – r" on page 4; exclude responses to "2-9" on page 4; and exclude normal newborn bassinets.**	3,357	
b. Discharges from Licensed Acute Care Beds: **include responses to "a – r" on page 4; exclude responses to "2-9" on page 4; and exclude normal newborn bassinets.**	3,291	
c. Average Daily Census: **include responses to "a – r" on page 4; exclude responses to "2-9" on page 4; and exclude normal newborn bassinets.**	34	
d. Was there a permanent change in the total number of licensed beds during the reporting period?	Yes	No X
If 'Yes', what is the current number of licensed beds?		
If 'Yes', please state reason(s) (such as additions, alterations, or conversions) which may have affected the change in bed complement:		
e. Observations: Number of patients in observation status and not admitted as inpatients, excluding Emergency Department patients.	928	

C. Designation and Accreditation

1. Are you a designated trauma center? ____ Yes X No
2. Are you a critical access hospital (CAH)? ____ Yes X No
3. Are you a long term care hospital (LTCH)? ____ Yes X No
4. If this facility is accredited by JCAHO or AOA, specify the accrediting body JCAHO, and indicate the date of the last survey 05 / 19 / 06 AOA: 04/21/04

D. Beds by Service (Inpatient – Do Not Include Observation Beds or Days of Care)

[Please provide a Beds by Service (p. 4) for each hospital campus (*see G.S. 131E-176(2c)*)]

Please indicate below the number of beds usually assigned (set up and staffed for use) to each of the following services and the number of census inpatient days of care rendered in each unit. NOTE: If your facility has a designated unit(s) for chemical dependency treatment and/or detoxification, please complete the patient origin sheet pertaining to Psychiatric and Substance Abuse Services. If your facility has a Nursing Facility unit and/or Adult Care Bed unit please complete the supplemental packet for Skilled Nursing Facility beds.

Licensed Acute Care (provide details below) *Campus* _____	Licensed Beds as of September 30, 2006	Staffed Beds as of September 30, 2006	Annual Census Inpt. Days of Care
Intensive Care Units			
a. Burn *			*
b. Cardiac (Combined ICU/CCU/Telemetry)	14	14	3378
c. Cardiovascular Surgery			
d. Medical/Surgical			
e. Neonatal Beds Level IV ** (Not Normal Newborn)			**
f. Pediatric			
g. Respiratory Pulmonary			
h. Other (List)			
Other Units			
i. Gynecology			
j. Medical/Surgical ***	40	40	*** 7751
k. Neonatal Level III ** (Not Normal Newborn)			**
l. Neonatal Level II ** (Not Normal Newborn)			**
m. Obstetric (including LDRP)	8	8	1281
n. Oncology			
o. Orthopedics			
p. Pediatric			
q. Other (List) _____			
1. Total General Acute Care Beds (a through r)	**62**	62	12,410
2. Comprehensive In-Patient Rehabilitation	0		
3. Inpatient Hospice	0		
4. Detoxification	0		
5. Substance Abuse / Chemical Dependency Treatment	0		
6. Psychiatry	41	36	12,395
7. Nursing Facility	0		
8. Adult Care (Home for the Aged)	0		
9. Other	0		
10. Totals (1 through 9)	**103**	98	24,805

* Please report only Census Days of Care of DRG's 504, 505, 506, 507, 508, 509, 510 and 511.

** Per C.O.N. rule definition. Refer to Section .1400 entitled Neonatal Services. (10A NCAC 14C)

*** Exclude swing-bed days. (See swing-bed information next page)

D. Beds by Service (Inpatient) *continued*

Number of Swing Beds *	**
Number of Skilled Nursing days in Swing Beds	818
Number of unlicensed observation beds	

* means a hospital designated as a swing-bed hospital by CMS (Centers for Medicare and Medicaid Services)

** There are 48 dual purpose beds, which include medical, surgical beds.

E. Reimbursement Source (For "Inpatient Days," show Acute Inpatient Days only, excluding normal newborns.)

Payer Source	Inpatient Days of Care	Emergency Cases	Outpatient Cases	Same Day Surgery Cases
Charity Care**				
Commercial Ins. [1]	2,348	4,585	15,576	2,103
Medicaid (including HMO)	1,608	3,242	3,034	419
Medicare (including HMO)	7,771	3,983	11,686	2,423
Private Pay / Self Pay	537	3,803	995	220
Other Gov't. [2]	146	165	944	62
Bad Debt				
All other				
TOTAL	12,410	15,778	32,235	5,227

** Charity Care Definition Health care services that never were expected to result in cash inflows Charity care results from a provider's policy to provide health care services free of charge to individuals who meet certain financial criteria

[1] Commercial Insurance includes all forms of managed care except Medicaid and Medicare HMO's

[2] Other Government includes Tricare and VA insurance programs

[3] Cases which originate from the Emergency Department

F. Services and Facilities

1. Obstetrics	Enter Number
a. Live births (Vaginal Deliveries)	364
b. Live births (Cesarean Section)	192
c. Stillbirths	2

d. Delivery Rooms - Delivery Only (not Cesarean Section)	0
e. Delivery Rooms - Labor and Delivery, Recovery	4
f. Delivery Rooms – LDRP (include Item "n" on Page 4)	0
g. Normal newborn bassinets (Level I Neonatal Services) Do not include with totals under the section entitled Beds by Service (Inpatient)	8

2. Abortion Services Number of procedures per Year 0

3. **Emergency Department Services** (cases equal visits to ED)

Number of cases/year: 13,987

Does this include fast track/urgent care ? ____ Yes _X_ No.

If "Yes," how many of these are urgent care? _____

	Hours of Operation		Hrs with physician on duty in ER suite	
	From	To	From	To
Monday		24 hours		24 hours
Tuesday		"		"
Wednesday		"		"
Thursday		"		"
Friday		"		"
Saturday		"		"
Sunday		"		"

4. **Medical Air Transport**: Owned or leased air ambulance service:

a. Does the facility operate an air ambulance service? __ Yes _X_ No
b. If "Yes", complete the following chart.

Type of Aircraft	Number of Aircraft	Number Owned	Number Leased	Number of Transports
Rotary				
Fixed Wing				

5. **Pathology and Medical Lab** (Check whether or not service is provided)

a. Blood Bank/Transfusion Services _X_ Yes __ No
b. Histopathology Laboratory _X_ Yes __ No
c. HIV Laboratory Testing _X_ Yes __ No
Number during month of September 2005
HIV Serology _____ **Screening test for employee exposures only.
HIV Culture _____
d. Organ Bank __ Yes _X_ No
e. Pap Smear Screening _X_ Yes __ No

6. **Transplantation Services** - Number of transplants

Type	Number	Type	Number
a. Bone Marrow-Allogenic		i. Kidney/Liver	
b. Bone Marrow-Autologous		j. Liver	
c. Cornea	2	k. Lung	
d. Heart		l. Pancreas	
e. Heart/Lung		m. Pancreas/Kidney	
f. Heart/Liver		n. Pancreas/Liver	
g. Heart/Kidney		o. Other	
h. Kidney			

Do you perform living donor transplants ? ____ Yes _X_ No.

7. **Specialized Cardiac Services** (for questions, call 855-3865 [Medical Facilities Planning])

(a) **Cardiac Catheterization**	**Diagnostic Cardiac Catheterization ICD-9 37.21, 37.22, 37.23, 37.25**	**Interventional Cardiac Catheterization-ICD-9 36.01, 36.02, 36.05, 36.06, 36.07, 36.09; 35.52, 35.71, 35.96**	**Electro-physiology 37.26, 37.27, 37.34, 37.70, 37.71, 37.72, 37.73, 37.74, 37.75, 37.76, 37.77, 37.79, 37.80, 37.81, 37.82, 37.83, 37.85, 37.86, 37.87, 37.89, 37.94, 37.95, 37.96, 37.97, 37.98, 37.99, 00.50, 00.51, 00.52, 00.53, 00.54**
1. Number of Units of Equipment			
2. Total Annual Number of Cases*			
3. Of Total in #2, Number of Patients Age 14 & under			
4. Of Total in #2, Number of Cases Performed in Mobile Unit**			

* One case is defined to be one visit or trip by a patient to an operating room or catheterization laboratory for a single or multiple procedures or catheterizations. Count each visit once regardless of the number of diagnostic, interventional, and/or EP procedures performed within that visit.

** Please report name of mobile vendor: _____

Number of operating hours per week on site: _____

(b) **Open Heart Surgery (utilizing heart/lung bypass machines)**	
1. Number of Dedicated Open Heart Surgery Operating Rooms	
2. Number of Heart-Lung Bypass Machines	
3. Total Annual Number of Procedures	
4. Of total in #3, Number of Procedures on Patients Age 14 & under	

8. Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases

a) Surgical Operating Rooms and Cases

[1] Please report *Surgical Operating Rooms* built to meet the specifications and standards for operating rooms required by the Construction Section of the Division of Facility Services, and which are fully equipped to perform surgical procedures. These surgical operating rooms include rooms located in Obstetrics and surgical suites. Please report the number of cases performed in these rooms during the reporting period. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was in the operating room.

NOTE: If this License includes more than one campus, please submit the Cumulative Totals and COPY this sheet and Submit a duplicate of this page for each campus.

(**Campus** – ***If multiple sites***: _____)

Type of Room [A]	Number of Rooms [B]	Of the Rooms in Column [B], the number "Not in Use" [C]	Inpatient Cases [D]	Ambulatory Cases [E]
Dedicated Open Heart Surgery (from 7b)				
Dedicated C-Section				
Other Dedicated Inpatient Surgery				
Dedicated Ambulatory Surgery				
Shared - Inpatient / Ambulatory Surgery	6	0	1,348	4,536
Total of Surgical Operating Rooms & Cases *(Columns [D] & [E] should equal Totals in 8(d))*	6	0	1,348	4,536

[2] Does this facility have **additional** surgical operating rooms (i.e., **not** listed above) that **are being developed** pursuant to a Certificate of Need or pursuant to the exemption provided in Senate Bill 714? ____ Yes _X_ No

If "Yes," please list the **Types of Rooms** and **Number of Rooms** being developed:

_____

b) Gastrointestinal Endoscopy Rooms and Cases

[1] Report the number of *Gastrointestinal Endoscopy Rooms* and the number of cases performed in these rooms during the reporting period. (***NOTE***: **Other procedure rooms** should be included in **Section 9** on **Page 10** of this application.) Count each patient as one case regardless of the number of gastrointestinal procedures performed while patient was in the GI endoscopy room. For GI Endoscopy Rooms, please also report the Total Number of GI Procedures performed.

Type of Room [A]	Number Of Rooms [B]	Of the Rooms in Column [B], the number "Not in Use" [C]	Inpatient Cases [D]	Ambulatory Cases [E]	Total Number of Procedures [F]
Gastrointestinal Endoscopy Rooms & Cases	1	0	GI: 189	GI: 712	GI: 901
			Non GI: 8	Non GI: 103	Non GI: 111

[2] Does this facility have **additional** Gastrointestinal Endoscopy Rooms (i.e., **not** listed above) that **are being developed** pursuant to a Certificate of Need or pursuant to the exemption provided in Senate Bill 714? ____ Yes _X_ No

If "Yes," please list the **Number of Rooms** being developed:

_____

8. Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases *continued*

c) Average Room Availability and Average Case Times:

Type of Room	"Resource Hours" * (*Average Hours per Room per Day Routinely Scheduled for Use*)	Average "Case Time" ** in Minutes for Inpatient Cases	Average "Case Time" ** in Minutes for Ambulatory Cases
Surgical Operating Rooms	8	90	60
Gastrointestinal Endoscopy Rooms	4	30	30

* **"Resource Hours"** - Average number of hours per Room per Day routinely scheduled to be available for performance of procedures. (**Example**: 2 rooms @ 8 hours per day plus 2 rooms @ 10 hours per day equals 36 hours per day; divided by 4 rooms equals an average of 9 hours / per room / per day)

** **"Case Time" = Time from Room Set-up Start to Room Clean-up Finish** Definition 2.4 from the "Procedural Times Glossary" of the AACD, as approved by ASA, ACS, and AORN. *NOTE: This definition includes all of the time for which a given procedure requires an OR/PR. It allows for the different duration of Room Set-up and Room Clean-up Times that occur because of the varying supply and equipment needs for a particular procedure. For purposes of scheduling and efficiency analysis, this definition is ideal because it includes all of the time that an OR/PR must be reserved for a given procedure*

d) Surgical Specialty - Of the cases in **Surgical Operating Rooms** (Item 8.a.[1]), enter the number of cases by surgical specialty area in the chart below:

Specialty Area	Inpatient Cases	Ambulatory Cases
Cesarean Sections	192	
Cystoscopy		
Endoscopy (all endo types performed in Surgical Operating Room)		
General	274	547
Gynecology	176	146
Neurosurgery/Spine	199	392
Open Heart		
Ophthalmology	2	1,370
Oral Surgery		19
Orthopedics	379	1,475
Otolaryngology	10	147
Plastic Surgery		
Podiatry	2	21
Thoracic (other than open heart)		3
Urology	94	374
Other (Specify) Cardiology/Oncology/vascular	20	45
Total Surgical Operating Room Cases *(Totals should equal totals 8.a[1], columns D & E)*	1,348	4,536

9. Non-Gastrointestinal Procedure Rooms and Cases

Please report only rooms or cases not reported in 8a or 8b: Other rooms not equipped or meeting all the specifications for an operating room, dedicated to the performance of procedures other than gastrointestinal endoscopy. (Do not list a room for more than one use). **Please note: Any procedures performed in these rooms should not be billed as having occurred in an operating room or reported in 8 as procedures performed in an operating room. Cases**: Count each patient as one case regardless of the number of procedures performed while patient was in the room.

Use	Number of Rooms	Inpatient Cases	Ambulatory Cases
Cast Procedures			
Cystoscopy			
Endoscopies (*other than GI Endoscopies*) unless they were performed in a surgical operating room			
Lithotripsy			
Special Procedures/Angiography (neuro & vascular but not including cardiac cath.)			
Sutures			
YAG Laser			
Other (Specify)			
Totals			

10a. Diagnostic Imaging and Lithotripsy Data

Indicate the number of machines/instruments and the number of the following types of procedures performed during the 12-month reporting period at your facility. For Hospitals that operate medical equipment at multiple sites, please provide a separate page for each site.

Imaging							
Fixed Equipment (Exclude Research & Policy AC-3 Units)	Number of Units	No. of Procedures: Inpatient	No. of Procedures: Outpatient	Total	No. of MRI Procedures *: With Contrast or Sedation	No. of MRI Procedures *: Without Contrast or Sedation	Total
CT Scanner	1	1,908	6,391	8,299			
MRI SkyLand	1		1,567	1,567	149	1,418	1,567
Open MRI Scanners included in row above							
Mammogram	1	2,815	29	2,844			
Other radiographic & fluoroscopic (See Note Below)							
Mobile Equipment Identify Vendor/Owner in space ( ) below:	Number of Units	No. of Procedures: Inpatient	No. of Procedures: Outpatient	Total	No. of MRI Procedures: With Contrast or Sedation	No. of MRI Procedures: Without Contrast or Sedation	Total
MRI #1 (GE LX Echospeed)	1						
MRI #2 ( )							
CT Scan ( )							
Nuclear Medicine Fixed Equipment	Number of Units	No. of Procedures: Inpatient	No. of Procedures: Outpatient	Total			
Dedicated PET Scanner							
Coincidence Camera							
SPECT							
Gamma Camera /Spect	1	726	1291	2,017			
Mobile Equipment Identify Vendor/Owner in space () below:	Number of Units	No. of Procedures: Inpatient	No. of Procedures: Outpatient	Total			
Dedicated PET Scanner (Alliance Imag.	1		92	92			
Coincidence Camera ( )							
SPECT ( )							
Gamma Camera ( )							
Policy AC-3 or Research Equipment	Number of Units	No. of Procedures: Inpatient	No. of Procedures: Outpatient	Total	No. of Procedures **: Clinical	No. of Procedures **: Research	Total
MRI pursuant to Policy AC-3:							
Other Human Research MRI Scanner							
PET pursuant to Policy AC-3							
Other Human Research PET Scanner							
Lithotripsy (Identify Vendor/Owner in space ( ) below)	Number of Units	No. of Procedures: Inpatient	No. of Procedures: Outpatient	Total			
Fixed ( )							
Mobile (Prime Medical)		0	5	5			

Note: Totals of MRI inpatients and outpatients should equal MRI totals with and without contrast or sedation

Note: Totals of MRI inpatients and outpatients should equal MRI totals for clinical and research procedures

MRI procedure is defined as a single discrete MRI study of one patient (single CPT coded procedure). An MRI study means one or more scans relative to a single diagnosis or symptom. *NOTE*: Please Report ALL Angiography procedures on page 10, in Table 9 under Special Procedures/Angiography Rooms.

PET procedure is defined as a single discrete PET scan of a patient (single CPT coded procedure), not counting other radiopharmaceutical or supply charge codes.

10b. MRI Procedures by CPT Codes

MRI Procedures by CPT Code		
CPT Code	CPT Description	Number of Procedures
70336	MRI Temporomandibular Joint(s)	
70540	MRI Orbit/Face/Neck w/o	
70542	MRI Orbit/Face/Neck with contrast	
70543	MRI Orbit/Face/Neck w/o & with	
70544	MRA Head w/o	48
70545	MRA Head with contrast	
70546	MRA Head w/o & with	2
70547	MRA Neck w/o	1
70548	MRA Neck with contrast	
70549	MRA Neck w/o & with	14
70551	MRI Brain w/o	160
70552	MRI Brain with contrast	
70553	MRI Brain w/o & with	459
7055A	IAC Screening	
71550	MRI Chest w/o	7
71551	MRI Chest with contrast	
71552	MRI Chest w/o & with	9
71555	MRA Chest with OR without contrast	
72126	Cervical Spine Infusion only	
72141	MRI Cervical Spine w/o	360
72142	MRI Cervical Spine with contrast	
72156	MRI Cervical Spine w/o & with	41
72146	MRI Thoracic Spine w/o	69
72147	MRI Thoracic Spine with contrast	
72157	MRI Thoracic Spine w/o & with	32
72148	MRI Lumbar Spine w/o	379
72149	MRI Lumbar Spine with contrast	
72158	MRI Lumbar Spine w/o & with	107
72159	MRA Spinal Canal w/o OR with contrast	
72195	MRI Pelvis w/o	24
72196	MRI Pelvis with contrast	1
72197	MRI Pelvis w/o & with	30
72198	MRA Pelvis w/o OR with Contrast	1
73218	MRI Upper Ext, other than joint w/o	11
73219	MRI Upper Ext, other than joint with contrast	
73220	MRI Upper Ext, other than joint w/o & with	8
73221	MRI Upper Ext any joint w/o	168
73222	MRI Upper Ext any joint with contrast	36
73223	MRI Upper Ext any joint w/o & with	5
73225	MRA Upper Ext w/o OR with contrast	
	Subtotal	1,980

10b. MRI Procedures by CPT Codes *continued. . . . .*

MRI Procedures by CPT Code		
CPT Code	CPT Description	Number of Procedures
73718	MRI Lower Ext other than joint w/o	33
73719	MRI Lower Ext other than joint with contrast	
73720	MRI Lower Ext other than joint w/o & with	43
73721	MRI Lower Ext any joint w/o	308
73722	MRI Lower Ext any joint with contrast	6
73723	MRI Lower Ext any joint w/o & with	15
73725	MRA Lower Ext w/o OR with contrast	1
74181	MRI Abdomen w/o	38
74182	MRI Abdomen with contrast	
74183	MRI Abdomen w/o & with	24
74185	MRA Abdomen w/o OR with contrast	17
75552	MRI Cardiac Morphology w/o	
75553	MRI Cardiac Morphology with contrast	
75554	MRI Cardiac Function Complete	
75555	MRI Cardiac Function Limited	
75556	MRI Cardiac Velocity Flow Mapping	
76093	MRI Breast, unilateral w/o and/or with contrast	
76094	MRI Breast, bilateral w/o and/or with contrast	49
76125	Cineradiography to complement exam	
76375	MRI 3-D Reconstruction	
76390	MRI Spectroscopy	
76393	MRI Guidance for needle placement	
76394	MRI Guidance for tissue ablation	
76400	MRI Bone Marrow blood supply	
7649A	MR functional imaging	
7649D	MRI infant spine comp w/ & w/o contrast	
7649E	Spine (infants) w/o infusion	
7649H	MR functional imaging	
N/A	Clinical Research Scans	
	Total Number of Procedures	2,514

10b. MRI Procedures by CPT Codes SKYLAND FIXED MRI

MRI Procedures by CPT Code		
CPT Code	CPT Description	Number of Procedures
70336	MRI Temporomandibular Joint(s)	2
70540	MRI Orbit/Face/Neck w/o	
70542	MRI Orbit/Face/Neck with contrast	
70543	MRI Orbit/Face/Neck w/o & with	1
70544	MRA Head w/o	12
70545	MRA Head with contrast	
70546	MRA Head w/o & with	
70547	MRA Neck w/o	
70548	MRA Neck with contrast	
70549	MRA Neck w/o & with	
70551	MRI Brain w/o	1
70552	MRI Brain with contrast	38
70553	MRI Brain w/o & with	1
7055A	IAC Screening	27
71550	MRI Chest w/o	
71551	MRI Chest with contrast	2
71552	MRI Chest w/o & with	
71555	MRA Chest with OR without contrast	
72126	Cervical Spine Infusion only	
72141	MRI Cervical Spine w/o	163
72142	MRI Cervical Spine with contrast	1
72156	MRI Cervical Spine w/o & with	10
72146	MRI Thoracic Spine w/o	46
72147	MRI Thoracic Spine with contrast	
72157	MRI Thoracic Spine w/o & with	1
72148	MRI Lumbar Spine w/o	313
72149	MRI Lumbar Spine with contrast	
72158	MRI Lumbar Spine w/o & with	88
72159	MRA Spinal Canal w/o OR with contrast	
72195	MRI Pelvis w/o	26
72196	MRI Pelvis with contrast	
72197	MRI Pelvis w/o & with	3
72198	MRA Pelvis w/o OR with Contrast	
73218	MRI Upper Ext, other than joint w/o	13
73219	MRI Upper Ext, other than joint with contrast	1
73220	MRI Upper Ext, other than joint w/o & with	
73221	MRI Upper Ext any joint w/o	224
73222	MRI Upper Ext any joint with contrast	
73223	MRI Upper Ext any joint w/o & with	
73225	MRA Upper Ext w/o OR with contrast	
	Subtotal	973

10b. MRI Procedures by CPT Codes *continued. . . .*

MRI Procedures by CPT Code

CPT Code	CPT Description	Number of Procedures
73718	MRI Lower Ext other than joint w/o	34
73719	MRI Lower Ext other than joint with contrast	
73720	MRI Lower Ext other than joint w/o & with	7
73721	MRI Lower Ext any joint w/o	544
73722	MRI Lower Ext any joint with contrast	1
73723	MRI Lower Ext any joint w/o & with	5
73725	MRA Lower Ext w/o OR with contrast	
74181	MRI Abdomen w/o	1
74182	MRI Abdomen with contrast	
74183	MRI Abdomen w/o & with	1
74185	MRA Abdomen w/o OR with contrast	1
75552	MRI Cardiac Morphology w/o	
75553	MRI Cardiac Morphology with contrast	
75554	MRI Cardiac Function Complete	
75555	MRI Cardiac Function Limited	
75556	MRI Cardiac Velocity Flow Mapping	
76093	MRI Breast, unilateral w/o and/or with contrast	
76094	MRI Breast, bilateral w/o and/or with contrast	
76125	Cineradiography to complement exam	
76375	MRI 3-D Reconstruction	
76390	MRI Spectroscopy	
76393	MRI Guidance for needle placement	
76394	MRI Guidance for tissue ablation	
76400	MRI Bone Marrow blood supply	
7649A	MR functional imaging	
7649D	MRI infant spine comp w/ & w/o contrast	
7649E	Spine (infants) w/o infusion	
7649H	MR functional imaging	
N/A	Clinical Research Scans	
	Total Number of Procedures	1,567

11. Radiation Oncology Treatment Data

CPT Code	Description	Number of Procedures	ESTVs/ Procedures Under ACR	Total ACR ESTVs	
	Simple Treatment Delivery:				
77401	Radiation treatment delivery		1.00		
77402	Radiation treatment delivery (<=5 MeV)		1.00		
77403	Radiation treatment delivery (6-10 MeV)		1.00		
77404	Radiation treatment delivery (11-19 MeV)		1.00		
77406	Radiation treatment delivery (>=20 MeV)		1.00		
	Intermediate Treatment Delivery:				
77407	Radiation treatment delivery (<=5 MeV)		1.00		
77408	Radiation treatment delivery (6-10 MeV)		1.00		
77409	Radiation treatment delivery (11-19 MeV)		1.00		
77411	Radiation treatment delivery (>=20 MeV)		1.00		
	Complex Treatment Delivery:				
77412	Radiation treatment delivery (<=5 MeV)		1.00		
77413	Radiation treatment delivery (6-10 MeV)		1.00		
77414	Radiation treatment delivery (11-19 MeV)		1.00		
77416	Radiation treatment delivery (>= 20 MeV)		1.00		
	Sub-Total				
For the increased time required for special techniques, ESTV values are indicated below:					
77417	Additional field check radiographs		.50		
77418	Intensity modulated radiation treatment (IMRT)delivery		1.00		
77432	Stereotactic radiosurg. treatment mgmt Linear Accelerator		3.00		
77432	Stereotactic radiosurg. Treatment mgmt. Gamma Knife		3.00		
	Total body irradiation		2.50		
	Hemibody irradiation		2.00		
	Intraoperative radiation therapy (conducted by bringing the anesthetized patient down to the linac)		10.00		
	Neutron and proton radiation therapy		2.00		
	Limb salvage irradiation		1.00		
	Pediatric Patient under anesthesia		1.50		
	Sub-Total				
	TOTALS:				

Note: For special techniques, list procedures under both the treatment delivery and the special techniques sections.

12. Radiation Oncology Treatment Data *continued*

a.	Number of unduplicated patients who receive a course of radiation oncology treatments (patients shall be counted more than once if they receive additional courses of treatment)	
b.	Total number of Linear Accelerator(s)	
c.	Number of Linear Accelerators configured for stereotactic radiosurgery	

12. Telemedicine

a. **Does your facility utilize telemedicine to have images read at another facility?** YES

b. **Does your facility read telemedicine images?** NO

13. Additional Services:

a) **Check if Service(s) is provided:**

	Check		Check
1. Cardiac Rehab Program (Outpatient)	X	5. Rehabilitation Outpatient Unit	X
2. Chemotherapy	X	6. Podiatric Services	X
3. Clinical Psychology Services		7. Genetic Counseling Service	
4. Dental Services		8. Acute Dialysis	

Number of Acute Dialysis Stations _____

b) **Hospice Inpatient Unit Data:**

Hospital-based hospice units with licensed hospice beds. List each county served and report **all patients by county of residence**. Use each patient's age on the admission day to the Licensed Hospice Inpatient Facility. **For age categories count each inpatient client only once.**

County of Residence	Age 0-17	Age 18-40	Age 41-59	Age 60-64	Age 65-74	Age 75-84	Age 85+	Total Patients Served	Total Days of Care	Deaths
Out of State										
Total All Ages										

13. Additional Services: *continued*

c) Mental Health and Substance Abuse

1. If psychiatric care has a different name than the hospital, please indicate:

   Hope Behavioral Health Services

2. If address is different than the hospital, please indicate:

3. Director of the above services:
   Rebecca M. Mayer, R.N., Ph. D.

Indicate the program/unit location in the **Service Categories** chart below. If it is in the hospital, include the room number. If it is located at another site, include the building name, program/unit name and address.

Service Categories: All applicants must complete the following table for all mental health services which are to be provided by the facility. If the service is not offered, leave the spaces blank.

Rule 10A NCAC 27G Licensure Rules For Mental Health Facilities	Location of Services	Beds Assigned by Age				
		0-12	13-17	Subtotal 0-17	18 & up	Total Beds
.1100 Partial hospitalization for individuals who are acutely mentally ill.	In-Patient					
.1200 Psychosocial rehabilitation facilities for individuals with severe and persistent mental illness						
.1300 Residential treatment facilities for children and adolescents who are emotionally disturbed or have a mental illness						
.1400 Day treatment for children and adolescents with emotional or behavioral disturbances						
.1500 Intensive residential treatment facilities for children & adolescents who are emotionally disturbed or who have a mental illness						

Rule 10A NCAC 13B Licensure Rules For Hospitals	Location of Services	Beds Assigned by Age				
		0-12	13-17	Subtotal 0-17	18 & up	Total Beds
.5200 Dedicated inpatient unit for individuals who have mental disorders	PRH				41	41

13. Additional Services: *continued*

c) Mental Health and Substance Abuse *continued*

Rule 10A NCAC 27G Licensure Rules for Substance Abuse Facilities	Location of Services	Beds Assigned by Age				
		0-12	13-17	Subtotal 0-17	18 & up	Total Beds
3100 Nonhospital medical detoxification for individuals who are substance abusers						
3200 Social setting detoxification for substance abusers						
.3300 Outpatient detoxification for substance abusers						
.3400 Residential treatment/ rehabilitation for individuals with substance abuse disorders						
.3500 Outpatient facilities for individuals with substance abuse disorders						
.3600 Outpatient narcotic addiction treatment						
.3700 Day treatment facilities for individuals with substance abuse disorders						

Rule 10A NCAC 13B Licensure Rules For Hospitals	Location of Services	Beds Assigned by Age				
		0-12	13-17	Subtotal 0-17	18 & up	Total Beds
.5200 Dedicated inpatient hospital unit for individuals who have substance abuse disorders (specify type) # of Treatment beds _____ # of Medical Detox beds _____						

Patient Origin -General Acute Care Inpatient Services

Facility County: Henderson

In an effort to document patterns of utilization of General Acute Care Inpatient Services in North Carolina hospitals, please provide the county of residence for each patient admitted to your facility.

County	No. of Admissions	County	No. of Admissions	County	No. of Admissions
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham	2	74. Pitt	
3. Alleghany		39. Granville		75. Polk	80
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery	1	42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood	64	80. Rowan	2
9. Bladen		45. Henderson	2,462	81. Rutherford	55
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe	840	47. Hoke		83. Scotland	
12. Burke	21	48. Hyde		84. Stanly	
13. Cabarrus	2	49. Iredell		85. Stokes	
14. Caldwell	3	50. Jackson	26	86. Surry	
15. Camden		51. Johnston		87. Swain	6
16. Carteret		52. Jones		88. Transylvania	75
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee	3	56. Macon	18	92. Wake	
21. Chowan		57. Madison	5	93. Warren	
22. Clay	2	58. Martin	21	94. Washington	
23. Cleveland	5	59. McDowell		95. Watauga	
24. Columbus	2	60. Mecklenburg	5	96. Wayne	
25. Craven		61. Mitchell	2	97. Wilkes	
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	7
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	
31. Duplin		67. Onslow		102. South Carolina	27
32. Durham		68. Orange		103. Tennessee	3
33. Edgecombe		69. Pamlico		104. Virginia	2
34. Forsyth		70. Pasquotank		105. Other States	39
35. Franklin		71. Pender		106. Other	43
36. Gaston	2	72. Perquimans		Total No. of Patients	3,825

Patient Origin – Inpatient Surgical Cases – Excluding GI Endoscopy Cases (In Dedicated Inpatient or Shared Operating Rooms)

Facility County: Henderson

In an effort to document patterns of "Inpatient" utilization of Surgical Operating Rooms in North Carolina hospitals, please provide the county of residence for each inpatient surgical patient served in your facility. Count each inpatient "once" regardless of the number of surgical procedures performed while the patient was in the operating room. However, each admission as an inpatient operating room patient should be reported separately.

The "Total" from this chart should match the "Total" reported in the **Inpatient Cases** "Column D" in the Table under 8(a), page 8

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham	2	74. Pitt	
3. Alleghany		39. Granville		75. Polk	26
4. Anson		40. Greene		76. Randolph	
5. Ashe	1	41. Guilford		77. Richmond	
6. Avery	2	42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood	73	80. Rowan	1
9. Bladen	1	45. Henderson	700	81. Rutherford	29
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe	296	47. Hoke		83. Scotland	
12. Burke	29	48. Hyde		84. Stanly	
13. Cabarrus	1	49. Iredell		85. Stokes	
14. Caldwell	5	50. Jackson	22	86. Surry	
15. Camden		51. Johnston		87. Swain	6
16. Carteret		52. Jones		88. Transylvania	28
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee		56. Macon	11	92. Wake	
21. Chowan		57. Madison	5	93. Warren	
22. Clay	1	58. Martin	18	94. Washington	
23. Cleveland	4	59. McDowell		95. Watauga	
24. Columbus	2	60. Mecklenburg		96. Wayne	
25. Craven		61. Mitchell	2	97. Wilkes	
26. Cumberland		62. Montgomery	2	98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	3
29. Davidson		65. New Hanover	1		
30. Davie		66. Northampton		101. Georgia	
31. Duplin		67. Onslow		102. South Carolina	20
32. Durham		68. Orange		103. Tennessee	3
33. Edgecombe		69. Pamlico		104. Virginia	2
34. Forsyth		70. Pasquotank		105. Other States	23
35. Franklin		71. Pender		106. Other	23
36. Gaston		72. Perquimans		**Total No. of Patients**	1,348

Patient Origin – Ambulatory Surgical Cases – Excluding GI Endoscopy Cases (*In Dedicated Ambulatory or Shared Operating Rooms*)

Facility County: Henderson

In an effort to document patterns of "Ambulatory" utilization of Surgical Operating Rooms in North Carolina hospitals, please provide the county of residence for each ambulatory surgery patient served in your facility. Count each ambulatory patient "once" regardless of the number of procedures performed while the patient was in the operating room. However, each admission as an ambulatory operating room patient should be reported separately.

The "Total" from this chart should match the "Total" reported in the **Ambulatory Cases**, "Column E" in the Table under 8(a), page 8.

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance	1	37. Gates		73. Person	
2. Alexander	7	38. Graham	19	74. Pitt	
3. Alleghany		39. Granville	1	75. Polk	110
4. Anson		40. Greene	1	76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery	13	42. Halifax		78. Robeson	1
7. Beaufort		43. Harnett	3	79. Rockingham	
8. Bertie		44. Haywood	211	80. Rowan	
9. Bladen		45. Henderson	2486	81. Rutherford	53
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe	998	47. Hoke		83. Scotland	
12. Burke	41	48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell	1	85. Stokes	
14. Caldwell	6	50. Jackson	52	86. Surry	
15. Camden		51. Johnston		87. Swain	35
16. Carteret		52. Jones		88. Transylvania	136
17. Caswell		53. Lee	1	89. Tyrrell	
18. Catawba	4	54. Lenoir		90. Union	1
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee	23	56. Macon	50	92. Wake	
21. Chowan		57. Madison	37	93. Warren	
22. Clay		58. Martin	58	94. Washington	
23. Cleveland		59. McDowell		95. Watauga	2
24. Columbus		60. Mecklenburg	1	96. Wayne	
25. Craven		61. Mitchell	24	97. Wilkes	
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	2
28. Dare		64. Nash		100. Yancey	36
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	3
31. Duplin		67. Onslow		102. South Carolina	42
32. Durham		68. Orange		103. Tennessee	5
33. Edgecombe	1	69. Pamlico		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other States	26
35. Franklin	1	71. Pender		106. Other	40
36. Gaston		72. Perquimans		**Total No. of Patients**	4,536

Patient Origin – Gastrointestinal Endoscopy (GI) Cases – *(Performed In Gastrointestinal Endoscopy Rooms)*

Facility County: Henderson

In an effort to document patterns of utilization of Gastrointestinal Endoscopy Rooms in North Carolina hospitals, please provide the county of residence for each GI Endoscopy patient served in your facility. Count each patient "once" regardless of the number of procedures performed while the patient was in the Gastrointestinal Endoscopy Room. However, each admission as a GI Endoscopy Room patient should be reported separately.

The "Total" from this chart should match the Combined Total reported as **Gastrointestinal Endoscopy Cases**, "Column D" plus "Column E" in the Table under 8(b), page 8.

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham	1	74. Pitt	
3. Alleghany		39. Granville		75. Polk	15
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood	14	80. Rowan	
9. Bladen		45. Henderson	744	81. Rutherford	8
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe	178	47. Hoke		83. Scotland	
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus	1	49. Iredell		85. Stokes	
14. Caldwell		50. Jackson	1	86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	21
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba	1	54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee	1	56. Macon	2	92. Wake	
21. Chowan		57. Madison	2	93. Warren	
22. Clay		58. Martin	2	94. Washington	
23. Cleveland		59. McDowell	1	95. Watauga	1
24. Columbus		60. Mecklenburg		96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	4
29. Davidson		65. New Hanover			
30. Davie	1	66. Northampton		101. Georgia	
31. Duplin		67. Onslow		102. South Carolina	4
32. Durham		68. Orange		103. Tennessee	
33. Edgecombe		69. Pamlico		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other States	5
35. Franklin		71. Pender		106. Other	4
36. Gaston		72. Perquimans		**Total No. of Patients**	1,012

All responses should pertain to October 1, 2005 through September 30, 2006. If otherwise, indicate the actual reporting period used on Page 3 of this document.

Patient Origin - Psychiatric and Substance Abuse Alamance through Johnston

Facility County: Henderson

Complete the following table below for inpatient Days of Care reported under Section .5200.

County of Patient Origin	Psychiatric Treatment Days of Care			Substance Abuse Treatment Days of Care			Detoxification Days of Care		
	Age 0-17	Age 18+	Totals	Age 0-17	Age 18+	Totals	Age 0-17	Age 18+	Totals
Alamance									
Alexander		1							
Alleghany									
Anson									
Ashe		1							
Avery		4							
Beaufort									
Bertie									
Bladen		1							
Brunswick		2							
Buncombe		327							
Burke		6							
Cabarrus		1							
Caldwell		1							
Camden									
Carteret									
Caswell									
Catawba		3							
Chatham									
Cherokee		17							
Chowan									
Clay		8							
Cleveland		17							
Columbus		3							
Craven									
Cumberland		1							
Currituck									
Dare									
Davidson									
Davie		2							
Duplin									
Durham		2							
Edgecombe									
Forsyth									
Franklin									
Gaston		7							
Gates									
Graham		3							
Granville									
Greene									
Guilford		2							
Halifax									
Harnett									
Haywood		86							
Henderson		280							
Hertford									
Hoke									
Hyde									
Iredell		5							
Jackson		30							
Johnston									

** Note: See counties: Jones through Yancey (including Out-of-State) on next page

Patient Origin - Psychiatric and Substance Abuse Jones through Yancey (including Out-of-State)

Facility County: Henderson

(Continued from previous page)

County of Patient Origin	Psychiatric Treatment Days of Care			Substance Abuse Treatment Days of Care			Detoxification Days of Care		
	Age 0-17	Age 18+	Totals	Age 0-17	Age 18+	Totals	Age 0-17	Age 18+	Totals
Jones									
Lee									
Lenoir									
Lincoln			4						
Macon			24						
Madison			25						
Martin			24						
McDowell									
Mecklenburg			4						
Mitchell			8						
Montgomery									
Moore									
Nash									
New Hanover			3						
Northampton									
Onslow			3						
Orange			2						
Pamlico									
Pasquotank									
Pender			1						
Perquimans									
Person			1						
Pitt									
Polk			5						
Randolph									
Richmond									
Robeson			1						
Rockingham									
Rowan									
Rutherford			31						
Sampson									
Scotland									
Stanly									
Stokes									
Surry			1						
Swain			12						
Transylvania			68						
Tyrrell									
Union									
Vance									
Wake			2						
Warren									
Washington									
Watauga			4						
Wayne									
Wilkes									
Wilson									
Yadkin			2						
Yancey			22						
Out of State			46						
TOTALS			1,103						

** Note: See counties Alamance through Johnston on previous page

Patient Origin - MRI Services

Facility County: Henderson

In an effort to document patterns of utilization of MRI Services in North Carolina, hospitals are asked to provide county of residence for each patient served in your facility. Patients served include patients receiving MRI procedures reported in Table 10a of this application (page 11).

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham		74. Pitt	1
3. Alleghany		39. Granville		75. Polk	53
4. Anson		40. Greene		76. Randolph	
5. Ashe	1	41. Guilford	1	77. Richmond	
6. Avery	1	42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood	46	80. Rowan	2
9. Bladen		45. Henderson	1,606	81. Rutherford	19
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe	457	47. Hoke		83. Scotland	
12. Burke	9	48. Hyde		84. Stanly	
13. Cabarrus	3	49. Iredell		85. Stokes	
14. Caldwell	2	50. Jackson	4	86. Surry	
15. Camden		51. Johnston	2	87. Swain	2
16. Carteret		52. Jones		88. Transylvania	72
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba	1	54. Lenoir	1	90. Union	
19. Chatham		55. Lincoln	3	91. Vance	
20. Cherokee	3	56. Macon	17	92. Wake	6
21. Chowan		57. Madison	7	93. Warren	
22. Clay		58. Martin	15	94. Washington	
23. Cleveland		59. McDowell		95. Watauga	
24. Columbus	5	60. Mecklenburg	2	96. Wayne	
25. Craven		61. Mitchell	1	97. Wilkes	
26. Cumberland	1	62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	2
29. Davidson	3	65. New Hanover			
30. Davie		66. Northampton		101. Georgia	13
31. Duplin		67. Onslow		102. South Carolina	39
32. Durham		68. Orange	1	103. Tennessee	3
33. Edgecombe		69. Pamlico	1	104. Virginia	8
34. Forsyth		70. Pasquotank		105. Other States	60
35. Franklin	1	71. Pender		106. Other	34
36. Gaston	5	72. Perquimans		Total No. of Patients	2,514

Mobile Services: True __X__ or False _____

Patient Origin - Radiation Oncology Treatment

Facility County: Henderson

In an effort to document patterns of utilization of Radiation Oncology Treatment in North Carolina, hospitals are asked to provide county of residence for each patient served in your facility. This data should only reflect the number of patients, not number of treatments. Patients reported should be patients receiving [linac] procedures listed in **Section 11** of this application. **Please count each patient only once.**

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham		74. Pitt	
3. Alleghany		39. Granville		75. Polk	
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood		80. Rowan	
9. Bladen		45. Henderson		81. Rutherford	
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe		47. Hoke		83. Scotland	
12. Burke		48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell		85. Stokes	
14. Caldwell		50. Jackson		86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee		56. Macon		92. Wake	
21. Chowan		57. Madison		93. Warren	
22. Clay		58. Martin		94. Washington	
23. Cleveland		59. McDowell		95. Watauga	
24. Columbus		60. Mecklenburg		96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	
31. Duplin		67. Onslow		102. South Carolina	
32. Durham		68. Orange		103. Tennessee	
33. Edgecombe		69. Pamlico		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other States	
35. Franklin		71. Pender		106. Other	
36. Gaston		72. Perquimans		**Total No. of Patients**	

Patient Origin – PET Scanner

Facility County: Henderson

In an effort to document patterns of utilization of PET Scanner in North Carolina, hospitals are asked to provide county of residence for each patient served in your facility. This data should only reflect the number of patients, not number of scans and should not include other radiopharmaceutical or supply charge codes. **Please count each patient only once.**

County	No. of Patients	County	No. of Patients	County	No. of Patients
1. Alamance		37. Gates		73. Person	
2. Alexander		38. Graham		74. Pitt	
3. Allegbany		39. Granville		75. Polk	1
4. Anson		40. Greene		76. Randolph	
5. Ashe		41. Guilford		77. Richmond	
6. Avery		42. Halifax		78. Robeson	
7. Beaufort		43. Harnett		79. Rockingham	
8. Bertie		44. Haywood		80. Rowan	
9. Bladen		45. Henderson	76	81. Rutherford	
10. Brunswick		46. Hertford		82. Sampson	
11. Buncombe	8	47. Hoke		83. Scotland	
12. Burke	1	48. Hyde		84. Stanly	
13. Cabarrus		49. Iredell		85. Stokes	
14. Caldwell		50. Jackson		86. Surry	
15. Camden		51. Johnston		87. Swain	
16. Carteret		52. Jones		88. Transylvania	5
17. Caswell		53. Lee		89. Tyrrell	
18. Catawba		54. Lenoir		90. Union	
19. Chatham		55. Lincoln		91. Vance	
20. Cherokee		56. Macon		92. Wake	
21. Chowan		57. Madison		93. Warren	
22. Clay		58. Martin	1	94. Washington	
23. Cleveland		59. McDowell		95. Watauga	
24. Columbus		60. Mecklenburg		96. Wayne	
25. Craven		61. Mitchell		97. Wilkes	
26. Cumberland		62. Montgomery		98. Wilson	
27. Currituck		63. Moore		99. Yadkin	
28. Dare		64. Nash		100. Yancey	
29. Davidson		65. New Hanover			
30. Davie		66. Northampton		101. Georgia	
31. Duplin		67. Onslow		102. South Carolina	
32. Durham		68. Orange		103. Tennessee	
33. Edgecombe		69. Pamlico		104. Virginia	
34. Forsyth		70. Pasquotank		105. Other States	
35. Franklin		71. Pender		106. Other	
36. Gaston		72. Perquimans		**Total No. of Patients**	92

This application must be completed and submitted with ONE COPY to the Acute and Home Care Licensure and Certification Section, Division of Facility Services prior to the issuance of a 2007 hospital license.

AUTHENTICATING SIGNATURE: The undersigned submits application for the year 2007 in accordance with Article 5, Chapter 131E of the General Statutes of North Carolina, and subject to the rules and codes adopted thereunder by the North Carolina Medical Care Commission (10A NCAC 13B), and certifies the accuracy of this information.

Signature: Jimm Bunch **Date:** 11-6-06

PRINT NAME OF APPROVING OFFICIAL Jimm Bunch

Please be advised, the license fee must accompany the completed application and be submitted to the Acute and Home Care Licensure and Certification Section, Division of Facility Services, prior to the issuance of a hospital license.

Oral Presentation Outline Supporting Park Ridge Hospital's Petition for One (1) Additional Operating Room in Henderson County

By Gary Qualls on Behalf of Park Ridge

I. Introduction

- Park Ridge seeks an Adjusted Need Determination to add the need for one (1) operating room in Henderson County
- Park Ridge is a not-for-profit hospital in Fletcher, Henderson County, with 62 acute care beds and six (6) operating rooms
- There are two hospitals in Henderson County
  - Park Ridge
  - Margaret Pardee
- There are no OR's in Henderson County outside of the two hospitals
  - Park Ridge – licensed for 6 OR's
  - Margaret Pardee – licensed for 10 OR's

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II. Why Is OR Needed? – Background

- Park Ridge's OR's are very busy
- But Park Ridge can't expand its OR capacity because Pardee staffs only 7 of its 10 OR's
  - Pardee has created an artificial OR surplus
- However, Pardee's utilization is not low enough for it to qualify under the 2008 SMFP exclusion for chronically underutilized facilities
- Problem stems from this:
  - In 2001, Pardee filed for – and received – a CON for 4 additional OR's
  - This was just before the CON statute was amended to subject all new OR's to the SMFP methodology
  - But Pardee has not used or staffed all of the OR's
- Thus, the need methodology is not working properly in this aberrant environment where Pardee is artificially suppressing demand

III. Why Is OR Needed? – Pardee Statistics

- Per Pardee's 2007 hospital license renewal application, 3 OR's reported as "not-in-use"
- But because the methodology counts licensed – not staffed – OR's, the 2008 SMFP shows a 2-OR surplus for Henderson County
- In this instance, OR's that are licensed but "not-in-use" and unstaffed should be considered chronically underutilized
- These unstaffed operating rooms are health care resources that are unavailable to the community **despite being approved over 5 years ago**.

IV. Why Is OR Needed? – Park Ridge's Statistics

- Meanwhile, Park Ridge's OR's are fully booked
  - All 6 OR's fully utilized
  - 2 of 6 OR's are routinely scheduled for extended hours
  - Park Ridge is approaching 123% of capacity – This is the over-capacity level at which Park Ridge's OR's will be utilized in 2009, using CON Section performance standards
  - While Pardee's OR demand has stagnated, physicians and patients are increasingly choosing Park Ridge for surgery
  - Thus Park Ridge needs an opportunity to seek more OR capacity

V. Outmigration

- Per 2006 DFS patient origin data:
  - 43% of Henderson County residents left the County for outpatient surgery
  - 36% of Henderson County residents left the County for inpatient surgery

VI. Adverse Consequences if Petition is Denied

- Patient satisfaction will suffer
- Park Ridge's ability to provide optimal surgical scheduling is hampered
- Increased difficulty in recruiting surgical nurses
- Even more Henderson County residents will leave the County for surgery unnecessarily

VII. This Request is Conservative & Would Help Henderson County Residents

- This is a conservative request – really a stop-gap measure
- Pardee's glut of OR's is an aberration
  - Will not open floodgates
  - But must do something because Pardee's under-utilization of operating rooms is hurting the community by precluding Park Ridge from applying for more ORs under the normal methodology
- There is no OR surplus to Henderson County residents
  - Surplus is on paper only – not a reality
- It is not fair to the people of Henderson County to ignore the reality on the ground
  - There are 13 – not 16 – staffed OR's in Henderson County
  - However, the OR need methodology recognizes 16 OR's in Henderson County
  - Pardee's self-imposed staffing limits are detrimental to patient accessibility
- A special adjustment to the OR need determination is justified for Henderson County to compensate for the chronically underutilized and unstaffed operating rooms at Pardee
- We appreciate that the SHCC is appropriately conservative in granting adjustments from any need methodology
- However, this situation is the paradigm of when a special needs adjustment is justified

Pardee

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MEDICAL FACILITIES
PLANNING SECTION

Margaret R. Pardee Memorial Hospital
800 North Justice Street
Hendersonville, NC 28791
Telephone (828) 696-1000

August 15, 2007

Victoria McClanahan, Planner
Medical Facilities Planning Section
Council Building
701 Barbour Drive
Raleigh, NC 27603

Re: Response to Park Ridge Hospital's August 3, 2007 Petition for One Surgical Operating Room in Henderson County

Dear Ms. McClanahan:

Park Ridge Hospital has submitted a petition for a special need adjustment of one surgical operating room in Henderson County. Park Ridge essentially argues that the operating room methodology should be adjusted to consider as chronically underutilized operating rooms Pardee Memorial Hospital's three operating rooms reported as not in use on the 2007 Hospital License Renewal Application. Pardee opposes Park Ridge's petition for the following reasons:

1. Pardee's three operating rooms referenced by the petition do not meet the definition of chronically underutilized. According to the Proposed 2008 SMFP, chronically underutilized operating rooms are defined as "licensed facilities operating at less than 40% utilization for the past two fiscal years, which have been licensed long enough to submit at least two License Renewal Applications to the Division of Facility Services." As noted on page 5 of Park Ridge's petition, Pardee's utilization of all ten operating rooms was 80% of the performance standard for the period 2005-2006, twice that of chronically underutilized operating rooms. Further, as also noted on page 5 of the petition, the construction of Pardee's four additional operating rooms (an increase from the prior six) was not completed until late 2005/early 2006. Consequently, on Pardee's 2006 License Renewal Application, the hospital noted only six operating rooms licensed. Thus, the three operating rooms at issue in the petition have not been licensed long enough to have been included on at least two License Renewal Applications.

2. Park Ridge's assertion that similar exclusions have been made for other facilities in disingenuous. Other exclusions have been made for facilities that have, in fact, had *chronically* underutilized facilities, but Pardee is not aware of any situation in which newly developed capacity was excluded as "chronically underutilized" during its ramp up period.

3. Park Ridge's assertion that three operating rooms are "simply inaccessible" also is incorrect. The three rooms are fully equipped and available to the community. The number of C-sections performed at Pardee has increased markedly in the last year, and one of the three operating rooms is now being used primarily for C-sections. It will be reported as a dedicated C-section room on Pardee's 2008 License Renewal Application. The remaining two operating rooms are fully equipped, can be staffed based on the surgical schedule, and are planned to be phased into use in the next two years. It is not unreasonable for Pardee to stagger the opening of the additional operating rooms, as volume increases over time and demands the additional capacity for routinely schedule procedures. In fact, it is not prudent health planning to develop facilities that are estimated to be operating above capacity at the time they are opened. Rather, appropriate health planning suggests developing facilities that will support projected volume in future years.

4. Pardee's operating room utilization for fiscal year 2007 is on pace to be consistent with the prior year's utilization and well in excess of 40% of the performance standard, whether calculated with 7, 8 or 10 rooms.

5. With the completion of the four additional operating rooms at Pardee, available facility capacity has not restricted access by Henderson County surgical patients nor forced patients to seek care outside the county. While Henderson County patients do leave the county for surgery, it is not typically due to the unavailability of operating rooms but rather to seek specialty services not offered at Pardee or Park Ridge, including open heart surgery, trauma surgery, neurosurgery, and gynecological oncology surgery, or based on physician referral preferences/relationships.

6. Pardee's slight decrease in surgical volume after 2003 is primarily from physician departures in the normal course of business for reasons such as retirement, relocation out of the area, or health concerns.

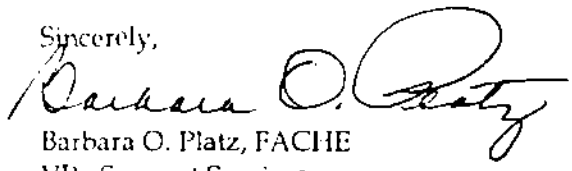
7. Pardee currently has a need for and is actively recruiting and assisting with the recruitment of at least four surgeons, including general and orthopedic surgeons. The recruitment of a spine surgeon is part of the plan to staff and utilize the 10th operating room.

8. The circumstances in Henderson County are not unique, as Park Ridge argues. Included as Attachment 1 is an analysis of all North Carolina hospitals that appear to have added new operating rooms since FY 2001. (The analysis is based on the change in the number of operating rooms reported on the hospital's license renewal application and/or the applicable State Medical Facilities Plan.) The analysis shows the utilization for each facility on a case-per-room-per-day basis for the first year following the opening of the new operating room. The shaded columns represent the type of room added to the hospital's inventory. Based on the utilization of the type of

room added to the hospital's inventory, more than 80 percent of the facilities experienced utilization below the performance standard during the first year of operation of the new room. Thus, the situation in Henderson County is common in facilities across the State.

Pardee contends that Park Ridge's petition is not consistent with the intent of the SMFP process for petitions for adjusted need determinations. The circumstances in Henderson County are not unique, and there are no special attributes of either organization that give rise to resource requirements that justify altering the standard operating room methodology. For these reasons, we respectfully request that the Acute Care Committee and the State Health Coordinating Council deny Park Ridge's petition.

Sincerely,



Barbara O. Platz, FACHE
VP - Support Services

OR utilization for year following addition
Excludes C-Section and Dedicated Open Heart

		Additional ORs			Total ORs			Cases per Room per Day		
Facility	Year	IP	AS	Shared	IP	AS	Shared	IP (2.4)	AS (4.8)	Shared (3.2)
University of North Carolina Hospitals	FY 2002			6		4	27	N/A	3.44	7.24
First Health Moore	FY 2002		4	1		4	9	N/A	3.87	3.77
Carolinas Medical Center	FY 2002		1	3		11	22	N/A	3.64	2.87
Duke University Hospital	FY 2002		1	2		8	33	N/A	3.04	2.52
Murphy Medical Center	FY 2002			2			4	N/A	N/A	2.48
Crawley Memorial Hospital, Inc	FY 2002			2			2	N/A	N/A	0.00
Thompson Regional Medical Center	FY 2002			2			8	N/A	N/A	1.85
Davie Hospital	FY 2002			2			6	N/A	N/A	2.23
Watson Medical Center	FY 2002			2			9	N/A	N/A	2.35
High Point Regional	FY 2002			1			9	N/A	N/A	2.91
Columbus County Hospital	FY 2002			1			4	N/A	N/A	2.05
Tyrrell District Hospital Corporation	FY 2002			1			2	N/A	N/A	0.04
Dixie County Hospital	FY 2002			1			2	N/A	N/A	0.04
Franklin Regional Medical Center	FY 2002			1			1	N/A	N/A	3.06
Halifax Regional	FY 2002			1			6	N/A	N/A	2.04
Harris Regional Hospital	FY 2002			1			6	N/A	N/A	2.55
CMC-Union	FY 2002			1			7	N/A	N/A	3.62
Hoke Memorial Hospital	FY 2002			1			2	N/A	N/A	0.44
Memorial Mission Hospital and Mission Surgicare	FY 2002		1		[illegible]	13	7	2.26	4.96	2.22
Davie Regional Medical Center	FY 2002						4	N/A	N/A	2.56
Lake Norman Regional Medical Center	FY 2002							N/A	N/A	2.89
Alamance Regional Medical Center	FY 2002			1			11	N/A	N/A	3.21
Heritage Hospital	FY 2002			1			5	N/A	N/A	1.92
NorthEast Medical Center	FY 2002			1		1	16	N/A	1.69	3.37
Cleveland Regional Medical Center	FY 2002			1			6	N/A	N/A	2.90
Ivey Hospital	FY 2003		6		9	17	1	3.33	3.10	4.19
North Carolina Baptist Hospitals, Inc	FY 2003			2	4		32	2.70	N/A	2.79
CMC-University	FY 2003		2	2		4	9	N/A	1.55	3.07
NorthEast Medical Center	FY 2003			1		5	16	N/A	0.93	3.32
CMC-Mercy, Pineville	FY 2003			3			17	N/A	N/A	2.61
Medical Park Hospital	FY 2003			2			14	N/A	N/A	3.20
Presbyterian Hospital	FY 2003			5			29	N/A	N/A	2.65
Randolph Hospital	FY 2003			2			8	N/A	N/A	3.13
Moses Cone Health System	FY 2003		2			12	38	N/A	2.86	2.38
Gaston Memorial	FY 2003		2			8	12	N/A	2.53	3.44
Presbyterian Matthews	FY 2003			2			8	N/A	N/A	4.69
Haywood Regional Medical Center	FY 2003			1			7	N/A	N/A	2.63
Park Ridge Hospital	FY 2003			1			7	N/A	N/A	3.60
Scotland Memorial Hospital	FY 2003			1			6	N/A	N/A	2.77
Rowan Regional Medical Center	FY 2003			1			8	N/A	N/A	4.24
Caldwell Memorial Hospital	FY 2003		1			3	4	N/A	2.19	2.18
University of North Carolina Hospitals	FY 2004			5		4	32	N/A	2.98	2.01
Forsyth Medical Center	FY 2004			4		2	18	N/A	4.48	2.75
North Carolina Baptist Hospitals, Inc	FY 2004			4	4		36	1.45	N/A	2.85
Cape Fear Valley	FY 2004			2			13	N/A	N/A	3.66
Transylvania Community Hospital	FY 2004			1			4	N/A	N/A	2.23
WakeMed Cary Hospital	FY 2004			1			9	N/A	N/A	2.86
Lake Norman Regional Medical Center	FY 2004			1			7	N/A	N/A	2.46
Presbyterian Huntersville	FY 2005	1		3	1		3	1.59	N/A	2.82
Forsyth Medical Center	FY 2005			1		2	19	N/A	4.54	2.81
Catawba Valley Medical Center	FY 2005			1			12	N/A	N/A	3.17
Lake Norman Regional Medical Center	FY 2005			1			7	N/A	N/A	2.53
Duke University Hospital	FY 2005			1		8	33	N/A	3.39	2.89
NorthEast Medical Center	FY 2005			1		5	16	N/A	3.01	2.85

OR Petition 3

PETITION FOR ADJUSTMENT TO NEED DETERMINATION TO ADD SIX OPERATING ROOMS TO THE PITT-GREENE OPERATING ROOM SERVICE AREA

Submitted To:
Mr. Michael C. Tarwater, Chair
Acute Care Services Committee
c/o Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

DHS Health Planning
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Medical Facilities
Planning Section

Petitioner
Pitt County Memorial Hospital
2100 Stantonsburg Road
P. O. Box 6028
Greenville, NC 27835-6028

Stephen J. Lawler, President
(252) 847-4451

I. Request

Pitt County Memorial Hospital, Inc. (PCMH) petitions for a special need determination in the 2008 State Medical Facilities Plan (SMFP) for six operating rooms (OR) in the Pitt-Greene Operating Room Service Area (P-G ORSA). The proposed 2008 SMFP shows a need for only 0.25 ORs in the P-G ORSA. A comprehensive analysis of the unique and special attributes of the geographic area and providers in the service area demonstrate the need for six or more operating rooms by 2010.

II. Rationale for the Proposed Adjustment

Background Information Regarding Petitioner

PCMH is a private, not-for-profit hospital that serves as the tertiary, regional referral hospital for eastern North Carolina. PCMH has over 750 acute care beds and has CON approval to build and operate over 100 additional acute care beds. PCMH has the only licensed inpatient and shared operating rooms in Pitt and Greene Counties. SSOP Services of Pitt, Inc. (SSOP) is an 8-bed freestanding ambulatory surgery center and a controlled affiliate of PCMH. SSOP operates the only licensed dedicated ambulatory surgery operating rooms in Pitt and Greene Counties. PCMH's Level I Trauma Center, Cardiovascular Center, Cancer Center, Children's Hospital, and Regional Rehabilitation Center are just a few examples of the highly specialized services that have been developed and expanded over the past 20 years in direct response to the primary/community care needs of Pitt and Greene Counties and the tertiary healthcare needs of the entire HSA VI region. PCMH's commitment to continue to provide

these specialized services and to sustain specialty designations such as the sole Level I Trauma Center and Level IV Neonatal unit in the eastern part of NC has impacted:

- the percentage growth of surgery cases at PCMH and SSOP relative to underlying population served,
- the number and mix of surgical case hours delivered by PCMH and SSOP,
- the average case time for inpatients and outpatients, and
- the capacity of existing operating rooms to manage a highly complex mix of surgical patients

These impacts are the basis for the evidence that the resource requirements for the Pitt-Greene OR service area differ from the requirements resulting from the application of the standard planning methodology for operating rooms.

PCMH & SSOP Are Sole Providers In The Pitt-Greene Operating Room Service Area

PCMH is the only tertiary regional referral center in NC located in a two-county OR Service Area. PCMH is also the sole provider of inpatient and shared operating rooms in the P-G ORSA. This attribute results in PCMH fulfilling a unique role as a community and specialized services hospital for Pitt and Greene Counties and a tertiary regional referral center for the entire HSA VI region. Greene County does not have a licensed facility providing operating rooms. Greene County is grouped with Pitt County to form the P-G ORSA since PCMH, the sole provider in Pitt County, serves the greatest number of surgical patients originating from Greene County. The majority of operating room service areas across NC has multiple providers of inpatient, shared and dedicated outpatient operating rooms. The majority of providers can therefore address any growth in surgical services demand and adjust to periodic constraints in capacity. The P-G ORSA has limited or no capacity to meet immediate or future needs for operating rooms because:

1) P-G ORSA has only one hospital and one free-standing dedicated ambulatory surgery facility,
2) The providers in the P-G ORSA historically, currently, and in the near term must serve not only as the sole primary care provider in these counties but also as the regional referral hospital for the 29 counties in HSA VI, and
3) There is no tertiary regional referral center located adjacent to the P-G ORSA that can address the demand for comprehensive surgical services that can only be met by the sole providers in the P-G ORSA.

The unique characteristics of the P-G ORSA geography and the sole providers in this OR service area make it impossible for PCMH to effectively manage the constraints in OR capacity without compromising the patients' access to timely, high quality, safe and cost effective care.

The SSOP, as the sole provider of licensed dedicated ambulatory surgery operating rooms in Pitt and Greene Counties, uses the American Society of Anesthesiologist classifications of physical status to assure surgical patients receive services in the appropriate

setting. Currently, additional specific criteria set by Medicare/Medicaid must be met in order for the provider to be reimbursed by Medicare/Medicaid. PCMH and SSOP continuously review the outpatient cases performed at the hospital to assure as many outpatients as possible and as appropriate are performed at the SSOP facility. These efforts have been especially intense in the past few years given the OR capacity constraints at PCMH. PCMH expects to see fewer gains in OR capacity using this approach since the majority of benefits in OR capacity due to this shift have already been realized.

Additionally, SSOP historical utilization data has demonstrated that this facility also serves more complex outpatients that any ambulatory surgery center in adjacent counties and in some cases in the entire region. Since SSOP is the sole provider of dedicated outpatient ORs in the P-G ORSA, it is limited in the type and complexity of patients it can serve.

PCMH & SSOP Serves Surgery Patients Beyond Pitt-Greene OR Service Area

The sole providers of licensed operating room services in the P-G ORSA have historically served a much broader service area than Pitt and Greene Counties. The table below compares the FY 2006 PCMH percent of patient origin from the P-G ORSA against the PCMH percent of patient origin from outside the P-G ORSA for acute care and surgery patients.

	Pitt & Greene Counties	Outside Pitt & Greene Counties
PCMH Patient Origin Inpatient & Outpatient Acute Care Admissions	41.9 %	58.1 %
PCMH Patient Origin Inpatient Surgery Cases	30.8 %	69.2 %
PCMH Patient Origin Outpatient Surgery Cases	41.5 %	58.5 %
PCMH Patient Origin Total Surgery Cases	35.8 %	63.2 %

The data above clearly shows that over 50% of PCMH's acute care admissions, inpatient surgery and outpatient surgery cases originate from outside Pitt and Greene Counties. PCMH, as the only tertiary regional referral center in eastern NC, serves all 29 counties of eastern NC and beyond, not just Pitt and Greene Counties. Even if other HSA VI counties have underutilized ORs, PCMH is still the only acute care provider in HSA VI who has the unique mix and availability of specialists and sub-specialist physicians, advanced centers of emphasis in cardiovascular, cancer, children's and surgical services and comprehensive services and technology to meet the demand for complex surgery services. Additionally,

PCMH is the only Level IV Neonatal facility and the only Level I Trauma Center in eastern NC. PCMH is also the only hospital that has a comprehensive Cardiovascular Center designed to address the unmet need for advanced cardiovascular care in a region with one of the nation's highest incidence of cardiac disease and mortality.

It is clear that the standard methodology used by the state to project future OR need does not recognize the unique attributes of PCMH in the P-G ORSA. The standard formula assumes that the number of surgical hours will increase or decrease in direct proportion to the change in the general population of the OR Service Area. This approach does not take into account the special role PCMH plays in eastern NC as the only tertiary, regional referral facility in HSA VI. Assuming surgical hours performed by PCMH using only Pitt and Greene Counties' general population change underestimates the volume and complexity of patients PCMH serves outside the P-G ORSA and severely underestimates projected growth.

Additionally, SSOP's historical and projected patient origin demonstrates that the SSOP serves a much broader region than just the P-G ORSA. The data table below clearly shows that over 54% of SSOP's cases originate from outside Pitt and Greene Counties. SSOP, as the only freestanding ambulatory surgery facility in the P-G ORSA, has provided services to every county in HSA VI and has served patients in 27 other counties in NC and patients from other states. Even if other HSA VI counties have underutilized dedicated ambulatory surgery ORs, SSOP has a unique and comprehensive mix of specialty surgery services. SSOP is the only freestanding ambulatory surgery center in eastern NC that offers all of the following specialty surgical services: dental, general surgery, gynecology, neurology, ophthalmology, oral, orthopedic, otolaryngology, plastics, podiatry, and urology. This comprehensive mix of surgical services makes SSOP a unique provider not only in the P-G ORSA but also in the eastern part of the state.

	Pitt & Greene Counties	**Outside Pitt & Greene Counties**
SSOP Patient Origin Outpatient Surgery Cases	45.7 %	54.3 %

The need for operating rooms in the P-G ORSA must consider the unique and special attributes of the geographic area served by PCMH and SSOP and the unique and special attributes associated with the services provided by the sole providers in the P-G ORSA. These attributes are not reflected in the standard methodology used to determine OR need.

Demand for ORs Exceeds Current and Projected OR Capacity In P-G ORSA

The unique and special attributes of the P-G ORSA geographic area and providers are the basis for the need for more operating rooms by 2010 in this service area. PCMH conducted an extensive analysis of the historical and projected utilization of sixteen service lines and

found that the demand for ORs in the P-G ORSA exceeds current and projected OR capacity. Current and projected OR need in the P-G ORSA is impacted by the following:

- Growth in OR volumes based on a service area beyond Pitt and Greene Counties,
- Growth in hours per case due to a unique population of surgery patients, and
- Operational capacity needed to serve a comprehensive mix of specialized surgical patients.

Wider Service Area

PCMH and SSOP both serve patients beyond the P-G ORSA. In order to recognize the impact of serving a wider service area, the population change rate used in the standard methodology must be adjusted. Using the overall population growth rate of eastern NC counties changes the P-G ORSA growth factor to no less than 0.80 % per year, which is higher than the 2-county service area population change rate used in the standard methodology. Assuming no other changes to the standard methodology, the OR need in the P-G ORSA would be over two ORs for this unique variable alone. However, additional variables must be considered before determining total OR need for the P-G ORSA. Below are the additional variables for consideration and statistics that support the need for six new ORs in the P-G ORSA in the 2008 SMFP.

Unique Population and Growth

The sole providers in the P-G ORSA serve a unique population of surgery patients, namely, surgery patients that originate from a region that state statistics clearly document has some of the highest rates of poverty, illiteracy, infant mortality rates, heart disease, cancer, diabetes, and pulmonary disease than any other region in the state. The growth in surgery cases and the length of time to complete more complex surgery cases at PCMH are directly impacted by the unique health status attributes of eastern NC. These differences have driven growth in surgery volumes at PCMH and SSOP at a rate nearly 50% higher than local and regional population growth. Other unique attributes of the geographic area include the presence of military bases, the double-digit growth in tourism and retirement communities in the eastern counties that are not fully represented in population statistics, and the fact that the eastern counties are aging at a faster rate than any other region in the state. These unique variables increase the numbers of surgical cases, the types of surgical cases, the OR hours needed to serve current and future patients, and the capacity needed to address a comprehensive mix of surgical patients.

Additionally, patients and physicians are demanding access to ORs during the week and during the early hours of the day. Operationally that means that the hospital must have sufficient OR capacity to do the majority of elective and non-elective cases Monday through Friday. Historical growth in surgical case volumes and surgical case times have exceeded current OR capacity. PCMH leadership is unable to meet the patients' and physicians' requests for OR time during the weekdays and on day shift. For the past three years PCMH has seen the number of routine, elective and scheduled cases that must be performed after 3pm climb to nearly 25% of the total number of surgical cases performed at PCMH. The

hospital has been forced to staff an average of seven ORs during the eight hours from 3pm-11pm every day just to meet the demand for routine, elective cases. Included in these numbers is one OR that must be staffed and available at all times in order for PCMH to meet its commitment as a Level I Trauma Center. Additionally, PCMH routinely staffs 3 ORs plus 1 trauma OR on Saturdays and additional ORs on Sundays to meet the demand for emergency and trauma cases, and in some cases, elective surgeries.

Capacity Needed to Address Demand Growth and Unique Mix of Surgical Patients

PCMH, due to its unique attributes as a sole provider of inpatient and shared ORs in the P-G ORSA, must have sufficient capacity to address the volume and unique mix of surgical patients both now and in the future. The standard methodology for determining OR need uses an occupancy rate of 80%. This occupancy rate does not recognize the unique factors impacting PCMH's need for additional OR capacity. PCMH provides a different level of surgical specialization that requires a different number, mix and type of ORs, staff, equipment, and supplies. These differences are needed to address the special attributes of tertiary and complex inpatients and outpatients who receive care in PCMH's ORs. There is less predictability in scheduling patients when a provider such as PCMH serves a wide range of specialty surgical services (e.g. cardiothoracic, ENT, GI, general surgery, gynecology, oncology, nephrology and transplant, orthopedics, reconstructive plastics, urology and vascular) and a broad range of patient acuity (simple, elective outpatient to extensive, unstable, complex trauma patient).

The current special rules for ORs assumes that inpatient ORs, operating at 80% capacity, can serve 2.4 inpatient cases per room per 9-hour day for 260 days per year and shared ORs can serve 3.2 cases per room per 9-hour day. Over 50% of PCMH's surgical cases are inpatients, which in and of itself is a unique factor for the majority of hospital-based ORs in NC. Based on the last 12 months of data, PCMH performed 10,161 inpatient surgery cases and 9,043 outpatient surgery cases and operated at over 85% capacity in its current 25 operating rooms. Additionally, during FY 2006 and in the last 12-month period, PCMH's average case time for outpatient surgery patients was greater than two hours. Operating at greater than 80% capacity, while at the same time providing care to ambulatory surgery patients whose average case times are 30% higher than the case time used in the standard formula for OR need, are direct indications of lack of sufficient OR capacity to meet current, much less future, needs.

PCMH's ORs are already operating above desired capacity. Additional attributes that make use of an 80% capacity assumption inappropriate for the providers in the P-G ORSA include:

- PCMH has over 140 active and consulting MDs with OR privileges. Additional capacity is needed to serve a large number of physicians providing specialized services.
- PCMH has twenty-four surgery residents and one surgery fellow. Insufficient OR capacity can severely limit opportunities for surgical medical education and research.

- The number of complex and highly specialized surgical cases at PCMH requires expanded OR capacity to manage turnaround times between complex, highly specialized cases and to separate contaminated cases from clean cases.
- By 2010, PCMH will have added over 100 new acute care medical-surgical beds. Since there is no OR need in the 2008 SMFP for the P-G ORSA, it is likely that PCMH will add these beds without being able to add a single operating room. Surgery patients' account for over 20% of PCMH's total patient admissions. Adding 100 new acute care beds without adding any ORs will result in significant gaps in services and will make it impossible for PCMH to sufficiently meet the needs of the P-G ORSA, much less the needs of a broader region.

Proposed Adjustment

The number and types of special attributes of the P-G ORSA and its providers demonstrate the need for additional ORs by 2010. Instead of attempting to associate OR need for each attribute, the petitioner recommends the following adjustments:

- Adjust growth factor to 0.080 for the P-G ORSA to reflect the population and demand growth of the wider region and the unique health status factors in PCMH's and SSOP's service areas. These factors drove historical volumes and will drive future demand.
- Adjust capacity assumption for the P-G ORSA to 75% to reflect the complexity and mix unique to this OR Service Area and the sole providers in the P-G ORSA.
- Adjust hours per outpatient case for PCMH's ambulatory surgeries to 2.0 hours per case to reflect current (and projected) average hours per ambulatory surgery case at PCMH.

These adjustments acknowledge the unique role played by the sole providers in this service area. The standard formula for projecting OR need cannot reflect the attributes unique to PCMH and SSOP. These attributes include population growth beyond the two-county service area, volume growth unique to a region with high incidence of chronic disease and mortality, the operational capacity necessary to serve the mix and complexity of surgical patients PCMH and SSOP serve, and OR hours needed to care for the large number of specialized and complex ambulatory surgeries at PCMH.

Applying the recommended adjustments above changes the OR need for P-G ORSA in the 2008 SMFP to six additional ORs using the following assumptions:

- PCMH inpatient surgery hours = 28,851.00 (unchanged)
- PCMH ambulatory surgery hours = 17,878 (2.0 hours/case x 8,939 cases)
- SSOP outpatient hours = 14,407.50 (unchanged)
- Total surgery hours for P-G ORSA = 61,136.5
- Projected surgical hours for 2010 (using new growth rate of 0.08) = 66,027.42
- Standard hours per OR per year = 1,755 (assumes 9hrs/day, 260 days/year, 75% capacity)
- Projected ORs in 2010 for P-G ORSA = 37.62
- Current OR in P-G ORSA after adjustments = 32
- Project ORs needed = 5.62 (Rounded = 6.0)

III. Adverse Effects if Requested Changes Are Not Made

The following list describes some of the adverse effects on the population of patients served by the sole providers in the P-G ORSA if additional ORs are not included in the 2008 SMFP:

- Patients will experience increased delays in access to the specialized services provided solely by PCMH as the regional referral facility for HSA VI. These delays could impact patient morbidity and mortality.
- Limited or no access to complex, high acuity tertiary surgical services due to limited OR capacity may result in patient's not receiving surgery care at all or patient's being forced to travel long distances to access similar services at other regional referral facilities.
- Physician recruitment has already been severely affected by the lack of OR capacity at PCMH and SSOP. Hours of operation have been extended to increase the number of hours of available OR time since PCMH continues to operate above reasonable OR capacity. As a result of this operational change, physician dissatisfaction has increased. Key physicians who provide highly specialized surgical services have left the facility. Physician recruitment, especially in the areas of surgical subspecialties needed at PCMH and for eastern NC to support the 24/7 demands of a Level I Trauma Center, has been extremely difficult. The obvious lack of OR capacity to handle current, much less future surgery demand, is severely affecting the delivery of vital surgical services at PCMH and SSOP.
- Extended hours of operation to manage the demand in surgical services has increased human resources, utilities and support services costs. Staff expenses such as shift differential and overtime have continued to rise in order to accommodate surgical case demand during the 3pm to11pm shift.
- Routine and elective patients who remain without food or water prior to surgery risk having their case cancelled due to the lack of OR hours (capacity) available during the day shift to handle routine and emergent case volumes. A number of healthcare research groups are currently analyzing the impact on quality and safety for patients who have surgical procedures performed late in the day versus on day shift.
- Patients must remain in the hospital overnight because their elective or routine surgical procedure was performed late in the day or early evening due to limited OR capacity. This results in higher costs for the patient and hospital.
- PCMH will open and operate over 100 new acute care beds before 2010. If the 2008 SMFP does not include the need for more ORs, PCMH will be unable to support the increased surgical volume associated with the operation of such a large number of new acute care beds.

Continued application of the standard formula for determining OR need will not address the unique and special attributes of the P-G ORSA or its sole providers.

IV. Alternatives Considered But Not Feasible

Alternative # 1 Modify existing resources

PCMH and SSOP cannot modify existing resources without continuing to compromise the availability and functioning of existing ORs. Procedures' volumes cannot be safely shifted to any other procedures' rooms without compromising patient safety or jeopardizing the delivery of other vital hospital services. The addition of operating rooms is contingent on CON approval and current SMFP shows no need for ORs in the P-G ORSA.

Alternative #2 - Reduce the number of ORs needed in the P-G ORSA

A need of less than six ORs in the P-G ORSA in the 2008 SMFP will significantly hinder the ability of both PCMH and SSOP to continue to serve the surgical patients who have historically used these facilities. Constructing or operating less than six more ORs will only increase the adverse effects noted above and may very well compromise the hospital's ability to sustain long-term its position as a regional referral center.

Alternative #3 - Wait until changes are made in the standard methodology

Future changes proposed by a special task force will not fully address the unique and special needs of PCMH and SSOP. Waiting until the changes are made in the 2009 SMFP will delay the construction or operation of additional ORs in the P-G ORSA and will severely compromise PCMH's ability to address the projected demand for surgery cases associated with the addition of over 100 new acute care beds beginning early 2009 through early 2010.

V. Evidence Proposed Change Would Not Result in Unnecessary Duplication of Health Resources

PCMH and SSOP are the sole providers in the P-G ORSA. Evidence presented in this petition demonstrates there is an unmet need today for ORs in the P-G ORSA given its unique attributes. No other provider in HSA VI can duplicate the scope and complexity of surgical services offered by PCMH or by SSOP. Patient waiting lists, extended operating room hours, and a growing volume of chronic health care issues in the P-G ORSA and beyond reflect an unmet need now and in the future. New ORs will address unmet need and not result in the unnecessary duplication of health resources. Projections of need presented in this petition and the proposed minor adjustments to the standard methodology do not result in any duplication of existing OR capacity.

Rec'd @ July 24
2007 Greenville
Public Hearing.

PITT COUNTY MEMORIAL HOSPITAL
University Health Systems of Eastern Carolina

Good Afternoon. My name is Walter Pofahl and I am currently the Chief of Staff at Pitt County Memorial Hospital. I am also a surgeon who works collaboratively with over 100 surgeons practicing in Pitt County. I am here today to implore the state to recognize the unmet need for operating rooms in the Pitt/Greene OR Service Area. I do not have a petition to submit today but I want to comment on a petition that I understand Pitt County Memorial Hospital plans to file by the August 3 deadline. This petition will highlight the unique and special issues that are impacting the need for more operating rooms in this OR service area.

As a practicing physician in this county, I have seen firsthand the problems that have resulted from not having enough operating rooms to handle the volume of patients we see at Pitt County Memorial Hospital, the sole hospital for these two counties and the only academic medical center in the 29-counties of eastern NC. We are routinely scheduling patients late in the afternoons and sometimes at night and on the weekends for elective cases. We have patients who must be NPO until late into the day because we do not have enough operating rooms to get their surgery done during the day shift. We have patients who are waiting days or weeks to get their surgery because of the lack of operating rooms.

Because Pitt County Memorial Hospital is an academic medical center, our inpatient and outpatient cases are routinely more complex and take longer than surgical cases done at other hospitals. We must have 24 hours, 7 days a week, and 365 days per year availability of operating rooms to meet our Level I Trauma requirements. We are the safety net for a huge, underserved, economically challenged area. We are the tertiary care center for eastern NC. This commitment to serve the entire region, not just Pitt and Greene counties makes us different and creates a unique situation when it comes to calculating operating room need. While this methodology to determine OR need may work for the average hospital or OR service area, it does not work for the Pitt/Greene OR service area because of the unique role Pitt County Memorial Hospital plays in this service are and in the entire eastern part of the state.

I speak for the more than 500 physicians on staff at Pitt County Memorial Hospital and over 100 surgeons practicing in this hospital when I state that we must have your support for the unique attributes of this service area that necessitates the need for new operating rooms in next year's plan.

PITT COUNTY MEMORIAL HOSPITAL
University Health Systems of Eastern Carolina

REC'D @ JULY 24 2007 GREENVILLE PUBLIC HEARING

Good Afternoon. My name is Steve Lawler and I am President for Pitt County Memorial Hospital. I am here today to let you know that Pitt County Memorial Hospital plans to file a special need petition by the August 3 deadline. This petition will outline the special and unique attributes of our geographic area and our institution that cannot be addressed by the standard methodology for determining operating room need in NC. This petition will challenge the state to look carefully at the reasons why we are different and to help us address what is clearly an unmet need for new operating rooms in our service area.

We applaud the efforts of the task force that studied the methodology for determining OR need. However, we are disappointed that no substantive changes to the formula for need were included in the 2008 draft SMFP. We eagerly anticipated the need for operating rooms would be clearly shown once the methodology were updated and improved. We cannot wait until the 2009 to have this need reflected in the SMFP. The patients that depend on our services cannot wait until 2009. We need these operating rooms in the 2008 plan in order for us to continue our commitment of care to this region as the only academic medical center, not to mention the only Level I Trauma Center and Level IV Neonatal Center.

We support our surgeons who clearly recognize the need for more operating rooms. We clearly have a number of attributes that make our situation different. We implore you to strongly consider our petition and to recognize the unique differences in this county and in the way in which Pitt County Memorial Hospital serves the eastern portion of our state.

The Brody School of Medicine
Department of Surgery
East Carolina University
600 Moye Boulevard • Greenville, NC 27834
252-847-5846 office • 252-847-0669 fax • rotondo@pcmh.com

Michael F. Rotondo, MD, FACS
Professor and Chair
Department of Surgery
Chief, Trauma and Surgical
Critical Care

August 1, 2007

DFS Health Planning
RECEIVED
AUG 03 2007
Medical Facilities
Planning Section

Mr. Michael C. Tarwater, Chair
Acute Care Services Committee
c/o Medical Facilities Planning Section
Division of Health Services Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

RE: Petition For Adjustment to OR Need Determination in the Pitt-Greene OR Service Area

Dear Mr. Tarwater:

I am writing in my capacity as Professor and Chairman for the Department of Surgery and Chief of the Trauma and Surgical Critical Care Division at Pitt County Memorial Hospital and The Brody School of Medicine at East Carolina University (BSOM). As a physician leader in the Department of Surgery, I know first hand the dire need for additional operating rooms at Pitt County Memorial Hospital (PCMH) and the SurgiCenter Services of Pitt County (SSOP). The 2008 State Medical Facilities Plan (SMFP) must show need for at least six operating rooms or our service area will continue to experience the consequences of inadequate operating room capacity.

PCMH, as the only regional referral facility for all of eastern NC and the only Level I Trauma Center in the east, must have timely access to enough operating rooms to provide the services demanded by the hospital's and SSOP's broad service area. Currently, patients and physicians are experiencing significant constraints due to the limited number of operating rooms in the service area. These constraints include patient delays in access to specialized surgical services that can only be provided by PCMH and SSOP and that could impact patient morbidity and mortality. We have extended hours of operation to increase operating room capacity, but patients and physicians are very dissatisfied with the unintended consequences of operating these services late into the evening and on weekends. Our hospital must have adequate operating room capacity to continue to meet our commitment as the only Level I Trauma Center in the east.

East Carolina University is an institution of the University of North Carolina. An equal opportunity/affirmative action employer, which accommodates disabilities for individuals with disabilities.

As the sole providers in the Pitt-Greene Operating Room Service Area, PCMH and SSOP has seen an unprecedented growth in surgery cases, surgery case times and overall acuity in the inpatients and outpatients we serve. This growth is fueled in part by the special attributes of PCMH and SSOP. The standard state methodology for determining operating room need does not consider these unique characteristics. Additionally, PCMH will open and operate over 100 new acute care beds before 2010. If the 2008 SMFP does not include the need for more ORs, PCMH will be unable to support the increased surgical volume associated with the operation of such a large number of acute care beds

We need operating rooms in the 2008 plan in order for us to continue our commitment of care to this region. The patients that we serve need access to more operating rooms. Our staff surgeons remain committed to meeting the challenges ahead, but cannot continue to meet these needs if additional operating rooms are not approved in the SMFP. Moreover, we are experiencing significant challenges in physician recruitment due to the lack of operating room capacity. Currently, we are in active recruitment for additional specialists in the areas of cancer surgery, pediatric surgery, transplantation surgery, neuroendovascular surgery, urology, hand surgery, and plastic surgery. Without the ability to provide adequate operating rooms, we have little chance of attracting these specialists whom our patients so desperately need.

PCMH is filing a special need petition on August 3, 2007 that will outline the special and unique attributes of our geographic area and our institution that cannot be addressed by the standard methodology for determining operating room need in NC. This petition will challenge the state to look carefully at the reasons why we are different and to help us address what is clearly an unmet need for new operating rooms in our service area.

I represent over 100 surgeons who clearly recognize the need for more operating rooms. I implore you to strongly consider PCMH's petition and to recognize the unique differences in this county and in the way in which PCMH and SSOP serve the eastern portion of our state. Thank you.

Sincerely,

Michael F. Rotondo

Michael F. Rotondo, MD, FACS
Professor and Chairman
Chief, Trauma and Surgical Critical Care
Department of Surgery, Brody School of Medicine

PITT COUNTY MEMORIAL HOSPITAL
University Health Systems of Eastern Carolina

August 1, 2007

Mr. Michael C. Tarwater, Chair
Acute Care Services Committee
c/o Medical Facilities Planning Section
Division of Health Services Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Petition For Adjustment to OR Need Determination in the Pitt-Greene OR Service Area

Dear Mr. Tarwater:

I am writing in my capacity as Chief of Staff for Pitt County Memorial Hospital (PCMH) and Associate Professor and Chief of the Division of Advanced Laparoscopic, Gastrointestinal and Endocrine Surgery for The Brody School of Medicine at East Carolina University (BSOM). As a physician leader for the hospital and a surgeon, I am well aware of the urgent need for additional operating rooms at Pitt County Memorial Hospital (PCMH) and the SurgiCenter Services of Pitt County (SSOP). The 2008 State Medical Facilities Plan (SMFP) does not show any need for operating rooms for the Pitt-Greene Operating Room Service Area. We need at least six operating rooms in the 2008 SMFP or our service area will not be able to meet the current or growing demand for specialized surgical services in eastern North Carolina.

I work collaboratively with over 100 surgeons practicing in Pitt County. I have participated in numerous discussions over the past few years during which physicians and patients have noted the severe shortage of operating room capacity in this area. This shortage has been attributed to a number of factors that are not only unique to the region that PCMH and SSOP serve, but also to the highly specialized nature of the surgical services offered only by these facilities. These factors are not and cannot be captured in the standard methodology the state uses to determine operating room need. PCMH will file a special need petition on August 3, 2007 explaining the adjustments that must be made in order for the SMFP to accurately represent the needs in this service area.

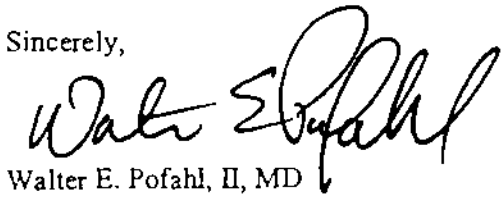
As a practicing physician in this county, I have experienced firsthand the problems patients and physicians have had to deal with as a result of not having enough operating rooms to handle the volume, complexity and unique mix of patients seen at PCMH. The problems include delays in surgery cases, extended stays for patients, lost physicians due to the inability to support practice demands, and ineffective recruitment due to limited operating room capacity. We cannot continue to sustain our commitments to this region as the only Level I Trauma Center and Children's Hospital if we do not get additional operating rooms.

2100 Stantonsburg Road P.O. Box 6028 Greenville, North Carolina 27835-6028

As the sole hospital for Pitt and Greene Counties and the only academic medical center in the 29-counties of eastern NC we cannot just assume that other facilities can meet this need. PCMH's inpatient and outpatient cases are routinely more complex and take longer than surgical cases done at other hospitals. We must have 24 hours a day, 7 days a week, and 365 days per year availability of operating rooms to meet our Level I Trauma requirements. We are **the** safety net for a huge, underserved, economically challenged area. These attributes alone create unusual and special need for operating rooms at PCMH and SSOP. While this methodology to determine OR need may work for the average hospital or OR service area, it does not work for the Pitt/Greene OR Service Area.

I speak for the more than 500 physicians on staff at PCMH and over 100 surgeons practicing in this hospital when I state that we must have your support for the unique attributes of this service area that necessitates the need for six new operating rooms in next year's plan. Thank you.

Sincerely,



Walter E. Pofahl, II, MD
Chief of Staff
Pitt County Memorial Hospital
Associate Professor and
Chief of the Division of Advanced Laparoscopic,
Gastrointestinal and Endocrine Surgery

/sc

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August 2, 2007

Mr. Michael C. Tarwater, Chair
Acute Care Services Committee
c/o Medical Facilities Planning Section
Division of Health Services Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Re: Petition For Adjustment to OR Need Determination in the Pitt-Greene OR Service Area

Dear Mr. Tarwater

I am writing in my capacity as Associate Chief of Surgery at Pitt County Memorial Hospital (PCMH), the Medical Director of SurgiCenter Services of Pitt (SSOP), as well as a professor in the Department of Surgery at The Brody School of Medicine at East Carolina University (BSOM). I am acutely aware of the urgent need for additional operating rooms and operating room capacity at PCMH and SSOP. We have been discussing for some time the need for additional operating rooms at SSOP and PCMH. PCMH, the only level I trauma center in eastern North Carolina, serves a rapidly growing local community and a broader 29 county service area. We need at least six additional operating rooms in the 2008 State Medical Facilities Plan (SMFP) to meet current and projected demand.

I work closely with over 100 surgeons who are practicing in Pitt County. The medical staff is united in their support for additional operating rooms. Although I understand that there may be the illusion of excess capacity in the region due to underutilization of operating rooms at other facilities, this really is just that, an illusion. The services that are provided here cannot be duplicated at any other facility in the region. As a result, PCMH will file a special need petition on August 3, 2007, explaining the adjustments that are necessary for the SMFP to accurately represent our service area. Again, as the only providers in this 29 county area that offer a unique level of surgical service, we are unable to meet

our current patient volume demands. Unless we are able to expand our operating room capacity appropriately, it is certain that we will face additional hardships in the future that primarily impact our patients. Our service is not just to Pitt County but also to all patients living in eastern North Carolina.

Our surgeons represent some of the most highly trained and specialized specialists and sub-specialists available. And, as a private practicing ENT specialist myself, I not only understand the unique issues facing our academic medical center, but I also understand the demands that must be met to support facilities who serve the private physicians that practice in this community. I ask that you strongly consider PCMH's petition. I hope you will agree with us – agree that we have a need that will help us meet our commitment to the people of this region.

Sincerely,

Eric O. Lindbeck, MD, FACA
Medical Director, SurgiCenter Services of Pitt, Inc.
Clinical Professor of Surgery
Associate Chief of Surgery
The Brody School of Medicine
East Carolina University

OR Petition 4

PETITION TO THE STATE HEALTH COORDINATING COUNCIL TO ADJUST THE 2008 STATE MEDICAL FACILITIES PLAN'S NEED DETERMINATION FOR ONE OPERATING ROOM FOR RANDOLPH COUNTY

Petition

Randolph Hospital, et al., hereby petitions the State Health Coordinating Council (SHCC) to adjust the 2008 State Medical Facilities Plan to allow for a special needs adjustment for one Operating Room in Randolph County.

Date August 1, 2007

Identification of Petitioners

Randolph Hospital
Attn: Steven E. Eblin, Vice President of Corporate Development
364 White Oak Street
Asheboro, NC 27203
336-629-8882
see @ randolphhospital.org

DPS Health Planning
RECEIVED

Orthopedic Surgery Center
Attn: Dr. Lance Sisco
138-A Dublin Square Road
Asheboro, NC 27203
(336) 629-2688

Medical Facilities
Planning Section

Surgical Associates of Asheboro
Attn: Dr. David Gimenez and Dr. Richard Evans
171 McArthur Street
Asheboro, NC 27203
(336) 625-2456

Randolph Ear, Nose, and Throat Associates
Attn: Dr. Charles West and Dr. Jonathan Wiggenhorn
124 N. Park Street
Asheboro, NC 27203
(336) 625-1007

Asheboro Urology Clinic
Attn: Dr. Daljit Caberwal, Dr. Prithvi Hanspal, and Dr. Roberto Chao
283 White Oak Street
Asheboro, NC 27203
(336) 625-3997

Central Carolina Women's Center
Attn: Dr. Craig Gaccione and Dr. Yates Lennon
237-A North Fayetteville Street
Asheboro, NC 27203
(336) 626-6371

Reasons for the Proposed Adjustment

The State Medical Facilities Plan allows for special needs petitions to be presented for consideration if a particular geographic area or institution has special or unique circumstances that give rise to resource requirements that differ from those provided by the standard methodology presented in the SMFP. Randolph County has encountered a unique circumstance that requires an additional Operating Room in order to provide continued access, quality, and reasonable costs of health care for the citizens of Randolph County. Specifically, Randolph County needs another Operating Room for the following reasons:

- To continue to provide appropriate access to the medically underserved who require surgical services
- To insure quality
- To promote cost effectiveness
- To support recruitment and retention of surgeons
- To provide patient choice and efficiencies associated with ambulatory surgery

Randolph Hospital is currently the sole provider of surgical services in Randolph County. The current operating room inventory of 5 rooms (excluding one c-section room) is used to provide inpatient and outpatient surgery to the estimated 141,000 people who live in Randolph County. The table below illustrates the ratio of operating rooms to population experienced in similar sized communities. This table reveals that Randolph County Citizens have the lowest degree of access to Operating Rooms of the comparative counties. This disparity causes a hardship as surgical services are not available in a timely fashion or they must travel away from their home to receive procedures that could be offered locally if there was additional Operating Room Capacity.

Population (per 1,000) compared to Operating Rooms
Randolph County and Similar Sized Counties
Source: Thomson, Market Planner Plus and 2008 Draft SMFP

Geography: County	2006 Population	ORs minus exclusions	2006 Population divided by number of ORs	Ratio of population (per 1,000) to each OR
CATAWBA, NC	160,089	37	4,327	4.3
IREDELL, NC	139,389	30	4,646	4.6
CABARRUS, NC	161,681	24	6,737	6.7
WILSON, NC	77,432	14	5,531	5.5
WAYNE, NC	117,676	13	9,052	9.1
CLEVELAND, NC	98,178	12	8,182	8.2
ROWAN, NC	121,335	11	11,030	11.0
ROBESON, NC	137,118	10	13,712	13.7
DAVIDSON, NC	136,164	9	15,129	15.1
ONSLOW, NC	156,182	9	17,354	17.4
UNION, NC	164,126	8	20,516	20.5
JOHNSTON, NC	124,744	7	17,821	17.8
RANDOLPH, NC	141,399	5	28,280	28.3

In the 2007 SMFP, Randolph County showed a need for an Operating Room of .30, but based on the methodology, the need had to be greater than .50 to trigger an allocation. In order to accommodate this capacity in the existing OR's and to provide the best experience to surgical patients and the medical staff, Randolph Hospital filed a Letter of No Review with the Certificate of Need Section to outfit a procedure room with Flouroscopy equipment in order to move cystoscopy procedures out of an Operating Room. This freed up more space in the Operating Room Suite for those cases that required a sterile setting. However, this temporary solution had the unintended consequence of moving Randolph County further away from triggering the methodology for a much needed additional Operating Room in the county as evidenced by the table provided below.

In practice, the operating rooms at Randolph Hospital are staffed for 8 hours a day, 5 days a week, for 253 days per year. (This allows for seven recognized holidays when procedures are not scheduled.) This translates into "standard hours of Operating Room availability" for Randolph County surgeons and patients of 1,619 hours (253 days x 8 hours a day at 80% utilization) instead of the 1,872 hours (260 days x 9 hours a day at 80% utilization) used in the current operating room methodology. If the current Operating Room methodology were adjusted to reflect the actual staffed scheduled availability of the Randolph County ORs, a need determination would have occurred in Randolph County in the 2007 SMFP. Even with decreasing surgery volumes experienced in 2006, this adjustment to the methodology would also trigger a need in the draft 2008 plan.

Current OR Methodology
Standard Hours of Utilization vs. Actual OR Availability in Randolph County
Source: 2007 SMFP and Draft 2008 SMFP

Operating Room Service Areas	Projection of Surgical Operating Room Requirements: Estimated Total Surgery Hours							Application of Growth Factor			
	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	Total Estimated Hours	Growth Factor [illegible]	Projected Surgical Hours Anticipated	Standard Hours per OR per Year [illegible]	Projected Surgical Operating Rooms Required
Randolph County 2005 Volumes from 2007 SMFP	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	5.30
Randolph County 2006 Volumes from 2008 SMFP	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	4.83
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	6.13
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	5.58

Operating Room Service Areas	2004 Inventory of Surgical Operating Rooms in Licensed Facilities with Adjustments: Inventory of Existing Operating Room			Adjustment	Adjustment	Adjustment	Adjusted Planning Inventory	Projected Surgical Operating Room Deficit or Surplus	Projected Need for New Surgical Operating Rooms
	Number of Inpatient Operating Rooms	Number of Ambulatory Operating Rooms	Number of Shared Operating Rooms	Deducted [illegible]	[illegible]	[illegible]	[illegible]	[illegible]	
Randolph County 2005 Volumes from 2007 SMFP	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	5.00	0.30	
Randolph County 2006 Volumes from 2008 SMFP	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	5.00	-0.17	
Randolph County 2005 Volumes from 2007 SMFP	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	5.00	1.13	
Randolph County 2006 Volumes from 2008 SMFP	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	5.00	0.58	

As evidenced in Randolph County, a small surplus according to the Operating Room methodology still translates into significant concerns in terms of scheduling, the ability to recruit surgical specialists, preferred start times, delayed cases, patient convenience, room availability for emergency cases, as well as delays in start time that then require overnight observations (increased cost).

Quality is also of the utmost importance when providing surgical services, or in any aspect of health care. While Randolph Hospital and the surgeons who perform cases there do an excellent job, the opportunity to offer surgery in an ambulatory setting would eliminate otherwise healthy outpatients requiring surgery being exposed to the inpatient environment and vice versa. Being able to separate these services would allow for the streamlining of processes that would improve turn around time and operating efficiencies that would therefore improve the quality of the service provided to the citizens of Randolph County.

By moving some of the outpatient surgery to an ASC, this would free up block time in the O.R. schedule at the hospital. The result of this would be increased room availability for emergency cases and less delayed cases. As patient access is increased, both in-patient and out-patient volumes will increase. This would allow for more capital

expenditures on state-of-the-art technology and equipment, as well as facility improvements.

Ambulatory Surgery Centers can make available appropriate, less costly surgical services to patients and improves access to surgical services in the market. ASC's can enjoy cost advantages over hospitals. CMS has proposed a new Medicare payment system that will begin to take effect in 2008. On average, Ambulatory Surgery Centers will be paid 35% less for the same Medicare procedure than if it were to be done in the Hospital Outpatient Department. Because the revised payment system will have a major effect on some procedures, this change in rates would be phased in over 4 years.

These discounts translate into savings for Government providers along with commercial providers. This may result in savings not only for the payors, but also for the patients as should be reflected with lower premiums. Co-pays for the patients also are less costly since the net payment to the ASC is less.

To demonstrate some of the savings, below is a table that includes the top CPT codes for procedures done in the ambulatory surgery center setting. The "HOPD" column shows what this procedure costs the insurance provider in the hospital setting. The "New ASC PMT" columns are projections of what the new Medicare payment system will pay for the same procedure in the ASC.

Cost Comparison of Cases
Hospital Outpatient compared to Ambulatory Surgery Center
Source: Nueterra Healthcare

CPT	Description	HOPD	New ASC Pmt
66984	EXTRACAPSULAR CATARACT REMV W/INSRT IOL PROSTH	$1,387.71	$ 902.01
66821	DISCISSION SEC MEMB CATARACT; LASER SURGERY	$ 299.07	$ 194.40
45378	COLONOSCOPY FLEX-PROX SPLEN FLEX; DX-SEP PROC	$ 509.34	$ 331.07
43239	UGI ENDO; W/BX 1/MX	$ 480.03	$ 312.02
62311	INJ 1 NOT NEUROLYTIC W/WO CM-DX/TX-EPID;LUMB/SAC	$ 357.90	$ 232.64
45385	COLONOSCOPY FLEX; W/REMV TUMOR/LES BY SNARE	$ 509.34	$ 331.07
45380	COLONSCPY FLXIBLE PROX SPLENIC FLXURE; W/BX 1/MX	$ 509.34	$ 331.07
45384	COLONOSCOPY FLEX; REMV TUMOR/LES HOT BX FORCEPS	$ 509.34	$ 331.07
43235	UGI ENDO; DX W/WO CLCT SPECMN-BRUSH/WASH-SP	$ 480.03	$ 312.02
52000	CYSTOURETHROSCOPY-SEP PROC	$ 412.93	$ 268.40
64476	INJ ANES/STEROID FACET JT/NRV; LUMB/SAC-EA ADD	$ 321.42	$ 208.92
64483	INJ ANES/STEROID EPIDURL; LUMB/SAC 1 LEVEL	$ 357.90	$ 232.64
64475	INJ ANES/STEROID FACET JT/NRV; LUMB/SAC-1LEVEL	$ 357.90	$ 232.64
64721	NEUROPLASTY &/OR TRANSPO; MEDIAN @ CARPAL TUNNEL	$1,030.75	$ 669.99
43248	UGI ENDO; W/INSRT GUIDE WIRE-DILAT ESOPHAGUS	$ 480.03	$ 312.02
28285	CORRECTION HAMMERTOE	$1,186.49	$ 771.22
G0105	COLOREC CANCR SCR; COLONSCPY INDIVIDUL@HIGH RISK	$ 449.56	$ 292.21
62310	INJ 1 NOT NEUROLYT-W/WO CM-DX/TX-EPID; CERV/THOR	$ 357.90	$ 232.64
55700	BX PROSTATE; NEEDLE/PUNCH SINGLE/MX ANY APPRCH	$ 264.42	$ 171.87

A need determination for an additional Operating Room for Randolph County will support the State Medical Facilities Plan objectives of Access to Care for the underserved, Improved Quality, and Cost-effective care.

Adverse Effects on the Population If the Adjustment is Not Made

The ability to recruit and retain physicians is paramount to the health and wellness of the people of Randolph County. Currently, there are vacancies in 3 surgical specialties which translates into a need for 4 surgeons. The physician recruitment office at Randolph Hospital fields questions from many prospective surgeons, and has encountered instances where several potential surgical candidates would not come and visit after hearing that there was not an Ambulatory Surgery Center in Randolph County. Also, one orthopedic surgery candidate decided not to come due to the unavailability of block time in the operating rooms. Dr. Lance Sisco, an Orthopedic Surgeon who practices in Asheboro and fellow petitioner, shared his thoughts about the effect of the lack of Operating Room capacity on recruitment and retention in a letter to the hospital recently. Dr. Sisco wrote:

"I am an orthopedic surgeon who has been in practice for 15 years. I have been on active staff at Randolph Hospital for the last 4 years. This community is in dire need of an Ambulatory Surgery Center, for many reasons. Briefly, an ASC would improve patient access to care, reduce costs, and improve quality of care. An additional O.R. in Randolph County would allow this to happen as a joint-venture between the physicians and the hospital.

Having an ASC here would greatly enhance our ability to recruit more orthopedic surgeons and other specialists to our community. Over the last 4 years, the hospital has been unsuccessful in recruiting an additional orthopedic surgeon. There are 4 orthopedic surgeons here, including myself. Two are in their 60's and very near retirement. My partner is 57, and wants to retire in 3 years. Soon, I may be the only orthopedic surgeon in Asheboro. This would very negatively impact patient access to orthopedic care. Emergency room orthopedic coverage would not be 24/7. We need at least 4 orthopedic surgeons here. We have interviewed several orthopedic surgeons over the last 4 years. All were very concerned over the lack of an ASC, and this played a major role in their decision not to come here.

An ASC delivers care much more efficiently, and this reduces costs. Health Insurance companies know this and steer their patients to ASC's in their preferred provider network, which are in Guilford County, some 25 miles away. This is an inconvenience to the patients in Randolph County. This out-migration of outpatient surgery patients greatly reduces our volume of surgery. This is the main reason our current O.R. volumes are artificially low. The longer this referral pattern continues the more market share we will lose. It could come to the point where it is not economically feasible for surgeons, such as myself, to practice in Asheboro. Ninety percent of the surgery I do is out-patient…"

In addition, Dr. Richard Evans, a general surgeon practicing in Asheboro and joint petitioner, writes:

"Randolph County is in dire need of Outpatient operating rooms or an Ambulatory Surgical Center. The Hospital currently doesn't have adequate capacity for the cases generated by the surgeons such that block time has been taken away from various surgeons just this past year. The operating room committee has labored extensively trying to maximize the number of cases done and improve utilization by employing evidence-based scheduling. This still has required the committee to deny surgeons operating room access. In addition there is no capacity for new surgeons to put their cases, resulting in difficulty attracting surgeons to the community. Much of the customer base in Randolph County bypasses the services of the hospital and goes outside of the county for their outpatient care since they can get more efficient care at Ambulatory care centers. Some of this is price driven as well as the fact that the hospital can't compete with these centers because of the efficiency. Thus Health plans and savvy consumers are directing the care elsewhere. Because of this disconnect the community suffers when the surgeons and specialists aren't able to generate adequate cases to support their practices resulting in specialists retiring and moving or failing to come and start practices.

By allocating additional operating rooms to the county, the care that citizens of Randolph County receive would be enhanced and the health care dollars can be efficiently utilized. Thus all aspects of the health care system can benefit."

Historically, Randolph Hospital has shown a positive correlation between physician recruitment and retention and surgical volume. This suggests that given access, patients want to stay home for their care. In order for Randolph Hospital and the surgeons who practice there to meet patient demand, patients need to be provided with the option of receiving care in an ambulatory surgery setting. Operating Rooms need to be readily available for urgent and emergent cases in the inpatient setting without compromising a patient's ability to receive non-emergent and elective procedures in an Ambulatory environment. The following table illustrates the ratio of population (per 1,000) to Operating Rooms for the counties contiguous to Randolph. This table illustrates that the citizens of Randolph County are at a disadvantage in the availability of operating rooms and that this requires them to seek care outside of the Operating Room Service Area. In fact, Chatham County's Critical Access Hospital has more OR capacity per population than Randolph County.

Population (per 1,000) compared to Operating Rooms
Randolph County and Contiguous Counties
Source: Thomson Market Planner Plus and 2008 Draft SMFP

Geography: County	2006 Population	ORs minus exclusions	2006 Population divided by number of ORs	Ratio of population (per 1,000) to each OR
Moore/ Hoke	111,848	27	4,143	4.1
Guilford	445,330	94	4,738	4.7
Montgomery	25,369	2	12,685	12.7
Alamance/Caswell	163,980	12	13,665	13.7
Davidson	136,164	9	15,129	15.1
Chatham	47,049	2	23,525	23.5
Randolph	141,399	5	28,280	28.3

While it might be argued that these counties have surpluses in Operating Room capacity, it cannot be argued that these surpluses translate into readily available operating room space. Rather, some degree of alternative facility site is necessary for the community to provide patients with adequate choice in where care is delivered as well as providing surgeons with appropriate facilities and available times that are conducive to the busy lives of their patients. In an ambulatory surgery center, it is necessary to adjust the scheduling so that there is ample time for patient recovery prior to the close of business. The current methodology does not take into account that in order to recognize the cost savings associated with outpatient surgery (reduced overnight stays), surgeries must be performed in the morning hours or preceding a weekend to allow for appropriate recovery for patients before being discharged home.

Dr. Charles West, an ENT surgeon who has practiced in Asheboro for 15 years and fellow petitioner, recently shared his experience with hospital staff. Dr. West explained that his patients often request to have procedures on Friday in order to recuperate over the weekend to avoid missing work. Because Dr. West only has surgical block time on Tuesdays, he is unable to accommodate this request. Therefore, the patient must decide whether to forego the procedure, miss extra days of work to accommodate Dr. West's schedule, or seek the service outside of Randolph County at a facility that may be able to offer more flexibility in scheduling the procedure. The capacity that an additional Operating Room would bring to Randolph County translates into 300 additional surgeries a year that could be done on a Friday to allow the citizens of Randolph County more choice and convenience in how and where their care is delivered.

The following information was taken from licensure renewal applications. This table illustrates that Randolph County citizens have operating room procedures largely in surrounding counties. In fact, the table below reveals that just in the contiguous counties, (which does not include OR procedures done at North Carolina Baptist, Duke, or UNC) Randolph County citizens could support 6 additional Operating Rooms using the current methodology.

Surgical Cases with Patient Origin of Randolph County
Source: 2006 and 2007 License Renewal Applications

		2005 cases on Randolph County Pts.	2006 cases on Randolph County Pts.
HealthSouth Surgical Center - GSO		220	157
Health South Southern Pines		574	507
High Point Surgical Center		789	752
Moses Cone Surgery Center		592	503
Surgical Eye Center - GSO		432	433
Wesley Long Surgical Center		179	199
Chatham Hospital	Inpt	9	15
	Outpt.	17	13
Alamance Regional	Inpt	6	8
	Outpt.	53	46
Thomasville Medical Center	Inpt	66	56
	Outpt.	249	246
Moses Cone Health System	Inpt	1354	1138
	Outpt.	670	984
High Point Regional	Inpt	483	481
	Outpt.	471	425
First Health Montgomery	Inpt	7	17
	Outpt.	64	56
First Health Moore Regional	Inpt	65	74
	Outpt.	93	55
Sum of Surgical Cases		**6393**	**6165**
Sum of OP cases		4403	4376
Weight for OP cases		1.5	1.5
Hours devoted to OP cases		6605	6564
Sum of Inpatient Cases		1990	1789
Weight for Inpatient Cases		3	3
Hours devoted to IP cases		5970	5367
OR hours needed to Accommodate Randolph County Patients treated outside of Randolph County		12575	11931
Standard Hours of Operation per OR		1872	1872
ORs being utilized in contiguous counties on Randolph County citizens		**6.7**	**6.4**

Randolph Hospital and the surgeons that operate in the operating rooms in Randolph County do not have the opportunity to grow their practices due to the constraints of only having access to the existing 5 operating rooms in Randolph County. In addition, the difficulty in recruiting and retaining physicians stands to have detrimental effects to the health care of citizens of Randolph County because adequate surgeons are needed to provide emergency backup to the emergency department at Randolph Hospital.

No Feasible Alternatives

Because the service area for operating rooms is defined by county, and the only operating rooms in the county are highly utilized, petitioning the state is the only alternative to add an OR to the 2008 SMFP for Randolph County. The addition of an OR allocation to Randolph County will enable applicants to further develop and expand access to surgical services that will benefit the service area.

The Requested Adjustment Will Not Unnecessarily Duplicate Health Services

Since no other entity provides surgical services in Randolph County, there is not a risk for duplicating health services. An additional Operating Room allocation for the county will simply allow for operating efficiencies which will improve quality, improve access, and improve cost savings to the community.

The allocation of this operating room will also allow for the collaboration of the hospital and numerous physicians in order to best address the changing health care needs of the population of Randolph County by creating an environment where multi-specialty Ambulatory Surgery can be offered to the citizens of Randolph County.

Conclusion

Based on the aforementioned reasons, we strongly encourage the SHCC to carefully consider the petition presented by Randolph Hospital, et al. and determine there is a need for one operating room in Randolph County.

Respectfully submitted this 1st day of August 2007.

By: Randolph Hospital, et al.
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DFS Health Planning
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Medical Facilities
Planning Section

Good afternoon. My name is Robert Morrison and I am the president of Randolph Hospital. I am here today to speak on behalf of a petition that is jointly being filed between Randolph Hospital and 10 surgeons who practice in Randolph County. This petition asks the State Health Coordinating Council (SHCC) to adjust the 2008 State Medical Facilities Plan to allow for a special needs adjustment for one Operating Room in Randolph County. For the sake of time, I won't read the petition to you, but rather provide an overview of why Randolph Hospital and the co-petitioners believe that this is imperative to the citizens of Randolph County. I hope that you will spend some time reviewing the tables and charts contained in the petition that explain why the current methodology is not meeting the health care needs of the citizens in Randolph County.

Specifically, Randolph County needs another Operating Room for the following reasons:

- To continue to provide appropriate access to the medically underserved who require surgical services
- To insure quality
- To promote cost effectiveness
- To support recruitment and retention of surgeons
- To provide patient choice and efficiencies associated with Ambulatory Surgery

Randolph Hospital is currently the sole provider of surgical services in Randolph County. The current Operating room inventory of 5 rooms (excluding one c-section room) is used to provide inpatient and outpatient surgery to the estimated 141,000 people who live in Randolph County. The petition illustrates the ratio of population to operating rooms

experienced in similar sized communities. This table reveals that Randolph County Citizens have the lowest degree of access to Operating Rooms of the comparative counties. Randolph County citizens have access to one OR per 28,300 citizens while similarly populated counties have ratios of one OR per 4,600 citizens to one OR per 15,000 citizens. This disparity causes a hardship as surgical services are not available in a timely fashion or patients must travel away from their home to receive procedures that could be offered locally if there was additional Operating Room capacity.

In the 2007 SMFP, Randolph County showed a need for an Operating Room of .30, but based on the methodology, the need had to be greater than .50 to trigger an OR allocation. In order to accommodate this capacity in the existing OR's and to provide the best experience to surgical patients and the medical staff, Randolph Hospital filed a Letter of No Review with the Certificate of Need Section to outfit a procedure room with flouroscopy equipment in order to move cystoscopy procedures out of an Operating Room. This freed up more space in the Operating Room Suite for those cases that required a sterile setting. However, this temporary solution had the unintended consequence of moving Randolph County further away from triggering the methodology for a much needed additional Operating Room in the county.

The ability to recruit and retain physicians is paramount to the health and wellness of the people of Randolph County. The physician recruitment office at Randolph Hospital fields questions from many prospective surgeons, and has encountered instances where several potential surgical candidates would not come and visit after hearing that there was not an Ambulatory Surgery Center in Randolph County. Also, one orthopedic surgery candidate decided not to come due to the unavailability of preferred block time in the operating rooms. Dr. Lance Sisco, an Orthopedic Surgeon who practices in Asheboro and fellow petitioner, shared his thoughts about the effect of the lack of Operating Room capacity on recruitment and retention in a letter to the hospital recently. Dr. Sisco wrote:

"Over the last 4 years, the hospital has been unsuccessful in recruiting an additional orthopedic surgeon. There are 4 orthopedic surgeons here, including myself. Two are in their 60's and very near retirement. My partner is 57, and wants to retire in 3 years.

Soon, I may be the only orthopedic surgeon in Asheboro. This would very negatively impact patient access to orthopedic care. Emergency room orthopedic coverage would not be 24/7. We need at least 4 orthopedic surgeons here. We have interviewed several orthopedic surgeons over the last 4 years. All were very concerned over the lack of an ASC, and this played a major role in their decision not to come here. It could come to the point where it is not economically feasible for surgeons, such as myself, to practice in Asheboro."

Historically, Randolph Hospital has shown a positive correlation between physician recruitment and retention and surgical volume. This suggests that given access, patients want to stay close to home for their care. Again, the ratio of population to OR's for the counties contiguous to Randolph is noteworthy. A table in the petition illustrates that the citizens of Randolph County are at a disadvantage in the availability of operating rooms and that this requires them to seek care outside of the Operating Room Service Area. While it might be argued that these surrounding counties have surpluses in Operating Room capacity, it cannot be argued that these surpluses translate into readily available operating room space. In addition, the petition looks at the volume of surgical cases that are done on Randolph County citizens in the contiguous counties. This revealed that Randolph County citizen's operating room utilization supports as many as 6 ORs outside of our county. We want to be able to provide this care close to home and to provide our community with a choice in where they receive their surgical care.

Dr. Charles West, an ENT surgeon who has practiced in Asheboro for 15 years and fellow petitioner, recently shared his experience with hospital staff. Dr. West explained that his patients often request to have procedures on Friday in order to recuperate over the weekend to avoid missing work. Because Dr. West only has surgical block time on Tuesdays, he is unable to accommodate this request. Therefore, the patient must decide whether to forego the procedure, miss extra days of work to accommodate Dr. West's schedule, or seek the service outside of Randolph County at a facility that may be able to offer more flexibility in scheduling the procedure.

In addition, the difficulty in recruiting and retaining physicians stands to have detrimental effects on the health care of citizens of Randolph County because adequate surgeons are needed to provide emergency backup to the emergency department at Randolph Hospital.

Based on the aforementioned reasons, we strongly encourage the SHCC to carefully consider the petition presented by Randolph Hospital and its surgeons and determine there is a need for one operating room in Randolph County. This will allow the hospital and its surgeons to work together to address these issues of capacity and allow the citizens of Randolph County improved access, continued quality, and cost-effective health care.

Thank you for your time and careful consideration.

OR Petition 5

PETITION FOR ADJUSTED NEED DETERMINATION

Petitioner:
Rex Hospital
4420 Lake Boone Trail
Raleigh, NC 27607

DHS Health Planning
RECEIVED

Represented by:
Rebekah Swain
Director, Strategic Planning
(919) 784-4483

Medical Facilities
Planning Section

Executive Summary:

Rex Hospital requests that the State Health Coordinating Council adjust the need determination in Wake County, NC to show a projected need of four operating rooms. Despite positive and welcome changes from the OR Methodology Workgroup, the methodology does not address the circumstances faced in Wake County. In addition to the chronically underutilized facilities that have now been excluded from the methodology, other providers in the county have not shown a need for additional operating rooms in the last four years. By contrast, Rex Hospital has shown a need for additional operating rooms in each of the last four years.

Background:

The petitioner, Rex Hospital, is located in Wake County and provides surgical services in thirty-one operating rooms. Twenty-seven of these rooms are licensed as shared inpatient and ambulatory surgery operating rooms and are located at Rex Hospital's main campus in western Raleigh. The remaining four rooms are licensed as dedicated ambulatory surgery operating rooms and are located at Rex Healthcare of Cary. Rex does not own or manage any other operating rooms.

As shown in the data contained in the 2008 SMFP, Rex is the largest provider of surgical services in Wake County. In the year ending September 30, 2006, more than 27,000 cases were performed at Rex -- 27% more than the next highest licensed provider.

Faced with increasing volume over several years and no available operating rooms in the SMFPs, Rex took action in 2005 to alleviate overcrowding in the operating rooms. Unlike many other facilities across the State, Rex already had separate, dedicated procedure areas for endoscopy and chronic pain treatment. In order to accommodate the increasing physician and patient demand for operating room time, Rex created a minor procedure area, moving minor procedures which do not require an operating room into more appropriate procedure rooms. In the year ending September 30, 2006, Rex performed 4,463 cases in those minor procedure rooms. Had these minor procedure cases still been performed in operating rooms, they would have generated a demand for 4.17 additional operating rooms by the State's methodology, thus raising Rex's total need for additional rooms as shown in the draft 2008 State Medical Facilities Plan to 6.95.

The operating room capacity this created at Rex Hospital was quickly filled. Inpatient surgery volumes increased by more than 13% in one year, and Rex's need for additional operating rooms only dipped slightly from 3.07 in the 2007 SMFP to 2.79 rooms in the draft 2008 SMFP

Analysis:
The proposed 2008 State Medical Facilities Plan (SMFP) implements a change to the methodology for the determination of need for operating rooms. As proposed by the OR Methodology Workgroup, facilities being utilized at a rate less than 40% are excluded from the inventory and their cases excluded from the calculation of demand. In Wake County, two facilities are therefore excluded – Raleigh Plastic Surgery Center, Inc., and Southern Eye Associates Ophthalmic Surgery Center. These single-specialty centers operate at 29.7% and 19.5% of capacity, respectively, as shown in Table 1.

Table 1. Operating Room Inventory and Utilization Data

	05-06 AS Cases	05-06 IP Cases	05-06 Total Cases	Included Rooms	% Utilization
Rex Hospital	18,222	9,255	27,477	31	94.9%
WakeMed Raleigh	13,629	7,941	21,570	25	94.6%
WakeMed Cary	6,770	1,467	8,237	9	86.4%
Wake Med Apex	0	0	0	4	0.0%
WakeMed Subtotal	20,399	9,408	29,807	38	82.7%
Duke Health Raleigh	8,155	2,366	10,521	13	79.4%
HealthSouth Blue Ridge	5,055	0	5,055	6	67.5%
Raleigh Women's Health	3,100		3,100	2	124.2%
Raleigh Plastics	371	0	371	1	29.7%
Southern Eye	487	0	487	2	19.5%
Total	55,789	21,029	76,818	93	84.3%

The exclusion of these two centers results in a reduction of the calculated oversupply of operating rooms by 2.21 rooms. When compared to the existing supply of operating rooms in Wake County, the revised methodology demonstrates an oversupply of 0.79 rooms, as shown in Table 2.

Table 2. OR Need in Wake County, Draft 2008 SMFP

	2005-06 Hours	2006-11 Growth	2010-11 Hours	2010-11 Rooms	Included Rooms	NEED (Surplus)
Rex Hospital	55,098	14.79%	63,247	33.79	31	2.79
WakeMed Raleigh	44,267	14.79%	50,814	27.14	25	2.14
WakeMed Cary	14,556	14.79%	16,709	8.93	9	(0.07)
Wake Med Apex	0	14.79%	0	0.00	4	(4.00)
WakeMed Subtotal	58,823	14.79%	67,522	36.07	38	(1.93)
Duke Health Raleigh	19,331	14.79%	22,189	11.85	13	(1.15)
HealthSouth Blue Ridge	7,583	14.79%	8,704	4.65	6	(1.35)
Raleigh Women's Health	4,650	14.79%	5,338	2.85	2	0.85
Raleigh Plastics	557	14.79%	639	0.34	1	(0.66)
Southern Eye	731	14.79%	839	0.45	2	(1.55)
Total (before exclusion)	146,771		168,478	90.00	93.00	(3.00)
Total (after exclusion)	145,484		167,001	89.21	90	**(0.79)**

Although this change to the methodology has had a significant impact in reducing the calculated oversupply in the market, it fails to address the continued high utilization of some providers and low utilization of others. In addition to the chronically underutilized facilities that have been excluded from the methodology, other providers in the county have not shown a need for additional operating rooms in the last four years. By contrast, only Rex Hospital and one other provider, Raleigh Women's Health, have each shown a need for additional operating rooms in all of the last four years. Each year, this need for additional operating rooms has been suppressed by the underutilization of other providers in the service area and no allocation of additional operating rooms has been made. The operating room need by facility is shown in Table 3, below.

Table 3. Calculation of operating room need by facility, 2005 – 2008 SMFPs

	2005	2006	2007	2008 Draft
Rex Hospital	1.98	1.94	3.07	2.79
WakeMed Raleigh	-3.34	-2.70	-1.48	2.14
WakeMed Cary	-2.45	-1.77	-1.36	-0.07
WakeMed Apex			-4.00	-4.00
WakeMed Subtotal	-5.79	-4.47	-6.84	-1.93
Duke Health Raleigh	-0.20	0.48	1.07	-1.15
HealthSouth Blue Ridge	-1.97	-1.87	-1.72	-1.35
Raleigh Women's Health	0.44	0.61	0.45	0.85
Raleigh Plastics	-0.67	-0.64	-0.61	-0.66
Southern Eye	-1.62	-1.58	-1.60	-1.55
Total	-7.82	-5.53	-6.18	-3.00

Rex Hospital requests that the State Health Coordinating Council allocate four operating rooms based upon the need for three generated by Rex Hospital and for one generated by Raleigh Women's Health. This facility-by-facility recognition of need is reflective of changes made to the acute care bed methodology in 2005, and accommodates for the common ownership of multiple facilities. This allocation would eliminate the restriction placed on highly-utilized facilities by lower utilized facilities. Although these utilization of these facilities is not low enough to meet the criteria of "chronically underutilized" and therefore excluded from the methodology, these facilities have prevented a determination of need in each of the last four State Medical Facilities Plans.

When this disparity in utilization is persistent over a period of several years, it indicates that other market forces are driving physicians and patients to utilize some facilities over others. The county-based methodology currently in place does not account for this preference; instead, is assumes that all operating rooms in the market are equally available for use by patients and physicians. It further assumes that if one facility is over utilized, volume will shift to other facilities in the market until all the facilities were well-utilized and a need is generated. Four years of data on utilization of Wake county surgical facilities shows that these assumptions are patently not applicable in this community. Despite a booming population and an overall increase in volumes of surgical cases, utilization of some facilities has decreased while utilization at Rex remains high – in spite of having moved more than four thousand minor cases to more appropriate settings.

As this data demonstrates, Rex has faced this need for some time but has awaited the outcome of the OR Workgroup. Because the changes recommended by the Workgroup do not adequately address the need faced in Wake County, Rex is compelled to request a special need determination. Surgical volumes continue to increase at a rate faster than the population growth factored into the existing need methodology. If no allocation of operating rooms is made in the 2008 plan, highly-utilized facilities such as Rex will have no opportunities to expand, creating a limit on the opportunity for physicians and patients to access their surgical facility of choice.

As shown in Table 4, below, the State's projected utilization of Rex Hospital operating rooms in 2011 is over 100%. Although further revisions to the OR methodology are expected, and allocation of ORs in Wake County may result from those revisions, Rex is compelled to request this special need determination now. As reflected in the projection methodology, rooms must be allocated in the 2008 plan in order to allow for the time required for a provider to apply, develop, and implement new operating rooms in the market before they are necessary in 2011.

Table 4. 2011 Projected Utilization by Provider

	2010-11 Hours	Hours/ Room	Included Rooms	2011 Utilization
Rex Hospital	63,247	1872	31	109%
WakeMed Raleigh	50,814		25	
WakeMed Cary	16,709		9	
Wake Med Apex	0		4	
WakeMed Subtotal	67,522	1872	38	94.9%
Duke Health Raleigh	22,189	1872	13	91.2%
HealthSouth Blue Ridge	8,704	1872	6	77.5%
Raleigh Women's Health	5,338	1872	2	143%
Raleigh Plastics	639	1872	1	34.1%
Southern Eye	839	1872	2	22.4%

We would also like to take this opportunity to thank the SHCC members for their hard work each year to develop the State Medical Facilities Plan; and to thank the staff of the planning, licensure, and certificate-of-need sections for their assistance throughout the year. We appreciate your time and attention today, and for your consideration of this special need determination for four operating rooms in Wake County.

RALEIGH SURGICAL GROUP, INC.

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August 20, 2007

Victoria McLanahan, Analyst
NC Division of Health Service Regulation
Medical Facilities Planning
2709 Mail Service Center
Raleigh, NC 27699-2709

Dear Ms. McLanahan:

I am a general surgeon practicing at Rex Hospital for the past sixteen years, and I have seen both the hospital and the county grow. I have observed Rex struggle over the years to accommodate the growing number of surgical cases done in the hospital. The shortage of operating room availability is well known to all of us that work there.

As we peer into the future with the growing population of Wake County, and the addition of surgical staff monthly to Rex Hospital, the availability of operating room space at Rex Hospital can only deteriorate. Shortages of operating room space is not only deleterious for Wake County citizens that use Rex Hospital, but it is also detrimental to the professional staff and support staff that work at Rex. Please consider this in the request of Rex Hospital for additional operating room capacity, and allow them to plan satisfactorily for the future. Thanks for your consideration.

Sincerely,

Richard A. Chiulli, M.D.

RAC/dhb

Cc: Rebekah Swain, Rex Health

2800 Blue Ridge Road, Suite 503 • Raleigh, NC 27607 • Telephone: 919.782.8210 • www.raleighsurgical.com

Operating Room Petition Materials Related to Petitions 6 and 7:

- Agency Report
- OR Petition 6: Mecklenburg Foot and Ankle Associates and Diabetic Foot Clinic, P.C.- Petition and Related Material
- OR Petition 7: Raleigh Orthopaedic Clinic- Petition and Related Comments

AGENCY REPORT

OR Petition 6: Mecklenburg Foot and Ankle Associates and Diabetic Foot Clinic, P.C.
OR Petition 7: Raleigh Orthopaedic Clinic

Petitioners

OR Petition 6:
Mecklenburg Foot and Ankle Associates and
Diabetic Foot Clinic, P.C.
Dr. Robert M. Liesman, F.A.C.F.A.S.
3535 Randolph Road
Randolph Building, Suite 107
Charlotte, NC 28211

OR Petition 7:
Karl Stein, Executive Director
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

Request

OR Petition 6: The Petition requests an adjusted need determination in the 2008 State Medical Facilities Plan for one single-specialty Operating Room dedicated for podiatric surgery cases only for Mecklenburg County.

OR Petition 7: The Petition requests an adjusted need determination in the 2008 State Medical Facilities Plan for six dedicated orthopedic ambulatory Operating Rooms to be developed in one or more freestanding (non-hospital) ambulatory surgery centers in Wake County.

Background Information

The Operating Room Need Methodology is based on reported surgical cases by type, i.e., inpatient cases and ambulatory/outpatient cases. The methodology incorporates a number of assumptions including: average case times for inpatient and for ambulatory procedures; average hours of operation; average days of operation per year; and anticipated percentage availability. These assumptions are intended to establish a baseline for projection of future operating room need. By their nature, "averages" do not match each individual facility's circumstances, but should be representative of general practices. The methodology also includes a "Growth Factor," linked to each service area's projected population change between the "data year" and the "target year" for need projections (*i.e., over a four-year period*).

During the spring of 2007, an Operating Room Methodology Work Group met four times and reviewed the methodology for projecting Operating Room need. One of the Work Group meetings included presentations made by interested parties who provided suggestions and recommendations on proposed changes to the methodology as well as their perspective on the adequacy of the methodology. The Work Group developed a set of recommendations at the last meeting. One of the Work Group's recommendations, to exclude facilities with chronically under utilized OR's from operating room need projections, was incorporated into the Proposed 2008 State Medical Facilities Plan.

In deference to the standard methodology, Chapter 2 of the Plan allows persons to petition for an adjusted need determination in consideration of "...unique or special attributes of a particular geographic area or institution...," if they believe their needs are not appropriately addressed by the standard methodology.

Analysis/Implications

To provide background, the operating room inventory, projected need and Year 2010 projected surpluses for Mecklenburg and Wake Counties (from Table 6B of the Proposed 2008 SMFP) are shown below:

County	Inpatient OR's	Ambulatory OR's	Shared OR's	Dedicated C-Section OR's (Excluded)	Trauma/Burn OR's (Excluded)	CON, Settlement, Previous Need Adjustments	Adjusted Planning Inventory	Year 2010 Projected Surplus
Mecklenburg	22	42	95	-12	-1	0	146	18.27
Wake	9	16	67	-5	-1	4	90	.79

In analyzing each of the petitions, the Agency noted differences in the issues raised and the rationale provided. However, common to both petitions and a salient point noted by the Agency, is each petitioner's request for a **single surgical specialty** adjusted need determination. Additionally, both petitions request **ambulatory surgery** operating rooms. Raleigh Orthopaedic Clinic explicitly requests ambulatory surgery operating rooms and Mecklenburg Foot and Ankle states on page 2 of their petition that the requested operating room would be "part of an ambulatory surgical center dedicated solely to podiatric surgery".

The current operating room methodology projects need for generic operating rooms, without regard to surgical specialty or type of setting. Consequently,

- Surgical utilization and operating room inventory data are collected and tracked in support of projecting need for generic operating rooms.
- There is no current mechanism for determining need for operating rooms for a particular surgical specialty or for a particular type of setting.

As to other issues raised by the petitions, the Agency wishes to highlight the following:

- Mecklenburg Foot and Ankle: Mecklenburg County's current operating room surplus is 18.72 OR's.
- Raleigh Orthopaedic Clinic: The petitioner contends that Wake County's four dedicated open-heart surgery operating rooms, located at WakeMed, are under utilized. Review of WakeMeds's 2007 Hospital License Renewal Application shows that 981 surgical cases were performed in the four dedicated open-heart surgery operating rooms from October 1, 2005-September 30, 2006. The table below shows projected Wake County operating room need from the Proposed 2008 SMFP (Column A.) and adjusted by excluding dedicated open-heart surgery operating rooms and cases (Column B.).

	A.	B.
	Proposed 2008 SMFP	**Excluding 4 Dedicated Open Heart Surgery OR's and 981 Cases**
Inpatient Cases	21029	20048
Estimated Hours for Inpatient Cases	63087	60144
Outpatient Cases	54931	54931
Estimated Hours for Outpatient Cases	82397	82397
Total estimated hours	145484	142541
Growth Factor	0.1479	0.1479
Projected Surgical Hours 2010	166999.51	163621.26
Inpatient OR's	9	5
Ambulatory OR's	16	16
Shared OR's	67	67
Dedicated C-Section OR's (excluded)	-5	-5
Trauma/Burn OR's (excluded)	-1	-1
CON, Settlement, Previous Need Adjustments	4	4
Adjusted Planning Inventory	90	86
Operating Rooms Required in 2010	89.21	87.40
Year 2010 Projected Surplus	-0.79	1.40

As the above table shows, excluding dedicated open heart surgery operating rooms and cases results in a projected 2010 need of 1.4 OR's for Wake County. The Agency concurs with Raleigh Orthopedic Clinic that Wake County's dedicated open-heart surgery rooms are underutilized.

Agency Recommendation

In consideration of the infeasibility of projecting need for single specialty operating rooms in a particular type of setting, the Agency recommends that the petitions be denied. The Agency encourages the petitioners to work with existing resources to maximize the efficient utilization of current surgical operating room capacity.

Further, the Agency recommends that the Acute Care Services Committee consider revising the methodology for projecting operating room need by excluding open-heart surgery operating rooms and cases from need determination projections.

OR Petition 6

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PETITION
FOR ADJUSTMENT
TO THE OPERATING ROOM NEED DETERMINATION

TO: Medical Facilities Planning Section
2714 Mail Service Center
Raleigh, North Carolina 27699-2714

FROM: Joy Heath Thomas, Esq. on Behalf of
Mecklenburg Foot and Ankle Associates
and Diabetic Foot Clinic, P.C.
(Dr. Robert M. Liesman, F.A.C.F.A.S.)

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Medical Facilities
Planning Section

DATE: July 30, 2007

Petitioner: Mecklenburg Foot and Ankle Associates
and Diabetic Foot Clinic, P.C.
Dr. Robert M. Liesman, F.A.C.F.A.S.
3535 Randolph Road
Randolph Building, Suite 107
Charlotte, North Carolina 28211
T (704) 442-8433
liesman@bellsouth.net

Statement of the Requested Adjustment with citation to the Need Determination in the Proposed SMFP for which the adjustment is proposed:

Petitioner seeks an adjustment to the Operating Room Need Determination which appears on page 70 of the Proposed State Medical Facilities Plan.

Petitioner asks for an adjustment to reflect a Need Determination for one single-specialty operating room dedicated for podiatric surgery cases only for Mecklenburg County.

Reasons for the Proposed Adjustment:

Statement of the Adverse Effects of No Adjustment

- The sole option for podiatric surgical privileges in Mecklenburg County exists at HealthSouth Surgery Center of Charlotte, a facility which

reported near-capacity utilization according to the State's Methodology and the data reported in the 2008 Proposed State Medical Facilities Plan. As a result, the public will suffer without an adjusted need determination that creates a reasonable alternative for the provision of podiatric surgery in Mecklenburg County.

Statement of Alternatives to the Proposed Adjustment

- There are no viable alternatives to the proposed adjusted need determination because hospitals in Mecklenburg County do not afford privileges for podiatric surgeons and the only facility which does offer such privileges has experienced growth which has caused its capabilities to be overextended.

Evidence of No Unnecessary Duplication Resulting from the Proposed Adjustment:

- The granting of this Petition for an adjusted need determination will not cause a duplication of existing resources because the only provider that extends privileges for podiatric surgeons is already operating at near capacity utilization.

Petitioner has assumed the same service area definitions as given in the program chapters of the Proposed SMFP. Petitioner is aware that the Medical Facilities Planning staff may request additional information and opinions from Petitioner or others who may be affected by the proposed adjustment.

Discussion

Petitioner seeks an adjusted need determination for one single-specialty operating room to be offered as part of an ambulatory surgical center dedicated solely to podiatric surgery.

HealthSouth's Overutilization

At present, the sole provider in Mecklenburg County which offers privileges for podiatric surgeons is HealthSouth Surgery Center of Charlotte ("HealthSouth"). In the 2007 State Medical Facilities Plan, HealthSouth reported 6,154 cases in 7 ambulatory rooms. Remarkably, per the Draft 2008 SMFP, HealthSouth has reported 9,814 cases in these same 7 ambulatory rooms. This represents a dramatic jump in utilization, comparing 2006 Licensure Data to 2007 Licensure Data.

At its reported utilization levels, HealthSouth is nearing full capacity even based on the State's formula assumption of 9 operating room hours per room 260 days per year. As a result of such utilization, it must be assumed that the capacity of the HealthSouth ambulatory rooms is limited due to high demand.

Without the requested need determination, Petitioner and other similarly-situated podiatric surgeons will be severely limited by capacity constraints which will negatively impact the provision of prompt and appropriate patient care. The utilization levels at HealthSouth can be expected to cause delays in patient scheduling and a lack of flexibility for urgent cases. The trend in increasing utilization will only worsen these dynamics in 2008.

Privileges Unavailable Elsewhere

Inasmuch as HealthSouth represents the sole option for podiatric surgeons to access operating rooms for the benefit of their patients, there is a clear need for an adjusted need determination which would permit the development of a single-specialty operating room dedicated to podiatric surgery. Licensure Data reveals that no other ASC in Mecklenburg County reported any Podiatry cases among the Specialty cases performed during the period from October 1, 2005 through September 30, 2006.

Without the ability to receive surgical intervention at the hands of their treating podiatrist, patients must be referred to a "general surgeon" who may lack the specific experience, familiarity with the patient, and specialized expertise that optimize patient care.

Petitioner is unable to control the privileges afforded by hospitals and ASC facilities in Mecklenburg County and has no alternative to pursuing an adjusted need determination to allow for the development of an operating room dedicated solely to podiatric surgery.

A Need Determination is Necessary to Address Lack of Access & Privileges

Absent a need determination that will permit the development of such an OR, Petitioner has no ability to gain reasonable access to OR capabilities in Mecklenburg County. Petitioner cannot expect reasonable access at HealthSouth due to its high utilization and Petitioner cannot obtain privileges elsewhere as there are no hospitals and no other ASC facilities which afford such privileges. Together the lack of access and privileges create a unique situation which thwarts patients' ability to receive care in an optimal setting from the physician of their choice in Mecklenburg County.

A Dedicated OR for Podiatry Cases is Appropriate

The 2008 SMFP should identify the need for one OR dedicated to podiatric surgery in order to provide residents of Mecklenburg County with adequate access to an operating room in which specially trained podiatric surgeons can promptly schedule and perform needed surgical cases.

There is no question that there is considerable demand for podiatric surgery. Petitioner's practice alone involves extensive provision of services including diabetic foot and wound care, reconstructive surgery of the foot and ankle and diabetic limb salvage which creates a demand for reasonably appropriate access to a surgical facility. Upon information and belief, twenty five or more podiatric surgeons serve patients in Mecklenburg County.

At HealthSouth alone, over 1,000 Podiatry cases were reported to have been performed between October 1, 2005 and September 30, 2006. Taking into account this reported volume of Podiatry cases, and assuming the additional volume of cases handled within the physician office setting or in hospital operating rooms, a dedicated Podiatry OR could be expected to easily reach eighty-percent utilization within its initial year of operation.

No Unnecessary Duplication or Negative Impact

The granting of this Petition will not unnecessarily duplicate existing capabilities because, with the exception of HealthSouth, no other provider offers OR time to podiatric surgeons. Hospitals in Mecklenburg County will not be adversely impacted by the establishment of an OR dedicated to podiatric surgical cases.

Conclusion

For all of the reasons outlined above, an adjusted need determination for an OR dedicated to podiatry cases in Mecklenburg County should be provided in the 2008 State Medical Facilities Plan.

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A Supplement to:

The Journal of Foot & Ankle Surgery

DIABETIC FOOT DISORDERS

A CLINICAL PRACTICE GUIDELINE

An official publication of the American College of Foot and Ankle Surgeons

Development and publication of this Clinical Practice Guideline was made possible by an Educational Grant Co-Sponsored by Johnson & Johnson Wound Management, a division of ETHICON, INC. and KCI USA, Inc.

Supplement to:

The Journal of Foot & Ankle Surgery

DIABETIC FOOT DISORDERS:
A CLINICAL PRACTICE GUIDELINE (2006 revision)

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Supplement to:

The Journal of Foot & Ankle Surgery

DIABETIC FOOT DISORDERS: A CLINICAL PRACTICE GUIDELINE (2006 revision)

ABSTRACT: *The prevalence of diabetes mellitus is growing at epidemic proportions in the United States and worldwide. Most alarming is the steady increase in type 2 diabetes, especially among young and obese people. An estimated 7% of the US population has diabetes, and because of the increased longevity of this population, diabetes associated complications are expected to rise in prevalence.*

Foot ulcerations, infections, Charcot neuroarthropathy, and peripheral arterial disease frequently result in gangrene and lower limb amputation. Consequently, foot disorders are leading causes of hospitalization for persons with diabetes and account for billion-dollar expenditures annually in the US. Although not all foot complications can be prevented, dramatic reductions in frequency have been achieved by taking a multidisciplinary approach to patient management. Using this concept, the authors present a clinical practice guideline for diabetic foot disorders based on currently available evidence, committee consensus, and current clinical practice. The pathophysiology and treatment of diabetic foot ulcers, infections, and the diabetic Charcot foot are reviewed. While these guidelines cannot and should not dictate the care of all affected patients, they provide evidence based guidance for general patterns of practice. If these concepts are embraced and incorporated into patient management protocols, a major reduction in diabetic limb amputations is certainly an attainable goal.

This clinical practice guideline (CPG) is based on the consensus of current clinical practice and review of the clinical literature. This guideline was developed by the Clinical Practice Guideline Diabetes Panel of the American College of Foot and Ankle Surgeons.

INTRODUCTION

The prevalence of diabetes mellitus is growing at epidemic proportions in the United States and worldwide (1). Most alarming is the steady increase in type 2 diabetes, especially among young and obese persons. An estimated 7% of Americans are afflicted with diabetes, and with the longevity of this population increasing, the prevalence of diabetes-related complications will continue to rise.

Foot disorders are a major source of morbidity and a leading cause of hospitalization for persons with diabetes. Ulceration, infection, gangrene, and amputation are significant complications of the disease, estimated to cost billions of dollars each year. Charcot foot, which of itself can lead to limb-threatening disorders, is another serious complication of long-standing diabetes. In addition to improving the management of ulcers, the leading precursor to lower extremity amputation in diabetic patients (2), clinicians must determine how to more effectively *prevent* ulceration. Although not all diabetic foot disorders can be prevented, it is possible to effect dramatic reductions in their incidence and morbidity through appropriate evidence-based prevention and management protocols.

Taking a multidisciplinary approach to diabetic foot disorders, many centers from around the world have noted consistent improvement in limb salvage rates. With this premise as our central theme, the authors present this clinical practice guideline based on currently available evidence. Three major pedal complications of diabetes are reviewed: diabetic foot ulcers, diabetic foot infections, and the diabetic Charcot foot. These guidelines are intended to provide evidence-based guidance for general patterns of practice and do not necessarily dictate the care of a particular patient.

EPIDEMIOLOGY OF DIABETIC FOOT DISORDERS

Diabetes is one of the foremost causes of death in many countries and a leading cause of blindness, renal failure, and nontraumatic amputation. Global prevalence of diabetes in 2003 was estimated to be 194 million (3). By 2030, this figure is predicted to rise to 366 million due to longer life expectancy and changing dietary habits (4).

The estimated incidence of diabetes in the US exceeds 1.5 million new cases annually, with an overall prevalence of 20.8 million people or 7% of the nation's population (5). An estimated 14.6 million persons are currently diagnosed with the disease, while an additional 6.2 million people who have diabetes remain undiagnosed; this represents a sixfold increase in the number of persons with diabetes over the past four decades (6). A higher incidence of diabetes occurs among non-Hispanic blacks, Hispanic Latino Americans, and Native Americans compared with non-Hispanic whites (7). Diagnosed diabetes is most prevalent in middle-aged and elderly populations, with the highest rates occurring in persons aged 65 years and older (8-10). As the sixth leading cause of death in the US, diabetes contributes to more than 224,000 deaths per year (5).

Table 1 Classification of Diabetes Mellitus *

Type 1 diabetes	absolute insulin deficiency
Type 2 diabetes	insulin resistant +/- insulin deficiency
Other types	genetic defects of β-cell function or insulin action
	endocrinopathies
	drug or chemical
	infections
Gestational diabetes	

* [illegible]

Four categories of diabetes are recognized (Table 1). Type 1, formerly insulin-dependent diabetes mellitus (IDDM), is an autoimmune disease affecting the pancreas. Individuals with type 1 diabetes are prone to ketosis and unable to produce endogenous insulin. Type 2, formerly non-insulin dependent diabetes mellitus (NIDDM), accounts for 90% to 95% of cases diagnosed. Type 2 diabetes is characterized by hyperglycemia in the presence of hyperinsulinemia due to peripheral insulin resistance. Gestational as well as genetic defects and endocrinopathies are recognized as other types of diabetes (11). Diabetes is associated with numerous complications related to microvascular, macrovascular, and metabolic etiologies. These include cerebrovascular, cardiovascular, and peripheral arterial disease, retinopathy, neuropathy, and nephropathy. Currently, cardiovascular complications are the most common cause of premature death among patients with diabetes (9, 12). Rates of heart disease and stroke are 2 to 4 times higher among diabetic adults compared with nondiabetic adults, accounting for about 65% of deaths in people with diabetes (5). Estimated total (direct and indirect) annual expenditures for diabetes management in 2002 was $132 billion, representing 1 of every 10 health care dollars spent in the US (13).

One of the most common complications of diabetes in the lower extremity is the diabetic foot ulcer. An estimated 15% of patients with diabetes will develop a lower extremity ulcer during the course of their disease (14-17). Several population-based studies indicate a 0.5% to 3% annual cumulative incidence of diabetic foot ulcers (18-21). According to one large British study of neuropathic patients, the 1-year incidence of initial foot ulcer was 7% (22). The prevalence of foot ulcers reported for a variety of populations ranges from 2% to 10% (16, 18, 22, 23). Neuropathy, deformity, high plantar pressure, poor glucose control, duration of diabetes, and male gender are all contributory factors for foot ulceration (see the following section, "Risk for Ulceration") (24-27). National hospital discharge data indicate that the average hospital length of stay (LOS) for diabetic patients with ulcer diagnoses was 59% longer than for diabetic patients without ulcers (16). While 7% to 20% of patients with foot ulcers will subsequently require an amputation, foot ulceration is the precursor to approximately 85% of lower extremity of amputations in persons with diabetes (28-31).

Diabetes continues to be the most common underlying cause of nontraumatic lower extremity amputations (LEAs) in the US and Europe (1, 32). More than 60% of LEAs in the US occur in people with diabetes, averaging 82,000 per year (5, 10). While the number of diabetes-related hospital discharges has progressively increased from 33,000 in 1980 to 84,000 in 1997, this number seems to have leveled off during the present decade. In 2002, there were 82,000 diabetes-related LEA discharges, accounting for 911,000 days of hospital stay with an average LOS of 11.2 days (10). The age-adjusted rate of amputation for that year was 5.2 per 1,000 persons with diabetes, a notable decrease from the highest rate of 8.1 per 1,000 in 1996.

In terms of level of diabetes-related lower limb amputations, toe amputations comprise the majority of procedures. The age-adjusted LEA rate in 2002 among persons with diabetes was highest for toe LEA (2.6 per 1,000 persons), followed by below-knee LEA (1.6 per 1,000 persons). For foot LEA and above-knee LEA, the age-adjusted rate was 0.8 per 1,000 persons. These trends in amputation level have essentially remained the same since 1993 (10). Generally, the LEA rate is 15 to 40 times higher in the diabetic versus

nondiabetic populations, and the rate is at least 50% higher in men versus women (8, 10, 12, 33). In 2002, the age-adjusted LEA rate among men was 7.0 per 1,000 persons with diabetes compared with to the rate among women reported at 3.3 per 1000 persons with diabetes (10).

Several ethnic differences occur in the frequency of diabetes-related amputations. Mexican (Hispanic) Americans, Native Americans, and African Americans each have at least a 1.5- to 2-fold greater risk for diabetes-related amputation than age-matched diabetic Caucasians (8, 10, 16, 17, 34, 35). When LEA risk is compared between diabetic and nondiabetic populations worldwide, it is apparent that both diabetes and ethnicity have profound implications on rates of lower limb amputation (1, 17).

Survival rates after amputation are generally lower for diabetic versus nondiabetic patients (16, 17, 29). The 3- and 5-year survival rates are about 50% and 40%, respectively, with cardiovascular disease being the major cause of death (8). Although mortality rates following major amputation are high among both diabetic and nondiabetic patients, a recent study reported no significant difference between these two populations. The mean survival was approximately 6.5 years, with a 68% mortality after 9 years regardless of diabetes status (36). An earlier study from Sweden reported a 5-year mortality rate of 68% after lower limb amputation, with survival rates lower among patients who underwent higher levels of amputation (29). Similar trends were found in a review of amputations within the Veterans Affairs system, but worse survival outcomes were observed for older patients, those with renal disease, and those with peripheral arterial disease (37). Researchers have reported a 50% incidence of serious contralateral foot lesion (ie, ulcer) following an LEA, and a 50% incidence of contralateral amputation within 2 to 5 years of an LEA (16, 29).

Total (direct and indirect) annual health care costs for persons with diabetes were estimated to be $132 billion in 2002. Direct medical expenditures, including hospitalization, medical care, and supplies, accounted for $91.8 billion (13). The estimated cost for foot ulcer care in the US ranges from $4,595 per ulcer episode to nearly $28,000 for the 2 years after diagnosis (19, 38). One report estimates 800,000 prevalent ulcer cases in the US, with costs averaging $5,457 per year per patient or total national annual costs of $5 billion (39). A study of Medicare claims data found that expenditures for patients with lower extremity ulcers averaged 3 times higher than expenditures for Medicare beneficiaries in general. With 24% of their total costs allocated to ulcer-related expenses, lower extremity ulcer patients cost the Medicare system $1.5 billion in 1995 (40). According to a large prospective study of diabetic patients with foot ulcers, about 7% will subsequently require a lower extremity amputation (31). While hospital LOSs for diabetes-related LEA have progressively decreased in the US, the overall direct costs remain high (10, 16). Direct and indirect costs of LEA — which range from $20,000 to $40,000 per event — vary by year, payer, level of amputation, LOS, and attendant comorbidities (16). If the lower figure is applied to the 82,000 amputations performed in 2002, estimated total costs of LEA might exceed $1.6 billion annually. When outpatient costs for ulcer care preceding these amputations is added, the estimated total costs in the US for diabetic foot disease can easily approach or exceed $6 billion annually.

Risk for Ulceration

Foot ulceration is the most common single precursor to lower extremity amputations among persons with diabetes (28-30). Treatment of infected foot wounds comprises up to one quarter of all diabetic hospital admissions in the US and Britain, making this the most common reason for diabetes-related hospitalization in these countries (41-43). The multifactorial nature of diabetic foot ulceration has been elucidated by numerous observational studies (16, 22, 24, 26, 27, 44-48). Risk factors identified include peripheral neuropathy, vascular disease, limited joint mobility, foot deformities, abnormal foot pressures, minor trauma, a history of ulceration or amputation, and impaired visual acuity (25, 49, 50). These and other putative causative factors are shown in Figure 1.

Peripheral sensory neuropathy in the face of unperceived trauma is the primary factor leading to diabetic foot ulcerations (24, 27, 46, 49). Approximately 45% to 60% of all diabetic ulcerations are purely neuropathic, while up to 45% have neuropathic and ischemic components (24, 51). According to an important prospective multicenter study, sensory neuropathy was the most frequent component in the causal sequence to ulceration in diabetic patients (24).

Other forms of neuropathy may also play a role in foot ulceration. Motor neuropathy resulting in anterior crural muscle atrophy or intrinsic muscle wasting can lead to foot deformities such as foot drop, equinus, hammertoe, and prominent plantar metatarsal heads (25, 26, 52-54). Ankle equinus with restricted dorsiflexory range of motion is fairly common in patients with diabetic neuropathy and can be a consequence of anterior crural muscle atrophy (55-60). The decreased ankle motion, which confers higher-than normal plantar pressures at the forefoot, has been implicated as a contributory cause of ulceration as well as recurrence or recalcitrance of existing ulcers (57, 58, 60, 61).

Autonomic neuropathy often results in dry skin with cracking and fissuring, creating a portal of entry for bacte-

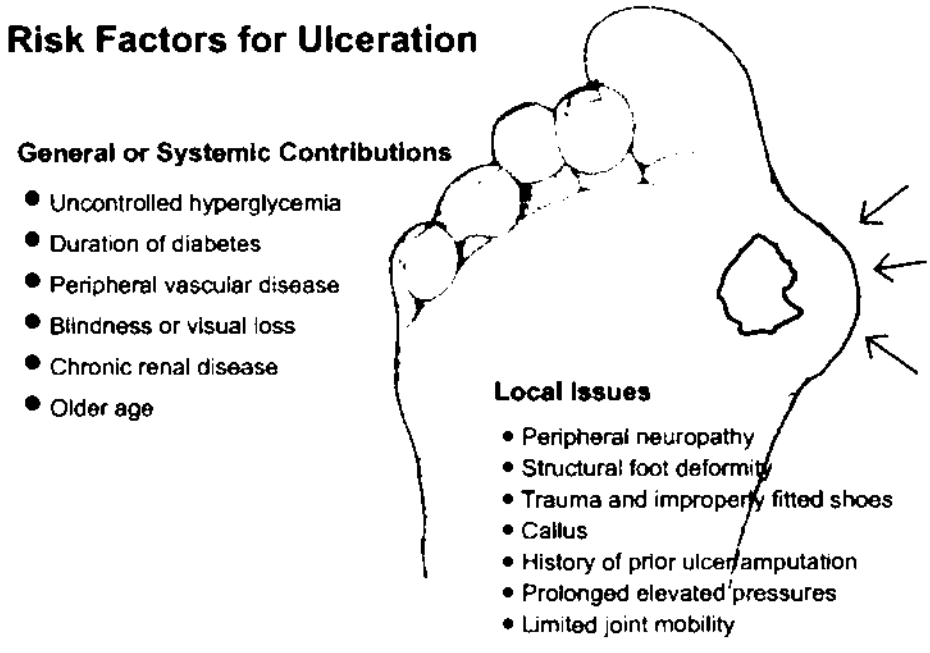


Figure 1 The risk factors for ulceration may be distinguished by general or systemic considerations versus those localized to the foot and its pathology.

ria (42, 63). Autosympathectomy with attendant sympathetic failure, arteriovenous shunting, and microvascular thermoregulatory dysfunction impairs normal tissue perfusion and microvascular responses to injury. These alterations can subsequently be implicated in the pathogenesis of ulceration (63-67).

Foot deformities resulting from neuropathy, abnormal biomechanics, congenital disorders, or prior surgical intervention may result in high focal foot pressures and increased risk of ulceration (24, 48, 50, 57, 68-71). The effects of motor neuropathy occur relatively early and lead to foot muscle atrophy with consequent development of hammertoes, fat pad displacement, and associated increases in plantar forefoot pressures (53, 72-75). Although most deformities cause high plantar pressures and plantar foot ulcerations, medial and dorsal ulcerations may develop as a result of footwear irritation. Common deformities might include prior partial foot amputations, prominent metatarsal heads, hammertoes, Charcot arthropathy, or hallux valgus (69, 76-79). A large prospective population-based study found that elevated plantar foot pressures are significantly associated with neuropathic ulceration and amputation (80). The study also revealed a trend for increased foot pressures as the number of pedal deformities increased.

Trauma to the foot in the presence of sensory neuropathy is an important component cause of ulceration (24). While trauma may include puncture wounds and blunt injury, a common injury leading to ulceration is moderate repetitive stress associated with walking or day-to-day activity (69, 76, 81). This is often manifested by callus formation under the metatarsal heads (48, 82, 83). A recent report suggests that even with moderate activity, ulceration may be precipitated by a higher degree of variability in activity or periodic "bursts" of activity (84). Shoe-related trauma has also been identified as a frequent precursor to foot ulceration (28, 51, 54, 85, 86).

Peripheral arterial disease (PAD) rarely leads to foot ulcerations directly. However, once ulceration develops, arterial insufficiency will result in prolonged healing, imparting an elevated risk of amputation (28, 87, 88). Additionally, attempts to resolve any infection will be impaired due to lack of oxygenation and difficulty in delivering antibiotics to the infection site. Therefore, early recognition and aggressive treatment of lower extremity ischemia are vital to lower limb salvage (30, 52, 89-91).

Limited joint mobility has also been described as a potential risk factor for ulceration (92-94). Glycosylation of collagen as a result of longstanding diabetes may lead to stiffening of capsular structures and ligaments (chiroarthropathy) (95). The subsequent reduction in ankle, subtalar, and first metatarsophalangeal (MTP) joint mobility has been shown to result in high focal plantar pressures with increased ulceration risk in patients with neuropathy (92, 96, 97). Several reports also attribute glycosylation and altered arrangement of Achilles tendon collagen to the propensity for diabetic patients to develop ankle equinus (98, 99).

Other factors frequently associated with heightened ulceration risk include nephropathy, poor diabetes control, duration of diabetes, visual loss, and advanced age (48, 69,

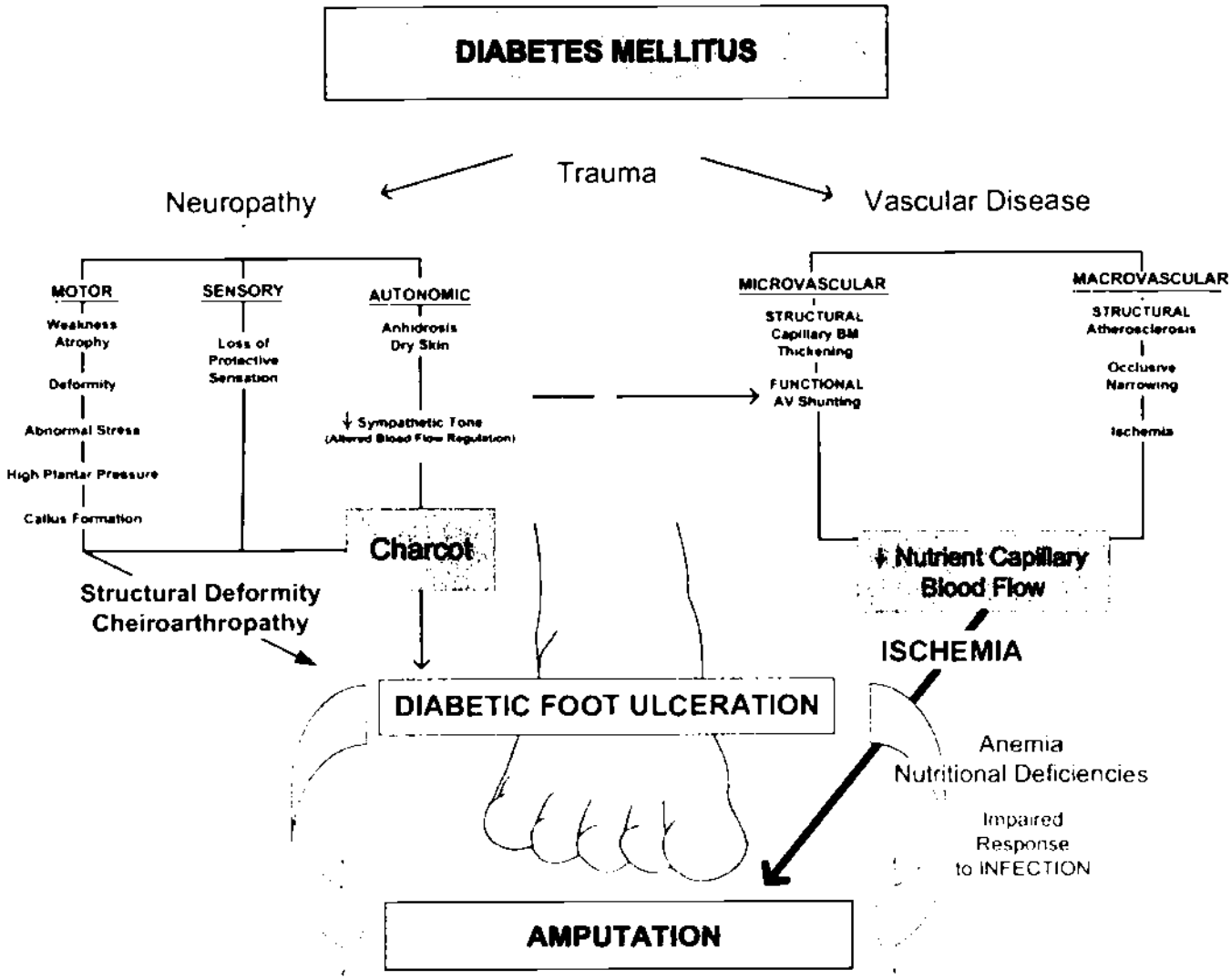


Figure 2 Diabetes mellitus is responsible for a variety of foot pathologies contributing to the complications of ulceration and amputation. Multiple pathologies may be implicated, from vascular disease to neuropathy to mechanical trauma.

93, 100). Soft tissue changes (other than cheiroarthropathy) in the feet of diabetic patients might also contribute to ulceration through the pathway of altered pressure distributions through the sole of the foot. Such alterations include a reported increased thickness of the plantar fascia with associated limitation of hallux dorsiflexion, decreased thickness of plantar soft tissue, accentuated hardness stiffness of the skin, and a propensity to develop calluses (82, 96, 101-105). While these changes are presumably caused by glycosylation of collagen, their sum effect is to enhance plantar pressures in gait. In the presence of neuropathy, the accentuated plantar pressures can be implicated in the development of ulceration (70, 80, 92, 106).

Mechanisms of Injury

The multifactorial etiology of diabetic foot ulcers is evidenced by the numerous pathophysiologic pathways that can potentially lead to this disorder (24, 43, 54, 62, 90, 107). Among these are two common mechanisms by which foot deformity and neuropathy may induce skin breakdown in persons with diabetes (69, 108, 109).

The first mechanism of injury refers to prolonged low pressure over a bony prominence (ie, bunion or hammertoe deformity). This generally causes wounds over the medial, lateral, and dorsal aspects of the forefoot and is associated with tight or ill-fitting shoes. Shoe trauma, in concert with loss of protective sensation and concomitant foot deformity, is the leading event precipitating foot ulceration in persons with diabetes (24, 28, 57, 85).

Regions of high pedal pressure are frequently associated with foot deformity (68, 73, 76, 77, 106, 107). When an abnormal focus of pressure is coupled with lack of protective sensation, the result can be development of a callus, blister, and ulcer (110). The other common mechanism of ulceration involves prolonged repetitive moderate stress (108). This normally occurs on the sole of the foot and is related to prominent metatarsal heads, atrophied or anteriorly displaced fat pads, structural deformity of the lower extremity, and prolonged walking. Rigid deformities such as hallux valgus, hallux rigidus, hammertoe, Charcot arthropathy, and limited range of motion of the ankle (equinus), subtalar, and MTP joints have been linked to the development of diabetic foot ulcers (27, 57, 71, 80, 94, 96). Numerous studies support the significant association between high plantar pressures and foot ulceration (26, 70, 80, 92, 106, 111, 112). Other biomechanical perturbations, including partial foot amputations, have the same adverse effects (57, 68, 80, 113).

Figure 2 summarizes the various pathways and contributing factors leading to diabetic foot complications.

Risk for Infection

Infections are common in diabetic patients and are often more severe than infections found in nondiabetic patients. Persons with diabetes have an increased risk for developing an infection of any kind and a several-fold risk for developing osteomyelitis (114). With an incidence of 36.5 per 1,000 persons per year, foot infections are among the most common lower extremity complications in the diabetic population (excluding neuropathy), second only to foot ulcers in frequency (115).

It is well documented that diabetic foot infections are frequently polymicrobial in nature (30, 116-121). Hyperglycemia, impaired immunologic responses, neuropathy, and peripheral arterial disease are the major predisposing factors leading to limb-threatening diabetic foot infections (122-124). Uncontrolled diabetes results in impaired ability of host leukocytes to fight bacterial pathogens, and ischemia also affects the ability to fight infections because delivery of antibiotics to the site of infection is impaired. Consequently, infection can develop, spread rapidly, and produce significant and irreversible tissue damage (125). Even in the presence of adequate arterial perfusion, underlying peripheral sensory neuropathy will often allow the progression of infection through continued walking or delay in recognition (126, 127).

Risk for Charcot Joint Disease

It has been estimated that less than 1% of persons with diabetes will develop Charcot joint disease (128-130). Data on the true incidence of neuroarthropathy in diabetes are limited by the paucity of prospective or population-based studies in the literature. One large population-based prospective study found an incidence of about 8.5 per 1,000 persons with diabetes per year (115), this equates to 0.85% per year and is probably the most reliable figure currently available. Much of the data clinicians rely upon have been extracted from retrospective studies of small, single-center cohorts. The incidence of reported Charcot cases is likely to be underestimated because many cases go undetected, especially in the early stages (131-134).

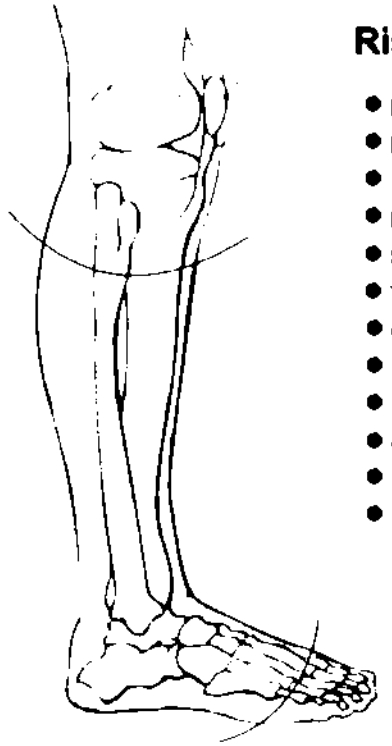
Primary risk factors for this potentially limb-threatening deformity are the presence of dense peripheral sensory neuropathy, normal circulation, and history of preceding trauma (often minor in nature) (50, 135, 136). Trauma is not limited to injuries such as sprains or contusions. Foot deformities, prior amputations, joint infections, or surgical trauma may result in sufficient stress that can lead to Charcot joint disease (137-140).

Risk for Amputation

The reported risk of lower extremity amputations in diabetic patients ranges from 2% to 16%, depending on study design and the populations studied (19, 21, 32, 115, 141-144). LEA rates can be 15 to 40 times higher among the diabetic versus nondiabetic populations (8, 16, 34, 35). Although one author suggests that amputation may be a marker not only for disease severity but also for disease management, it is clear that amputation remains a global problem for all persons with diabetes (32, 143). The same risk factors that predispose to ulceration can also generally be considered contributing causes of amputation, albeit with several modifications (Fig 3).

While peripheral arterial disease may not always be an independent risk factor for ulceration when controlling for neuropathy, it can be a significant risk factor for amputation (24, 28, 88, 142, 145, 146). PAD affecting the feet and legs is present in 8% of adult diabetic patients at diagnosis and in 45% after 20 years (147, 148). The incidence of amputation is 4 to 7 times greater for diabetic men and women than for their nondiabetic counterparts. Impairment of arterial perfusion may be an isolated cause for amputation and a predisposing factor for gangrene. Early diagnosis, control of risk factors, and medical management as well as timely revascularization may aid in avoiding limb loss (30, 52, 77, 88, 149).

Figure 3 The risk factors for amputation are multifactorial and similar to those for ulceration.



Risk Factors for Amputation

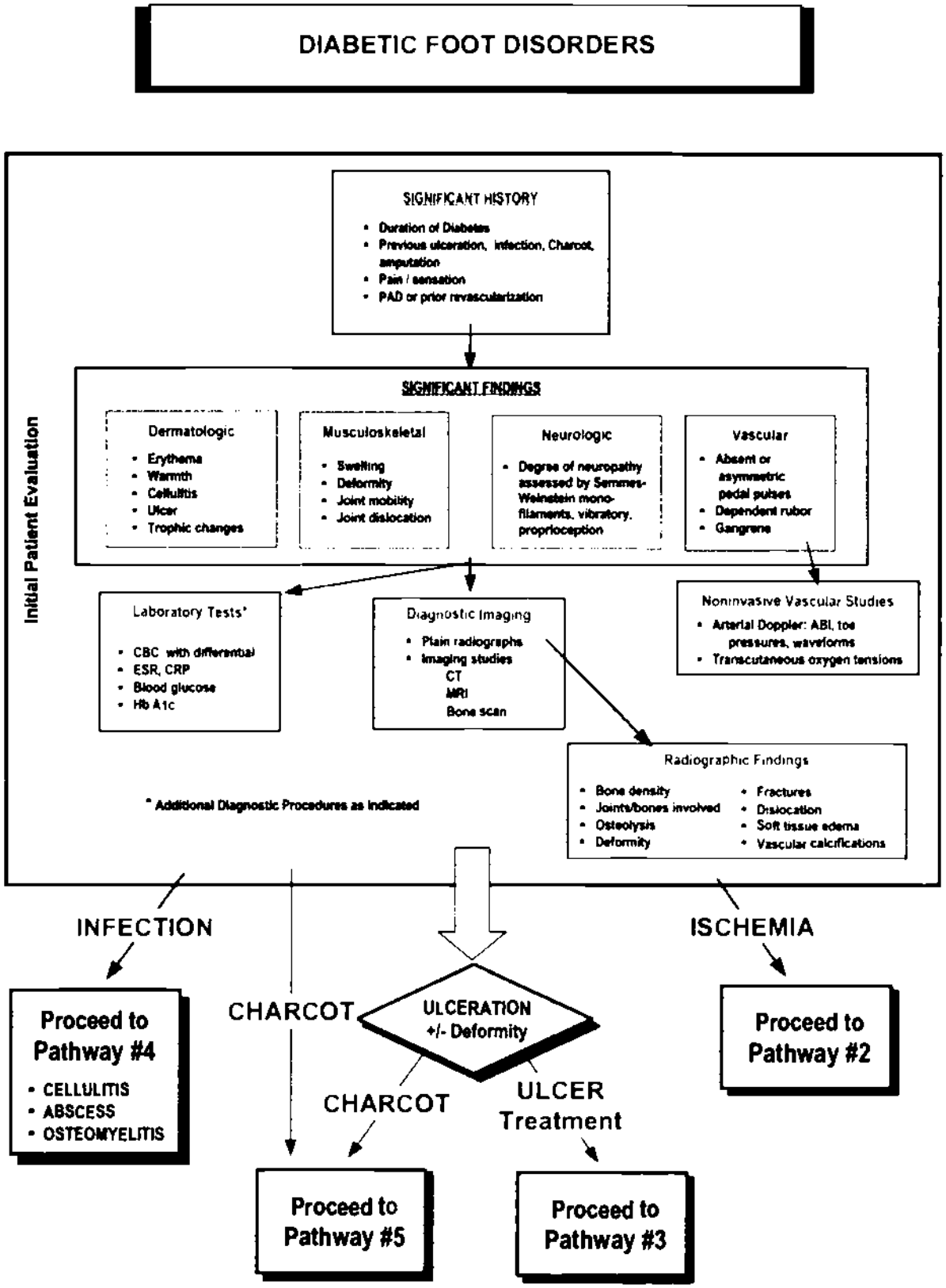
- Neuropathy LOPS
- Peripheral arterial disease (PAD)
- Infection
- History of prior foot ulcer or amputation
- Structural foot deformity
- Trauma
- Charcot foot
- Impaired vision
- Poor glycemic control
- Older age
- Male Sex
- Ethnicity (greatest rates in blacks & Hispanics)

While infection is not often implicated in the pathway leading to ulceration, it is a significant risk factor in the causal pathway to amputation (24, 28). Lack of wound healing, systemic sepsis, or unresolved infection can lead to extensive tissue necrosis and gangrene, requiring amputation to prevent more proximal limb loss. This includes soft tissue infection with severe tissue destruction, deep space abscess, or osteomyelitis. Adequate debridement may require amputation at some level as a means of removing all infected material (77, 123, 150, 151).

Another frequently described risk factor for amputation is chronic hyperglycemia. Results of the Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS) support the long-held theory that chronic poor control of diabetes is associated with a host of systemic complications (152, 153). The link between degree of glucose control and incidence or progression of numerous diabetic complications has been well established by these and other studies (154, 155). Such complications include peripheral neuropathy, microangiopathy, microcirculatory disturbances, impaired leukocyte phagocytosis, and glycosylation of tissue proteins. Each has adverse effects on the diabetic foot. They can contribute to the etiology of foot ulceration, delay normal wound healing, and subsequently lead to amputation (25, 30, 48, 50, 72). Several studies have reported a significant correlation between elevated glucose and LEA (21, 141, 156-161). Amputation has also been associated with other diabetes-related comorbidities such as nephropathy, retinopathy, and cardiovascular disease (21, 48, 144). Aggressive glucose control, management of associated comorbidities, and appropriate lower extremity care coordinated in a team environment may indeed lower overall risk for amputation (30, 90, 162-166).

The best predictor of amputation is a history of previous amputation. A past history of a lower extremity ulceration or amputation increases the risk for further ulceration, infection, and subsequent amputation (29, 142, 157, 167). It may also be inferred that patients with previous ulceration possess all the risk factors for developing another ulceration, having demonstrated that they already have the component elements in the causal pathway (24, 27, 28, 57). Up to 34% of patients develop another ulcer within 1 year after healing an index wound, and the 5-year rate of developing a new ulcer is 70% (164, 168). The recurrence rate is higher for patients with a previous amputation because of abnormal distribution of plantar pressures and altered osseous architecture. The cumulative risks of neuropathy, deformity, high plantar pressure, poor glucose control, and male gender are all additive factors for pedal ulceration in these diabetic patients (26, 46, 50, 57, 111). Re-amputation can be attributed to disease progression, nonhealing wounds, and additional risk factors for limb loss that develop as a result of the first amputation. Tragically, the 5-year survival rate

PATHWAY #1


DIABETIC FOOT DISORDERS
Initial Patient Evaluation
SIGNIFICANT HISTORY
• Duration of Diabetes
• Previous ulceration, infection, Charcot, amputation
• Pain / sensation
• PAD or prior revascularization
SIGNIFICANT FINDINGS
Dermatologic
• Erythema
• Warmth
• Cellulitis
• Ulcer
• Trophic changes
Musculoskeletal
• Swelling
• Deformity
• Joint mobility
• Joint dislocation
Neurologic
• Degree of neuropathy assessed by Semmes-Weinstein mono-filaments, vibratory, proprioception
Vascular
• Absent or asymmetric pedal pulses
• Dependent rubor
• Gangrene
Laboratory Tests*
• CBC with differential
• ESR, CRP
• Blood glucose
• Hb A1c
Diagnostic Imaging
• Plain radiographs
• Imaging studies
CT
MRI
Bone scan
Noninvasive Vascular Studies
• Arterial Doppler: ABI, toe pressures, waveforms
• Transcutaneous oxygen tensions
Radiographic Findings
• Bone density
• Joints/bones involved
• Osteolysis
• Deformity
• Fractures
• Dislocation
• Soft tissue edema
• Vascular calcifications
* Additional Diagnostic Procedures as indicated
INFECTION
CHARCOT
ULCERATION +/- Deformity
ISCHEMIA
Proceed to Pathway #4
• CELLULITIS
• ABSCESS
• OSTEOMYELITIS
CHARCOT
ULCER Treatment
Proceed to Pathway #2
Proceed to Pathway #5
Proceed to Pathway #3

after a diabetes-related LEA has been reported to be as low as 28% to 31% (169, 170). Persons with renal failure or more proximal levels of amputation have a poor prognosis and higher mortality rate. Those who undergo a diabetes-related amputation have a 40% to 50% chance of undergoing a contralateral amputation within 2 years (36, 171, 172).

ASSESSMENT OF THE DIABETIC FOOT (Pathway 1)

The pedal manifestations of diabetes are well documented and potentially limb-threatening when left untreated. Recognition of risk factors and treatment of diabetic foot disorders require the skill of a specialized practitioner to diagnose, manage, treat, and counsel the patient. Integration of knowledge and experience through a multidisciplinary team approach promotes more effective treatment, thereby improving outcomes and limiting the risk of lower extremity amputation (30, 173).

The evaluation of the diabetic foot involves careful assimilation of the patient's history and physical findings with the results of necessary diagnostic procedures (Pathway 1). Screening tools may be valuable in evaluating the patient and determining risk level (Appendix 1). Early detection of foot pathology, especially in high-risk patients, can lead to earlier intervention and thereby reduce the potential for hospitalization and amputation (100). This is also facilitated by an understanding of the underlying pathophysiology of diabetic foot disorders and associated risk factors. Identification of abnormal historical and or physical findings can therefore improve the prognosis for a favorable outcome through appropriate and early referral (91, 174).

History

A thorough medical and foot history must be obtained from the patient. The history should address several specific diabetic foot issues (Table 2).

Physical Examination

All patients with diabetes require a pedal inspection whenever they present to any health care practitioner, and

Table 2 **Medical History**

Global History	Foot Specific History	
	General	Wound / Ulcer History
• Diabetes - duration	• Daily activities, including work	• Location
• Glycemic management/control	• Footwear	• Duration
• Cardiovascular, renal and opthalmic evaluations	• Chemical exposures	• Inciting event or trauma
• Other comorbidities	• Callus formation	• Recurrence
• Treating physicians	• Foot deformites	• Infection
• Nutritional status	• Previous foot infections, surgery	• Hospitalization
• Social habits: alcohol, tobacco, drugs	• Neuropathic symptoms	• Wound care
• Current medications	• Claudication or rest pain	• Off-loading techniques
• Allergies		• Wound response
• Previous hospitalizations/surgery		• Patient compliance
		• Interference with wound care (Family or social problems for patient)
		• Previous foot trauma or surgery
		• Presence of edema - unilateral vs bilateral
		• Charcot foot - previous or active
		• Charcot treatment

they should receive a thorough lower extremity examination at least once annually (175). Patients with complaints relating to the diabetic foot require more frequent detailed evaluations. The examination should be performed systematically so that important aspects are not overlooked (62). It begins with a gross evaluation of the patient and extremities. Any obvious problem can then receive closer scrutiny.

Key components of the foot examination are presented in Table 3. Although not specifically mentioned in this section, it is assumed that a general medical assessment (including vital sign measurements) will be obtained.

Diagnostic Procedures

Diagnostic procedures may be indicated in the assessment and care of the diabetic foot. Consideration should be given to the following tests in concert with those suggested by members of the consulting team. It should be noted that many of the following tests lack the ability to impart a definitive diagnosis, necessitating clinical correlation.

Laboratory Tests

Clinical laboratory tests that may be needed in appropriate clinical situations include fasting or random blood glucose, glycohemoglobin (HbA1c), complete blood count (CBC) with or without differential, erythrocyte sedimentation rate (ESR), serum chemistries, C-reactive protein, alkaline phosphatase, wound and blood cultures, and urinalysis. Caution must be exercised in the interpretation of laboratory tests in these patients, because several reports have documented the absence of leukocytosis in the presence of severe foot infections (117, 122, 151, 176-178). A common sign of persistent infection is recalcitrant hyperglycemia despite usual antihyperglycemic regimens (150).

Imaging Studies

The diabetic foot may be predisposed to both common and unusual infectious or noninfectious processes, partially because of the complex nature of diabetes and its associated vascular and neuropathic complications. As a result, imaging presentations will vary due to lack of specificity in complex clinical circumstances (179-181). Such variability creates a challenge in the interpretation of imaging studies. Therefore, imaging studies should only be ordered to establish or confirm a suspected diagnosis and or direct patient management. Distinguishing osteomyelitis from aseptic neuropathic arthropathy is not easy, and all imaging studies (Fig. 4) must be interpreted in conjunction with the clinical findings (123, 151).

Plain radiographs should be the initial imaging study in diabetic patients with signs and symptoms of a diabetic foot disorder (180, 182). Radiographs can detect osteomyelitis, osteolysis, fractures, dislocations seen in neuropathic arthropathy, medial arterial calcification, soft tissue gas, and foreign bodies as well as structural foot deformities, presence of arthritis, and biomechanical alterations (183). Acute osteomyelitis might not demonstrate osseous changes for up to 14 days. Serial radiographs should be obtained in the face of an initial negative radiographic image and a high clinical suspicion of osseous disease (117, 123).

Technetium-99 methylene diphosphonate (Tc-99 MDP) bone scans are often used in diabetic foot infection to determine the presence of osteomyelitis. Although highly sensitive, this modality lacks specificity in the neuropathic foot (184, 185). Osteomyelitis, fractures, arthritis, and neuropathic arthropathy will all demonstrate increased radiotracer uptake. However, a negative bone scan is strong evidence against the presence of infection. To improve the specificity of nuclear imaging, white blood cells can be labeled with Tc-99 hexamethylpropyleneamineoxime (Tc-99 HMPAO), indium-111 oxime, or gallium-67 citrate (179, 186-189).

Indium-111 selectively labels polymorphonuclear leukocytes and is more specific for acute infections than Tc-99 MDP scanning. Chronic infections and inflammation are not well imaged with indium-111, because chronic inflammatory cells (ie, lymphocytes) predominate and are not well labeled with indium. Combining Tc-99 MDP and indium-111 increases the specificity of diagnosing osteomyelitis (190). This combined technique is useful, because the Tc-99 MDP scan localizes the anatomic site of inflammation and the indium-111 labels the infected bone (180, 191). The indium-111 scan is not typically positive in aseptic neuropathic arthropathy, although false-positive indium scans can occur (192-194). A 100% sensitivity and 89% specificity have been reported with the combined technique in evaluating diabetic infections (190, 191, 195).

In Tc-99 HMPAO scanning, white blood cells are labeled in a similar manner as in indium scanning. However, with Tc-99 MHPAO scans, imaging occurs 4 hours following administration versus 24 hours postadministration with indium scanning. Tc-99 HMPAO uses a smaller radiation dose, is less expensive, and offers improved resolution compared with indium scanning. The sensitivity and specificity of both techniques are comparable (186, 196). Tc-99 HMPAO scans cannot be combined with Tc-99 MDP scans because of similar labeling characteristics.

Tc-99 sulfur colloid is useful in distinguishing osteomyelitis from neuropathic arthropathy (183). This tracer is picked up by the bone marrow and any hematopoietically-active marrow will be positive. Infected bone replaces normal bone marrow, so it shows up as a relative

Table 3 **Lower Extremity Diabetic Foot Exam**

Vascular Examination

- Palpation of pulses
  Common femoral, popliteal
  Dorsalis pedis, posterior tibial
- Handheld Doppler examination
- Skin / limb color changes
  Cyanosis, erythema
  Elevation pallor, dependent rubor
- Presence of edema
- Temperature gradient
  (ipsilateral and contralateral extremity)
- Dermal thermometry
- Integementary changes
  Skin atrophy - thin, smooth, parchment-like skin
  Abnormal wrinkling
  Absence of hair growth
  Onychodystrophy
- Previous hospitalizations/surgery

Neurologic Examination

- Vibration perception
  Tuning fork 128 cps
  Measurement of vibration perception threshold (biothesiometer)
- Light pressure:
  Semmes-Weinstein 10 gram monofilament
- Light touch: cotton wool
- Two point discrimination
- Pain: pinprick (sterile needle)
- Temperature perception: hot and cold
- Deep tendon reflexes: patella, Achilles
- Clonus testing
- Babinski test
- Romberg test

Footwear Examination

- Type of shoe (athletic, oxford, comfort, etc.)
- Fit
- Depth of toe box
- Shoewear, patterns of wear
- Lining wear
- Foreign bodies
- Insoles, orthoses

Dermatologic Examination

- Skin appearance
  - Color, texture, turgor, quality
  - Dry skin
- Calluses
  - Discoloration / subcallus hemorrhage
- Fissures (especially posterior heels)
- Nail appearance
  - Onychomycosis, dystrophic, gryphotic
  - Atrophy or hypertrophy
  - Paronychia
- Hair growth
- Ulceration, gangrene, infection
  Note location, size, depth, infection status, etc.
- Interdigital lesions
- Tinea pedis
- Markers of diabetes
  - Shin spots - diabetic dermopathy
  - Necrobiosis lipoidica diabeticorum
  - Bullosum diabeticorum
  - Granuloma annulare
  - Acanthosis nigricans

Musculoskeletal Examination

- Biomechanical abnormalities
- Structural deformities
  - Hammertoe, bunion, tailor's bunion
  - Hallux limitus/rigidus
  - Flat or high-arched feet
  - Charcot deformities
  - Postsurgical deformities (amputations)
- Prior amputation
- Limited joint mobility
- Tendo-Achilles contractures / equinus
- Gait evaluation
- Muscle group strength testing
  - passive and active, non-weightbearing and weightbearing
  - Foot drop
  - Atrophy - intrinsic muscle atrophy
- Plantar pressure assessment
  - Computerized devices
  - Harris ink mat, pressure sensitive foot mat

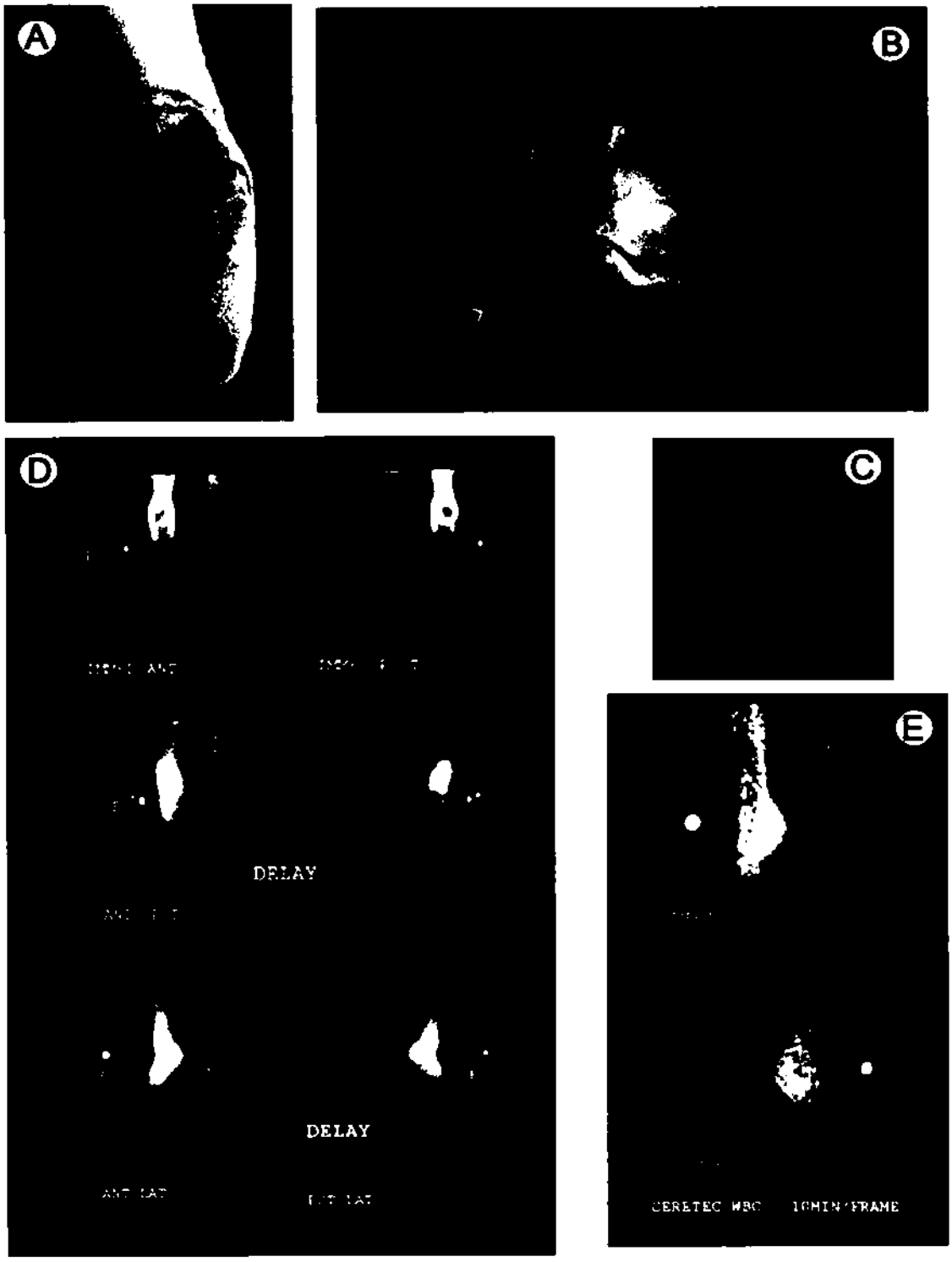


Figure 4 Diagnostic imaging plays an important role in the evaluation of diabetic foot infections. *(A)* This patient presented with a deep foul-smelling necrotic ulcer of the heel that had been present for more than 1 month. *(B)* In the past, a technetium bone scan typically would be performed, but the imaging is nonspecific and many false positive results interpretative as osteomyelitis were seen. *(C)* White blood cell tagged imaging with indium or technetium is a more reliable technique for detecting the presence of infection.

"cold spot." This technique is best combined with indium scanning, and osteomyelitis would appear as a "hot" indium scan and a "cold" sulfur colloid scan (183, 193).

Computed tomography (CT) scans may be indicated in the assessment of suspected bone and joint pathology not evident on plain radiographs (180, 197). CT offers high anatomic detail and resolution of bone with osseous fragmentation and joint subluxation (198). Subluxation of the transverse tarsal or tarsometatarsal joints can be seen prior to being visualized on radiographs.

Magnetic resonance imaging (MRI) is usually preferred over CT for the investigation of osteomyelitis, because of its enhanced resolution and ability to visualize the extent of any infectious process (183, 199). MRI is often used in evaluating soft tissue and bone pathology. This scan may be indicated to aid in the diagnosis of osteomyelitis, deep abscess, septic joint, and tendon rupture. It is a readily available modality that has a very high sensitivity for bone infection and can also be used for surgical planning (123, 200-203). Despite its high cost, MRI has gained wide acceptance in the management of diabetic foot infections. When neuropathic arthropathy is present, the T1 and T2 bone images are hypointense (ie, decreased signal) and the soft tissues show edema. Increased signal on T-2 bone images is seen in osteomyelitis, however, tumors and avascular necrosis can also be hyperintense on T-2 (204). MRI is an excellent modality for assessing the presence of a soft tissue abscess, especially if gadolinium administration is utilized (205, 206). Postcontrast fat suppression images should be obtained, if available (207).

Positive emission tomography (PET) scanning is a promising new technique for distinguishing osteomyelitis from neuropathic arthropathy, but it currently is not widely available (109, 208, 209). A recent meta-analysis comparing the diagnostic accuracy of PET scanning with bone and leukocyte scanning found that PET scans were the most accurate modality for diagnosing osteomyelitis, providing a sensitivity of 96% and specificity of 91% (190). When PET scanning was unavailable, an indium-labeled leukocyte scan was found to be an acceptable alternative, offering a sensitivity of 84% and specificity of 80% in the peripheral skeleton (190).

The use of ultrasound for detecting chronic osteomyelitis has been shown to be superior to plain radiographs, providing sensitivity comparable to Tc-99 MDP bone scanning (210). Although ultrasound is a widely available, cost-effective imaging modality, MRI is more accurate and is the imaging study of choice if radiographs are normal and clinical suspicion is high for bone or soft tissue infection (211).

Vascular Evaluation

The lower extremity must be assessed for vascular and neuropathic risk factors. Although positive findings in the neurologic examination rarely require further evaluation, positive findings of vascular insufficiency may require further consultation. The indications for vascular consultation include an ankle brachial index of less than 0.7, toe blood pressures less than 40 mmHg, or transcutaneous oxygen tension ($TcPO_2$) levels less than 30 mmHg, since these measures of arterial perfusion are associated with impaired wound healing (27, 47, 87, 90, 212, 213).

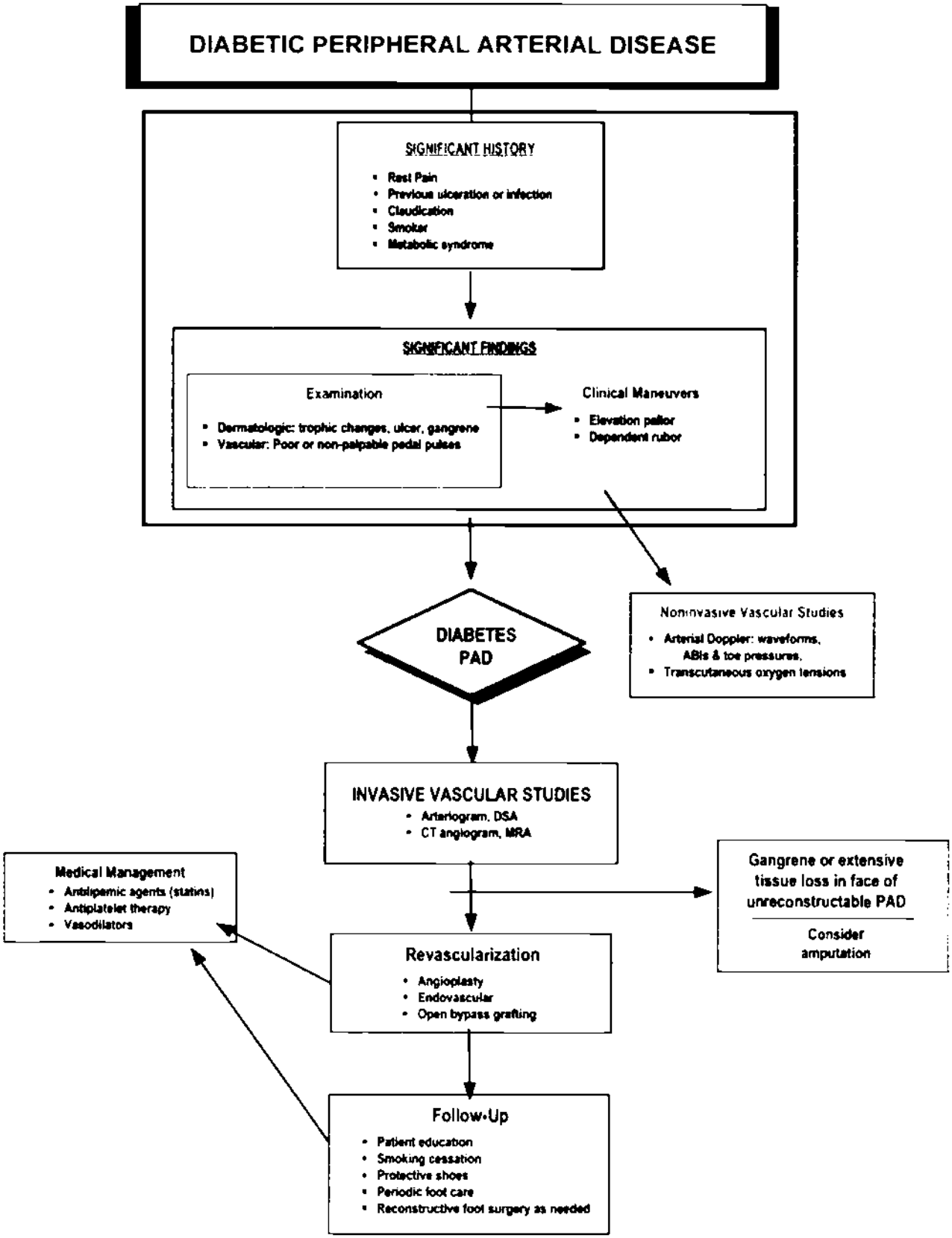
If the history and physical examination suggest ischemia (ie, absent pedal pulses) or if a nonhealing ulcer is present, further evaluation in the form of noninvasive testing is warranted (Pathway 2).

Noninvasive arterial studies should be performed to determine lower extremity perfusion. Such studies may include Doppler segmental arterial pressures and waveform analysis, ankle-brachial indices (ABI), toe blood pressures, and $TcPO_2$ (89, 214, 215). Ankle-brachial indices may be misleading, because ankle pressures can be falsely elevated due to medial arterial calcinosis and noncompressibility of affected arteries (52, 216, 217). A growing body evidence suggests that toe blood pressures in diabetic patients may have a role in predicting foot ulceration risk as well as predicting successful wound healing (213, 218, 219). $TcPO_2$ measurements have received similar support in the literature (47, 87, 212). Although not consistently predictive of wound healing outcomes, these physiologic measures of tissue oxygenation are highly predictive of wound healing failure at levels below 25 mmHg (87, 212, 220). Both tests can be performed distally on the foot regardless of arterial calcification in the major pedal arteries, and they are both favorable at pressures in the range of 40 mmHg (90, 212, 213).

Laser Doppler velocimetry and measurement of skin perfusion pressure (SPP) have primarily been used in research settings, but can accurately assess blood flow and oxygen tension in the superficial arterioles and capillaries of the skin (220-225). Several recent reports indicate that laser Doppler measurement of SPP can be highly predictive of critical limb ischemia and wound healing failure at levels less than 30 mmHg (223, 224).

Vascular consultation should be considered in the presence of abnormal noninvasive arterial studies or a nonhealing ulceration (30, 54, 173, 215, 226). Arteriography with clearly visualized distal runoff allows appropriate assessment for potential revascularization (227-229). Magnetic resonance angiography (230) or CT angiogram are alternatives for evaluation of distal arterial perfusion (229, 231).

PATHWAY #2


DIABETIC PERIPHERAL ARTERIAL DISEASE
SIGNIFICANT HISTORY
Rest Pain
Previous ulceration or infection
Claudication
Smoker
Metabolic syndrome
SIGNIFICANT FINDINGS
Examination
Dermatologic: trophic changes, ulcer, gangrene
Vascular: Poor or non-palpable pedal pulses
Clinical Maneuvers
Elevation pallor
Dependent rubor
DIABETES PAD
Noninvasive Vascular Studies
Arterial Doppler: waveforms, ABIs & toe pressures,
Transcutaneous oxygen tensions
INVASIVE VASCULAR STUDIES
Arteriogram, DSA
CT angiogram, MRA
Gangrene or extensive tissue loss in face of unreconstructable PAD
Consider amputation
Medical Management
Antilipemic agents (statins)
Antiplatelet therapy
Vasodilators
Revascularization
Angioplasty
Endovascular
Open bypass grafting
Follow-Up
Patient education
Smoking cessation
Protective shoes
Periodic foot care
Reconstructive foot surgery as needed

Neurologic Evaluation

Peripheral sensory neuropathy is the major risk factor for diabetic foot ulceration (24, 26, 27, 46, 50). The patient history and physical examination utilizing the 5.07 Semmes-Weinstein monofilament (10-g) wire are sufficient to identify individuals at risk for ulceration (26, 232-235).

Vibration perception threshold assessment with the biothesiometer is also useful in identifying patients at high risk for ulceration (44, 57, 236). More sophisticated studies such as nerve conduction studies are rarely necessary to diagnose peripheral sensory neuropathy. Patients with neuropathic ulcerations usually have such profound sensory neuropathy that these studies add little to their clinical management (49).

Plantar Foot Pressure Assessment

High plantar foot pressure is a significant risk factor for ulceration (26, 45, 59, 70, 76, 80, 237). Measurement of high plantar foot pressure is possible utilizing a variety of modalities. Several computerized systems can provide quantitative measurement of plantar foot pressure (76, 81, 238-241). While these measurements may be important in identifying areas of the foot at risk for ulceration and possibly in evaluating orthotic adjustments (57, 59), they are primarily used in diabetic foot research. The Harris mat, while not as sophisticated, can provide a qualitative measurement of plantar foot pressures and can identify potentially vulnerable areas for ulceration (242). A newer noncomputerized device (PressureStat®, Footlogic, New York City, NY), which is similar to the Harris mat and uses pressure-sensitive contact sheets that provide a semi-quantitative estimation of pressure distribution under the foot, has been suggested as an inexpensive screening tool for identifying areas at high risk for ulceration (76, 243).

Risk Stratification

Following a thorough diabetic foot examination, the patient may be classified according to a cumulative risk category. This enables the physician to design a treatment plan and determine whether the patient is at risk for ulceration or amputation. Several risk stratification schemes have been proposed, assigning different weights to important risk factors for ulceration including peripheral neuropathy, arterial insufficiency, deformity, high plantar pressures, and prior history of ulceration or amputation (48, 57, 62, 90, 244-246). Although no one system has been universally adopted to predict complications, Table 4 presents a simplified risk stratification that has been endorsed by an international consensus group and others (90, 247).

THE HEALTHY DIABETIC FOOT: PREVENTION STRATEGIES

A healthy, intact diabetic foot is best maintained by a consistent and recurrent preventive treatment strategy (2, 30, 43, 48, 90, 163, 246, 248). This is best accomplished through a multidisciplinary approach involving a team of specialists and personnel who provide a coordinated process of care (Fig. 5). Team members may include a podiatrist, internist, ophthalmologist, endocrinologist, infectious disease specialist, cardiologist, nephrologist, vascular surgeon, orthopedic surgeon, nurse (educator, wound care, and home care), and pedorthist/orthotist.

Patient and family education assumes a primary role in prevention. Such education encompasses instruction in glucose assessment, insulin administration, diet, daily foot inspection and care, proper footwear, and the necessity for prompt treatment of new lesions (163, 174, 249-251). Regularly scheduled podiatric visits, including debridement of calluses and toenails, are opportunities for frequent foot examination and patient education (163, 252). Such visits can provide early warning of impending problems and subsequent modification of activity and care (30, 253).

Diabetes is a lifelong problem, and the incidence of diabetic foot complications increases with age and dura-

Table 4 **Risk Categorization System**

Category	Risk Profile	Evaluation Frequency
0	Normal	Annual
1	Peripheral neuropathy (LOPS)	Semi-annual
2	Neuropathy, deformity and/or PAD	Quarterly
3	Previous ulcer or amputation	Monthy to quarterly

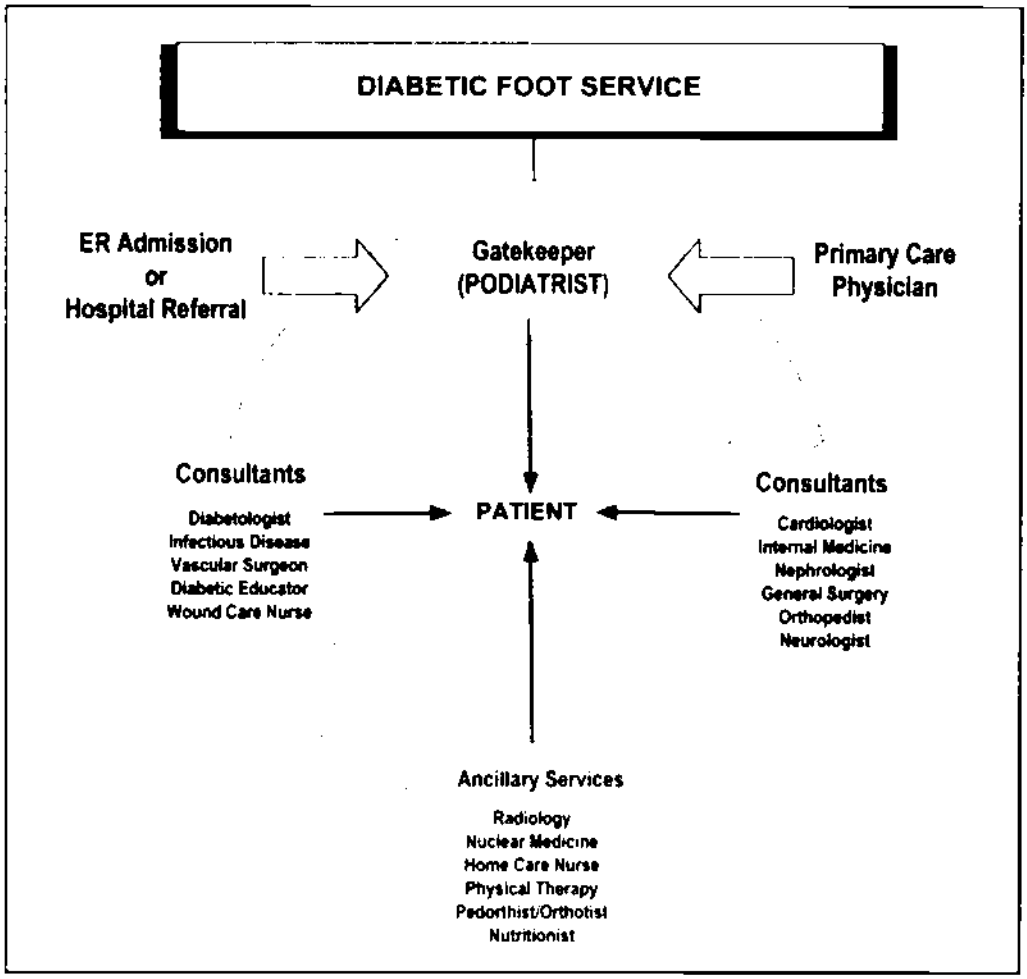


Figure 5 A diabetic foot service is composed of a variety of specialists generally needed to evaluate and treat the pathology seen in the patient with diabetes. Effective management must include appropriate consultation for treatment of known comorbidities.

tion of the disease. A recent Markov analysis of the cost effectiveness of foot care according to published guidelines found that such preventive care can improve survival, reduce ulceration and amputation rates, is cost-effective, and can even save on long-term costs when compared with standard care (254).

Risk stratification based on the presence of predisposing causal risk factors, including prior history of ulceration, also serves as a guide to the frequency of foot care visits. By identifying high-risk patient and tailoring a total foot care prevention program accordingly, the incidences of ulceration and lower extremity amputations can be reduced (253, 255-258).

Therapeutic shoes with pressure-relieving insoles and high toe boxes are important adjunctive treatments that can reduce the occurrence of ulceration and resultant amputation in high-risk patients (51, 86, 259-262). While most studies support the efficacy of protective footwear in this regard, two reports suggest that shoes in the absence of a comprehensive prevention program might not be sufficient to prevent new lesions (263, 264). Nevertheless, patients with foot deformities that cannot be accommodated by standard therapeutic footwear should have custom shoes that provide appropriate fit, depth, and a rocker insole (260, 265-269). If structural deformities cannot be accommodated by therapeutic footwear, prophylactic surgical correction should be considered, but patients must be carefully selected (173, 255, 270-273).

Diabetic patients at risk for foot lesions must be educated about risk factors and the importance of foot care (48, 274-276), including the need for self-inspection and surveillance, monitoring foot temperatures, appropriate daily foot hygiene, use of proper footwear, good diabetes control, and prompt recognition and professional treatment of newly dis-

covered lesions. Home temperature assessment of the foot has been shown to reduce the incidence of foot ulcers 10-fold compared with standard preventive care (277). Patients with visual or physical impairments that preclude their own care should engage the assistance of family or friends to aid in this regard (275). When combined with a comprehensive approach to preventive foot care, patient education can reduce the frequency and morbidity of limb threatening diabetic foot lesions (274, 278, 279).

Provider education is equally important in prevention, since not all clinicians are cognizant of important signs and risk factors for pedal complications (163, 174, 276). Furthermore, provider education is effective in reinforcing proper diabetes management and foot care practices, resulting in reductions in ulceration and adverse lower extremity outcomes (48, 276, 280-282).

PATHOLOGIC ENTITIES OF THE DIABETIC FOOT (Foot Ulcer, Infection, Charcot Foot)

Effective management of diabetic foot disorders requires knowledge of the potential pathologies, the associated classification systems, and the principle tenets of intervention. Ulceration, infection, and Charcot arthropathy are the most significant of these pathologies and classification systems have been developed for each entity. While the conditions may be seen either as an isolated event or coexisting in the same extremity, each entity is examined independently in this clinical practice guideline.

DIABETIC FOOT ULCERS (Pathway 3)

Evaluation of Ulcers

The initial evaluation of the diabetic foot ulcer must be comprehensive and systematic to ascertain the parameters that might have led to its onset as well as determine the presence of factors that can impair wound healing (25, 52, 54). Critical in this regard are assessments for vascular perfusion (ischemia), infection osteomyelitis, and neuropathy. As previously discussed, a thorough vascular evaluation must be performed, this includes palpation of pulses, clinical evaluation of capillary filling time, venous filling time, pallor on elevation, and dependent rubor (283). If pulses are not palpable or if clinical findings suggest ischemia, noninvasive arterial evaluation (e.g., segmental Doppler pressures with waveforms, ankle brachial indices, toe pressures, $TcPO_2$ measurements) and vascular surgical consultation are warranted. When required, these physiologic and anatomic data can be supplemented with the use of magnetic resonance angiography (230) or CT angiography (CTA) and subsequent use of arteriography with digital subtraction angiography (DSA) as necessary (77, 89, 284).

Description of the ulcer characteristics on presentation is essential for the mapping of the ulcer's progress during treatment (30, 43). While some characteristics are more important than others, they all have prognostic value during management. The presumed etiology of the ulcer (ie, chemical vs mechanical) and character of the lesion (neuropathic, ischemic, or neuroischemic) should be determined (90). The evaluation should also describe the size and depth of the ulcer as well as the margins, base, and geographic location on the extremity or foot. All but the most superficial ulcers should be examined with a blunt, sterile probe. The description should note whether the sterile probe detects sinus tract formation, undermining of the ulcer margins, or dissection of the ulcer into tendon sheaths, bone, or joints. A positive probe to bone (PTB) finding is highly predictive of osteomyelitis, although the frequency of false-negative tests reduces its sensitivity (119, 123, 285). Perhaps most importantly, the positive predictive value for PTB falls off significantly when the prevalence of osteomyelitis decreases (286).

The existence and character of odor or exudate should be noted. Cultures may be necessary when signs of inflammation are present. Generally, clinically uninfected ulcers without inflammation should not be cultured (30, 123). Current recommendations for culture and sensitivity include thorough surgical preparation of the wound site with curettage of the wound base for specimen or with aspiration of abscess material (30, 287).

Classification of Ulcers

Appropriate classification of the foot wound is based on a thorough assessment. Classification should facilitate treatment and be generally predictive of expected outcomes. Several systems of ulcer classification are currently in use in the US and abroad to describe these lesions and communicate severity (62, 90, 288-292). Perhaps the easiest system is to classify lesions as neuropathic, ischemic, or neuroischemic, with descriptors of wound size, depth, and infection (90). Regardless of which system is used, the clinician must be able to easily categorize the wound and, once classified, the ensuing treatment should be directed by the underlying severity of pathology.

Although no single system has been universally adopted, the classification system most often used was described and popularized by Wagner (292). In the Wagner system (Table 5), foot lesions are divided into six grades based on the depth of the wound and extent of tissue necrosis. Since these grades fail to consider the important roles of infection, ischemia, and other comorbid factors, subsequent authors have modified the classification system by including

PATHWAY #3

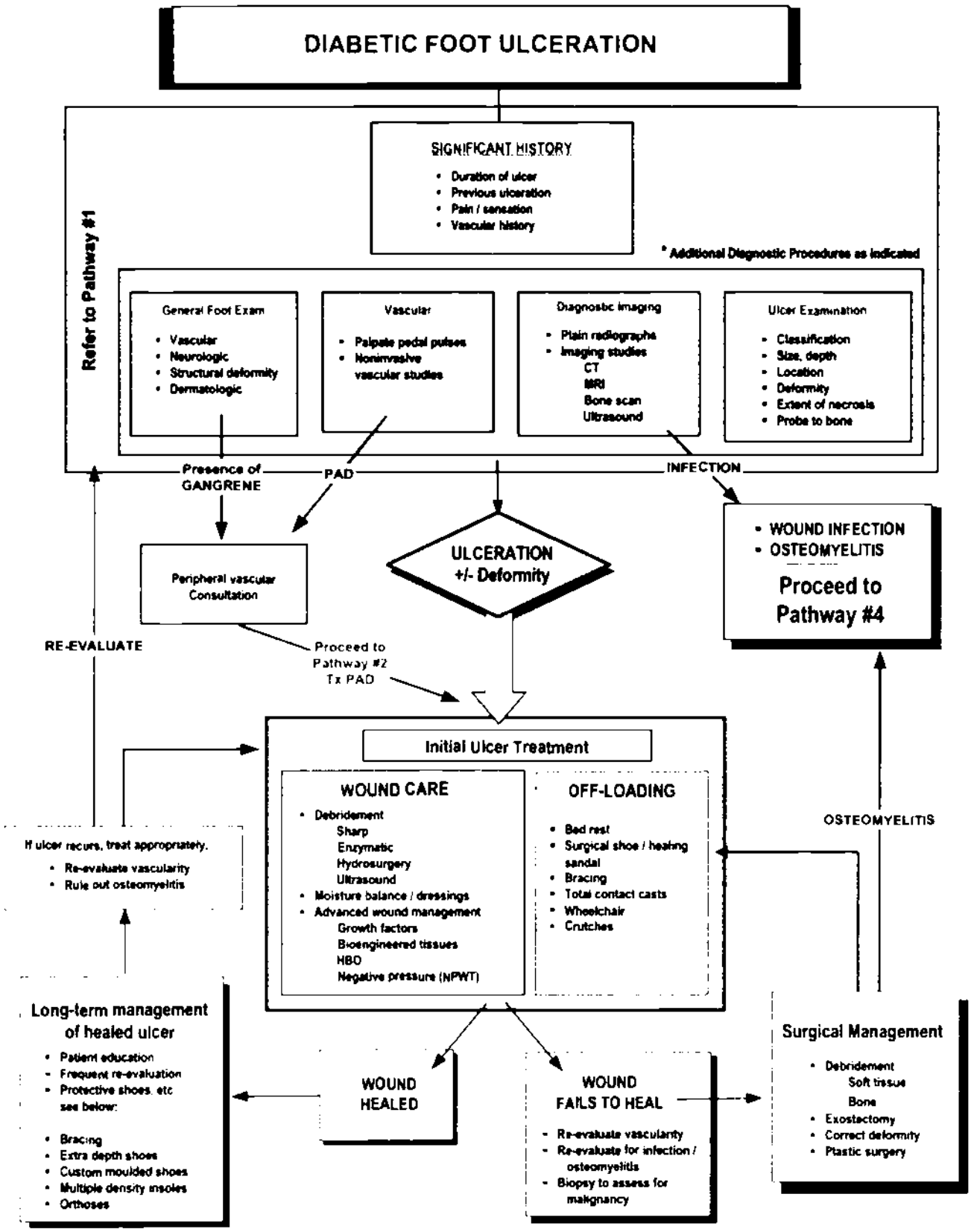

DIABETIC FOOT ULCERATION
SIGNIFICANT HISTORY
• Duration of ulcer
• Previous ulceration
• Pain / sensation
• Vascular history
Refer to Pathway #1
* Additional Diagnostic Procedures as indicated
General Foot Exam
• Vascular
• Neurologic
• Structural deformity
• Dermatologic
Vascular
• Palpate pedal pulses
• Noninvasive vascular studies
Diagnostic imaging
• Plain radiographs
• Imaging studies
CT
MRI
Bone scan
Ultrasound
Ulcer Examination
• Classification
• Size, depth
• Location
• Deformity
• Extent of necrosis
• Probe to bone
Presence of GANGRENE
PAD
INFECTION
Peripheral vascular Consultation
ULCERATION +/- Deformity
• WOUND INFECTION
• OSTEOMYELITIS
Proceed to Pathway #4
RE-EVALUATE
Proceed to Pathway #2 Tx PAD
Initial Ulcer Treatment
WOUND CARE
• Debridement
Sharp
Enzymatic
Hydrosurgery
Ultrasound
• Moisture balance / dressings
• Advanced wound management
Growth factors
Bioengineered tissues
HBO
Negative pressure (NPWT)
OFF-LOADING
• Bed rest
• Surgical shoe / healing sandal
• Bracing
• Total contact casts
• Wheelchair
• Crutches
OSTEOMYELITIS
If ulcer recurs, treat appropriately.
• Re-evaluate vascularity
• Rule out osteomyelitis
Long-term management of healed ulcer
• Patient education
• Frequent re-evaluation
• Protective shoes, etc see below:
• Bracing
• Extra depth shoes
• Custom moulded shoes
• Multiple density insoles
• Orthoses
WOUND HEALED
WOUND FAILS TO HEAL
• Re-evaluate vascularity
• Re-evaluate for infection / osteomyelitis
• Biopsy to assess for malignancy
Surgical Management
• Debridement
Soft tissue
Bone
• Exostectomy
• Correct deformity
• Plastic surgery

Table 5 Wagner Classification System

Grade	Lesion
0	No open lesions: may have deformity or cellulitis
1	Superficial ulcer
2	Deep ulcer to tendon or joint capsule
3	Deep ulcer with abscess, osteomyelitis, or joint sepis
4	Local gangrene - forefoot or heel
5	Gangrene of entire foot

descriptors for these considerations (62, 290, 291). For example, the University of Texas San Antonio (UTSA) system (Table 6) associates lesion depth with both ischemia and infection (290). This system has been validated and is generally predictive of outcome, since increasing grade and stage of wounds are less likely to heal without revascularization or amputation (290, 293). The UTSA system is now widely used in many clinical trials and diabetic foot centers. Another hybrid system, the PEDIS system, evaluates five basic characteristics: perfusion, extent size, depth tissue loss, infection and sensation (294) (Table 7). While this system has yet to be validated, it provides the benefit of having been developed by a consensus body.

Imaging studies play an important role in the assessment and evaluation of the diabetic foot ulcer (179, 180, 183, 197). Plain x-rays are indicated based on the extent and nature of the ulcer. Clinical change in the appearance of the ulcer or failure to heal with appropriate treatment may dictate repeating the radiograph periodically to monitor for osseous involvement (30). Additional imaging modalities such as nuclear medicine scans, ultrasonography, MRI, and CT may be indicated, depending on the clinical picture. These modalities have been previously discussed in this document.

Figure 6 summarizes the important elements of the overall assessment of the patient with a diabetic foot ulcer. The assessment addresses underlying pathophysiology, possible causal factors, and significant predictors of outcome (25, 49, 54, 100, 272).

Treatment of Diabetic Ulcers: Guiding Principles

The primary treatment goal for diabetic foot ulcers is to obtain wound closure as expeditiously as possible. Resolving foot ulcers and decreasing the recurrence rate can lower the probability of lower extremity amputation in the diabetic patient (30, 43, 162, 168, 295-297). The Wound Healing Society defines a chronic wound as one that has failed to proceed through an orderly and timely repair process to produce anatomic and functional integrity (288). A chronic wound is further defined as one in which the healing cascade has been disrupted at some point, leading to prolonged inflammation and failure to re-epithelialize and allowing for further breakdown and infection. Early advanced or appropriate wound care practices may be more cost-effective than standard care practices for decreasing the incidence of lower extremity amputations (43, 298).

The essential therapeutic areas of diabetic ulcer management are as follows: management of comorbidities, evaluation of vascular status and appropriate treatment, assessment of lifestyle psychosocial factors; ulcer assessment and evaluation; tissue management wound bed preparation, and pressure relief.

Management of Comorbidities

Because diabetes is a multi-organ systemic disease, all comorbidities that affect wound healing must be assessed and managed by a multidisciplinary team for optimal outcomes in the diabetic foot ulcer (163-165, 173, 278, 299-301). Many systemic manifestations affect wound healing. Among the most common comorbidities are hyperglycemia and vascular diseases such as cerebral vascular accidents, transient ischemic attacks, myocardial infarctions, angina, valvular heart disease, atrial fibrillation, aneurysms, renal dysfunction, hypertension, hypercholesterolemia, and hyperlipidemia (48, 275, 302-304).

Evaluation of Vascular Status

Arterial perfusion is a vital component for healing and must be assessed in the ulcerated patient, since impaired circulation contributes significantly to nonhealing of ulcers and subsequent risk for amputation (52, 77, 89, 214, 305). Early evaluation and referral are important (91). Symptoms of vascular insufficiency may include edema, altered skin characteristics (lack of hair, diseased nails, altered moisture), slow healing, cool or cold extremities, and impaired arterial pulsation. Vascular reconstructive surgery of the occluded limb improves prognosis and may be required prior to debridement, foot sparing surgery, and partial amputation (88, 227, 306, 307).

Assessment of Lifestyle/Psychosocial Factors

Lifestyle and psychosocial factors may influence wound healing. For example, smoking has a profound effect on

Table 6 **University of Texas Classification System**

Stage	Grade O	Grade I	Grade II	Grade III
A	Pre- or post-ulcerative lesions completely epithelized	Superficial wound not involving tendon, capsule, or bone	Wound penetrating to tendon or capsule	Wound penetrating to bone or joint
B	Infected	Infected	Infected	Infected
C	Ischemic	Ischemic	Ischemic	Ischemic
D	Infected and ischemic	Infected and ischemic	Infected and ischemic	Infected and ischemic

wound healing due to its associated vasoconstriction and low oxygen-carrying capacity of blood (308, 309). Other factors (eg, alcohol and drug abuse, eating habits, obesity, malnutrition, and mobility and activity levels) should also be noted. In addition, depression and mental illness may impact the outcome of treatment, since these conditions can directly affect the patient's adherence to recommendations and attitude towards healing (310, 311).

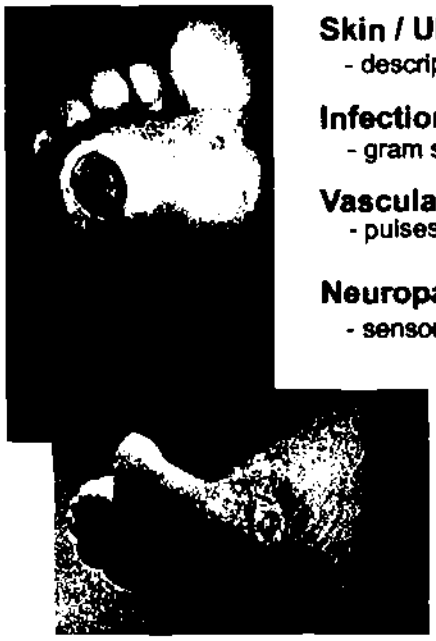
Ulcer Assessment and Evaluation

The importance of a thorough and systematic evaluation of any ulceration cannot be overemphasized; indeed, the findings of an ulcer-specific examination will directly guide subsequent treatment (25, 100). Initial evaluation and detailed description of any ulcer should encompasses location, size, depth, shape, inflammation, edema, exudate (quality and quantity), past treatment, and duration (123, 272). The margins of the ulcer should be assessed for callus formation, maceration, and erythema. The presence of erythema along with other signs such as tenderness and warmth might suggest infection (312). The quality of the tissue (ie, moist, granular, desiccated, necrotic, undermining, slough, eschar, or liquefied) should be noted (313). Thorough evaluation is used to determine the presence of sinus track or deep abscess.

Table 7 **PEDIS Ulcer Classification**

	Grade 1	Grade 2	Grade 3	Grade 4
Perfusion	Normal	Non-critical PAD	Critical limb ischemia	
Extent/size (cm^2)				
Depth tissue loss	Full thickness	Deep	Bone and / or joint	
Infection	None	Mild	Moderate / severe	SIRS*
Sensation	Intact	LOPS		

* Systemic inflammatory response syndrome



Skin / Ulcer
- description, depth, location, classification

Infection
- gram stain, cultures, radiographs, scans

Vascular
- pulses, color, skin temperatures, Doppler, $TcPO_2$

Neuropathy
- sensory disturbances, monofilament, VPT, DTRs

Deformity
- deformity, joint mobility, contractures

Etiology
- mechanical, thermal, chemical

Figure 6 Assessment of a diabetic foot ulcer includes not only a description of the skin lesion but also the findings necessary for accurate assessment of the contributing factors and etiology.

Frequent re-evaluation with response-directed treatment is essential. Once the ulcer is healed, management consists of decreasing the probability of recurrence.

Tissue Management / Wound Bed Preparation

Debridement. Debridement of necrotic tissue is an integral component in the treatment of chronic wounds since they will not heal in the presence of unviable tissue, debris, or critical colonization (314, 315). Undermined tissue or closed wound spaces will otherwise harbor bacterial growth (312, 316, 317). Debridement serves various functions: removal of necrotic tissue and callus, reduction of pressure, evaluation of the wound bed, evaluation of tracking and tunneling, and reduction of bacterial burden (318, 319). Debridement facilitates drainage and stimulates healing (320). However, debridement may be contraindicated in arterial ulcers (321). Additionally, except in avascular cases, adequate debridement must always precede the application of topical wound healing agents, dressings, or wound closure procedures (30, 288, 322, 323). Of the five types of debridement (surgical, enzymatic, autolytic, mechanical, biological), only surgical debridement has been proven to be efficacious in clinical trials (323).

Surgical debridement. Surgical debridement is the cornerstone of management of diabetic foot ulcers. Thorough sharp debridement of all nonviable soft tissue and bone from the open wound is accomplished primarily with a scalpel, tissue nippers, curettes, and curved scissors (324). Excision of necrotic tissue extends as deeply and proximally as necessary until healthy, bleeding soft tissue and bone are encountered. Any callus tissue surrounding the ulcer must also be removed. The main purpose of surgical debridement is to turn a chronic ulcer into an acute, healing wound (325). A diabetic ulcer associated with a deep abscess requires hospital admission and immediate incision and drainage (178). Joint resection or partial amputation of the foot is necessary if osteomyelitis, joint infection, or gangrene are present (41, 100, 123, 151, 180, 271). The principles guiding the surgical management of diabetic foot ulcers are discussed under "Surgical Management of the Diabetic Foot."

Necrotic tissue removed on a regular basis can expedite the rate at which a wound heals and has been shown to increase the probability of attaining full secondary closure (323, 326). Less frequent surgical debridement can reduce the rate of wound healing and secondarily increase the risk of infection. Surgical debridement is repeated as often as needed if new necrotic tissue continues to form (327). Frequent debridement, referred to as "maintenance debridement," is commonly required (328). While the terms surgical debridement and sharp debridement are often used synonymously, some clinicians refer to surgical debridement as that done in an operating room whereas sharp debridement is performed in a clinic setting (325).

Hydrosurgery (Versajet ®, Smith & Nephew, Inc., London, UK) is a novel system indicated for the surgical debridement of damaged and necrotic tissue in traumatic, ulcerated, and chronic wounds, surgical incisions, and burns

(329, 330). Among its properties are precision, selective cutting, and minimal thermal damage to the tissues (331).

When surgical or sharp debridement is not indicated, other types of debridement can be used. For example, vascular wounds may benefit from enzymatic debridement, while an extremely painful wound may benefit from autolytic debridement. Mechanical debridement is often used to cleanse wounds prior to surgical or sharp debridement. In areas where the medical staff is not trained in surgical or sharp debridement, these other forms of debridement may be useful (325).

Enzymatic debridement. A highly selective method, enzymatic debridement consists of the application of exogenous proteolytic enzymes manufactured specifically for wound debridement. Various enzymes have been developed, including bacterial collagenase, plant derived papain urea, fibrinolysin DNAse, trypsin, streptokinase-streptodornase combination, only the first three products are widely available commercially (319). Collagenases are enzymes that are isolated from *Clostridium histolyticum*. These display high specificity for the major collagen types (I and II), but they not active against keratin, fat, or fibrin (312, 332, 333). Papain, obtained from the papaya plant, is effective in the breakdown of fibrinous material and necrotic tissue. When combined with urea, it denatures nonviable protein matter (312). The enzymatic compounds are inactivated by hydrogen peroxide, alcohol, and heavy metals, including silver, lead, and mercury (334). One study found that wounds treated with papain-urea developed granulation tissue faster than those treated with collagenase, but no contrasts between rates of complete wound healing were made (335).

Autolytic debridement. Autolytic debridement occurs naturally in a healthy, moist wound environment when arterial perfusion and venous drainage are maintained.

Mechanical debridement. A nonselective, physical method of removing necrotic tissue, mechanical debridement may include wet-to-dry dressings and high-pressure irrigation or pulsed lavage and hydrotherapy (30, 62, 336, 337). Wet-to-dry is one of the most commonly prescribed and overused methods of debridement in acute care settings (312, 338). Hydrotherapy in the form of whirlpool may remove surface skin, bacteria, wound exudates, and debris. There may be justification in the early stages of a wound for the use of this technique, but it is detrimental to friable granulation tissue (312, 334).

Biological (larval) therapy. Larval therapy utilizes the sterile form of the *Lucilia sericata* blowfly for the debridement of necrotic and infected wounds. Maggots secrete a powerful proteolytic enzyme that liquefies necrotic tissue (339-342). It has been noted that wound odor and bacterial count, including methicillin-resistant *Staphylococcus aureus*, diminish significantly (343) with larval therapy. Larval therapy seems to be beneficial, but there is paucity of controlled studies to support its routine use in the diabetic foot wound.

Moisture Balance. One of the major breakthroughs in wound management over the past 50 years was the demonstration that moisture accelerates re-epithelialization in a wound (315, 344, 345). Tissue moisture balance is a term used to convey the importance of keeping wounds moist and free of excess fluids. A moist wound environment promotes granulation and autolytic processes (325). Effective management of chronic wound fluids is an essential part of wound bed preparation; it also helps in addressing the issues of cellular dysfunction and biochemical imbalance (328, 346-348).

Wound dressings can be categorized as passive, active, or interactive (349). Passive dressings primarily provide a protective function. Active and interactive dressings and therapies are capable of modifying a wound's physiology by stimulating cellular activity and growth factor release (350). An example is ORC/collagen (Promogran™, Johnson & Johnson, Inc., New Brunswick, NJ). Composed of collagen and oxidized regenerated cellulose, this bioreabsorbable matrix decreases tissue destruction and prevents growth factor degradation (351, 352). Recently, silver has been added to this product (Prisma™, Johnson & Johnson, Inc., New Brunswick, NJ) to also provide an effective antibacterial barrier. Although these products are commonly used in clinical practice, they have not yet been conclusively shown to expedite wound healing. A wide variety of wound care products is available; a brief listing of dressings and topical agents is presented in Table 8.

Inflammation and Infection. In chronic wounds, inflammation persists due to recurrent tissue trauma and the presence of contaminants. Nonhealing wounds can become "stuck" in the inflammatory phase of healing, increasing cytokine response with subsequent elevated protease levels and impaired growth factor activity (314, 347, 352-357). The presence of infection must be ascertained and identified as local (soft tissue or osseous), ascending, and/or systemic. In diabetes, where the host response is reduced and normal signs of infection (i.e., fever, pain, leukocytosis) may be absent, other factors such as elevated glucose levels can be helpful as an indicator of infection (41, 358). It is important to obtain specimens for culture prior to antimicrobial therapy. Tissue specimens collected by curettage or biopsy are preferred, because they provide more accurate results than superficial swabs (287).

Table 8 **Wound Care Products**

Category	Indications	Contraindications
Dressings		
Gauze pads (312, 338, 352) - sterile gauze - sterile cotton	- Low to heavily draining wounds or surgical wounds - Wet to dry debridement	- Undefined
Transparent films (312, 352) - polyurethane film with drainage adhesive layer, semipermeable	- Dry to minimally draining wounds - Promote tissue hydration	- Infection - Significant drainage - Over prominence or friction
Hydrogels (312, 352) - gel, sheet, gauze (95% water or glycerin)	- Dry to minimally draining wounds	- Moderate or heavy drainage
Foam (312, 352) - polyurethane foam (open cell, absorbent)	- Moderate, large exudate - Clean wound surface - Super absorbent and conformable to topography	- Dry wounds
Hydrocolloids (312, 352) - wafer with adhesion, (carboxymethylcellulose,pectin, gelatin) impermeable to oxygen	- Low to moderate drainage * Prevents tissue hydration	- Heavy drainage - Sinus tract
Calcium alginates (312, 352) - fiber pad derived form seaweed (may be combined with silver or collagen)	- Heavy exudative wounds	- Minimal drainage or dry wounds
Collagen dressings (302, 312, 325, 352) - particles or composite pads with collagen component (derived from bovine collagen)	- Low to heavily draining wounds	- Dry wounds
Antimicrobial dressings (312, 334, 352) - contain silver iodine in various forms preparations (eg, cadoxemer iodine)	- Infected or clean wounds to prevent infection	- Allergies to components
Topical Therapies / Agents		
Saline (302, 352) **Amorphous hydrogels** **Skin cleansers** - isotonic solutions for irrigation, hydrating dressings	- Clean or infected wounds	- Undefined
Detergents/Antiseptics (302, 352) - povidone-iodine, - chlorhexidine - chloroxylenol - hypochlorite - benzethonium chloride	- Contaminated or infected wounds	- Healthy granulating wounds
Topical Antibiotics (302, 320, 352) - bacitracin, neomycin - mupirocin, polymyxin B - silver sulfadiazine - mafenide (creams, ointments)	- Contaminated or infected wounds	- Healthy granulating wounds
Enzymes (302, 312, 319, 328, 332-335) - collagenase - papain-urea	- Necrotic tissue - Escharotic wounds	- Healthy or infected wounds

Advanced Wound Care Modalities. Wound bed preparation offers clinicians a comprehensive approach to removing barriers to healing and stimulating the healing process so that the benefits of advanced wound care can be maximized (314, 359). Advanced care may sometimes be the only means of rapidly and effectively attaining wound closure (360). The advent of therapeutic growth factors, gene therapy, tissue-engineered constructs, stem cell therapy, and other drugs and devices that act through cellular and molecular-based mechanisms is enabling the modern surgeon and wound-care provider to actively promote wound angiogenesis to accelerate healing (361-363).

Growth factor therapy. Chronic ulcers have demonstrated benefit from autologous platelet releasates or genetically-engineered products such as recombinant DNA platelet-derived growth factor becaplermin gel (Regranex™, Johnson & Johnson, Inc., New Brunswick, NJ) (361, 362, 364). This agent has been shown to stimulate chemotaxis and mitogenesis of neutrophils, fibroblasts, monocytes and other components that form the cellular basis of wound healing (326, 365-368). In one pivotal randomized placebo controlled blinded trial involving patients with full thickness diabetic foot ulcers, recombinant human platelet-derived growth factor (becaplermin) demonstrated a 43% increase in complete closure versus placebo gel (50% vs 35%) (362). Other growth factors, including vascular endothelial growth factor (VEGF), fibroblast growth factor (FGF), and keratinocyte growth factor (KGF), have been under study but are not yet approved for use in the US.

Autologous platelet-rich plasma treatments (Fig. 7) utilize the patient's own blood to create a gel that is applied to the wound (364). Activation of the plasma after centrifugation stimulates the release of multiple growth factors from the platelet's alpha granules and the conversion of the plasma fibrinogen to a fibrin matrix scaffold. Both actions may assist with new tissue formation. A large retrospective study reviewing this treatment protocol in commercial wound healing centers suggested a benefit in healing larger, more severe neuropathic ulcerations (369).

Bioengineered tissues. Bioengineered tissues have been shown to significantly increase complete wound closure in venous and diabetic foot ulcers (370-374). Currently, two bioengineered tissues have been approved to treat diabetic foot ulcers in the US: Apligraf™ (Organogenesis Inc., Canton, MA), and Dermagraft™ (Smith & Nephew, Inc., London, UK); both have demonstrated efficacy in randomized, controlled trials. Tissue-engineered skin substitutes can provide the cellular substrate and molecular components necessary to accelerate wound healing and angiogenesis. They function both as biologic dressings and as delivery systems for growth factors and extracellular matrix components through the activity of live human fibroblasts contained in their dermal elements (370, 375).

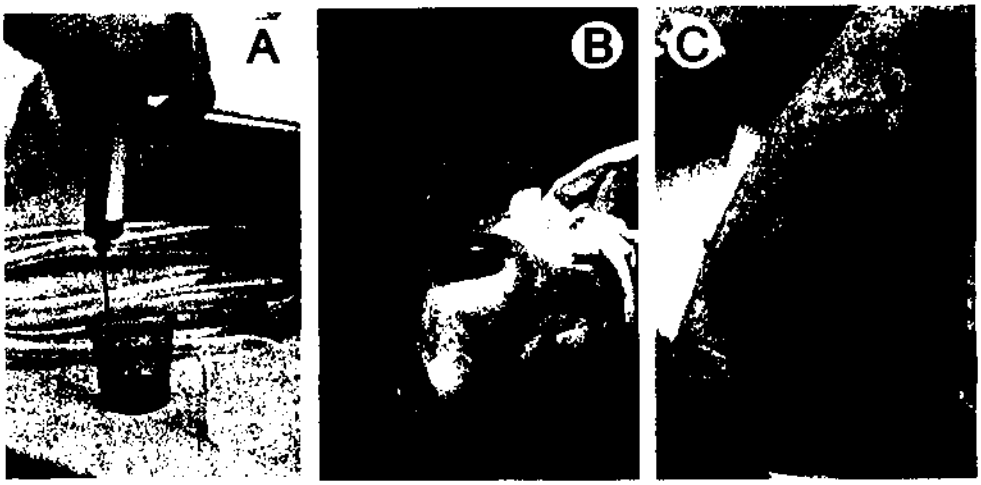


Figure 7 New technologies have been developed that have proved useful for management of diabetic ulcerations. *(A)* Platelet-rich plasma (PRP) involves use of the patient's blood, which is collected and then fractionated through centrifugation. A platelet-rich and platelet-poor supernatant remains. *(B)* This case involved use of autologous platelet-rich plasma gel activated with thrombin and placed onto a healthy wound bed. *(C)* The platelet gel or clot may also be covered with a synthetic skin graft substitute.

Bilayered skin substitutes (living cells) include bilayered skin equivalent (Apligraf™) and cultured composite skin (OrCel™ bilayered cellular matrix, Ortech International, Inc., New York City, NY). Apligraf™ has been shown to significantly reduce the time to complete wound closure in venous and diabetic ulcers (371, 376). Dermagraft™ is no longer available in the US.

Extracellular matrices (nonliving) are generally derived from devitalized tissue to produce an immunologically inert acellular dermal matrix. These include dermal regeneration template (Integra™, Integra LifeSciences Holdings Corp., Plainsboro, NJ), allogenic dermal matrix (AlloDerm™, LifeCell, Branchburg, NJ), matrix of human dermal fibroblasts (TransCyte™, Smith & Nephew, Inc., London, UK), and porcine small intestine submucosa (Oasis™, Healthpoint, Fort Worth, TX). Oasis™, composed of structural cellular components and growth factors utilized to promote natural tissue remodeling (377, 378), recently completed a randomized trial that showed non-inferiority to becaplermin gel in the healing of diabetic foot ulcers (379). Integra™ dermal regeneration template, a collagen-chondroitin sponge overlaid with silicone originally developed for burns, has been shown to be ideally suited to chronic and pathologic wounds (380).

Adjunctive Modalities. Regenerative tissue matrix (GraftJacket™, Wright, Arlington, TN) is a new therapy used in diabetic foot ulcers, although it has not undergone any randomized clinical trials to date (381). This allograft skin is minimally processed to remove epidermal and dermal cells while preserving the bioactive components and structure of dermis. This results in a framework that supports cellular repopulation and vascularization.

Hyperbaric oxygen therapy (HBO) has shown promise in the treatment of diabetic foot wounds with hypoxia severe enough to interfere with healing (382-387). However, most of the HBO studies were hampered by methodological errors that preclude any definite role for this modality in the routine treatment of diabetic foot ulcers (382, 388, 389). Nevertheless, in 2003, Medicare and Medicaid coverage for HBO extended to ulcers classified as Wagner grade 3 or higher that failed standard wound care therapy. Clearly, a large multicenter randomized clinical trial is needed to properly test the efficacy of this expensive modality (388).

Several new ultrasound devices are being used to both debride the wound and provide ultrasonic therapy. The MIST Therapy™ system (Celleration™, Eden Prairie, MN) is an ultrasonic device approved by the Food and Drug Administration (FDA) for wound debridement and cleansing. MIST Therapy™ uses a fine saline spray that allows ultrasound to be administered directly to the wound bed without contact to the affected tissue, thus minimizing potential trauma to delicate capillary buds and emerging islands of epithelium (390-392).

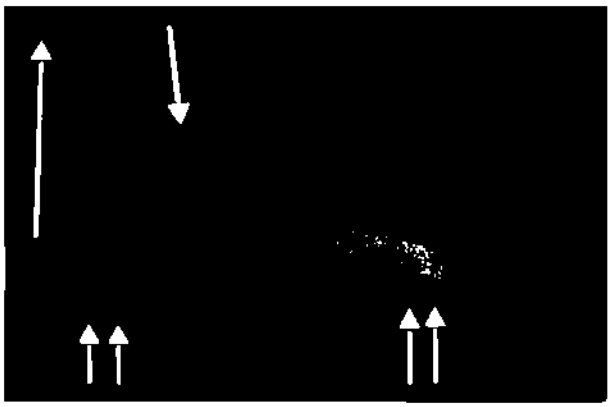
Negative pressure wound therapy (NPWT) has become a common adjunctive treatment modality for diabetic foot ulcerations (393-397). Use of a vacuum-assisted closure® device (V.A.C.®, KCI, San Antonio, TX) promotes wound healing through the application of topical, subatmospheric, or "negative" pressure to the wound base (398, 399). This therapy removes edema and chronic exudate, reduces bacterial colonization, enhances formation of new blood vessels, increases cellular proliferation, and improves wound oxygenation as the result of applied mechanical force. These actions are synergistic (400, 401). Numerous applications of this modality have proven successful, including use over exposed bone, tendons, and hardware to generate granulation tissue (394, 395, 402-405). It is also frequently used to facilitate adherence of split thickness skin grafts, rotational flaps, or tissue substitutes to a wound bed (396, 406-409). A recent clinical trial of the V.A.C.® device for the treatment of open amputation wounds in the diabetic foot showed significantly faster healing and development of granulation tissue with NPWT compared with standard moist wound care (410).

The rationale for using electrical stimulation in wound healing stems from the fact that the human body has an endogenous bioelectric system that enhances healing of bone fractures and soft tissue wounds. Laboratory and clinical studies provide an abundance of support for the use of electrical stimulation in wound care (411, 412). In a randomized, controlled study evaluating wound healing using electrical stimulation in neuropathic ulcers, significant differences in healed ulcer areas and number of healed ulcers at 12 weeks were found in the group receiving electrical stimulation compared with the control group (413).

Pressure Relief/Off-loading

The reduction of pressure to the diabetic foot ulcer is essential to treatment (26, 76, 80, 107, 414-417). Proper off-loading and pressure reduction prevents further trauma and promotes healing. This is particularly important in the diabetic patient with decreased or absent sensation in the lower extremities (50, 418). Furthermore, recent studies provide evidence that minor trauma (eg, repetitive stress, shoe pressure) plays a major role in the causal pathway to ulceration (24). A list of off-loading modalities is presented in Figure 8.

The choice of off-loading modality should be determined by the patient's physical characteristics and ability to comply with treatment as well as by the location and severity of the ulcer. Various health care centers prefer specific initial modalities, but frequently clinicians must alternate treat-



- Total nonweightbearing: crutches, bed rest, wheelchair
- Total contact casting
- Foot casts or boot
- Removable walking brace with rocker bottom sole
- Total contact orthoses - custom walking braces
- Patella tendon-bearing braces
- Half shoes or wedge shoes
- Healing sandal - surgical shoe + molded plastazote foot bed
- Accommodative dressings: felt, foam, felted foam
- Shoe cutouts - toe box, medial, lateral, dorsal pressure points
- Assistive devices: crutches, walker, cane

Figure 8 Diabetic foot ulcers are most often located under weightbearing areas of the foot. Essentials of management include "off-loading" of the foot or area of ulceration. Healed ulcers may be managed with shoes and variations of molded or multiple density insoles, while the total contact cast remains the standard approach to off-loading areas of ulceration.

ments based on the clinical progress of the wound. Even as simple a method as a felted foam aperture pad has been found to be effective in removing pressure and promoting healing of foot ulcers (419-421). A study published in 2001 noted that use of a total contact cast (TCC) healed a higher portion of wounds in a shorter time than a half shoe or removable cast walker (RCW) (414). More recently, investigators compared TCC use with that of a removable cast walker that was rendered irremovable (iTCC) by circumferential wrapping of an RCW with a single strip of fiberglass casting material. They concluded that the latter may be equally efficacious, faster to place, easier to use, and less expensive than TCC in the treatment of diabetic neuropathic plantar foot ulcers (422). The findings of this study and another study also suggest that modification of the RCW into an irremovable device may improve patient compliance, thereby increasing the proportion of healed ulcers and the rate of healing of diabetic neuropathic wounds (417).

Regardless of the modality selected, no patient should return to an unmodified shoe until complete healing of the ulcer has occurred (30, 77, 90, 255). Furthermore, any shoe that resulted in the formation of an ulcer should never again be worn by the patient.

Wounds That Fail to Heal

Wounds that do not respond to appropriate care, including debridement, off-loading, and topical wound therapies, must be reassessed. Infection and ischemia are especially important considerations and common reasons for failure to heal.

The presence of infection must be determined and identified as either soft tissue, osseous, or both. Excessive bioburden can be indicated by pale or friable granulation tissue, persistent drainage, or fibrinous surface layer (314).

Table 9 Factors Favoring Wound Chronicity (426)

- Nutritional deficiency
  - Protein calorie
  - Vitamins
  - Minerals
- Tissue hypoxia
  - Ischemia
  - Venous insufficiency
  - Edema
- Infection / bioburden
- Metabolic
  - Diabetes
  - Chronic renal insuffiency
- Malignancy
- Immune compromise
  - Immunosuppressive drugs
  - Steroids
- Mechanical
  - Pressure
  - Shear
  - Friction
  - Repetitive injury
- Miscellaneous
  - Inadequate debridement
  - Toxic wound care products
  - Radiation therapy
  - Aging / debility

Indicators for frank infection will also include pain (especially in the neuropathic patient), erythema, and induration. When bone or joint is visible or palpable at the depth of the ulcer, osseous infection becomes more likely (285, 423). A thorough discussion of the management of infected wounds is presented later in this document and summarized in Pathway 4.

Unrecognized ischemia will also impair wound healing and must be diagnosed prior to development of infection or ischemic necrosis of the ulcer. When no progress or enlargement of the wound has taken place, re-examination of the vascular status of the extremity is warranted (Pathway 2). This should include arterial Doppler segmental pressures with waveforms, digital arterial pressures, or measurement of transcutaneous oxygen partial pressures ($TcPO_2$) (52, 212). Vascular surgical consultation should also be considered for further evaluation and treatment.

Other parameters critical to wound healing should also be addressed, including the need for further debridement or a change in off-loading modality. Nonadherence to prescribed treatments or off-loading can be especially problematic in patients with peripheral neuropathy (424, 425). Additional concerns may include renal insufficiency, biochemical imbalances, chronic anemia, nutritional deficiencies, or ulceration due to nondiabetic etiologies (ie, radiation, malignancy, etc) (354, 426). Biopsy of chronic, nonhealing wounds should always be considered. Table 9 summarizes the range of possible impediments to wound healing.

DIABETIC FOOT INFECTIONS (Pathway 4)

Foot infection is a major reason for hospitalization among patients with diabetes and also an important causal factor for lower limb amputation (122, 151, 427). There are various presentations of diabetic foot infections as well as several ways to classify these entities (428).

Classification of Diabetic Foot Infections

Foot infections may be described in terms of severity, extent of involvement, clinical appearance, location, and etiology. Any system for classifying these infections should also serve to facilitate management and predict outcomes. One well accepted method simply provides two categories: non-limb-threatening and limb-threatening infections (30, 41, 77, 151, 177, 429). This scheme implies severity of infection and, accordingly, directs subsequent management while also portending a general prognosis for outcome.

Clinically, non-limb-threatening infections are usually seen with ulceration that is superficial, without significant ischemia, and a wound that does not probe to bone or joint (41). Ulceration, however, does not need to be present, since non-limb-threatening infections can result from small puncture wounds, scratches, or simple fissures. Cellulitis in this category of infections is 2 cm or less from the ulceration or portal of entry. Patients with non-limb threatening infections are medically stable and usually do not present with signs and symptoms of systemic involvement. This relatively mild to moderate infection can be managed on an outpatient basis, with close supervision from the clinician (30, 430).

Limb-threatening diabetic foot infections have cellulitis that extends beyond 2 cm (430). Additional clinical features may include fever, edema, lymphangitis, hyperglycemia, leukocytosis, and ischemia, however, the diabetic patient with a relatively severe infection may not necessarily present with these signs and symptoms (178). If an ulcer is present it may probe to bone or joint, which is highly predictive of osteomyelitis (285). Therefore, it is important to review the patient's entire clinical assessment (see Table 3) to guide the clinician to the proper course of treatment. Gangrene, abscesses, osteomyelitis, and necrotizing fasciitis may also

PATHWAY #4

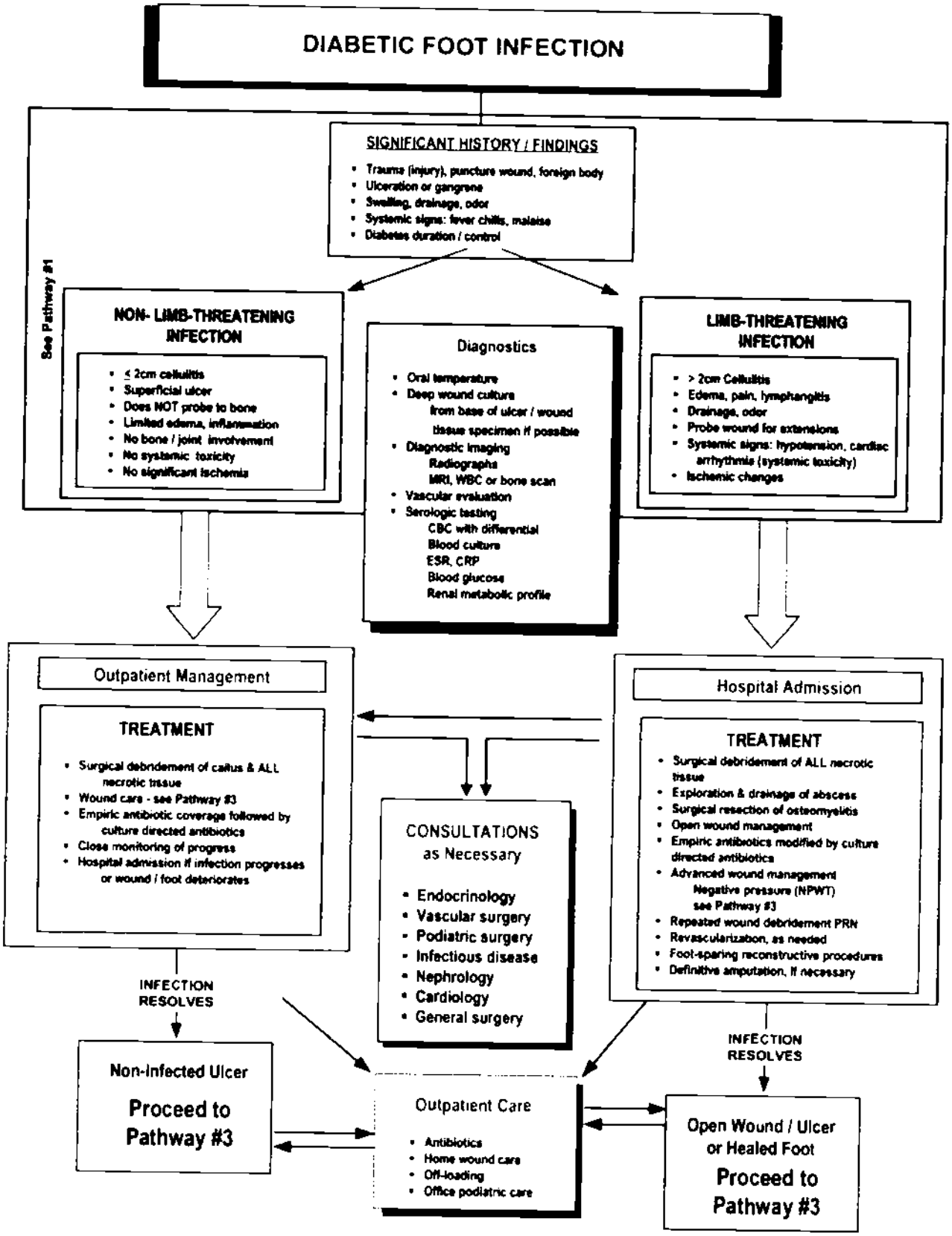

DIABETIC FOOT INFECTION
SIGNIFICANT HISTORY / FINDINGS
Trauma (injury), puncture wound, foreign body
Ulceration or gangrene
Swelling, drainage, odor
Systemic signs: fever chills, malaise
Diabetes duration / control
See Pathway #1
NON- LIMB-THREATENING INFECTION
≤ 2cm cellulitis
Superficial ulcer
Does NOT probe to bone
Limited edema, inflammation
No bone / joint involvement
No systemic toxicity
No significant ischemia
Diagnostics
Oral temperature
Deep wound culture
from base of ulcer / wound
tissue specimen if possible
Diagnostic imaging
Radiographs
MRI, WBC or bone scan
Vascular evaluation
Serologic testing
CBC with differential
Blood culture
ESR, CRP
Blood glucose
Renal metabolic profile
LIMB-THREATENING INFECTION
> 2cm Cellulitis
Edema, pain, lymphangitis
Drainage, odor
Probe wound for extensions
Systemic signs: hypotension, cardiac arrhythmia (systemic toxicity)
Ischemic changes
Outpatient Management
TREATMENT
Surgical debridement of callus & ALL necrotic tissue
Wound care - see Pathway #3
Empiric antibiotic coverage followed by culture directed antibiotics
Close monitoring of progress
Hospital admission if infection progresses or wound / foot deteriorates
Hospital Admission
TREATMENT
Surgical debridement of ALL necrotic tissue
Exploration & drainage of abscess
Surgical resection of osteomyelitis
Open wound management
Empiric antibiotics modified by culture directed antibiotics
Advanced wound management
Negative pressure (NPWT)
see Pathway #3
Repeated wound debridement PRN
Revascularization, as needed
Foot-sparing reconstructive procedures
Definitive amputation, if necessary
CONSULTATIONS as Necessary
Endocrinology
Vascular surgery
Podiatric surgery
Infectious disease
Nephrology
Cardiology
General surgery
INFECTION RESOLVES
INFECTION RESOLVES
Non-Infected Ulcer
Proceed to Pathway #3
Outpatient Care
Antibiotics
Home wound care
Off-loading
Office podiatric care
Open Wound / Ulcer or Healed Foot
Proceed to Pathway #3

Table 10 **IDSA Guidelines for the Clinical Classification of Diabetic Foot Infections**

Clinical Evidence of Infection	Infection Severity	PEDIS Grade
Wound lacking purulence or any manifestations of inflammation	Uninfected	1
Presence of ≥2 manifestations of inflammation (purulence, erythema, pain, tenderness, warmth, or induration), but cellulitis/erythema extends ≤2 cm from margins of ulcer, and infection is limited to the skin or superficial subcutaneous tissues; no other local complications or systemic illness	Mild	2
Infection (as above) in a patient who is systemically well and metabolically stable but has 1 of the following characteristics: cellulitis extending >2 cm, lymphangitic streaking, spread beneath the superficial fascia, deep-tissue abscess, gangrene, and involvement of muscle, tendon, joint, or bone	Moderate	3
Infection in a patient with systemic toxicity or metabolic instability (eg, fever, chills, tachycardia, hypotension, confusion, vomiting, leukocytosis, acidosis, severe hyperglycemia, or azotemia)	Severe	4

be present. Hospitalization is required to treat the infection as well as systemic sequelae. Patients with poor vascular status and ischemia have an increased potential for amputation and require prompt consultation for potential revascularization (30, 77, 200).

In 2004, the Infectious Disease Society of America (IDSA) developed new guidelines for the diagnosis and treatment of diabetic foot infections (123). The guidelines incorporate the infection portion of the PEDIS system into IDSA's preferred clinical classification for infections in the diabetic foot (Table 10).

Assessment of Diabetic Foot Infections

When evaluating the patient with a diabetic foot infection, a problem-directed history and physical examination should be obtained. A systematic approach to the complete assessment of these patients is required, since there is evidence that they are often inadequately evaluated, even when hospitalized (431). The past medical history should assess the patient's neurologic, cardiovascular, renal, and dermatologic status. Use of current medications as well as previous antibiotics may interfere with planned treatments or indicate that standard treatments will likely be ineffective. Pain should be considered an unreliable symptom in individuals with peripheral neuropathy. The patient should be questioned regarding previous ulcerations, infections, trauma, and surgeries at the present site or at any other past location of infection.

Constitutional symptoms (eg, nausea, malaise, fatigue, vomiting, fever, chills) are important clinical clues when presented with an infected diabetic foot. Severe infection or sepsis must be considered when these symptoms are present. However, in about 50% of diabetic patients presenting with significant infection, systemic signs (fever and leukocytosis) are absent (178). Frequently, the only indication of infection is unexplained or recalcitrant hyperglycemia. Laboratory testing might include a CBC with or without differential, blood cultures, glycosylated hemoglobin, fasting blood sugar, sedimentation rate, and urinalysis. Other tests should be performed as indicated by the patient's condition or comorbidities.

The history of the wound or infection should include the onset, duration, and appearance before infection of the area. Depth or size of the ulcer, amount of drainage, swelling, color, odor, and extent of infection should be evaluated. The infection or ulcer should be probed to determine the presence of bone or joint involvement, sinus tracts, or extension into tendon sheaths. The latter are common routes for the spread of infection both distally and proximally. Reliable aerobic and anaerobic cultures should be obtained from

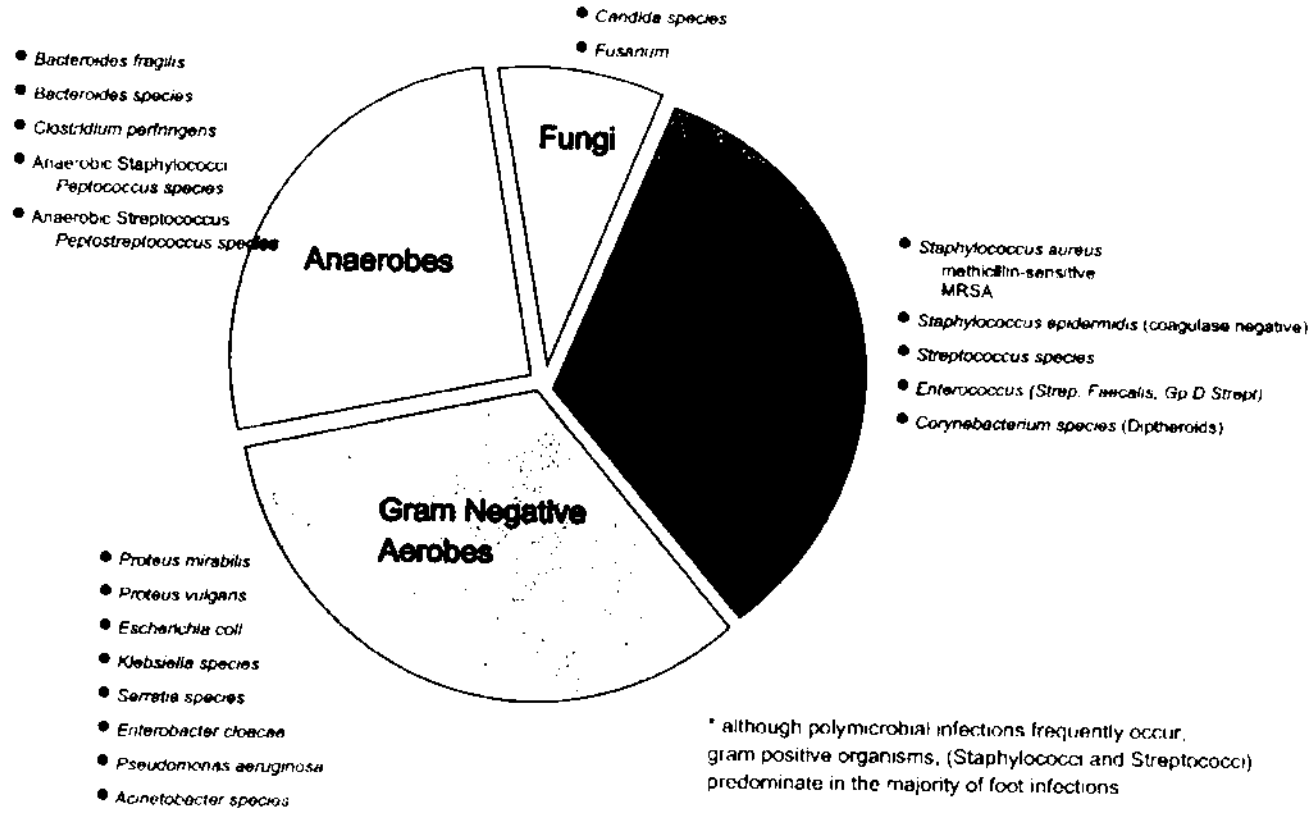


Figure 9 Diabetic foot infections are generally considered polymicrobial, because multiple organisms are frequently found in a wound milieu. *Staphylococcus* and *Streptococcus* remain the most important organisms causing infection.

purulent drainage or curettage of the ulcer base, since studies have shown good concordance with the true pathogen (116, 428, 432). Simple swab cultures of an ulcer surface are generally not advisable because they tend to be unreliable, especially in the presence of osteomyelitis or sinus tracts (123, 433, 434).

For patients with clinically uninfected or noninflamed neuropathic ulcers, the role of antibiotic therapy is still in question (30). Therefore, in these instances, wound culture is probably unnecessary (123). If osteomyelitis is suspected, bone cultures are necessary to make the definitive diagnosis and isolate the true pathogen (180, 435, 436). However, this must be balanced against the potential for contaminating noninfected bone in the presence of an active soft tissue infection. Intraoperative frozen section is also useful in assessing for deep infection. The presence of more than 5 to 10 neutrophils per high power field is suggestive of acute infection (437).

The majority of wounds are caused by *Staphylococcus aureus*, beta-hemolytic streptococci, and other gram positive cocci (Fig 9) (151, 438, 439). Although community-acquired cases of resistant bacterial infections have been reported, patients who have been previously hospitalized with an open wound are more likely to develop an infection from resistant bacteria such as methicillin-resistant *S aureus* (MRSA) and vancomycin resistant enterococci (VRE) (440). Chronic wounds may develop a more complex assortment of bacteria, including gram negative rods, obligate anaerobes, *Pseudomonas aeruginosa*, and enterococci.

Imaging studies are also important in the overall assessment of diabetic foot infections, notwithstanding their shortcomings. Plain film x rays may indicate the presence of bony erosions and or gas in the soft tissues. It should be noted that the demonstration of osteomyelitis by plain radiographs lags the onset of bone involvement by 10 to 14 days (180, 197). Radionucleotide bone scans such as Tc 99 may demonstrate abnormal uptake of the radionucleotide before changes are visible on radiographs (179). This may be less specific in patients with peripheral neuropathy or with any preexisting osseous condition that causes increased bone turnover (eg, surgery, fracture, neuropathic arthropathy) (441). A combination of scans such as the Tc-99m and an indium-labeled leukocyte scan or the Tc-99m HMPAO-labeled leukocyte scan may aid the clinician in differential-

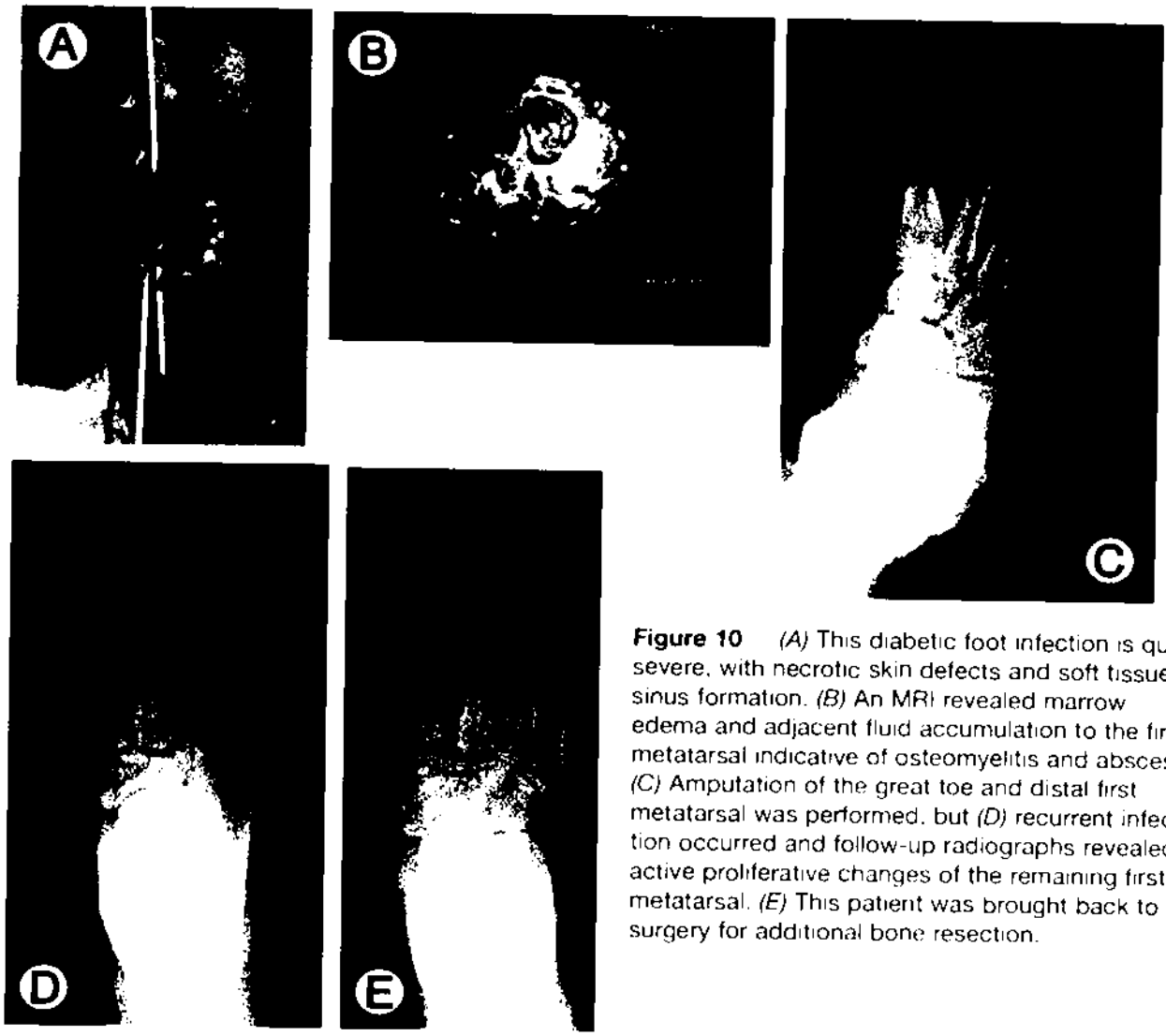


Figure 10 *(A)* This diabetic foot infection is quite severe, with necrotic skin defects and soft tissue sinus formation. *(B)* An MRI revealed marrow edema and adjacent fluid accumulation to the first metatarsal indicative of osteomyelitis and abscess. *(C)* Amputation of the great toe and distal first metatarsal was performed, but *(D)* recurrent infection occurred and follow-up radiographs revealed active proliferative changes of the remaining first metatarsal. *(E)* This patient was brought back to surgery for additional bone resection.

ing Charcot arthropathy and osteomyelitis with greater accuracy (185, 186, 203). MRI has generally supplanted the CT scan in the early diagnosis of osteomyelitis (Fig 10), due to its higher tissue contrast and ability to detect both soft tissue and marrow inflammation (183, 200, 202, 442). Additionally, MRI can be used to follow the resolution of infection or as an aid in surgical planning (201, 443). However, none of these imaging modalities are 100% sensitive and specific for diagnosing or ruling out bone infection. Furthermore, these tests are expensive and may not be readily available. Appropriate clinical assessment and diagnostic acumen should therefore remain the guiding principles to management.

Treatment of Diabetic Foot Infections

Diabetic foot infections should be managed through a multidisciplinary team approach utilizing appropriate consultations (173, 178, 300). Hospitalization of patients with limb-threatening infections is mandatory. All diabetic foot infections must be monitored closely. Equally important for the best possible outcome are patient compliance and education, especially in outpatient management.

Treatment of Non-Limb-Threatening Infections

Treatment of diabetic foot infections is guided by the severity of the infection. As previously discussed, non-limb-threatening infections involve superficial ulcerations without significant ischemia and they do not involve bone or joint (430). Typically, cellulitis does not extend 2 cm beyond the ulcer margins and there is an absence of systemic symptoms (e.g. fever, chills, nausea, vomiting). These less severe infections that frequently complicate diabetic foot ulcers, may be initially treated in an outpatient setting (41, 438, 444). Many mild or moderate infections are

monomicrobial, with *S aureus*, *S epidermidis*, and streptococci the most common pathogens (119, 121, 439). Reliable specimens for cultures may be obtained through curettage of the infected ulcer (120, 123, 445, 446). In addition to the standard treatment for ulcerations (ie, nonweightbearing and dressing changes), oral antibiotic therapy is usually sufficient as initial therapy (Table 11). Antimicrobial treatment should be started as soon as possible with an agent providing adequate gram positive coverage, recognizing that gram negative organisms might also be involved (287, 438, 439). Although the incidence of MRSA infections has increased dramatically in the past several years, methicillin-sensitive *S aureus* (MSSA) remains the most likely pathogen in community-acquired diabetic foot infections (123, 447). Therefore, initial antibiotic coverage must be tailored to cover MSSA, unless a reliable culture and sensitivity is available or there is a history of other pathogens (eg, MRSA, *Pseudomonas*, enterococcus) that require specific coverage. Antibiotics should be adjusted according to culture results and the patient's response to treatment.

While many useful oral antimicrobial agents (eg, cephalexin, clindamycin, amoxicillin clavulanate, levofloxacin) are available for managing mild to moderate diabetic foot infections, relatively few have been studied or have demonstrated superiority in prospective randomized clinical trials (123). Therefore, IDSA guidelines contain no specific recommendations for antimicrobial regimens in the management of diabetic foot infections.

All antibiotic treatments should be monitored for development of resistance. Most cases of cellulitis respond within 3 to 5 days of initiation of appropriate antibiotics. If cellulitis is slow to respond, worsens, or recurs following several days of treatment, the ulceration should be reassessed and possibly recultured. Bacteria frequently develop resistance to an antimicrobial agent, especially with prolonged therapy. This is not uncommon with the quinolones.

Table 11 Empiric Antibiotic Therapy: Diabetic Foot Infections

Limb-Threatening

- Ampicillin / Sulbactam
- Ticarcillin / Clavulanate
- Piperacillin / Tazobactam
- Ceftazidime + Clindamycin
- Cefotaxime + Clindamycin
- Fluoroquinolone + Clindamycin
- Vancomycin + Levofloxacin + Metronidazole
- Linezolid
- Imipenem / Cilastatin
- Ertapenem
- Tigecycline

Life-Threatening

- Ampicillin / Sulbactam + Aztreonam
- Piperacillin / Tazobactam + Vancomycin
- Vancomycin + Metronidazole + Ceftazidime
- Imipenem / Cilastatin
- Fluoroquinolone + Vancomycin + Metronidazole
- Ertapenem
- Tigecycline

Non-Limb-Threatening*

- Cephalosporin (Cefphalexin, Cefadroxil, Cefdinir)
- Fluoroquinolones (Levofloxacin, Moxifloxacin, Gatifloxacin)
- Penicillins (Dicloxacillin, Amoxicillin/Clavulanate)
- Linezolid
- Trimethoprim / Sulfamethoxazole
- Doxycycline

* Generally oral agents are utilized for non-limb-threatening infections as most are treated outpatient

Superinfection can also develop when antibiotics select out opportunistic organisms, as in the case of *Pseudomonas* or yeast (*Candida* sp). Because MRSA infections have become increasingly more common pathogens and are associated with prior antimicrobial exposure (447, 448), patients with clinical infection and a prior history of MRSA should be considered to have the same pathogen until proven otherwise and treated accordingly.

Antimicrobial therapy alone is not sufficient for treating infections associated with foot ulcers (272, 449, 450). The wound should be assessed and cleansed thoroughly, using proper debridement as indicated. While there are several topical antimicrobial agents that can be used on the infected wound, there is little data on topical treatment (287). Therefore, such therapy at present can only be considered adjunctive to systemic antimicrobial therapy.

The wound should be managed according to the principles discussed previously. Most importantly, the patient should be reassessed within 48 to 72 hours. If no improvement is noted, hospitalization with intravenous antibiotics should be considered. Management of this type of infection should also include close monitoring of the patient's hyperglycemia and general health status. Patient compliance as well as a reduction in the pressure of the infected limb must be considered early on in the treatment of any diabetic foot infection (77, 451).

Treatment of Limb-Threatening Infections

By definition, limb-threatening infections are much more serious and more often acute compared with the milder non-limb-threatening infections. In the PEDIS system (Table 10), limb-threatening infections are classified as grade 3 or 4, depending on severity and the presence of systemic manifestations (122, 123, 452). Neuropathy often predisposes such infections to progression to an emergent situation before the patient even becomes aware of the infection's presence. Limb-threatening infections may have life-threatening complications, especially when left untreated. Because of diabetes-associated immunosuppression, up to 50% of patients with limb-threatening infections may exhibit no systemic symptoms or leukocytosis (118, 178, 453). However, other patients present with evidence of systemic toxicity, including fever, chills, loss of appetite, and malaise. Such findings in diabetic patients should alert clinicians to the severity of infection. Most will note uncontrollable hyperglycemia despite usual therapy and loss of appetite (41, 454).

Limb-threatening infections are recognized as having one or more of the following findings: greater than 2 cm of cellulitis around an ulcer, lymphangitis, soft tissue necrosis, fluctuance, odor, gangrene, osteomyelitis (30, 77, 430). When such an infection is recognized, the patient requires emergent hospital admission for appropriate intervention (116, 200, 272). Upon admission, a complete history and physical examination are undertaken. The patient's cardiovascular, renal, and neurologic risks should be evaluated to assess for secondary complications of diabetes and associated comorbidities. A thorough foot evaluation is undertaken to determine the clinical extent of the infectious process. Vascular status must be assessed to ensure that appropriate arterial inflow is present. If perfusion is inadequate, this should be addressed prior to definitive reconstruction to enhance healing at a more distal level.

Radiographs are necessary to evaluate for evidence of osteomyelitis or soft tissue gas. If gas is identified in the ankle or hindfoot, radiographs of the lower leg should be obtained to assess the extent of the gas formation. Blood cultures are required if clinical findings indicate septicemia. Other appropriate laboratory studies, including CBC with differential and sedimentation rate, are obtained as warranted. Glucose management must be initiated to optimize metabolic perturbations and improve leukocyte function (455). The patient's nutritional and metabolic status must be assessed and properly maintained, since relatively common nutritional and metabolic impairments in these patients can adversely affect wound healing and resolution of infection (314, 456, 457).

Consultations are typically required in the risk assessment and management of these complex cases. Medical, endocrinology, cardiology, nephrology, and diabetic teaching nurse consultations are often routinely needed to optimize patient care and fully assess surgical risks (181, 429). Infectious disease and vascular surgery consultations are also obtained when complex infections or significant ischemia are identified, respectively. A multidisciplinary approach to the management of these cases has been shown to significantly improve outcomes (163, 165, 173, 278, 300, 458–461).

Early surgical treatment of the affected site is typically necessary as an integral part of infection management (178, 451, 460, 462). This may include simple debridement of the soft tissues, wide incision and drainage of the pedal compartments, or open amputation to eliminate extensive areas of infection (124, 463, 464). At the time of debridement, aerobic, anaerobic, and fungal tissue cultures should be obtained from the depth of the wound to provide reliability (287, 432, 446). Although many initial drainage procedures can be performed at the bedside for neuropathic patients, most require thorough debridement in the operating room. Anesthesia for such interventions may include local, region-

al, or general anesthetics. However, spinal blocks are typically avoided in patients who may be septic.

Even the sickest of patients should be considered for emergent incision, drainage, and debridement procedures, because their illness in this regard is directly attributable to the infection severity. Such life-threatening infections necessitate immediate surgical attention, without delay in obtaining radiologic or medical work-up of other comorbid conditions (41, 77, 462, 463). Polymicrobial infection should be anticipated in these patients (Fig 9), with a variety of gram positive cocci, gram negative rods, and anaerobic organisms predominating (287, 465, 466). Accordingly, empirical antibiotic therapy typically includes broad-spectrum coverage for more common isolates from each of these three categories (Table 11). Fully comprehensive empiric coverage is usually unnecessary unless the infection is life-threatening (118, 123).

Hospital therapies are usually initiated with intravenous medications, although most oral fluoroquinolones and oral linezolid have the same bioavailability as parenteral therapy (119, 438, 467). Once wound culture results become available, the initial antimicrobial therapy may require adjustment to provide more specific coverage or provide therapy against resistant organisms causing persisting infection. Recent evidence also supports the efficacy of initial parenteral therapy followed by the appropriate oral agent in the management of these patients (438, 466, 468). If the patient develops evidence of recurrent infection while receiving antibiotic therapy, repeat cultures should be obtained to assess for superinfection. Methicillin-resistant staphylococci, which have emerged as important pathogens in chronically-treated diabetic foot ulcer patients (447, 448), must be detected early and treated appropriately to avoid further tissue loss or extension of infection.

The surgical wound may require repeated surgical debridement to completely eradicate infection and soft tissue necrosis (451, 460, 463). Wound care is initiated on day 1 or day 2 postsurgery and may initially involve saline gauze dressing changes. Other dressings may be used to aid in healing. Negative pressure wound therapy (V.A.C.®, KCI, San Antonio, TX) has been found particularly useful in this regard (393, 404, 410). If the wound fails to show signs of healing, the patient's vascularity, nutritional status, infection control, and wound off-loading must be re-evaluated.

Once soft tissue infection is under control and management of any osseous infection has been initiated, consideration may be given to wound closure or definitive amputation. Restoration and maintenance of function and independence is the ultimate goal for the patient (77, 463). The residual extremity requires close follow-up, regular diabetic foot exams, periodic foot care, and appropriate footwear therapy (25, 30, 151, 272).

Osteomyelitis and joint infection (Fig 11), when identified by clinical assessment or imaging studies, require a sampling of bone for microbiologic and histopathologic evaluation (200, 469). If the patient's soft tissue infection is controlled, consideration may be given to stopping antibiot-

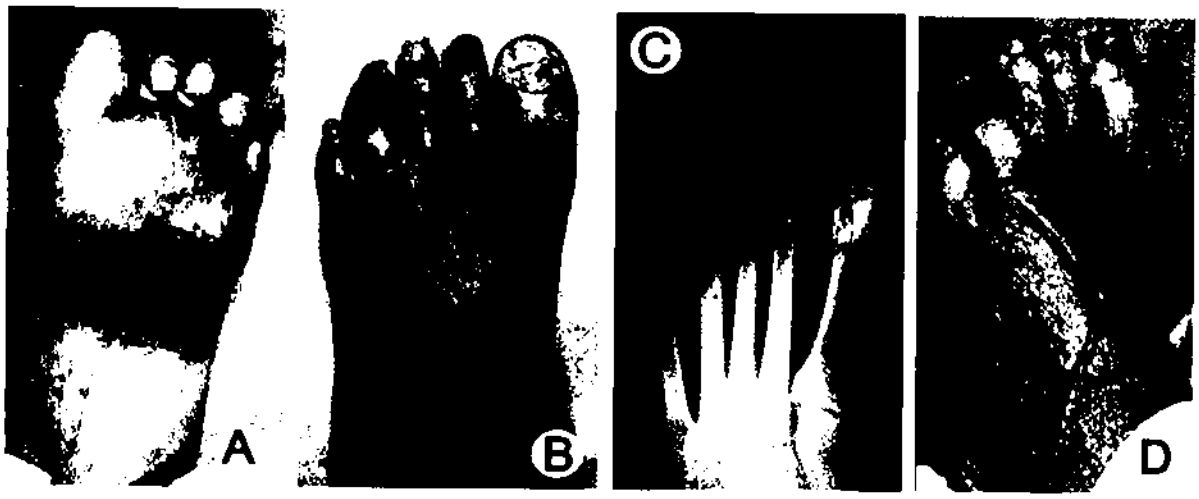


Figure 11 This 60-year-old female with diabetes and a history of plantar callus presented with *(A)* ulceration sub 4th metatarsal head and *(B)* 4th left toe, and poor diabetic control. A severe foot infection was apparent and *(C)* radiographs showed erosive disorganization of the 4th MTP joint. The patient developed a foot infection secondary to the plantar callus that progressed to osteomyelitis of the 4th toe and 4th metatarsal. *(D)* She was treated with parenteral antibiotics and ray resection.

ic therapy 24 to 48 hours presurgery to improve culture accuracy. A diagnosis of osteomyelitis requires that both culture and biopsy studies reveal positive findings, including necrosis, chronic inflammatory infiltrates, and positive isolation of bacteria (180). Resection of infected bone with or without local amputation and concurrent antimicrobial therapy is the most optimal management for osteomyelitis (124, 470). However, the routine need for surgery in this condition has recently been questioned (435). In some cases, based on patient morbidity or preferences, medical therapy alone for osteomyelitis might be warranted (123). If the affected bone has been completely resected or amputated, the infection may be treated as a soft tissue infection. However, if residual bone is present in the wound, the patient will likely require 4 to 8 weeks of antibiotic therapy based on the culture results (119, 287).

Intravenous or oral agents may be used, depending on the microbial isolates and infection severity (123). Antibiotic impregnated bone cement has been advocated for treatment of osteomyelitis, but it should only be used if the bone has been thoroughly debrided and the soft tissue envelope is adequate for wound closure following antibiotic-impregnated bead placement (471, 472). Gentamicin, tobramycin, or vancomycin are typically used in the beads. It is generally recommended that antibiotic beads be removed 2 weeks or so after placement. An alternative to bone cement is absorbable bone graft substitutes mixed with antibiotic powder (473). The pellets are gradually resorbed as the antibiotic is eluted, thus offering the advantage of avoiding a second operation for removal. While widely used in this regard, studies are lacking as to the efficacy of either modality compared with systemic antimicrobial therapy alone. If the infection fails to respond to therapy, the patient should be fully reassessed as previously discussed.

DIABETIC CHARCOT FOOT (NEUROPATHIC OSTEOARTHROPATHY) (Pathway 5)

Charcot foot (neuropathic osteoarthropathy) is a progressive condition characterized by joint dislocation, pathologic fractures, and severe destruction of the pedal architecture. This condition can therefore result in debilitating deformity or even amputation (129, 131, 133-135, 474).

Etiology of Neuropathic Osteoarthropathy

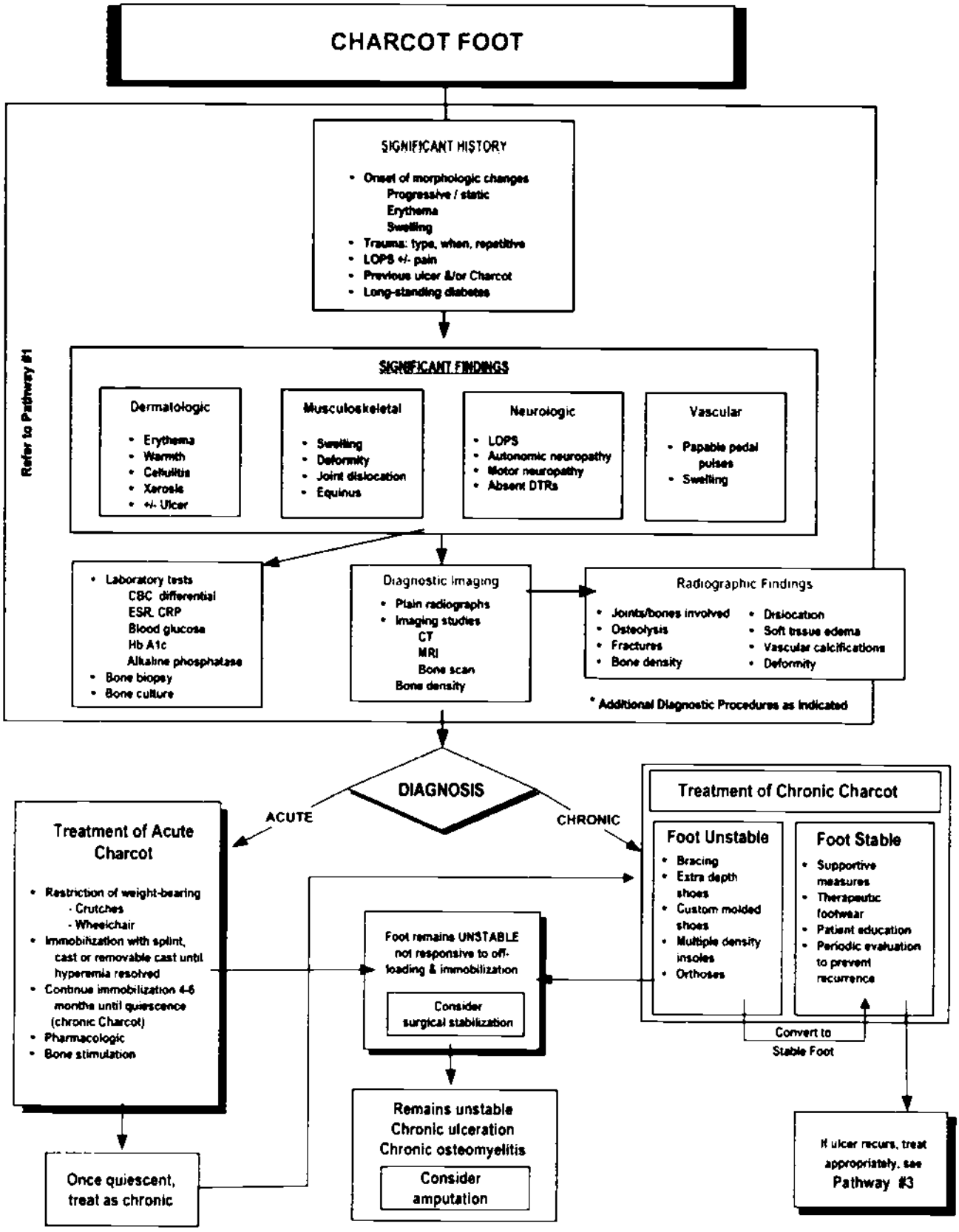
The etiology of Charcot neuroarthropathy is most likely a combination of the effects involved in the neurovascular and neurotraumatic theories (79, 129, 130, 135, 138, 140, 475-477). Trauma superimposed on a severely neuropathic extremity is the most widely accepted theory regarding the development of an acute Charcot foot (478). As a result of associated autonomic neuropathy, blood flow to the foot increases, resulting in osteopenia and attendant weakness of the bone (130, 139, 476, 479, 480). Because of the loss of protective sensation that accompanies peripheral sensory neuropathy, the patient is unaware of the initiating trauma and the profound osseous destruction that often occurs during ambulation. A vicious cycle ensues in which the patient continues to walk on the injured foot, allowing further damage to occur (129, 134, 478, 481) (Fig 12).

There is good evidence suggesting that the effects of neuropathy combined with associated vascular response are involved in the development of Charcot arthropathy (479, 482). Additionally, recent findings suggest that type 1 diabetes may have a greater preponderance of decreased bone density than type 2 diabetes (130, 483). Furthermore, the age of onset for acute Charcot arthropathy appears to be lower for type 1 than type 2 diabetes. Large cohorts of patients or patients with type 2 diabetes alone tend to be in their sixth to seventh decades at presentation, while patients with type 1 diabetes generally develop neuroarthropathy in the fourth to fifth decades (478, 483, 484). Various metabolic factors have also been implicated as potentially etiologic. One recent theory receiving much interest is the role of proinflammatory cytokines and the RANK-L - N-FkB pathway (485, 486). RANK-L, a member of the TNF-a superfamily, causes upregulation of the nuclear transcription factor kB (NF-kB), leading to an increase in osteoclastogenesis and subsequent osteolysis. A decoy receptor for RANK-L, osteoprotegerin (OPG), modulates the activity of RANK-L and NF-kB expression. The excessive inflammation characteristic of the acute Charcot event likely disturbs the normal RANK-L OPG balance and promotes the excessive osteolysis seen in this disorder. Vascular calcification, which is common in these patients, is also linked to this pathway (479, 487, 488).

Clinical Diagnosis of Acute Charcot Arthropathy

The initial diagnosis of acute Charcot arthropathy is often clinical, based on profound unilateral swelling, increased skin temperature, erythema, joint effusion, and bone resorption in an insensate foot (136, 478, 489, 490). These characteristics in the presence of intact skin are often pathognomonic of acute neuroarthropathy. In more than 75% of cases, the patient will present with some degree of pain in an otherwise insensate extremity (135). The diagnosis is complicated by the fact that in some cases, patients first present with a concomitant ulceration, raising questions of potential contiguous osteomyelitis (140, 491, 492).

PATHWAY #5


CHARCOT FOOT
SIGNIFICANT HISTORY
• Onset of morphologic changes
Progressive / static
Erythema
Swelling
• Trauma: type, when, repetitive
• LOPS +/- pain
• Previous ulcer &/or Charcot
• Long-standing diabetes
Refer to Pathway #1
SIGNIFICANT FINDINGS
Dermatologic
• Erythema
• Warmth
• Cellulitis
• Xerosis
• +/- Ulcer
Musculoskeletal
• Swelling
• Deformity
• Joint dislocation
• Equinus
Neurologic
• LOPS
• Autonomic neuropathy
• Motor neuropathy
• Absent DTRs
Vascular
• Papable pedal pulses
• Swelling
• Laboratory tests
CBC differential
ESR, CRP
Blood glucose
Hb A1c
Alkaline phosphatase
• Bone biopsy
• Bone culture
Diagnostic Imaging
• Plain radiographs
• Imaging studies
CT
MRI
Bone scan
Bone density
Radiographic Findings
• Joints/bones involved
• Osteolysis
• Fractures
• Bone density
• Dislocation
• Soft tissue edema
• Vascular calcifications
• Deformity
* Additional Diagnostic Procedures as indicated
DIAGNOSIS
ACUTE
CHRONIC
Treatment of Acute Charcot
• Restriction of weight-bearing
- Crutches
- Wheelchair
• Immobilization with splint, cast or removable cast until hyperemia resolved
• Continue immobilization 4-6 months until quiescence (chronic Charcot)
• Pharmacologic
• Bone stimulation
Once quiescent, treat as chronic
Foot remains UNSTABLE not responsive to off-loading & immobilization
Consider surgical stabilization
Remains unstable
Chronic ulceration
Chronic osteomyelitis
Consider amputation
Treatment of Chronic Charcot
Foot Unstable
• Bracing
• Extra depth shoes
• Custom molded shoes
• Multiple density insoles
• Orthoses
Foot Stable
• Supportive measures
• Therapeutic footwear
• Patient education
• Periodic evaluation to prevent recurrence
Convert to Stable Foot
If ulcer recurs, treat appropriately, see Pathway #3

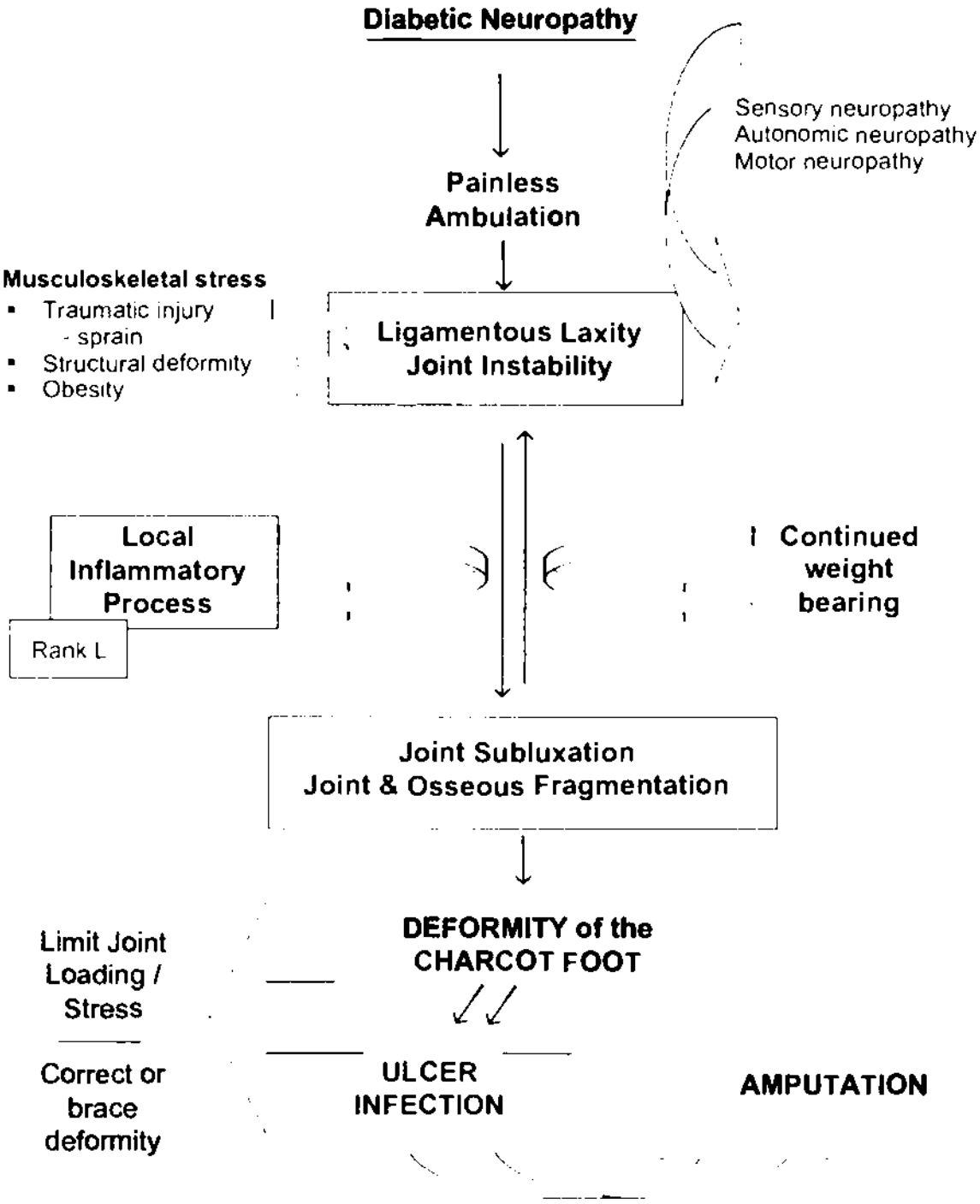


Figure 12 Diabetic neuroarthropathy, or Charcot foot, is believed to be a neurologically-mediated complication of diabetes, with the development modified by musculoskeletal stress. The result is osseous fragmentation and joint subluxation with often significant morphologic changes in the architecture of the foot. Complications of the Charcot foot include ulceration under areas of bony prominence and potential amputation often related to infection/osteomyelitis that develops adjacent to the area of ulceration.

If the patient presents with a warm, edematous, erythematous, insensate foot, plain radiographs are invaluable in ascertaining presence of osteoarthropathy (493, 494). In most cases, no further imaging studies are required to make the correct diagnosis. With a concomitant wound, it may be difficult to differentiate acute Charcot arthropathy from osteomyelitis using plain radiographs alone (133, 183). Additional laboratory studies may prove useful in arriving at a correct diagnosis. The white blood cell count (WBC) with a left shift will often be elevated in acute osteomyelitis, although this can be blunted in diabetic patients (453). While the erythrocyte sedimentation rate and C-reactive protein level may also be elevated in acute infection, they often respond similarly to any inflammatory process and are therefore nonspecific. Bone biopsy, when indicated, is the most specific method for distinguishing osteomyelitis from osteoarthropathy in these circumstances. A biopsy consisting of multiple shards of bone and soft tissue embedded in the deep layers of synovium is pathognomonic for neuropathic osteoarthropathy (495).

Technetium bone scans are generally nonspecific in assisting in the differentiation between osteomyelitis and acute Charcot arthropathy (179, 185). Indium scanning, while more expensive, has been shown to be more specific (179, 193, 496). Additional studies to aid in differentiating osteoarthropathy from osteomyelitis include bone scans utilizing Tc HMPAO-labeled white blood cells, MRI, and PET scanning (183, 186, 190, 207).

Other serologic markers can be helpful for the diagnosis of acute Charcot osteoarthropathy. A marker for increased osteoclastic activity, ICPT (carboxyterminal telopeptide of type I collagen), has been shown to be elevated but occurs without increased levels of procollagen carboxyterminal propeptide (PICP), a marker for osteoblastic activity (497-499). Nonetheless, the most important diagnostic aid in this situation remains a high index of clinical suspicion when a neuropathic patient presents with a swollen or deformed foot (478, 493, 494).

Classification of Charcot Arthropathy

The most common classification system of Charcot arthropathy—the Eichenholtz classification system—is based on radiographic appearance as well as physiologic stages of the process. It divides the condition into three stages—developmental, coalescent, and reconstructive (495). The developmental stage is characterized by significant soft tissue swelling, osteochondral fragmentation, or joint dislocation of varying degrees. The coalescent stage is marked by a reduction in soft tissue swelling, bone callus proliferation, and consolidation of fractures. The reconstructive stage is denoted by bony ankylosis and hypertrophic proliferation.

Radiologically, the Eichenholtz system is very descriptive and useful, but its practical applicability has limitations. In clinical practice, the initial stage is considered active, while the coalescent and reconstructive stages are considered quiescent or reparative. More recently, several authors have proposed an earlier stage 0 that corresponds to the initial inflammatory period following injury but prior to the development of characteristic bony radiographic changes (500-503). This prodromal period might be considered a "Charcot *in situ*" stage. Diagnosis of the condition during this period, in which no deformity has yet developed, could ostensibly arrest further progression of the destructive inflammatory process (494).

Another popular classification system is based on five anatomic sites of involvement but does not describe disease activity (129, 136) (Fig. 13). Several other classification schemes are described in the literature, but none has been found to be superior or predictive of outcome (500, 504-506).

Management of Acute Charcot Neuroarthropathy

Immobilization and stress reduction are the mainstays of treatment for acute Charcot arthropathy (129, 131, 135, 136, 478, 507, 508). Many clinicians advocate complete non-weightbearing through the use of crutches or other assistive modalities during the initial acute period. While this is an accepted form of treatment, three-point gait may in fact increase pressure to the contralateral limb, thereby predisposing it to repetitive stress and ulceration or neuropathic fracture (509). A short leg plaster or fiberglass non-weightbearing cast can additionally be used for acute Charcot events, even in patients with noninfected ulcerations (129, 135, 481). A soft compressive dressing in concert with a removable cast walker or pneumatic walking brace can also be used effectively in this regard (136, 139). Some centers prefer to initially apply a weightbearing total contact cast in the management of acute osteoarthropathy (135, 140, 493, 510-512). These ambulatory total contact casts should be changed at least every 1 to 2 weeks to adjust to limb volume changes as the edema decreases.

Following the initial period of off-loading, reductions in skin temperature and edema indicate the stage of quiescence, at which point the patient progresses into the postacute phase of treatment. Progression to protected weightbearing is permitted, usually with the aid of an assistive device. Through the use of appropriately applied total contact casts or other off-loading modalities (e.g., fixed ankle walker, bivalved casts, total contact prosthetic walkers,

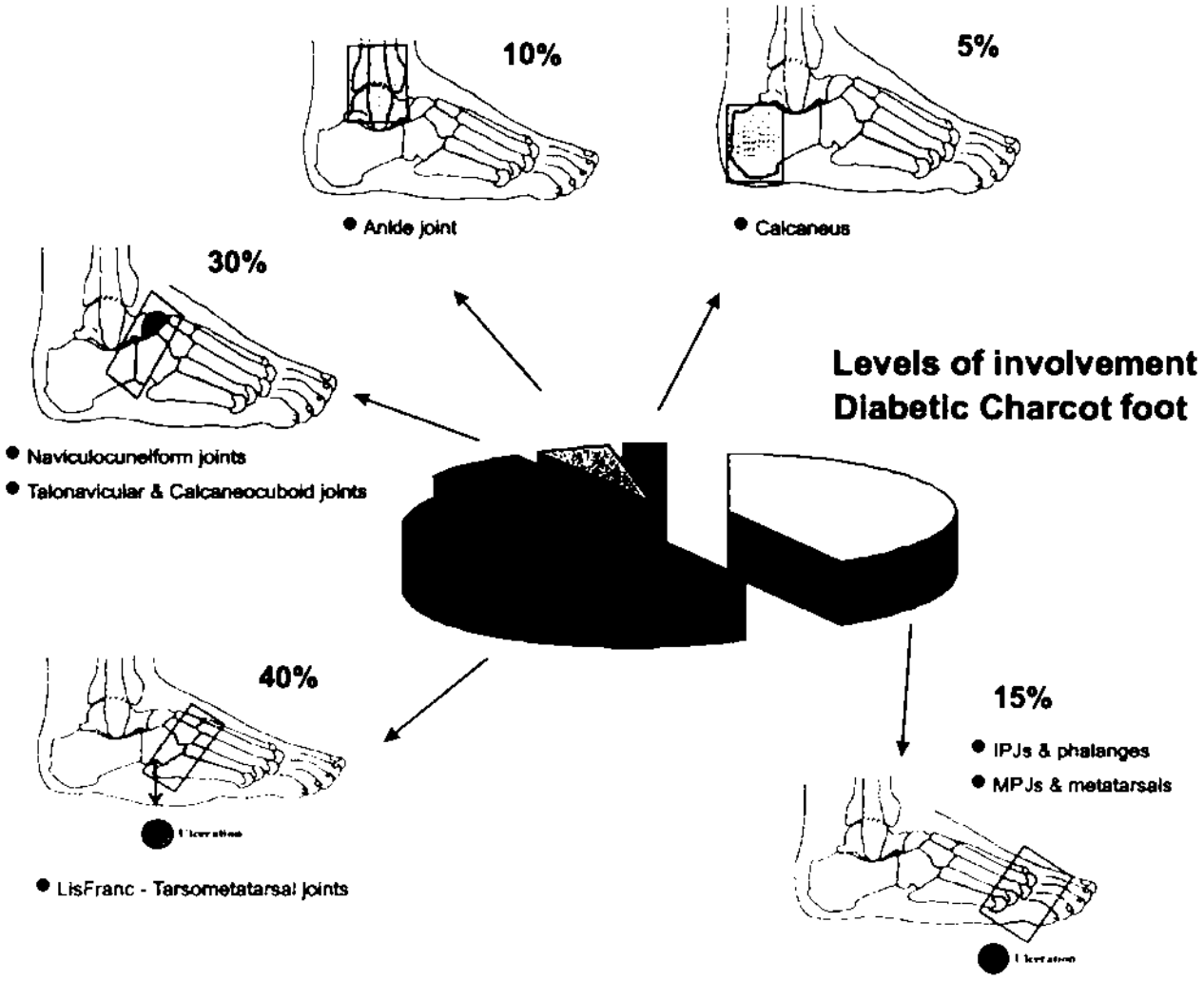


Figure 13 Diabetic neuroarthropathy may be classified according to the anatomic location of joint involvement. The relative percentage of frequency of involvement is given. (Adapted from Sanders LJ and Frykberg RG. *The High Risk Foot in Diabetes Mellitus*, p108. Churchill Livingstone, New York, 1991)

patellar tendon bearing braces), most patients may safely ambulate while bony consolidation of fractures progresses (129, 135, 477, 478). Charcot restraint orthotic walkers (CROW) or other similar total contact prosthetic walkers have gained acceptance as useful protective modalities for the initial period of weightbearing (513-515). A more readily available option is a pneumatic walking brace or similar removable cast walker that might incorporate a cushioned foot bed or insole. These "instant total contact casts" are made nonremovable by simply applying tape or a fiberglass cast roll around the body of the walker to help encourage compliance (50, 516).

The mean time of rest and immobilization (casting followed by removable cast walker) prior to return to permanent footwear is approximately 4 to 6 months (133-135, 474, 478, 493). Custom full-length inserts and comfort or extra-depth shoes should be worn when protective bracing is no longer required (136, 138, 513). Moderately unstable ankles will benefit from an ankle foot orthosis (AFO) and high-top therapeutic shoe, while a severely unstable or maligned rearfoot will require a patellar tendon-bearing (PTB) brace incorporated into a custom shoe (493, 517, 518). The PTB brace has reportedly decreased mean rearfoot peak forces by at least 32% (517).

There is recent interest in the adjunctive use of bisphosphonate therapy in acute Charcot arthropathy to help expedite conversion of the acute process to the quiescent, reparative stage (519-521). These pyrophosphate analogs are potent inhibitors of osteoclastic bone resorption and are widely used in the treatment of osteoporosis, Paget's disease, and reflex sympathetic dystrophy syndrome (50, 130). One randomized trial in the UK compared the use of a sin-

gle intravenous infusion of pamidronate with the use of saline infusion (498). The treatment group had significant declines in temperature and bone turnover markers (deoxypyridinoline crosslinks and bone specific alkaline phosphatase) in subsequent weeks compared with the control group, but no differences in clinical or radiographic outcomes were reported. A small trial comparing 6 months of oral alendronate plus off-loading with standard off-loading alone in acute Charcot patients found that the study group had significant reductions in ICTP and hydroxyproline, both of which are markers of bone resorption and increased foot bone density (499); no differences in clinical outcomes were noted.

Similarly, electrical bone growth stimulation has been applied to the management of acute neuroarthropathy to promote rapid consolidation of fractures (522-524). Low-intensity pulsed ultrasound (LIPUS) has also been suggested as a useful adjunct in promoting healing of Charcot fractures (525). Although promising in theory, none of these adjunctive treatments have yet been conclusively proven effective through large prospective multicenter, randomized trials.

Surgical Management of Charcot Osteoarthropathy

Reconstructive surgery in acute Charcot may be considered if a deformity or instability exists that cannot effectively be controlled or accommodated by immobilization and off-loading (136, 140, 478, 500, 510, 511, 526). If the neuroarthropathy is identified in its early stages and non-weightbearing is instituted, surgery is usually unnecessary. According to consensus opinion, surgery in the acute stage is generally nonadvisable due to the extreme hyperemia, osteopenia, and edema present (131, 132, 134, 135, 477, 511, 527, 528). However, surgical intervention during the acute phase may be considered in the presence of acute subluxation without osteochondral fragmentation (509, 529). One small series reported successful arthrodeses rates with preserved foot function in patients with acute arthropathy of the midfoot (530). Nevertheless, this aggressive surgical approach needs confirmation through larger comparative trials prior to its adoption in the routine management of the acute Charcot foot.

As few as 4% to as many as 51% of patients presenting to tertiary centers are reported to undergo surgical procedures for Charcot deformities (474, 527, 528). However, such centers often receive chronic cases from multiple referral

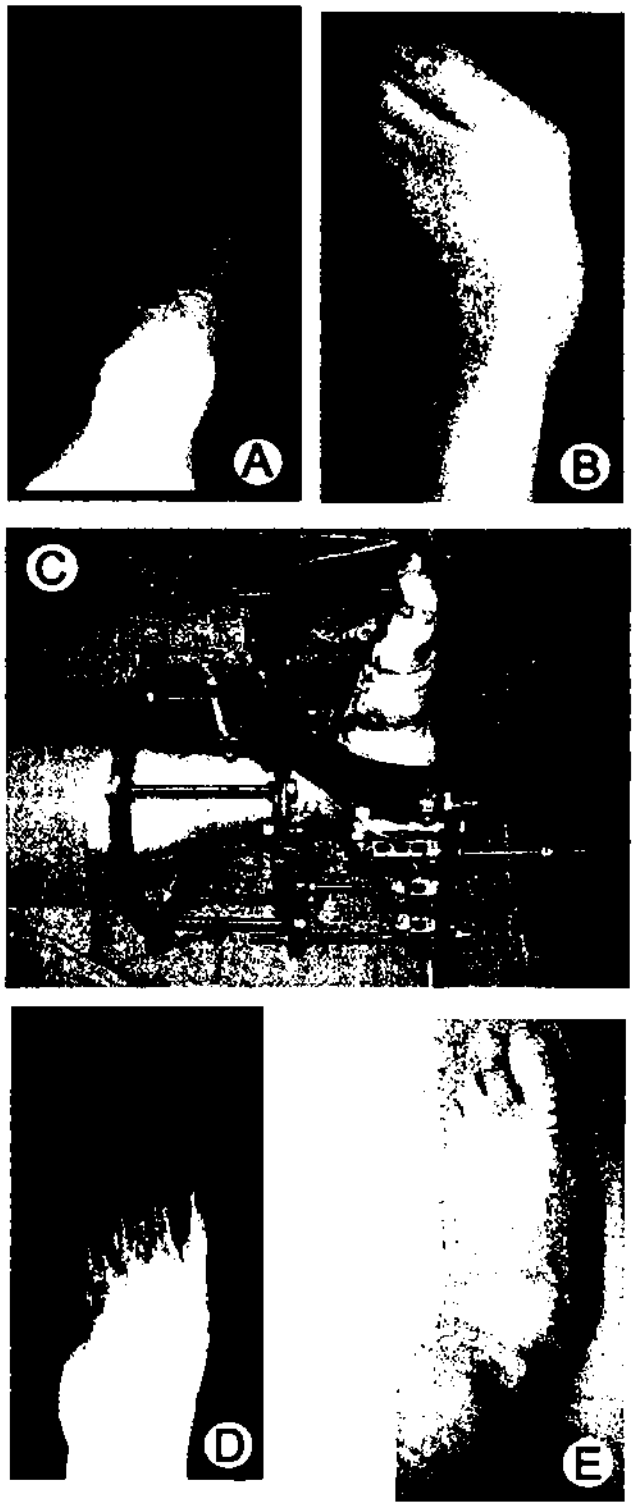


Figure 14 Severe midfoot collapse due to Charcot neuroarthropathy as shown *(A)* on radiograph and *(B)* in clinical presentation. *(C)* This patient was treated with tarsometatarsal arthrodesis using a multiplanar circular external fixator. *(D)* A postoperative radiograph and *(E)* clinical photograph at 4 months postoperative are shown here.

sources and with various degrees of deformity present, therefore, their rate of operation on these patients does not reflect the true incidence or need for such treatment in the community. A recent review of one center's experience with midfoot neuroarthropathy in 198 patients (201 feet) indicated that more than half of these patients could be successfully managed without surgery (510). Hence, large population-based studies are needed to assess the need for surgical intervention and compare the efficacy of various conservative therapies (474, 493, 520).

The goal of any surgery on the acute or chronic Charcot foot is to create a stable, plantigrade foot that may be appropriately accommodated (140, 478, 510, 530, 531). Most operations on chronic Charcot feet consist of exostectomies for prominent plantar ("rocker-bottom") deformities causing ulceration when the remainder of the foot is stable (135, 505, 511, 532) (Fig. 14). However, more complex arthrodesis procedures are performed with increasing frequency and success, often using circular external fixation or intramedullary nails (140, 478, 526, 531, 533-537). These include isolated or multiple midfoot (Fig. 15) or hindfoot fusions, triple arthrodeses, tibiocalcaneal fusions (Fig. 16), and ankle fusions (538-542).

Following surgery, patients are immobilized until skin temperatures and postoperative edema normalize. As with patients treated nonsurgically, after prolonged cast immobi-

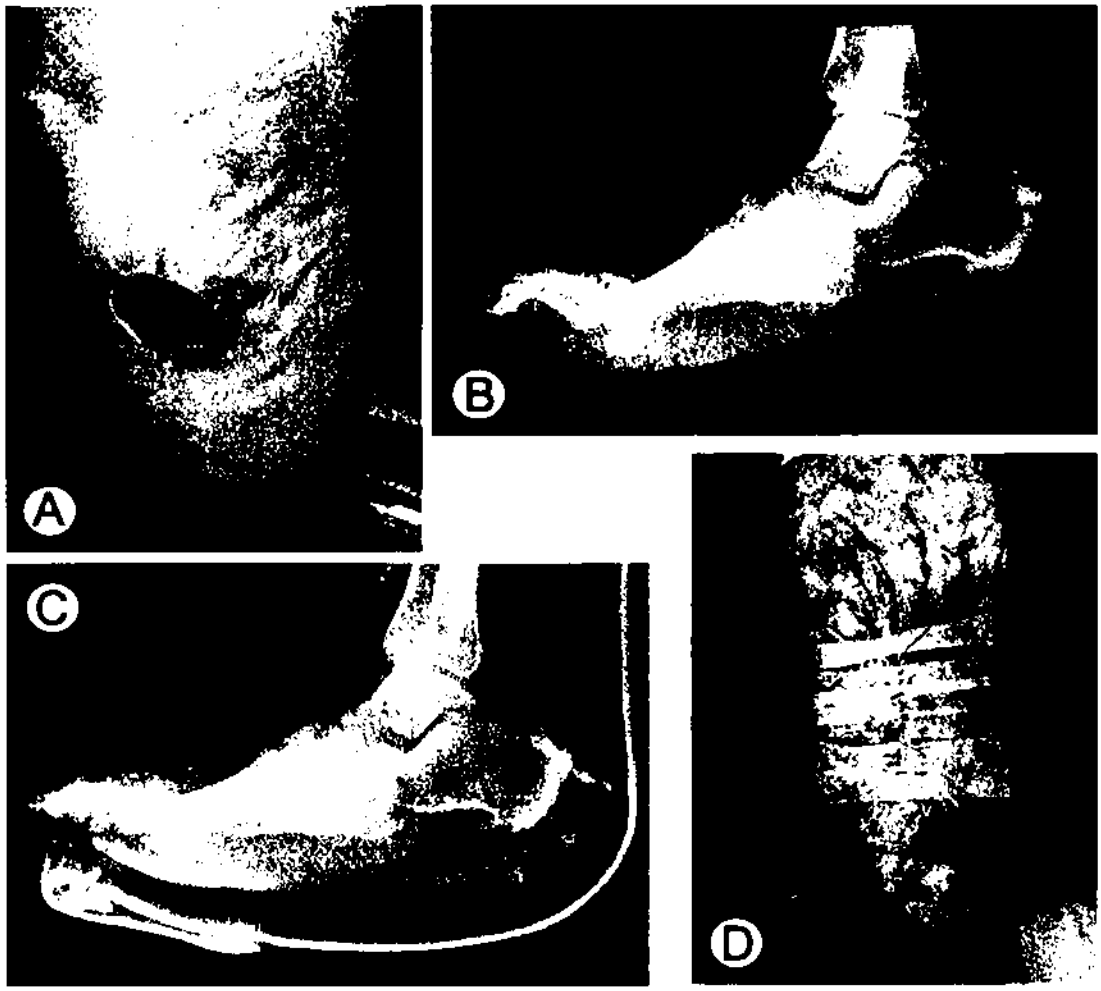


Figure 15 *(A)* This Charcot patient presented with a recalcitrant ulceration below an area of bony prominence, *(B)* as shown on radiograph. Surgical management consisted of excision of the ulcer, *(C)* exostectomy, and *(D)* primary wound closure.

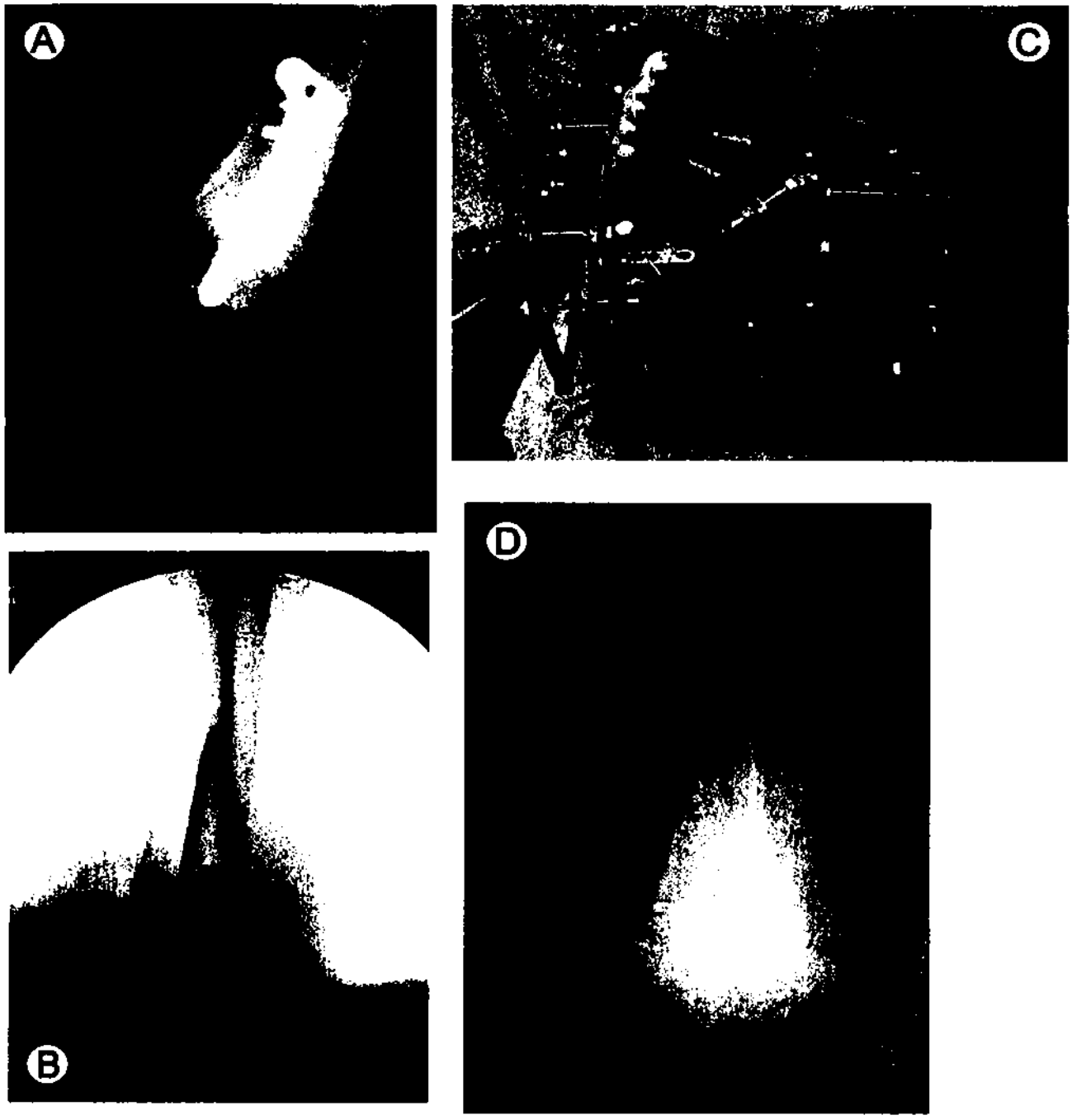
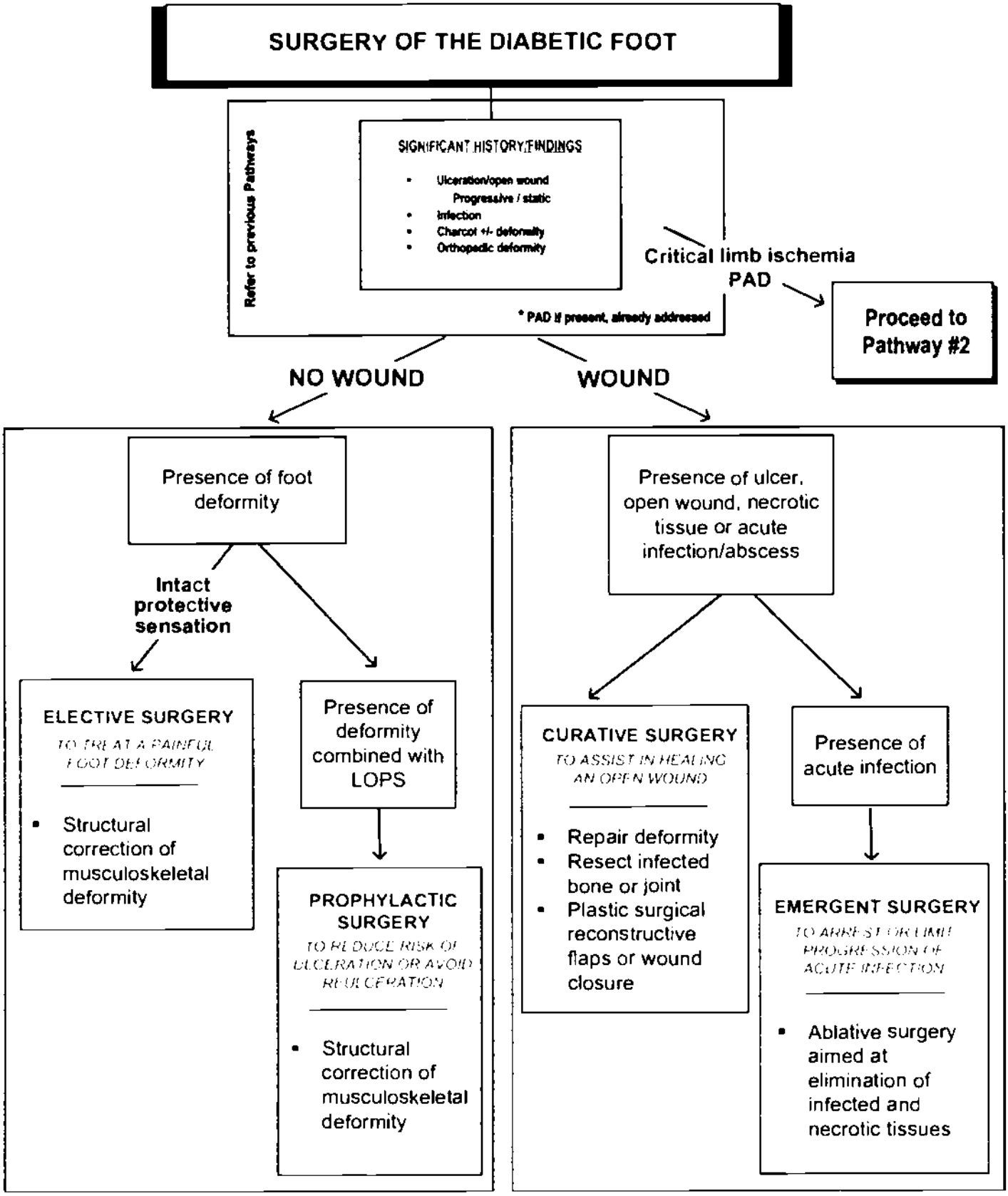


Figure 16 This neuropathic diabetic patient sustained an ankle fracture and underwent open reduction internal fixation. *(A)* At 3 months postoperatively, radiographs revealed Charcot disorganization and loss of reduction. *(B)* The patient was brought back to surgery for talectomy and tibiocalcaneal fusion, shown in this intraoperative image. *(C)* A multiplanar circular external fixator was applied to accomplish the arthrodesis procedure. *(D)* Radiograph shows union at the arthrodesis site at 5 months postoperative.

PATHWAY #6


SURGERY OF THE DIABETIC FOOT
Refer to previous Pathways
SIGNIFICANT HISTORY/FINDINGS
Ulceration/open wound
Progressive / static
Infection
Charcot +/- deformity
Orthopedic deformity
* PAD if present, already addressed
Critical limb ischemia
PAD
Proceed to Pathway #2
NO WOUND
WOUND
Presence of foot deformity
Intact protective sensation
ELECTIVE SURGERY
TO TREAT A PAINFUL FOOT DEFORMITY
Structural correction of musculoskeletal deformity
Presence of deformity combined with LOPS
PROPHYLACTIC SURGERY
TO REDUCE RISK OF ULCERATION OR AVOID REULCERATION
Structural correction of musculoskeletal deformity
Presence of ulcer, open wound, necrotic tissue or acute infection/abscess
CURATIVE SURGERY
TO ASSIST IN HEALING AN OPEN WOUND
Repair deformity
Resect infected bone or joint
Plastic surgical reconstructive flaps or wound closure
Presence of acute infection
EMERGENT SURGERY
TO ARREST OR LIMIT PROGRESSION OF ACUTE INFECTION
Ablative surgery aimed at elimination of infected and necrotic tissues

lization patients transition to a removable cast walker, followed by permanent prescription footwear or bracing (135, 543). Mean time from surgery to therapeutic shoes has been reported to be about 27 weeks (7 months) (135, 140, 530). Careful patient selection and management is the rule with these complex diabetic cases, since amputation can be a complication of failed surgical procedures (138, 474, 511, 527, 528, 533).

SURGICAL MANAGEMENT OF THE DIABETIC FOOT (Pathway 6)

Surgical management of the diabetic lower extremity can be a daunting task, but with appropriate patient and procedural selection, successful resolution of ulceration and correction of inciting pathology may be achieved (270). Diabetic foot surgery performed in the absence of critical limb ischemia is based on three fundamental variables: presence or absence of neuropathy (LOPS), presence or absence of an open wound, and presence or absence of acute limb-threatening infection (270).

Classifications of Surgery

Surgical intervention has previously been classified as curative, ablative, or elective (100, 271). More recently, a modification of this scheme has been proposed that encompasses more procedures and a broader spectrum of patients (270), as follows:

Class I: *Elective* foot surgery (performed to treat a painful deformity in a patient without loss of protective sensation)

Class II: *Prophylactic* foot surgery (performed to reduce risk of ulceration or re-ulceration in patients with loss of protective sensation but without open wound)

Class III: *Curative* foot surgery (performed to assist in healing an open wound)

Class IV: *Emergent* foot surgery (performed to arrest or limit progression of acute infection)

For any of these classes, the presence of critical ischemia should prompt a vascular surgical evaluation to consider the urgency of the procedure and possible revascularization prior to or subsequent to the procedure.

Elective Surgery. The goal of elective surgery is to relieve the pain associated with particular deformities such as hammertoes, bunions, and bone spurs in patients without peripheral sensory neuropathy and at low risk for ulceration. Essentially any type of reconstructive foot operation can fall into this category, including rearfoot and ankle arthrodeses as well as Achilles tendon lengthenings (544). However, amputations are generally not performed as elective procedures, except in cases of severe deformity or instability resulting from prior injury or neuromuscular diseases.

Prophylactic Surgery. Prophylactic procedures are indicated to prevent ulceration from occurring or recurring in patients with neuropathy, including those with a past history of ulceration (but without active ulceration). These pro-

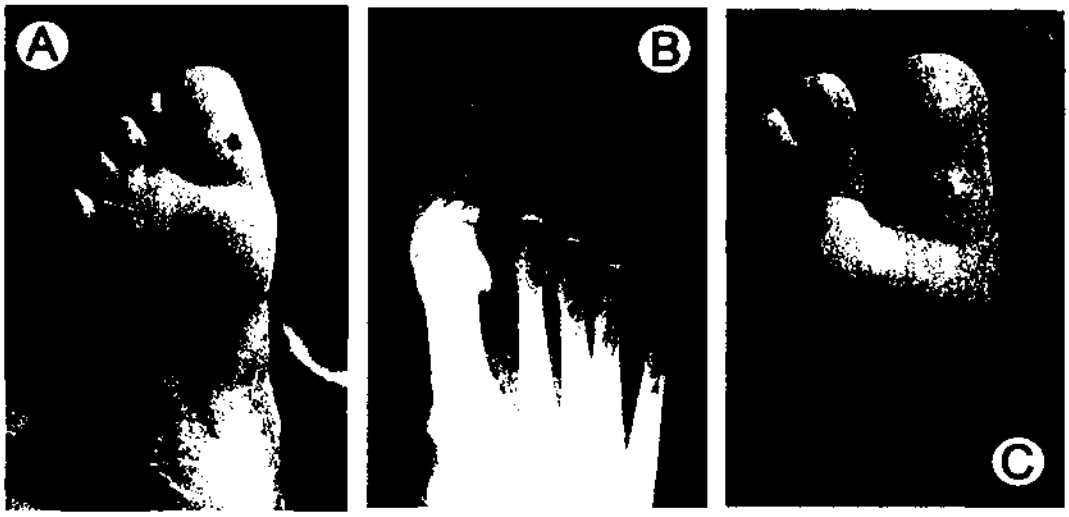


Figure 17 This patient has a *(A)* hallux ulceration related to the loss of normal joint mobility that is often seen in diabetes. During weightbearing, this clinical hallux limitus/rigidus places untoward pressure at the interphalangeal joint. *(B)* Radiograph illustrates planned resection arthroplasty of the 1st MTP joint. *(C)* The ulcer subsequently healed during the immediate postoperative period.

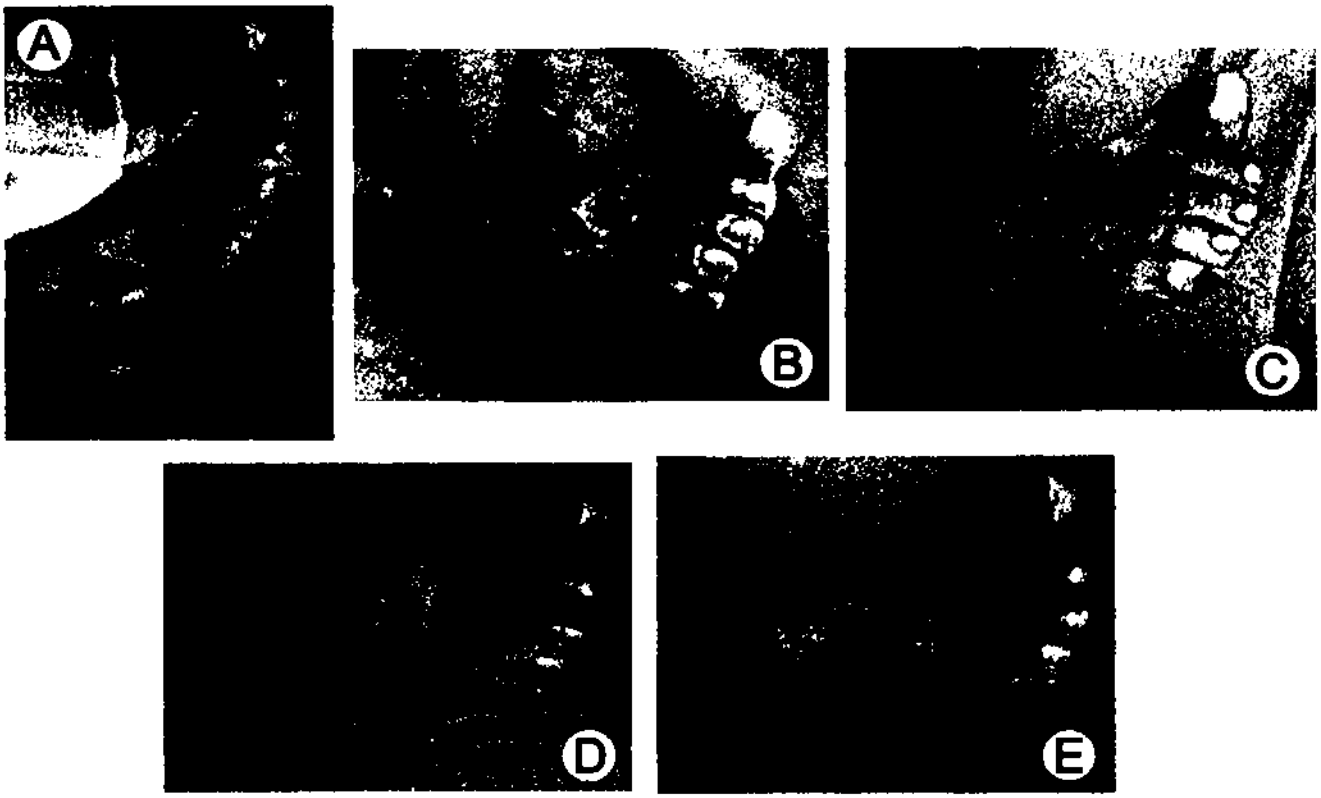


Figure 18 This diabetic patient presented with *(A)* a bullous abscess with peripheral cellulitis. Initial treatment included debridement, revealing *(B)* extensive necrosis. Local wound care allowed for *(C)* development of a healthy granulating wound base, followed by application of a split-thickness skin graft. *(D)* Foot at 3 weeks postoperative and *(E)* later at 7 weeks shows healing of this potential limb-threatening infection.

cedures involve correcting an underlying tendon, bone, or joint deformity. Many reconstructive procedures in this category would be considered elective if the patient did not have sensory neuropathy and a higher risk for ulceration (270).

Curative Surgery. Curative procedures are performed to effect healing of a nonhealing ulcer or a chronically recurring ulcer when off-loading and standard wound care techniques are not effective (100, 271). These include multiple surgical procedures aimed at removing areas of chronically increased peak pressure as well as procedures for resecting infected bone or joints as an alternative to partial foot amputation (30, 54, 77, 173). Operations frequently performed in this regard include exostectomy, digital arthroplasty, sesamoidectomy, single or multiple metatarsal head resection, joint resection (Fig 17), or partial calcanectomy (272, 273, 545-557). Some surgeons have proposed the advantages of combining plastic surgical flaps and skin grafts with these procedures to expedite wound healing and provide for more durable soft tissue coverage (54, 173, 558-563).

Emergent Surgery. Emergent procedures are performed to stop the progression of infection. Such ablative surgical intervention, most often involving amputation, requires removal of all infected and necrotic tissue to the level of viable soft tissue and bone (Fig 18). When possible, they are also performed in a manner to allow for the maximum function from the remaining portion of the limb (77, 272).

Wounds may be closed primarily if the surgeon is confident no infection or ischemic tissue remains and if enough soft tissue is available. Other wounds may initially be packed open, requiring well controlled and frequently assessed wound care, with delayed primary closure or closure by secondary intention. Another popular option is negative pressure wound therapy using a V.A.C.® device, which has been found to significantly expedite granulation tissue formation and healing of open partial-foot amputations (410). Mechanical assistance using a variety of skin-stretching devices are the surgeon's option and may help attain delayed primary closure for some wounds (564, 565). More often, V.A.C.® therapy is used to manage large or

deeper wounds until delayed primary closure can be achieved (393, 404, 566). Other approaches include plastic surgical techniques utilizing split and full-thickness skin grafts and a variety of flaps (173, 558, 559, 562, 563).

Each patient must be assessed for the selection of the surgical management that best meets his or her needs. Secondary wound healing with or without adjunctive wound therapies may still be the best choice for some patients. Pathway 6 lists the various types of surgical procedures commonly used for managing diabetic foot complications.

In the carefully selected patient, prophylactic or elective surgical correction of structural deformities that cannot be accommodated by therapeutic footwear can serve to reduce high pressure areas and ultimately prevent ulcer recurrence (255, 270, 271, 273, 545, 547, 548, 550, 567-569). Many of the procedures mentioned in the discussion on curative surgery would also be indicated in the elective prophylactic reconstruction of the nonulcerated foot. Common operations performed in this regard include the correction of hammertoes, bunions, and various exostoses of the foot. Tendo-achilles lengthening procedures are often performed as ancillary procedures to reduce forefoot pressures that contribute to recurrent ulcerations (55, 58, 61, 568, 570).

Once healed, these surgical patients are at high risk for future ulceration and require appropriate ongoing care consistent with those prevention strategies already discussed (30, 163, 173, 253, 255, 256, 571).

Amputation Considerations

Amputation, a well recognized consequence in the management of the diabetic foot, is performed for a variety of reasons and can be characterized as curative or emergent. Indications for amputation include removal of gangrenous or infected tissue, often to control or arrest the spread of infection; removal of portions of the foot that frequently

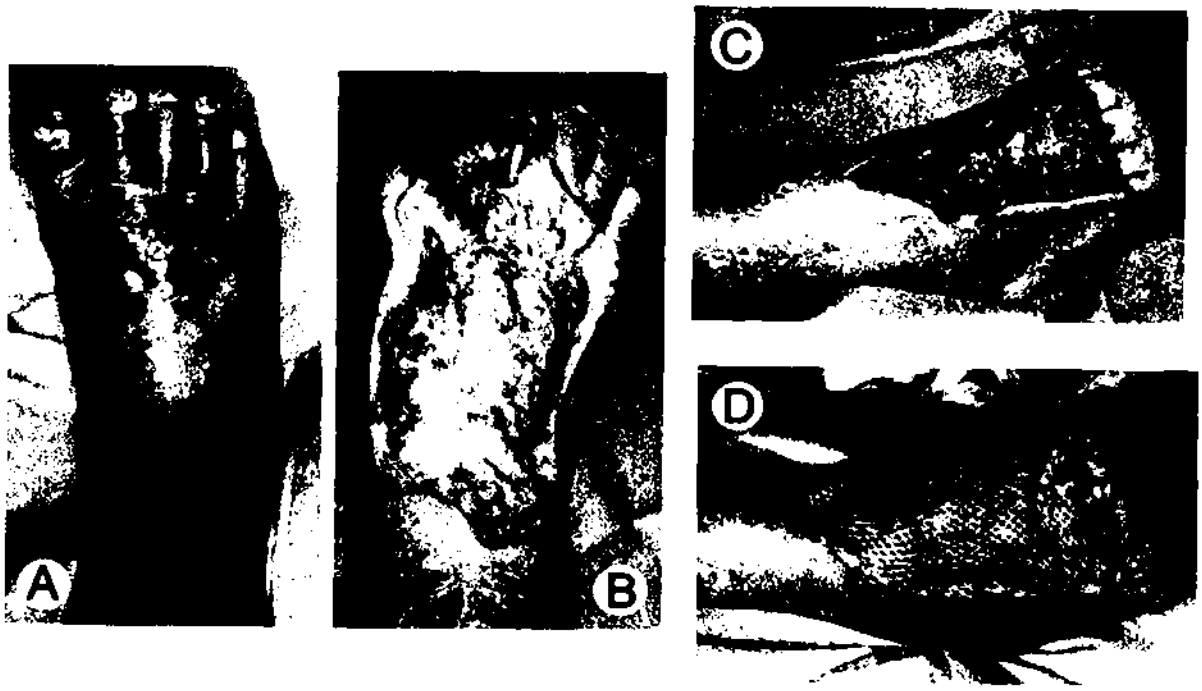


Figure 19 *(A)* This 65-year-old male presented with a severe limb-threatening infection with deep necrosis of the forefoot. *(B)* He underwent incision and drainage with wound debridement including tendons on the dorsum of the foot and hallux amputation. *(C)* This was later converted to a transmetatarsal amputation with continuing dorsal wound care. *(D)* Good granular response allowed for later placement of a split-thickness skin graft.

Amputation Prevention Program

1. Podiatric Foot Care
   - Regular visits, examinations, and footcare
   - Risk assessment
   - Early detection and treatment of new lesions
2. Protective Shoes
   - Adequate room to protect from injury
   - Well cushioned walking sneakers
   - Extra depth or custom-molded shoes
   - Shoe modifications as needed
3. Pressure Reduction
   - Cushioned multiple density insoles
   - Custom orthotic devices or braces
   - Padded hosiery
   - Pressure measurements - computerized or pressure sensitive mat
4. Prophylactic Surgery
   - Correct structural deformity: hammertoes, bunion, exostoses
   - Prevent recurrent ulcers over deformities
5. Preventive Education
   - Patient education - need for daily inspection & necessity for early intervention
   - Physician education - significance of foot lesions, importance of regular foot examinations, & current concepts of diabetic foot management

Figure 20 An effective amputation prevention program includes regular podiatric foot care, protective shoes, and pressure reduction as well as prophylactic foot surgery combined with both patient and physician education programs.

ulcerate, and creation of a functional unit that can accommodate either normal or modified shoe gear.

In general, the amputation should be performed at a level that balances preservation of limb length and function with the capacity for the surgical site to heal primarily (572-575). Although this concept is intuitive, several factors may influence the selection of the level of amputation. It is well recognized that energy expenditure increases as the level of amputation becomes more proximal (576, 577). Simple tasks such as ambulating to the bathroom or other activities of daily living become increasingly more difficult for the patient commensurate with the level of amputation. In addition, patients with more proximal amputations are far more difficult to rehabilitate to a functional community or household ambulation level.

Recent advances in vascular surgery have enabled the level of amputation to become more distal or "limb sparing" (77, 166, 173). The capacity to re-establish distal perfusion with endovascular techniques or bypass surgery to the distal tibial, peroneal, and pedal arteries has greatly enhanced the potential for more distal amputation (306, 307). In most circumstances, patients should be given the opportunity for vascular surgical intervention prior to definitive amputation so that the most distal level of amputation can be successful.

Goals of Selection of Amputation Level

The selection of the level of amputation should incorporate the following goals:

- Creation of a distal stump that can be easily accommodated by a shoe insert, orthotic device, modified shoe gear, or prosthesis
- Creation of a distal stump that is durable and unlikely to break down from exogenous pressure

- Creation of a distal stump that will not cause muscle or other dynamic imbalances. Examples include medial migration of the lesser digits after 1st MTP joint disarticulation, varus deformity and lateral overload after 5th ray resection; and equinus contracture after transmetatarsal or Chopart amputation.
- Healing with primary intention. In most instances it is advisable to perform an amputation at the most distal level that would allow for primary healing. Unfortunately, there are few objective tests or strategies that can consistently and reliably predict healing potential.

The cost of failure of an amputation at a given level is multifaceted. Increased costs associated with a more proximal level of amputation involve hospitalization, surgical procedures, prostheses, and psychological effects on the patient. It is difficult to stratify the importance of each of these parameters; each should be given consideration before any amputation.

Curative Versus Emergent Surgery

Although it is usually preferable to perform the amputation in an elective, controlled environment, this is not always possible or prudent. When infection, necrotizing fasciitis, or gas gangrene are present, an open amputation may need to be done on an emergent basis (150, 578) (Fig. 19). Prior to the definitive amputation, residual infection and ischemia can be addressed. When performed under elective and stable conditions, the amputation should be fashioned so that it is curative. This generally means that the primary incision site can be closed primarily and that no further surgery is anticipated. With primary or even secondary wound healing, the patient can then be fitted for appropriate shoe gear or walking aids. When performed under emergent conditions, the procedure should usually be done proximal to the level of all necrotic tissue. It is anticipated that additional surgical procedures will be necessary to attain a closed wound and a stump that can accommodate shoes, custom inserts, or a prosthesis (575).

Amputation prevention strategies are identical to those employed for preventing ulceration and have previously been discussed (Fig. 20). Prevention is best facilitated through a multidisciplinary approach that focuses not only on the aggressive management of diabetic foot lesions or infections, but also on periodic screening of all diabetic patients, regular surveillance of high-risk persons, education on risk factors and daily foot care, and provision of therapeutic footwear for patients with a history of ulceration, ischemia, or structural deformities (163, 251, 255, 301).

CONCLUSION

Ulceration, infection, gangrene, and lower extremity amputation are complications often encountered in patients with diabetes mellitus. These complications frequently result in extensive morbidity, repeated hospitalizations, and mortality. They take a tremendous toll on the patient's physical and mental well-being as well as impose a substantial economic burden, often removing the patient from the workforce and placing a financial drain on the health care system. According to a recent study, the mean annual cost of treating an uninfected ulcer was $9,306, while the cost of treating an ulcer with osteomyelitis exceeded $45,000 (579). Indeed, the estimated annual cost of treating diabetic peripheral neuropathy with its complications (including ulceration and amputation) ranges from $1.5 and $13 billion (40, 579).

Not all diabetic foot complications can be prevented, but it is possible to dramatically reduce their incidence through appropriate management and prevention programs. The multidisciplinary team approach to diabetic foot disorders has been demonstrated as the optimal method to achieve favorable rates of limb salvage in the high-risk diabetic patient (165, 166, 173, 253, 278, 300, 458, 459). Foot care programs emphasizing preventive management can reduce the incidence of foot ulceration through modification of self-care practices, appropriate evaluation of risk factors, and formulation of treatment protocols aimed at early intervention, limb preservation, and prevention of new lesions. The foot and ankle surgeon should play an integral role in this scheme, providing ongoing surveillance, education, and management of new or impending lesions (48, 255, 296). A significant reduction in both major and minor diabetic limb amputations is certainly attainable if clinicians embrace these principles and incorporate them into daily patient care.

Appendix 1 p1

Diabetic Foot Evaluation

Patient

Chart #

Age

Date

Mark areas of callus, ulcer or pre-ulcer erythema, swelling, tenderness or deformity

Medications

Type 1
Type 2
Rx - Insulin
- Incretin
- Oral Hypoglycemic
- Diet

Diabetes duration

Attending MD

Height

Weight

BP

HbA1C

History of

- Foot Ulcer
- Infection
- Amputation
- Revascularization
- Renal Disease
- CAD
- Stroke
- Tobacco
- Alcohol

- Paresthesia/Tingling
- Numbness
- Burning
- Sharp Pain
- Night Pain
- Muscle Weakness
- Gait Difficulties
- Claudication

Shoes

Skin:

- Turgor
- Color
- Temperature
- Texture

Lesions
- Fissures
- Dry
- Calloses
- Ulcers

Nails

Musculoskeletal

- Joint Flexibility
- Deformities
- Lack Sides of
- High Pressure
- Gait assessment

Appendix 1 p2

Neurologic Exam

Sensory - Semmes Weinstein Monofilament
Ability to detect 5.07 or 10 gm Monofilament + or -

Right

Left

Deep Tendon Reflexes (+Present, -Absent)

	Right	Left
Patella		
Achilles		

Vascular Exam

	Right		Left		Pulse Exam
Pulses					
Dorsalis Pedis	0 +1 +2 +3		0 +1 +2 +3		[illegible]
Posterior Tibia	0 +1 +2 +3		0 +1 +2 +3		[illegible]
Elevation Rubor	Absent	Present	Absent	Present	
Dependent Rubor	Absent	Present	Absent	Present	
Capillary Filling Time	+1 [illegible] +3		+1 [illegible] +3		
Edema	Absent				

Risk Status

- 0 No Sensory Neuropathy, No PAD
  - Negative Hx of Foot Ulcer
- I Neuropathy (LOPS), No PAD, No Deformity
- II Sensory Neuropathy + PAD & or
  - Foot Deformity
- III Previous Foot Ulcer or Amputation
  - Prior Ulceration & or Amputation
  - Charcot Deformity [illegible]

Recommended Management

- Periodic Foot Care
- Extra Depth Shoes
- Multiple Density Inserts, MDI, Orthotics
- Bracing
- Vascular Testing, Doppler
- Consultation
- Other, Diabetic Education

Examiner

Date

Appendix 2: Definitions

Amputation: The complete or partial removal of a limb or body appendage by surgical or traumatic means. A minor amputation is defined as occurring distal or through the tarsometatarsal joint (Forefoot, Transmetatarsal, and Lisfranc). Major amputations are those that occur proximal to the tarsometatarsal joint (Chopart, Boyd, Syme, Below Knee, and Above Knee).

Charcot foot (arthropathy, osteoarthropathy, neuroarthropathy): Non-infectious destruction of bone and joint that is associated with neuropathy.

Diabetic foot: Describes the foot of a diabetic patient that has the potential risk of pathologic consequences, including infection, ulceration, and destruction of deep tissues associated with neurologic abnormalities, various degrees of peripheral arterial disease, and metabolic complications of diabetes in the lower limb. (Based on the World Health Organization definition).

Diabetes, type 1: Formerly called insulin-dependent diabetes mellitus (IDDM), describes an autoimmune disease of younger individuals with a lack of insulin production that causes hyperglycemia and a tendency toward ketosis.

Diabetes, type 2: Formerly called non-insulin-dependent diabetes mellitus (NIDDM), describes a metabolic disorder resulting from the body's inability to produce enough insulin or properly utilize insulin. Individuals with type 2 diabetes also have hyperglycemia but are ketosis resistant.

Epidemiology: The study of frequency, determinants, and distribution of disease.

Gangrene: The death or necrosis of a part of the body secondary to injury, infection, and or lack of blood supply. This indicates irreversible damage where healing cannot be anticipated without loss of some part of the extremity.

Incidence: The rate at which new cases of disease occur within a specified time period.

Infection: An invasion and multiplication within body tissues by organisms such as bacteria, fungi, or yeast, with or without the clinical manifestation of disease.

Intrinsic minus foot: Describes a neuropathic foot with intrinsic muscle wasting and associated claw toe deformities.

Ischemia: The impairment of blood flow secondary to an obstruction or constriction of arterial inflow.

LEAP: Acronym for Lower Extremity Amputation Prevention program.

Limited joint mobility: Describes the stiffness or restricted range of motion of a joint (cheiroarthropathy) due to protein glycosylation.

LOPS: Acronym for loss of protective sensation. Describes the progression of neuropathy in the diabetic foot to the point that the foot is at risk for ulceration.

Neuropathy: A nerve dysfunction affecting sensory, motor, and or autonomic fibers, with varying degrees of impairment, symptoms, and signs. **Diabetic peripheral neuropathy** is the presence of symptoms and or signs of peripheral nerve dysfunction in individuals with diabetes after exclusion of other causes.

Prevalence: A measure of frequency describing the percent of persons in a given population with a stated disease or characteristic at a point in time.

Ulceration (ulcer): A partial- or full-thickness defect in the skin that may extend to subcuticular tissue, tendon, muscle, bone, or joint.

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NOTES

Infections of the diabetic foot

This page deals primarily with the medical management of infections of the diabetic foot. If you are a patient looking for more information you may wish to visit the * or other national associations.

(*This website is not specifically endorsed by Ossur, but includes a lot of useful information.)

Infections of the diabetic foot

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Taddino TE, A Survey of Wound Monitoring and Topical Antimicrobial Therapy Practices in the Treatment of Burn Injury, J Burn Care Rehab, 1990;11:423-7

Eaglstein WH, Chronic Wounds, Surgical Cl N Am, June 1997, VOL. 77 Num 3, 689-700.

Do you need to culture to determine the appropriate antibiotic?

In most cases, physicians start with empiric antibiotic therapy when infection is noted. Culturing the infected ulcer/wound is critical because it will isolate the pathogens responsible for the infection and antibiotic sensitivities will allow the physician to choose the appropriate antibiotic. Using the culture specific antibiotic will also help reduce bacterial resistance.

Lipsky BA, A Current Approach to Diabetic Foot Infections, Current Infectious Disease Reports, 1999, 1:253-260.

Levine N, The Quantitative Swab Culture and Smear: A Quick, Simple Method for Determining the Number of Viable Aerobic Bacteria on Open Wounds, J Trauma, 1976;16(2):89.

When is surgery indicated in an infected diabetic foot ulcer?

Surgery is indicated when the ulcer/ wound shows signs of deep infection. Surgery needs to be considered in patients that have non-healing ulcerations due to an underlying osteomyelitis.

Tan J, Can Aggressive Treatment of Diabetic Foot Infections Reduce the need for Above the Ankle Amputation, Clinical Infectious Disease,1998 , 23:286-91.

Bamberger DM, Osteomyelitis in the foot of Diabetic Patients: Long-term results, Prognostic Factors, and the Role of Antimicrobial and Surgical Therapy, Am J of Med, 1987 ; 83:653-60.

How do you know how much to resect?

In an amputation, the surgeon must resect proximal to the level of infected tissue or the unsalvageable body part. A surgeon must also take into account if the patients has peripheral vascular disease and decide at what level the patient will be able to heal an amputation.

Bowker JH, Partial Foot amputations and disarticulations, Foot Ankle Clinics, 2:153, 1997.

Brodsky JW, Diabetic Foot Infections, Ortho Cl N Am, Vol.22, No. 3: 473-88, 1991.

What labs do you obtain when you suspect infection?

Labs most physicians obtain are CBC with differential, ESR, and a HA1C.

Seltzman CL, Diabetic Foot Infections, AAOS Instructional Course Lectures, Vol. 48:317-320, 1999.

Calhoun JH, Osteomyelitis of the Diabetic Foot, Wounds, 2000;12(6suppl B):48B-54B.

What are the criteria for hospital admission?

In most cases, patients are admitted for infection of the foot when they require parenteral antibiotics, failed course of oral antibiotics, and when a surgical procedure is planned. Patients may also be admitted if they have low compliance rates or can not care for themselves.

Eneroth M, Clinical Characteristics and Outcomes in 223 Diabetic Patients with Deep Foot Infections, Foot & Ankle International, Vol. 18, No. 11, Nov 97: 716-22.

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What are the clinical characteristics of diabetic foot infections?

The classic signs of infection are swelling, redness, pain, and odor. In diabetic patients, physicians must also look for purulent discharge and crepitus from gas forming organisms that tend to infect diabetic patients.

Boulton AJ, Diabetic Foot Ulcers: A Framework for Prevention and Care, Wound Rep Reg 1999;7:7-16.

Dow G, Infections in Chronic Wounds: Controversies in Diagnosis and Treatment, Ostomy Wound Management, 1999;45(6):23-40.

Are elevated WBCs and temperature always present in patients with a diabetic foot infection?

In many cases, diabetic patients will lack clinical signs of infection such as chills, fever, and leukocytosis upon presentation. Physicians must be aware that patients with diabetes may not mount an inflammatory response in presence of an infection.

Bamberger DM, Osteomyelitis in the foot of diabetic patients: long-term results, prognostic factors, and the role of antimicrobial and surgical therapy, Am J Med, 83:653-660, 1987.

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Antimicrobial therapy for diabetic foot infections

A practical approach

Kevin W. Shea, MD

VOL 106 / NO 1 / JULY 1999 / POSTGRADUATE MEDICINE

CME learning objectives

- To identify factors that influence antibiotic selection in the treatment of diabetic foot infections
- To understand the microbiology of the infected diabetic foot
- To establish an effective antimicrobial regimen for empirical treatment of diabetic foot infections

This is the second of three articles on the diabetic foot

See p. 3

This page is best viewed with a browser that supports tables

Preview: Foot infections in patients with diabetes mellitus are among the most common bacterial infections encountered in clinical practice. Unfortunately, these infections and their sequelae are also the most common cause of disability and the reason for most hospital admissions among diabetic patients. This article outlines the factors to consider when choosing appropriate treatment for these patients and provides a practical approach to empirical antibiotic therapy.
Shea KW. Antimicrobial therapy for diabetic foot infections: a practical approach. Postgrad Med 1999;106(1):85-94

In the United States, diabetes mellitus accounts for about half of all nontraumatic lower extremity amputations, with a rate exceeding 40 times that for people who do not have

diabetes (1). Foot ulceration and infection are clearly risks for subsequent amputation. Early recognition of lesions and prompt initiation of appropriate antibiotic therapy, as well as surgical debridement of necrotic or devascularized soft tissue and bone, are essential for controlling the infection and preventing additional morbidity (2-7).

Factors that influence antimicrobial selection

Initial management of diabetic foot infections and choice of empirical antimicrobial therapy are influenced by various factors (table 1). These include the severity of the illness (local and systemic), the likely causative pathogens, and coexisting complications, such as underlying osteomyelitis. Host-specific factors (eg, glycemic control, history of drug allergy, concomitant renal disease) directly influence the need for hospital admission and can affect the choice of specific agents or their dosing interval. Finally, drug-specific factors, such as cost and side effects, can be important, especially in the outpatient setting.

Factor	Major influence
Infection-specific	
Severity, wound class	Hospitalization, route of administration, surgical intervention
Microbiology	Empirical or specific therapy
Prior treatment	Likelihood of resistance
Osteomyelitis	Pharmacodynamics, duration of therapy
Host-specific	
Allergies	Empirical or specific therapy
Glycemic control	Hospitalization
Gastroparesis	Route
Renal disease	Dosage
Arterial insufficiency	Surgical intervention
Drug-specific	
Pharmacokinetics	Route, dosage
Pharmacodynamics	Route, dosage
Side effects	Compliance
Cost	Compliance

Severity of illness

Various wound classification systems have been used to characterize diabetic foot infections. The Wagner system, based on wound depth and appearance, has been successfully incorporated into treatment protocols when combined with proper infectious disease principles (2).

Improved outcomes in the protocol groups probably reflect early, aggressive surgical intervention--an approach clearly borne out by other investigations (4).

Less formal classification schemes, based on clinical assessment of severity, have been advocated to aid empirical antimicrobial selection (table 2). These strategies sometimes help define the need for hospitalization, the route of antibiotic administration, or the aggressiveness of complementary surgical intervention.

Mild infection
Localized cellulitis
Superficial ulceration
Minimal purulence
No systemic signs or symptoms

Moderate infection
Cellulitis of foot or ankle
Deep or penetrating ulceration
Plantar abscess
Acute osteomyelitis
Systemic signs or symptoms

Severe infection
Proximal cellulitis, lymphangitis
Gangrene, necrotizing fasciitis
Clinical septicemia

Adapted from Joseph (6).

Many diabetic patients with limb-threatening infections have no symptoms or signs of systemic illness (8). In addition, severity of infection does not predict the causative pathogen and should not be the only basis for decisions about antimicrobial therapy.

The "fear factor" of using higher-than-needed doses of antibiotics or of adding other agents is not usually constructive and increases both the cost of treatment and the potential for side effects. For example, cellulitis is generally a superficial infection of the skin, and the major causes are streptococci and *Staphylococcus aureus*. Agents that provide coverage for these, such as an antistaphylococcal penicillin or a first-generation cephalosporin, are appropriate for initial therapy. Severe illness with lymphangitis or clinical sepsis represents a later stage of the same disease process. Thus, the initial choice of antibiotic remains the same.

Outpatient management of mild to moderate foot infections is clearly preferable to hospitalization, assuming adequate

wound care is available (7). However, more severe infections usually require hospitalization, intravenous antibiotics initially, and aggressive surgical debridement or drainage. Cure with antibiotics alone should not be attempted. Early surgical intervention can reduce the duration of antimicrobial therapy and restore full ambulation faster while reducing the risk for future above-ankle amputations (4,8). Correction of documented atherosclerotic, large-vessel occlusive disease is also needed to maximize healing and save the limb (3).

Causes of infection

An understanding of the bacteriology of diabetic foot infections is important in guiding antibiotic selection and correlating culture results with appropriate definitive therapy (9-11).

Culture of material carefully collected from abscess cavities or by surgical biopsy of deep soft tissue or bone provides the most useful guide to treatment and minimizes the potential for contamination. Routine swab cultures of an ulcerative lesion are often difficult to interpret because of the number of pathogens found on the wound's surface. Even a noninfected, chronic pedal ulcer is likely to yield several organisms on culture, but the findings are of little clinical significance. Culture of material from sinus tracts is also unreliable.

Before an infected wound is cultured, care should be taken to remove any overlying necrotic debris from the site. Vigorously scrubbing the wound with saline-moistened sterile gauze often can accomplish this. Culture of the wound base, preferably from expressed pus, can then be attempted. Specimens obtained from curettage of the base of the ulcer correlate best with results from deep-tissue culture (7,9).

Gram's stain is often helpful for interpreting culture results and should always be requested from the microbiology laboratory. A surface culture may grow several organisms, while Gram's stain may reveal only a single bacterial morphology. In a typical scenario, *S aureus* and two different gram-negative bacilli are found on culture, whereas Gram's stain reveals only gram-positive cocci. In this situation, *S aureus* is the predominant pathogen, and therapy should be directed accordingly.

The polymicrobial nature of most infections of the diabetic foot is well known, with an average of five or six organisms involved (9,11). A mixture of aerobic and anaerobic organisms is common. In one study (11), anaerobic organisms were recovered from 90% of cultures. Foul-smelling drainage and the presence of gas in the tissues, detected by clinical or radiographic evaluation, often predict a mixed polymicrobial infection.

Although diabetic foot infections tend to be polymicrobial, there are some exceptions. As mentioned earlier, cellulitis of nonulcerated skin is nearly always caused by streptococci or

S aureus. Occasionally, enteric gram-negative bacilli cause a localized cellulitis in diabetic patients. In any case, relatively narrow-spectrum antibiotics can be safaly used to treat cellulitis, regardless of severity.

Infections related to superficial ulceration are most commonly caused by aerobic gram-positive cocci, whereas gram-negative aerobes and anaerobes are uncommon causes (7). On the other hand, infections associated with deep or penetrating ulcers and those characterized by marked tissue necrosis or gangrene should always be presumed to be mixed infections and therefore treated with broad-spectrum antibiotics.

S aureus is the most commonly isolated pathogen and accounts for most infections in which only a single pathogen is recovered (7,10). Coagulase-negative staphylococci, enterococci, and group B streptococci are also frequently isolated (9,10). Aerobic gram-negative bacilli are common in mixed infections, with *Proteus* species, *Escherichia coli*, and members of the *Klebsiella* and *Enterobacter* species being isolated most often. Unfortunately, it is often difficult to distinguish true infection caused by these organisms from surface colonization. Therefore, culture results must be interpreted carefully. *Pseudomonas aeruginosa*, for example, is an organism associated with moisture and is often recovered from surface cultures of chronic ulcers, especially in patients previously treated with antibiotics. This usually represents colonization only; specific therapy for *P aeruginosa* is rarely indicated.

Anaerobic isolates are often found when appropriate collection techniques are used (9-11). *Bacteroides* species, *Clostridium* species, and anaerobic streptococci, such as *Peptococcus* and *Peptostreptococcus* species, are the most common anaerobic pathogens involved in diabetic foot infections. Adequate coverage for these organisms is important when initial empirical therapy is started.

Therapeutic options

After all factors are considered, the initial therapy for diabetic foot infections remains empirical. summarizes one approach to choosing an effective antimicrobial regimen. Subsequent culture results should be used to guide, and hopefully narrow, further antibiotic therapy and to define appropriate oral step-down therapy in patients initially treated with intravenous antibiotics.

Agents with favorable pharmacokinetics, such as the fluoroquinolones in combination with clindamycin hydrochloride (Cleocin) or metronidazole (Flagyl, Protostat), provide an oral alternative to intravenous therapy and may allow more patients with moderate infection to be treated as outpatients. However, these agents are effective only when combined with appropriate wound care and should not be used when more cost-effective agents with a narrower spectrum would suffice.

Mild to moderate cellulitis, including that associated with

superficial ulceration, is effectively treated with narrow-spectrum agents. Dicloxacillin sodium (Dycill, Dynapen, Pathocil), the oral first-generation cephalosporins (eg, cephalexin [Biocef, Keflex], cefadroxil [Duricef]), and clindamycin are all available in generic preparations and provide good defense against staphylococci and streptococci. Cefadroxil may be the preferred agent because of better bioavailability and a longer half-life that allows twice-daily dosing. Clindamycin is the drug of choice in patients with severe penicillin allergy. For severe cases of cellulitis in patients requiring hospitalization, an intravenous first-generation cephalosporin (eg, cefazolin sodium [Ancef, Kefzol, Zolicef]) is preferred.

For deeply penetrating pedal ulcers, it is advisable to increase coverage against common enteric gram-negative bacilli and anaerobes. In the outpatient setting, amoxicillin and clavulanate potassium (Augmentin) provides adequate coverage for staphylococci, streptococci (including enterococci), and anaerobes (including *Bacteroides fragilis*). In patients allergic to penicillin, a fluoroquinolone plus clindamycin or metronidazole provides comparable coverage (12). The older fluoroquinolones, such as ciprofloxacin (Cipro), should not be used alone, despite reports of efficacy (13). Ciprofloxacin has only marginal activity against aerobic streptococci and provides no significant anaerobic coverage.

For the hospitalized patient with a penetrating pedal ulcer, intravenous beta-lactam/beta-lactamase inhibitor combinations provide optimal coverage (14,15). The combination drugs ampicillin sodium and sulbactam sodium (Unasyn), ticarcillin and clavulanate potassium (Timentin), and piperacillin sodium and tazobactam sodium (Zosyn) all provide broad-spectrum coverage, which includes *S aureus* (methicillin sodium-susceptible strains), streptococci, and most anaerobes. Ampicillin-sulbactam has the best activity against enterococci and may be the preferred agent in patients with fairly acute infection. For patients with recalcitrant infections or those who have received extensive antibiotic therapy in the past, ticarcillin-clavulanate and piperacillin-tazobactam may be preferred because of their increased activity against nosocomial gram-negative bacilli.

Alternatively, the second-generation cephalosporins cefoxitin sodium (Mefoxin) and cefotetan disodium (Cefotan) and the third-generation cephalosporin ceftizoxime sodium (Ceftizox) have sufficient anaerobic activity to warrant consideration as monotherapy for moderate infections. Ceftizoxime has somewhat better gram-negative activity, while none of these drugs eradicate enterococci. In fact, many of these agents are no longer included in hospital formularies because of the availability of less expensive alternatives.

The other third-generation cephalosporins, often the workhorse drugs in many hospitals, should not be used as monotherapy for diabetic foot infections. Ceftriaxone sodium (Rocephin) and cefotaxime sodium (Claforan) have moderate antistaphylococcal activity but are unreliable when used to treat deep-seated staphylococcal infections. Ceftazidime has relatively poor gram-positive activity, and all these drugs lack significant anaerobic coverage.

In patients with a history of severe penicillin allergy (eg, anaphylaxis, angioedema), combination therapy can provide adequate empirical coverage. Clindamycin combined with aztreonam (Azactam) or a fluoroquinolone (eg, ciprofloxacin, levofloxacin [Levaquin]) is effective.

Aminoglycosides should not be used in combination therapy, if possible. In diabetic patients, who may have some degree of underlying nephropathy, the potential toxic effects of these agents is a prime concern, especially since less toxic alternatives are available. In addition, aminoglycosides are inactivated in an acidic environment, such as that found in abscess cavities. They have minimal penetration into bone, thus making them a poor choice for patients with osteomyelitis.

Osteomyelitis

Contiguous osteomyelitis may be present in one third to two thirds of diabetic patients with moderate to severe pedal infections (16,17). Underlying sensory neuropathy and vascular impairment are important risk factors for development of pedal osteomyelitis, which usually arises from chronic infection of overlying ulcerations. An important caveat is the increased likelihood of acute osteomyelitis in patients with puncture injuries, possibly due to direct penetration and inoculation to bone. In either case, the presence of osteomyelitis and any delay in its diagnosis increase the risk for subsequent amputation (5,17). When osteomyelitis is present, it is important to establish an accurate diagnosis and define the pathogen involved whenever possible. Clearly, the presence of osteomyelitis has both prognostic and therapeutic implications.

Clinically, a history of a chronically draining ulcer should raise suspicion of underlying osteomyelitis, especially in patients with large or deep ulcers of a neuropathic foot. Exposed bone at the base of the ulcer or the ability to palpate bone with a blunt probe is highly predictive of underlying osteomyelitis (17,18).

The erythrocyte sedimentation rate (ESR) is a diagnostically useful and inexpensive test. While lacking sensitivity, especially when dealing with small bones, a markedly elevated ESR (70 to 100 mm/hr) is fairly predictive of osteomyelitis (16,17). Also, serial ESR determinations are often helpful in evaluating response to therapy.

Radiographically, the diagnosis of osteomyelitis is not always straightforward. Also, bony abnormalities are not usually evident on plain films until 2 to 3 weeks after initial infection, and any changes seen may be indistinguishable from the destructive effects of diabetic osteopathy (Charcot's joint). Radionuclide bone scanning, while very sensitive, has poor specificity and is often positive in patients with neuropathic osteopathy, previous infection, or fracture.

Indium-111-labeled leukocyte scanning has shown the best overall accuracy for diagnosing osteomyelitis, with reported

sensitivity of 89% to 100% and specificity of 78% to 96% (17,19). However, the cost-effectiveness of such noninvasive testing has been called into question. Prolonged, culture-guided antimicrobial therapy after surgical debridement may be equally effective but less costly than approaches using various radiologic testing (20).

Bone biopsy is the only definitive method to diagnose osteomyelitis. In addition to histopathologic confirmation, biopsy can provide useful culture and sensitivity results on which to base definitive antimicrobial therapy. This tends to be most helpful in cases of chronic osteomyelitis, in which surface and tissue cultures are often unreliable and recovery of multidrug-resistant organisms is more likely.

When contiguous osteomyelitis is confirmed or likely, the choice of antimicrobial therapy may need to be revised. Although intravenous therapy has been the mainstay of osteomyelitis treatment, this is changing somewhat because of better understanding of pharmacodynamic principles of oral therapy. For example, oral fluoroquinolones provide excellent bioavailability and achieve outstanding tissue penetration, including into bone (12,21). Oral clindamycin also has good bioavailability and bone penetration and maintains excellent activity against staphylococci, streptococci, and anaerobes. Other oral agents that are effective in more selected situations include rifampin (Rifadin, Rimactane), trimethoprim-sulfamethoxazole (Bactrim, Septra), metronidazole, and minocycline hydrochloride (Minocin).

Treatment of osteomyelitis usually requires at least 4 to 6 weeks of directed antimicrobial therapy, compared with 7 to 14 days for isolated soft-tissue infection. However, treatment times vary widely and are usually related to underlying host factors or wound management. One study (13) noted that the rate of successful 1-year outcome was significantly better in patients whose wounds were closed upon completion of therapy, compared with those with persistent open wounds. Whether this was due to severity of the infection or underlying host factors related to wound healing is unclear.

Summary

Infection of the diabetic foot is a common problem in clinical practice and is associated with significant morbidity. Optimal management requires a multidisciplinary approach. Aggressive surgical debridement and wound management, carefully chosen antimicrobial therapy, and modification of host factors (ie, hyperglycemia, concomitant arterial insufficiency) are all equally important for a successful outcome. Empirical antibiotic selection should be followed by culture-guided definitive therapy.

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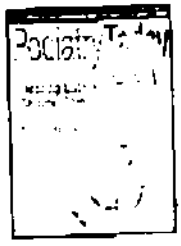
PodiatryToday

Feature:
A Closer Look At Diabetic Foot Infections



With a strong emphasis on the recent guidelines of the Infectious Diseases Society of America (IDSA), these authors discuss how to differentiate among mild, moderate and severe infections, and discuss appropriate antibiotic therapy to manage these infected wounds.

Diabetic foot infections arising from ulcerations are the largest non-traumatic cause of lower extremity amputations. Contributing factors include peripheral neuropathy and vascular disease, rigid pedal deformities, local trauma and pressure, extensive soft tissue loss, multi-system failure, non-compliance and severe infection.

Over the decades, there have been a number of shifts in the way clinicians approach diabetic foot infections (DFIs). Throughout the '60s and into the '70s, clinicians felt most DFIs were, like other skin and skin structure infections, caused primarily by the gram-positive aerobic cocci, *Staphylococcus aureus* and *Streptococcus*.

See p. 6

In the early '80s, some of the emerging literature used more sophisticated culturing modalities and laboratory techniques.[1] Researchers were finding multiple organisms, primarily anaerobic gram negative rods, that had not been isolated from these infections in the past. Soon, all DFI were being called "polymicrobial" with mixed flora containing aerobic gram-positive cocci, gram-negative rods and anaerobic cocci and rods. There was an emphasis by clinicians to ensure that all of these isolates were covered by an overly broad-spectrum empiric antibiotic regimen, pending deep culture reports.

A critical look at these studies shows many of them did not represent everyday clinical experience. There was little stratification based on the severity of the infections. Most of the

Here one can see cellulitis on a patient's right foot with localized signs of infection. Early aggressive surgical debridement is crucial to avoid subsequent proximal amputations.

studies examined end-stage, severe, chronic, malodorous, necrotic infections. In fact, the literature actually referred to just this type of severe process as the "diabetic foot." In some cases, the researchers actually obtained cultures from amputation specimens in the morgue or pathology laboratory. Clinicians did not consider the wide range of clinical presentation of infections in these patients. Unfortunately, this concept of the polymicrobial DFI is still alive today not only in podiatric circles but throughout most of medicine.

Around 1990, the thinking on DFI started changing again. Lipsky and Pecoraro looked at "uncomplicated" infections in the diabetic lower extremity and compared the efficacy of cephalexin with clindamycin.[2] The study showed both drugs had similar effects. This was particularly interesting for a number of reasons. It was one of the first times DFI were not all grouped together as a severe, limb threatening process. There could be "uncomplicated" presentations.

More importantly, when they compared the spectrum of activity of each drug, Lipsky and Pecoraro noted that cephalexin has activity against gram positive cocci and some gram negatives but no coverage against anaerobic organisms. Clindamycin shares the activity against the gram positive cocci but adds anaerobic coverage and has no activity against the gram negatives. In terms of coverage, the only organisms these drugs had in common were *Staphylococcus* and *Streptococcus*. One could conclude that these gram positive organisms were the primary pathogens despite what other bacteria may have been isolated from these uncomplicated DFIs.

Gram-Positive Cocci: Why It Is An Essential Consideration

Understanding the importance of gram-positive cocci, in particular *Staphylococcus aureus* and Group B *Streptococcus*, is critical in the current antibiotic approach to DFIs. The recent Infectious Diseases Society of America (IDSA) Diabetic Foot Infection Guidelines emphasize the following point:

This photo reveals a preoperative photograph of a diabetic foot infection.

"Aerobic gram positive cocci (especially *Staphylococcus aureus*) are the predominant pathogens in diabetic foot infections. Patients who have chronic wounds or who have recently received antibiotic therapy may also be infected with gram negative rods, and those with foot ischemia or gangrene may also have obligate anaerobes."[3]

The guidelines specifically note the dated thinking that all DFIs are mixed infections is not evidence based. There is a difference in microbial

flora based on the severity of the infection and the presence of comorbidities. Even in the more complicated infections in which a myriad of other organisms may be isolated, their importance as primary pathogens needing antibiotic coverage is debatable. Many represent colonization only.

Assessing The Impact of MRSA

While the number and types of true pathogens in the majority of DFIs may be limited to *Staphylococcus* and *Streptococcus*, it does not mean that the clinician can rest assured that traditional therapies active against these two organisms will be enough.

In the past five years, there has been a seemingly logarithmic growth in the incidence of methicillin resistant *Staphylococcus aureus* (MRSA) as a pathogen in the diabetic foot. This organism was once associated only with nosocomial infections but now community-acquired strains of MRSA have become common in DFI cases. While it is outside the scope of this feature to review MRSA in detail, it is important to examine the situation in the diabetic foot.

As recently as 1996, Goldstein reported that 20 percent of the staphylococcal isolates from his diabetic foot population in California were methicillin resistant.[4] In 1999, Tentolouris showed 40 percent of the staphylococcal isolates in their diabetic foot clinic in the United Kingdom were methicillin resistant.[5] In 2003, the same group published a follow-up study entitled "Methicillin resistant *Staphylococcus aureus* in the diabetic foot clinic: A worsening problem."[6] Although the absolute percentage of MRSA among their staphylococcal isolates only increased to 42.2 percent, the number of patients that actually presented with MRSA doubled. Fortunately, their study found many of these MRSA isolates could be treated effectively with debridement, topical therapy and isolation.

What does this mean in terms of empiric antibiotic therapy? Does one have to include MRSA coverage in the mix? At this point, in most locales, the incidence of MRSA has not reached the level of medical probability. In other words, it is not yet "more likely than not" that MRSA is in the wound, which is the legal definition of medical probability. Therefore, empiric MRSA coverage is probably not warranted for most diabetic foot infections. However, one may consider empiric coverage when treating patients at high risk for MRSA (see "Which Patients Are At High Risk For MRSA?" below).[7]

Which Patients Are At High Risk For MRSA?[7]

- Recent hospitalization (one to 24 months)
- Recent outpatient visit (within 12 months)
- Recent nursing home admission
- Recent antibiotic exposure (one to 12 months)
- Chronic illness (e.g. diabetes, ESRD,

malignancy)
- Injection drug use
- Close contact with MRSA patient

Rethinking Empiric Antibiotic Therapy For DFIs

Despite the overall prevalence of diabetic foot infections, there are surprisingly few large scale, randomized, controlled clinical trials specific to the condition.[3] The central premise of most empiric antibiotic therapy for these infections is that there must be a broad spectrum of coverage to handle not only the gram positive cocci but also the gram negative rods and the anaerobic organisms.

However, as we discussed above, this thinking is radically changing in line with the newer theories of pathogenicity. More and more clinicians are appreciating that antibiotic coverage should concentrate on the gram positive cocci and that one should reserve broader spectrum choices only for those patients at risk for a true polymicrobial infection. Even in these more severe infections, in which one may isolate multiple types of organisms, the need for truly broad-spectrum coverage is undergoing re-evaluation. The current thinking has likened the microbial flora of a diabetic infection to a snake in which the gram positive cocci represent the head of the snake and all the rest of the organisms comprise the body. Once one removes the head of the snake, the rest will die. Almost as surely, if one kills the *Staphylococcus* and *Streptococcus*, the remaining organisms too will be inconsequential.

Traditional lines of thinking are also changing with regard to oral versus parenteral therapy. Many clinicians have a misconception that intravenous antibiotics are somehow "stronger" or "more potent." Actually, any number of oral antibiotics have bioavailabilities that are similar regardless of whether the drug is given orally or parenterally. Examples include the quinolones, trimethoprim/sulfa and linezolid. In the case of linezolid, the oral bioavailability is actually greater than the IV form.

This photo reveals the management of the infection with an early surgical intervention.

With any of these drugs, there is really no reason to give the drug parenterally as the oral medication will work every bit as well. There will also be a significant cost savings in not having to maintain an IV line and there is less risk of complications such as line sepsis. Even in drugs that do not have equivalent bioavailability between oral and parenteral forms, given the proper dosing, a compliant patient and a functioning GI tract, there is no reason why the oral regimen should not be effective. Even in the case of osteomyelitis, which has long been considered a prototypical disease that required

long-term IV therapy, oral regimens are finding success and favor.

Mild DFIs: What Are The Best Treatment Options?

The IDSA Guidelines divide the severity of DFIs into four distinct categories: non-infected, mild infection, moderate infection and severe infection. Non-infected ulcers do not require culturing or antibiotics. Let us take a closer look at the remaining three categories of DFIs.

Mild (uncomplicated) infection. Infected ulcerations with only localized signs of inflammation fall under the category of mild infections. These lesions are infected almost exclusively with the aerobic gram positive cocci *Staphylococcus* and *Streptococcus*. In fact, the bacteriology of these lesions is so well accepted that culturing is really not even necessary. Since, by definition, these are localized processes, treatment usually begins with any oral antibiotic with sufficient activity against these two organisms. One would not empirically address MRSA unless the patient presents with risk factors for MRSA (see "Which Patients Are At High Risk For MRSA?" above).

There are some commonly used oral antibiotics for mild diabetic foot infections that are listed below (see "A Guide To Oral Antibiotics For Mild DFIs"). While the list in the sidebar is not exhaustive, one may employ any antibiotic with activity against *Staph* and *Strep*. In podiatric medicine, amoxicillin/clavulanic acid is possibly the most commonly used antibiotic for these infections. This again dates back to a time when clinicians considered it necessary to use a drug with broad spectrum, anti-anaerobic activity. Although amoxicillin/clavulanic acid is effective, the drug is expensive and one probably doesn't need the broad spectrum activity.

A Guide To Oral Antibiotics For Mild DFIs

Cephalexin: 500 mg q 6-8h
Cefdinir: 300 mg q 12 h
Amoxicillin/Clavulanate: 500-875 mg q12h
Clindamycin: 150-300 mg q8-12h
Levofloxacin: 500 mg q24h

Overall, cephalexin is the most commonly used oral antibiotic in podiatry. It has a long safety history and decent activity against the important pathogens. On the downside, most clinicians tend to have patients take the medication three to four times per day, which may affect compliance.

Cefdinir is a cephalosporin that actually has significantly better in vitro activity against *Staph* and *Strep* than cephalexin. It also has the advantage of being a twice-a-day drug. In patients with a true allergy to penicillin, oral

clindamycin is an excellent choice for these mild infections. Levofloxacin is another option for penicillin- or cephalosporin-sensitive patients.

However, be aware that not all quinolones are equal in this regard. Avoid using ciprofloxacin in cases in which *Staph* is expected since *Staph* develops rapid resistance and the drug is far from optimal. Also be aware there is a major issue with quinolone cross-resistance. If a *Staphylococcus* develops resistance to ciprofloxacin, there is a good chance it is resistant across the class.

Essential Insights On Managing Complicated Infections

Moderate to severe (complicated) infections. These infections can be limb- or life-threatening. More often than not, hospitalization is required to stabilize the patient not only from an infection standpoint but also metabolically. Urgent surgical incision and drainage is frequently required. As discussed above, these infections tend to grow out a greater variety of organisms. While it may only be necessary to treat the gram positive cocci at this point in time, it is still prudent to begin a broader spectrum course of therapy and narrow it down as the patient responds.

In many hospitals, beta-lactam/beta-lactamase inhibitor compounds, such as piperacillin/tazobactam or ampicillin/sulbactam, are considered first line therapy for complicated diabetic foot infections. These drugs have a spectrum of activity that consists of excellent gram positive and anaerobic coverage with variable activity against the gram negatives. Piperacillin/tazobactam is the better of these compounds in this regard. For the most part, however, the drugs are interchangeable and frequently only one or the other is available on a given formulary.

Recent data shows that ertapenem, a penem class antibiotic, is as effective at one gram per day IV/IM as the four times a day dosing of piperacillin/tazobactam.8 Using the once-a-day therapy facilitates a much lower cost and more convenience for the patient, especially in the outpatient setting. This study, which enrolled close to 600 patients, is the largest single trial to date examining antibiotic therapy of complicated DFIs.

In patients with sensitivity to a beta-lactam drug, the combination of parenteral clindamycin along with an oral quinolone gives empiric, broad-spectrum coverage. Clindamycin will cover the gram-positive organisms and the anaerobes while the quinolone will pick up the gram-negative organisms.

A number of newer generation quinolones also have potential activity against the wide variety of pathogens one finds in these complicated DFIs. Although trovafloxacin was essentially pulled from the market

This photo reveals delayed primary closure without any

because of toxicities, newer drugs such as moxifloxacin, gatifloxacin and garenoxacin may show promise. Unfortunately, the data is still not overly convincing.

Incision to the skin closure (before photo).

For patients with a documented MRSA or those who are at high risk for MRSA, linezolid is becoming the drug of choice. This is only the third antibiotic to be granted a specific indication for DFIs by the FDA. The pivotal trial that led to the FDA approval compared linezolid (po or IV) to amoxicillin/clavulanic acid (po) and ampicillin/sulbactam (IV).[9] The researchers found that linezolid had superior efficacy for cases of infected ulcerations.

More recent data compared linezolid to vancomycin for the treatment of complicated skin and skin structure infections (CSSSIs). In a large trial of 1,200 patients, Weigelt found linezolid to be statistically superior to vancomycin in the treatment of CSSSIs caused by MRSA.[10] In a similar but smaller study, Sharpe found that linezolid was not only superior to vancomycin but also noted there were seven amputations in the patients treated with vancomycin and none in the patients treated with linezolid.[11]

How To Facilitate Clean Wounds And Appropriate Wound Closure

When treating DFIs, one of the most important factors to consider is the need for early surgical intervention as resulting limb- or life-threatening infections can lead to subsequent amputation. Initial surgery to address the severe infection should precede the need of vascular reconstruction. One should remove all pus, devitalized and infected soft tissue or bone from the wound, thereby converting the defect to a surgically clean acute wound. Keep in mind that one may have to perform this process more than once before the wound is ready for closure.

Ensuring a thorough vascular examination and performing possible reconstruction if necessary are also critical to the healing process of the DFIs. When the patient has intact vascular status, consider a primary wound closure for the non-infected chronic wound. If the wound bed has enough granular tissue and is free from any necrotic and infected soft tissue and/or bone, one may perform a delayed primary closure. When it comes to infected and draining wounds, leave these packed open initially. There are a variety of plastic surgery techniques one may employ to close the wound.

Initial incision planning is very important to facilitate the delayed primary closure process. Aggressive surgical debridement and appropriate adjunctive therapy are also vital to facilitating healing of DFIs. Adjunctive modalities may include negative pressure vacuum therapy, hyperbaric oxygen therapy, local wound care, growth factor stimulators and offloading devices.

Pertinent Pointers On Employing Antibiotic Bone Cement

The use of antibiotic-loaded bone cement is one surgical modality that may help accelerate healing in DFIs. After performing proper soft tissue and osseous debridement of the infected structures, one can place antibiotic-loaded synthetic spacers between the resected osseous structures. The spacers provide a biological function as they sterilize the affected area by providing a local concentration of antibiotic. The spacers also provide a structural function as they fill the resultant "dead space" and maintain osseous position by preventing periarticular soft tissue contraction that makes subsequent osseous reconstruction more difficult.

To this end, the use of antibiotic-loaded polymethylmethacrylate bone cement (AL-PMMA-BC) has been commonly used since 1970 when Bucholz and Engelbrecht first described its use in infected total hip arthroplasties.[14] Since that time, many authors have described the use of AL-PMMA-BC in treating foot and ankle osteomyelitis.[13-17] Although no studies have documented an actual cure with this treatment alone, when researchers combined it with parenteral antibiotic therapy, AL-PMMA-BC provided a bactericidal effect in the rat model.[18] Since the polymerization process of PMMA-BC is highly exothermic (i.e., the mean heat of reaction is 94° C), the antibiotic one chooses must be heat stable and should exist in a powder form for even distribution throughout the PMMA-BC.[19]

Fortunately, there are a number of available antibiotics that are heat stable, exist in powdered form and are compatible with PMMA-BC.[20] Vancomycin and tobramycin are the most commonly added antibiotics to PMMA-BC. However, with the development of multi-drug resistant bacterial organisms, such as MRSA, vancomycin-resistant *Staphylococcus aureus* (VRSA) and vancomycin resistant *Enterococcus* (VRE), one should be very cautious before using antibiotic-loaded bone cement. Surgeons should also be aware of the possibility of severe inflammatory reactions about the implantation site with frequent serous drainage.[21-23]

This intraoperative photograph shows a chain of AL-PMMA-BC beads on a suture interposed within a previously infected joint.

The release or elution of antibiotic from PMMA-BC is obviously an important consideration and researchers have identified several factors that directly affect the success of the antibiotic delivery system.[19,24-28] Interestingly, some authors have shown the combination of vancomycin and gentamycin decreases the release of vancomycin by more than 50 percent without affecting the release of gentamycin.[28] Since there are several commercially available forms of PMMA-BC that are pre-loaded with gentamycin, one should avoid adding vancomycin to these PMMA-BCs and instead add pure PMMA-BC that is devoid of

A Closer Look At Diabetic Foot Infections

gentamycin.

Researchers have shown that vancomycin maintains the MIC of susceptible organisms for up to 12 days while gentamycin has the same effect for up to 30 days and tobramycin for up to 90 days.[29,30]

Following the soft-tissue and osseous debridement, it is common to leave the AL-PMMA-BC in place for between seven to 10 days. One would subsequently perform a repeat irrigation and debridement with AL-PMMA-BC exchange or a definitive reconstruction if clinical, pathological and systemic signs and symptoms support this approach. It is interesting to note that authors have also shown that AL-PMMA-BC stimulates platelet activation and thereby releases growth factors from the wound that may enhance soft tissue and osseous healing adjacent to the implantation of the modality.[31]

There is a simple technique to creating rounded beads. Fill a 10 cc syringe with the AL-PMMA-BC while it is still in a semi-solid state. Then dispense the appropriately sized bead onto a heavy gauge suture or monofilament wire to create a chain of beads approximately 6 mm in diameter. Ensure that the beads are evenly spaced every 5 mm. This allows the chain to be malleable and fill the defect evenly.

A Guide To Antibiotics For Complicated DFIs

Piperacillin/tazobactam: 3.375g q6h, 4.5g q8h
Ampicillin/sulbactam: 3g q6h
Ertapenem: 1g q24h
Clindamycin (IV) and quinolone (oral): 600-900mg q8h
Linezolid (MRSA): 600mg q12h po
Expanded spectrum quinolone: varies by drug

Final Thoughts

In recent years, there have been interesting developments in the treatment of DFIs. While ensuring a multidisciplinary approach remains vital to managing these infections and other comorbidities, the understanding of the pathogenic organisms has changed and a number of new antibiotics have recently become available to treat these infections.

In the near future, we believe that more antibiotics will be granted a specific FDA indication for the treatment of DFIs. Indeed, early aggressive surgical debridement and appropriate antibiotic therapy are necessary to successfully treat severe foot infections and permit a quicker recovery.

Dr. Joseph is a consultant in lower extremity infectious diseases and is a Fellow of the

Infectious Diseases Society of America. He is an Attending Podiatrist at the Coatesville Veterans Affairs Medical Center in Coatesville, Pa.

Dr. Zgonis is an Assistant Professor in the Department of Orthopaedics/Podiatry Division of the University of Texas Health Science Center at San Antonio. He is an Adjunct Assistant Professor of Surgery at the College of Podiatric Medicine and Surgery at Des Moines University in Des Moines, Iowa. Dr. Zgonis is an Associate of the American College of Foot and Ankle Surgeons.

Dr. Roukis is a Fellow of the American College of Foot and Ankle Surgeons. He practices at the Weil Foot and Ankle Institute in Des Plaines, Ill.

For related articles on diabetic foot infections, see "MRSA: Where Do We Go From Here?" in the March 2005 issue, the April 2004 supplement "Treating MRSA Infections," "Are Your Antibiotic Prescriptions In Line With Evidence-Based Medicine" in the May 2005 issue or check out the archives at www.podiatrytoday.com.

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OR Petition 7

DFS Health Planning
RECEIVED

Raleigh Orthopaedic Clinic, PA
Petition for Need Determination for Six Orthopedic Ambulatory Surgery Operating Rooms in Wake County

Medical Facilities
Planning Section

EXECUTIVE SUMMARY

Each year, the State Health Coordinating Council publishes a Proposed State Medical Facilities Plan and then holds public hearings and receives petitions for special need determinations for regulated healthcare services. Raleigh Orthopaedic Clinic (ROC) has serious concerns that the Proposed 2008 Plan includes no additional operating rooms for Wake County. In fact, no additional operating rooms have been allocated to Wake County by the Plans in over ten years.

Raleigh Orthopaedic Clinic petitions for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms to be developed in one or more freestanding (non-hospital) ambulatory surgery centers in Wake County.

ROC physicians know that an orthopedic ambulatory surgery center (ASC) can offer patients exceptional quality and customer service, lower costs, more efficient scheduling and better teamwork. The American Academy of Orthopaedic Surgeons states "ASCs provide benefit to both patients and orthopaedic surgeons because many musculoskeletal surgical procedures can be provided in an efficient, cost effective manner. ASCs can improve the quality of care received by the patients and delivered by the physician."

The rationale for the ROC petition is summarized:

- Wake County has 9.93 operating rooms per 100,000 population, far less than comparable counties and 22 percent less than the statewide rate of 12.75 ORs per 100,000 persons.
- ASCs generally have greater scheduling efficiency and higher patient satisfaction as compared to hospitals. While 73 percent of all surgery cases are ambulatory, 89 percent of the operating rooms in Wake County are hospital-based.
- In 2006, over 6,000 Wake County patients obtained ambulatory surgery in another county; more ambulatory surgery patients left Wake County in 2006 as compared to Mecklenburg and Forsyth Counties.
- No dedicated orthopedic ambulatory surgery operating rooms exist in Wake County even though orthopedic ambulatory surgery procedures comprise 23 percent of the total outpatient cases.
- Orthopedic procedures performed in freestanding ambulatory surgery centers offer <u>30 to 40 percent lower charges and reimbursement rates.</u>
- ROC physicians have already established exemplary records for providing charity care in their offices and at the area hospitals.

Approval of the petition will <u>benefit the community</u> by allowing new providers to compete and improve access to dedicated orthopedic ambulatory surgery operating rooms. The ASC will offer greater convenience, higher patient satisfaction and lower costs and charges. Like hospitals, the proposed ambulatory surgery center will be licensed, accredited and required to provide care to Medicare, Medicaid, insured patients and charity care patients.

PETITION

DFS Facility Planning
RECEIVED

Medical Facilities
Planning Section

TO: Medical Facilities Planning Section
Division of Facility Services
701 Barbour Drive
2714 Mail Service Center
Raleigh, NC 27699-2714

PETITIONER: Karl Stein, Executive Director
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612
919 863-6801

DATE: July 31, 2007

RE: Petition for Need Determination for Six Orthopedic Ambulatory Surgery Operating Rooms in Wake County

I. Introduction

Raleigh Orthopaedic Clinic (ROC), with nineteen physicians, is the largest orthopedic practice in Wake County. ROC physicians have privileges at Rex Hospital and WakeMed (New Bern and North locations). The group has four office locations and serves patients from all of Wake County and a large region of eastern North Carolina. In 2006, ROC physicians performed over 7,300 orthopedic surgical procedures; ambulatory surgery procedures comprised 76 percent of the total.

ROC physicians helped found and are active participants in the Wake County Medical Society's Project Access, which provides free office visits for low income patients. In addition, ROC physicians choose to provide healthcare services to uninsured and indigent patients including emergency department coverage and inpatient and outpatient consults and procedures. The ROC practice and its individual physicians pay property taxes and income taxes and generously contribute to a wide range of charities. ROC physicians are extremely involved in research, education, community agencies, and professional organizations. The estimated total value of the community benefits for their charitable professional services exceeds 1.2 million dollars per year when including Project Access, charity care, bad debt, and the individual physicians' financial contributions and professional time provided to schools, agencies and societies. Please see Attachment 1.

ROC surgeons recognize that an orthopedic ambulatory surgery center (ASC) can offer patients exceptional quality and customer service, lower costs, more efficient scheduling and better teamwork. The American Academy of Orthopaedic Surgeons states that "ASCs provide benefit to both patients and orthopaedic surgeons because many musculoskeletal surgical procedures can be provided in an efficient, cost effective manner. ASCs can improve the quality of care received by the patients and delivered by the physician." The benefits of Ambulatory Surgery Centers (ASCs) are described in the articles in Attachments 2 and 3.

Orthopedic ambulatory surgery represents the largest volume of all the surgical specialties and offers a tremendous opportunity to improve patient satisfaction and cost savings. The need is great, because demand for orthopedic surgery to increase by at least four percent per year based on national statistics and even more based on the exceptional population growth rate for Wake County.

Raleigh Orthopedic Clinic has worked diligently through the regulatory process for several years in an effort to provide ambulatory surgery services to residents of Wake County. ROC has submitted three annual petitions to the State Health Coordinating Council for adjusted need determinations for ambulatory orthopedic operating rooms in Wake County. These previous petitions were denied. Earlier this year, ROC also made a formal presentation to the Operating Room Work Group regarding ways to improve the planning process and promote fairness. (Please see Attachment 4 for a copy of the presentation by Raleigh Orthopaedic Clinic, PA.)

The State Medical Facilities Plan has provided no need determinations for additional surgical operating rooms in Wake County in the past five years. Therefore new providers have been precluded from submitting CON applications to construct new surgical facilities. However, during this same time period, Wake County hospitals found several inventive ways to add surgical capacity and establish new facility locations including:

- Converting and relocating existing endoscopy procedure rooms to become surgical operating rooms
- Relocating existing operating rooms to develop new satellite facilities that are "extensions" of the hospital
- Adding dedicated C-section operating rooms
- Converting C-section rooms to surgical operating rooms
- Adding minor surgery "procedure rooms" (these are rooms within the hospital that are not built or equipped to the same construction standards as a licensed surgical operating room and are not CON-approved)

For years the hospitals in Wake County have increased their surgery capacity (even though no need for additional licensed ORs appeared in the State Plan) and have blocked the entry of any new surgical provider that could provide more cost effective ambulatory surgery. The Proposed 2008 State Medical Facilities Plan shows a projected surplus of **0.79** operating rooms in Wake County. This small surplus of operating rooms means no need exists for new surgical operating rooms in Wake County.

ROC contends that the current operating room methodology does not accurately assess the future needs of the population or recognize the limitations of the operating rooms in Wake County. The OR methodology also omits the surgery volume that has been shifted to the minor surgery procedure rooms. If these surgery cases were properly included in the demand calculations, Wake County would then show a need for additional full service operating rooms.

Raleigh Orthopaedic Clinic petitions for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms to be developed in one or more freestanding (non-hospital) ambulatory surgery centers.

II. Rationale for the Proposed Changes

The current OR methodology in the Proposed 2008 State Medical Facilities Plan does not accurately assess the ambulatory surgery operating room needs of Wake County:

1 No dedicated orthopedic ambulatory surgery operating rooms exist in Wake County even though orthopedic ambulatory cases comprise 23 percent of the total outpatient cases. Orthopedic procedures performed in freestanding ambulatory surgery centers offer substantially lower costs, charges and reimbursement for insured patients and Medicare and Medicaid programs. Cost savings result in lower out-of-pocket costs for patients and lower payments / less expense to the payors. Please see Attachment 6.

2 The current methodology and CON process has allowed existing Wake County providers to add many "minor procedure rooms" to perform surgical cases. These procedure rooms are not constructed or equipped to the same standards as licensed operating rooms. Shifting surgery cases from licensed operating rooms to the minor procedure rooms does not promote access to quality healthcare. Please see Attachment 7.

3 Minor surgery procedure room cases (including some procedures requiring general anesthesia) are not counted in the OR methodology even though the same types of cases performed in these procedure rooms in Raleigh hospitals are often performed in licensed operating rooms at hospitals elsewhere in the State. Shifting surgery cases out of the licensed operating rooms suppresses the growth in total surgery utilization in the OR methodology and postpones the need to add licensed operating rooms

through need determinations. This miscounting of cases is particularly bad in Wake County because there are so many minor procedure rooms in use.

4 The operating room methodology is skewed by the erroneously reported hours and days of operation in the Wake County hospital license renewal applications. Few operating rooms where scheduled procedures are performed are actually staffed beyond eight hours per day. For planning purposes the hours of utilization for C-sections and emergency trauma cases should be excluded from the hours-of-operation calculations. The operating rooms where ambulatory orthopedic surgery cases can be scheduled are available Monday through Friday only and all of the ambulatory and shared rooms (inpatient and ambulatory) are closed on major holidays. The assumption that scheduled surgery cases are performed 260 days per year in Wake County is wrong; a more realistic figure is 255 days.

5 Open heart services and heart lung bypass equipment at WakeMed and Rex Hospitals function at less than 40 percent of capacity (see page 80 of the Proposed 2008 Plan). Averaging less than one case per room per day, these dedicated open heart inpatient operating rooms are not available for any type of ambulatory surgery. The operating room inventory for Wake County includes the <u>four dedicated open heart operating rooms at WakeMed</u> that are underutilized. During the previous year, the four open heart rooms at WakeMed performed a total of 931 cases. If these four dedicated open heart rooms and associated cases were excluded from the operating room need calculation, even with no other changes to the methodology, Wake County would show a deficit of two operating rooms as seen in Attachment 5. Rex has operating rooms used exclusively for cardiovascular surgery, although it does not classify them for regulatory purposes as dedicated open heart operating rooms. If these rooms and cases were excluded the deficit would be even higher.

6 Hospitals generally have lower surgery scheduling efficiency and lower patient satisfaction as compared to ambulatory surgery centers. Please also see Attachment 8 for data regarding hospital acquired infections. Based on these circumstances, patients need improved access to freestanding ambulatory surgery centers.

7 Existing surgery resources (licensed ORs and "procedure rooms") in Wake County are inadequate to meet the needs of orthopedic ambulatory surgery patients. Patient origin data demonstrates that <u>thousands of Wake County patients</u> are leaving their home county to obtain ambulatory surgery in other counties. Please see the chart on page 5. This requires patients to travel in the darkness, while hungry, after sedation, and while in pain. Some caregivers are confronted with extended travel distances while simultaneously attending to their patient needs. And when problems arise, the on-call physicians in the local hospital are unfamiliar with the circumstances of the out-of-town surgery.

8 ROC physicians have already established exemplary records for providing charity care in their offices and in the hospital (in addition to providing uncompensated on-call coverage for emergency patients). ROC suggests that the CON applications for the proposed additional orthopedic ambulatory operating rooms be required to meet a defined minimum percentage and dollar amount for charity care. Please see the letters in Attachment 9.

9 ROC is petitioning (for the fourth time) for ambulatory orthopedic operating rooms to fulfill the needs of Wake County and to overcome the limitations and obstacles posed by the present OR methodology and CON regulations. The ROC petition has extensive community support as seen in Attachment 10.

The following analysis explains the unique characteristics of Wake County and the problems with the 2008 OR methodology:

Lack of Adequate Access to Ambulatory Operating Rooms in both North Carolina and Wake County

North Carolina has a total of 49 freestanding ambulatory surgery centers. Nearby, South Carolina and Tennessee, both with smaller populations, have 56 and 128 ASCs respectively. Most states with similar size populations have far more ASCs:

Ohio	168
Georgia	204
New Jersey	166
Washington	197

While 25 states have no CON regulations, many of the remaining CON states have exemptions from CON review for single specialty ASCs or separate and streamlined CON / licensure processes.

Within North Carolina, Wake County citizens have access to fewer operating rooms per 100,000 population than other comparable counties and the overall North Carolina population. The OR Planning Inventory statistics from the Proposed 2008 State Medical Facility Plan are examined and compared on a per capita basis compared as follows:

2005-06 Operating Room Data	Number of Licensed Surgery Providers (All Facilities)	2008 OR Planning Inventory - Total Number of Licensed ORs	2010 Projected Population	ORs per 100,000 (Excluding Chronically Underutilized ORs, C-Section and Trauma Rooms)
Wake County	**9**	**90**	**906,800**	**9.93**
Mecklenburg	**13**	**146**	**930,663**	**15.69**
Forsyth	**5**	**83**	**351,864**	**23.59**
North Carolina	**171**	**1209**	**9,485,138**	**12.75**

Sources: Draft 2008 SMFP
OR Planning Inventory based on Column S page 67 - 68
(Excludes ORs in Chronically Underutilized Facilities, C-Section Rooms and Trauma Rooms)
North Carolina State Demographics (Updated in June, 2007)

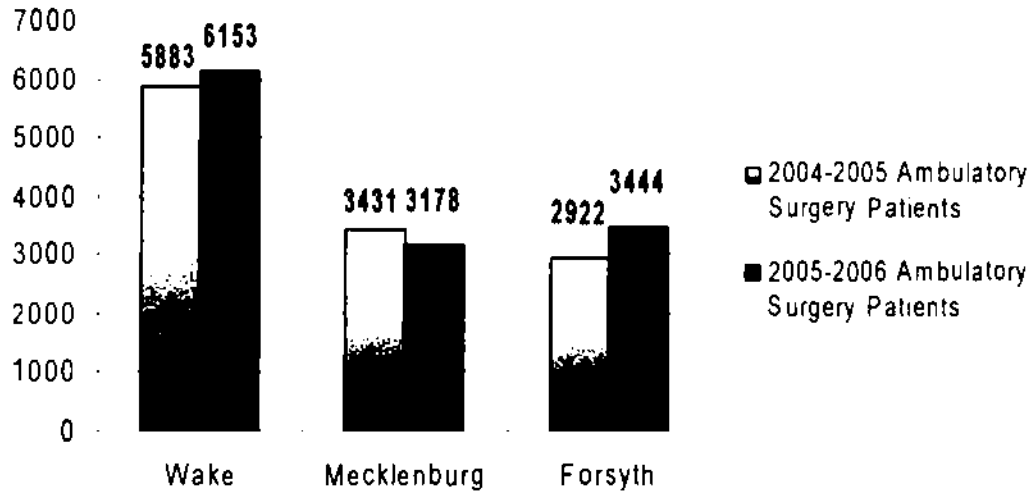
Wake County has fewer surgery facilities and fewer licensed operating rooms per capita as compared to Mecklenburg and Forsyth Counties as well as to the overall North Carolina population.

"North Carolina and particularly Wake County now lag behind many other metropolitan areas in terms of the availability of specialized ambulatory surgery operating rooms. Wake County patients deserve access to state-of-the-art orthopedic ambulatory surgery operating rooms. These operating rooms will be specially equipped and staffed by highly trained surgical teams adept at performing the highest quality orthopedic procedures."

Robert Wyker, MD

The lack of an adequate number and types of surgical operating rooms restricts access for patients and surgeons in Wake County. The number of Wake County patients that leave their home county to obtain ambulatory surgery procedures at facilities in other counties is another measure of the shortage of operating rooms.

Number of Patients Obtaining Ambulatory Surgery Procedures Outside of Their Home Counties



Source: Division of Facility Services, Medical Facilities Planning Section, Patient Origin Data, 2004-05 and 2005-06
Analysis of Data and Chart by Strategic Healthcare Consultants

Patient origin data demonstrates that thousands of Wake County patients are leaving their home county to obtain ambulatory surgery. The 6,153 statistic means that more than 12 percent of all the Wake County ambulatory surgery patients left their home county to obtain ambulatory surgery procedures in other counties. Thousands of patients leaving Wake County to obtain ambulatory surgery represent a huge quality concern. This situation should be remedied because: 1) it forces patients and their families to drive long distances in the pre-dawn traffic to surgery; 2) it discriminates against patients without transportation or financial means; 3) it prevents loved ones from being at the surgery because they cannot miss a whole day of work for the commute; 4) it forces the patient (now in pain and recovering from anesthesia) to travel to get back home after surgery; 5) it means late night problems must be handled by local emergency room doctors who are unfamiliar with the medical case; 6) it prevents continuity of care because the travel discourages adequate pre- and post-op follow up appointments.

Of these 6,153 ambulatory surgery patients that left Wake County to go to other facilities, ROC estimates 1,300 to 1,400 (20 to 25 percent) were ambulatory orthopedic surgery cases. Approval of the ROC petition will improve access to ambulatory orthopedic surgery and reduce the need for Wake patients to leave their home county to obtain surgery.

Orthopedic Ambulatory Surgery Represents the Largest Component of Ambulatory Surgery in Wake County

In 2006, ambulatory orthopedic surgery cases performed in Wake County totaled 12,884 cases or 23 percent of the total ambulatory surgery volume. Orthopedic ambulatory surgery represents the largest volume of procedures and thus the greatest opportunity for substantial cost savings for patients and the healthcare system. The next table shows the 2005-06 ambulatory surgery volume by specialty category and by facility.

Wake County Ambulatory Surgery Cases Performed in Licensed Operating Rooms	WakeMed Raleigh All	WakeMed Cary	Rex	Duke Health	HealthSouth	Raleigh Plastic Surgery	Raleigh Women's Health	Southern Eye Associates	TOTAL	% of Total
Cystoscopy	602	0	27	0	0	0	0	0	629	**1%**
Endoscopy	15	0	8	41	0	0	0	0	64	**0%**
General	2,739	2,629	3,740	2,651	0	0	0	0	11,759	**21%**
Gynecology	1,607	1,480	2,587	314	0	0	3,100	0	9,088	**16%**
Neurosurgery	700	0	493	192	0	0	0	0	1,385	**2%**
Open Heart	0	0	0	0	0	0	0	0	0	**0%**
Ophthalmology	764	516	670	547	0	0	0	487	2,984	**5%**
Oral Surgery	1,085	201	13	9	10	0	0	0	1,318	**2%**
Orthopedics	2,557	708	3,589	3,962	2,068	0	0	0	12,884	**23%**
Otolaryngology	2,227	836	3,108	0	2,446	0	0	0	8,617	**15%**
Plastic Surgery	259	128	2,366	337	1	371	0	0	3,462	**6%**
Podiatry	207	0	401	1	530	0	0	0	1,139	**2%**
Thoracic	9	17	4	0	0	0	0	0	30	**0%**
Urology	826	254	804	101	0	0	0	0	1,985	**4%**
Other	33	1	412	0	0	0	0	0	446	**1%**
TOTALS	13,629	6,770	18,222	8,155	5,055	371	3,100	487	55,789	**100%**

(The above volumes do not include the hundreds of hand surgery, ophthalmic surgery and pain procedures that previously were performed in licensed ORs but recently have been shifted to the minor procedure rooms that do not meet full licensure standards for operating rooms.)

No facility in Wake County has even one dedicated ambulatory orthopedic surgery operating room.

Multi-specialty operating rooms are a concern because with the mix of different surgical specialties the equipment and staff to have to be changed throughout the day. This causes extended between-case set-up and cleaning times and detracts from overall efficiency. Multi-specialty shared operating rooms are most likely to have schedule delays due to the ill-assorted medley of inpatient and outpatient cases of varying specialties and equipment set up requirements.

HealthSouth Blue Ridge Surgery Center is the only freestanding (non-hospital) ambulatory surgery center where ambulatory orthopedic cases are performed; it has six multi-specialty ambulatory operating rooms.

The only dedicated ambulatory surgery licensed operating rooms in Wake County are listed as follows:

Raleigh Plastic Surgery Center Inc. (Plastic Surgery)
Raleigh Women's Health Organization (Gynecology)
Southern Eye Associates Ophthalmic Center (Ophthalmology)

Each of the above single specialty ambulatory surgery centers represents a specialty with lower volumes and percentages of the total ambulatory surgery demand than orthopedic surgery. And while two of these facilities are underutilized, none of these single specialty operating rooms can be used to perform orthopedic surgery. Single specialty ambulatory surgery centers must obtain CON approval to add a new surgical specialty even if the proposed change has zero capital cost. Also, these ASC facilities were not constructed to current OR standards for orthopedic cases. Based on these circumstances, ROC is convinced that none of the existing single specialty ambulatory surgery centers can support orthopedic surgery.

Wake County does have four dedicated open heart operating rooms, all located at WakeMed; Rex Hospital provides open heart surgery in rooms dedicated to cardiovascular surgery but not so designated with the state. Over the past decade, open heart surgery procedures in Wake County have declined 10 percent from a combined total of 1,673 cases in 1998 down to 1,490 in 2006. Page 80 of the Proposed 2008 Plan shows that heart-lung bypass units are underutilized across the state. In Wake County, the 1,490 open heart surgery cases represent less than two percent of the total surgery volume and yet dedicated open heart rooms remain in the OR need methodology calculation. If these four dedicated open heart rooms and associated cases were excluded from the operating room need calculation, even with no other changes to the methodology, Wake County would show a deficit of two operating rooms as seen in Attachment 5.

Existing Resources are Inadequate and Ineffective

The population of Wake County is projected grow by 16.8 percent or 138,266 persons over the next five years. Raleigh population growth has outpaced every other NC metropolitan service area. To accommodate this growth, numerous major transportation improvement projects are ongoing and seven new schools are being built. The petitioner is convinced that the incredible population growth of Wake County will continue to surpass the capacity of the existing operating rooms. Furthermore, the present allocation of operating rooms (that are primarily hospital-based) is outdated and incredibly inefficient, as illustrated by the dedicated open heart operating rooms that have experienced consistent declines in utilization.

Outpatient surgery will continue to comprise the majority of all surgery. Orthopedic surgery already represents the largest percentage of ambulatory surgical utilization and is projected to experience strong growth in outpatient demand due to changes in technology, physician recruitment and the growth and aging of the population. The existing Wake County hospitals and facilities have been ineffective at improving ambulatory surgery access and quality of care as follows.

1. Many of the existing inpatient, ambulatory and shared operating rooms in Wake County are too small to be properly prepared for specialized orthopedic procedures. The inadequately sized rooms take longer to set up with equipment and to clean between cases.

2. Multi-specialty operating rooms often require changes to the surgery schedule, the room set-ups and the staffing assignments. This daily juggling act of operating rooms, equipment and staff delays procedures, increases labor costs and frustrates surgeons.

3. Wake County's existing surgical providers are unwilling to add or develop dedicated orthopedic operating rooms. ROC surgeons believe that the lack of dedicated orthopedic rooms increases the risk of incidents and complications.

4. Over the years, the hospitals have been dispersing operating rooms and emergency departments to establish new facilities. Orthopedic surgeons find it increasingly difficult to obtain additional operating room time at any one surgical facility.

5. Wake County hospitals that have developed minor surgery "procedure rooms" have gained surgery capacity that is less effective than licensed and fully functional operating rooms. In fact the hospitals' license renewal forms document that these minor procedure rooms are **"not equipped or meeting all the specifications for an operating room..."** Neither the specific physical limitations nor the billing rates for these minor surgery procedure rooms are publicly disclosed in the hospital license renewal applications. Please see Attachment 7 for additional documentation.

6. Hospital patients are increasingly at risk for hospital acquired nosocomial infections as documented in Attachment 8. Nosocomial infection risks are lower at ASCs.

Approval of the petition for six (6) dedicated orthopedic ambulatory surgery operating rooms will promote positive competition and improve quality in Wake County. ROC is committed to construct ambulatory orthopedic rooms that meet or exceed the local, state and federal OR construction and accreditation standards.

Cost Savings for Ambulatory Surgery Centers (ASCs) as Compared to Hospital Outpatient Surgery

There are huge cost savings related to ambulatory surgery procedures performed in freestanding ASCs as compared to hospital outpatient surgery. The Centers for Medicare and Medicaid announced plans to expand the range of services for which ASCs will be paid a facility fee. It will pay ASCs a projected 62% of outpatient procedure fees paid to hospitals. (Please see Attachment 6.) Medicare coinsurance rates are significantly lower for ASCs as compared to hospital outpatient departments.

The following chart compares the Medicare 2008 HOPPS (Hospital Outpatient Prospective Payment System) rates paid to hospitals with the 2008 ASC payments for a few frequently performed types of orthopedic ambulatory procedures.

CPT/ HCPCS	Short Description	HOPPS 2008 Rates	Estimated CY 2008 Fully Implemented Payment	ASC Payment as Percentage of HOPPS Payment
23107	Explore treat shoulder joint	1867.88	1069.09	57.2%
26020	Drain hand tendon sheath	1071.44	687.24	64.1%
29825	Shoulder arthroscopy/surgery	1875.55	1217.77	64.9%
29876	Knee arthroscopy/surgery	1875.55	1217.77	64.9%
29887	Knee arthroscopy/surgery	1875.55	1217.77	64.9%

Even with these huge cost savings, the petitioner expects that Wake hospitals will complain that shifting orthopedic surgery cases from the hospital to a dedicated ASC will cause financial hardship for the hospitals and diminish their ability to provide indigent care. ROC points out that the three hospital systems in Wake County are among the wealthiest nonprofit healthcare systems in North Carolina. Nonprofit organizations have been granted enormous tax exemptions, and some receive multi-million dollar government subsidies for indigent care. Nonprofit hospitals across the country are being questioned as to whether their charitable contributions to the community measure up to the benefits of their tax exempt status.

ROC is convinced that approval of this petition will give a new ASC provider and a for-profit entity an opportunity to prove their willingness to provide charity care, expand access and pay taxes. If the State Health Coordinating Council has concerns about charity care related to ambulatory surgery centers, a change in the regulatory standards can be implemented that requires applicants to provide charity care at or above the level of the existing surgery providers. Please see Attachment 9 for additional data, regulatory recommendations and a commitment by Raleigh Orthopaedic Clinic to expand charity care.

Orthopedic Ambulatory Surgery Operating Rooms

Several trends are making orthopedic surgery move to the outpatient setting quicker than other specialties.

Anesthetic techniques including oxygen saturation monitoring, EEG monitoring of consciousness, new short-acting drugs, and new drug-reversal agents have made outpatient surgery very safe. At the same time, better cardiovascular health in the growing elderly population has vastly increased the need for orthopedic procedures.

Miniaturization of orthopedic instruments and implants is making it possible to perform an ever widening variety of orthopedic procedures on an outpatient basis. Many procedures that once required an incision are now performed percutaneously.

Regional anesthetic techniques have made inpatient orthopedic surgery much less common. These include techniques that:

- numb the arm or leg without putting the patient to sleep
- reduce cardiovascular stress on the patient and make post-op observation shorter
- allow larger surgeries to be performed at an outpatient center
- numb the arm or leg for 6-12 hours

Raleigh Orthopedic Clinic surgeons now perform a sufficient volume of ambulatory surgery cases to easily support the full-time utilization of six ambulatory surgery operating rooms. In addition, ongoing physician recruitment by ROC will increase future ambulatory surgery utilization.

Ambulatory surgery operating rooms that are specifically designed, equipped and staffed for orthopedic procedures offer the most effective option for improving patient satisfaction and quality, reducing the risk of infection, and providing cost effective healthcare services. These are sometimes called "focused factories" by healthcare experts. The current standards for operating room design state that dimensions of up to 30 x 30 ft are needed to accommodate specialized orthopedic procedures. Few existing operating rooms in Wake County measure up to this standard.

The current Certificate of Need regulation for surgical operating rooms, 10A NCAC 14C .2106 (d), is provided as follows: *"In competitive reviews, an applicant proposing to perform ambulatory surgical procedures in at least three specialty areas shall be considered more favorably than an applicant proposing to perform ambulatory surgical procedures in fewer than three specialty areas."*

Based on this regulation, Raleigh Orthopaedic Clinic believes that if the standard OR methodology ever shows a need for any additional operating rooms in Wake County, there would be no chance for an orthopedic (single specialty) ambulatory surgery center to obtain CON approval. Petitioning for a special need determination for up to six orthopedic ambulatory surgery operating rooms best responds to the need in the community and would negate this biased regulation.

ROC Analysis of Wake County Operating Rooms and Procedure Rooms

The petitioner calculated the need for six additional operating rooms based on a review of the OR methodology in the 2008 Plan with two modifications:

One modification to the calculation is that the surgery procedures that were performed in the minor procedure rooms in 2005-06 are added back into the total surgery volumes for the licensed ORs. As seen in Step 2 of the table on the following page, thousands of cases have been diverted to the hospitals' procedure rooms. ROC believes that shifting surgery patients to a procedure room with limited capabilities does not improve access and undermines the planning process.

The second modification relates to the annual hours of operating room availability. ROC contends that the annual hours of availability for operating rooms should be based on 1836 hours (9 hrs per day, 255 days per year and 80% productivity) instead of 1872 hours. Most ambulatory and shared operating rooms in Wake County are closed for major holidays making these rooms available only 255 weekdays per year and not the 260 days currently used in the methodology.

	Wake County Operating Room Data and Inventory Information - 2008 Plan with ROC Recommended Changes	Inpatient Cases minus C Section	Ambulatory Cases	Combined Inpatient plus Ambulatory
1)	Wake County Operating Room Volumes (Proposed 2008 Plan)	21029	55789	76818
2)	Add back in the surgery cases that were redirected to minor procedure rooms			
	Wake County Minor Procedure Room Surgery Cases			
	Rex Hospital Minor Procedure - Non GI Endoscopy Surgery Cases	44	4397	4441
	WakeMed Minor Procedure - Non GI Endoscopy Surgery Cases	0	294	294
	Total Cases with Minor Procedure Room Surgery Added	21073	60480	81553
3)	Hours per case (same assumption as OR methodology)	3.0	1.5	
	Total Estimated Hours	63219	90720	153939
4)	Population Growth Factor 2006-2010 (same assumption as OR methodology)			0.1479
	Total Surgical Hours Anticipated in 2010			176,707
5)	ROC Recommended Hours per Room			
	9 hrs per day / 255 days per year / 80%			1836
6)	Projected Number of ORs Needed			96.2
7)	Adjusted Planning Inventory for Wake ORs (same as OR methodology)			90.0
8)	Projected Need for Additional ORs in 2010			**6.2**

Steps 1, 3, 4 and 7 above are consistent with the data and assumptions in the OR methodology of the Proposed 2008 Plan. The changes to the methodology in Steps 2 and 5 are based on the unique circumstances in Wake County as described in this petition.

ROC also asserts that all six of the operating rooms need to be orthopedic ambulatory operating rooms because:

1 Orthopedics represents the largest volume and percentage of ambulatory surgery; no dedicated ambulatory orthopedic ORs exist.

2 Orthopedic surgery requires larger operating rooms to accommodate advanced technology.

3 Dedicated orthopedic ambulatory surgery operating rooms offer Wake County the greatest opportunity to improve quality of care, maximize efficiency and deliver substantial cost savings.

III. Requested Changes

The standard Operating Room methodology in the Proposed 2008 State Medical Facilities Plan does not adequately consider the unique characteristics of Wake County.

Raleigh Orthopaedic Clinic petitions for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms to be developed in one or more freestanding (non-hospital) ambulatory surgery centers.

IV. Adverse Effects if the Changes Are Not Made

The expected adverse effects include:

- Wake County patients will be forced to travel to other counties for routine outpatient surgeries, which is unsafe for the patients, inconvenient for their families, and unfair to the Wake County physicians who are forced to provide emergency care for any complications.
- Wake County patients will be forced to pay for surgery at the higher hospital prices, instead of the lower price of a non-hospital ambulatory surgery center. Patients in this hospital-dominated market have little choice but to continue paying high hospital costs and deductibles for ambulatory surgery procedures that could be safely performed in an efficient, low-cost outpatient facility. This is especially harmful to patients because high-deductible insurance plans are becoming the norm.
- Wake County patients will experience delays and inconvenience in scheduling outpatient orthopedic surgery. Wake County orthopedic surgeons are working harder than ever in an inefficient system for scheduling and performing outpatient surgery. Population growth in the county will outpace the availability of operating room time making it increasingly difficulty to schedule patients for surgery in a timely manner.
- Wake County patients will have less access to operating rooms with consistent staffing and equipment. We feel that consistency in staffing and equipment makes orthopedic surgery safer in operating rooms dedicated to that type of surgery. In the current environment, consistency of staffing and equipment is getting less common. The number of ambulatory surgery operating rooms in Wake County is actually decreasing due to their conversion to shared operating rooms. As a result, the merged scheduling of outpatient cases with inpatient cases causes a higher percentage of procedures that are delayed or rescheduled. This causes difficulties for both patients and surgeons. Schedule delays decrease staff efficiency, diminish patient satisfaction, and can compromise quality of care.

- Wake County patients will have more surgery in hospital procedure rooms that are not equipped or designed to full operating room standards. It is uncertain if the surgery patients and the surgeons have been appropriately informed regarding the limitations of these minor surgery rooms. The need for hospitals to move surgery into these less-regulated procedure rooms would be reduced if this petition were approved to create more operating rooms in Wake County.

- Wake County will have fewer orthopedic surgeons to share the on-call coverage for emergency rooms. Restricted availability and inefficiency of in the current operating rooms make it increasingly difficult to recruit new orthopedic surgeons to Wake County. This county has a reputation for overcrowded and slow operating rooms. Existing operating rooms available to orthopedic surgeons are at high utilization. Also, surgeons state that they are twenty to thirty percent more productive in an ambulatory surgery center as opposed to a hospital surgery suite. Adjacent counties and states have more operating room availability and specialized orthopedic facilities. For these regions new surgeons prefer to locate in other communities without these problems. This limits the number of surgeons available to share in on-call coverage for emergency rooms for the rapidly growing population of Wake County.

V. Alternatives Considered

Maintaining the status quo is not an acceptable alternative because Wake County has high demand for orthopedic ambulatory surgery but limited operating room capacity. The standard OR methodology does not take into consideration the special characteristics of the service area. Projecting no need determinations for operating rooms encourages the development of more minor surgery procedure rooms that lack the equipment and facility characteristics of a fully licensed operating room. These procedure rooms are not constructed or equipped to meet the standards of licensed ORs. The physicians with Raleigh Orthopaedic Clinic are convinced that Wake County patients deserve access to a specialized facility that focuses on orthopedic surgical care.

Submitting a petition for an adjusted need determination for ambulatory surgery operating rooms in each of the six Health Service Areas is an option that was previously pursued without success. This alternative generated considerable discussion and members of the State Health Coordinating Council advised the petitioners to submit individual petitions for adjusted need determinations in specific service areas.

Submitting a petition for a need determination for multi-specialty ambulatory surgery operating rooms in Wake County is not an effective option because the need for specialized surgical capacity is most pronounced for orthopedic surgery.

As previously discussed, there are now more surgical specialists competing to book procedures in fewer multi-specialty ambulatory surgery operating rooms. Existing multi-specialty ambulatory surgery hospitals and facilities have fallen short with regard to providing consistent access and effective scheduling for orthopedic surgery cases. Orthopedic surgery typically requires larger operating rooms in order to accommodate the necessary equipment and special orthopedic operating tables.

The ROC petition request offers the most effective alternative to improve quality, expand access and deliver tremendous cost savings. An orthopedic ASC will help attract additional high-quality orthopedic surgeons who can then share in the charity work and on-call responsibilities. Orthopedic surgeons want the efficiency and consistent staffing that a dedicated orthopedic ASC will provide.

VI. Evidence That the Proposed Changes Would Not Result in Unnecessary Duplication of Health Resources

The following evidence is provided that the requested change will not result in unnecessary duplication of health resources:

1) The operating room inventory in the Proposed 2008 State Medical Facilities Plan shows no orthopedic (single specialty) ambulatory surgery operating rooms in Wake County. The requested orthopedic ambulatory operating rooms are not duplicative of the existing single specialty ambulatory surgery facilities for plastic surgery, gynecology and ophthalmology.
2) Raleigh Orthopedic Clinic has confirmed that no CON applications have been submitted to add orthopedic surgery to the existing single specialty operating room facilities.
3) The petition for six orthopedic ambulatory surgery operating rooms does not duplicate the types of surgical operating rooms that are owned by the hospitals in Wake County. Hospital-based operating rooms are distinctly different because most are multi-specialty and the designation of the rooms (inpatient, ambulatory and shared) can be changed without having to obtain CON or other regulatory approval.
4) The ROC petition does not duplicate minor surgery "procedure rooms" that have been developed by hospitals as substitutes for a licensed operating room.
5) ROC is seeking what does not exist in Wake County – dedicated orthopedic ambulatory surgery operating rooms that will be consistently focused on quality, patient satisfaction and cost effectiveness.

VII. Conclusion

Approval of this petition is justified because the proposal is consistent with the basic principals of the State Medical Facilities Plan regarding quality, cost effectiveness and improving access. The requested change for dedicated orthopedic ambulatory operating rooms in Wake County is based on a unique set of circumstances; the extraordinary population growth, the disparity in the number of licensed operating rooms per capita, the excessive number of ambulatory surgery patients that leave their home county, and the tremendous benefits in terms of cost savings and improved patient care.

Raleigh Orthopaedic Clinic intends to continue to push for changes in the State Medical Facilities Plan, the Certificate of Need regulations and the administrative rules related to operating rooms until the unique needs of Wake County can be met.

Attachments

1) Raleigh Orthopaedic Clinic Physician Involvement
2) Position Statement, Ambulatory Surgery Centers, American Academy of Orthopaedic Surgeons
3) Ambulatory Surgery Centers, A Positive Trend in Healthcare
4) ROC Presentation to the Operating Room Work Group
5) Calculations of Wake County OR Need Omitting Dedicated Open Heart Cases and ORs
6) Documentation Regarding Changes in Medicare Reimbursement
7) Hospital License Renewal Applications Showing Minor Surgery Procedure Rooms
8) Articles Regarding Hospital Infections
9) Commitment to Provide Charity Care
10) Community Support Letters

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Attachment 2

Position Statement

Ambulatory Surgical Centers

An Ambulatory Surgical Center (ASC) exclusively furnishes outpatient surgical services. There are currently more than 3700 Medicare-certified ASCs representing a doubling in the past decade. In 2001, ASCs supported 3 million surgical procedures and received about $1.6 billion in Medicare payments.[1] Notwithstanding this growth, ASCs accounted for less than 1 percent of total Medicare spending in 2001.[2]

The number of ASCs has grown because of rapid advances in technology and medicine. The American Association of Orthopaedic Surgeons (AAOS), as one of the leading advocates for patient safety, believes that many procedures that were previously performed only in the hospital inpatient setting can now be safely performed in ASCs. For example, many orthopaedic procedures can be performed in ASCs because of advancements in arthroscopic equipment and techniques. The improvement of short-acting, general anesthesia has reduced operative and recovery times and has made it possible to perform more procedures in ASCs.

ASCs have also grown because they offer numerous benefits to the patient and the orthopaedic surgeon. For musculoskeletal patients, ASCs can be convenient because of shorter wait times before and after surgery. Furthermore, coinsurance rates are often lower when compared to other outpatient healthcare settings.[3]

Many musculoskeletal procedures are highly technical and specialized. ASCs allow orthopaedic surgeons to design a site where they can perform these complex procedures more efficiently than in other outpatient settings. For example, the operating room in an ASC is often customized for a specific procedure, such as arthroscopy. Equipment and supplies are setup for specific procedures, and the same clinical staff often works together on a daily basis. This makes it easier to schedule and perform surgery in an ASC, which can translate into improved efficiency, cost-effective use of resources, and better outcomes for patients.

The decision to perform procedures in an ASC should largely rest with physicians because they can assess the best venue for optimizing care. The physician would consider the anesthetic risk, age, and general medical condition of the patient; the expected duration and complexity of the operation; the anticipated degree of postoperative pain and discomfort; and the probability of complications. An operation would not be performed in an ambulatory setting – irrespective of convenience or cost – if the risk to the patient is increased. Improving the patient's quality of care and outcome should be the guiding principle in determining whether a procedure should be performed in an ASC.

Reimbursement for procedures performed in ASCs must adequately capture all labor, equipment, and supply costs required to operate an ASC. Furthermore, ASC payment systems should be designed so that they can react to changes in technology or prices. Medicare and private insurers must work closely with the ASC and physician community in order to ensure fair payment is received for services provided. Failure to do so can create problems. For example, although many implant procedures can be safely performed in ASCs, many payers do not reimburse for implant hardware. This is a serious problem because the implant device is often the costliest part of a procedure. The result is that

physicians cannot perform certain implant procedures in ASCs because reimbursement rates do not account for necessary costs, which are reimbursed in more expensive inpatient facilities.

The AAOS believes that many surgical procedures can be safely performed in ASCs. ASCs provide a benefit to both patients and orthopaedic surgeons because many musculoskeletal surgical procedures can be provided in an efficient, cost-effective manner. ASCs can improve the quality of care received by the patient and delivered by the physician. The growth and development of ASCs must not be hampered by restrictive payment or coverage policies from either Medicare or other private payers.

1. MedPAC Report to Congress, Medicare Payment Policy March 2003, p. 136.
2. MedPAC, p. 136
3. MedPAC, p. 140

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Attachment 3

Ambulatory Surgery Centers

A POSITIVE TREND IN HEALTH CARE

A PROGRESSIVE MODEL FOR SURGICAL SERVICES

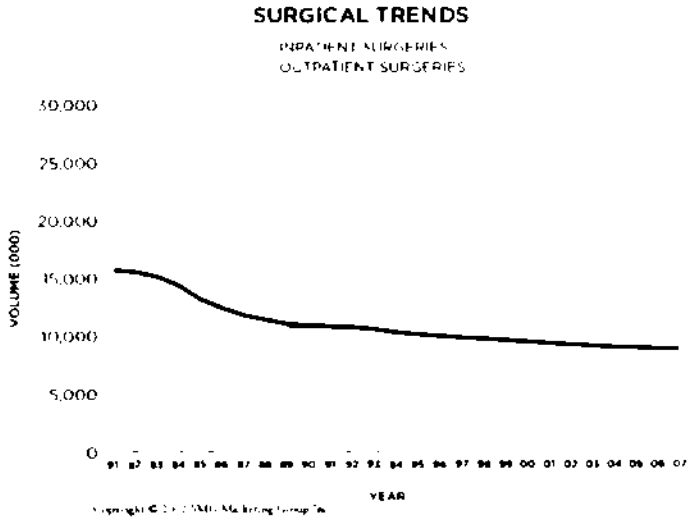
As our nation struggles with how to improve a troubled health care system, the experience of ASCs is a rare example of a successful transformation in health care delivery.

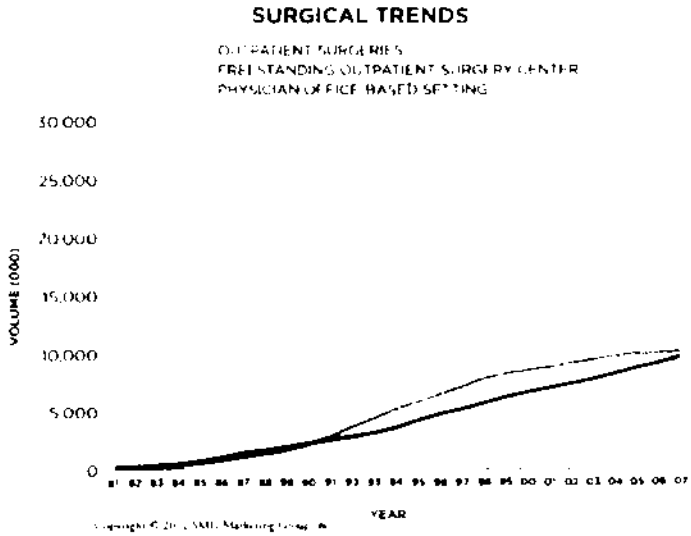
Thirty years ago, virtually all surgery was performed in hospitals. Waits of weeks or months for an appointment were not uncommon, and patients typically spent several days in the hospital and several weeks out of work in recovery. In many countries, surgery is still like this today, but not in the United States.

Physicians have led the development of ASCs. The first facility was opened in 1970 by two physicians who saw an opportunity to establish a high-quality, cost-effective alternative to inpatient hospital care for surgical services. Faced with frustrations like scheduling delays, limited operating room availability, and challenges in obtaining new equipment due to hospital budgets and policies, physicians were looking for a better way - and developed it in ASCs.

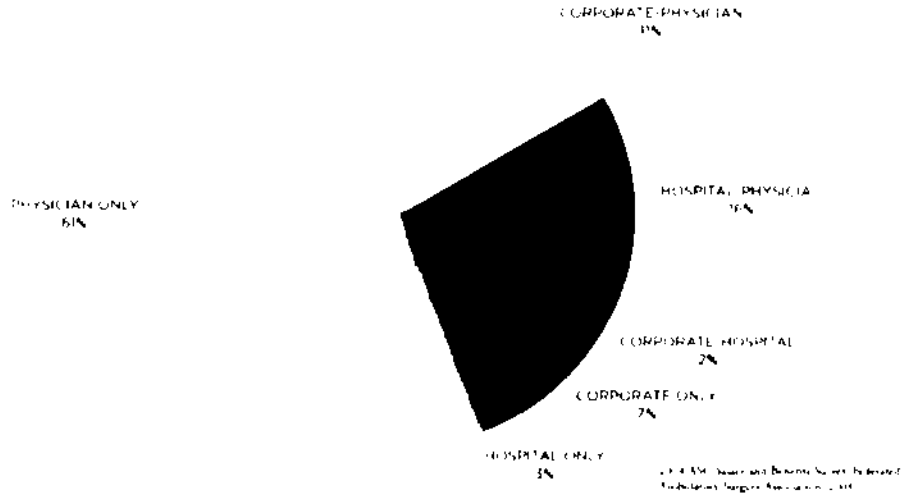
Physicians continue to provide the impetus for the development of new ASCs. By operating in ASCs instead of hospitals, physicians gain the opportunity to have more direct control over their surgical practices.[1] In the ASC setting, physicians are able to schedule procedures more conveniently, assemble teams of specially-trained and highly skilled staff, ensure the equipment and supplies being used are best suited to their technique, and design facilities tailored to their specialties. Simply stated, physicians are striving for, and have found in ASCs, the professional autonomy over their work environment and over the quality of care that has not been available to them in hospitals. These benefits explain why physicians who do not have ownership interest in ASCs (and therefore do not benefit financially from performing procedures in an ASC) choose to work in ASCs in such high numbers.

Given the history of their involvement with making ASCs a reality, it is not surprising physicians continue to have ownership in virtually all (90%) ASCs. But what is more interesting to note is how many ASCs are jointly owned by local hospitals that now increasingly recognize and embrace the value of the ASC model. According to the most recent data available, hospitals have ownership interest in 21% of all ASCs; 3% are owned entirely by hospitals.[2]





ASC OWNERSHIP STRUCTURE

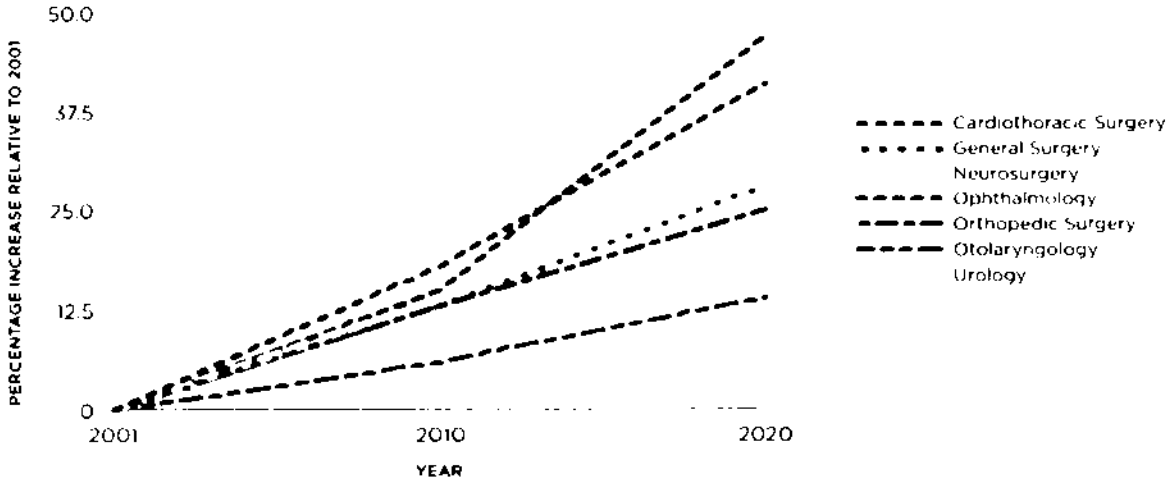


ASCs ALLOW PHYSICIANS TO WORK EFFICIENTLY

A recent analysis examined the impact of the aging population on the demand for surgical procedures and attendant need for surgical subspecialists. This study concluded that the aging population would be a major force in driving significant growth in the demand for surgical services. The forecasted growth in work by the year 2020 varied from 14 percent to 47 percent, depending on specialty.[1] Meeting these surgical needs will be a challenge. Solutions include increasing the number of surgical residency positions, increasing the workloads of surgeons in the workforce, and improving the efficiency of surgeons.

Utilizing settings that allow physicians to practice efficiently will help mitigate the impact of the aging population on the anticipated shortage in the surgery workforce. ASCs offer physicians the ability to work more efficiently and are therefore uniquely positioned to play an important role in managing the increased need for surgical services as it arises in the years ahead.

FORECASTED DEMAND GROWTH IN THE NUMBER OF PROCEDURES BY SPECIALTY



[illegible] DA, [illegible] H, Maggard MA, Ko CY. The aging population and its impact on the surgery workforce. Ann Surg. 2003 Aug;238(2):[illegible]

[illegible] REGULATED TO ENSURE QUALITY AND SAFETY

Health care facilities in the United States are highly regulated by federal and state entities. ASCs are not excluded from this oversight.

The safety and quality of care offered in ASCs is evaluated by independent observers through three processes: state licensure, Medicare certification and voluntary accreditation.

Most states require ASCs to be licensed in order to operate. Each state determines the specific requirements ASCs must meet for licensure. Most state licensure programs require rigorous initial and ongoing inspection and reporting.

All ASCs serving Medicare beneficiaries must be certified by the Medicare program. In order to be certified, an ASC must comply with standards developed by the federal government for the specific purpose of ensuring the safety of the patient and the quality of the facility, physicians, staff, services and management of the ASC. The ASC must demonstrate compliance with these Medicare standards initially and on an ongoing basis.

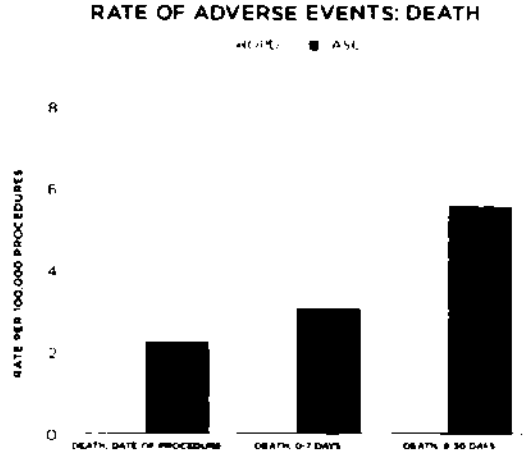
In addition to state and federal inspections, many ASCs choose to go through voluntary accreditation by an independent accrediting organization. Accrediting organizations for ASCs include the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for the Accreditation of Ambulatory Surgery Facilities (AAAASF) and the American Osteopathic Association (AOA). ASCs must meet specific standards during on-site inspections by these organizations in order to be accredited. All accrediting organizations require an ASC to engage in external benchmarking, which allows the facility to compare its performance to the performance of other ASCs.

In addition to requiring certification in order to participate in the Medicare program, federal regulations also limit the scope of surgical procedures reimbursed in ASCs.[5] Generally, services are limited to elective procedures with short anesthesia and operating times not requiring an overnight stay. These limitations do not apply to hospital outpatient departments (HOPDs).[6]

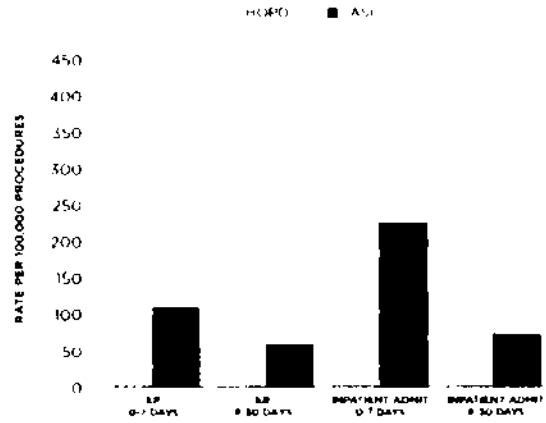
The federal government views ASCs and HOPDs as distinct types of providers. As a result, the federal regulations governing HOPDs and ASCs differ. Another reason for differing regulations is that, in a hospital, the same operating room may be used interchangeably to provide services to both inpatients and outpatients. For example, a procedure room in the HOPD may be used to perform a service for an inpatient and then used to perform the same procedure for an ambulatory patient who is discharged home immediately thereafter. In other words, ambulatory patients seen on an outpatient basis in an HOPD may utilize exactly the same facilities used to provide services to patients who have been admitted to the hospital. Consequently, the inpatient standards for hospitals are applied to HOPDs.[7]

On the other hand, ASCs provide services in facilities specifically designed to perform selected outpatient surgical services. The different requirements developed by the federal government appropriately reflect the fundamental differences in the hospital setting versus the ASC.[8]

ASCs consistently perform as well as, if not better than, HOPDs when quality and safety is examined. A recent study[9] included an examination of the rates of inpatient hospital admission and death in elderly patients following common outpatient surgical procedures in HOPDs and ASCs. Rates of inpatient hospital admission and death were lower in freestanding ASCs as compared to HOPDs. Even after controlling for factors associated with higher-risk patients, ASCs had low adverse outcome rates.



Hosokawa P.R., Henderson W.G., Khuri S.F., Daley J., Inpatient hospital admission and death after outpatient surgery in elderly patients: comparisons of patient and procedure characteristics and hospital rates, Arch Surg 2008;143(1):[illegible]



Hosokawa P.R., Henderson W.G., Khuri S.F., Daley J., Inpatient hospital admission and death after outpatient surgery in elderly patients: comparisons of patient and procedure characteristics and hospital rates, Arch Surg 2008;143(1):[illegible]

SPECIFIC FEDERAL REQUIREMENTS GOVERNING ASCs

In order to participate in the Medicare program, ASCs are required to meet certain conditions set by the federal government designed to ensure the facility is operated in a manner that ensures the safety of patients and the quality of services. Some of these requirements are highlighted in more detail below.

ASCs are required to maintain complete, comprehensive and accurate medical records. The content of these records must include a medical history and physical examination relevant to the reason for the surgery and the type of anesthesia planned. In addition, a physician must examine the patient immediately before surgery to evaluate the risk of anesthesia and the procedure to be performed. Prior to discharge each patient must be evaluated by a physician for proper anesthesia recovery.

CMS requires ASCs to ensure patients do not acquire infections during their care at these facilities. ASCs must establish a program for identifying and preventing infections, maintaining a sanitary environment, and reporting outcomes to appropriate authorities. The program must be one of active surveillance and include specific procedures for prevention, early detection, control, and investigation of infectious and communicable diseases in accordance with the recommendations of the Centers for Disease Control. In fact, ASCs have historically had very low infection rates.[10]

A registered nurse trained in the use of emergency equipment and in cardiopulmonary resuscitation must be available whenever a patient is in the ASC. To further protect patient safety, ASCs are also required to have an effective means of transferring patients to a hospital for additional care in the event an emergency occurs. Written guidelines outlining arrangements for ambulance services and transfer of medical information are mandatory. An ASC must have a written transfer agreement with a local hospital, or all physicians performing surgery in the ASC must have admitting privileges at the designated hospital. Although these safeguards are in place, hospital admissions as a result of complications following ambulatory surgery are rare.[9,11]

Continuous quality improvement is an important means of assuring patients are receiving the best care possible. ASCs are required to implement and monitor policies that ensure the facility provides quality health care in a safe environment. An ASC, with the active participation of the medical staff, is required to conduct an ongoing, comprehensive assessment of the quality of care provided.

The excellent outcomes associated with ambulatory surgery reflect the commitment that the ASC industry has made to quality and safety. One of the many reasons that ASCs continue to be so successful with patients, physicians and insurers is their keen focus on ensuring the quality of the services provided.

Medicare Requirements for ASCs and Hospitals Are The Same Where Services are Comparable

Compliance with state licensure law	☑	☑
Governing body	☑	☑
Surgical services	☑	☑
Evaluation of quality	☑	☑
Environment	☑	☑
Medical staff	☑	☑
Nursing services	☑	☑
Medical records	☑	☑
Pharmaceutical services	☑	☑
Laboratory services	☑	☑
Radiologic services	☑	☑

Source: 42 CFR 416, 42 CFR 482

A fundamental change in the way the government assures the quality of health care services is well underway. The Department of Health and Human Services has launched its Quality Initiative to assure quality health care through accountability and public disclosure.

The ASC industry is excited to have the opportunity to make its excellent outcomes more widely known to the public through this initiative. Leaders from the ASC industry, along with associations and related organizations with a focus on health care quality and safety, have come together in a collaborative effort to identify specific measures for quality appropriate to ASCs. This group, the ASC Quality Collaboration, strongly endorses the vision that measures of quality which are appropriate to ASCs should be congruent with measures utilized for other outpatient surgery settings. The continued development of these measures will involve a number of different stakeholders including ASC clinical and administrative leaders, health policy researchers, CMS and other key federal and state governmental agencies. The group will also work with the National Quality Forum to achieve consensus on the proposed quality measures.

PATIENT SATISFACTION

Patient satisfaction is a hallmark of the ASC industry. This year, more than eight million Americans will undergo surgery in an ASC. Virtually all of those patients will return home the same day and will resume most normal activities within a matter of days. Talk to these patients and you will hear how overwhelmingly satisfied they are with their ASC experience. Recent surveys show average patient satisfaction levels in ASCs exceeding 90 percent.[4] Safe and high quality services, ease of scheduling, greater personal attention and lower costs are among the main reasons cited for the growing popularity of ASCs as a place for having surgery.

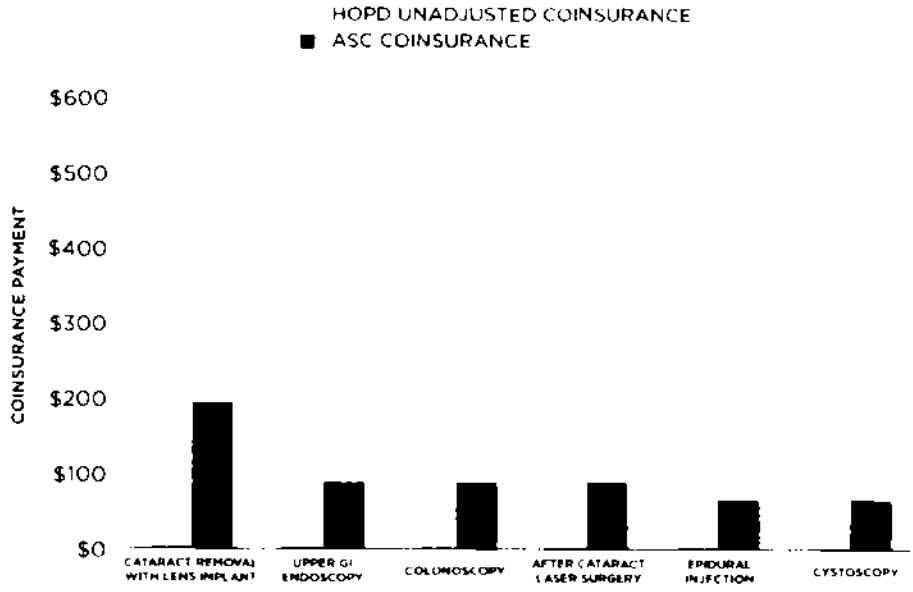
SUPPORTIVE CARE AT SIGNIFICANT COST SAVINGS

Not only are ASCs focused on ensuring patients have the best surgical experience possible, the care they provide is also more affordable. One of the reasons ASCs have been so successful is they offer valuable surgical and procedural services at a lower cost when compared to hospital charges for the same services. Beginning in 2007, Medicare payments to ASCs will be lower than or equal to Medicare payments to HOPDs for comparable services for 100 percent of procedures.[12]

In addition, patients typically pay less coinsurance for procedures performed in the ASC than for comparable procedures in the hospital setting. For example, a Medicare beneficiary could pay as much as $496 in coinsurance for a cataract extraction procedure performed in a HOPD, whereas that same beneficiary's copayment in the ASC would be only $195; a Medicare beneficiary could pay as much as $186 in coinsurance for a colonoscopy performed in a HOPD, whereas that same beneficiary's copayment for the same procedure performed in an ASC would be only $89. By having surgery in the ASC the patient may save as much as 61%, or more than $300, compared to their out-of-pocket coinsurance for the same procedure in the hospital.

Without the emergence of ASCs as an option for care, health care expenditures would have been billions of dollars higher over the past three decades. Studies have shown the Medicare program would pay approximately $464 million more per year if all procedures performed in an ASC were instead furnished at a hospital.[13] Private insurance companies tend to save similarly, which means employers also incur lower health care costs by utilizing ASC services. Employers and insurers, particularly managed care entities, are driving ASC growth in many areas, because they recognize ASCs are able to deliver consistent, high quality outcomes at a significant savings. As the number of surgical procedures performed in ASCs grows, the Medicare program may realize even greater savings - and of course Medicare beneficiaries will realize additional out-of-pocket savings as well.[14]

MEDICARE COINSURANCE RATES ARE LOWER IN ASCs



MedPAC Report to the Congress, Medicare Payment Policy, March 2004

THE ASC INDUSTRY SUPPORTS DISCLOSURE OF PRICING INFORMATION

It is the general practice of ASCs to make pricing information available to the patient in advance of surgery. The industry is eager to make price transparency a reality, not only for Medicare beneficiaries, but for all patients. To offer maximum benefit to the consumer, these disclosures should outline the total price of the planned surgical procedure and the specific portion for which the patient would be responsible. This will empower health care consumers as they evaluate and compare costs for the same service amongst various health care providers.

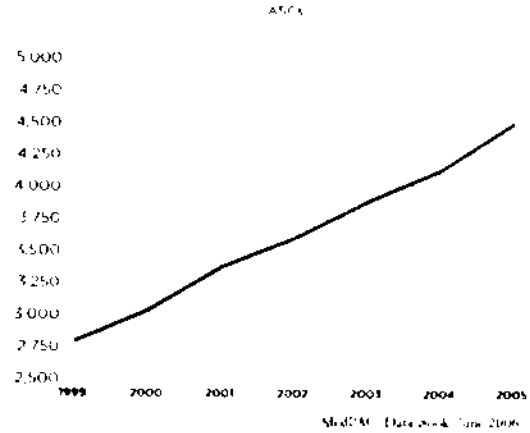
ASCs IMPROVE PATIENT CHOICE, DEMAND FOR ASCS GROWS

Technological advancement has allowed a growing range of procedures to be performed safely on an outpatient basis. Faster acting and more effective anesthetics and less invasive techniques, such as arthroscopy, have driven this outpatient migration. Procedures that only a few years ago required major incisions, long-acting anesthetics and extended convalescence can now be performed through closed techniques utilizing short-acting anesthetics, and with minimal recovery time. As medical innovation continues to advance, more and more procedures will be able to be performed safely in the outpatient setting.

The number of ASCs continues to grow in response to demand from the key participants in surgical care – patients, physicians and insurers. This demand has been made possible by technology, but has been driven by high levels of patient satisfaction, efficient physician practice, high levels of quality and the cost savings that have benefited all. The number of Medicare certified ASCs has grown from 2786 in 1999 to 4506 in 2005, with an average annual growth rate of 8.3%.[14]

Further impetus to future ASC growth has been given by MedPAC, which has recommended that the CMS list of approved ASC procedures be expanded. This would allow a broader range of choice for patients and surgeons. Specifically, MedPAC has recommended the procedures approved for the ASC setting be revised so that ASCs can receive payment for any surgical procedure, with the exception of those surgeries requiring an overnight stay or which pose a significant safety risk when furnished in an ASC.8 Adoption of these recommendations would allow Medicare beneficiaries to access an extended range of surgical services – a range of surgical services which is already available to patients with private insurance.[15]

NUMBER OF MEDICARE-CERTIFIED ASCs



ASCs WILL CONTINUE TO LEAD INNOVATION IN OUTPATIENT SURGICAL CARE

As leaders of the revolution in surgical care who led to the establishment of affordable and safe outpatient surgery, the ASC industry has shown itself to be ahead of the curve in identifying promising avenues for improving the delivery of health care.

With a solid track record of performance in stakeholder satisfaction, safety, quality and cost management, the ASC industry is already embracing the changes that will allow it to continue to play a leading role in raising the standards of performance in the delivery of outpatient surgical services.

As always, the ASC industry welcomes any opportunity to clarify the services it offers, the regulations and standards governing its operations, and the ways in which it ensures safe, high-quality care for patients.

POLICY CONSIDERATIONS

Given the continued fiscal challenges posed by administering health care programs, policy makers and regulators should continue to focus on fostering innovative methods of health care delivery that offer safe, high-quality care so progressive changes in the nation's health care system can be implemented.

Support should be reserved for those policies that promote the utilization of sites of service providing more affordable care while maintaining high quality and safety standards. In light of the many benefits ASCs have brought to the nation's health care system, it will be important for future payment and coverage policies to continue to strengthen access to and utilization of ASCs.

ENDNOTES

1 "Ambulatory Surgery Centers." Encyclopedia of Surgery. Ed. Anthony J. Senagore. Thomson Gale. 2004.

2 2004 ASC Salary and Benefits Survey, Federated Ambulatory Surgery Association. 2004.

3 Etzioni DA, Liu JH, Maggard MA, Ko CY. The aging population and its impact on the surgery workforce. Ann Surg. 2003 Aug;238(2):170-7.

4 Press Ganey Associates, 2004.

5 Centers for Medicare and Medicaid Services ASC Website, http://www.cms.hhs.gov/center/asc.asp

6 70 Fed. Reg. pp.68916-68964, November 10, 2005.

7 42 C.F.R. §482

8 42 C.F.R. §416

9 Fleisher LA, Pasternak LR, Herbert R, Anderson GF. Inpatient hospital admission and death after outpatient surgery in elderly patients: importance of patient and system characteristics and location of care. Arch Surg. 2004 Jan;139(1):67-72.

10 FASA, FASA Outcomes Monitoring Project, 4th Quarter 2005

11 Natof HE. Complications associated with ambulatory surgery. JAMA. 1980 Sep 5;244(10):1116-8.

12 Deficit Reduction Act of 2005.

13 MedPAC, Report to the Congress: Medicare Payment Policy, March 2004.

14 MedPAC, Data Book, June 2006.

15 Thomson Medstat, MarketScan® Outpatient Claims Data, 2005.

This report was prepared by the ASC Coalition and is further supported by the following organizations:

Alabama Ambulatory Surgery Association

American Association of Ambulatory Surgery Centers

AmSurg

Arizona Ambulatory Surgery Center Association

Arkansas Ambulatory Surgery Association

California Ambulatory Surgery Association

Colorado Ambulatory Surgery Center Association

FASA

Florida Society of Ambulatory Surgical Centers

Foundation for Ambulatory Surgery in America

Freestanding Ambulatory Surgery Center Association of Tennessee

Georgia Society of Ambulatory Surgery Centers

Healthmark Industries Co

HealthSouth

Idaho Ambulatory Surgery Center Association

Illinois Freestanding Surgery Center Association

Indiana Federation of Ambulatory Surgical Centers

Iowa Association of Ambulatory Surgery Centers

Kansas Association of Ambulatory Surgery Centers

Kentucky Ambulatory Surgery Center Association

Louisiana Ambulatory Surgery Association

Maine Ambulatory Surgery Center Coalition

Maryland Ambulatory Surgical Association

Massachusettes Association of Ambulatory Surgery Centers

Mississippi Ambulatory Surgery Association

Missouri Ambulatory Surgery Center Association

National Surgical Care

Nevada Ambulatory Surgery Association

New Hampshire Ambulatory Surgery Center

NovaMed

Nueterra Healthcare

Ohio Association of Ambulatory Surgery Centers

Pennsylvania Ambulatory Surgery Association

South Carolina Ambulatory Surgery Center Association

South Dakota Association of Specialty Care Providers

Symbion Healthcare

Texas Ambulatory Surgery Center Society

United Surgical Partners International

Utah Ambulatory Surgery Center Association

Washington Ambulatory Surgery Center Association

Wisconsin Surgery Center Association

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Attachment 4

OR Work Group Public Hearing Presentation
Raleigh Orthopaedic Clinic

Good morning. My name is Karl Stein and I am the administrator for Raleigh Orthopaedic Clinic. During my healthcare career I previously served as an administrator at a community hospital in Indiana.

Raleigh Orthopaedic Clinic is comprised of nineteen physicians and is the largest orthopedic practice in Wake County. Our physicians have privileges at Rex Hospital and WakeMed's New Bern and North locations. The group has four office locations and serves patients from all of Wake County and a large region of eastern North Carolina. In 2005, ROC physicians performed a total of 6,700 surgical procedures; ambulatory surgery procedures comprised 72 percent of the total. ROC physicians helped found and are active participants in the Wake County Medical Society's Project Access, which provides free office visits for low income patients.

Raleigh Orthopaedic Clinic has submitted multiple petitions to change the operating room methodology. We have petitioned for an adjusted need determination for ambulatory ORs in Wake County. Also, we jointly petitioned with other groups that proposed additional OR need determinations in each of the health service areas across the state. Even though our petitions have been denied, I am optimistic about the willingness of the OR Work Group to listen to our concerns and make needed changes.

My comments to you are encompassed by three main points:

1) Make changes that promote fairness.
2) Fix the methodology so that OR capacity is routinely added to keep pace with the growth in surgery demand.
3) Operational issues related to patient access, charity care, accreditation, staffing levels and quality should be addressed through the Certificate of Need review / conditional approval process.

When I talk about fairness, I ask you to make the OR methodology fair to all concerned. You should judge the current OR policies and methodology from the perspective of the average surgeon or the administrator of an average sized community hospital. Ask them what they think about the manipulations of the OR policies and CON process that resulted in the conversion of endoscopy rooms to operating rooms. You know that when loopholes like that are exploited, it undermines the entire process. Please consider making changes to the language in the OR Chapter to include statements such as:

"Additions to the operating room inventory must be consistent with and not exceed the OR need determinations in the SMFP. C-section operating rooms, dedicated open heart rooms, trauma operating rooms, other special operating rooms, endoscopy procedure rooms or other procedure rooms (that have been excluded from the OR adjusted planning inventory in the SMFP) can not be converted and / relocated to become surgical operating rooms unless CON approval has first been obtained in response to SMFP-published OR need determinations that are open to all CON applicants. "

Fairness also relates to the equitable distribution of surgical operating rooms. In at least one of our previous petitions we discussed the fact that there is a huge disparity in the number of operating rooms per capita from one county to another. Surprisingly, Wake County has substantially fewer surgical operating rooms as compared to the other large metropolitan counties like Mecklenburg, Durham, Forsyth and Guilford.

Look at the availability of operating rooms in rural counties. The OR methodology has no mechanism to improve geographic access. With the present methodology it is most unlikely that a new ambulatory surgery center could ever be developed in a small rural county.

You really need to look at the OR methodology to see if it works to decrease the disparity over time. My sense is that the current OR methodology is really broken -- it has allowed a

few hospital systems across the state to become exceedingly dominant in their markets while the smaller hospitals and physician groups are totally shut out. Please fix the methodology to give the surgeons and the community hospitals a level playing field to compete for CON approval.

Keeping pace with demand is my second point. Look at the actual growth rates in surgery volumes across the state in the handout and the chart. Over the past three years, inpatient surgery has shown no growth. In contrast, ambulatory surgery has increased steadily. I expect that in future years the inpatient surgery growth will increase somewhat due to the growth and aging of the population and ambulatory surgery cases will certainly continue to increase. How many people here think that the statewide growth of at least 2.5 percent in total surgery cases is too optimistic?

Based on the statewide surgery data, I strongly encourage you to modify the methodology so that it will generate at least 2.5 percent additional OR capacity each year. This translates to approximately 30+ additional operating rooms each year. This can be accomplished by changing the assumption of the annual hours per operating room from the current 1872 annual hours down to 1632 annual hours.

Now, there are three components that support justification for the 1632 annual hours assumption:

The majority of operating rooms across the state are staffed only one shift per day for 8 hours.

255 days per year is the number of actual workdays that surgery cases can be scheduled, which is 260 annual weekdays minus an average of 5 weekday holidays per year.

80 percent availability relates to maintenance, cleaning and staffing factors that preclude an operating room from being fully scheduled.

These three factors multiplied together yield 1632 annual hours.

What will happen if we don't fix the OR methodology is that tensions between hospitals and surgeons will increase and patient care will suffer. Raleigh Orthopaedic Clinic surgeons already have real difficulty scheduling surgery cases at the existing surgery facilities in Wake County. We have plans to recruit additional surgeons but we have no assurances that they will be able to gain access to the few existing ORs that are appropriate for their orthopedic specialties. If OR capacity does not increase to keep pace with demand, then we should stop spending money on recruitment.

The current methodology shows no need for additional operating rooms anywhere in the state through 2009. I think that having another planning year that puts no operating rooms in the pipeline for development would be a serious mistake. Also consider that a methodology that is overly frugal in terms of the number of OR need determinations will raise the stakes in competitive CON reviews and will guarantee lengthy and costly litigation.

My last point relates to operational issues including accreditation, staffing levels, quality, patient access and charity care. All of these issues should be addressed through the Certificate of Need regulations, competitive review and conditional approval process. The CON Section routinely attaches conditions to their CON approvals to ensure that the project will be developed in material compliance with the representations in the application. In addition, the CON law already provides the mechanisms for the Department to take enforcement action in Wake County Superior Court. With these regulatory provisions already in place, the OR methodology has no need to pre-qualifying potential CON applicants.

Please also know that the Raleigh Orthopaedic Clinic physicians willingly provide charity care to hospital inpatients and patients in our offices. If we ever have an opportunity to pursue CON approval for operating rooms, we would certainly commit to provide both access for all patient payor categories and a substantial level of charity care.

Thank you for your attention.

Attachment 5

Wake County Operating Room Data and Inventory Information - 2008 Plan with WakeMed Dedicated Open Heart Rooms and Cases Excluded	Inpatient Cases minus C Section	Ambulatory Cases	Combined Inpatient plus Ambulatory
Wake County Operating Room Volumes (Proposed 2008 Plan)	21029	55789	76818
Subtract 4 Dedicated ORs and Open Heart Cases	-931	0	0
Revised Statistics	20098	55789	75887
Hours per case (same assumption as OR methodology)	3.0	1.5	
Total Estimated Hours	60294.0	83683.5	143977.5
Population Growth Factor 2006-2010 (same assumption as OR methodology)			0.1479
Total Surgical Hours Anticipated in 2010			165,272
ROC Recommended Hours per Room			
9 hrs per day / 260 days per year / 80%			1872
Projected Number of ORs Needed			88.3
Adjusted Planning Inventory for Wake ORs (same as OR methodology)			90.0
Subtract 4 Open Heart ORs			-4.0
			86.0
Projected Need for Additional ORs in 2010 (excluding 4 Open Heart ORs)			**2.3**

Attachment 6

Media Release Database

Overview
Press Releases
Fact Sheets
Testimonies
Speeches

Press Releases

Details for: CMS REVISES PAYMENT STRUCTURE FOR AMBULATORY SURGICAL CENTERS AND PROPOSES POLICY AND PAYMENT CHANGES FOR HOSPITAL OUTPATIENT

Return to List

For Immediate Release: Monday, July 16, 2007

Contact: CMS Office of Public Affairs
202-690-6145

CMS REVISES PAYMENT STRUCTURE FOR AMBULATORY SURGICAL CENTERS AND PROPOSES POLICY AND PAYMENT CHANGES FOR HOSPITAL OUTPATIENT

NEW STEPS TO ENCOURAGE HOSPITAL EFFICIENCIES AND QUALITY

The Centers for Medicare & Medicaid Services (CMS) today issued a final rule revising the payment system for services furnished to people with Medicare in ambulatory surgical centers (ASCs) to better align payments for similar services furnished in a hospital outpatient department (HOPD) or a physician's office. CMS also issued a proposed rule that would update Medicare payment for services in HOPDs under the Outpatient Prospective Payment System (OPPS) and would set new payment rates for ASCs under the revised system effective for services in calendar year (CY) 2008.

The ASC final rule expands beneficiary access to surgical procedures in ASCs and implements steps to make ASC payments more accurate, while aligning payments across Medicare's payment systems to encourage efficient and appropriate choices of outpatient settings for ambulatory surgical procedures. CMS expects to make payments of almost $3 billion in CY 2008 to the approximately 4,600 ASCs that participate in Medicare.

"The system we are announcing today will promote the goals of quality and efficiency in care furnished to people with Medicare in ambulatory surgical centers," said CMS Acting Administrator, Leslie V. Norwalk, Esq. "In addition, this revised system will take a major step toward eliminating financial incentives for choosing one care setting over another, thus assuring that patients' needs come first."

The proposed OPPS/ASC rule, published concurrently with the ASC final rule, would implement new steps to encourage more efficient care in hospital outpatient departments by providing hospitals with greater flexibility to manage their resources. The proposal also would ensure appropriate payment for high quality hospital outpatient services under the hospital Outpatient Prospective Payment System (OPPS). The reforms included in this proposed rule are intended to encourage quality and constrain rapid and accelerating growth in Medicare volume and expenditures for hospital outpatient services.

"As the number of services provided in hospital outpatient setting continues to increase annually," said Ms. Norwalk, "we are committed to working with hospitals to ensure the care provided to beneficiaries is appropriate, cost-effective and high quality. Today's proposed rule includes proposed hospital quality measures specific to hospital outpatient care, following the quality measures that have been successfully implemented in the hospital inpatient setting. In addition, this rule's proposal to increase the size of the OPPS payment bundles will give hospitals the flexibility to manage their resources in the most efficient way possible."

Revised Payment Methodology For ASCs

The final rule allows ASCs to be paid for any surgical procedure that CMS determines does not pose a significant safety risk to Medicare beneficiaries when performed in an ASC and that is not expected to require an overnight stay. As a result, the final rule adds about 790 procedures for ASC payment beginning in CY 2008. The proposed OPPS/ASC rule would add several additional procedures, which would result in approximately 3,300 covered surgical procedures under the revised ASC payment system. CMS expects that as a result of the significant expansion of surgical procedures paid in ASCs, beneficiaries will experience greater access to surgical services in appropriate settings.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required CMS to revise the ASC payment system no later than January 1, 2008. Consistent with the recommendations of the November 2006 Government Accountability Office Report (GAO Report) on ASC costs and payment, CMS is implementing the revised ASC payment system using hospital OPPS relative payment weights as a guide.

The revised ASC payment rates are based on the ambulatory payment classifications (APCs) used to group procedures under the OPPS. As required by the MMA, the revised ASC payment system is budget neutral; that is, it is estimated to have no net effect on Medicare expenditures in CY 2008 compared to the level of expenditures that would have occurred in the absence of the revised payment system. Consistent with the GAO Report, which found that procedures performed in ASCs are generally less costly than those performed in the HOPD, the proposed ASC payment rates for CY 2008 are estimated to be set at 65 percent of the OPPS rates for the corresponding procedures.

Many of the surgical procedures that are included as covered surgical procedures eligible for payment in ASCs under the revised system are procedures that have been performed predominantly in physicians' offices. To avoid creating payment incentives to perform those services in ASCs when they could be safely performed at less cost to Medicare and the beneficiary in a physician's office, payment for surgical procedures identified as 'office-based' is capped at the nonfacility practice expense component of Medicare's Physician Fee Schedule (MPFS) payment rate in the physician office setting. A separate payment to the physician performing these surgical procedures would be made for their professional services provided in the ASC facility.

Under the revised system, Medicare will make separate payment for covered ancillary services, such as radiology services and some drugs and biologicals that are provided integral to covered surgical procedures. Medicare will also provide separate payment to ASCs for the brachytherapy sources that are implanted through surgically placed needles in the treatment of prostate cancer. In addition, Medicare will make payment adjustments for those ASC procedures with high device costs which ensure that the ASC payment includes the same payment for an implantable device as when the procedure is performed in a hospital outpatient department. Procedures with high device costs are those in the OPPS for which the cost of the device equals or exceeds 50 percent of the median cost of the APC.

The ASC payment system will be updated annually through proposed and final rulemaking in close association with updates to the OPPS and the MPFS. The ASC payment rates in the CY 2008 OPPS/ASC proposed rule are based upon the policies of final ASC rule, updated to comport with the proposed OPPS APC recalibration and proposed OPPS payment policies for CY 2008.

The final CY 2008 ASC payment rates will be published in the OPPS/ASC final rule in November 2007, some of which will be incrementally phased in over a four year transition period, with their full implementation in CY 2011. In addition, CMS will account for geographic wage variation in individual ASC payments by applying the wage index to 50 percent of the ASC payment.

Proposed 2008 Policy And Payment Changes For HOPDs And ASCs

Prior to the implementation of the OPPS, beneficiary coinsurance for hospital outpatient services often resulted in beneficiary responsibility for more than half of the actual payment for the HOPD services. In the CY 2008 proposed rule, beneficiary liability under the OPPS would continue to be reduced under a formula that is designed to provide a gradual transition to 20 percent coinsurance. Based on the proposed rule, the aggregate beneficiary liability is estimated to be 26 percent of the total payment, and almost 3100 services (or 23 percent of all types of services billed under the OPPS) would meet the target coinsurance of 20 percent, increased from about 2600 (or 19 percent of all types of services) in CY 2007.

The proposed rule includes a 3.3 percent inflation update in Medicare payment rates for services paid under the OPPS for CY 2008. CMS projects that hospitals would receive $34.9 billion in CY 2008 for outpatient services furnished to Medicare beneficiaries under the proposed rule. The proposed changes would affect outpatient services furnished by general acute care hospitals, inpatient rehabilitation facilities, inpatient psychiatric facilities, long-term acute care hospitals, children's hospitals, and cancer hospitals.

These statutory payment increases are projected to continue a trend of rapid growth in hospital outpatient expenditures. CMS projects that the expenditures under the OPPS in CY 2008 will be approximately 10.5 percent higher than the estimated CY 2007 expenditures. The current rate of growth in expenditures is of great concern to CMS because of its impact not only on taxpayers, but also on beneficiaries whose monthly premiums must pay for 25 percent of Part B expenditures.

While payments to hospitals under the OPPS have increased over the years, these payment increases have not been specifically tied to quality improvements. The statute now requires that the annual payment update factor in CY 2009 and subsequent years be reduced by 2.0 percentage points for hospitals that do not report quality measures. This proposed rule proposes 10 hospital outpatient quality measures for purposes of the quality reporting requirement.

The proposed quality measures include five emergency department acute myocardial infarction transfer measures, two surgical care improvement measures, and one measure each for the treatment of heart failure, community-acquired pneumonia, and diabetes. CMS is also seeking public comment on 30 additional measures that are under consideration for reporting in future years.

CMS is also proposing to increase the size of the OPPS payment bundles as recommended by the Medicare Payment Advisory Commission (MedPAC). This proposal would provide greater flexibility to hospitals in implementing efficient care. Currently, certain items and services, including low cost drugs, anesthesia services, operating and recovery room use, implantable devices, and medical supplies are packaged in the payment for the associated APCs. CMS is proposing to package payment for seven additional categories of supportive and ancillary services in order to encourage hospital efficiencies in selecting the most clinically appropriate diagnostic and treatment approaches.

In addition, CMS is proposing to establish a new type of APC, called a composite APC, through which a single payment would be made for multiple major procedures performed in a single hospital encounter. CMS is proposing to establish two composite APCs for 2008, one for low dose rate prostate brachytherapy and one for cardiac electrophysiological evaluation and ablation. These composite APCs allow CMS to use the most complete data for rate setting when procedures are commonly provided in combination with one another.

Attachment 7

North Carolina Department of Health and Human Services
Division of Facility Services
Acute and Home Care Licensure and Certification Section
1205 Umstead Drive, 2712 Mail Service Center
Raleigh, North Carolina 27699-2712
Telephone: (919) 855-4620 Fax: (919) 715-3073

For Official Use Only
License # H0065 Medicare # **340114**
Computer: 953429
PC KJ Date 1-3-07

License Fee: **$7,175.00**

2007
HOSPITAL LICENSE
RENEWAL APPLICATION

Legal Identity of Applicant: **Rex Hospital, Inc.**
(Full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service.)

Doing Business As
(d/b/a) name(s) under which the facility or services are advertised or presented to the public:

PRIMARY: **Rex Hospital**
Other: Rex Healthcare
Other: Rex Rehab. & Nursing Center of Raleigh

Facility Mailing Address: 4420 Lake Boone Trail
Raleigh, NC 27607

Facility Site Address: 4420 Lake Boone Trail
Raleigh, NC 27607
County: Wake
Telephone: (919)784-3100
Fax: (919)784-3336

Administrator/Director: David Strong
Title: President
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Chief Executive Officer: Gary L. Park **Title:** CEO
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Name of the person to contact for any questions regarding this form:

Name: Marcus M. Wilson **Telephone:** (919) 784-6394

E-Mail: marcus.wilson@rexhealth.com

FEE PAID
Date 12 / 29 / 06
Amount $ 7,175.00
Check Other
556654

*The N.C. Department of Health and Human Services does not discriminate on the basis of race, color, national origin, religion, age, or disability in employment or the provision of services.

7. **Specialized Cardiac Services** (for questions, call 855-3865 [Medical Facilities Planning])

(a) Cardiac Catheterization	**Diagnostic Cardiac Catheterization ICD-9 37.21, 37.22, 37.23, 37.25**	**Interventional Cardiac Catheterization- ICD-9 36.01, 36.02, 36.05, 36.06, 36.07, 36.09; 35.52, 35.71, 35.96**	**Electro-physiology 37.26, 37.27, 37.34, 37.70, 37.71, 37.72, 37.73, 37.74, 37.75, 37.76, 37.77, 37.79, 37.80, 37.81, 37.82, 37.83, 37.85, 37.86, 37.87, 37.89, 37.94, 37.95, 37.96, 37.97, 37.98, 37.99, 00.50, 00.51, 00.52, 00.53, 00.54**
1. Number of Units of Equipment	3		1
2. Total Annual Number of Cases*	2,086	1,102	458
3. Of Total in #2, Number of Patients Age 14 & under	0	0	0
4. Of Total in #2, Number of Cases Performed in Mobile Unit**	0	0	0

* One case is defined to be one visit or trip by a patient to an operating room or catheterization laboratory for a single or multiple procedures or catheterizations. Count each visit once regardless of the number of diagnostic, interventional, and/or EP procedures performed within that visit.

** Please report name of mobile vendor: _____

Number of operating hours per week on site: _____

(b) Open Heart Surgery (utilizing heart/lung bypass machines)	
1. Number of Dedicated Open Heart Surgery Operating Rooms	0
2. Number of Heart-Lung Bypass Machines	3
3. Total Annual Number of Procedures	359
4. Of total in #3, Number of Procedures on Patients Age 14 & under	0

8. Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases

a) Surgical Operating Rooms and Cases

[1] Please report *Surgical Operating Rooms* built to meet the specifications and standards for operating rooms required by the Construction Section of the Division of Facility Services, and which are fully equipped to perform surgical procedures. These surgical operating rooms include rooms located in Obstetrics and surgical suites. Please report the number of cases performed in these rooms during the reporting period. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was in the operating room.

NOTE: If this License includes more than one campus, please submit the Cumulative Totals **and** COPY this sheet and Submit a duplicate of this page for each campus.

(**Campus** – ***If multiple sites:*** Rex Hospital - Main Campus Raleigh)

Type of Room [A]	Number of Rooms [B]	Of the Rooms in Column [B], the number "Not in Use" [C]	Inpatient Cases [D]	Ambulatory Cases [E]
Dedicated Open Heart Surgery (from 7b)	0	0	0	
Dedicated C-Section	0	0	0	
Other Dedicated Inpatient Surgery	0	0	0	
Dedicated Ambulatory Surgery	0	0		
Shared - Inpatient / Ambulatory Surgery	27	0	9,255	15,323
Total of Surgical Operating Rooms & Cases *(Columns [D] & [E] should equal Totals in 8(d))*	27	0	9,255	15,323

[2] Does this facility have **additional** surgical operating rooms (i.e., **not** listed above) that **are being developed** pursuant to a Certificate of Need or pursuant to the exemption provided in Senate Bill 714? ____ Yes X No

If "Yes," please list the **Types of Rooms** and **Number of Rooms** being developed:

b) Gastrointestinal Endoscopy Rooms and Cases

[1] Report the number of *Gastrointestinal Endoscopy Rooms* and the number of cases performed in these rooms during the reporting period. (***NOTE***: **Other procedure rooms** should be included in **Section 9** on **Page 10** of this application.) Count each patient as one case regardless of the number of gastrointestinal procedures performed while patient was in the GI endoscopy room. For GI Endoscopy Rooms, please also report the Total Number of GI Procedures performed.

Type of Room [A]	Number Of Rooms [B]	Of the Rooms in Column [B], the number "Not in Use" [C]	Inpatient Cases [D]	Ambulatory Cases [E]	Total Number of Procedures [F]
Gastrointestinal Endoscopy Rooms & Cases	4	0	GI: 992	GI: 5,795	GI: 8,012
			Non GI: 88	Non GI: 122	Non GI: 211

[2] Does this facility have **additional** Gastrointestinal Endoscopy Rooms (i.e., **not** listed above) that **are being developed** pursuant to a Certificate of Need or pursuant to the exemption provided in Senate Bill 714? ____ Yes X No

If "Yes," please list the **Number of Rooms** being developed:

8. Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases

a) Surgical Operating Rooms and Cases

[1] Please report *Surgical Operating Rooms* built to meet the specifications and standards for operating rooms required by the Construction Section of the Division of Facility Services, and which are fully equipped to perform surgical procedures. These surgical operating rooms include rooms located in Obstetrics and surgical suites. Please report the number of cases performed in these rooms during the reporting period. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was in the operating room.

NOTE: If this License includes more than one campus, please submit the Cumulative Totals **and** COPY this sheet and Submit a duplicate of this page for each campus.

(**Campus** – *If multiple sites*: Rex Healthcare of Cary)

Type of Room [A]	Number of Rooms [B]	Of the Rooms in Column [B], the number "Not in Use" [C]	Inpatient Cases [D]	Ambulatory Cases [E]
Dedicated Open Heart Surgery (from 7b)	0	0	0	
Dedicated C-Section	0	0	0	
Other Dedicated Inpatient Surgery	0	0	0	
Dedicated Ambulatory Surgery	4	0		2,899
Shared - Inpatient / Ambulatory Surgery	0	0	0	0
Total of Surgical Operating Rooms & Cases *(Columns [D] & [E] should equal Totals in 8(d))*	4	0	0	2,899

[2] Does this facility have **additional** surgical operating rooms (i.e., **not** listed above) **that are being developed** pursuant to a Certificate of Need or pursuant to the exemption provided in Senate Bill 714? _____ Yes __X__ No

If "Yes," please list the **Types of Rooms** and **Number of Rooms** being developed:

_____

b) Gastrointestinal Endoscopy Rooms and Cases

[1] Report the number of *Gastrointestinal Endoscopy Rooms* and the number of cases performed in these rooms during the reporting period. (*NOTE*: **Other procedure rooms** should be included in **Section 9** on **Page 10** of this application.) Count each patient as one case regardless of the number of gastrointestinal procedures performed while patient was in the GI endoscopy room. For GI Endoscopy Rooms, please also report the Total Number of GI Procedures performed.

Type of Room [A]	Number Of Rooms [B]	Of the Rooms in Column [B], the number "Not in Use" [C]	Inpatient Cases [D]	Ambulatory Cases [E]	Total Number of Procedures [F]
Gastrointestinal Endoscopy Rooms & Cases	0	0	GI: 0	GI: 0	GI: 0
			Non GI: 0	Non GI: 0	Non GI: 0

[2] Does this facility have **additional** Gastrointestinal Endoscopy Rooms (i.e., **not** listed above) **that are being developed** pursuant to a Certificate of Need or pursuant to the exemption provided in Senate Bill 714? _____ Yes __0__ No

If "Yes," please list the **Number of Rooms** being developed:

_____

8. Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases *continued*

c) Average Room Availability and Average Case Times:

Type of Room	"Resource Hours" * *(Average Hours per Room per Day Routinely Scheduled for Use)*	Average "Case Time" ** in Minutes for Inpatient Cases	Average "Case Time" ** in Minutes for Ambulatory Cases
Surgical Operating Rooms	9.67	160	108
Gastrointestinal Endoscopy Rooms	7.75	52	44

* **"Resource Hours"** = Average number of hours per Room per Day routinely scheduled to be available for performance of procedures. (**Example**: 2 rooms @ 8 hours per day plus 2 rooms @ 10 hours per day equals 36 hours per day; divided by 4 rooms equals an average of 9 hours / per room / per day.)

** **"Case Time" = Time from Room Set-up Start to Room Clean-up Finish**. Definition 2.4 from the "Procedural Times Glossary" of the AACD, as approved by ASA, ACS, and AORN. *NOTE: This definition includes all of the time for which a given procedure requires an OR/PR. It allows for the different duration of Room Set-up and Room Clean-up Times that occur because of the varying supply and equipment needs for a particular procedure. For purposes of scheduling and efficiency analysis, this definition is ideal because it includes all of the time that an OR/PR must be reserved for a given procedure.*

d) Surgical Specialty - Of the cases in **Surgical Operating Rooms** (Item 8.a.[1]), enter the number of cases by surgical specialty area in the chart below:

Specialty Area	Inpatient Cases	Ambulatory Cases
Cesarean Sections	2,068	
Cystoscopy	3	27
Endoscopy (all endo types performed in Surgical Operating Room)	3	8
General	1,955	3,740
Gynecology	947	2,587
Neurosurgery	147	493
Open Heart	359	
Ophthalmology	6	670
Oral Surgery	1	13
Orthopedics	2,352	3,589
Otolaryngology	62	3,108
Plastic Surgery	351	2,366
Podiatry	1	401
Thoracic (other than open heart)	37	4
Urology	427	804
Other (Specify)	536	412
Total Surgical Operating Room Cases *(Totals should equal totals 8.a[1], columns D & E)*	9,255	18,222

9. Non-Gastrointestinal Procedure Rooms and Cases

Please report only rooms or cases not reported in 8a or 8b: Other rooms not equipped or meeting all the specifications for an operating room, dedicated to the performance of procedures other than gastrointestinal endoscopy. (Do not list a room for more than one use). **Please note: Any procedures performed in these rooms should not be billed as having occurred in an operating room or reported in 8 as procedures performed in an operating room. Cases**: Count each patient as one case regardless of the number of procedures performed while patient was in the room.

Use	Number of Rooms	Inpatient Cases	Ambulatory Cases
Cast Procedures	0	0	0
Cystoscopy	1	170	461
Endoscopies *(other than GI Endoscopies)* unless they were performed in a surgical operating room	0	0	0
Lithotripsy*	1	9	399
Special Procedures/Angiography (neuro & vascular but not including cardiac cath.)	3	1,301	2,614
Sutures	0	0	0
YAG Laser	0	4	3
Other (Specify) Minor Procedures**	4	66	4,397
Totals	9	1,550	7,874

* Lithotripsy is provided by a mobile service. From October 1, 2005 to July 9, 2006 lithotripsy services were available 8 days per month. With the addition of a second mobile service that increased to 12 days per month beginning July 10, 2006

** As of October 17, 2005, Rex added 4 minor procedure rooms, closed one minor procedure room and the YAG laser room, for a new total of 9 procedure rooms

North Carolina Department of Health and Human Services
Division of Facility Services
Acute and Home Care Licensure and Certification Section
1205 Umstead Drive, 2712 Mail Service Center
Raleigh, North Carolina 27699-2712
Telephone: (919) 855-4620 Fax: (919) 715-3073

For Official Use Only
License # H0199 Medicare # **340069**
Computer: 943528
PC KJ Date 12/19/06

License Fee: **$8,275.00**

2007
HOSPITAL LICENSE
RENEWAL APPLICATION

Legal Identity of Applicant: **WakeMed**
(Full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service.)

Doing Business As
(d/b/a) name(s) under which the facility or services are advertised or presented to the public:

PRIMARY: **WakeMed**
Other:
Other:

Facility Mailing Address: P O Box 14465
Raleigh, NC 27620-4465

Facility Site Address: 3000 New Bern Ave
Raleigh, NC 27610
County: Wake
Telephone: (919)350-8000
Fax: (919)350-8868

Administrator/Director: William K Atkinson, Ph.D.
Title: President and CEO
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Chief Executive Officer: William K Atkinson, Ph.D. **Title:** President and CEO
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Name of the person to contact for any questions regarding this form:

Name: W. Stan Taylor, Vice President, Corporate Planning and Managed Care **Telephone:** 919-350-8108

E-Mail: staylor@wakemed.org

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"The N.C. Department of Health and Human Services does not discriminate on the basis of race, color, national origin, religion, age, or disability in employment or the provision of services."

7. **Specialized Cardiac Services** (for questions, call 855-3865 [Medical Facilities Planning])

(a) Cardiac Catheterization	**Diagnostic Cardiac Catheterization ICD-9 37.21, 37.22, 37.23, 37.25**	**Interventional Cardiac Catheterization- ICD-9 36.01, 36.02, 36.05, 36.06, 36.07, 36.09; 35.52, 35.71, 35.96**	**Electro-physiology 37.26, 37.27, 37.34, 37.70, 37.71, 37.72, 37.73, 37.74, 37.75, 37.76, 37.77, 37.79, 37.80, 37.81, 37.82, 37.83, 37.85, 37.86, 37.87, 37.89, 37.94, 37.95, 37.96, 37.97, 37.98, 37.99, 00.50, 00.51, 00.52, 00.53, 00.54**
1. Number of Units of Equipment	8		2
2. Total Annual Number of Cases*	5,536 (8,302)***	3,521 (3,521)***	1,120 (1,417)***
3. Of Total in #2, Number of Patients Age 14 & under	0	0	0
4. Of Total in #2, Number of Cases Performed in Mobile Unit**	0	0	0

***Procedures done in each category

* One case is defined to be one visit or trip by a patient to an operating room or catheterization laboratory for a single or multiple procedures or catheterizations. Count each visit once regardless of the number of diagnostic, interventional, and/or EP procedures performed within that visit.

** Please report name of mobile vendor: not applicable

Number of operating hours per week on site: not applicable

(b) Open Heart Surgery (utilizing heart/lung bypass machines)	
1. Number of Dedicated Open Heart Surgery Operating Rooms	4
2. Number of Heart-Lung Bypass Machines	6
3. Total Annual Number of Procedures	931
4. Of total in #3, Number of Procedures on Patients Age 14 & under	0

8. Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases

a) Surgical Operating Rooms and Cases

[1] Please report *Surgical Operating Rooms* built to meet the specifications and standards for operating rooms required by the Construction Section of the Division of Facility Services, and which are fully equipped to perform surgical procedures. These surgical operating rooms include rooms located in Obstetrics and surgical suites. Please report the number of cases performed in these rooms during the reporting period. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was in the operating room.

NOTE: If this License includes more than one campus, please submit the Cumulative Totals **and** COPY this sheet and Submit a duplicate of this page for each campus.

(Campus – *If multiple sites*: WakeMed Raleigh ALL SITES)

Type of Room [A]	Number of Rooms [B]	Of the Rooms in Column [B], the number "Not in Use" [C]	Inpatient Cases [D]	Ambulatory Cases [E]
Dedicated Open Heart Surgery (from 7b)	4	0	981	
Dedicated C-Section	3	0	1,194	
Other Dedicated Inpatient Surgery	0	0	0	
Dedicated Ambulatory Surgery	4	0		3,519
Shared - Inpatient / Ambulatory Surgery	18	0	6,960	10,110
Total of Surgical Operating Rooms & Cases *(Columns [D] & [E] should equal Totals in 8(d))*	**29**	**0**	**9,135**	**13,629**

[2] Does this facility have **additional** surgical operating rooms (i.e., **not** listed above) that **are being developed** pursuant to a Certificate of Need or pursuant to the exemption provided in Senate Bill 714? _____ Yes _____ No

If "Yes," please list the **Types of Rooms** and **Number of Rooms** being developed:

_____

b) Gastrointestinal Endoscopy Rooms and Cases

[1] Report the number of *Gastrointestinal Endoscopy Rooms* and the number of cases performed in these rooms during the reporting period. (***NOTE*: Other procedure rooms** should be included in **Section 9** on **Page 10** of this application.) Count each patient as one case regardless of the number of gastrointestinal procedures performed while patient was in the GI endoscopy room. For GI Endoscopy Rooms, please also report the Total Number of GI Procedures performed.

Type of Room [A]	Number Of Rooms [B]	Of the Rooms in Column [B], the number "Not in Use" [C]	Inpatient Cases [D]	Ambulatory Cases [E]	Total Number of Procedures [F]
Gastrointestinal Endoscopy Rooms & Cases	6	0	GI: 2,642	GI: 4,376	GI: 7,018
			Non GI:	Non GI:	Non GI:

[2] Does this facility have **additional** Gastrointestinal Endoscopy Rooms (i.e., **not** listed above) that **are being developed** pursuant to a Certificate of Need or pursuant to the exemption provided in Senate Bill 714? _____ Yes __X__ No

If "Yes," please list the **Number of Rooms** being developed:

_____

Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases *continued*

c) Average Room Availability and Average Case Times: WAKEMED RALEIGH ALL SITES

Type of Room	"Resource Hours" * *(Average Hours per Room per Day Routinely Scheduled for Use)*	Average "Case Time" ** in Minutes for Inpatient Cases	Average "Case Time" ** in Minutes for Ambulatory Cases
Surgical Operating Rooms	7.4/hours/room/day/ 365 days per year	178 Main OR 372 Open Heart	120 Main OR 69 Open Heart
Gastrointestinal Endoscopy Rooms	5.7/hours/room/day/ 365 days per year	44	54

* **"Resource Hours"** = Average number of hours per Room per Day routinely scheduled to be available for performance of procedures. (**Example**: 2 rooms @ 8 hours per day plus 2 rooms @ 10 hours per day equals 36 hours per day; divided by 4 rooms equals an average of 9 hours / per room / per day.)

** **"Case Time" = Time from Room Set-up Start to Room Clean-up Finish.** Definition 2.4 from the "Procedural Times Glossary" of the AACD, as approved by ASA, ACS, and AORN. *NOTE: This definition includes all of the time for which a given procedure requires an OR/PR. It allows for the different duration of Room Set-up and Room Clean-up Times that occur because of the varying supply and equipment needs for a particular procedure. For purposes of scheduling and efficiency analysis, this definition is ideal because it includes all of the time that an OR/PR must be reserved for a given procedure.*

d) Surgical Specialty - Of the cases in **Surgical Operating Rooms** (Item 8.a.[1]), enter the number of cases by surgical specialty area in the chart below:

Specialty Area	Inpatient Cases	Ambulatory Cases
Cesarean Sections	1,194	
Cystoscopy	164	602
Endoscopy (all endo types performed in Surgical Operating Room)	10	15
General	2,211	2,739
Gynecology	534	1,607
Neurosurgery	705	700
Open Heart	981	[illegible]
Ophthalmology	1	764
Oral Surgery	42	1,085
Orthopedics	1,771	2,557
Otolaryngology	316	2,227
Plastic Surgery	99	259
Podiatry	0	207
Thoracic (other than open heart)	476	9
Urology	337	826
Other (Specify) (Vascular)	294	33
Total Surgical Operating Room Cases *(Totals should equal totals 8.a[1], columns D & E)*	9,135	13,630

9. Non-Gastrointestinal Procedure Rooms and Cases — WAKEMED RALEIGH ALL SITES

Please report only rooms or cases not reported in 8a or 8b: Other rooms not equipped or meeting all the specifications for an operating room, dedicated to the performance of procedures other than gastrointestinal endoscopy. (Do not list a room for more than one use). **Please note: Any procedures performed in these rooms should not be billed as having occurred in an operating room or reported in 8 as procedures performed in an operating room. Cases**: Count each patient as one case regardless of the number of procedures performed while patient was in the room.

Use	Number of Rooms	Inpatient Cases	Ambulatory Cases
Cast Procedures			
Cystoscopy			
Endoscopies *(other than GI Endoscopies)* unless they were performed in a surgical operating room			
Lithotripsy	0		0
Special Procedures/Angiography (neuro & vascular but not including cardiac cath.)	3	9,158	9,346
Sutures			
YAG Laser			
Other (Specify) Minor Procedure	1		294
Totals	**4**	**9,158**	**9,640**

North Carolina Department of Health and Human Services
Division of Facility Services
Acute and Home Care Licensure and Certification Section
1205 Umstead Drive, 2712 Mail Service Center
Raleigh, North Carolina 27699-2712
Telephone: (919) 855-4620 Fax: (919) 715-3073

For Official Use Only
License # H0238 Medicare # **340073**
Computer: 923421
PC KJ Date 12-6-06

License Fee: **$2,775.00**

2007
HOSPITAL LICENSE
RENEWAL APPLICATION

Legal Identity of Applicant: **Duke University Health System, Inc.**
(Full legal name of corporation, partnership, individual, or other legal entity owning the enterprise or service.)

Doing Business As
(d/b/a) name(s) under which the facility or services are advertised or presented to the public:

PRIMARY: ~~Duke Health Raleigh Hospital~~ ... Duke Raleigh Hospital
Other: DHRH Sports Medicine and Physical Therapy
Other: The Plaza Pharmacist

Facility Mailing Address: 3400 Wake Forest Road
Raleigh, NC 27611-8280

Facility Site Address: 3400 Wake Forest Rd
Raleigh, NC 27609
County: Wake
Telephone: (919)954-3000
Fax: (919)954-3900

Administrator/Director: ~~James Kanan~~ - Douglas B. Vinsel
Title: CEO
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Chief Executive Officer: Douglas B. Vinsel **Title:** CEO
(Designated agent (individual) responsible to the governing body (owner) for the management of the licensed facility)

Name of the person to contact for any questions regarding this form:

Name: Richard J. Gannotta, COO **Telephone:** 954-3101

E-Mail: Rick.Gannotta@duke.edu

CS

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"The N.C. Department of Health and Human Services does not discriminate on the basis of race, color, national origin, religion, age, or disability in employment or the provision of services."

8. Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases

a) Surgical Operating Rooms and Cases

[1] Please report *Surgical Operating Rooms* built to meet the specifications and standards for operating rooms required by the Construction Section of the Division of Facility Services, and which are fully equipped to perform surgical procedures. These surgical operating rooms include rooms located in Obstetrics and surgical suites. Please report the number of cases performed in these rooms during the reporting period. Count each patient undergoing surgery as one case regardless of the number of surgical procedures performed while the patient was in the operating room.

NOTE: If this License includes more than one campus, please submit the Cumulative Totals **and** COPY this sheet and Submit a duplicate of this page for each campus.

(Campus – *If multiple sites*: _____)

Type of Room [A]	Number of Rooms [B]	Of the Rooms in Column [B], the number "Not in Use" [C]	Inpatient Cases [D]	Ambulatory Cases [E]
Dedicated Open Heart Surgery (from 7b)	0	0	0	
Dedicated C-Section - See addendum	1	1	120	
Other Dedicated Inpatient Surgery	0	0	0	
Dedicated Ambulatory Surgery	0	0		
Shared - Inpatient / Ambulatory Surgery	12	0	2366	8155
Total of Surgical Operating Rooms & Cases *(Columns [D] & [E] should equal Totals in 8(d))*	13	1	2486	8155

[2] Does this facility have **additional** surgical operating rooms (i.e., **not** listed above) that **are being developed** pursuant to a Certificate of Need or pursuant to the exemption provided in Senate Bill 714? ____ Yes __X__ No

If "Yes," please list the **Types of Rooms** and **Number of Rooms** being developed:

_____

b) Gastrointestinal Endoscopy Rooms and Cases

[1] Report the number of *Gastrointestinal Endoscopy Rooms* and the number of cases performed in these rooms during the reporting period. (*NOTE*: **Other procedure rooms** should be included in **Section 9** on **Page 10** of this application.) Count each patient as one case regardless of the number of gastrointestinal procedures performed while patient was in the GI endoscopy room. For GI Endoscopy Rooms, please also report the Total Number of GI Procedures performed.

Type of Room [A]	Number Of Rooms [B]	Of the Rooms in Column [B], the number "Not in Use" [C]	Inpatient Cases [D]	Ambulatory Cases [E]	Total Number of Procedures [F]
Gastrointestinal Endoscopy Rooms & Cases	3	0	GI: 342	GI: 5281	GI: 6885
			Non GI: 35	Non GI: 138	Non GI: 211

[2] Does this facility have **additional** Gastrointestinal Endoscopy Rooms (i.e., **not** listed above) that **are being developed** pursuant to a Certificate of Need or pursuant to the exemption provided in Senate Bill 714? ____ Yes __X__ No

If "Yes," please list the **Number of Rooms** being developed:

_____

Addendum to Page 8

Type of Room
Column A
Line 2

Dedicated C-Section room was closed and converted to a shared OR room on December 1, 2005

8. Surgical Operating Rooms and Gastrointestinal Endoscopy Rooms with Cases *continued*

c) Average Room Availability and Average Case Times:

Type of Room	"Resource Hours" * *(Average Hours per Room per Day Routinely Scheduled for Use)*	Average "Case Time" ** In Minutes for Inpatient Cases	Average "Case Time" ** in Minutes for Ambulatory Cases
Surgical Operating Rooms	10	171	72
Gastrointestinal Endoscopy Rooms	8.0	50	38

* **"Resource Hours"** = Average number of hours per Room per Day routinely scheduled to be available for performance of procedures. (**Example**: 2 rooms @ 8 hours per day plus 2 rooms @ 10 hours per day equals 36 hours per day; divided by 4 rooms equals an average of 9 hours / per room / per day.)

** **"Case Time"** = **Time from Room Set-up Start to Room Clean-up Finish**. Definition 2.4 from the "Procedural Times Glossary" of the AACD, as approved by ASA, ACS, and AORN. *NOTE: This definition includes all of the time for which a given procedure requires an OR/PR. It allows for the different duration of Room Set-up and Room Clean-up Times that occur because of the varying supply and equipment needs for a particular procedure. For purposes of scheduling and efficiency analysis, this definition is ideal because it includes all of the time that an OR/PR must be reserved for a given procedure.*

d) Surgical Specialty - Of the cases in **Surgical Operating Rooms** (Item 8.a.[1]), enter the number of cases by surgical specialty area in the chart below:

Specialty Area	Inpatient Cases	Ambulatory Cases
Cesarean Sections	120	
Cystoscopy	0	0
Endoscopy (all endo types performed in Surgical Operating Room)	7	41
General	866	2651
Gynecology	185	314
Neurosurgery	141	192
Open Heart	0	
Ophthalmology	5	547
Oral Surgery	8	9
Orthopedics	1107	3962
Otolaryngology	0	0
Plastic Surgery	9	337
Podiatry	0	1
Thoracic (other than open heart)	0	0
Urology	38	101
Other (Specify)		
Total Surgical Operating Room Cases *(Totals should equal totals 8.a[1], columns D & E)*	2486	8155

9. Non-Gastrointestinal Procedure Rooms and Cases

Please report only rooms or cases not reported in 8a or 8b: Other rooms not equipped or meeting all the specifications for an operating room, dedicated to the performance of procedures other than gastrointestinal endoscopy. (Do not list a room for more than one use). **Please note: Any procedures performed in these rooms should not be billed as having occurred in an operating room or reported in 8 as procedures performed in an operating room. Cases**: Count each patient as one case regardless of the number of procedures performed while patient was in the room.

Use	Number of Rooms	Inpatient Cases	Ambulatory Cases
Cast Procedures	0	0	0
Cystoscopy	1	30	190
Endoscopies *(other than GI Endoscopies)* unless they were performed in a surgical operating room	0	0	0
Lithotripsy	0	0	0
Special Procedures/Angiography (neuro & vascular but not including cardiac cath.)	1	263	393
Sutures	0	0	0
YAG Laser	0	0	0
** Other (Specify) Pain Clinic	3	19	4825
Totals	5	312	5408

* Bronchoscopies performed in Endo room

** Includes consults and follow up visits
Inpatient
Ambulatory

Attachment 8

Archives of Internal Medicine
Vol. 165 No. 15, Aug 8/22, 2005

The Burden of *Staphylococcus aureus* Infections on Hospitals in the United States

An Analysis of the 2000 and 2001 Nationwide Inpatient Sample Database

Gary A. Noskin, MD; Robert J. Rubin, MD; Jerome J. Schentag, PharmD; Jan Kluytmans, MD, PhD; Edwin C. Hedblom, PharmD; Maartje Smulders, MS, MPH; Elizabeth Lapetina, AB; Eric Gemmen, MA

Arch Intern Med. 2005;165:1756-1761.

Background Previous studies have investigated the impact of *Staphylococcus aureus* infections on individual hospitals, but to date, no study using nationally representative data has estimated this burden.

Methods This is a retrospective analysis of the 2000 and 2001 editions of the Agency for Healthcare Research and Quality's Nationwide Inpatient Sample database, which represents a stratified 20% sample of hospitals in the United States. All inpatient discharge data from 994 hospitals in 28 states during 2000 and from 986 hospitals in 33 states during 2001, representing approximately 14 million inpatient stays, were analyzed to determine the association of *S aureus* infections with length of stay, total charges, and in-hospital mortality.

Results *Staphylococcus aureus* infection was reported as a discharge diagnosis for 0.8% of all hospital inpatients, or 292 045 stays per year. Inpatients with *S aureus* infection had, on average, 3 times the length of hospital stay (14.3 vs 4.5 days; $P<.001$), 3 times the total charges ($48 824 vs $14 141; $P<.001$), and 5 times the risk of in-hospital death (11.2% vs 2.3%; $P<.001$) than inpatients without this infection. Even when controlling for hospital fixed effects and for patient differences in diagnosis-related groups, age, sex, race, and comorbidities, the differences in mean length of stay, total charges, and mortality were significantly higher for hospitalizations associated with *S aureus*.

Conclusions *Staphylococcus aureus* infections represent a considerable burden to US hospitals, particularly among high-risk patient populations. The potential benefits to hospitals in terms of reduced use of resources and costs as well as improved outcomes from preventing *S aureus* infections are significant.

Author Affiliations: Department of Medicine, Division of Infectious Diseases, Feinberg School of Medicine, Northwestern University, and Northwestern Memorial Hospital, Chicago, Ill (Dr Noskin); Department of Medicine, Division of Nephrology and Hypertension, Georgetown University, Washington, DC (Dr Rubin); School of Pharmacy, University of Buffalo, Buffalo, NY (Dr Schentag); Laboratory of Microbiology and Infection Control, Amphia Hospital, Breda, the Netherlands (Dr Kluytmans); 3M Medical Division, St Paul, Minn (Dr Hedblom); and Quintiles Strategic Research Services, Falls Church, Va (Mss Smulders and Lapetina and Mr Gemmen).

Data Show Scourge of Hospital Infections

By Ceci Connolly
Washington Post Staff Writer
Wednesday, July 13, 2005; A01

Nearly 12,000 Pennsylvanians contracted infections during a hospital stay in 2004, costing an extra $2 billion in care and at least 1,500 preventable deaths, according to state figures released yesterday that officials say represent a conservative measure of one of the deadliest problems in modern medicine.

As the first state to collect data on hospital-acquired infections, Pennsylvania has put hard numbers on a troubling phenomenon that until now has only been estimated. Even so, the true infection rate and cost is probably much higher, the report's authors said, because of underreporting by many hospitals. The actual tally could be as high as 115,000 infections, based on billing claims the hospitals submitted to insurers, the report said.

"Pennsylvania is 4 percent of the population, which means you may have an additional 100 people dying per day" nationwide because of hospital-acquired infections, said Marc P. Volavka, executive director of the Pennsylvania Health Care Cost Containment Council, the agency that issued the report. "That comes to an additional $50 billion" in medical charges in the United States annually, he said.

As health care spending has skyrocketed, employers, which often pay the bills, have begun pressing hospitals to work to reduce a variety of mistakes -- from incorrect medications to avoidable infections -- to improve care and reduce costs. As part of that effort, Pennsylvania began last year to require every acute care hospital to report the number of infections contracted in the hospital in four major categories: surgical, bloodstream, pneumonia and urinary tract.

The mortality rate was highest -- 32 percent -- for patients who developed pneumonia while using a ventilator. The most common were urinary tract infections transmitted to patients using a catheter. The average cost to treat a Pennsylvania hospital patient who developed an infection was $29,000, compared with $8,300 for those who did not, the report found.

"Each quarter, the number of reported infections went up, and that trend we believe will continue in 2005 as more and more hospitals realize they need to come into compliance," Volavka said.

Nationally, the Centers for Disease Control and Prevention in Atlanta has estimated that as many as 2 million infections are acquired in hospitals each year, resulting in 90,000 deaths, said Denise Cardo, director of the Division of Healthcare Quality Promotion.

"This is terrible and this is not new," she said. "There are many more things we need to do in terms of preventing those infections, not just counting them."

Hospital executives cautioned that they are still working out the kinks in the data collection, and stressed that many efforts are underway to reduce preventable infections and other errors.

"Can we do better? Absolutely," said Elliot J. Sussman, president and chief executive of Lehigh Valley Hospital and Health Network in Allentown, Pa. "And this report can be a stimulus to do so."

Sussman, who has been a leader in the safety movement, said it is "ridiculous" to read that 16 hospitals reported not a single infection.

In Seattle, Michael Westley, medical director of the critical care unit at Virginia Mason Medical Center, is leading an effort to reduce ventilator-associated pneumonia cases through simple steps such as keeping the patient's head elevated and ensuring the patient breathes independently for at least a few minutes each day.

"If you do those things and you do them every day, the experience has been the numbers of those infections go down," he said. "While our hospitals in general are safe, they could be even safer by routinely employing low-tech interventions."

Westley and other experts say the simplest remedy is hand-washing. Another common but preventable risk is caused by shaving an area prior to surgery, a procedure that creates abrasions that can become easily infected. The preferred technique is clipping hair.

In Pennsylvania, state officials and industry executives haggled over the numbers, particularly the report's estimate that the tally of hospital-acquired infections may be as high as 115,000.

"We think that's remarkably high," said Carolyn F. Scanlan, head of the Hospital and Healthsystem Association of Pennsylvania. She said many of the infections that hospitals billed for may have been acquired before admission.

Volavka, however, said his staff, working with infectious-disease specialists, screened out the infections most likely to have occurred before a patient arrived at the hospital.

Either the true number of hospital-acquired infections is much higher than 12,000 or hospitals are charging for infections that do not exist, said Kitty Gallagher, president of the Lehigh Valley Business Conference on Health Care and a member of the state commission. "Either way you look at it, the employers are paying for these infections."

Several other states, including Virginia, have passed laws requiring similar reporting by hospitals. Thirty states, including Maryland, are considering similar legislation but do not currently collect data on hospital-acquired infections.

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Health
News for Healthier Living

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1.2 Million U.S. Patients Get Resistant Staph Each Year

Basic infection control can help stop the deadly bug, experts say

By Steven Reinberg
HealthDay Reporter

MONDAY, June 25 (HealthDay News) -- As many as 1.2 million U.S. hospital patients may be infected each year with a virulent staph infection that's resistant to antibiotics -- a rate almost 10 times greater than previous estimates, a new study finds.

The research, conducted by the Association for Professionals in Infection Control and Epidemiology, also found that as many as 119,000 hospital patients each year may die from the tough-to-treat strain of bacterium, called methicillin-resistant *Staphylococcus aureus* (MRSA). The germ is spread by touch and can lead to dangerous skin infections, blood infections and pneumonia.

"This is a wakeup call that hospital administrators should understand the importance of this problem," said report author Dr. William Jarvis, an epidemiologist and president of the consulting firm, Jason and Jarvis Associates.

The rate of MRSA was higher than previously been estimated, Jarvis said. "Not only did we find MRSA in all states in all facilities, but 66 percent of it was on the medical service, which runs counter to previous beliefs that most MRSA was in intensive care units," he added.

One expert agreed that more needs to be done to fight this looming threat.

"In the early years of the 21st century, we are seeing the value of antibiotics decline as more and more germs become resistant to them," said Dr. David Katz, the director of the Prevention Research Center at Yale University School of Medicine. "Methicillin resistant *Staph aureus* is one important example of this trend," he said.

The findings were based on surveys sent to 10,000 nurses, doctors, and other infection-control practitioners and included data on almost 8,000 infected patients from every state. More than 1,200 health care facilities - 21 percent of the nation's total -- were included in the survey.

The researchers found that 46.3 of every 1,000 patients had active MRSA, which is eight to 11 times higher that previously estimated.

The report, the *National Prevalence Study of Methicillin-Resistant Staphylococcus aureus (MRSA) in U.S. Healthcare Facilities*, was released Monday.

In contrast, one 2005 study, by the U.S. Centers for Disease Control and Prevention, estimated the MRSA infection rate at about 3.9 per 1,000 patients.

"Patients need to be aware of their risk of infection," said Kathy Warye, chief executive officer of the Association for Professionals in Infection Control and Epidemiology, which sponsored the study.

"If they have any underlying disease, such as diabetes or a heart condition, and it is likely they will be going

into a health care facility, they should speak with their physician about the risks they may be encountering," Warye said.

In addition, patients need to be assertive in making sure that the staff follows proper infection control procedures, Warye said.

Jarvis said that basic steps can be taken to curb the rising rate of infection.

First, patients who are most at risk for MRSA need to be identified and tested, he said. Patients who are infected need to be placed in isolation. In addition, health care workers need to follow proper procedures to prevent the spread of MRSA, including washing their hands and disinfecting the environment around the patient.

"Indiscriminate use of antibiotics in both hospitalized and outpatients is part of this problem," Katz added. "So is failure by patients to complete courses of antibiotics as prescribed. And perhaps an even greater influence is the widespread use of antibiotics in feed animals," which also creates resistant strains, he said.

"Having advanced medicine with the introduction of antibiotics, we cannot let it regress by allowing the drugs to become useless. Policies to curtail the spread of resistant germs are urgently needed," Katz said.

More information

For more information on MRSA, visit the **U.S. Centers for Disease Control and Prevention**.

SOURCES: Kathy Warye, chief executive officer, Association for Professionals in Infection Control and Epidemiology, Washington, D.C.; William Jarvis, M.D., president, Jason and Jarvis Associates, Hilton Head Island, S.C.; David Katz, M.D., M.P.H., director, Prevention Research Center, Yale University School of Medicine, New Haven, Conn.; June 25, 2007, report, *National Prevalence Study of Methicillin-Resistant Staphylococcus aureus (MRSA) in U.S. Healthcare Facilities*

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Attachment 9

ORTHOPAEDIC SURGEONS
STEPHEN P. MONTGOMERY, M.D.
WALLACE F. ANDREW, JR., M.D.
ROBERT T. WYKER, M.D.
LEONARD D. NELSON, JR., M.D.
LYMAN S. W. SMITH, M.D.
BRADLEY K. VAUGHN, M.D.
JEFFREY K. KOBS, M.D.
DANIEL J. ALBRIGHT, M.D.
G. HADLEY CALLAWAY, M.D.
DAVID W. BOONE, M.D.
JOEL D. KRAKAUER, M.D.
KEITH P. MANKIN, M.D.
MARK R. MIKLES, M.D.
WILLIAM M. ISBELL, M.D.
HARRISON G. TUTTLE, M.D.
JOHN B. CHIAVETTA, M.D.
PHYSIATRISTS
DWAYNE E. PATTERSON, M.D.
CARA B. SIEGEL, M.D.
PODIATRIST
CARROLL D. KRATZER, D.P.M.
EXECUTIVE DIRECTOR
KARL F. STEIN
RETIRED
Hugh A. Thompson, M.D.
Walter S. Hunt, Jr., M.D.
Thomas B. Dameron, Jr., M.D.
Thomas F. Castelloe, M.D.
Donald B. Reibel, M.D.
C. Phil Moer, M.D.
Robert B. Nelson, M.D.
John W. Packer, M.D.
W. Jason McCarter, Jr., M.D.
MAILING ADDRESS
3515 Glenwood Avenue
Raleigh, North Carolina 27612
PHONE: (919) 781-5600
APPOINTMENTS: (919) 863-6808
www.raleighortho.com

RALEIGH ORTHOPAEDIC CLINIC

July 23, 2007

Mr. Robert J. Fitzgerald, Director
NC Division of Health Service Regulation
2701 Mail Service Center
Raleigh, NC 27699-2701

RE: Charity Care Analysis for Same Day Surgery Performed at Wake County Facilities

Dear Mr. Fitzgerald,

Raleigh Orthopaedic Clinic, PA intends to submit a petition for an adjusted need determination for six orthopedic ambulatory surgery operating rooms in Wake County. This letter documents the commitment of Raleigh Orthopaedic Clinic, PA to improve access to ambulatory surgery for all patients and to provide charity care.

The chart below summarizes the numbers and percentages of charity care cases reported in the 2007 License Renewal applications data submitted by Wake County hospitals and ambulatory surgery centers. (The license forms use the terms "same day surgery" instead of ambulatory surgery.)

License Renewal Applications - 2005-2006 Reporting Period	# Reported Charity Care Same Day Surgery Cases	Total # of Reported Same Day Surgery Cases (All Payors)	Charity % of Total Same Day Surgery Cases
Duke Raleigh Hospital	85	8,155	1.04%
WakeMed Raleigh Campus All Sites	981	18,408	5.33%
WakeMed Cary	159	13,269	0.86%
Rex - All locations	517	18,222	2.84%
HealthSouth	1	6,717	0.01%
Raleigh Plastic Surgery	0	787	0.00%
Southern Eye Associates	0	587	0.00%
Totals	1,743	66,145	2.6%

As seen above, not all facilities provided access for charity care patients. Based on the analysis above, it is clear that the citizens of Wake County lack appropriate access to ambulatory surgery facilities that are willing to provide charity care access

RALEIGH OFFICE
CARY OFFICE
GARNER OFFICE
NORTH WAKE OFFICE
CENTRAL BILLING OFFICE
Garner, North Carolina 27529

Raleigh Orthopaedic Clinic recognizes an opportunity to make positive changes and improve access for all patient payor categories. We are convinced that an orthopedic ambulatory surgery center that provides charity care would be of great benefit to Wake County.

If operating room need determinations are included in the State Medical Facilities Plan, the issue of improving charity care patient access should be addressed through changes in the regulatory criteria in 10A NCAC 14C .2100. Raleigh Orthopaedic Clinic suggests the following additional standards to be added to the criteria:

The applicant is required to demonstrate that the utilization is reasonably projected to include percentages of charity care cases at or above the average of all existing surgery providers in the service area.

The applicant shall provide a description of strategies and activities that will ensure access and utilization by indigent patients.

Please accept this letter as a written commitment that ROC surgeons are strongly committed to provide charity care in a dedicated orthopedic ambulatory surgery center to meet or exceed the average percentages of the existing surgery facilities. ROC surgeons intend for this charity care commitment for a proposed ambulatory surgery facility would be in addition to the charity care professional fees.

Please contact me if you have questions regarding the suggested changes to 10A NCAC 14C .2100 criteria and standards for surgical services and operating rooms.

Sincerely,

Karl Stein
Executive Director

Cc: Sandra B. Greene, DrPH
725 Airport Road
Chapel Hill, NC 27599

Attachment 10

July 24, 2007

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

RE: Raleigh Orthopaedic Clinic Petition for Dedicated Orthopedic Ambulatory Operating Rooms

Dear Mr. Stein,

I am writing in support of the ROC petition that seeks an adjusted need determination for six orthopedic ambulatory operating rooms to be allocated to Wake County in the 2008 State Medical Facility Plan. Patient safety will be enhanced by increasing the availability of ambulatory operating rooms.

Please recognize that adverse events are common in hospitals. Two large studies, one conducted in Colorado and Utah and the other in New York, found that adverse events occurred in 2.9 and 3.7 percent of hospitalizations, respectively.[1] These studies were the impetus for the landmark report of the Institute of Medicine, *To Err is Human*.

Adverse events in ambulatory surgery centers appear to be less common. Two large separate studies looked at factors contributing to return hospital visits, hospital readmissions and prolonged stay after ambulatory surgery performed at a major ambulatory surgery center in Toronto.[2] The researchers found that of 17,638 consecutive patients having ambulatory surgery, 193 readmissions occurred within thirty days (readmission rate of 1.1 percent). The complication rate was a very low 1.5 percent.

Ambulatory surgery centers have a lower incidence of wound infections. A comparative study by Miller et al. of surgical site infections (SSI) in inpatient and ambulatory surgery settings found that the SSI rate in ambulatory surgery was only about 35 percent of that in inpatient settings and 38 percent of that in a "mixed" group.[3] These differences are quite large, and were not explained by risk adjustment for severity of condition or by differences in patient populations. This raises the possibility that for some conditions and procedures—such as those that expose the patient to risks of surgical infections—the ambulatory setting may be safer.

Accreditation requires a surgery center to have extensive safety policies and procedures. Accrediting agencies include the Joint Commission for Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care (AAAHC), and the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF). Good public policy would encourage all surgery centers to become accredited and licensed.

North Carolina regulations prohibit the licensure and accreditation of many surgery centers. The state has a two-tiered system of surgery centers; licensed, accredited surgery centers are subject to CON regulation, which severely limits their number. Office-based surgery centers are not subject to CON regulation. They are subject to Medical Board safety guidelines but are prohibited by the Division of Facilities Services from seeking licensure or accreditation.

The CON program's restrictive "need formulas" have forced surgery out of the accreditation system and thereby have worked against public safety. Single-specialty physician-controlled surgery centers should be able to obtain a CON without being subject to a need formula. Increased patient safety would result because the centers could then become licensed and accredited.

In conclusion, patient safety will be enhanced by making Certificates of Need for ambulatory operating rooms more available.

Sincerely,

Hadley Callaway

Hadley Callaway, MD

References

1. Brennan, Troyen A.; Leape, Lucian L.; Laird, Nan M., et al. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study I. N Engl J Med. 324:370376, 1991. See also: Leape, Lucian L.; Brennan, Troyen A.; Laird, Nan M., et al. The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II. N Engl J Med. 324(6):377384, 1991. See also: Thomas, Eric J.; Studdert, David M.; Burstin, Helen R., et al. Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado. Med Care forthcoming Spring 2000.

2. Mezei G. and Chung F. Return hospital visits and hospital readmission after ambulatory surgery. *Annals of Surgery* 230(5):721-7, 1999.

3. Miller K, Martin D, Gustafson T. Differences between inpatient and ambulatory surgical site infection rates are not explained by risk adjustment. *Infection Control and Hospital Epidemiology* February 2000.

BAYADA NURSES
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July 26, 2007

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

RE: Raleigh Orthopaedic Clinic Petition for Dedicated Orthopedic Ambulatory Operating Rooms

Dear Mr. Stein,

I am writing to express my support of the ROC petition that seeks an adjusted need determination for six orthopedic ambulatory operating rooms to be allocated to Wake County in the 2008 State Medical Facility Plan. As the Division Director for Bayada Nurses, I have frequent contact with numerous healthcare professionals in Wake County.

The tremendous population growth for Wake County will create much greater need for healthcare resources than other areas of the state. I was surprised to learn that Wake County has a scarcity of operating rooms and thousands of Wake County ambulatory surgery patients left their home county to obtain surgical procedures. Your petition offers a valid alternative to improve competition, reduce healthcare costs and expand patient choice. Please let me know if I can provide additional support.

Sincerely

Tom Myler

BAYADA NURSES • 5505 Creedmoor Rd • Suite 230 • Raleigh, NC 27612 • FAX 919 785 2191 • 919 785 2900
Toll Free 800 [illegible] • [illegible]

PROJECT ACCESS
A Program Of The Wake County Medical Society

2500 Blue Ridge Road, Suite 312
Raleigh, NC 27607
(919) 783-0404

July 27, 2007

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, North Carolina 27612

RE: Support for Raleigh Orthopaedic Clinic's petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms

Dear Mr. Stein:

I am writing in my capacity as Director, Project Access of Wake County to support the petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms in Wake County. Raleigh Orthopaedic Clinic physicians have lead the county's orthopedic community in providing medical and surgical care, including substantial uncompensated indigent care coverage in association with the Project Access volunteer physician program.

Since 2001, Raleigh Orthopaedic Clinic physicians have provided approximately $800,000 of uncompensated care to indigent citizens in our community associated with the Project Access Program.

It is not enough to say "thank you" Raleigh Orthopaedic Clinic for the almost unlimited donated care. Rather I want to say thank you by offering this unrestricted endorsement of your expansion plans that the whole community might benefit from the expanded care capacity.

Sincerely,

Paul Harrison /mab

Paul Harrison, Director
Project Access Manager

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

RE: Raleigh Orthopaedic Clinic Petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms

Dear Mr. Stein:

I am writing in support of your petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms in Wake County. Raleigh Orthopaedic Clinic physicians provide an extensive array of surgical patient care including indigent care and uncompensated emergency department coverage. Key factors that support the proposal include:

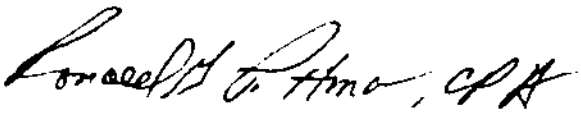
- Wake County citizens have access to fewer operating rooms per capita than citizens of comparable counties as well as fewer operating rooms per capita as compared to the statewide average.

- The petition demonstrates that an orthopedic ambulatory surgery center (ASC) can offer patients exceptional quality, lower cost, and more convenient access. Costs and charges for care at a freestanding ambulatory surgery centers are projected to be thirty percent less than the same surgical procedure performed in a hospital.

- Orthopedic ambulatory surgery represents the largest volume of all the surgical specialties performed on an outpatient basis and offers a tremendous opportunity to improve patient satisfaction and cost savings.

Wake County citizens need to have improved access to licensed operating rooms and a choice of new providers for a freestanding ambulatory surgery center. Positive competition will encourage hospitals to expand their hours of surgical service and to focus on improving patient and physician satisfaction.

Sincerely,



RONALD G. PITTMAN, CPA
Partner

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

FLEISHMAN HILLARD

Fleishman-Hillard Inc.
4350 Lassiter at North Hills Ave.
Suite 260
Raleigh, NC 27609
Tel 919-457-0744
Cell 919-555-3675
Fax 919-457-0741
britt.carter@fleishman.com
www.fleishman.com

Britt W. Carter
Senior Vice President
and General Manager

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

RE: Raleigh Orthopaedic Clinic Petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms

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Sincerely,

Samuel T. Wyrick III
7-23-07

Atty Sam Wyrick
Wyrick, Robbins & Yates
4101 Lake Boone trail
Raleigh NC 27607

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Tina Goertz

A.T. ALLEN & COMPANY

TINA M. GOERTZ, CPA

[illegible] NATIONAL DRIVE, SUITE 100 · RALEIGH
(919) [illegible]

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

President
Fulcrum Strategies

FulcrumStrategies
Superior Provider Advocates
Ron Howrigon
Phone: 919 753 4141 • Fax: 919.639.8303
P.O. Box 469 • Garner, NC 27529

CHURCH STREET
COMPANY

July 24, 2007

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

George D. [illegible]

George DeLoache, President

800 BARRETT DRIVE, SUITE 101 RALEIGH, NORTH CAROLINA 27609 PHONE (919) 787-1115 FAX (919) 787-1242

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Sincerely,

Betty Lou Ward
1321 Deerhurst Dr.
Raleigh, N.C. 27614

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Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Edith R Mogle CPA

EDITH R. MOGLE, CPA

A.T. ALLEN
& COMPANY
Limited Liability Partnership

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

James E. Carter Jr. CPA

JAMES E. CARTER, JR., CPA

A.T. ALLEN
& COMPANY

Heather L. Drake, CPA

Hughes Pittman & Gupton, LLP
1500 Sunday Drive, Suite 300
Raleigh, North Carolina 27607

919.232.5957 direct
919.787.9765 main
919.787.9384 fax

www.hpgcpas.com
hldrake@hpgcpas.com

Certified Public Accountants

CPA

Raleigh, NC 27612

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Sincerely,

Heather L. Drake

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Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Walter Skellie Hunt III

26 July 07

INTERNATIONAL CHIMNEY CORPORATION
Engineers & Contractors Since 1927

W. Skellie Hunt III – *Project Manager*
Historic Preservation Division

Mail: P.O. Box 260
Buffalo, NY 14231-0260
Office: ~~125 Shystanoll Drive~~ 5451 Reserve Dr
Wilmington, NC 28409

Headquarters: 716-634-3967
1-800-828-1446
Fax: 716-634-3983
N. Carolina Office: 910-350-0339
Cell: 973-819-6789

www.internationalchimney.com

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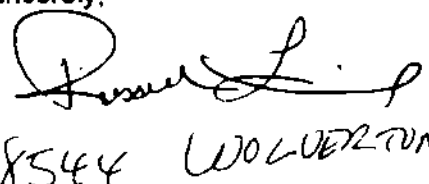

[signature]

8544 WOLVERTON FIELDS DR.
WAKE FOREST, NC 27587

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Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Eric W. Schmidt
Winfield & Associates Marketing & Advert

Eric Schmidt
PRESIDENT
WINFIELD & associates
marketing • advertising
3221 Blue Ridge Road [illegible]
phone [illegible]
www.[illegible]

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Sincerely,

W. Rich Redding

W. Rich Redding, DVM, MS, DACVS
Clinical Associate Professor
Equine Orthopedics and Lameness

NC STATE

Department of Clinical Sciences
College of Veterinary Medicine
4700 Hillsborough Street
Raleigh, NC 27606

919.513.6286 (Office)
919.513.6717 (Fax)
919.513.6630 (Equine Surgery Service)
rich_redding@ncsu.edu

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Raleigh, NC 27612

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Sincerely,

Randy Southerland

Shear Alternatives

PEACHTREE MARKET
7400-7 Six Forks Rd.
Raleigh, NC 27615
(919) 848-1988

Date:_____ Time:_____

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Raleigh Orthopaedic Clinic
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Sincerely, CFP

Jonathan S. Phillips, CFP®
First Vice President Investments

WACHOVIA SECURITIES

Wachovia Securities, LLC
8540 Colonnade Center Drive, Suite 101
Raleigh, NC 27615-3052
Tel 919 841-5360
Fax 919 841 5410
800 462 3939
jonathan.s.phillips@wachovia.com

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Charles B. McBrayer
First Vice President - Investments
Quantum Portfolio Manager

WACHOVIA SECURITIES

Wachovia Securities, LLC
8540 Colonnade Center Drive, Suite 10
Raleigh, NC 27615
Tel 919 841 5400, 919 841 5359
Fax 919 841 5410
800 462 3939
charles.mcbrayer@wach...

Hutchison Law Group

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3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Fred D. Hutchison

[illegible] www.[illegible] FAX [illegible] 5410 Trinity Road, Suite 400, Raleigh, NC 27607

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Raleigh, NC 27612

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Willard L Arthur
3300 APACHE DR.
RALEIGH, NC. 27609

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3515 Glenwood Avenue
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John M. Moore
2900 Pannock Ct.
Ral. NC 27604

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3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Ronald R Hanna
1304 Meuse Ridge Dr.
Clayton N.C.

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Roger A. Sitler
2723 Cameron Pond Drive
Cary, NC 27519

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Raleigh Orthopaedic Clinic
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Raleigh, NC 27612

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Elizabeth W Jordan
1809 Marilyn Dr.
Raleigh NC 27607

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Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Todd Hostetler
124 Martin Hill Dr.
Youngsville NC 27596

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

RE: Raleigh Orthopaedic Clinic Petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms

Dear Mr. Stein:

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Sincerely,

Rachel C. Baker
104 N. Ellington St.
Apex, N.C. 27502

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Dorie Price
102 Satterwhite Dr.
Knightdale NC 27545

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Elizabeth Walker
312 Hunter St.
Cary NC 27511

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Roxanna Dudley
5400 Algonie Drive
Raleigh, NC 27609

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

RE: Raleigh Orthopaedic Clinic Petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms

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Sincerely,

10815 Buffalo Rd
Clayton NC 27527

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

T. B. Wester
6540 Vintage Ridge LN.
Fuquay, N.C. 27526

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Shannon Hughes

7911 OAK ESTATES ST. APT. 1118

RALEIGH, NC 27617

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

F. A. Mullaney
7245 Manor Oaks Drive
Raleigh N.C.
27615

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Patricia S Young
4211 Windsor Place
Raleigh NC 27609

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Carl McGill

1208 EVA MAC DR

Raleigh. NC 27610

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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5416 Shadowbrook Dr.
Raleigh, NC 27612

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Christina McFarman

1913 Kudrowhare
Morrisville, NC 27560

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

7905 Ridge Point Lane
Raleigh, NC 27615

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Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Victor F. [illegible]
217 N MAIN ST
FRANKLINTON, NC 27525

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Philip M. Roberts
154 Adcock Rd
Whitakers NC 27891

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

John D Lyon, Jr
2623 Cooper Dr.
Raleigh, NC 27608

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Susan L. Munda

Susan L Munda
Accounts Payable

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

WILLIAMS
REALTY & BUILDING
COMPANY, INC.

J. Cross Williams Jr.

3711 Glenwood Avenue, Raleigh, NC 27612
PO Box 18271, Raleigh, NC 27619
wbco.com

cross@wbco.com

919 781 7107 Office
919 787 2316 Fax
919 427 1257 Mobile

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Dawn Mottley
60 Logan Lane
Middlesex, NC
27557

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

MARK MATTSON
1207 KIMBOLTON DR
CARY, NC 27511

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Elizabeth Ruba
1629 Air Park Drive
Apex, NC 27523

Mr. Kart Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Lucy M. Calabria
704 Fairway Dr.
Clayton, NC 27520

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Wake County citizens need to have improved access to licensed operating rooms and a choice of new providers for a freestanding ambulatory surgery center. Positive competition will encourage hospitals to expand their hours of surgical service and to focus on improving patient and physician satisfaction.

Sincerely,

11300 Rums Mill Rd
Raleigh, NC 27614

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

RE: Raleigh Orthopaedic Clinic Petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms

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Sincerely,

Michael Sola
531 Hickorywood Blvd
Cary, NC 27519

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

K Jackson

KEITH JACKSON
4821 WATERFORD VILLAGE WAY
RALEIGH NC 27601

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Hal S. Atkinson Jr

Hal S. Atkinson Jr
112 Cromwell Ct.
Raleigh, NC 27614

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Thomas Earl Barwick
Martin & Jones Law Offices

7/23/07

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Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Mark Helms, D.D.S.

mark Helms DDS
7505 Rainwater Rd.
Raleigh NC 27615

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Patty Carter, CFP®
Edward Jones

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Jane M. Mauney
8504 Pierce Olive Rd
Apex NC 27539

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Mike Maurer
8504 Pierce Olive Rd.
Apex, NC 27539

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Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Robin Green

4016 Beau Sain St.
Raleigh NC 27604

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Pamela Lamy

8544 WOLVERTON FIELDS DR
WAKE FOREST, NC 27587

Have Your Cake
Pam Lamy The Cake Lady
Owner/Chef
8544 Wolverton Fields Dr
Wake Forest, NC 27587
919-740-5418 (Mobile)
919-342-0363 (Office)
866-898-8572 (Fax)
planning@haveyourcakeonline.com
www.haveyourcakeonline.com

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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1117 Harvest Mill Ct
Raleigh, NC 27610

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3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Warren Baldwin
3405 Ingram Dr.
Raleigh, NC 27604

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Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Raleigh, NC 27604

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Raleigh, NC 27612

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Sincerely,

Ernest W. Warner Jr. CPA

A.T. ALLEN & COMPANY

ERNEST W. WARNER, JR., CPA
Partner

Mr. Karl Stein
Raleigh Orthopaedic Clinic
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Raleigh, NC 27612

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JOE KIMOSH
11300 RUMSHILL
RALEIGH 27614

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3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Susan Wait
121 Donna Place
Cary, NC 27513

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Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Daisy Sanders
2420 Fall Lane apt 105
Raleigh, NC 27604

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Margaret A. Frankland
4100 Stanaver Place
Raleigh NC 27612

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Sincerely,

Edward L. Moody

A.T. ALLEN
& COMPANY

EDWARD L. MOODY
Business Manager

Sherwood H. Smith, Jr.
P.O. Box 1551
Raleigh, North Carolina 27602
919-546-6382

July 27, 2007

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, North Carolina 27612

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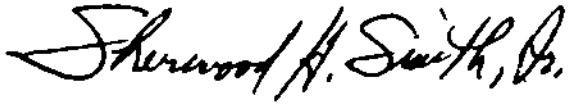

SHSJR:jw

Deborah Gooken
Vice President
Integrated Solutions

Cardinal Health
5104 Chin Page Road
Durham, NC 27703
919 454 1156 main
919 468 1326 fax
deborah.gooken@cardinal.com

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

CardinalHealth

cardinalhealth.com

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Sincerely,

Deborah Gooken

[redacted]

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3515 Glenwood Avenue
Raleigh, NC 27612

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RE: Raleigh Orthopaedic Clinic Petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms

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I am writing in support of your petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms in Wake County. Raleigh Orthopaedic Clinic physicians provide an extensive array of surgical patient care including indigent care and uncompensated emergency department coverage. Key factors that support the proposal include:

- Wake County citizens have access to fewer operating rooms per capita than citizens of comparable counties as well as fewer operating rooms per capita as compared to the statewide average.

- The petition demonstrates that an orthopedic ambulatory surgery center (ASC) can offer patients exceptional quality, lower cost, and more convenient access. Costs and charges for care at a freestanding ambulatory surgery centers are projected to be thirty percent less than the same surgical procedure performed in a hospital.

- Orthopedic ambulatory surgery represents the largest volume of all the surgical specialties performed on an outpatient basis and offers a tremendous opportunity to improve patient satisfaction and cost savings.

Wake County citizens need to have improved access to licensed operating rooms and a choice of new providers for a freestanding ambulatory surgery center. Positive competition will encourage hospitals to expand their hours of surgical service and to focus on improving patient and physician satisfaction.

Sincerely,

Todd R. Crouse
President, Crouse & Associates, Inc.
4513 Creedmoor Rd. #505
Raleigh, NC 27612
919-781-1811

Wendell H. Murphy
Post Office Box 280
Rose Hill, North Carolina 28458

July 31, 2007

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, North Carolina 27612

RE: Raleigh Orthopaedic Clinic Petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms

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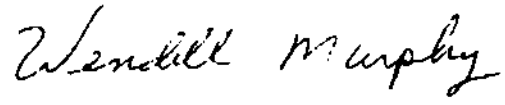
Sincerely



Wendell H. Murphy

WHM/djm

DHS Health Planning
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2007
Medical Facilities
Planning Section

Raleigh Orthopaedic Clinic, PA
Petition for Need Determination for Six Orthopedic Ambulatory Surgery Operating Rooms in Wake County

EXECUTIVE SUMMARY

Each year, the State Health Coordinating Council publishes a Proposed State Medical Facilities Plan and then holds public hearings and receives petitions for special need determinations for regulated healthcare services. Raleigh Orthopaedic Clinic (ROC) has serious concerns that the Proposed 2008 Plan includes no additional operating rooms for Wake County. In fact, no additional operating rooms have been allocated to Wake County by the Plans in over ten years.

Raleigh Orthopaedic Clinic petitions for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms to be developed in one or more freestanding (non-hospital) ambulatory surgery centers in Wake County.

ROC physicians know that an orthopedic ambulatory surgery center (ASC) can offer patients exceptional quality and customer service, lower costs, more efficient scheduling and better teamwork. The American Academy of Orthopaedic Surgeons states "ASCs provide benefit to both patients and orthopaedic surgeons because many musculoskeletal surgical procedures can be provided in an efficient, cost effective manner. ASCs can improve the quality of care received by the patients and delivered by the physician."

The rationale for the ROC petition is summarized:

- Wake County has 9.93 operating rooms per 100,000 population, far less than comparable counties and 22 percent less than the statewide rate of 12.75 ORs per 100,000 persons.
- ASCs generally have greater scheduling efficiency and higher patient satisfaction as compared to hospitals. While 73 percent of all surgery cases are ambulatory, 89 percent of the operating rooms in Wake County are hospital-based.
- In 2006, over 6,000 Wake County patients obtained ambulatory surgery in another county; more ambulatory surgery patients left Wake County in 2006 as compared to Mecklenburg and Forsyth Counties.
- No dedicated orthopedic ambulatory surgery operating rooms exist in Wake County even though orthopedic ambulatory surgery procedures comprise 23 percent of the total outpatient cases.
- Orthopedic procedures performed in freestanding ambulatory surgery centers offer <u>30 to 40 percent lower charges and reimbursement rates.</u>
- ROC physicians have already established exemplary records for providing charity care in their offices and at the area hospitals.

Approval of the petition will <u>benefit the community</u> by allowing new providers to compete and improve access to dedicated orthopedic ambulatory surgery operating rooms. The ASC will offer greater convenience, higher patient satisfaction and lower costs and charges. Like hospitals, the proposed ambulatory surgery center will be licensed, accredited and required to provide care to Medicare, Medicaid, insured patients and charity care patients.

Rec'd @ July 24
2007 GREENVILLE
PUBLIC HEARING

Karl Stein, Executive Director
Raleigh Orthopaedic Clinic

DFS Health Planning
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Medical Facilities
Planning Section

Proposed 2008 State Medical Facilities Plan
Public Hearing Presentation

My name is Karl Stein. I am the Executive Director of Raleigh Orthopaedic Clinic. I am here today to speak about the shortage of operating rooms in Wake County.

Rapid population growth in Wake County has caused a shortage of operating rooms. This shortage causes delays and hardships for patients.

Raleigh Orthopaedic Clinic petitions for a special need determination for Wake County for six (6) dedicated orthopedic ambulatory operating rooms to be developed in one or more freestanding (non-hospital) ambulatory surgery centers.

The current OR methodology in the Proposed 2008 State Medical Facilities Plan does not accurately assess the ambulatory surgery operating room needs of Wake County. Shortcomings of the current OR methodology include:

- The State Medical Facilities Plan has not shown a need for operating rooms in Wake County for many years, despite the fastest population growth among NC counties and approximately 200,000 new county residents over ten years. We think this is implausible and conclude that the operating room need formula does not work correctly in the case of Wake County.

- Established providers have gained added new operating rooms and by-passed the CON process by exploiting loop holes in the regulations/law. new Certificates of Need through non-competitive channels, even though the current methodology showed no need. This has rendered the need formula irrelevant to established providers and unfairly blocks new providers from any hope of participation.

- The current methodology and CON process allow existing providers to add "minor procedure rooms" to perform surgical cases. These procedure rooms are not constructed or equipped to the same standards as licensed operating rooms. Shifting surgery cases from licensed operating rooms to the minor procedure rooms <u>does not promote access to quality healthcare.</u>

- Patients may not be aware these "minor procedure rooms" are nearly always billed out to patients and/or insurance companies at the same rate as the licensed ORs, nor do they meet the requirements of licensed ORs.

- The OR methodology is also inaccurate for Wake County because the

calculations include the **four** dedicated open heart operating rooms that are extremely underutilized, performing at less than 40 percent capacity. If the volume of open heart cases and the four dedicated operating rooms were excluded from the methodology, the methodology would show a deficit operating rooms.

- The current methodology does not facilitate the growth of ambulatory surgery centers. In Wake County, hospitals generally have lower surgery scheduling efficiency and lower patient satisfaction as compared to ambulatory surgery centers.

- In this era of drug-resistant bacteria, surgical infections are a major concern for patients and surgeons. Ambulatory surgery centers have demonstrated much lower infection rates than hospitals for outpatient surgery, even after controlling for co-morbid conditions of patients.

- In 2006, over 6,000 Wake County patients had to leave Wake County to get their surgery. They had long commutes for surgery and follow-up visits. If they had a complication, a local doctor unfamiliar with the case had to see them in the emergency room. This is unsafe and unfair.

- There are no dedicated orthopedic operating rooms Wake County, even though orthopedics accounts for is 23 percent of all outpatient surgeries. We need dedicated orthopedic rooms with specialized surgical teams to provide top quality.

- Orthopedic procedures performed in freestanding ambulatory surgery centers offer substantially lower costs, charges and reimbursement for insured patients and Medicare and Medicaid programs. The cost to patients can be 30 to 40 percent lower in non-hospital ambulatory surgery centers. This is especially important for patients with high-deductible insurance plans.

CLINIC

Raleigh Orthopaedic physicians are leaders in providing charity care. We pledge to continue charity care in any new operating rooms.

Thank you for considering our petition for a special need determination for Wake County for six (6) dedicated orthopedic ambulatory operating rooms to be developed in one or more freestanding (non-hospital) ambulatory surgery centers.

REC'D @ JULY 30, 2007 PUBLIC HEARING IN WILMINGTON

Hadley Callaway, MD
Orthopedic Surgeon
Raleigh Orthopaedic Clinic

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JUL 30 2007
MEDICAL FACILITIES
PLANNING SECTION

Public Hearing Presentation
Proposed 2008 State Medical Facilities Plan
Wilmington, NC, July 30, 2007

My name is Hadley Callaway. I am an orthopedic surgeon at Raleigh Orthopaedic Clinic. I am here today to speak about the shortage of operating rooms in Wake County.

Rapid population growth in Wake County has caused a shortage of operating rooms. This shortage causes delays and hardships for patients.

Raleigh Orthopaedic Clinic petitions for a special need determination for Wake County for six (6) dedicated orthopedic ambulatory operating rooms to be developed in one or more freestanding (non-hospital) ambulatory surgery centers.

The current OR methodology in the Proposed 2008 State Medical Facilities Plan does not accurately assess the ambulatory surgery operating room needs of Wake County. Shortcomings of the current OR methodology include:

1. The State Medical Facilities Plan has not shown a need for operating rooms in Wake County for many years, despite the fastest population growth among NC counties and approximately 200,000 new county residents over ten years. We think this is implausible and conclude that the operating room need formula does not work correctly in the case of Wake County.

2. Established providers have gained added new operating rooms and by-passed the CON process by exploiting loop holes in the regulations/law, new Certificates of Need through non-competitive channels, even though the current methodology showed no need. This has rendered the need formula irrelevant to established providers and unfairly blocks new providers from any hope of participation. I hope you would agree that the unusual circumstance of <u>no new provider having the opportunity even to apply for an operating room</u> for ten years in the fastest-growing county of the state would merit an exemption to the need formula.

3. The current methodology and CON process have allowed existing providers in Wake County to add a substantial number of "minor procedure rooms" to perform surgical cases. These procedure rooms are not constructed or equipped to the same standards as licensed operating rooms. Shifting surgery cases from licensed operating rooms to the minor procedure rooms <u>does not promote access to quality healthcare.</u>

4. Patients may not be aware these "minor procedure rooms" are nearly always billed out to patients and/or insurance companies at the same rate as the licensed ORs, nor do they meet the requirements of licensed ORs.

5. The OR methodology is also inaccurate for Wake County because the calculations include the **four** dedicated open heart operating rooms that are

extremely underutilized, performing less than 40 percent capacity. If the volume of open heart cases and the four dedicated operating rooms were excluded from the methodology, the methodology would show a deficit operating rooms. Another hospital has cardiovascular operating rooms (in practice, although not listed so on the license renewal) which are also underutilized and could also be excluded.

6. The current methodology does not facilitate the growth of ambulatory surgery centers. In Wake County, hospitals generally have lower surgery scheduling efficiency and lower patient satisfaction as compared to ambulatory surgery centers.

7. In this era of drug-resistant bacteria, surgical infections are a major concern for patients and surgeons. Ambulatory surgery centers have demonstrated much lower infection rates than hospitals for outpatient surgery, even after controlling for co-morbid conditions of patients.

8. In 2006, over 6,000 Wake County patients had to leave Wake County to get their surgery. They had long commutes for surgery and follow-up visits. It is unsafe for a family member to drive long distances in traffic while managing a sedated patient. If the patient had a complication, a local doctor unfamiliar with the case had to see them in the emergency room. This is unsafe and unfair, both for Wake County patients and Wake County physicians who are providing the emergency on-call coverage.

9. There are no dedicated orthopedic operating rooms Wake County, even though orthopedics accounts for is 23 percent of all outpatient surgeries. We need dedicated orthopedic rooms with specialized surgical teams to provide top quality.

10. Orthopedic procedures performed in freestanding ambulatory surgery centers offer substantially lower costs, charges and reimbursement for insured patients and Medicare and Medicaid programs. The cost to patients can be 30 to 40 percent lower in non-hospital ambulatory surgery centers. This is especially important for patients with high-deductible insurance plans.

Raleigh Orthopaedic physicians are leaders in providing charity care. We pledge to continue charity care in any new operating rooms.

Thank you for considering our petition for a special need determination for Wake County for six (6) dedicated orthopedic ambulatory operating rooms to be developed in one or more freestanding (non-hospital) ambulatory surgery centers.

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AUG 02 2007

Medical Facilities
Planning Section

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

RE: Raleigh Orthopaedic Clinic Petition for a special need determination for six (6) dedicated orthopedic ambulatory operating rooms

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Sincerely,

Rhl J. Don

DFS Health Planning
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AUG 02 2007

Medical Facilities
Planning Section

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DAIL PROPERTIES

July 31, 2007

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Medical Facilities
Planning Section

Mr. Karl Stein

Raleigh Orthopaedic Clinic

3515 Glenwood Avenue

Raleigh, NC 27612

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Sincerely,

Curtis Dail

125 Timber Drive • Garner, North Carolina 27529
(919) 779-7707 FAX (919) 779-3547

DFS Health Planning
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AUG 02 2007
Medical Facilities
Planning Section

BATCHELOR, TILLERY & ROBERTS, LLP

RONALD A. BATCHELOR

Mr. Karl Stein
Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
Raleigh, NC 27612

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Wendell H. Murphy
Post Office Box 250
Rose Hill, North Carolina 28458

DFS Health Planning
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AUG 03 2007
Medical Facilities
Planning Section

July 31, 2007

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Raleigh Orthopaedic Clinic
3515 Glenwood Avenue
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Mr. Karl Stein
July 31, 2007
Page 2

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I should also note that Raleigh Orthopaedic serves many patients outside Wake County including my family. I sincerely hope that they receive approval for the requested six (6) orthopedic ambulatory operating rooms.

Sincerely

Wendell Murphy

Wendell H. Murphy

WHM/djm

Operating Room Comments
(Not Related to Petitions)

- Letter from Donnie C. Lambeth, NC Baptist Hospital

- Letter signed by following:
    - W. Stan Taylor, Wake Medical Center
    - Rebekah Swain, Rex Hospital
    - Duncan Yaggy, Duke University Hospital
    - Barbara Freedy, Novant Health
    - Kelly Butler, Randolph Hospital
    - Molly M. Dickinson, High Point Regional Hospital
    - Amy Graham, FirstHealth of the Carolinas
    - Jennifer Houlihan, Wake Forest University Baptist Medical Center
    - Kristi Hubbard, New Hanover Regional Medical Center
    - Melissa K. Shearer, Moses Cone Health System
    - Dee Jay Zerman, UNC Hospitals
    -
- Letter from Mike Vicario, North Carolina Hospital Association

- Letter from W. Stan Taylor, Wake Medical Center

Wake Forest University Baptist

Donny C. Lambeth
Interim President
Chief Operating Officer
North Carolina Baptist Hospital

Phone: 336/ 716-3003
Fax: 336/ 716-2067
E-Mail: dlambeth@wfubmc.edu

August 2, 2007

DFS Health Planning
RECEIVED
AUG 03 2007
Medical Facilities
Planning Section

Dr. Dan A. Myers, Chairman
State Health Coordinating Council
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-214

RE: Comments – Billing Dataset Usage in Operating Room Need Methodology

Dear Dr. Myers,

I would like to take this opportunity on behalf of Wake Forest University Baptist Medical Center (WFUBMC) to thank the OR workgroup members for their time and effort in developing recommendations to further refine the OR need methodologies. It is important for hospitals, physicians and other providers to work with the state in providing the most accurate and credible data in all areas to ensure that appropriate planning takes place to meet the healthcare needs of the citizens of North Carolina. Hospital representatives, along with physicians, have been active in workgroups related to the revision of the acute care bed, operating room, GI endoscopy procedure rooms, gamma knife, PET scanner, and MRI scanner need methodologies. However, for many reasons I believe that using patient-level, claims/billing data processed by Thomson/Solucient in place of hospital and ambulatory surgical facility (ASF)-reported aggregate data for the operating room need methodology is premature and further discussion needs to take place prior to adoption by the State Health Coordinating Council (SHCC).

Therefore, I am submitting comments concerning the proposed change to billing/claims data processed by Thomson/Solucient from hospital and ambulatory surgical facility-reported data for the need determination of operating rooms. My concerns are outlined in the following comments:

1. At a meeting hosted by the North Carolina Hospital Association on July 12, 2007, representatives from Thomson/Solucient expressed concern and a lack of confidence as to the appropriateness of their patient-level, claims/billing dataset in its present format for use in the operating room need methodology for the annual State Medical Facilities Plan (SMFP). It is also important to note that the current SMFP operating room need methodology is based on a count of ***operating room cases*** and the Thomson/Solucient dataset is based on a count of ***surgical procedures***. Operating room cases and surgical procedures represent counts of two fundamentally different items and it cannot be assumed that the existing SMFP operating room need methodology can be applied to a surgical procedure count dataset and yield a valid operating room need determination. By design, the proposal to convert to a surgical procedure dataset must also trigger an examination of the current operating room need methodology which is based on an operating room case count.

   I believe that the expressed concern by Thomson/Solucient is related to the following issues:

   - The UB-92 form, which hospitals have used since the early 1990s, has been eliminated and the new UB-04 form is now utilized. The Centers for Medicare & Medicaid Services expect a learning curve for the new form and the possibility of incorrect filings.

- The SMFP currently utilizes patient-level, billing/claims data processed by Thomson/Solucient for its acute care bed need methodology, but an acute care bed day can only occur in an acute care bed. However, procedures billed using the UB-04 form can occur in many locations of the Hospital; including operating rooms, procedure rooms, special procedure rooms, GI endoscopy procedure rooms, treatment rooms, Emergency Department exam rooms, inpatient rooms, cardiac catheterization rooms, and dedicated angiography rooms. The UB form does not permit for the identification of where a procedure was performed or even if the procedure requires an operating room. In fact, the current NCHA/Thomson ambulatory surgery database includes many procedures that do not require use of an operating room, such as sutures, cardiac catheterization and insertion of a catheter.

  Some OR workgroup members made it clear that they were more concerned with knowing **what** procedures were performed in hospitals and ambulatory surgery centers, as opposed to **where** the procedures were performed in them. The intent for usage of this billing/claims data needs clarification, as a methodology for determining need that is not based on utilization of the resource (operating room) itself is difficult to understand.

  Furthermore, if the intent of the OR workgroup is to identify "all" procedures performed in a county to determine operating room need, then the Thomson/Solucient data fails to capture all procedures not performed in a hospital, including physician offices, plastic surgery centers, dentist offices, etc. Until this issue alone is more fully addressed, I believe it would be premature to consider using the Thomson/Solucient data in the operating room need methodology. Focusing on the type of procedures performed in hospitals and ASFs suggests a possible expansion of the scope of CON regulation, which would seem to be beyond the initial charge of the OR workgroup as articulated by Dr. Myers during the first quarter of 2007.

2. It has been stated several times by OR workgroup members that billing/claims data is "more accurate because hospitals are less likely to err on billing statements." In fact, hospitals make every attempt to be accurate on all reported utilization data, which includes billing/claims statements, as well as the Hospital License Renewal Application (HLRA).

3. Whether ICD-9-CM or CPT, procedure codes are dynamic and will require constant review and updating to ensure accuracy. As an example, the 1999 HLRA included eight (8) cardiac catheterization codes and three (3) electrophysiology codes, as compared to the 2007 HLRA which included thirteen (13) cardiac catheterization codes and thirty-one (31) electrophysiology codes. The Centers for Medicare & Medicaid Services' Hospital Inpatient and Ambulatory Surgery Center procedure lists include over 4,100 CPT procedure codes, as compared to the over 3,500 ICD-9-CM procedure codes.

4. There is a necessary lag from the time data is reported until it is incorporated in the need methodologies in the SMFP. Therefore, the operating room methodology for the 2010 SMFP will utilize data submitted beginning with Federal Fiscal Year 2008, which begins October 1, 2007 (in just two (2) months). It is my belief that hospitals, ambulatory surgery centers and Thomson/Solucient are not prepared to use billing/claim data submitted in this short timeframe for a new need methodology. There are too many questions that need to be answered before a complete, accurate patient-level database using billing/claim data processed by Thomson/Solucient can be available for use in the operating room methodology.

5. The current operating room need methodology uses hospital and ASF reported operating room **cases**, as opposed to **procedures**. The expansion of billing/claim data collection for procedures performed outside of operating rooms suggests a broadening of the scope of **what** is CON-regulated, and it is not clear that this was within the charge of the OR workgroup. No discussion has occurred as to how the operating room need methodology will be changed to use surgical procedures rather than surgical cases in determining operating room need. That may need to be the subject of an additional workgroup, even though the SMPF operating room need methodology was significantly revised and updated in the 2004 SMFP.

   I believe that before the current SMFP operating room need methodology is significantly revised, that several variables should be considered for update:

   - Examine and update the definitions of inpatient and outpatient operating room capacity.
   - Better understand and analyze the minutes per operating room case information the licensed operating room providers have annually submitted since 2004 to the Division of Health Service Regulation.
   - Update the standard hours per operating room per year, if this remains an element of the SMFP operating room need methodology.

In conclusion, WFUBMC welcomes the prospect of revising the current operating room need methodology, but we are concerned with the integrity of the surgical data. We prefer the data be accurate, whether it is hospital or ASF-reported aggregate data or patient-level data processed by Thomson/Solucient, and desire a thoroughly discussed need methodology. At a minimum, these discussions should address the issues raised in my comments to assure the appropriateness of any revised operating room need methodology data. Thank you for the opportunity to voice my concerns through these comments.

Sincerely,

Donny C. Lambeth
Interim President/COO

1 August 2007

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AUG 03 2007

Medical Facilities
Planning Section

Dr. Dan A. Myers, Chairman
State Health Coordinating Council
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-214

RE: Comments – Billing Dataset Usage in Operating Room Need Methodology

Dear Dr. Myers,

We would like to take this opportunity to thank the OR Workgroup members for all their time and effort in developing recommendations to further refine the OR need methodology. It is important for hospitals, physicians and other providers to work with the State to provide the most accurate and credible data in all areas to ensure that appropriate planning takes place and that the healthcare needs of the citizens of North Carolina are met. Hospitals have worked closely with the Division of Health Service Regulation throughout the planning and implementation process to make transitions to new datasets and need methodologies as smooth as possible. We have been active in workgroups related to the revision of the acute care bed, operating room, GI endoscopy procedure room, gamma knife, PET scanner, and MRI scanner need methodologies. Based on this experience, we believe that using patient-level, claims/billing data processed by Thomson/Solucient in place of hospital and ambulatory surgical facility (ASF)-reported aggregate data for the operating room need methodology is premature and needs to be discussed at greater length before it is adopted by the SHCC

Therefore, the undersigned planning staff from hospitals throughout North Carolina are submitting these comments concerning the proposed change to using billing/claims data processed by Thomson/Solucient for the need determination of operating rooms. The undersigned represent community, referral, tertiary, and teaching hospitals that range in size from 145 beds to over 800 beds and from 6 operating rooms to over 40 operating rooms. These hospitals represent a cross-section of the 115 hospitals operating in North Carolina.

Our concerns are detailed in the following comments:

First, at a meeting hosted by the North Carolina Hospital Association on July 12th, 2007 representatives from Thomson/Solucient expressed concern and a lack of confidence as to the appropriateness of their patient-level, claims/billing dataset in its present format for use in the operating room need methodology for the annual State Medical Facilities Plan (SMFP).

We believe that the expressed concern by Thomson/Solucient is related to the following issues:

- The UB-92 form, which hospitals have used since the early 1990s, has been eliminated and the new UB-04 form is now utilized. The Centers for Medicare & Medicaid Services expect a learning curve for the new form and the possibility of incorrect filings

  For example, even the Healthcare Cost and Utilization Project, which is a family of health care databases and related software tools and products developed through a Federal-State-Industry partnership and sponsored by the Agency for Healthcare Research and Quality (AHRQ) raised concerns that billing data from UB forms may not always be accurate.

- The current range of codes that are required to be reported to the Thomson/Solucient database include procedures that can occur in many locations in the hospital: including operating rooms, procedure rooms, special procedure rooms, GI endoscopy procedure rooms, treatment rooms, Emergency Department exam rooms, inpatient rooms, cardiac catheterization rooms, and dedicated angiography rooms. The UB form does not identify where a procedure was performed or if the procedure requires an operating room. In fact, the current Thomson/Solucient ambulatory surgery database includes many procedures that do not require use of an operating room, such as sutures, cardiac catheterization and insertion of a urinary catheter.

  Some Operating Room Workgroup members made it clear that they were concerned with knowing **what** procedures were performed in hospitals and ambulatory surgery centers, as opposed to **where** the procedures were performed in them. While the Thomson/Solucient database would be more likely to accomplish this count of defined procedures, it is unclear how it will be determined which procedures will be included and what methodology will be used for calculating operating room need from this procedure count data. We believe that until this issue is addressed more fully that it would be premature to consider using the Thomson/Solucient data in the operating room need methodology

  Furthermore, if the intent of the Operating Room Workgroup is to identify "all" procedures performed in a service area in order to determine operating room need, then the Thomson/Solucient is not sufficient. This database fails to capture procedures performed in physician offices, plastic surgery centers, dentist offices, etc. Focusing on the count of procedures performed in multiple locations

suggests a possible expansion of the scope of CON regulation, which would seem to be beyond the initial charge of the Operating Room Workgroup as you articulated it during the first quarter of 2007

- The Thomson/Solucient database is in a period of transition from reporting primarily in terms of ICD-9 procedure codes to using CPT procedure codes. While the impact of this change is not yet completely understood, two things are evident. The range of CPT codes that are required to be reported is broader than that of ICD-9, and as hospitals move to CPT reporting, we can expect the dataset to triple in size. In addition, the CPT-based reporting will not include a primary procedure, making it much more difficult to classify types of procedures or define a set of cases by procedure code.

Second, it has been opined several times by Operating Room Workgroup members that billing/claims data is "more accurate because hospitals are less likely to err on billing statements." In fact, hospitals make every attempt to be accurate on all reported utilization data, which includes billing/claims statements, as well as the Hospital License Renewal Application (HLRA). After the second Operating Room Workgroup meeting it became obvious that data reported on both the HLRA and the ASF License Renewal Application can be inaccurate. However, inaccuracies on the HLRA and ASF LRA are more likely due to lack of clear instructions and definitions on the LRA's. For example, even Workgroup members were confused by a question regarding "Same Day Surgery Cases" (2007 HLRA, page 5), as compared to the definition of "Ambulatory Cases" (2007 HLRA, pages 8 and 9). We believe that changes to the HLRA could improve the integrity of the data, and we welcome the opportunity to submit this data electronically, where automatic accuracy reviews can be instantly incorporated

Third, whether ICD-9-CM or CPT, procedure codes continue to be created and eliminated as new techniques are developed. Any list of codes used in the OR methodology will require constant review and updating to ensure accuracy. As an example, the 1999 HLRA included eight (8) cardiac catheterization codes and three (3) electrophysiology codes, as compared to the 2007 HLRA which included thirteen (13) cardiac catheterization codes and thirty-one (31) electrophysiology codes In fact, the Centers for Medicare & Medicaid Services' Hospital Inpatient and Ambulatory Surgery Center procedure lists include over 4,100 CPT procedure codes, as compared to the over 3,500 ICD-9-CM procedure codes.

Fourth, there is a necessary lag from the time data is reported until it is incorporated in the need methodologies in the SMFP. The workgroup has recommended that a new dataset be used for the 2010

SMFP. That will require using data submitted beginning with Federal Fiscal Year 2008, which begins October 1, 2007, just two (2) months from now. It is our belief that hospitals, ambulatory surgery centers, and Thomson/Solucient are not prepared to use billing/claims data submitted in two months time for a new need methodology. There are too many questions that need to be answered before a complete, accurate patient-level database using billing/claims data processed by Thomson/Solucient can be available for use in the operating room methodology.

We ask that the SHCC delay the recommendation to change the data source for the OR methodology in the SMFP. As we have outlined in this document, there are many issues that need to be addressed before the data collection can occur, and we do not believe these issues can be addressed in the next sixty days. We believe that several variables from the existing methodology should be considered for more immediate adoption by the SHCC to improve the OR need methodology.

- Examine and update the definitions of inpatient and outpatient operating room capacity to better reflect actual availability
- Better understand and analyze the minutes per operating room case information that the licensed operating room providers have annually submitted since 2004 to the Division of Health Service Regulation
- Update the Standard Hours Per Operating Room per Year

In conclusion, we want to emphasize that we welcome the revision of the current operating room need methodology, but we are concerned with the appropriate usage of the Thomson/Solucient billing/claims database. We want data used in the SMFP to be accurate, whether it is hospital or ASF-reported aggregate data or patient-level data processed by Thomson/Solucient, and want a thoroughly discussed need methodology, even one that may evolve over time. At a minimum, these discussions should address the issues raised in our comments to assure the appropriateness of any revised operating room need methodology data.

Thank you for the opportunity to voice our concerns through these comments.

Sincerely,

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Randolph Hospital

Molly M. Dickinson
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High Point Regional Health System

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August 3, 2007

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AUG 03 2007

Medical Facilities
Planning Section

Dr. Dan A. Myers, Chairman
State Health Coordinating Council
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Dr. Myers:

On behalf of WakeMed, I would like to take this opportunity to provide comments regarding the recent recommendations from the Operating Room Methodology Work Group. We appreciate all the hard work that the Work Group has done in analyzing the issues and in developing its recommendations; however, we have ongoing concerns regarding Recommendations 3A and 5.

Regarding Recommendation 3A – "Uniform Procedure Count," WakeMed recognizes the need for accurate data; however, it believes that there are too many issues with the billing data for it to provide the level of accuracy required by the State. Billing data is coded and designed to meet payor requirements for reimbursement. By its very nature, it is not designed to meet planning needs. Indeed, at a recent meeting of hospital planners and state representatives, a Thomson representative agreed that the data was not suited for this purpose. For example:

- There is no reliable way to determine where a procedure was performed. Some minor procedures may be performed in an emergency department treatment room or in a minor procedure room, as opposed to an operating room. Although it has been suggested that revenue codes can provide that level of detail, for some CPT codes, the revenue codes are automatically assigned, regardless of where the procedure is performed.
- Claims data are dynamic; i.e., coding may be changed based on subsequent review of patient care or based on payor requirements. For example, patient status may be changed from inpatient to outpatient, or vice versa. If the Thomson data are submitted and the claim is later changed, that will affect the accuracy of the data. Given that inpatient procedures are allotted 180 minutes in the OR methodology as opposed to 90 minutes for outpatient procedures, this could have an impact on the outcome of the methodology. Also, claims that are in pending status at the time of data submission may never be submitted.
- In some instances, e.g., if a patient qualifies for charity care or for a full write-off of charges, a claim may not be generated for that patient. Therefore, the final count will be understated. This could have a greater impact on facilities which provide higher levels of charity care, such as WakeMed.

Based on discussions held in recent meetings at the North Carolina Hospital Association, it appears that there is still no consensus on the specific data that should be collected from hospitals, whether it should be all surgical procedures, regardless of where they are performed; specific cases based on designated CPT or ICD codes; or whether it should be only those cases that are performed in surgical operating rooms. It is important that this be determined before the OR methodology is modified. For example, should hospitals be required to report all

surgical cases, regardless of where they are performed, the OR methodology will need to incorporate minor procedure rooms. Otherwise, the case count will be inflated and will likely generate a significant need for additional operating rooms, because the OR inventory (included in the formula denominator) will not include minor procedure rooms, but the corresponding procedures will be included in the formula numerator.

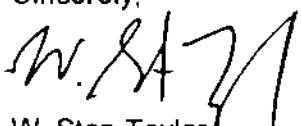
WakeMed also believes that it will be difficult to implement Recommendation 5 "Convene a panel of experts to determine which ICD and CPT procedure codes should be included when planning for operating room capacity". As shown in The Dartmouth Atlas of Health Care, physician practice patterns vary significantly in different regions of the country based on where the physician was trained, local standards of care, etc. Similarly, WakeMed believes that there is likely significant variation across the State regarding how and where procedures are performed, and that it will be difficult and expensive to reach consensus. For example, some procedures may routinely be performed laparascopically on an outpatient basis in urban areas; however, for the same diagnosis in a rural area, a surgeon may still perform open procedures and subsequently admit the patient. It may also be difficult to find physicians willing to donate their time to work on this project, given that there are over 1,000 ICD procedure codes.

WakeMed submits these suggestions for consideration:

- Specifics regarding the data to be collected need to be resolved. Based on that decision, corresponding adjustments should be made to the OR inventory and OR methodology.
- The State should continue its efforts to work with hospitals to ensure that the data submitted on licensure applications are accurate. Holding educational sessions would promote accuracy and consistency among NC hospitals.
- Alternative sources of data that have not yet been considered may meet the State's needs, such as electronic OR logs.

WakeMed recognizes that this is a complicated issue that will not be easy to resolve. However, we believe that at this time, using claims data for this purpose is not feasible. We appreciate this opportunity to submit comments and we look forward to continuing to work with the State on this project.

Sincerely,



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DFS Health Planning
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AUG 03 2007
Medical Facilities
Planning Section

Medical Facilities Planning Section
Division of Health Service Regulation
2714 Mail Service Center
Raleigh, NC 27699-2714

Dear Ms. McClanahan and Members of the State Health Coordinating Council:

The State Health Coordinating Council (SHCC) has received and approved several recommendations from the Operating Room Need Methodology Workgroup. Recommendations 3A and 3B pertain to data sources used for the methodology, and Recommendation 5 includes a process to establish which procedures should be reported.

For the reasons listed below, NCHA recommends that the SHCC consider establishing a new target year beyond the 2010 SMFP (using 2008 data) for applying these data to the methodology. The data should be reviewed, along with the licensure data, until the SHCC is satisfied that reporting issues have been addressed and that the two sources of data are consistent within a reasonable threshold.

In consultation with its member hospitals and the state's certified data processor, Thomson Healthcare, NCHA makes the following observations related to the Workgroup's recommendations.

Recommendation 3B - License Renewal Application: Improve the License Renewal Application Data to make it more accurate and verifiable by revising terminology, clarifying definitions, and providing instruction and guidance regarding key data elements. Focus specifically on improving the reporting of average resource hours, inpatient case time, outpatient case time, and number of inpatient and outpatient cases. Consider the feasibility of electronic data reporting.

NCHA hospitals met with representatives from the Division of Health Service Regulation (DHSR) during the summer. Hospitals provided recommendations to address the concerns of the workgroup by clarifying, updating and revising the form, with special attention to the need for improved instructions and definitions. Even a methodology that relies on verifiable billing data to count surgeries will require an accurate licensure form to gather other data such as surgical hours and operating room counts.

NCHA believes the adoption of an electronic licensure reporting process is needed and would help to avoid inaccuracies as well as transcription and mathematical errors that can occur with the current licensure reporting form.

Recommendation 3A - "Uniform Procedure Count": Recommend the SHCC adopt utilization of accurate verifiable billing data to count the number of procedures that require the use of an operating room, in both inpatient and outpatient surgical facilities.

NCHA is continuing its research of the issues involved in using the Patient Data System ambulatory procedure database *(administered by Thomson Healthcare - the state certified data processor)*, to count procedures that require the use of an operating room. We have met with hospitals, DHSR, Thomson Healthcare and others, and have reviewed policy and payment changes at federal and state levels. We believe that there are significant changes that are already affecting the reporting of ambulatory procedures and that should be considered before implementing a process of using next years (October 2007 - September 2008) PDS ambulatory procedure data for the 2010 SMFP.

- In spring of this year NCHA learned of a new requirement from two major payers (Medicare and Blue Cross/Shield) that hospitals submit claims using CPT codes rather than the ICD-9 codes that hospitals were previously required to use. This follows a HIPAA Transactions and Code Sets Rule requirement and is expected to impact all North Carolina hospitals and eventually all payers as they move to require CPT codes for ambulatory procedures. Hospitals that choose to *report* data to Thomson using CPT codes are expected to lose some comparability with their ICD-9 coded inpatient procedures, so there may be reluctance among some to report using CPT codes. Further, hospitals will typically be unable to report CPT codes without changes to their internal information systems, changes required by their clearinghouses, and / or their system vendors.

- Two hospital members that were preparing to submit CPT coded data reports subsequently found large increases in their procedure counts, some of which were determined to be caused by procedures that were included in the state's CPT range but not in the ICD-9 range. *(The code ranges that were used by the Medical Database Commission are still used.)* The incomparability among the code ranges for the two systems is expected to result in significant discrepancies in reported codes, resulting in major procedure count differences from prior years, according to several hospitals' own internal analyses. This will need to be resolved before the PDS can be successfully used for state planning.

- Inpatient surgery billings include any outpatient procedures performed within 72 hours of an inpatient surgery, so any additional surgery related data within this timeframe would not be captured.

- Other billing changes are also in the transition process. The UB-92 billing manual has just been replaced with the UB-04 manual, introducing changes to payer codes. HHS is in the process of transitioning hospitals to their own NPI (National Provider Identifier) codes, which are different from Medicare provider numbers and apply differently to each part of an institution. HHS is also in the process of transitioning from UPIN (Unique Physician Identification Number) codes to NPI codes for physicians. HHS is also changing diagnoses codes to a present-on-admission indicator, for which alone HHS has indicated it expects a two-year learning curve and the possibility of incorrect filings. This represents yet another dynamic that potentially complicates use of the ambulatory surgery data for planning purposes.

Recommendation 5 - Panel of experts: Recommend DFS convene a panel of experts to determine which ICD and CPT procedure codes should be included when planning for operating room capacity. This list would be used with the "Uniform Billing" data to ensure the same procedures are counted in each facility regardless of where the procedures are performed.

- Thomson Healthcare and some on the workgroup have noted that ambulatory billing data does not include the site of a surgical service or denote whether an operating room was used. While a "panel of experts" may be able to establish which procedure codes should require the use of an operating room and be used to plan for total operating room capacity; it will not be possible to use PDS data to determine how

many surgeries were performed in existing operating rooms for any prior year. Only the licensure forms provide this information.

- Thomson Healthcare has indicated that while it would eventually like to see the outpatient database used for state planning purposes, there is less consistency—that is, greater variation—in payers' requirements for sending data for payment of outpatient claims as compared with inpatient claims. The outpatient billing process is more complicated and less standardized than the inpatient billing process. Given the number of transitional issues and changing payer requirements occurring over the next two years, the use of outpatient billing data beginning in FY 2008 would result in variations between the licensure data and billing data that would be very difficult to resolve. Attempting a reconciliation of the two data sources would impose significant burdens on hospitals.

NCHA assists hospitals with billing related issues and is aware, through regular meetings and discussions with payers and hospitals, of a number of billing logic issues that could affect outpatient claims and volumes. In addition, there are many billing and information systems, each with limited, differing capabilities in hospitals from which data are extracted for reporting to Thomson. Hospitals use system software vendors, claims clearinghouses, and in-house IT staff, alone or in combination, to derive data files for Thomson. In the process of billing, a clearinghouse may require different coding than the hospital submits, and may change the coding to meet its own requirements. So the hospital's internal system may not contain the coding that was ultimately required for transmission of a claim to a payer, and justifying the internal system to what Thomson receives may not be possible for reasons beyond the control of the hospital.

NCHA supports using the most accurate data available for the operating room methodology. However, the issues pertaining to coding, regulations, reimbursement and technology are changing rapidly and could not have been incorporated into the workgroup recommendations with any level of detail. Many of these challenges were not fully described or known at the time the workgroup made its recommendations. We request that the SHCC consider these factors in its work to establish an accurate and verifiable methodology for operating rooms.

Thank you for your continued work in improving the health planning process, and please let us know how we can assist. Please feel free to contact me if you have questions.

Sincerely,

Mike Vicario
Vice-President of Regulatory Affairs