American Association of Neurological Surgeons
2006 Workforce Survey

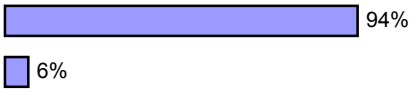
Sample Size= 770

Return Rate

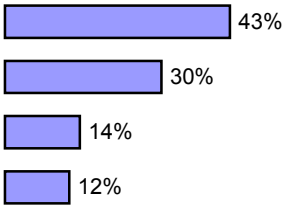
	Members Invited	Survey Completed	Return Rate
Survey completed on-line	2,552	770	**30.2%**

Emergency Call Coverage

1. Do you take ER call?	*Sample Size*	*%*
Yes	722	**93.8%**
No	48	**6.2%**
Total	770	



2. At how many hospitals do you provide emergency call coverage?	*Sample Size*	*%*
1	312	**43.2%**
2	217	**30.1%**
3	104	**14.4%**
4 or more	89	**12.3%**
Total	722	



3. How many hours, on average, do you work per week on each of the following?	*Sample Size*	***Average***	***Median (50th%)***
Overall	711	**70.3**	**70**
In direct patient care	711	**56.0**	**55**
On research or education	711	**5.5**	**3**
On administrative work	711	**7.9**	**5**
Other	86	**4.2**	**0**

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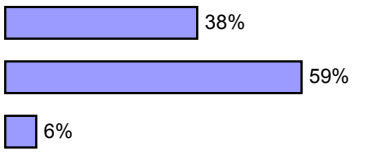
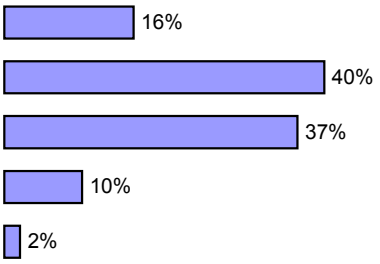
Emergency Call Coverage, Con't.

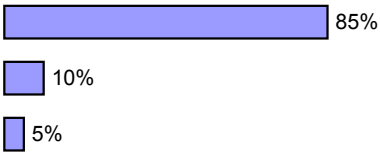
4. Please indicate the option that best describes the type of hospital where you practice. (If you cover more than one hospital, check all that apply):	*Sample Size*	*%*
Academic Medical Center	292	**37.9%**
Community Hospital	451	**58.6%**
Other	47	**6.1%**
Total participants *(some selected more than one choice)*	770	



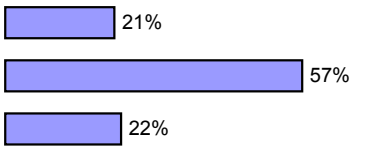
5. If any of these hospitals serve as trauma centers, please select the trauma level(s). (Select all that apply):	*Sample Size*	*%*
Not a trauma center	125	**16.2%**
Level 1	309	**40.1%**
Level 2	283	**36.8%**
Level 3	75	**9.7%**
Other	15	**1.9%**
Total participants *(some selected more than one choice)*	770	



6. Do any of these hospitals require taking call?	*Sample Size*	*%*
Yes, all of them	600	**84.6%**
Yes, some of them	73	**10.3%**
No	36	**5.1%**
Total	709	

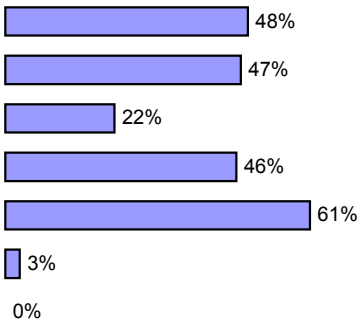


7. How often, on average, do you personally cover emergency or trauma call at your hospital(s)? ("Week" includes weekends)	*Sample Size*	*%*
One day/night a week or less	148	**20.9%**
Two or three days/nights per week	403	**56.9%**
Four or more days/nights per week	157	**22.2%**
Total	708	

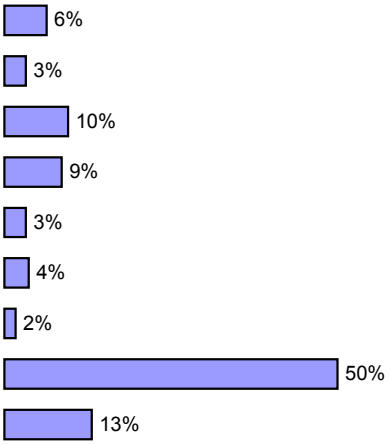


Emergency Call Coverage, Con't.

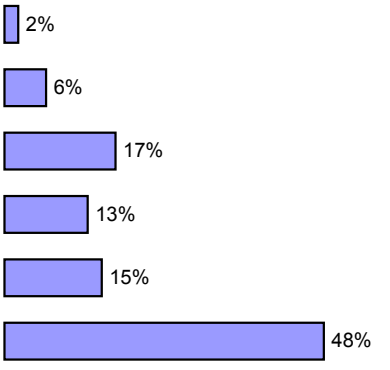
8. For what services do you take call? (Please select all that apply):	*Sample Size*	*%*
Cranial	371	**48.2%**
Spinal	360	**46.8%**
Pediatric	167	**21.7%**
Trauma	353	**45.8%**
I cover all neurosurgical services	466	**60.5%**
Other	22	**2.9%**
I do not take call	0	**0.0%**
Total participants *(some selected more than one choice)*	770	



9. Do you receive a monetary stipend for emergency call coverage?	*Sample Size*	*%*
$500 or less a day/night	45	**6.4%**
$501 to $750 a day/night	23	**3.3%**
$751 to $1,000 a day/night	68	**9.6%**
$1,001 to $1,500 a day/night	61	**8.6%**
$1,501 to $2,000 a day/night	23	**3.3%**
$2,001 to $3,000 a day/night	26	**3.7%**
$3,000 or more a day/night	12	**1.7%**
Do not receive a monetary stipend	355	**50.3%**
Not paid by day/night-another compensation arrangement	93	**13.2%**
Total	706	



10. If you do not take calls, please indicate why not:	*Sample Size*	*%*
Malpractice Insurance company no longer covers for the services	1	**2.1%**
Malpractice Insurance company offers a premium reduction for eliminating trauma call (or other ER	3	**6.3%**
Insufficient pay for emergency services	8	**16.7%**
Lifestyle interference	6	**12.5%**
Disruption of routine practice schedule	7	**14.6%**
Other	23	**47.9%**
Total	48	



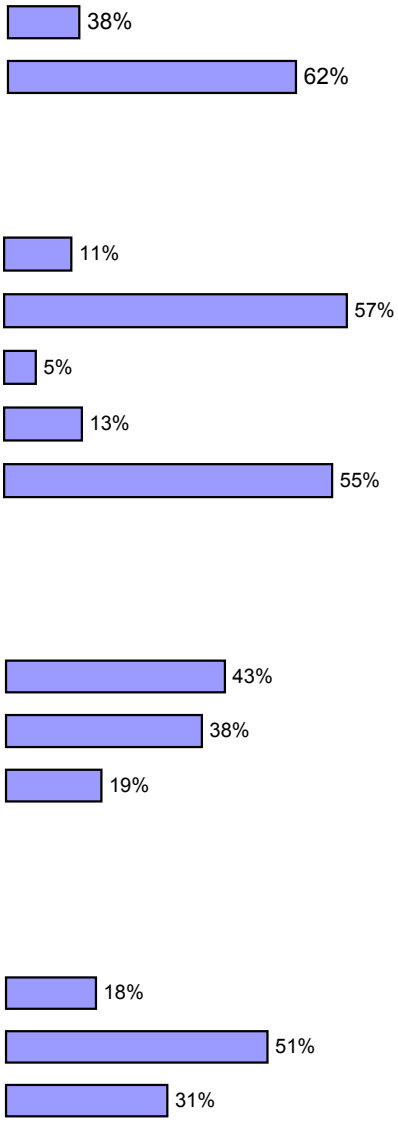
Your Practice

11. Have you limited the type of procedures performed by your practice?	*Sample Size*	*%*
Yes	286	**37.9%**
No	468	**62.1%**
Total	754	

12. Please specify how you have limited your practice? (Please select all that apply):	*Sample Size*	*%*
Eliminated cranial	32	**11.2%**
Eliminated pediatrics	163	**57.0%**
Eliminated spine	15	**5.2%**
Eliminated trauma	37	**12.9%**
Other	156	**54.5%**
Eligible participants *(some selected more than one choice)*	286	

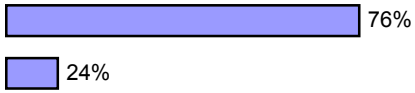
13. Has your neurosurgical group been involved in developing a hospital's plan for transfer of patients?	*Sample Size*	*%*
Yes	323	**42.9%**
No	289	**38.4%**
There is no transfer plan at any of the hospitals I cover	141	**18.7%**
Total	753	

14. Has your neurological group been involved in developing a plan for a hospital's ER going off-line?	*Sample Size*	*%*
Yes	132	**17.5%**
No	384	**51.0%**
There is no transfer plan at any of the hospitals I cover	237	**31.5%**
Total	753	



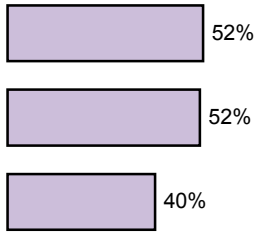
Your Practice, Con't.			
15. Would you be willing to participate in this type of planning for coverage in your area?	*Sample Size*	*%*	
Yes	486	**64.5%**	65%
No	70	**9.3%**	9%
Don't know	197	**26.2%**	26%
Total	753		
16. Have you experienced any cost reduction or discount on your malpractice insurance for not taking call?	*Sample Size*	*%*	
Yes	17	**2.3%**	2%
No	735	**97.7%**	98%
Total	752		
17. Please estimate how much your premium deduction or discount is:	*Sample Size*	*%*	
5% or less	2	**11.8%**	12%
6 to 10%	3	**17.6%**	18%
11% or more	12	**70.6%**	71%
Total	17		
18. What is the yearly cost of your malpractice insurance?	*Sample Size*	*%*	
$50,000 to $80,000	301	**40.2%**	40%
$80,001 to $100,000	138	**18.4%**	18%
$100,001 to $120,000	102	**13.6%**	14%
$120,001 to $150,000	71	**9.5%**	9%
$150,001 to $200,000	75	**10.0%**	10%
$200,001 or more	62	**8.3%**	8%
Total	749		

Your Practice, Con't.			
19. Do you perceive call coverage as a problem in your geographic area?		*Sample Size*	*%*
	Yes	570	**76.1%**
	No	179	**23.9%**
Total		749	



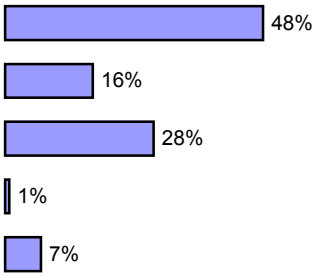
20. Please rate your agreement with the following statements about the current call system in your area:

Attributes	*Sample Size*	*Don't know/ NA*	Strongly Disagree	Disagree	Agree	Strongly Agree
The system works in the best interest of patients	734	14	**20.4%**	**27.1%**	**39.9%**	**12.5%**
The system is effective	736	12	**20.1%**	**28.3%**	**42.3%**	**9.4%**
The system allows neurosurgeons enough time "off" call	723	25	**30.8%**	**29.6%**	**33.6%**	**5.9%**

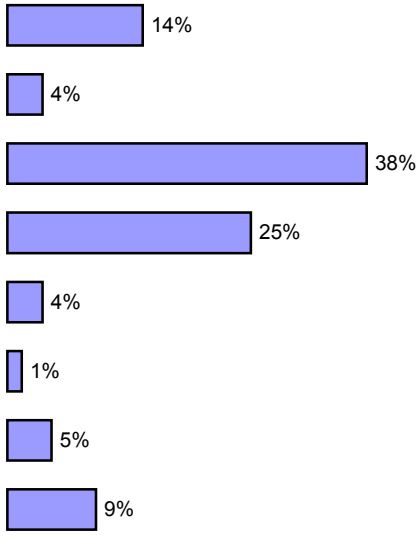


Demographic Information

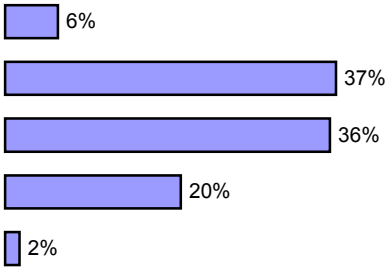
21. The category that best describes your type of practice:	*Sample Size*	*%*
Private	361	**48.3%**
Private (academic affiliate or appointment)	123	**16.4%**
Full-time Academic	208	**27.8%**
Federal Government	6	**0.8%**
Other	50	**6.7%**
Total	748	



22. Please select the category that best describes your type of practice:	*Sample Size*	*%*
Solo	104	**14.2%**
Solo practice, shared facilities	27	**3.7%**
Small neurosurgical group (2-5 neurosurgeons)	276	**37.6%**
Medium neurosurgical group (6-20 neurosurgeons)	187	**25.5%**
Large neurosurgical group (more than 20 neurosurgeons)	27	**3.7%**
Small multi-specialty (2-5 physicians)	11	**1.5%**
Medium multi-specialty (6-20 physicians)	34	**4.6%**
Large multi-specialty (more than 20 physicians)	68	**9.3%**
Total	734	

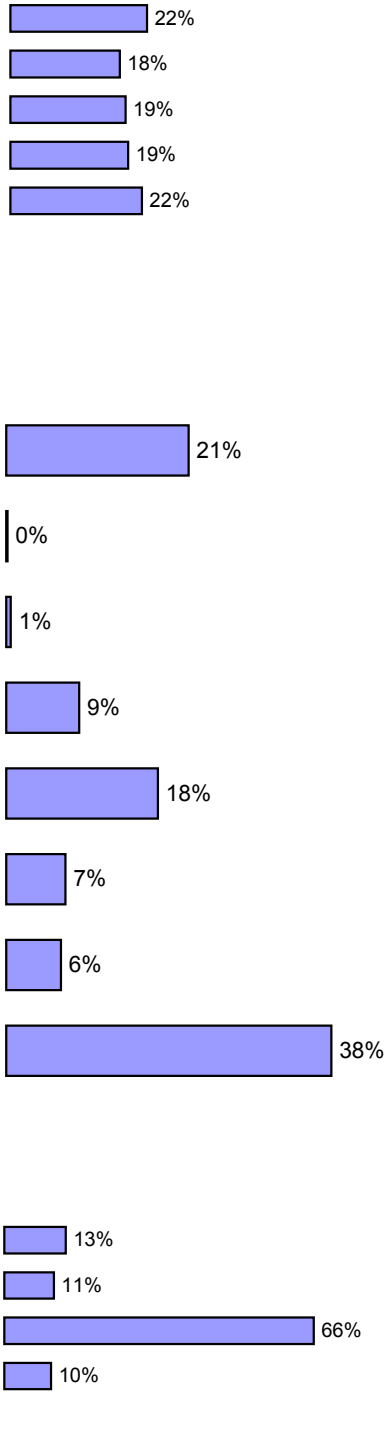


23. Which category best represents your age?	*Sample Size*	*%*
35 years old or younger	44	**5.9%**
36 to 45 years old	275	**36.8%**
46 to 55 years old	270	**36.1%**
56 to 65 years old	146	**19.5%**
66 years old or older	12	**1.6%**
Total	747	



Demographic Information, Con't.					
24. Please select the states in which you practice:					
	Sample Size	*%*		*Sample Size*	*%*
Alabama	15	**1.9%**	Montana	7	**0.9%**
Alaska	1	**0.1%**	Nebraska	8	**1.0%**
Arizona	16	**2.0%**	Nevada	2	**0.3%**
Arkansas Chapter	3	**0.4%**	New Hampshire	5	**0.6%**
California	57	**7.2%**	New Jersey	20	**2.5%**
Colorado	19	**2.4%**	New Mexico	1	**0.1%**
Connecticut	11	**1.4%**	New York	53	**6.7%**
Delaware	2	**0.3%**	North Carolina	30	**3.8%**
District of Columbia	5	**0.6%**	North Dakota	4	**0.5%**
Florida	40	**5.0%**	Ohio	30	**3.8%**
Georgia	22	**2.8%**	Oklahoma	11	**1.4%**
Hawaii	2	**0.3%**	Oregon	11	**1.4%**
Idaho	3	**0.4%**	Pennsylvania	33	**4.2%**
Illinois	44	**5.5%**	Rhode Island	1	**0.1%**
Indiana	21	**2.6%**	South Carolina	17	**2.1%**
Iowa	9	**1.1%**	South Dakota	5	**0.6%**
Kansas	5	**0.6%**	Tennessee	21	**2.6%**
Kentucky	4	**0.5%**	Texas	46	**5.8%**
Louisiana	17	**2.1%**	Utah	7	**0.9%**
Maine	6	**0.8%**	Vermont	3	**0.4%**
Maryland	19	**2.4%**	Virginia	16	**2.0%**
Massachusetts	19	**2.4%**	Washington	15	**1.9%**
Michigan	21	**2.6%**	West Virginia	6	**0.8%**
Minnesota	15	**1.9%**	Wisconsin	19	**2.4%**
Mississippi	17	**2.1%**	Wyoming	3	**0.4%**
Missouri	27	**3.4%**	Puerto Rico	4	**0.5%**
			Total participants (some selected more than one choice)	*794*	

Demographic Information, Con't.		
25. Please select the year (range) you expect to stop taking call:	*Sample Size*	*%*
2010 or sooner	167	**22.4%**
2011 to 2015	134	**17.9%**
2016 to 2020	141	**18.9%**
2021 or later	144	**19.3%**
Don't know	161	**21.6%**
Total	747	
26. If you are planning to stop taking call, please indicate why. Select the one answer that plays the most important role in your decision:	*Sample Size*	*%*
Retiring	160	**21.4%**
Malpractice insurance company no longer covers for the call services	1	**0.1%**
Malpractice insurance company offers a premium reduction for eliminating trauma call (or other ER services)	4	**0.5%**
Insufficient pay for emergency services	64	**8.6%**
Lifestyle interference	133	**17.8%**
Disruption of routine practice schedule	52	**7.0%**
Other	48	**6.4%**
I have no plans to stop taking call	285	**38.2%**
Total	747	
27. Are you retiring because of any of the following:	*Sample Size*	*%*
On call demands were too excessive	21	**13.1%**
Malpractice premiums were too high	17	**10.6%**
No, I planned to retire anyway	106	**66.3%**
Other	16	**10.0%**
Total	160	



Participant's Comments and Responses to Open-ended Questions

3. How many hours, on average, do you work per week on each of the following? Other (Please specify):

Admin for State of NJ	d--m insurance paperwork	Organizations
ADMINISTRATIVE	driving from place to place, paper work	PAPERWORK
AMA	driving to hospitals	peer review
BILLING	er coverage, just waiting	Physician Review Committee for malpractice carrier
business development	extramural activities	Plus on-call
CALL	hospital chief of stall work	political issues
Charts, dictations, phone calls, e-mail.	hospital volunteer	programming
Chief of Staff	legal-expert	PROJECTS
committees etc	lunch and breakfast	pt paperwork
committees, budget	misc	records reviews/reports
commuting	N/A, None (27)	resident ed
consulting	national meeting work	running around
coordinating meetings, development	nursing, er, physical therapy, icu, meetings.	teaching
Director, Medical Mutual Insurance Company of Maine	office paper work	Waiting on ER patients, Waiting for OR time etc
		wasting time on the internet

4. Please indicate the option that best describes the type of hospital where you practice. Other (Please specify):

academic-no neurosurgery residents	level 1 trauma center	Private tertiary teaching hosp
ACS Level II trauma hospital	level 1 trauma hospital- non-profit-non academic	regional community/teaching
Children's Hospital	medical center with neuro residency	Regional medical center/trauma center
Clinic	metropolitan level 1 trauma center	REGIONAL REFERRAL CENTER
combined private and academic	military (2)	Regional Teaching hospital of Harvard Medical School
county hospital	Mixed	Specialty hospital.
County hospitals, Trauma center	multispecialty clinic and hospital	Tertiary care hospital
free-standing children's hospital	None	tertiary center
full service medical centers	Non-Profit, non-academic Level-I trauma center	tertiary medical center
group practice with Univ. affiliation	pediatric hosp, level II trauma center	tertiary non academic
HMO referral	private academic	Tertiary referral center but not academic
Hybrid academic/community	Private Hospital	trauma center (2)
Kaiser Permanente	Private Practice	VA Hospital (3)
large multispeciality	private regional referral center	Veterans

5. If any of these hospitals serve as trauma centers, please select the trauma level(s). Other (Please specify):

believes it is a trauma center	Level 4 (2)	Not certified as level 1 but clearly as busy as a level 1 ER

but no level 1 for 300 miles	no trauma designation, but we are it for 5 counties. Level I overflies us, everything else stays	Peds level one only
Cover Level 1 trauma routinely due to lack of Level 1 centers in town	non mva trauma	UNDESIGNATED LEVEL 3
I don't know the levels criteria	Non Trauma center	unknown
Level 2, but cover all services	None	

8. For what services do you take call? Other (Please specify):

all spine, most cranial services.	lazy neurologists	Some Pediatric (> 12 y/o) Trauma
carotid	only do peds if true emergency---send most out	Stroke
endovascular	pain	stroke (endovascular)
endovascular/interventional radiology	pediatric emergencies only	they sneak in everything, neurology, etc
Exclusively a pediatric hospital	pediatric only (to age 22) but all services are provided	vascular
I am back up (second call) 330 days/year.	peripheral nerve (3)	vascular-5 days a week
I'm at a pediatric facility only	single system injury trauma	

9. Do you receive a monetary stipend for emergency call coverage? Not paid by day/night, but have another

$1000 FOR EACH TRAUMA CODE. AVERAGES LESS THAN ONCE A MONTH($10,000/YR)	I am a salaried employee of a practice group owned by the hospital.	part of salary package
$1300 per emergent visit to the ED for trauma	I am employed by the hospital my salary includes compensation for ER coverage	paid for my return to hospital/OR on set amount per time basis
$1300 per trauma pt seen	I am employed by the hospital	per month $25000, plus an additional amount for any acute head injuries
$500/patient if Level One after 1700 and before 0600	I am paid an academic salary to teach and cover call. The neighboring hospital pays $1500 nightly for call.	Provide malpractice insurance, otherwise would not be able to practice in Illinois
$500-750/night when exceeding frequency of 1 in 6 call.	I am paid for trauma call but not specifically for generic emergency call at two hospitals. By contract, I am not permitted to disclose the amount.	Question is somewhat vague in that I get paid $500 per night from each of 3 hospitals. As well, I am reimbursed 120% of Medicare for indigent care and Medi-Cal patients.
1/3 call for the ER plus trauma as part of admitting privileges. 1/3 call for trauma only, plus 1/3 call backing up another neurosurgeon for trauma (he takes call at another hospital also) for 200,000/year	I am part of a clinic. 10 nights a month covered by my salary. Any additional nights I take will be reimbursed at $2000/day/night	Receive compensation at 110% of Medicare for services provided to no pay and public aid/Medicaid patients.
According to hours spent	I get paid a basic salary	Receive compensation if call exceeds more than one out of four

Participant's Comments and Responses to Open-ended Questions

after age 60 $1000 a day/night	If I take more than 2 calls a week, I am compensated 1800 a night. Averages about 2-4 extra calls a month.	Receive malpractice insurance plus $500/night
am paid 2k per 24 hours for level 1 trauma call. Am paid ZERO for general neuro call (approx 12-15 days per month)	Included in Salary	recent new contract for Medicare rates for all unfunded pts
Annual salary from MedCenter	increased the salary to meet the demand of call every other night	reimbursement through state trauma fund
annual stipend for er and indigent coverage	Indigent care □	Reimbursement from the State for trauma call coverage
Annual Stipend to department	Indirect support to department from hospital	Required to take call as part of a "salaried" position with the hospital.
Arrangement with one hospital group for neurosurgical services, including program development and call coverage	Locum Tenens arrangement with outside agency	Salaried position (6)
At 1 hospital we get $500 per night, at the other 2 I get nothing	Lump sum for group coverage at Level 1 center	salaried, full time employee of HMO
At some hospitals, our group is paid a fixed amount to provide Neurosurgical services, which includes ER call.	MONTHLY	Salary subsidy provided by hospital for covering trauma at our Level 1 trauma center
built into salary	No compensation is presently arranged, but we are in negotiations and will no longer agree to uncompensated call coverage.	salary through FPP
Compensated for uninsured or underinsured patient per consult or per surgery	no payment	Since Hospital get funding for indigent If call is not paid them they paid Medicare rate
Compensated when call exceeds 1-in-4 in any month	none	Some facilities pay, others do not. Variation in pay whether on site or transfer.
Cover multiple hospitals that pay varying amounts for call ranging from $350 a day/night to $1100 a day/night.	Not paid at all	stipend at one hospital, no stipend at the other two
department currently receives $60,000 per year for "trauma support"	on salary at free standing peds hosp	take call a week at a time at $2000 per week
Different at each hospital - one no monetary stipend, one paid per patient seen in ER, one $900/nite	ONE HOSP PAYS $1000 PER 24 HR AND THE OTHER PAYS ZIP	The 4 man group receives an annual stipend
DIRECTORSHIP INDIRECTLY COMPENSATES FOR SUPERVISION OF MY NURSE PRACTITIONER AND PAYS MY NURSE PRACTITIONER	one HOSPITAL PAYS $1500/ NITE AND THE OTHER PAYS $500/NITE	the department is paid an annual contract for services through the trauma center

Participant's Comments and Responses to Open-ended Questions

employed by hospital	only one of the hospitals pays for call coverage	The hospital pays the department of surgery for call services by the division of neurosurgery
Employed by hospital and compensation reflects call	Our department receives roughly $1000 per night for ER coverage	The trauma services guarantees a fee for service payment based on a specified conversion factor and RVU schedule no matter what the insurance status of the patient.
employed by hospital full time	Our group gets ~ $3000/day for two neurosurgeons to be on call.	The University Hospital (Level 1)provides some general support to the Department of Neurosurgery
Employed by hospital to cover neurosurgery clinic as well as the ER	Paid a salary by the hospital	Trauma center pays 47,000 annually for covering 1 in 4 weeks, VA pays approximately 300/day, University hospital does not pay for call coverage.
Employed by the hospital; emergency call coverage responsibilities included in contractual duties to the hospital	paid at level one center, none at the other three--- being negotiated at one other	Uninsured patients fees paid at set rate
Every third weekend can be covered Friday 5PM to Monday 7AM by outside neurosurgeon for $2500.□ □ Rarely are we able to get outside coverage.	Paid at one of the three @$1000/ day. Nothing at the other two due to hospital not agreeing to pay for the availability.	We are paid $1000/night at 1 of the 3 hospitals
group of three neurosurgeons has paid compensation of specified amount to cover call	Paid for trauma call at one of the 3 hospitals.	We have a contract pending, but have not been paid yet. Awaiting response from OIG, letter pending.. $850 a day. Initial verbal response from OIG leans against approving daily compensation.
Guaranteed Base salary per year	Paid for trauma call only 1500 to 2500	we receive a transfer of funds generated through hospital admissions
Hospital covers an indigent care stipend	paid if called in, in 2 hosp. Financial arrangement for development of Nsurg at other two hosp that includes ER call	
Hospital employee (3)	Paid per hour worked overtime	
Hospital provides programmatic support to the trauma team, some of this is salary support to 1 FTE of Neurosurgery Faculty time. This works out to around $750 per night to the department.	Part of academic compensation	

10. If you do not take calls, please indicate why not: Other (Please specify):

"senior active medical staff" status in 2005, for which I am exempted from emergency call coverage responsibility	High liability	No longer required after age 60 or 25 years of service
#3(our hosp. doesn't pay);#4;#5	high malpractice risk with low pay	over age limit required by bylaws of hospital
20 YEAR RELEASE	Hospital bylaws give this choice after 55 & 10 yrs on active staff	RESIDENTS TAKE CALL
age (2)	I am now age 65	Retired
All of the above	I work at a Cancer Hospital.	Retired 9/1/05
AT AGE 65, AND 31+ YEARS OF TAKING ER CALL, MY PARTNERS AGREED TO EXCUSE ME FROM CALL.	JUNIOR PARTNER DUTY	Retired from ER call after 20 years.
cardiovascular health issues -- control of hours and stress levels	My group does not require after age 55	
currently military in a second specialty	No ER at my hospital.	

12. Please specify how you have limited your practice? Other (Please specify):

adult patient	Eliminated Cranial at one hospital	no aneurysms b/c no endovascular
aneurysms	eliminated degenerative spine	no aneurysms or complex cases
Aneurysm surgery	eliminated endovascular	no aneurysms, avms, minimal pediatrics
Aneurysm, AVM, Acoustic, Transsphenoidal, Epilepsy, Movement Disorder	eliminated intracranial aneurysms since there is no endovascular person at our hospital	no aneurysms, no complex tumors
Aneurysms (8)	eliminated major spine	no carotid surgery
aneurysms sent to a hosp. with interventional radiology	Eliminated neurovascular (4)	no complex cranial cases
aneurysms, AVMs, Stereotactic, pituitary, lumbar or thoracic fusions, VP shunts	Eliminated Neurovascular (No Interventionists Available)	no instrumented spine, minimal vascular
avoid aneurysms	Eliminated posterior fossa aneurysms	no Medicare
can't do as much elective work	Eliminated some ped at center that loss its peds icu. but not because I wanted to eliminate it.	no more aneurysms
cerebrovascular (3)	eliminated spinal cord injury management, no aneurysm surgery	NO PITUITARY
certain cases go to ortho	eliminated spine trauma	NO SPINAL INSTRUMENTATION
Certain types of degenerative spine work	Eliminated subarachnoid hemorrhage	no thoracic or lumbar trauma
certain very complex, high-risk intra-crainial and spinal cases: for example, posterior circulation aneurysms	Eliminated subarachnoid hemorrhage	No vascular (3)
Complex aneurysm, complex peds	eliminated tumor and very complex spine	no vascular or pit or base tumors
complex spine	eliminated vascular (6)	Non-operative Neurosurgery
complex thoracic spine	eliminated vascular neurosurgery	only do pediatrics

Participant's Comments and Responses to Open-ended Questions

complex thoracolumbar spine	eliminated vascular surgery	pain
COMPLEX VASCULAR	Eliminated vascular, and higher level peds	pediatrics only
complicated intracranial work	eliminated very high risk	penetrating head injuries
deep brain sterotaxsis, aneurysm	eliminated workers comp.; eliminated lumbar spine reconstruction	Peripheral Nerves
Do not clip aneurysms- no interventional neuroradiology available	eliminated lumbar degenerative	poor paying by the hour cases
do not do complex vascular	exclusively pediatric	Practice limited to benign brain tumors/skull base surgery
do pediatrics primarily	FUNCTIONAL AND PAIN	Practice only on pediatric patients
elective peds	high risk surgery	refer non -emergent cranial and pediatrics to my partners
elective peds, adult scoliosis	I do not cover new pediatric consults but cover my partner's practice	Restricted Peds to Emergency only, no neurovascular
eliminate vascular	I do spine, peds, and trauma only when on call; otherwise I do vascular and skull base exclusively	retired
eliminated adult	I refer aneurysms out	selected cranial, i.e. aneurysms, deep tumors, intracavitary spine approaches
ELIMINATED ANEURYSM	intracranial aneurysm	selective about case complexity
Eliminated aneurysm/vascular surgery and high risk intracranial or spinal surgeries.	left neurosurgery to do aerospace med	send aneurysms and avms to vascular NS specialists
eliminated aneurysmal SAH (2)	Lengthy, complex cranial cases	SEND CRANIAL VASCULAR TO EMORY
Eliminated aneurysms (5)	Limit more difficult cranial and spinal cases as too risky for malpractice issues.	Send vascular to the university (we have no interventional)
Eliminated aneurysms after volume/quality article 2 years ago.	LIMITED CRANIAL	stopped ped tumors and some peds
ELIMINATED ANEURYSMS SURGERY	lumbar instrumentation; Pediatrics	Stopped aneurysm surgery
eliminated aneurysms, AVMs, vesibular schwannomas	Lumbar Spinal Fusion	stopped doing aneurysm surgery
eliminated AVM's, aneurysms, carotids, and shunts	More referrals to outside centers	subaracnoid hemorrhage
eliminated cerebrovascualr	most aneurysms	subaranoid hemorrhage
ELIMINATED CEREBROVASCULAR	most vascular and peds, due to risk of litigation. Any case that looks like the patient/family has litigation in mind.	vascular (3)
eliminated cerebrovascular & skull base	most vascular sent out	vascular neurosurgery
eliminated cerebrovascular/ltd. tumors	multiple trauma	Vascular with partner trained in endovascular

eliminated certain cranial and spine procedures	n/z	vascular, lumbar spine instrumentation
eliminated certain fx and all SAH	Neuroendoscopy, Colloid Cyst, skull base	vascular/aneurysm
eliminated complex spine	neurovascular	voluntarily limited practice to brain and spine tumor and gamma knife, no trauma, no degenerative spine, no vascular, no pediatrics
Eliminated Complex Vascular	no adults	Will eliminate cranial after Mar 30 because of malpractice cost

21. Please select the category that best describes your type of practice. Other (Please specify):

clinic	Hospital employed (11)	multispecialty clinic--employed
employed	Hospital Employee, closed physician group	Now retired (2)
Employee	Hospital Employee, community hospital	only trauma/er call
employee multi-specialty ped group within a pediatric hospital with academic affiliation	hospital employee, private hospital	part academic / part government
employee of free standing peds hosp, academic center	hospital owned	private group - 4 neurosurgeons
employee of hospital where I take call	Kaiser Permanente	Private Practice but as a Hospital Employee
full time employee HMO	large group	Private, group of 3 neurosurgeons.
group with residents covering public hospitals	large multispecialty group	Private/academic, we have a neurosurgery residency program for DOs
Hospital affiliated	Locum tenens (2)	private/multispecialty group
Hospital based (3)	mix academic/private	salary
hospital based, hospital employee, pediatric academic hospital which self-insures	multispecialty	university-county
hospital district employee	Multispecialty clinic (3)	We all work for the government, yet receive no pension or benefits, even on a pro-rated basis!!!!!

22. Please select the category that best describes the size of your practice. Other (Please specify):

2 man limited to peds.	Employee	only two neurosurgeons
2 neurosurgeons in pediatric hospital with training programs	hospital based (2)	Pediatric call group within a larger academic neurosurgical group
Academic practice, solo trauma covering	Locum tenens (2)	solo, cost sharing group
All 200+ physicians are hospital employees	multi-specialty academic	total number includes neurosugery attending and residents
Cancer center	Now retired	was solo, now military in a different specialty

26. If you are planning to stop taking call, please indicate why. Select the one answer that plays the most important role in your decision. Other (Please specify):

Age (2)	group allows to stop call a 55 years of age	Incompatible with other obligations
age 60 not mandatory	have reached age 60	It's all of the above and general lack of appreciation from patients, families or the hospital
all of the above except insurance	High liability	no call after age 60
ALREADY STOPPED	High liability, low reimbursement, poor lifestyle.	No call required after age 65y/0
All the Above	high risk low pay poor lifestyle	NO LONGER REQUIRED AT AGE 59
Already retired from call.	hospital bylaws allow it after 20 yrs of service	no longer take call
already stopped taking ER call this year because of exemption due to my "senior active" medical staff status	hospital bylaws stop at age 60	Other junior members of my dept. will do so
At age 65 with retirement as Chief	hospital policy allows	Plan to fully retire in 2-3 years
burned out on trauma call	hospital REQUIRES me to take call	Reach Senior Level.
Can stop call coverage at age 55	hospital sends backs to ortho but we take trauma call	REDUCTION OF MALPRACTICE
can stop taking ER call after being at my hospital for 25 years --only 8 years to go	hospital stops requiring it at age 60	See how I feel at 55
change in type of practice	I don't take call now	Stopped 8 years ago
Cut back because of age	I no longer take calls (2)	system would not let me enter ans.
discontinued for health/stress issues 2003	I plan on leaving neurosurgical practice for another career	Transition to medical director of a specialty clinic
ER call not required by hospitals	I semi-retired (closed practice, cover trauma) mostly lifestyle interference	UNCERTAIN OF FUTURE
	I stopped taking call 5 years ago	Will stop taking call at age 60, or earlier if possible

27. Are you retiring because of any of the following? Other (Please specify):

Change to different role/job	I'll retire when I'm through practicing, unrelated to call issues.	POLITICS
combination of all of the above and cannot predict the future environment	legal risk not worth it	Stress of Neurosurgical Practice
Decreasing reimbursement: it isn't worth it	Medicine has gone to the pits	the last questions were poorly designed
DO OTHER THINGS	Not for 10 yrs	will retire when cannot physically perform
growing tired of all the hassle in medicine	not retiring (2)	
I will probably retire after 2020	Please note: I retired from practice in the state of KY. I subsequently was offered my present position.	

American Association of Neurological Surgeons
2006 WORKFORCE SURVEY

Thank you for helping the AANS Executive Committee gather the necessary information to evaluate issues surrounding neurosurgical workforce shortages. The information you provide in this survey will help us identify and quantify problems, and recommend solutions. Your response will help us begin developing programs and services that will help neurosurgeons as we continue to work on the larger issues of our practice environment.

Section 1- Emergency Call Coverage

1. Do you take ER call?
   - __ Yes
   - __ No (skip to question 10)

2. At how many hospitals do you provide emergency call coverage?
   - __ 1
   - __ 2
   - __ 3
   - __ 4 or more

3 - How many hours, on average, do you work per week on each of the following? Please enter the number in the space provided.
   - __ Overall
   - __ In direct patient care
   - __ On research or education
   - __ On administrative work
   - __ Other (please specify): _____

4. Please indicate the option that best describes the type of hospital where you practice. If you cover more than one hospital, check all that apply:
   - __ Academic medical center
   - __ Community hospital
   - __ Other (please specify): _____

5. If any of these hospitals serve as trauma centers, please select the trauma level(s); *check all that apply*:
   - __ Not a trauma center
   - __ Level 1
   - __ Level 2
   - __ Level 3
   - ___ Other (please specify): _____

6. Do any of these hospitals require taking call?
   - __ Yes, all of them
   - __ Yes, some of them
   - __ No

7. How often, on average, do you personally cover emergency or trauma call at your hospital(s)? "Week" includes weekends.
   - __ One day/night a week or less
   - __ Two-three days/nights per week
   - __ Four or more days/nights per week

8. For what services do you take call? *Please check all that apply.*
   - __ Cranial
   - __ Spinal
   - __ Pediatric
   - __ Trauma
   - __ I cover all neurosurgical services
   - __ Other (please specify): _____
   - __ I do not take call

9. Do you receive a monetary stipend for emergency call coverage?
   - ___$500 /day (night) or less
   - ___$501 to $750 /day
   - ___$751 to $1000 /day
   - ___$1001 to $1500 /day
   - ___$1501 to $2000 /day
   - ___$2001 to $3000 /day
   - ___Over $3000 /day
   - ___Not paid by day, but have another compensation arrangement. (please specify): _____

10. If you do not take call, please indicate why not.

   - __ Malpractice Insurance company no longer covers for the services
   - __ Malpractice Insurance company offers a premium reduction for eliminating trauma call (or other ER services)
   - __ Insufficient pay for emergency services
   - __ Lifestyle interference
   - __ Disruption of routine practice schedule
   - __ Other (please specify): _____

Section 2- Your Practice

11 - Have you limited the <u>type of procedures</u> performed by your practice?
   - __ Yes
   - __ No (skip to question 13)

12. How have limited your practice? Please check all that apply.

   - __ Eliminated cranial
   - __ Eliminated pediatrics
   - __ Eliminated spine
   - __ Eliminated trauma
   - __ Other (please specify): _____

13. Has your neurosurgical group been involved in developing a hospital's plan for transfer of patients?
   - __ Yes
   - __ No
   - __ There is no transfer plan at any of the hospitals I cover

14. Has your neurosurgical group been involved in developing a plan for a hospital's ER going off line?

__ Yes
__ No
__ There is no plan for going off line at any of the hospitals I cover

15. Would you be willing to participate in this type of planning for coverage in your area?

__ Yes
__ No
__ Don't know

16. Have you experienced any cost reduction or discount on your malpractice insurance for not taking call?

__ Yes
__ No (skip to question 16)

17. Please estimate how much your premium deduction or discount is:

__ 5% or less
__ 6-10%
__ 11% or over

18. What is the yearly cost of your Malpractice Insurance?

__ $50,000—$80,000
__ $80,001—$100,000
__ $100,001—$120,000
__ $120,001—-$150,000
__ $150,001—$200,000
__ $200,001 or more

19. Do you perceive call coverage as a problem in your geographic area?

__ Yes
__ No

20. Please rate your agreement with the following statements about the current call system in your area.

	Strongly Agree	*Agree*	*Disagree*	*Strongly Disagree*	*Don't Know/NA*
The system works in the best interest of patients					
The system is effective					
The system allows neurosurgeons enough time "off" call					

Section 3: Demographic Information

21. Please select the category that best describes your type of practice. (Check only one):
- __ Private
- __ Private (academic affiliate or appointment)
- __ Full-time Academic
- __ Federal Government
- __ Other

22. Please select the category that best describes your practice setting. If you practice in a university setting, please select the one that best approximates your size. (Check only one):
- __ Solo
- __ Solo practice, shared facilities
- __ Small neurosurgical group (2-5 neurosurgeons)
- __ Medium neurosurgical group (6-20 neurosurgeons)
- __ Large neurosurgical group (more than 20 neurosurgeons)
- __ Small multi-specialty (2-5 physicians)
- __ Medium multi-specialty (6-20 physicians)
- __ Large multi-specialty (more than 20 physicians)

23. Which category best represents your age?
- __ Younger than 35
- __ 36-45
- __ 46-55
- __ 56-65
- __ 66 or older

24. Please select the states in which you practice: _____

25. Please select the year (range) you expect to stop taking call:
- __ 2010 or sooner
- __ 2011 – 2015
- __ 2016 – 2020
- __ 2021 or later
- __ Don't know

26. If you are planning to stop taking call, please indicate why. Select the one answer that plays the most important role in your decision.

- __ Retiring
- __ Malpractice Insurance company no longer covers for the call services
- __ Malpractice Insurance company offers a premium reduction for eliminating trauma call (or other ER services)
- __ Insufficient pay for emergency services
- __ Lifestyle interference
- __ Disruption of routine practice schedule
- __ Other (please specify): _____
- __ I have no plans to stop taking call

27. If you are retiring, are you retiring <u>because</u> of any of the following?
    - __ On call demands were too excessive
    - __ Malpractice premiums were too high
    - __ No, I planned to retire anyway
    - __ Other (please specify): _____

Thank you for completing this survey.

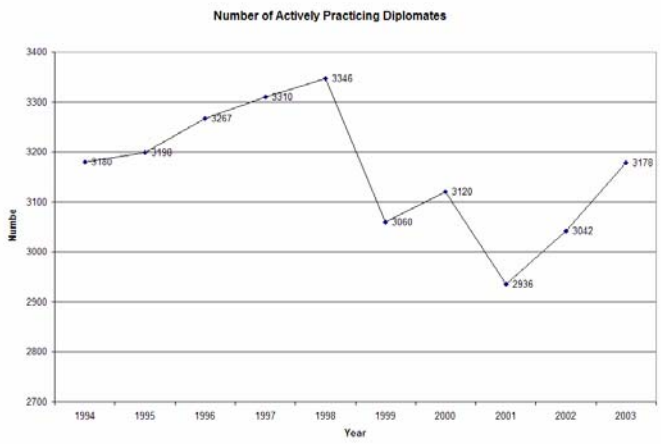
Report to the CNS Executive Committee:
Neurosurgery, Acute Care Surgery, and Trauma Care

Background:

The American Association for the Surgery of Trauma (AAST), has developed "a committee to develop the reorganized specialty of trauma, surgical critical care, and emergency surgery". This is also known as the "Committee on the Acute Care Surgeon". This group is interested in developing a surgical subspecialty focused on emergency surgical care. This subspecialty would incorporate portions of numerous disciplines, including various aspects of general surgery, vascular surgery, and thoracic surgery, as well as selected areas of neurosurgical emergency care, orthopedic surgery, vascular, and critical care disciplines. At least a portion of the genesis of this effort appears to be an observed decrease in the involvement of neurosurgeons in trauma care.

Neurosurgery (Workforce):

The number of neurosurgeons has been stable for over a decade, with the peak being 1998 when there were 3,346 practicing neurosurgeons. Nationally, there is about one neurosurgeon for each 55,000 citizens. Further, the population of neurosurgeons is aging, with approximately 1400 (44%) of neurosurgeons over age 50 and approximately 600 (19%) over age 60. Despite this, neurosurgeons as a group are busier than ever. Barker et al., in 2005, reported a 50% increase in the volume of cranial surgery between 1998 and 2001. While data on spinal surgery are harder to come by, data from the National Inpatient Sample reveal a 16% increase in hospital admissions for spinal degenerative disease, a figure which ignores the current trend toward outpatient spinal surgery. Finally, professional liability issues have produced dramatic changes in the current and future neurosurgical workforce: As a result of rising insurance costs, 43% of neurosurgeons have, or are considering, restricting their practices, 29% either plan to, or are considering, retiring, and 19% either plan to, or are considering, moving (2002 CSNS Survey). These numbers have led to a perceived shortage of neurosurgical manpower in all subspecialty disciplines, both on a regional and national basis.



Of the three specialties affected most by an influx of trauma patients, Neurosurgery is by far the smallest: 3,178 Practicing Board Certified Neurosurgeons versus 35,403 Board Certified General Surgeons and 22,711 Board Certified Orthopaedic Surgeons. (ABMS (2004), ABNS (2004)). This observation led Dr. Ralph Dacey, in a 2003 letter to the ACGME, to opine that "…the burdens of emergency care for head and spinal cord injury and for hemorrhagic stroke fall disproportionately on neurosurgeons because of their small numbers."

Numerical data regarding the economic viability of neurotrauma care for neurosurgeons is particularly difficult to come by. Nevertheless, unsubstantiated testimonials regarding the difficulty of making a living in this subspecialty abound:

> *"A generation ago, physicians covered emergency rooms as part of the responsibilities of medical staff membership and as a way to serve the community. A lot has changed since then. The Emergency Medical Treatment and Labor Act, EMTALA, transformed this noble duty into yet another legal requirement. At the same time, most neurosurgeons report that their emergency rooms have become much busier in recent years. Finally, although practice expenses have been skyrocketing recently, our relative rates of reimbursement have not kept up for many years—assuming that the emergency patients for whom we get out of bed in the middle of the night have financial resources, which is often not the case. These unfunded emergencies continue to displace reimbursed elective cases even though neurosurgeons have had to increase the volume of their clinical work simply to meet expenses and keep their practices open. In effect, the moral obligation to provide emergency care has been replaced by an unfunded federal mandate that penalizes the failure to provide such care." (A. Valadka, Neurotrauma and Critical Care News, Fall, 2004).*

and:

> *"In addition, eliminating trauma call and emergency call from their practices offers several advantages. First, revenues from trauma call rarely generated much, if any, income; often, these procedures were performed at a loss. In addition, such cases often interfered with profitable elective surgeries by competing for operating room time or by causing surgeons to work many hours the night before elective operative schedules." (P. Letarte, Neurotrauma and Critical Care News, Spring, 2004).*

Both of these quotations reference the concept of *opportunity cost* for neurotrauma care. Opportunity cost is the cost of an alternative that must be forgone in order to pursue a certain action. Put another way, it is the loss or gain that one could have received by taking an alternative action. In a free market economy, it is assumed that all parties will seek to take the action with the lowest opportunity cost (greatest benefit/utility). In the present case, the opportunity cost of emergency and trauma care is the difference for the neurosurgeon in benefit/utility between the trauma care rendered and the benefit/utility that he or she could have received by rendering non-emergency, non-trauma care during the same period of time. Benefit/utility is measured not only in dollars but by multiple means, including also such things as personal satisfaction and lack of discomfort. The opportunity cost for trauma care becomes a progressively

greater factor when the neurosurgeon is busier and thus has less time available when there are not economically more attractive options.

A suggested area of further investigation is to determine this value numerically for the profession of neurosurgery.

Surgery (Workforce):

As noted above, there are currently greater than 35,000 Board certified General Surgeons in the United States. As a specialty, Surgery has found itself increasingly fragmented by sub specialization from within (notably, Thoracic Surgery and Vascular Surgery), and increasingly threatened by the encroachment of other specialties from without (notably, ENT and Plastics). There are currently 1,051 PGY-1 general surgery positions available per year, of which 99.3% were filled in 2005. There are 117 Surgical Critical Care Fellowship positions available per year, in 68 active training programs. For 2005, greater than 50% (59) of the positions were unfilled and 41/68 programs unfilled.

In 2003, the ACS Committee on Trauma and American Association for the Surgery of Trauma held a summit to discuss the "future of trauma surgery". At the time it was concluded that the current specialty of trauma surgery was non-viable for the following reasons: not enough OR time, too much "babysitting of patients", and poor reimbursement. Yet, it was felt that there still exists a need for surgery care in the acute setting. It was concluded that a new specialty should be developed ("Acute Care Surgery") that encompassed areas of thoracic surgery, surgical critical care, and emergency general surgery. Development of a curriculum was undertaken, a process which is well underway at this time.

Until very recently, organized neurosurgery had not been involved in any of the decision-making as they were not originally included in the development of the curriculum, training, or certification. The statement has been made that, if organized neurosurgery were to oppose acute care surgeons performing ICP monitor insertion or any other neurosurgical procedures, neurosurgery "would have to come up with ways to have a neurosurgeon take care of emergency patients expeditiously."

It is proposed that training in this new discipline will take the form of a two-year, 100% clinical fellowship, to be undertaken after 4 or 5 years of General Surgery residency training. Nine months will be comprised of surgical critical care, similar to the surgery current critical care fellowship experience. The remaining 15 months will incorporate 2-3 months each of vascular surgery, gastrointestinal surgery, and thoracic surgery, with the remaining time being divided between neurosurgery, interventional radiology, endoscopy, and trauma general surgery. After completion of training, it is envisioned that these individuals will function as "surgical hospitalists", on the payroll or at least involved in a revenue sharing

arrangement with the hospitals they serve. A major consideration in the development of this program was the establishment of stable work hours (shift-work) for these practitioners.

It is anticipated that trainees will be certified to perform a number of procedures traditionally outside the field of general surgery. While numerous traditionally neurosurgical procedures have, at one time or another, been included on this list, the placement of intraparenchymal ICP monitors is currently the only solid entry. Interestingly, the inclusion of this procedure is *not felt to be core to the development of this specialty*, per se. It does nothing to counter the core problems of not enough OR time, too much "babysitting of patients", and poor reimbursement (G. Jerry Jurkovich, MD, personal communication). In fact, in a 2004 survey of AAST members, "Addition of selected orthopedic and neurosurgical procedures" was found to be the least desirable of 11 possible "ideal" trauma practice attributes.

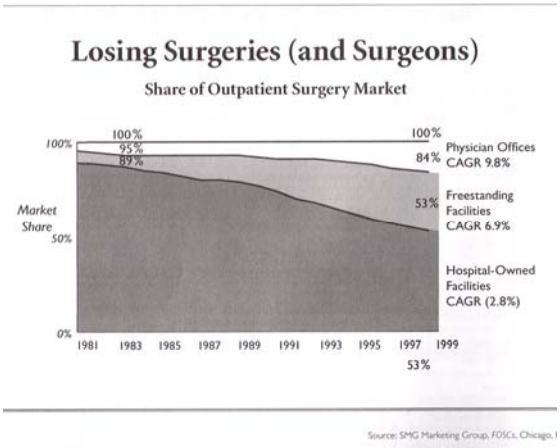
The reasons for the inclusion of this procedure appear to be twofold. First, the ability for Acute Care Surgeons to place ICP monitors is described as a public health function in that it serves as a potential mechanism for filling a perceived void in neurotrauma care. It is argued that, because most neurotrauma patients are cared for in a nonsurgical manner, the burden and, therefore, scarcity, of neurosurgical neurotrauma care would be lessened by this ability. Second, it serves to make trainees in this discipline more marketable by holding out the potential for more sophisticated "brain trauma care" at facilities lacking the services of a neurosurgeon.

Interestingly it has been recognized that Acute Care Surgery as a specialty is no more economically viable than the previous Surgery Critical Care specialty without government subsidies. However, vigorous efforts are underway in support of such subsidies, with the goal of channeling any such funds into the coffers of Acute Care Surgeons. It must be kept in mind that a 2002-2003 study by Rodriguez et al. documented that "The addition of emergency surgery did not improve the financial viability of trauma and critical care as a specialty" and that, "Without significant hospital or governmental support, the only viable financial option is to develop a substantial private practice the cross subsidizes the practice of trauma and critical care" (Rodriguez and Polk, Ann Surg, 2005). The effects of widening of the current trauma surgery scope of practice on liability and liability premiums does not appear to have been examined in detail by the AAST committee (J. Weigelt, personal communication).

Hospitals

Currently, the JCAHO reports approximately 4,400 accredited hospitals, accounting for 80% of all hospitals and 90% of all hospital beds. Even if all neurosurgeons were to participate in emergency trauma care, which is clearly not the case, there would not be even one neurosurgeon for each hospital. Further,

neurosurgical care is becoming progressively more centralized. The number of hospitals with any admissions for DRG-1 (craniotomy other than trauma, adult) is decreasing at a rate of 27/year (Barker et al. Neurosurgery 55, 2004). This clustering of neurosurgeons has the effect of further reducing the number of facilities that can expect to have even one neurosurgeon on staff.



Of these 4,400 accredited hospitals, approximately 100 (2003) are physician-owned specialty hospitals with little (55) or no (45) capacity for emergency trauma care. While the number of physician-owned specialty hospitals is currently relatively small, this number is expected to grow. Further, in many cases, more patients within a given specialty are treated in specialty hospitals than at the comparable departments at local general hospitals (GAO Report on Specialty Hospitals, 2004). There are also approximately 3,000 outpatient surgery centers, with no capacity for trauma care. Neurosurgeons that choose either of the latter as their primary site of practice have effectively removed themselves from the pool of neurosurgeons available for emergency neurotrauma care.

There are currently 211 ACS verified trauma centers (96 Level I, 86 Level II, 29 Level III) (ACS, Dec, 2005) (Appendix I). Regionalization, in this instance, has been facilitated by regulations promulgated by the ACS COT itself. Overall, there are 1154 trauma centers certified by either the ACS or local governmental agencies, with 190 level I centers (MacKenzie et al., JAMA, 2003). At a minimum, each level I center would need to be associated with a minimum of three neurosurgeons for 24/7/365 coverage.

It is currently unclear whether trauma care is a profitable enterprise for general hospitals. The lack of physician-owned specialty hospitals devoted to trauma or neurotrauma care certainly argues against this. It also appears that the economic viability of trauma care is regionalized. Clearly, trauma care is viable in individual regions, for different reasons. Governmental subsidies have been cited as the reason for the viability and success of the Washington State trauma system. However, a 2002 survey of trauma/EMS experts from all 50 states identified “finances” as the most common weakness (38/50) associated with state trauma systems and/or delivery or trauma care. “Finances” was also listed as the most common (49/50) threat to same (Mann et al., J Trauma, 2005).

Effects on Neurosurgery and Neurosurgical Care:

Neurosurgery, as a profession, must be prepared to answer the following fundamental questions regarding its role in neurotrauma care:

1. Will neurosurgeons will be primarily involved in trauma care in its delivery for the good of the patient, regardless of the opportunity cost
2. If neurosurgery chooses to be involved, how should neurosurgery best manage access in light of limited resources?
3. If neurosurgery chooses not to be involved, will it actively train others to replace neurosurgeons?

Thus far, organized neurosurgery, primarily represented by Dr. Alex Valadka, has strongly opposed the inclusion of traditionally neurosurgical procedures in the core curriculum of an acute care specialty and disengagement from neurotrauma care. External arguments against inclusion include:

1. **The ability of an acute care surgeon to place an ICP monitor is inappropriate on the basis that these practitioners will not be capable of dealing with potential complications or the surgical management of intracranial hypertension.** The ability to perform a craniotomy is not part of the curriculum.
2. **Placement of an ICP monitor is but one small part of an overall management scenario that the acute care surgeon has not been trained to execute.** The first step in the management of elevated ICP is the evacuation of a mass lesion. The acute care surgeon is not trained to perform this procedure, nor is this individual trained to make the decision to do so. In addition, the placement of a ventriculostomy and institution of ventricular drainage is an early and central component of the management of elevated ICP (Management and Prognosis of Severe Traumatic Brain Injury, 2000). Placement of a ventriculostomy is not a part of the acute care surgery curriculum. Without the ability to effectively manage elevated ICP, the value of ICP monitor placement is questionable.
3. **This represents a decline in the quality of neurotrauma care.** Neurosurgeons are the most qualified to treat the patient with neural injury. The required training period for neurosurgery is 6 years, with nearly continuous exposure to neurotrauma, versus approximately 3 months for acute care general surgeons. A recurring complaint amongst trauma surgeons is that neurotrauma care is frequently delegated to lower level residents or physician extenders, albeit under the direction of attending neurosurgeons. The three month experience of the acute care general surgeon does not represent an improvement.

Internal arguments against inclusion include:

1. **This is the first step of a "slippery slope" which will result in the eventual loss of neurotrauma care for the specialty of neurosurgery.** The loss of this subspecialty within the area of neurosurgery is felt to be

associated with significant negative repercussions. Specifically, there appears to be concern within the neurosurgical community that any loss of neurotrauma will lead to further narrowing of the specialty, as has largely occurred with peripheral nerve surgery and had almost occurred with spinal surgery. With the arguments above, it is conceivable and has already happened in parts of the U.S., that what begins with ICP monitors, eventually extends to ventriculostomy and craniotomy for mass lesions and intracranial hypertension.

Organized neurosurgery, though, has not stated as of yet, unlike with spine over 15 years ago, that it is the purview of the neurosurgeon to handle neurotrauma care. While there are a number of issues, (e.g.) reimbursement for these types of services is currently and primarily felt to be poor for neurosurgeons, increased liability risk, impact on elective case load, etc., it is certainly possible that this might not always be the case. In addition, as was seen with EC-IC bypass study, it is possible for one unanticipated new trial or medical breakthrough to completely eliminate a major portion of neurosurgical practice and/ or cause revaluation of present cases that would make neurotrauma and its care more attractive. Anticipated elimination of a major portion of neurosurgical practice through abdication should therefore be avoided.

2. **This effort will lead to neurosurgical consults and patient transfers only in the most dire of circumstances.** In the absence of neurosurgical care, brain injured patients will be cared for as best as possible given the limitations of the facility and practitioners involved. When these capabilities are exceeded, an emergent call for assistance will likely be issued, frequently when the patient is in extremis due to the need for a ventriculostomy, craniotomy, or brain death examination.

Three additional arguments against inclusion appear worthy of consideration:

1. **The employment of acute care surgeons in order to offer more sophisticated "brain trauma care" to facilities lacking the services of a neurosurgeon is inappropriate.** The capability of an institution to provide this limited level of brain trauma care may result in patients with clearly surgical disease being taken to these facilities, only to be then transferred, after a substantial delay, to a facility with a neurosurgeon. In many cases, these facilities will be separated by only short distances.
2. **Given that the current acute care surgery formula is acknowledged to also be non-viable without governmental subsidies, there is a significant chance that it will fail to gain acceptance.** There is certainly no guarantee that additional governmental funding will materialize to support this initiative financially. In this instance, the burden of brain trauma care will fall back to neurosurgeons. Neurosurgeons, after having lost experience and, perhaps, interest, in neurotrauma care, will be

unlikely to return to this now *demonstrably* economically nonviable duty. Thus, the problem will be made worse.

3. **This strategy may result in loss of subsidies for on-call coverage for neurosurgeons.** Institutions may be unwilling to continue these subsidies if non-neurosurgical brain trauma care meeting ACS minimum criteria is available through acute care general surgeons. While the ACS COT has yet to propose this change to the Gold Book criteria, it is certainly consistent with the goals of this committee.

Despite the above, there are a number of internal neurosurgical arguments that can be made in support of transfer of neurotrauma care to the acute care surgery specialty. While these arguments do not address the issue of ICP monitoring per se, they are relevant to the more fundamental question of whether neurosurgeons will be primarily involved in trauma care delivery for the good of the patient, regardless of the opportunity cost.

1. **Without major changes in the health care delivery system, the specialty of neurosurgery cannot possibly deliver the volume of trauma care required by society.** Therefore some type of shift of neurotrauma care duties is inevitable.
2. **Neurotrauma care is felt to be poorly reimbursed, a liability risk, and disruptive to the neurosurgeon's lifestyle.** Therefore neurosurgery should be gratified that someone else is willing to do this.
3. **The "opportunity cost" of trauma care is too high in that it detracts from the time available for neurosurgeons to engage in more profitable enterprises.** Therefore neurosurgery should be gratified that someone else is willing to do this.
4. **The elimination of some amount of trauma care from the workload at academic medical centers may allow training programs to better spread the resident experience across all neurosurgical disciplines.** Many neurosurgical residency programs are searching for ways to decrease the burden of neurotrauma care on the residency program, particularly with the advent of work hours restrictions.

Potential Responses to the Inclusion of ICP Monitor Placement in the Curriculum for Acute Care Surgery Training and the Abdication of the Neurotrauma Care

Potential responses **to the specific issue** of inclusion of ICP monitor placement in the curriculum for acute care surgery training include:

1. **Take no action.** This will likely result in the short-term removal of this procedure from the curriculum. The current curriculum relies on the cooperation of neurosurgeons willing to train acute care surgery fellows in ICP monitor placement. Most attending trauma surgeons do not have hospital privileges to perform this procedure, nor are they likely to obtain

them without training and the approval of local neurosurgeons. Without such training, it is unclear how acute care surgery fellows will be able to acquire sufficient experience to be certified as competent to perform this procedure.

Long-term, the danger in this strategy is that it will be perceived as disinterest on the part of neurosurgery, opening the door for a broader inclusion of neurosurgical procedures in the next iteration of the curriculum. Regardless of the official position of "organized neurosurgery", it is already known that some neurosurgeons are perfectly willing to train acute care surgeons to insert ICP monitors and perform ventriculostomies. While lack of interest on the part of neurosurgery would likely slow down the development of this aspect of the acute care surgery specialty, it will not stop the process, provided that the AAST Committee on the Acute Care Surgeon retains its current inertia.

2. **Work with the AAST and ACS to facilitate proper training of acute care surgery fellows in neurotrauma care and performance of this procedure.** Acknowledge that neurosurgeons are unable to provide this service, assist in the training, and make sure that acute care surgeons perform these services competently. This includes significant education regarding indications for neurosurgical consultation and patient transfer.
3. **Oppose inclusion of ICP monitor placement and the care of the neurotrauma patient in the curriculum.** Neurosurgery certainly has a wealth of viable reasons, both for the public good, as well as for the profession, to oppose this. These have been elaborated above. Care must be taken not to let this opposition degenerate into threats.

In addition, it recommended that the following response be tendered, regardless of neurosurgery's response above:

***Propose restrictions.** In the interest of public safety, neurosurgery *should* propose that ICP monitors not be placed by acute care surgeons unless there is a neurosurgeon on-call, *in that specific facility*, available for backup in the event of a complication.

Potential Strategies to Increase the Participation of Neurosurgeons in Neurotrauma Care

With regard to the greater issue of whether neurosurgeons will be primarily involved in trauma care delivery for the good of the patient, *there can be no question in the minds of neurosurgeons that they are the best able to provide care for the neurotrauma patient*. While many neurosurgeons remain ambivalent about the issue of continuing to deliver this care, attitudes generally fall into one of two categories.

One group of neurosurgeons is anxious to continue to provide neurotrauma care, as this provides a reasonable income stream in their region, improves and maintains collegial relations with hospital and community physicians, and provides generally positive exposure to the patient base in their community. Further, many practitioners feel that it is their civic duty to provide this care. As well, academic centers overall would likely be interested in maintaining some presence in neurotrauma and neurocritical care since it serves as the basis for all other neurosurgical care.

A second, and seemingly growing, group of neurosurgeons has examined the issue of neurotrauma care using an economic model, and have come to the conclusion that it is simply not an economically viable enterprise in its current form. Thus, with a variety of economically more attractive options available, this group wishes to withdraw from neurotrauma care.

Despite the issues raised as to why neurosurgeons may be withdrawing from neurotrauma care, strong support by the leadership of organized neurosurgery advocating the involvement of neurosurgeons directly in the care of the neurotrauma patient might help to alleviate the anxiety of continued coverage in the short term and improve the involvement of neurosurgeons in neurotrauma care. However, organized neurosurgery must also prioritize its agenda to address the issues of reimbursement, liability, trauma systems, and workload/ workforce issues. The former, without the latter, is unlikely to result in meaningful long term improvement.

The following non-mutually exclusive list of potential actions is offered for consideration. All items are potential solutions to the perceived shortage of neurosurgical manpower within the discipline of neurotrauma care and all begin to address the issues which dissuade neurosurgeons from participation in neurotrauma care:

1. **Work with the AAST and ACS COT to secure compensation for trauma care commensurate with the time, liability risk, opportunity costs, and lifestyle disruption inherent in this type of work.** Although this is in some respects the most difficult solution, it is also the most likely to work. Whether or not neurosurgery chooses to work with the AAST and ACS COT in the development of acute care surgery, better reimbursement for neurotrauma care will reduce the associated opportunity costs. Market forces will bring practitioners back into the neurotrauma field, once a critical price point is reached. Because there are very few unique CPT codes for trauma care, an increase in reimbursement on the physician side would ideally involve some mechanism other than the current CPT system in order to identify this type of work. Development of trauma-related CPT codes would devalue non-trauma codes under the current system. This system would have to function with all governmental and non-governmental insurers, including “self-pay”.

2. **Work with the AAST and ACS COT to secure immunity from professional liability actions for trauma care.** Again, this reduces the opportunity costs for trauma care. In addition, some individuals may choose a practice exclusively devoted to trauma care in order to avoid legal entanglements and insurance costs altogether. The constitutionality of this suggestion is unclear.
3. **Appeal to the better nature of hospitals and hospital systems to provide increased stipends for neurosurgeons to participate in call coverage and neurotrauma care.** There is anecdotal evidence to suggest that this strategy has worked in some hospital systems in some areas. The success of this strategy ultimately depends on whether trauma care is perceived as beneficial (economic or otherwise) to a given hospital or hospital system. This would be extremely difficult to legislate and therefore would likely be unevenly applied across the country.
4. **Propose that neurosurgery, as a profession, cease accepting insurance (both private and governmental) as a form of payment.** This idea has been proposed by Gregory Przybylski, MD, as a potential solution to the larger issue of declining reimbursement for neurosurgeons. In this way, neurosurgeons could charge for a service in proportion to the time/effort/expertise/opportunity cost involved. Depending on how this strategy was implemented, trauma reimbursement might increase proportionally. Obviously, the success of this solution would depend on nearly 100% participation by neurosurgeons, would decimate the specialty of spinal surgery (unless orthopaedic surgery adopted a similar strategy), and would engender a tremendous amount of ill will. Further, depending upon implementation, there may be antitrust issues involved.
5. **Propose Regionalization of Care.** The thought is that all trauma patients, including neurotrauma patients, could be better served if cared for in regionalized trauma centers possessing all necessary resources, including neurosurgeons. This would obviate the need for ICP monitor placement in the acute care surgery curriculum. It is interesting to note that this was the goal of the ACS COT when it developed the American College of Surgeons Trauma Consultation and Verification Program. The mission of this program was:

> *"To create national guidelines for the purpose of optimizing trauma care in the United States. This objective may be accomplished through a voluntary review of potential and existing trauma centers so that trauma centers may provide an organized and systemic approach to the care of the injured patient. Essential elements include trained and capable personnel, adequate facilities, and ongoing self-assessment as outlined in the "Resources for Optimal Care of the Injured Patient", 1998 document.*

Given the widespread acceptance of this noble concept and its associated guide, "Resources for Optimal Care of the Injured Patient: 1999", it is difficult to conceive how regionalization of trauma care could be more effectively put into place short of governmental mandate. Nevertheless it

is useful to consider how such a system might work should such a mandate occur.

It has been estimated that one such trauma center would be needed for each 3,000,000 Americans. This number could actually be higher given the unequal distribution of the population. Currently, there are approximately 300,000,000 Americans yielding a need for a minimum of 100 such centers. Again, given that each would need to be associated with a minimum of three full-time trauma neurosurgeons for 24/7/365 coverage, at least 300 such individuals would be needed, or approximately 10% of the entire neurosurgical work force. Again due to the associated opportunity costs, without substantial government subsidies, immunity from professional liability actions, and other measures, it is unclear how many neurosurgeons will desire to participate in this system.

6. **Propose a System of "Regional Cooperation".** Regionalization implies that every trauma patient is transported to one place, with the danger that patients with minor injuries flood the system and make it impossible for patients with more serious (and more appropriate) injuries to be transported to the regional trauma facility. *Regional cooperation,* instead, would require hospitals to work together to share the load. This process would be facilitated by pre-hospital triage of trauma patients such that patients with less severe injuries go to the less well-equipped/well-staffed hospitals while those with more severe injuries go to the regional trauma center.

   Again, this strategy was presaged by the ACS Committee on Trauma in 1976, when the "Classification System of Trauma Center Level" was developed. This concept was further elaborated in the "Resources for Optimal Care of the Injured Patient: 1999" and subsequent revisions. These documents allowed for trauma centers to be classified into five different "levels" (I-V), based on resources, with the idea that more severely injured patients would be transferred to those facilities with greater resources. In addition, 35/50 states have adopted their own criteria for trauma center designation, usually similar to those promulgated by the ACS COT.

   Again, given the widespread acceptance of this noble concept, it is difficult to conceive how it could be more effectively put into place short of governmental mandate. Despite the perception that this strategy has failed to alleviate a national shortage of neurosurgical manpower, there are some examples of the successful implementation of regional cooperation, such as in Washington State and surrounding areas. Even in this example, however, nearly all neurotrauma patients, regardless of injury severity, are transferred to the Level I trauma center (Harborview Medical Center), despite the fact that many surrounding facilities have one

or more neurosurgeons on their staff (Hoke Overland, King County Medic One, personal communication).

It is again useful to consider how *regional cooperation* might work should a governmental mandate occur. This proposal is largely facilities-based and does not directly address the issue of physician (neurosurgeon) choice to participate in trauma care. However, in the absence of an appropriate alternate physician-owned specialty hospital, most neurosurgeons do need access to a full service hospital to continue practice. Therefore, if all hospitals were classified with respect to their ability to care for trauma patients based on the ACS COT system and all neurosurgeons practicing at these facilities were required to participate in trauma care, it is possible that more neurosurgeons would participate in this care. This is a negative reinforcement strategy that decreases the opportunity cost of trauma care by reducing the benefit/utility of non-participation.

There is some evidence that the first part of this strategy has been implemented in some areas. Indeed, six states have already categorized all or nearly all hospitals into one of five levels of trauma care, with an additional four having categorized at least 50% of facilities. It is interesting to note that two of these ten states (OK, TX) are among the states with the highest number of physician-owned specialty hospitals. It is unknown whether such a system would threaten the viability of the current full service hospital system within the current reimbursement environment.

The second part of this strategy is highly problematic for neurosurgery, in that it directly conflicts with the 2002 "Joint Section of Neurotrauma/Critical Care Position Statement on Reconciling On-Call Responsibilities with EMTALA Requirements." This document states that:

> *"…Ultimately, only the individual neurosurgeon can determine the limits of his or her ability to provide continued coverage. Hospitals should not force or coerce neurosurgeons to provide continuous on-call coverage when it is impossible or unreasonable for neurosurgeons to do so."*

Without a retraction or clarification of this position statement, any neurosurgeon not wishing to participate in neurotrauma care could, in theory, put forth a cogent argument as to why he or she is unable to provide coverage.

7. **Propose "Radical Regionalization of Care".** In this system all trauma care would be performed by government owned and operated facilities. These facilities would operate in compliance with the ACS guide "Resources for Optimal Care of the Injured Patient: 1999". All practitioners would be employees of the Federal Government and would therefore have sovereign immunity. All compensation would come from governmental sources. This system has the potential to lower opportunity

costs to a sufficient degree to attract neurosurgeons, provided that physician salaries are above a critical price point. In addition, it has the potential to decrease health insurance costs for all Americans by removing trauma-related health care expenses from the equation. Unfortunately, this system could certainly also be viewed as a first step toward nationalized health care.

Appendix I: ACS Verified Trauma Centers

ACS Verified Hospital	City	State	Level	Expiration Date
Alaska Native Medical Center	Anchorage	AK	Level II	7/15/06
University of Alabama	Birmingham	AL	Level I	1/29/06
St. Joseph's Hospital and Medical Center	Phoenix	AZ	Level I	11/4/07
Mercy San Juan Medical Center	Carmichael	CA	Level II	11/4/06
Palomar Medical Center	Escondido	CA	Level II	6/7/06
Scripps Memorial Hospital	La Jolla	CA	Level II	7/14/06
Cedars-Sinai Medical Center	Los Angeles	CA	Level I	9/23/06
LAC + USC Medical Center	Los Angeles	CA	Level I	9/9/06
UCLA Medical Center	Los Angeles	CA	Level I	6/11/07
UC Irvine Medical Center	Orange	CA	Level I	8/5/06
Sutter Roseville Medical Center	Roseville	CA	Level II	7/28/07
UC Davis Medical Center	Sacramento	CA	Level I Adult & Pediatric	5/28/06
Children's Hospital & Health Center	San Diego	CA	Level I Pediatric	6/19/06
Scripps Mercy Hospital	San Diego	CA	Level I	7/14/06
Sharp Memorial Hospital	San Diego	CA	Level II	7/14/06
University of California San Diego Medical Center	San Diego	CA	Level I	6/7/06
San Francisco General Hospital and Medical Center	San Francisco	CA	Level I Adult & Pediatric	6/3/07
Western Medical Center	Santa Ana	CA	Level II	8/8/08
Santa Barbara Cottage Hospital	Santa Barbara	CA	Level II	1/19/08
Stanford University Medical Center	Stanford	CA	Level I	5/28/06
Children's Hospital - Denver	Denver	CO	Level I	5/2/06
Denver Health Medical Center	Denver	CO	Level I	3/27/06
St. Anthony Central Hospital	Denver	CO	Level I	3/27/06
Swedish Medical Center	Englewood	CO	Level I Adult & Pediatric	10/26/08
Poudre Valley Hospital	Fort Collins	CO	Level II	8/23/06
Banner Health Systems-North Colorado Medical Center	Greeley	CO	Level II	8/22/06
North Colorado Medical Center	Greeley	CO	Level II	8/22/06
Littleton Adventist Hospital	Littleton	CO	Level II	12/14/07
St. Mary-Corwin Medical Center	Pueblo	CO	Level II	1/25/08
Danbury Hospital	Danbury	CT	Level II	5/21/06
Hartford Hospital	Hartford	CT	Level I Adult	10/26/08
St. Francis Medical Center	Hartford	CT	Level II	7/10/06
New Britain General Hospital	New Britain	CT	Level III	2/4/06
Yale New Haven Hospital	New Haven	CT	Level I Adult & Pediatric	1/12/08
Hospital of St. Raphael	"New Haven			
"	CT	Level II	12/17/05	
Norwalk Hospital	Norwalk	CT	Level II	4/11/08
William W. Backus Hospital	Norwich	CT	Level II	12/5/06
The Stamford Hospital	Stamford	CT	Level II	2/13/06
Children's National Medical Center	Washington	DC	Level I Pediatric	7/15/07

Howard University Hospital	Washington	DC	Level I	7/15/07
Washington Hospital Center	Washington	DC	Level I	11/1/07
Bayhealth Medical Center / Kent General Hospital	Dover	DE	Level III	12/9/06
Beebe Medical Center	Lewes	DE	Level III	10/26/08
Bayhealth Medical Center-Milford Memorial Hospital	Milford	DE	Level III	10/26/08
Christiana Hospital	Newark	DE	Level I Adult & Pediatric	4/21/07
Nanticoke Memorial Hospital	Seaford	DE	Level III	8/18/06
Queen's Medical Center	Honolulu	HI	Level II	1/8/07
Iowa Methodist Medical Center	Des Moines	IA	Level I Adult & Pediatric	3/17/08
Mercy Medical Center	Des Moines	IA	Level II Adult & Pediatric	10/26/08
Mercy Medical Center	Sioux City	IA	Level II	4/13/07
Eastern Idaho Regional Medical Center	Idaho Falls	ID	Level III	9/29/07
Portneuf Medical Center	Pocatello	ID	Level III	12/5/05
St. Mary's Medical Center	Evansville	IN	Level II Adult & Pediatric	2/4/08
Parkview Memorial Hospital	Fort Wayne	IN	Level II	6/7/06
Clarian/Methodist Hospital	Indianapolis	IN	Level I, Adult & Pediatric	10/26/08
IU/Wishard Memorial Hospital	Indianapolis	IN	Level I	9/13/07
Memorial Hospital of South Bend	South Bend	IN	Level II	11/3/07
University of Kansas Medical Center	Kansas City	KS	Level I	7/30/06
Via Christi Regional Medical Center (St. Francis Campus)	Wichita	KS	Level I Adult & Pediatric	12/12/06
Wesley Medical Center	Wichita	KS	Level I	6/1/08
Taylor Regional Hospital	Campbellsville	KY	Level III Adult	10/26/08
Charity Hospital	New Orleans	LA	Level I	2/2/06
Beth Israel Deaconess Medical Center	Boston	MA	Level I	1/6/08
Boston Medical Center	Boston	MA	Level I Adult & Pediatric	1/22/07
Brigham & Women's Hospital	Boston	MA	Level I	7/27/07
Children's Hospital Boston	Boston	MA	Level I Pediatric	8/25/08
Massachusetts General Hospital	Boston	MA	Level I	7/27/07
Massachusetts General Hospital for Children	Boston	MA	Level I Pediatric	7/31/06
Lahey Clinic	Burlington	MA	Level II	7/28/07
Lawrence General Hospital	Lawrence	MA	Level III	6/4/06
Caritas Holy Family Hospital	Methuen	MA	Level III	8/12/07
Anna Jaques Hospital	Newburyport	MA	Level III	6/4/06
Berkshire Medical Center	Pittsfield	MA	Level II Adult & Pediatric	1/27/08
C. S. Mott Children's Hospital	Ann Arbor	MI	Level I Pediatric	7/18/06
St. Joseph Mercy Hospital	Ann Arbor	MI	Level II	7/2/07
Children's Hospital of Michigan	Detroit	MI	Level I Pediatric	11/18/07
Detroit Receiving Hospital	Detroit	MI	Level I	5/11/08
Henry Ford Hospital	Detroit	MI	Level I	7/7/07
Hurley Medical Center	Flint	MI	Level I	7/21/06
Genesys Regional Medical Center	Grand Blanc	MI	Level II	1/23/07
Spectrum Health - Downtown Campus	Grand Rapids	MI	Level II	6/19/06
St. Mary's Mercy Medical Center	Grand Rapids	MI	Level II	11/18/07

Borgess Medical Center	Kalamazoo	MI	Level I	1/27/06
Bronson Methodist Hospital	Kalamazoo	MI	Level I	3/24/06
William Beaumont Hospital	Royal Oak	MI	Level I Adult & Pediatric	12/14/07
St. Luke's Hospital	Duluth	MN	Level II	4/28/06
St. Mary's Hospital	Duluth	MN	Level II Adult & Pediatric	12/23/06
Hennepin County Medical Center	Minneapolis	MN	Level I Adult & Pediatric	11/4/06
North Memorial Medical Center	Robbinsdale	MN	Level I Adult & Pediatric	1/28/08
St. Cloud Hospital	St. Cloud	MN	Level II Adult & Pediatric	8/18/07
University of Missouri Hospitals & Clinics	Columbia	MO	Level I Adult & Pediatric	12/17/05
Barnes Jewish Hospital	St. Louis	MO	Level I Adult	1/22/06
Deaconess Billings Clinic	Billings	MT	Level II	4/29/07
St. Vincent Hospital and Health Center	Billings	MT	Level II	11/24/07
Bozeman Deaconess Hospital	Bozeman	MT	Level III	11/18/07
Benefis Healthcare	Great Falls	MT	Level II	12/5/05
Community Medical Center	Missoula	MT	Level III	10/7/08
St. Patrick Hospital and Health Sciences Center	Missoula	MT	Level II	5/7/07
Carolinas Medical Center	Charlotte	NC	Level I Adult & Pediatric	2/1/08
Duke University Medical Center	Durham	NC	Level I Adult & Pediatric	4/14/07
Pitt County Memorial Hospital	Greenville	NC	Level I Adult & Pediatric	7/15/08
NC Baptist Hospitals, Inc.	Winston Salem	NC	Level I	3/17/07
Wake Forest University Baptist Medical Center	Winston-Salem	NC	Level I Adult & Pediatric	3/17/07
Medcenter One, Inc.	Bismarck	ND	Level II	5/10/07
St. Alexius Medical Center	Bismarck	ND	Level II	3/19/06
St. Joseph's Hospital and Health Center	Dickinson	ND	Level III	4/29/07
Innovis Health	Fargo	ND	Level II	6/4/07
MeritCare Hospital	Fargo	ND	Level II	6/7/06
Altru Health System	Grand Forks	ND	Level II	2/3/08
Trinity Hospital	Minot	ND	Level II	10/29/07
Good Samaritan Hospital	Kearney	NE	Level II Adult	7/25/06
BryanLGH Medical Center West	Lincoln	NE	Level II Adult	6/30/06
Regional West Medical Center	Scottsbluff	NE	Level II Adult	1/28/08
Atlantic City Medical Center	Atlantic City	NJ	Level II Adult & Pediatric	9/2/07
Cooper University Hospital	Camden	NJ	Level I Adult & Pediatric	6/27/08
Hackensack University Medical Center	Hackensack	NJ	Level II Adult & Pediatric	9/29/07
Jersey City Medical Center	Jersey City	NJ	Level II Adult & Pediatric	6/20/06
Morristown Memorial Hospital	Morristown	NJ	Level I Adult & Pediatric	12/18/05
Jersey Shore University Medical Center	Neptune	NJ	Level II	2/4/08
Robert Wood Johnson University Hospital	New Brunswick	NJ	Level I Adult & Pediatric	7/25/06
New Jersey Trauma Center at the University Hospital	Newark	NJ	Level I Adult & Pediatric	1/27/06
St. Joseph's Regional Medical Center	Paterson	NJ	Level II Adult & Pediatric	7/24/06
Capital Health System	Trenton	NJ	Level II	4/23/07
University of New Mexico Hospital	Albuquerque	NM	Level I	12/10/06
Sunrise Hospital & Medical Center	Las Vegas	NV	Level II Adult & Pediatric	10/26/08
University Medical Center of Southern Nevada	Las Vegas	NV	Level I Adult & Pediatric	2/2/08

Akron Children's Hospital	Akron	OH	Level II Pediatric	11/18/07
Akron General Medical Center	Akron	OH	Level I Adult	6/7/06
Summa Health System - Akron City Hospital	Akron	OH	Level I	9/29/07
Southeastern Ohio Regional Medical Center	Cambridge	OH	Level III	8/8/08
Aultman Hospital	Canton	OH	Level II Adult & Pediatric	11/23/07
Mercy Medical Center	Canton	OH	Level II	4/3/08
Bethesda North Hospital	Cincinnati	OH	Level III	12/11/06
Cincinnati Children's Hospital	Cincinnati	OH	Level I Pediatric	6/30/06
The University Hospital	Cincinnati	OH	Level I	8/8/08
MetroHealth Medical Center	Cleveland	OH	Level I Adult & Pediatric	2/8/08
Rainbow Babies and Children's Hospital	Cleveland	OH	Level I Pediatric	7/22/06
Children's Hospital, Inc.	Columbus	OH	Level I Pediatric	7/23/07
Grant Medical Center	Columbus	OH	Level I Adult	5/1/06
Grant/Riverside Methodist Hospital	Columbus	OH	Level II	11/18/07
Mount Carmel West Hospital	Columbus	OH	Level II Adult	4/19/07
Ohio State University Medical Center	Columbus	OH	Level I Adult	8/21/06
Children's Medical Center	Dayton	OH	Level II Pediatric	8/8/08
Good Samaritan Hospital	Dayton	OH	Level II Adult	1/22/07
Miami Valley Hospital	Dayton	OH	Level I Adult & Pediatric	10/29/07
Defiance Regional Medical Center	Defiance	OH	Level III Adult & Pediatric	1/23/07
Huron Hospital	East Cleveland	OH	Level II Adult	10/29/07
Blanchard Valley Regional Health Center	Findlay	OH	Level III	1/21/08
Lima Memorial Health System	Lima	OH	Level II	8/25/08
St. Rita's Medical Center	Lima	OH	Level II Adult & Pediatric	11/17/06
MedCentral Mansfield	Mansfield	OH	Level II Adult	6/2/07
East Ohio Regional Hospital	Martins Ferry	OH	Level III Adult & Pediatric	9/29/07
Doctors Hospital of Stark County	Massillon	OH	Level III	10/29/07
Hillcrest Hospital	Mayfield Heights	OH	Level II Adult	11/18/08
Southwest General Health Center	Middleburg Heights	OH	Level III Adult	11/19/06
Middletown Regional Medical Center	Middletown	OH	Level III Adult	5/3/07
St. Charles Mercy Hospital	Oregon	OH	Level III	5/25/07
Robinson Memorial Hospital	Ravenna	OH	Level III Adult	4/29/07
Flower Hospital	Sylvania	OH	Level III	8/17/07
Medical College of Ohio	Toledo	OH	Level I Adult	10/29/07
St. Vincent Mercy Medical Center	Toledo	OH	Level I Adult & Pediatric	5/11/08
The Toledo Hospital	Toledo	OH	Level I Adult & Pediatric	6/27/08
St. Joseph Health Center	Warren	OH	Level III	6/1/08
Greene Memorial Hospital	Xenia	OH	Level III Adult	5/2/08
St. Elizabeth Health Center	Youngstown	OH	Level I Adult & Pediatric	2/1/08
Oklahoma University Medical Center	Oklahoma City	OK	Level I Adult & Pediatric	2/9/08
Legacy Emanuel Hospital	Portland	OR	Level I	4/28/06
Rhode Island Hospital	Providence	RI	Level I Adult & Pediatric	2/1/08

Avera Queen of Peace Hospital	Mitchell	SD	Level III	6/7/06
Avera McKennan Hospital	Sioux Falls	SD	Level II	1/8/07
Sioux Valley Hospital	Sioux Falls	SD	Level II	8/12/07
Brackenridge Hospital	Austin	TX	Level II	3/19/06
Baylor University Medical Center	Dallas	TX	Level I Adult	11/18/08
Children's Medical Center Dallas	Dallas	TX	Level I Pediatric	1/27/08
Methodist Dallas Medical Center	Dallas	TX	Level II	6/11/07
Thomason Hospital	El Paso	TX	Level I	1/27/08
William Beaumont Army Medical Center	El Paso	TX	Level II	8/21/06
Brooke Army Medical Center	Fort Sam Houston	TX	Level I	1/19/08
Harris Methodist Fort Worth Hospital	Fort Worth	TX	Level II Adult	1/22/06
JPS Health Network	Fort Worth	TX	Level II Adult	7/14/07
University of Texas Medical Branch	Galveston	TX	Level I Adult & Pediatric	10/26/08
Ben Taub General Hospital	Houston	TX	Level I	7/30/06
Memorial Hermann Hospital	Houston	TX	Level I	5/1/06
Good Shepherd Medical Center	Longview	TX	Level II Adult	10/26/08
Covenant Children's Hospital	Lubbock	TX	Level II Pediatric	4/17/06
Covenant Medical Center	Lubbock	TX	Level II Adult	4/17/06
University Medical Center	Lubbock	TX	Level I	8/7/06
University Health System	San Antonio	TX	Level I	1/28/08
Wilford Hall Medical Center (Lackland AFB)	San Antonio	TX	Level I Adult & Pediatric	7/28/07
Wadley Regional Medical Center	Texarkana	TX	Level II	1/17/06
East Texas Medical Center	Tyler	TX	Level I	3/18/07
Mother Frances Hospital	Tyler	TX	Level II Adult	3/18/07
Hillcrest Baptist Medical Center	Waco	TX	Level II	6/1/08
Ogden Regional Medical Center	Ogden	UT	Level II	1/1/06
LDS Hospital	Salt Lake City	UT	Level I	6/17/07
Primary Children's Medical Center	Salt Lake City	UT	Level I Pediatric	1/30/07
University of Utah Hospital	Salt Lake City	UT	Level I	6/17/07
Fletcher Allen Health Care	Burlington	VT	Level I Adult & Pediatric	11/18/07
Luther Midelfort Hospital	Eau Claire	WI	Level II Adult	11/18/08
Aurora Baycare Medical Center	Green Bay	WI	Level II	11/2/07
St. Vincent Hospital	Green Bay	WI	Level II	1/21/06
Gundersen Lutheran Medical Center	La Crosse	WI	Level I Adult	2/3/08
University of Wisconsin Hospital and Clinics	Madison	WI	Level I Adult & Pediatric	7/22/07
St. Joseph's Hospital and Health Center	Marshfield	WI	Level II	11/12/06
Children's Hospital of Wisconsin	Milwaukee	WI	Level I Pediatric	7/27/07
Froedtert Hospital	Milwaukee	WI	Level I Adult	12/23/06
Theda Clark Medical Center	Neenah	WI	Level II	9/28/07
Charleston Area Medical Center	Charleston	WV	Level II Adult & Pediatric	3/30/08
Cabell Huntington Hospital	Huntington	WV	Level II Adult & Pediatric	10/26/08
West Virginia University Hospitals, Inc.	Morgantown	WV	Level I Adult & Pediatric	6/27/08

Saving Lives When Minutes Count:
Briefing on a Public Health Model for Trauma Systems

February 24, 2006
HC-5, The Capitol Building
12:30-2:00 p.m. Lunch Provided
(If Members cannot attend, please send health staff)

Moderators:

Howard R. Champion, MD, FRCS, FACS; Professor of Surgery, Founder and President, Coalition for American Trauma Care

William Rasco, FACHE; President/CEO, Greater San Antonio Hospital Council

Speakers:

Michael Briggs and daughter Wimberly; South Carolina family impacted by trauma

Robert Bass, MD, **FACEP;** Director, Maryland Institute for Emergency Medical Services Systems; President, National Association of State EMS Officials

Wayne Meredith, MD. FACS; Director, Division of Surgical Services, Richard T. Myers Professor and Chairman, Department of General Surgery, Wake Forest University Medical Center; Chair, American College of Surgeons' Committee on Trauma

Honorary Congressional Sponsors:

The Honorable Bill Frist
The Honorable Lindsey Graham
The Honorable Gene Green
The Honorable Patty Murray
The Honorable Jack Reed
The Honorable Pat Roberts
The Honorable Mike Simpson

Organizational Sponsors (to date):

Champions ($750)

American Academy of Orthopaedic Surgeons

Sponsors ($500)

American Association of Neurological Surgeons/Congress of Neurological Surgeons
American College of Emergency Physicians*
American College of Osteopathic Surgeons
American College of Surgeons*

American Hospital Association*
American Osteopathic Association
American Trauma Society*
Coalition for American Trauma Care*
National Association of State EMS Officials*

Friends ($250)
Orthopaedic Trauma Association

*Steering Committee Organizations

Sponsor Contact: Marcia Mabee, MPH, PhD; Executive Director, Coalition for American Trauma Care mmabee@ix.netcom.com
703-709-3001

NEUROSURGEONS TO PRESERVE HEALTH CARE ACCESS

DOCTORS for MEDICAL LIABILITY REFORM DMLR

Medical Liability Reform Update

Neurosurgeons to Preserve Health Care Access

Through NPHCA, neurosurgery raised nearly one million dollars in 2005 to fund its medical liability campaign, which has, and will continue to be used to help fund the Doctors for Medical Liability Campaign. Since we have adequate funds on hand to meet our current DMLR obligations, fundraising activities for 2006 will be focused on encouraging neurosurgeons to contribute to the newly created AANSPAC. The PAC funds will be used to support political candidates who favor medical liability reform

Doctors for Medical Liability Reform

Through its advocacy organization, Neurosurgeons to Preserve Health Care Access (NPHCA), the AANS and CNS continue to lead the Doctors for Medical Liability Reform (DMLR) effort.
The focus of DMLR's 2005 activities was to build a large grassroots network of activists who support the passage of medical liability reform legislation. The 2005 Annual Report highlights these activities and accomplishments for the year. **(See attached)** Also provided with the Washington Committee meeting agenda materials is a cd-rom, which contains DMLR's "mini-documentary" about the crisis and 2 animations. These were widely distributed via our internet/e-mail campaign.

Since October 2005, DMLR has successfully launched a nationwide grassroots recruitment and advocacy campaign designed to build a network of physicians, patients and concerned citizens to support federal medical liability reform. In just the first four months of its campaign, DMLR has achieved significant results. The activities and accomplishments outlined below will be built on and expanded throughout 2006.

Twenty-three Million Radio Listeners Hear DMLR Messages – 23 million people learned about the patient access to care crisis and DMLR's Protect Patients Now campaign from radio interviews with our spokespersons. These interviews were broadcast 960 times on 813 stations in our target states and nationally.

DMLR Builds Grassroots Network of 105,648 People – DMLR has built a database of 105,648 physicians, patients and concerned citizens to date, which will be expanded throughout 2006. This grassroots network will be kept up-to-date on all DMLR activities and reform efforts and will be mobilized as needed.

DMLR's Creative Content Viewed by 46,818 People – Some unique and compelling Internet content was developed to deliver our messages and to drive traffic to our web site. DMLR's two animations were viewed 16,490 times and the mini-documentary was viewed 30,328 times.

New Web Site Receives 403,060 Hits, 16,690 Actions Taken – The newly redesigned Protect Patients Now web site received 403,060 hits from 44,405 unique visitors. This increased traffic resulted in 16,690 actions taken which were facilitated by our new Action Center.

DMLR's Petition Signed by 10,810 People – DMLR developed a petition to support comprehensive federal medical liability reform that has been signed by 10,810 physicians, patients and concerned citizens.

Grassroots Network Sends 5,738 Letters to Congress – In response to just one request to our grassroots network asking them to write their Senators, 5,738 letters to Congress have been sent using the streamlined interactive tool on the Protect Patients Now web site.

DMLR Internet Advertising Creates 30 Million Impressions – To drive additional traffic to the Protect Patients Now web site, several ads were produced and placed on web sites visited by potential supporters of medical liability reform. These ads resulted in 30 million impressions and 14,374 additional visits to our web site.

70,657 Emails to Rented Lists Add to Grassroots Network – To recruit additional physicians, patients and concerned citizens to join our grassroots network, DMLR rented several email lists of potential supporters. A total of 70,657 emails were sent to these lists, which resulted in 1,325 clicks through to our web site.

DMLR will be holding a Steering Committee meeting on February 17, 2006 at which time final strategy and plans for the remainder of 2006 will be discussed and implemented. More information will be available at the Washington Committee meeting.

Legislative Update.

Getting 60 votes in the U.S. Senate continues to be our obstacle. The House of Representatives passed the HEALTH Act again last July but to date there has been no activity in the Senate. We anticipate that Senator Enzi will hold a hearing sometime in March and the Senate will consider legislation sometime during "health week(s)", which will begin sometime in early May.

In the meantime, Washington Office staff is working with key Senate and White House staff to develop legislation that includes a cap on non-economic damages, but that might attract a few democrats. Several democrats have supported the class action and asbestos tort reform bills, and may be more willing to support medical liability reform.

2005

Annual Report 2005





Getting the Nation Behind Us

DOCTORS *for* MEDICAL LIABILITY REFORM

DMLR

DOCTORS *for* MEDICAL LIABILITY REFORM

DMLR

Doctors for Medical Liability Reform (DMLR)

is a national coalition of nine medical specialties representing more than 230,000 U.S. physicians who have come together to solve the medical liability crisis that is sweeping our nation and threatening patient access to quality health care.

In 2005, DMLR launched a nationwide grassroots recruitment and advocacy campaign called *Getting the Nation Behind Us*, part of our ongoing effort to mobilize support for federal legislation that will address the medical liability crisis on a national level.

Medical liability reform enjoys broad support among the American people, and national reform legislation has already passed in the U.S. House of Representatives. But it has been blocked in the Senate by a mere handful of votes. A minority of Senators, many of whom receive financial backing from the powerful personal injury lawyer lobby, have been able to prevent reform from even reaching the Senate floor for an up or down vote.

President Bush has repeatedly called upon Congress to pass medical liability reform and pledged to sign it into law. Our task is to reach out to the American people and their elected representatives, overcome the special interests, and *Get the Nation Behind Us* as we work to pass these vital reforms.

Member Organizations

American Academy of Dermatology Association
American Association of Orthopaedic Surgeons
American College of Cardiology
American College of Emergency Physicians
American College of Obstetricians and Gynecologists
American College of Surgeons Professional Association
American Society of Plastic Surgeons
Neurosurgeons to Preserve Health Care Access
The Society of Thoracic Surgeons

To Our Physician Members and Colleagues

Dear Members and Colleagues:

In 2005, DMLR successfully launched our nationwide recruitment and advocacy campaign as part of Protect Patients Now, laying a solid foundation for a significantly expanded grassroots mobilization effort in 2006. We call it, *Getting the Nation Behind Us*.

A strong, positive response to our 2005 activities gives us the momentum we need to seize the initiative in 2006: raising public awareness of the medical liability crisis, bringing reform to a vote in the U.S. Senate and making it a high-profile issue in our target states during the mid-term elections.

The key to *Getting the Nation Behind Us* is grassroots activism. While we may not be able to match the financial clout of the personal injury lawyers, the urgency of our message resonates with the American people. By mobilizing activists on our side – arming them with the information they need and organizing them into an effective, coordinated campaign – we can carry our message to the American people and to the U.S. Congress, and we can overcome the special interests in Washington.

Our focus in 2005 was to identify, educate and recruit likely supporters. Highlights include:

- More than 23 million people heard radio interviews with our doctors, which were broadcast 960 times on 813 stations;
- Almost 83,000 physicians, patients and concerned citizens received a mailing from DMLR educating them on the medical liability crisis and encouraging their support;
- We compiled an email list of 84,000 people as part of an ongoing on-line recruitment, education and mobilization effort; an additional 70,000 emails were sent to rented lists;
- More than 24,600 unique visitors logged more than 173,000 total hits on the new web site, www.ProtectPatientsNow.org, which was redesigned as a sleek, user-friendly source of pertinent information and up-to-date news;
- We created a series of clever and compelling animations and distributed them via the Internet. The animations were viewed more than 21,000 times;
- Our on-line ads were displayed 16.7 million times;
- We produced a compelling mini-documentary for the web on the medical liability crisis and the threat to patient access to care.

In the following pages, you can read about the full range of our 2005 initiatives in greater detail.

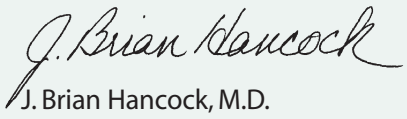
We are connecting with the nation, and we look forward to an even stronger 2006 as we continue to fully mobilize our grassroots campaign to win support in Congress.

As doctors, we don't usually think of ourselves as activists; we're busy taking care of patients. But every day we are on the front lines of this crisis and see its effects on our specialties, our practices and our patients. That's why doctors are becoming increasingly outspoken and are demanding a solution. At the same time we have many natural allies, including business owners, other health care providers and politically active/concerned citizens. And our greatest source of strength is the more than 295 million Americans whose health and well-being rely on continued access to quality medical care.

Your enduring participation and support are critical to our success. Working together, we made great strides in 2005. With your help, we will redouble our efforts to *Get the Nation Behind Us* in 2006 and work toward passage of the medical liability reform our nation so critically needs.

Sincerely,

Stuart L. Weinstein, M.D.
Chair
American Association of Orthopaedic Surgeons



J. Brian Hancock, M.D.
Vice-Chair
American College of Emergency Physicians

Earned Media

Radio Media Tours: 23 Million Listeners

In 2005, DMLR made its presence known on the airwaves. During morning and evening commutes, more than 23 million people listened as DMLR spokespeople fielded questions on medical liability reform in interviews broadcast over more than 800 stations.

As part of the tour, each of our three spokespeople pre-recorded a news release that was drafted in advance, giving us maximum control of our message, and custom fed to selected markets both nationally and in two target states, Washington and Maryland.

John M. Gibbons, Jr., M.D., past president of the American College of Obstetricians and Gynecologists, reached almost 20 million listeners on his national tour; Cynthia Wolfe, M.D., an Emergency Room Physician in Olympia, Washington, spoke to more than 260,000 people in her home state; and John Caruso, M.D., a neurosurgeon, garnered an audience of more than 3 million in Maryland.

Media Roundtable Discussion with Senator Santorum

On October, 6, 2005, we held a Capitol Hill roundtable discussion featuring Senator Rick Santorum (R-PA), Stuart L. Weinstein, M.D., Chairman of DMLR, and Yale Law School professor George Priest. The goal of the event was to establish DMLR as a resource for members of the press – all of whom received a press kit with background information on DMLR and a copy of our first animation on CD-ROM — and build connections with elite opinion makers in Washington, D.C.

The resulting news story included a link to our redesigned web site, and representatives of the American Enterprise Institute — one of the oldest and most respected think tanks in Washington, D.C. — invited our speakers to participate in a conference on medical liability reform planned for the Spring of 2006.

On-Line Advocacy

In 2005 we began to build a comprehensive and creative on-line presence to inform, recruit and support DMLR grassroots activists in our campaign to *Get the Nation Behind Us*.

There are several key advantages to on-line advocacy programs: they allow us to track our effectiveness, giving real-time feedback on which messages are working and which are not. High hit rates and Send to Friend activity means the message is strong and effective.

On-line advocacy also enables us to communicate with our grassroots network, react to news events and respond to attacks by the trial bar at a moment's notice. On-line capability allows us to both target our messages to specific audiences and reach out to the broad public.

The Web Site: 173,000 Hits

The Nerve Center of Our Grassroots Campaign

With the Internet becoming an increasingly dominant information source for a tech-savvy public, DMLR utilized a combination of techniques, including mass e-mails, eye-catching internet ads, direct mail, and radio broadcasts to draw people to our fully remodeled web site, www.ProtectPatientsNow.org. Boasting streamlined graphics, a user-friendly interface, innovative animation, streaming video and interactive capabilities, the new site will serve as an all purpose nerve-center for our grassroots campaign.

When fully reconstructed in 2006, www.ProtectPatientsNow.org will become the resource for up-to-date information on the medical liability crisis for activists, spokespeople and press, with easily digestible fact sheets, talking points, background briefs and streaming video documentaries that coordinate and focus our message for maximum impact.

Already, our fully interactive site is an organizing tool in itself. Drawn by creative animations and dramatic video, visitors are encouraged to contact members of Congress, sign our petition, and even donate to the cause. Doctors and patients are urged to join our effort to end medical lawsuit abuse. Links will connect visitors to grassroots activities in their areas.

The response in just the first few months is exciting:

- 24,682 unique visitors logged more than 173,000 hits on our site since its redesign;
- 1,214 people signed our on-line petition;
- 684 people used our page to contact their Senators and Congressmen;
- 624 people signed up to receive regular updates and to join our effort.

The site is not only energizing support, it is also supplementing our other efforts. The petition will be the centerpiece of an earned media opportunity when we hand it to reform supporters at a press conference on Capitol Hill. Meanwhile, the petition and other interactive features help us assemble one of the most important tools in grassroots organizing: lists of activists, our armies of concerned citizens who will help us take our campaign to the next level.

Mini-Documentary for the Web

The Crisis Is Now

"Imagine a member of your family is in an accident and suffers head trauma…but the closest neurosurgeon is an hour away and the clock is ticking…"

So begins our compelling documentary on the high personal cost of the medical liability crisis, which is now available in streaming video on our web site at www.ProtectPatientsNow.org. A simple click brings up a professional-quality, *20/20*-style news story in which doctors and patients share their heart-wrenching personal accounts, and an insightful narrative examines the causes of the crisis and the broader impact of living without liability reform.

Building on DMLR's successful production of earlier documentaries on local liability issues, we sought to creatively leverage our previous investment to produce a product that would address a national audience. The existing footage was re-edited, and a new voice-over added. The result is an original, cost-effective and compelling piece of reporting that will inform viewers and set a high standard for media coverage of our issue.

Within days of posting the video on our site, doctors contacted us asking for CDs of the documentary to play in their waiting rooms.

Animated E-mails: Sent to 154,000 Individuals

Informing and Entertaining

How do you capture people's attention, draw traffic to your web site, and get people to spend time on your site rather than the millions of others out there?

This is the new science and art of Internet advocacy and DMLR is exploring several innovative techniques, including creative animations that entertain as they inform. We posted two animations satirizing personal injury lawyers getting rich at the expense of doctors' careers and patients' health and sent mass e-mails to 84,000 people on our lists with an animated teaser and a link to our web site. Approximately 30% of recipients (almost 10% higher than the industry average) opened the e-mail, and an additional 6,000 people viewed the animation without e-mail prompts. To expand our reach, we also sent 70,000 e-mails to lists rented from other organizations.

The animations have hit a chord and have become an effective tool in *Getting the Nation Behind Us*. The animations are the most requested page on our web site as well as the most frequent entry page, and the response of those writing to us has been highly positive. Many chose to send the animations on to friends, family and co-workers, creating the viral marketing — in which exciting, innovative content builds its own momentum — that all advertisers are looking for today.

On-Line Advertising: 16.7 Million Reached

The New Frontier of Advertising

On-line advertising allows us to communicate key messages to our target audiences, create an interactive relationship that enhances list-building, on-line fundraising and other interactive response activities, and track how effectively our messages are maximizing the expenditure of advertising dollars.

A series of eye-catching video and animated advertisements were tested on both traditional and non-traditional media web sites such as the *Baltimore Sun, The Seattle Post-Intelligencer, the Drudge Report, Roll Call*, physician blogs, women's blogs and conservative political blogs. *The Drudge Report*, with more than 10 million page views, was the most frequent referrer to our web site. Altogether, our ads reached some 16.7 million people.

Direct Mail

83,000 Pieces Mailed

Supplementing our on-line grassroots recruitment and advocacy campaign, we are reaching out to physicians, patients and concerned citizens through an active direct mail program, sending a variety of mailings to a number of different lists to test which messages and lists are most effective in reaching our target audience.

We mailed almost 83,000 pieces, the majority of them signed by our Chair, Stuart L. Weinstein, M.D., asking recipients to reach out to patients (in the case of doctors), contact members of Congress, sign our petition, and send us their e-mail address in order to keep informed. The overall response rate was very encouraging, with Dr. Weinstein's letter to patients/concerned citizens evoking an impressive 8% response (2% is considered high in direct mail). More than 1,600 people signed our petition.

Direct mail was part of an integrated effort to educate, energize and mobilize our supporters as we seek to *Get the Nation Behind Us*. The e-mails help us build our lists, while the petition signatures will be combined with the signatures we have collected on-line and become the centerpiece of an earned media press-conference with allies in the Senate and House announcing growing public support for reforming our medical liability system.

Looking to the Future

Our grassroots campaign to *Get the Nation Behind Us* had a strong start in 2005. In 2006, we plan to ramp up our efforts on every front to pass liability reform in Congress.

This election year is a prime opportunity to press for a vote in the Senate. We know where the candidates stand, and the people will too, as we pull out all the stops with:

- a state-targeted e-mail and letter writing campaign;
- town hall meetings;
- a Capitol Hill news conference announcing the result of our petition drive;
- candidate pledges;
- voter pledges;
- rallies;
- radio;
- direct mail;
- and a continued build-out of our on-line advocacy capabilities.

Our medical system in the United States is the finest in the world, but today it is under attack and in crisis. As doctors, we are on the front lines of the crisis and see its harmful effects everyday, but it is patients who ultimately suffer the greatest harm.

We have the American people on our side, and we have the tools to make their voices heard in Congress. Remember, we are only a handful of votes away from solving the liability crisis. Working together, we can and must succeed. The future of American healthcare depends on it.





DOCTORS *for* MEDICAL LIABILITY REFORM
DMLR

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Drugs and Devices Update

FDA Proposed Rule to Reclassify Intervertebral Body Fusion Device

On February 9, 2006, the FDA published a proposed rule in the *Federal Register* **(see attachment)** that would reclassify intervertebral body fusion devices that contain bone grafting material, from Class III to Class II, and retain those that contain any therapeutic biological (e.g. bone morphogenic protein) in Class III. The agency proposed this reclassification based on the recommends of the Orthopaedic and Rehabilitation Devices Panel on December 11, 2003.

The AANS/CNS Drugs and Devices Forum and leaders of the Spine Section are reviewing the proposal and will develop a draft for review and comment by AANS and CNS leadership. The deadline for comments is May 9, 2005.

Brain Tumor Stakeholders Meeting

On January 20, 2006, the FDA held a public workshop on Brain Tumor Clinical Trial Endpoints. The workshop included a series of presentations examining different types of clinical trial endpoints for primary brain tumor drug approvals and discussion by a panel of physicians and other experts.

The Panel included one neurosurgeon, Frederick Barker, MD, from Boston. Another neurosurgeon, Mitch Burger, MD, was invited but unable to attend. Others serving on the panel included 3 Radiation Oncologists, 2 Neuroradiologists, 1 Pediatric Neuro-Oncologist, 2 Neuro-Oncologists, 1 industry representative, 2 biostatisticians, a patient representative, and a specialist in neurocognative testing.

FDA staff began the meeting by giving some background information about the drug approval process. The FDA grants approval for oncology drugs in one of two ways. Regular approval is based on "end points that demonstrate that the drug provides a longer life, a better life, or a favorable effect on an established surrogate for a longer life or better life." Accelerated approval is based on "a surrogate end point that is less well established but that is reasonably likely to predict a longer or a better life." FDA staff stated that they are looking for guidance in developing appropriate end points that are meaningful and not "too soft," but that allow for flexibility in the development of useful drugs. Some of the issues raised at the meeting will be addressed by the Oncologic Drugs Advisory Committee (ODAC). By law, the FDA can only take advice from ODAC. The AANS/CNS Neurosurgical Devices Forum will continue to monitor FDA ODAC activity for brain tumor drugs.

The morning session focused on imaging based outcomes for clinical trial endpoints. James Provenzale, MD, and Nicholas Patronas, MD, neuroradiologists, gave presentations on MRI and PET imaging of brain tumors to assess therapeutic response to treatment. Karla Ballman and Kathleen Lamborn, biostatisticians, gave reports on progression –free survival. Kathleen Lamborn gave a report based on data from the North American Brain Tumor Consortium. Following this session Dr. Brem made public comments on behalf of AANS and CNS about the limitations of imaging to assess progress. He stated that some treatments can cause

misleading conclusions from images taken soon after treatment. Several panel members referred to Dr. Brem's comments throughout the day.

The afternoon session included a discussion of quality of life issues. Issues raised included the difficulty of measuring quality of life. Some of the measures included ability to perform activities of daily life, motor skill function, and sensory awareness.

The last hour of the program was devoted to a presentation by three staff members from the National Cancer Institute: Jeffrey Abrams, MD, Tracy Lugo-Lively, PhD, and Lalitha Shankar, MD, PhD. The purpose of the presentation was to discuss research priorities to develop and validate the appropriateness of clinical trial endpoints. They provided an update on NCI randomized trials with biomarkers. NCI staff stated that biomarkers are "not ready for prime time," but clinical trials are on going and NCI is hoping the biomarkers will be useful in the future.

Cranial Band Letter to FDA

The Neurosurgical Drugs and Devices Forum has been working with FDA staff to address the unintended consequence of a "de novo" approval of a 1998 cranial helmet application. After much discussion with the FDA, two avenues seemed most productive. One is to educate the members of the Pediatric Section on the process their hospital orthotics lab can take to try to gain approval of devices they were making before the FDA action. Mark Proctor, MD, has presented this issue to the Pediatric Section. Dr. Proctor has spent much effort and many hours on the cranial bands project.

The second action is to submit a petition to exempt the device from Class II requirements. Dr. Proctor, MD, drafted a letter **(see attachment)** from AANS, CNS, and the AANS/CNS Joint Section on Pediatric Neurosurgery to the FDA asking that the FDA exempt cranial helmets from Class II requirements. The letter was vetted by the AANS and CNS leadership, Joint Pediatric Section, and legal counsel and sent to the FDA in February, 2006.

ahead locational marginal pricing congestion charges (or other direct assignment of congestion costs) for the period covered and quantity specified. Once allocated, the financial coverage provided by the right should not be modified during its term except in the case of extraordinary circumstances or through voluntary agreement of both the holder of the right and the transmission organization.

(3) Long-term firm transmission rights made feasible by transmission upgrades or expansions must be available upon request to any party that pays for such upgrades or expansions in accordance with the transmission organization's prevailing cost allocation methods for upgrades or expansions. The term of the rights should be equal to the life of the facility (or facilities) or a lesser term requested by the party paying for the upgrade or expansion.

(4) Long-term firm transmission rights must be made available with terms (and/or rights to renewal) that are sufficient to meet the needs of load-serving entities to hedge long-term power supply arrangements made or planned to satisfy a service obligation. The length of term of renewals may be different from the original term.

(5) Load-serving entities with long-term power supply arrangements to meet a service obligation must have priority to existing transmission capacity that supports long-term firm transmission rights requested to hedge such arrangements.

(6) A long-term transmission right held by a load-serving entity to support a service obligation should be re-assignable to another entity that acquires that service obligation.

(7) The initial allocation of the long-term firm transmission rights shall not require recipients to participate in an auction.

(8) Allocation of long-term firm transmission rights should balance any adverse economic impact between participants receiving and not receiving the right.

[FR Doc. 06–1195 Filed 2–8–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 2006N–0019]

Orthopedic Devices; Reclassification of the Intervertebral Body Fusion Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify intervertebral body fusion devices that contain bone grafting material, from class III (premarket approval) into class II (special controls), and retain those that contain any therapeutic biologic (e.g., bone morphogenic protein) in class III. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance document that would serve as the special control if FDA reclassifies this device. The agency is proposing this reclassification based on the recommendation of the Orthopaedic and Rehabilitation Devices Panel (the Panel).

DATES: Submit written or electronic comments by May 10, 2006. See section X of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. 2006N–0019, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the followings ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/courier (for paper, disk, or CD–ROM submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jodi N. Anderson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036, ext. 186.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (Public Law 101–629), the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), and the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has done the following: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's

recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified postamendments devices is governed by section 513(f) of the act. This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order classifying the device in class I or class II. FDA's regulations in 21 CFR 860.134 set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Under section 513(f)(3)(B)(i) of the act, the Secretary may, for good cause shown, refer a proposed reclassification to a device classification panel. The Panel shall make a recommendation to the Secretary respecting approval or denial of the proposed reclassification. Under section 513(f)(3)(B)(i), any such recommendation must contain the following: (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device with respect to which the proposed reclassification was initiated.

II. Regulatory History of the Device

The intervertebral body fusion device is a postamendments device classified into class III under section 513(f)(1) of the act. It is intended for intervertebral body fusion. The intervertebral body fusion device cannot be placed in commercial distribution for implantation unless it is reclassified under section 513(f)(3), or subject to an approved PMA under section 515 of the act.

Based on information discussed at a December 11, 2003, Panel meeting (see section IV of this document) regarding the intervertebral body fusion device, the FDA believes potential risks associated with the intervertebral body fusion device, except those that contain any therapeutic biologic, can be addressed by special controls in the form of a guidance document. Thus, FDA is proposing to reclassify intervertebral body fusion devices that contain bone grafting material from class III into class II. Consistent with the act and the regulation, FDA referred the proposal to the Panel for its recommendation on the requested changes in classification.

Intervertebral body fusion devices that include any therapeutic biologic (e.g., bone morphogenic protein) will remain in class III. FDA believes that there is insufficient information to determine that general and special controls would provide a reasonable assurance of their safety and effectiveness.

III. Device Description

The following device description is based on the Panel's recommendation and the agency's review:

An intervertebral body fusion device is an implanted single or multiple component spinal device made from a variety of materials, including titanium and polymers. The device is inserted into the intervertebral body space of the cervical or lumbosacral spine, and is intended for intervertebral body fusion.

IV. Recommendation of the Panel

At a public meeting on December 11, 2003, the Panel recommended unanimously that the intervertebral body fusion device, except those that contain any therapeutic biologic, be reclassified from class III into class II (Ref. 1). The Panel believed that class II with special controls, in addition to the general controls, would provide reasonable assurance of the safety and effectiveness of the device. The Panel also recommended that the proposed special controls for the device be mechanical, animal, and clinical testing, labeling, sterilization, and biocompatibility as suggested by FDA staff.

V. Risks to Health

After considering the information in the Panel's recommendation, as well as other information, including Medical Device Reports (MDRs), FDA has evaluated the risks to health associated with use of the intervertebral body fusion device that contains bone grafting material and determined that the following risks to health are associated with its use:

A. Infection

Infection of the soft tissue, bony tissue, and the disc space is a potential risk to health associated with all surgical procedures and implanted spinal devices. Material composition or impurities, wear debris, operative time, and operative environment may compromise the vascular supply to the area or affect the immune system, which could increase the risk of infection. Improper sterilization or packaging may also increase the risk of infection.

B. Adverse Tissue Reaction

Adverse tissue reaction is a potential risk to health associated with all implanted devices. The implantation of the intervertebral body fusion device will elicit a mild inflammatory reaction typical of a normal foreign body response. Incompatible materials or impurities in the materials and wear debris may increase the severity of a local tissue reaction or cause a systemic tissue reaction. If the materials used in the manufacture of intervertebral body fusion device are not biocompatible, the patient could have an adverse tissue reaction.

C. Pain and Loss of Function

Pain and loss of function are risks to health associated with any implanted spinal device. Some device-related complications that may cause pain and loss of function include device fracture, deformation, loosening, extrusion, or migration due to inappropriate patient or device selection. The wear of materials, which may cause osteolysis (dissolution of bone), and component disassembly, fracture, or failure may also result in pain and loss of function.

D. Soft Tissue Injury

Soft tissue injury is a risk to health associated with all spinal surgery. This includes injury to major blood vessels, viscera, nerve roots, spinal cord, and cauda equina.

E. Vertebral Endplate Injury

Vertebral endplate injury is a risk to health associated with the insertion of an intervertebral body fusion device. Surgically inserting a device with a different geometry and modulus of elasticity than bone may lead to vertebral fracture, sinking of the device into the vertebral endplate (subsidence), collapse of the local blood supply, and collapse of the vertebral end plate.

F. Reoperation

Reoperation is a risk to health associated with any surgery. The need for reoperation could result from a failed intervertebral body device or component of the device, from nerve root decompression or adjacent level disease, or from reasons related to any surgery, e.g., infection or bleeding.

G. Pseudarthrosis (i.e., non-union)

Pseudarthrosis (i.e., non-union) is a risk associated with all spinal fusion surgeries. It signifies failure of the bony fusion mass and results in persistent instability.

VI. Summary of the Reasons for the Reclassification

FDA believes that the intervertebral body fusion device that contains bone grafting material should be reclassified into class II because special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device. In addition, there is sufficient information to establish special controls to provide such assurance.

VII. Summary of the Data Upon Which the Reclassification is Based

As discussed previously in this document, FDA is proposing this reclassification based on the Panel's recommendation. In addition FDA has reviewed MDRs related to this device. After evaluating this information, FDA believes that the potential risks to health associated with use of the intervertebral body fusion device described in section V of this document can be addressed by special controls. In addition, there is reasonable knowledge of the benefits of the device, including the provision of mechanical support, which aids in fusion procedures of the anterior spinal column.

VIII. Special Controls

FDA believes that the draft guidance document entitled ''Class II Special Controls Guidance Document: Intervertebral Body Fusion Device'' (the class II special controls guidance document), in addition to providing general controls, can address the risks to health associated with the use of the device and described in section V of this document. FDA believes further that the class II special controls guidance document, which incorporates voluntary consensus standards and labeling recommendations, addresses the Panel's concerns regarding the content of a special controls guidance document. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the draft guidance document that the agency intends to use as the special control for this device.

The class II special controls guidance document contains specific recommendations with regard to device performance testing and other information FDA believes should be included in premarket notification submissions (510(k)s) for the intervertebral body fusion device that contains bone grafting material. Sections of the draft special controls guidance document address the following topics: Material characterization, mechanical testing, animal testing, clinical testing, sterility, biocompatibility, and labeling. FDA has identified the risks to health associated with the use of the device in the first column of table 1 of this document and the recommended mitigation measures identified in the class II special controls guidance document in the second column.

TABLE 1.

Identified Risk	Recommended Mitigation Measures
Infection	Sterility
Adverse Tissue Reaction	Biocompatibility
Pain and Loss of Function	Mechanical Testing Animal Data Clinical Data Labeling
Soft Tissue Injury	Labeling
Vertebral Endplate Injury	Material Characterization Mechanical Testing Biocompatibility Labeling
Reoperation	Labeling
Psuedoarthrosis (i.e., non-union)	Labeling

Following the effective date of a final rule based on this proposal, any firm submitting a 510(k) premarket notification for an intervertebral body fusion device will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurance of safety and effectiveness.

IX. FDA's Findings

FDA believes the intervertebral body fusion device that contains bone grafting material should be reclassified into class II because special controls, in addition to general controls, can provide reasonable assurance of the safety and effectiveness of the device. In addition, there is sufficient information to establish special controls to provide such assurance. FDA, therefore, is proposing to reclassify the intervertebral body fusion device that contains bone grafting material into class II and establish the class II special controls guidance document as the special control for that device, and to retain in class III those devices that contain any therapeutic biologic.

X. Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

XI. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed reclassification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment, nor an environmental impact statement is required.

XII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic,

environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of this device from class III to class II will relieve all manufacturers of the device of the costs of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

XIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

XIV. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

FDA also tentatively concludes that the special controls guidance document does not contain new information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the draft guidance document entitled ''Class II Special Controls Guidance Document: Intervertebral Body Fusion Device;'' the notice contains an analysis of the paperwork burden for the draft guidance.

XV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this proposal. Submit a single copy of electronic comments or two paper copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

XVI. References

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Orthopedic and Rehabilitation Devices Panel Meeting Transcript, pp. 1–141, December 11, 2003.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 888 be amended as follows:

PART 888—ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 888.3080 is added to subpart D to read as follows:

§ 888.3080 Intervertebral body fusion device.

(a) *Identification.* An intervertebral body fusion device is an implanted single or multiple component spinal device made from a variety of materials, including titanium and polymers. The device is inserted into the intervertebral body space of the cervical or lumbosacral spine, and is intended for intervertebral body fusion.

(b) *Classification.* (1) Class II (special controls) for intervertebral body fusion devices that contain bone grafting material. The special control is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Intervertebral Body Fusion Device.'' See § 888.1(e) for the availability of this guidance document.

(2) Class III (premarket approval) for intervertebral body fusion devices that include any therapeutic biologic (e.g., bone morphogenic protein). Intervertebral body fusion devices that contain any therapeutic biologic require premarket approval.

(c) *Date premarket approval application (PMA) or notice of product development protocol (PDP) is required.* Devices described in paragraph (b)(2) of this section shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: February 1, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–1736 Filed 2–8–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD05–06–006]

RIN 1625-AA08

Special Local Regulations for Marine Events; Maryland Swim for Life, Chester River, Chestertown, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend the special local regulations at 33 CFR 100.533, established for the ''Maryland Swim for Life'' held annually on the waters of the Chester River, near Chestertown, Maryland by changing the event date to the third Saturday in June. This proposed rule is intended to restrict vessel traffic in portions of the Chester River and is necessary to provide for the safety of life on navigable waters during the event.

DATES: Comments and related material must reach the Coast Guard on or before April 10, 2006.

ADDRESSES: You may mail comments and related material to Commander (oax), Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia

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February 9, 2006

Dockets Management Branch
HFA-305, Food and Drug Administration
Dept. of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: Petition to Exempt Cranial Orthoses from Premarket Notification Requirements

Gentlepersons:

On behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), the AANS/CNS Section on Pediatric Neurosurgery and the AANS/CNS Drugs and Devices Committee, we are petitioning to exempt the Class II device "cranial orthoses" from the premarket notification requirements under section 510(m)(2), as provided by Food and Drug Administration (FDA) Modernization Act. Cranial orthoses are neurological devices that are reviewed under Part 882 by the Office of General, Restorative, and Neurological Devices.

Cranial orthoses are commonly used devices for the treatment of infant skull deformity and have been in documented use since 1978[3]. Since the 1998 FDA Class II designation for this type of device[9], access to the device has been significantly limited and the cost for the device has markedly increased. It is the expert opinion of our organizations that many patients who would benefit from the use of cranial orthoses are now unable to pursue this well accepted treatment due to financial and geographic access limitations. Furthermore, we believe that a premarket notification for this type of Class II device is not necessary to ensure the safety and effectiveness of the device. Our reasoning for this position is detailed below.

In a January 21, 1998 *Federal Register* notice (63 FR 3142), the FDA described the criteria the agency feels appropriate to determine which Class II device types should be exempt from the premarket notification (510(k)) requirements. A significant concern of the FDA is whether premarket notification for the device is necessary to provide reasonable assurance of safety and effectiveness of the device. We believe the cranial orthoses do not require premarket notification to ensure their safe application.

Background

Cranial orthoses are custom made devices designed to treat changes to an infant's head as a result of either intrauterine constraint, post-natal changes related to sleep position, or post-surgically after correction of prematurely fused skull bones[3,4,6,7,10,11]. There has been a true epidemic of this condition since the initiation of the "back to sleep" program by the American Academy of Pediatrics (AAP) in 1992[1]. This program, which has successfully reduced the incidence of Sudden Infant Death

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Syndrome, has had the unintended effect of a vast increase in the incidence of deformational plagiocephaly (aka. positional molding). The AAP, in a recent document[2], has reinforced the need for this sleep behavior, meaning that the incidence of infant skull deformity will likely increase. Prior to 1998, pediatric craniofacial and neurological surgeons treating this condition were often able to have the cranial orthotic devices made by local hospitals and orthotists. After the approval of a "de novo" application for cranial orthoses as Class II neurology devices by the FDA in 1998 (Federal Register, 63 FR: 40650-40652)[7,9], production of these orthoses were primarily reduced to large national conglomerates that had the resources available to pursue premarket notification. The net effect has been, on average, a 300-400% increase in helmet price, reduced willingness of insurance companies to pay for helmet therapy, reduced geographic access, and a significant increase in the number of families who are unable to pursue this treatment option for the condition after it has been diagnosed.

Cranial Orthoses Meet FDA's Exemption Requirements

The FDA considers the following four factors in deciding if a device can be exempt from premarket notification:

(1) The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials.

There now exists greater than 27 years of documented use of cranial orthoses[3]. They are, and always have been, produced and distributed only by prescription and under the direction of a physician. In standard practice, these devices are prescribed almost exclusively by neurosurgeons and plastic surgeons with expertise in pediatric craniofacial conditions, although other physicians may prescribe them. They are never available without the oversight of a physician. We have been unable to find any documented examples of false or misleading claims regarding their use. Even when these devices are produced by larger corporations, their use is always directed by a physician and they are serviced locally by qualified orthotists with expertise in using these devices.

The device design is such that it offers a protective shield to the flattened areas of an infant's skull[4,7,10] (i.e. a passive design which is not intended to limit skull growth, just allow growth to occur in the portions of the skull where growth was being limited by external forces). Studies have shown that head circumference growth is unaffected by helmet use[5]. The device is composed of standard synthetic materials commonly used in the manufacturing of orthoses for many parts of the body, including the cranium, extremities, and trunk. These materials are well tolerated and very inert, with little chance for negative reactions. The internal portion, which is the only portion which touches the cranium, is a cross-linked polyethylene foam which is commercially available. The external shell is a copolymer mix of polypropylene. The only other material used is Velcro to externally secure the orthosis. All of the materials which contact the child have been approved by the Occupational Safety and Health Administration (OSHA) for use and their OSHA status is "not considered hazardous under OSHA" (Material Safety Data Sheets, U.S. Department of Labor form OMB No. 1218-0072).

(2) Characteristics of the device necessary for its safe and effective performance are well established.

There are many published articles in peer-reviewed medical literature documenting the indications for the device and the characteristics needed for safe and effective performance[3,4,6,7,10,11]. General routines include 12-22 hours of helmet use per day for an average treatment course of two-four

months, depending on clinical response as judged by the treating health care professional. The device requires regular follow up by the orthotist during the course of use to avoid pressure points from developing as the cranium grows, but no other ongoing maintenance.

(3) Changes in the device that could affect safety and effectiveness will either: (a) be readily detectable by users by visual examination or other means such as routine testing before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment.

The manufacturing profile for these devices is well established. Through casting or laser scanning a negative of the cranium is made. This is followed by a positive mold of the cranium, and then the manufacturing of the orthosis itself. Few changes to the device are likely based on the effective profile of the current device. The effects of any changes that would be made will be easily detectable by inspection of the cranium and scalp for pressure points. Anthropometric measurements of the skull using simple caliper measuring devices or topographic laser scanning easily determine the effectiveness of the device. Misdiagnosis of craniosynostosis (premature fusion of the skull sutures) as deformational plagiocephaly, although rare, would not be adversely affected by the device. Craniosynostosis leads to an intrinsic lack of skull growth and therefore a cranial orthosis applied to uncorrected craniosynostosis will have no impact either positively or negatively.

(4) Any changes to the device would not be likely to result in a change in the device's classification.

Few changes to this device are anticipated. The orthosis is so simple and effective that we do not anticipate any alteration to its basic design. The device is a passive system which allows growth of deficient areas of the skull by shielding these areas, without a reduction of other parts of the skull (i.e. it does not lead to active compression of the skull, it only allows for growth of the skull). We do not anticipate any changes in the device profile that could change the devices classification. Of course, even if these devices are exempted, they would still be subject to the limitations on exemptions.

Limitation on Exemption

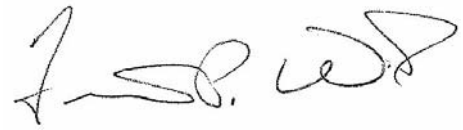
As per the limitation on exemptions described by the FDA, an exemption from the requirement of premarket notification for a cranial orthosis is only to apply to those devices that have characteristics of commercially distributed devices described above. A cranial orthosis would not be exempt from premarket notification if it (1) has an intended use that is different from the intended use of a legally marketed device in that generic type; e.g., the device is intended for a different medical purpose, or the device is intended for lay use instead of use by health care professionals; or (2) operates using a different fundamental scientific technology than that used by a legally marketed device in that generic type.
In addition, an exemption from the requirement of premarket notification does not mean that the device is exempt from any other statutory or regulatory requirements. We propose that all cranial orthoses remain available only on the advice of a physician and by prescription, that inappropriate applications of the device by avoided by close oversight of the device by health care professionals, and that labeling accompany all orthoses. The labeling should include instructions for the parents on appropriate application of the device, care and cleaning recommendations, and warning signs of an ill-fitting device.

Conclusion

In summary, we believe that cranial orthoses for remolding of the infant skull are benign biocompatible devices that should be exempt from the premarket Class II notification requirements. They will remain available by prescription only, under the care of a qualified physician and orthotist, and be accompanied by appropriate labeling. We strongly believe that this exemption will greatly increase the availability of these devices to children-at-need, whose access to the device has been greatly reduced by current requirements.

Thank you for considering our request. If you have any questions or require addition information please contact us.

Sincerely,



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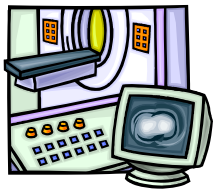


Diagnostic Imaging Update

Neuroimaging Takes Big Hit in Budget Reconciliation

The Problem

In February 2006, Congress passed the Deficit Reduction Act of 2005, which included a provision to repeal the Medicare physician payment cut of 4.4 percent that went into affect on January 1. This provision cost approximately $10 billion. In order to pay for provision, Congress found "off-sets" in other parts of the Medicare Part B program. One of those areas was imaging services. Under the bill, physicians billing for the technical portion of an imaging service will now be paid the lesser of the Medicare Physician Fee Schedule or the Hospital Outpatient Prospective Payment System rate. This change generates billions of dollars in savings for the Medicare program. The provision was literally inserted at the last minute to the surprise of all the physician community, including the radiologists (many of whom will likely be devastated by these changes). The provision affects all imaging that takes place outside the hospital setting, including physician offices, independent diagnostic testing facilities, etc and takes effect on Jan. 1, 2007. It is separate from the recent regulation passed by CMS mandating imaging discounts for multiple scans on the same day.

Unfortunately, MRI takes the largest hit of all of the imaging modalities, with cuts between 20 and 50 percent. Also, MRI of the brain and spine are hit particularly hard and produce some of the largest cost savings. Below is a chart showing the top seven savings-generating codes. As you can see, four of the seven involve neuroimaging:

Code	Description	PFS Rate	HOPPS Rate	Reduction	Percent	# Billed	Savings
70553	MRI brain w/o&w/dye	$995.19	$506.26	$488.93	-49.13%	275,461	$134,680,706
78465	Heart image, 3d multiple	$471.44	$397.11	$74.33	-15.77%	1,592,662	$118,390,371
76075	DXA bone density, axial	$123.92	$72.50	$51.22	-41.34%	1,573,761	$80,615,592
93880	Extracranial study	$216.77	$152.01	$64.76	-29.88%	1,208,174	$78,245,818
93325	Doppler echo exam, heart	$118.24	$89.99	$28.25	-23.89%	2,707,484	$76,486,964
72148	MRI lumbar spine w/o dye	$497.22	$349.20	$148.02	-29.77%	415,779	$61,541,612
72158	MRI lumbar spine w/&w/o dye	$995.19	$506.26	$488.93	-49.93%	100,622	$49,196,953

This provision will have a drastic impact on private practice neurosurgeons who own or lease an MRI machine in their office. Information from an Indianapolis practice, who's machine is fully depreciated and who are no longer paying for a maintenance contract, shows that the changes will cut their profit by more than 10 percent if the rate changes only apply to Medicare (the practice has a fairly low Medicare population). If private payers adopt the rate changes as well, their profit will likely be cut by more than 65 percent and they would barely be able to cover costs on the unit. The changes also will have a direct impact on several leasing arrangements and joint ventures they have with other magnets and groups. It is likely other private practices, many of which have long-term leasing and maintenance contracts for the equipment, will take a similar hit.

A chart listing some commonly used neuroimaging codes; the '06 Medicare Physician Payment Rate; the '06 HOPPS rate; the reduction the code will have on Jan. 1, 2007 and the percent that reduction will be is included at the end of this report. Again, this is only for the technical fee (or the

technical portion of a global fee) and does not affect the professional fee paid for the actual reading of the scan.

In addition to the issue described above, the imaging cuts pose two additional problems: 1) decreased availability and increased waiting times for neuroimaging services as imaging moves back into the hospital and 2) a bad precedent of cutting some physician services to pay for increases in others (in this case, cutting imaging to pay for a freeze in the conversion factor).

Coalition Activities

Over the past year and half, the radiologists have been lobbying hard for changes in imaging payment policy. This obviously is not what they had in mind. Because the volume and overall costs for imaging services have increased dramatically over the past five years, the radiologists anticipated Congress and CMS would be looking to rein in or cut imaging services. Their lobbying strategy has been to admit there is a lot of overuse and misuse in the system and to blame it on non-radiologists who own imaging equipment and self-refer. They have called for standards and credentialing to rein in these allegedly fraudulent physicians. To date, radiology's attacks have largely been aimed at cardiology, urology and orthopaedic surgery. These groups in response created the Coalition for Patient Centered Imaging (CPCI). After several reports on this issue, the Washington Committee decided not to donate money to CPCI, but has signed on to various letters and statements. In a recent meeting, Bill Thomas (R-CA), chair of the Ways and Means Committee, stated standards and credentialing in imaging will "definitely" happen in the next year or two. He did state, however, that he is not inclined to take the radiologists proposal of "only radiologists can perform or bill for imaging services" and would be open to looking at suggestions from other groups on what the imaging standards should be, especially for neuroimaging because of the prevalence of "repeat" scans.

Reaction to the Cuts

In response to these cuts, a large group of physician groups and equipment manufacturers have gathered to plan a strategy to repeal or at least lessen the effects of the cuts. This group includes the radiologists, cardiologists, neurologists, orthopaedic surgeons and other physician groups as well as manufacturers including Siemens, General Electric and others. The group is currently referred to as the "Big Tent" group because it is pulling together many groups that are traditionally at odds with each other (namely the radiologists and cardiologists). CPCI in the mean time has decided not to actively focus on the imaging cuts included in the bill, but instead has decided to continue to focus on the issue of standards and credentialing (this is because they do not want to duplicate efforts and because many of the groups actively leading CPCI focus primarily on ultrasound, including urology and ob-gyns, and are not affected by the budget reconciliation cuts).

The Big Tent's goal is to repeal the cuts, or at least lessen their impact by capping the amount a specific code can be cut in a given year. While this is, of course, a noble cause, it must be considered in the realm of all Medicare payment policy. Medicare physician payment cuts are again slated for January 1, 2007, the exact time when the imaging cuts are also scheduled to go into effect. Repealing, or lessening, the imaging cuts would increase the cost of preventing the 2007 Medicare physician payment cuts. **(See attachments for** the Big Tent's talking points for Hill meetings and a recent letter sent to the Hill**)**. To date, neurosurgery has continued monitoring this situation, but has not actively lobbied the issue.

Code	Description	06 PFS Rate	06 HOPPS Rate	Reduction	Percent
70551	MRI brain w/o dye	$447.95	$349.20	$98.75	-22.04%
70552	MRI brain w/dye	$537.39	$371	$166.39	-30.95%
70553	MRI brain w/&w/o dye	$995.19	$506.26	$488.93	-49.13%
72141	MRI neck spine w/o dye	$447.95	$349.20	$98.75	-22.04%
72142	MRI neck spine w/ dye	$537.39	$371	$166.39	-30.95%
72146	MRI chest spine w/o dye	$497.22	$349.20	$148.02	-29.77%
72147	MRI chest spine w/ dye	$537.39	$371	$166.39	-30.96%
72148	MRI lumbar spine w/o dye	$497.22	$349.20	$148.02	-29.77%
72149	MRI lumbar spine w/dye	$537.39	$371	$166.39	-30.96%
72156	MRI neck spine w/&w/o dye	$995.19	$506.26	$488.93	-49.13%
72157	MRI chest spine w/&w/o dye	$995.19	$506.26	$488.93	-49.13%
72158	MRI lumbar spine w&w/o dye	$995.19	$506.26	$488.93	-49.13%
70544	MR angiography head w/o dye	$447.95	$349.20	$98.75	-22.04%
70545	MR angiography head w/dye	$447.95	$371	$76.95	-17.18%
70546	MR angiography head w/&w/odye	$873.92	$506.26	$367.66	-42.07%
70547	MR angiography neck w/o dye	$447.95	$349.20	$98.75	-22.04%
70548	MR angiography w/dye	$447.95	$371	$76.95	-17.18%
70549	MR angiography w&w/o dye	$873.92	$506.26	$367.66	-42.07%
70450	CT head/brain w/o dye	$188.73	$188.10	$0.63	-0.33%
70460	CT head/brain w/dye	$226.63	$255.43	$0.00	0.00%
70470	CT head/brain w/&w/o dye	$282.72	$303.82	$0.00	0.00%
70490	CT soft tissue neck w/o dye	$188.73	$188.10	$0.63	-0.33%
70491	CT soft tissue neck w/dye	$226.63	$255.43	$0.00	0.00%
71250	CT thorax w/o dye	$236.48	$188.10	$48.38	-20.46%
71260	CT thorax w/dye	$282.72	$255.43	$27.29	-9.65%
71270	CT thorax w/&w/o dye	$353.96	$303.82	$50.14	-14.17%
72125	CT neck spine w/o dye	$236.48	$188.10	$48.38	-20.46%
72126	CT neck spine w/dye	$282.72	$255.43	$27.29	-9.65%
72127	CT neck spine w/&w/o dye	$353.96	$303.82	$50.14	-14.17%
72128	CT chest spine w/o dye	$236.48	$188.10	$48.38	-20.46%
72129	CT chest spine w/dye	$282.72	$255.43	$27.29	-9.65%
72130	CT chest w/&w/o dye	$353.96	$303.82	$50.14	-14.17%
72131	CT lumbar spine w/o dye	$236.48	$188.10	$48.38	-20.46%
72132	CT lumbar spine w/dye	$282.72	$255.43	$27.29	-9.65%
72133	CT lumbar spine w/&w/o dye	$353.96	$303.82	$50.14	-14.17%
70496	CT angiography, head	$424.83	$297.22	$127.61	-30.04%
70498	CT angiography, spine	$424.83	$297.22	$127.61	-30.04%
93880	Extracranial study	$216.77	$152.01	$64.76	-29.88%
93886	Intracranial study	$256.95	$152.01	$104.94	-40.84%

Changes in Imaging Payment Policy Negatively Impact Medicare Beneficiaries
The Impact of the Deficit Reduction Omnibus Reconciliation Act of 2005

Section 5102 of the Deficit Reduction Omnibus Reconciliation Act of 2005 (DRA) calls for a reduction in payments for imaging services under the Physician Fee Schedule (PFS). Specifically, effective January 1, 2007, the payment for the technical component (e.g., equipment, non-physician personnel, supplies, and overhead) of an imaging service will be set at the Hospital Outpatient Department (HOPD) payment rate, if the PFS payment rate is higher. This change in payment policy, which has never been discussed by Congress in any public forum, has the potential to drive imaging from the physician office and free-standing facilities back into hospital outpatient departments, thus limiting Medicare beneficiaries' access to critical imaging services that allow for more timely diagnosis and initiation of treatment.

Provision Limits Medicare Beneficiary Access to High Quality Imaging Services:
The imaging payment provision enacted in the DRA will undermine beneficiary access to imaging services by increasing co-pays, wait times and travel time for Medicare beneficiaries.

- **Higher Costs for Medicare Patients:** In most instances, beneficiaries do pay higher co-pays for imaging services in the hospital outpatient department, as co-pays are 40% in the HOPD versus 20% outside of the HOPD and the 40% in the HODP is based on charges versus 20% of the actual payment, as is the case with the Physician Fee Schedule.
  - For example, the patient's share of the payment for a CT of the head/brain (without dye) is $38 when this procedure is performed in a physician office or free-standing imaging center. The patient's co-pay doubles to $75 when that same service is provided in the hospital outpatient department instead of the physician's office or a free-standing facility.

- **Longer Wait Times for Medicare Patients:** On average, patients already wait 10 days to two weeks for non-urgent imaging services in the hospital outpatient department. Reduced access to imaging services in the physician's office and in free-standing imaging centers could increase these wait times dramatically.
  - For example, patients who have a history of stroke could end up having to wait for up to 6 weeks for a vascular ultrasound study in the HOPD due to hospitals currently reporting only 4.5% excess capacity that could be filled by these patients.

- **Reduced Access For Medicare Patients in Rural Areas:** Beneficiaries may be forced to drive long distances for needed imaging services due to:
  - A lack of providers; and
  - Because this provision undermines efforts to encourage telemedicine by making it uneconomical to own and maintain equipment in low-use and rural areas even if tele-read by a specialist located at another site.

The Magnitude of the Payment Cuts is not "Inherently Reasonable":
The magnitude of the payment cuts that this provision will exact on imaging services provided in physician offices and free-standing facility is enormous.

Imaging services account for just 10 percent of total Medicare spending, but represent more than one-third of the Medicare cuts in the 2005 Reconciliation Act. In addition, by linking payments for imaging services to the HOPD rate, the reimbursement is no severed from the actual costs of owning and operating imaging equipment, greatly reducing funds available for equipment maintenance and well-trained staff to support the equipment.

- **Ultrasound**
  - Reimbursement for ultrasound guidance procedures performed as part of a minimally invasive biopsy for the diagnosis of breast cancer **(**a biopsy method which saved the Medicare program $88 million from 2001 – 2003**)** would be reduced by 35 percent.

- **PET/Nuclear Medicine**
  - Reimbursement for PET/CT exams used to diagnosis cancerous tumors and determine the effectiveness of cancer treatment would be reduced by upwards of 50 percent **(**an unprecedented cut for a new technology whose HCPCS code was just provided by CMS in April 2005.

- **DEXA**
  - Reimbursement for bone densitometry studies necessary for the diagnosis of women at risk for osteoporosis (a recently enacted Medicare screening benefit) would be reduced by over 40%.

- **MRI**
  - Reimbursement for MR angiography of the head used to detect the location of aneurysms would be reduced by 42%.

Medicare Reimbursement Systems Differ for Hospital Outpatient Departments versus for Physician Offices and Free-Standing Facilities:
The Medicare statute establishes different payment systems for each site of service for good reasons. The different payment formulas for each site of service are specifically designed by Congress to take into account the unique differences and costs of providing care in each setting. Thus, linking reimbursement under the PFR system to the HOPD system ignores the value of the PFS payment system and its direct and indirect cost inputs.

- **Physician Offices and Imaging Centers' Payments are Resource-based; whereas Hospital Outpatient Departments Payments are Charge-Based.**
  - <u>There are substantial differences in the cost structure between non-hospital and hospital providers of care:</u> Non-hospital locations such as physician offices and imaging centers have different cost structures from hospitals and their payment is resource based, reflecting the actual costs of providing the service. Hospital outpatient payment rates are charge based and can vary substantially each year with relative changes in hospital charging practices bearing little if any relation to actual costs.
  - <u>Methods to set Medicare OPD payment levels systematically underestimate the costs:</u> The HOPD system for calculating hospital outpatient department payments does not adequately account for capital equipment purchases – which are significant in the case of imaging services. Hospitals include capital equipment in their general

overhead costs and thus receive payments for capital, such as imaging equipment, in each service the hospital bills. Furthermore, hospitals also receive a separate, add-on payment for capital as part of their payment for each inpatient discharge which is intended to defray costs for capital equipment. In contrast, under the PFS, the cost for the use of the equipment is incorporated into the technical component payment assigned to each individual imaging CPT code.

- OPD rates are further reduced to subsidize the costs of outliers and pass-through payments that come back to the hospital: Hospital outpatient payment rates are all reduced by as much as 20% to create a reserve to cover the costs of outliers and pass-through payments, which are paid to hospitals and to satisfy budget neutrality caps required by law. Therefore, these "carve-outs" and "caps" would have to be added back into the APC rates before a comparison between outpatient payment and MPFS payment could be used to impose payment policies that cause any type of reductions.
- Non-hospital providers are less able to average out payment losses: Hospital's breadth of services, in comparison to a physician's office or free-standing imaging center, affords a better opportunity for hospitals to average out costs over the range of services grouped under a single APC with a common payment rate under the HOPD. This differs under the PFS as each code is assigned a separate, specific payment rate determined by actual costs of providing that specific service.

Draft – February 7, 2005

The Honorable J. Dennis Hastert
Speaker of the U.S. House of Representatives
H-232 Capitol Building
Washington, DC 20515-6501

Dear Speaker Hastert:

We are writing to request your assistance in re-opening the discussion regarding Section 5102 of the Deficit Reduction Omnibus Reconciliation Act of 2005 (DRA). Effective January 1, 2007, Section 5102 will require the Centers for Medicare and Medicaid Services to implement a change in payment policy reducing the Physician Fee Schedule (PFS) payment for the technical component of an imaging service to the Hospital Outpatient Department (HOPD) rate, if the PFS payment is higher.

We are extremely concerned that this change in payment policy, which has never been discussed in a public forum, will drive imaging services from physician offices and free-standing facilities back to the hospital outpatient departments undermining beneficiary access to imaging by increasing individual co-pays for Medicare beneficiaries, increasing their wait times for these critical services, and increasing their travel time to this medically appropriate care.

Beneficiaries often pay higher co-pays for imaging services in the hospital outpatient department, as co-pays are based on charges versus the actual payment, as is the case with the PFS. For example, the patient's share of the payment for a carotid ultrasound study—a test to diagnose arterial disease that leads to stroke—increases by 40 percent when that service is provided in the hospital outpatient department instead of the physician's office or a free-standing facility.

On average, patients already wait ten days to two weeks for imaging services in the hospital outpatient department. Reduced access to imaging in the physician's office and in free-standing imaging centers could increase those wait times dramatically with patients who have a history of stroke having to wait up to 6 weeks for a vascular ultrasound study.

The impact of this provision on Medicare patients in rural areas will be especially devastating. Beneficiaries may be forced to drive long distances for needed imaging services due to a lack of providers and because this provision undermines efforts to encourage telemedicine by making it uneconomical to own and maintain equipment in low-use and rural areas even, if tele-read by a specialist located at another site.

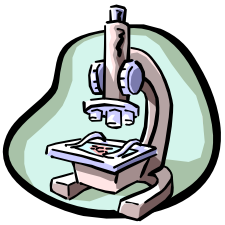
The magnitude of the payment cuts that this provision will exact on imaging services provided in physician offices and free-standing facility is enormous, with many imaging procedures seeing reductions of greater than 40%.

Imaging services account for just 10 percent of total Medicare spending, but represent more than one-third of the Medicare cuts in the 2005 DRA. The amount of these reductions does not appear to be inherently reasonable by Medicare standards.

Given the ramifications to Medicare beneficiaries outlined above, we respectfully request that you personally address this policy provision from DRA immediately. Furthermore, we would like to request a meeting with you and your staff to present additional information regarding the local impact of Section 5102 on Medicare beneficiaries and to discuss a way to address these negative impacts before the January 1, 2007. We will be in touch with your office to schedule this meeting.

If you or your staff have any questions or would like additional information, please do not hesitate to contact Jill Rathbun at 703-486-4200 or email at jill_rathbun@galileogrp.com.

Sincerely,



Biomedical Research Issues Update

NIH 2006 Funding Levels

The FY 2006 Labor, Health and Human Services budget bill cut the NIH budget by one percent, or $286 million. As a result of the cut, all non-competing awards for research project grants (RPG) will be funded at 97.65 percent. Competing RPGs are being managed individually, with the average award being made at the FY 2005 level.

NINDS' budget was cut by .05 percent while medical research inflation was over three and a half percent. As a result of the cuts and the likelihood of future cuts or flat-funding, NINDS will likely have to cut or reduce several award programs. In a recent meeting, Story Landis, PhD, Director of the NINDS, pointed to the Young Investigators Award as a possible target for reduced funding because many of the institute's other projects are in the middle of multi-year funding obligations (currently, only 15 to 20 percent of the institute's funding is discretionary because of multi-year grants). In addition, Dr. Landis stated several other projects will likely be done on a smaller scale. Because of the recent cuts and flat-funding, the institute's payline has gone from 26 percent at the time of the doubling in the late 1990s to 12 percent in 2005. In addition, while NINDS used to fund one in two meritorious applications, it now funds only one in four.

NIH 2007 Funding Levels

The President's 2007 budget proposal calls for flat-funding for NIH. Because of medical research inflation, this will equate to a cut for NINDS and other institutes.

NINDS Research Priorities

In a recent meeting, Dr. Landis highlighted several of the institute's funding priorities. Currently, NINDS is feeling pressure to undertake several high-profile research projects that have direct-to-patient implications. These types of projects and results are essential to defending funding levels (research that leads to reduced healthcare costs is especially helpful). On the other hand, the institute feels that many pharmaceutical companies are skipping the essential research steps of animal testing and early pre-clinical trial testing and, as a result, are having poor results with therapies designed to promote neuroprotection. NINDS also plans to focus research projects that highlight this type of work. Some of NINDS' research priorities include:

The Emergency Neurological Clinical Trials Network – NINDS is attempting to set up designated research centers for neurotrauma research. The project may expand to stroke. The purpose of this program is to have several designated centers across the country that can efficiently and quickly be mobilized to run neurotrauma research programs. The program itself is designed to organize the physicians and the institution into a designated neurotrauma hub. The P1 would be an ER physician and there would be designated specialists, including neurosurgeons, as part of the research team. The center would be a hub for transfers for other local ERs as well. The goal is to have a permanent structure in place that can test clinical treatments with a short turnaround time. One of the projects Dr. Landis suggested this program might undertake is SAH and blood pressure.

Stroke – currently only 10 percent of the NINDS budget goes toward stroke research. NINDS is working on an epidemiology study in the stroke belt, among other projects. NINDS also has an ongoing stroke project at the Washington Hospital Center in DC. NHLBI is also funding several stroke-related grants.

Stents – NINDS is funding a study related to stents for the prevention of strokes. Dr. Landis compared this study to the infamous aspirin vs. warfin study.

Vascular dementia – this is also one of NINDS' priorities this year.

NIH Roadmap – it should be noted that NIH Roadmap projects are funded separately from institution projects. The roadmap initiative is currently working on a neuroimaging study and a study involving nervous system membrane proteins.

Inspector General Compliance Guidance

In December, the Office of the Inspector General set out draft compliance guidance for recipients of extramural research awards from the National Institutes of Health (NIH) and other agencies of the U.S. Public Health Service (PHS). In the regulation, the OIG identified three potential areas as "high risk" for fraud and abuse: (1) Time and effort reporting, (2) properly allocating charges to award projects, and (3) reporting of financial support from other sources. A sample of the OIG's comments for each area is provided below:

Time and Effort Reporting - One critical compliance issue is the accurate reporting of research time and effort. Because the compensation for the personal services of researchers—both direct salary and fringe benefits—is typically a major cost of a project, it is critical that the portion of the researcher's compensation for particular research projects be accurately reported. One reason that we view time and effort reporting as a critical risk area is that many researchers have multiple responsibilities—sometimes involving teaching, research, and clinical work— that must be accurately measured and monitored. In the course of a researcher's workday, the separation between these areas of activity can sometimes be hard to discern, which heightens the need to have effective timekeeping systems. For this reason, institutions need to be especially vigilant in accurately reporting the percentage of time devoted to projects. Accurate time and effort reporting systems are essential to ensure that PHS and other funding sources are properly charged for the activities of researchers. The failure to maintain accurate time and effort reporting may result in overcharges to funding sources and, in certain circumstances, could subject an institution to civil or criminal fraud investigations.

We are aware of situations in which researchers falsely report the amount of time they intend to devote to research projects…Some recent cases we have seen involved the ''commitment of effort'' by researchers wherein the Government believed that the institution failed to account properly for the clinical practice time of researchers, in addition to their academic and research time at the institution.

Properly Allocating Charges to Award Projects - Research institutions commonly receive multiple awards for a single research area. It is essential that accounting systems properly separate the amount of funding from each funding source. Institutions must also be vigilant about clearly fraudulent practices such as principal investigators on different projects banking or trading award funds among themselves.

Reporting Financial Support From Other Sources- As with the proper reporting of time and effort and the allocation of charges, the reporting of financial support from other sources is critical for the awarding agency to understand the commitment of resources by the grantee to a particular project or award. Without complete and accurate information on other funding sources, PHS may be unable to determine whether a particular project should be funded and the amount of such funding. In some cases, failure to identify other support for a research project could cause PHS to provide duplicate funding to the project.

The regulation sets forth a variety of tactics academic institutions should institute to ensure proper compliance. These tactics include written guidelines for research, appointment of a medical research compliance officer to oversee researcher compliance, written disciplinary protocols for non-compliance and more. The Association of American Medical Colleges and three other groups sent in written comments to the OIG. These comments called for complete withdraw of the regulation under the idea that research institutions are already doing plenty to ensure good stewardship of federal funds. The groups also stated they are “profoundly concerned” about the description and inclusion of the risk areas. These concerns and the plan as presented by the OIG will likely play out over the next several months.

Specialty Hospitals Update

Budget Legislation Extends Moratorium

The Deficit Reduction Act of 2005 (DRA) included a provision that extends CMS' freeze on issuing new provider numbers for specialty hospitals for as much as another six months while CMS prepares a congressionally mandated plan to amend federal regulations to address perceived reimbursement problems. If CMS fails to submit the final report within the six month time period, then the suspension of enrollment will be extended by an additional two months. The CMS report is expected to reduce overall payment levels to specialty hospitals because the hospitals tend to treat healthier patients.

The DRA directs CMS to develop a strategic and implementing plan addressing the proportionality of investment return; whether the investment is a bona fide investment; and whether the Secretary should require annual disclosure of investment information. In addition, the DRA requires CMS to consider the provision by specialty hospitals for care to Medicaid patients and patients receiving charity care.

The DRA does not further amend the Stark law or otherwise affect existing physician-owned specialty hospitals, giving these facilities the ability to expand services and investors.

Reports and Studies

Specialty hospitals generally treat Medicare patients with lower-severity illnesses compared to the severity of illness in patients treated in community hospitals, but they also provide competition to other hospitals that may, in turn, reap quality improvement benefits, according to a study in the journal *Health Affairs*. The study, in the January/February issue of the journal, also said that specialty hospitals, which are owned by doctors and compete with community hospitals, generally provide high-quality care "to satisfied patients." The report said the doctor owners of the specialty facilities are more likely than others to refer to their own facilities, but there are reasons other than profit for this.

A Feb. 8 press release from RTI International, the research firm that employs lead study author Leslie Greenwald, said the facilities for orthopedic, surgery, and cardiac specialty care offer high-quality services to communities. Greenwald said: "While our research shows that physician owners often refer patients to their own facilities, it also suggests that many physicians make those referrals for reasons not related to profits, such as insurance contracts, patient preferences, scheduling of procedures and the location of the hospital in relation to physician offices." Greenwald is a senior scientist at RTI International, based in Research Triangle Park, N.C.

The study said that community hospitals are fighting back against the doctor-owned specialty facilities by taking actions such as buying primary care practices that feed patients to the hospitals, by negotiating exclusive managed care contracts, and by opening heart and orthopedic "centers of excellence" on campus for the specialists. The study authors further found that, although specialty facilities have been criticized for having an unfair advantage over

the community hospitals, "we found that they actually stimulate a competitive environment in some markets, which could have positive effects on quality of care." And while the specialty facilities provide less uncompensated care, they "do contribute substantial tax revenues, contrary to the notion that these facilities are simply a drain on community resources," the study said. The study said that for-profit hospitals are not required by the Internal Revenue Service to provide uncompensated care because they pay taxes instead.

The study, which was funded by the Centers for Medicare & Medicaid Services, was conducted to support work by the Department of Health and Human Services to issue a congressionally required report on the topic of specialty hospitals. The 2003 Medicare law required the HHS report. The title of the journal study is "Specialty Versus Community Hospitals: Referrals, Quality, and Community Benefits."

As for the objection sometimes raised that the specialty facilities take on less seriously ill patients, the study said this favorable selection "arises from the flawed Medicare payment system that overpays for healthy surgical cases." The payment system, and not necessarily physician ownership, encourages investors to open the specialized facilities, the study said. Changing these self-referral incentives for doctors could be addressed "much more directly and effectively through review and modifications to the Medicare [diagnosis-related groups] payment methodology than through policies that limit only referrals to specialty hospitals," the study concluded.

The study examined the ownership structure of the specialty facilities. It said that, while the doctor owners do tend to favor their own facilities when it comes to referrals, it is the size of the ownership, and not ownership by itself, that appears to be the important factor. Most physician owners of specialty hospitals tend to have a very small share of ownership, and perhaps as a result, make few referrals to the facility, the study said.

Case study interviews found that many local doctors invested in the specialty facility either due to a personal relationship with the major owners or to ensure they could refer patients to the facility.

The study was based on Medicare claims data, patient focus groups, IRS data, and visits to sites in six markets: Dayton, Ohio; Fresno, Calif.; Hot Springs, Ark.; Oklahoma City, Okla.; Rapid City, S.D.; and Tucson, Ariz.

Meanwhile, a study issued Jan. 25 on specialty hospitals by the Center for Studying Health System Change (HSC) said these facilities have detrimental economic effects on health care market dynamics. Purchasers in three communities with significant specialty hospital development—Indianapolis, Little Rock and Phoenix—generally believe specialty hospitals are contributing to a medical arms race that is driving up costs without demonstrating clear quality advantages, according to a study released today by the Center for Studying Health System Change (HSC).

While specialty hospitals have received significant scrutiny in relation to Medicare payment policies, the new HSC study focuses on the impact of specialty hospitals on employer-sponsored health coverage and local health care market dynamics. Health plans and employers in the three communities have had time to observe the impact of specialty hospitals on overall costs; price competition and quality among hospitals; whether contract negotiations with general hospitals are affected by the market entry of specialty hospitals; and whether employers want specialty hospitals included in health plan networks.

"While purchasers are predisposed to favoring increased competition to help keep prices low, what we heard generally from health plans and employers is that specialty hospitals are contributing to higher costs without any clear quality benefits," said Paul B. Ginsburg, Ph.D., president of HSC, a nonpartisan policy research organization funded principally by The Robert Wood Johnson Foundation.

Some purchasers reported receiving significant price discounts on specific cardiac or orthopedics services because of new specialty hospital competition, while others did not. Even if specialty hospitals have lower unit costs, some purchasers believe that referring physicians, especially those with a financial interest in the specialty hospital, increase volume by inducing patient demand for elective procedures. The higher volume raises costs more than the savings achieved from lower prices from competition, leading to increased aggregate costs. Although there was some evidence of increased price competition, purchasers observed that the more important outcome was the perceived need for general hospitals to compete aggressively with the new physician-owned specialty hospitals by developing similar dedicated centers, as distinct hospitals-within-hospitals or freestanding facilities.

"There's no question that physician-owned specialty hospitals have caused general hospital competitive juices to flow, but those juices are flowing toward expansion of lucrative specialty services not necessarily toward improved quality and efficiency," said HSC Senior Consulting Researcher Robert A. Berenson, M.D., of The Urban Institute and coauthor of the study with HSC Consulting Researchers Gloria Bazzoli of Virginia Commonwealth University and Melanie Au of Mathematica Policy Research.

The study's findings are detailed in a new HSC Issue Brief—*Do Specialty Hospitals Promote Price Competition?* The study is based on HSC's 2005 site visits to 12 nationally representative communities, including three with significant specialty hospital development: Indianapolis; Little Rock; and Phoenix.

Other key findings of the study include:

- Purchasers observed that general hospitals responded to the loss of profitable services by raising prices on services where there is less competition. In general, purchasers thought that the current level of specialty hospital competition was too limited to interfere with general hospitals' ability to raise prices on other services to offset losses from specialty hospital competition
- Employers generally did not expressly demand the inclusion of specialty hospitals in health plan networks, although health plans tried to respond to the general desire of employers for broad, inclusive hospital networks. Consistent with plans' desire for broad networks, community hospitals generally were unable to prevent plans from contracting with specialty hospital competitors.

From: Barbara E. Peck [bpeck@neurosurgery.org]
Sent: Friday, February 17, 2006 1:16 PM
To: Katie O. Orrico
Cc: Dr. Harbaugh; Resnick (Daniel)
Subject: VTE Measures Comments

I'm currently working with ACS on our comments to the VTE quality measures. We've run into a few problems and I wanted to give you an update:

1) There are two separate VTE projects going on concurrently at NQF. One project is the NQF-JCAHO project. This project involves the 22 measures you saw a couple of weeks ago and that Dr. Resnick provided comment on. There is a separate NQF consensus project happening at the same time. ACS assumed the two projects used the same measures and have only been focused on commenting on the 22 measures in the NQF-JCAHO project. However, when I pulled the info on the NQF consensus project, it became apparent the two projects are totally different and use totally different quality measures. Confused?

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3) The NQF consensus project only includes two measures: Did you order VTE prophylaxis as recommended? Did the patient receive VTE prophylaxis as recommended? The "as recommended" is the key. There is a large listing of ICD-9 classifications, including intracranial neurosurgery and elective spinal surgery. VTE prophylaxis is recommended for all of these classifications. There are a variety of prophylaxises to choose from and decision trees to help the physician figure out which to order. These measures were submitted directly by CMS and I think the intention is to use these measures for physician pay-for-performance.

4) The NQF-JCAHO and the NQF consensus project measures do not appear to be entirely consistent with each other. For example, the NQF-JCAHO measure 3 appears to say "order VTE prophylaxis for all medical and surgical patients over 18 admitted to the hospital for more than 24 hours" and the NQF consensus project is limiting that order to patients with certain ICD-9 classifications.

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quality measures, list of ICD-9 codes and decision trees are located. If we are going to comment on these measures, someone needs to look at them from a scientific standpoint ASAP.

Please let me what you think our plan of action should be. I'm in the office today, but I'll be on an AQUA conference call from 3-4:30. Otherwise, you can reach me over the weekend at (703) 418-6350.

From: Robert E. Harbaugh [reh1@mac.com]
Sent: Wednesday, February 22, 2006 2:35 PM
To: Resnick (Daniel)
Cc: Barbara E. Peck; Katie O. Orrico; Dr. Harbaugh
Subject: RE: VTE Measures Comments

Thanks, Dan

Bob

On Wednesday, February 22, 2006, at 12:45PM, Resnick (Daniel)
<resnick@neurosurg.wisc.edu> wrote:

>Hi Barb and Bob,
>I reviewed the NQF statement and the appendices. Please correct me if I
>am wrong about any of the following, but here is my take on things:
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> evidence based protocols for the assignment of risk for VTE and the use of prophylaxis.
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>Cc: Dr. Harbaugh; Resnick (Daniel)

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Robert E. Harbaugh, MD, FACS. FAHA
Professor and Chairman, Department of Neurosurgery
Professor, Department of Engineering Science and Mechanics
Penn State Hershey Medical Center/Penn State University
C3830 Biomedical Research Building
500 University Drive, Hershey, PA 17003
Phone: 717-531-4383
e-mail: rharbaugh@psu.edu

From: Barbara E. Peck [bpeck@neurosurgery.org]
Sent: Wednesday, February 22, 2006 12:16 PM
To: Resnick (Daniel); Katie O. Orrico
Cc: Dr. Harbaugh
Subject: RE: VTE Measures Comments

Dr. Resnick,
Here's the scoop:

1) We are being asked to comment on three things in the NQF packet: A) an overall statement of policy; 2) 17 key characteristics for preferred practices; and 3) two quality measures.

The policy statement is found on page 10. It if very general and says "Every healthcare facility shall have a written policy appropriate for its scope, that is evidence-based and drives continuous quality improvement related to venous thromboembolism risk assessment, prophylaxis, diagnosis and treatment."

The 17 key characteristics are listed on pages 12-14. They are broken into several areas including General Recommendations, risk assessment/stratification recommendations, prophylaxis recommendations, diagnosis recommendations and treatment and monitoring recommendations.

Finally, there are two quality measure found on page 14, with most of the supporting documents in the appendixes.

Based on what you said, I don't think we have any comments on the policy statement or the key characteristics. The purpose of the policy statement and the key characteristics is to set the tone for the entire VTE project. All future VTE projects undertaken by NQF must by in line with the policy statement and key characteristics.

For the quality measures, I just want to verify a few things with you:

1) While the chart lists "Intracranial Neurosurgery, Appendix A, Table 5.17" and "Elective Spinal Surgery, Appendix A, Table 5.18", I also found a lot of neurosurgical-looking things on table 5.10. For example, there's a large listing of procedures with codes of 1.14 - 5.20 that look neurosurgical to me (things like "division of intraspinal nerve root", "repair of vertebral fracture" "division of trigeminal nerve" and "lumbar sympathectomy." In addition, there's other neurosurgical looking things listed from 7.61 - 7.99 (pituitary gland stuff) and some cerebrovascular stuff around 38.10, 39.28, 39.51 and some more spine stuff up near 81.31 and 81.64 (fusion and refusion of various parts of the spine). Did you see all of those and do you still agree that prophylaxis is appropriate for all those codes?

2) The listing for elective spine surgery has a note after it that says "(with additional risk factors such as advanced age, known malignancy, presence of neurologic deficit,

previous VTE or an anterior surgical approach)". Did you see that listing and do you agree with it?

I know this material is lengthy and confusing so I just wanted to make sure you saw the two points listed above.

As for the other JCAHO measures sent out earlier, they will be brought up during "phase II" of the project and we will have an opportunity to comment on them at that time.

Thanks!

-----Original Message-----
From: Resnick (Daniel) [mailto:resnick@neurosurg.wisc.edu]
Sent: Wednesday, February 22, 2006 12:49 PM
To: Barbara E. Peck; Katie O. Orrico
Cc: Dr. Harbaugh
Subject: RE: VTE Measures Comments

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THE NATIONAL QUALITY FORUM

TO: NQF Members

FR: NQF Staff

RE: Pre-voting review for *National Voluntary Consensus Standards for Prevention and Care of Venous Thromboembolism: Policy, Preferred Practices, and Performance Measures*

DA: January 31, 2006

Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary thromboembolism (PE), is the most common preventable cause of hospital death. More than 900,000 Americans suffer DVT each year, and 500,000 of these persons develop PE, which causes some 300,000 deaths. Current estimates suggest that less than 50 percent of patients diagnosed and hospitalized with DVT had received prophylaxis. In 2003, recognizing that the incidence of DVT/VTE is a significant patient safety issue, NQF endorsed Safe Practice 17: *Evaluate each patient upon admission, and regularly thereafter, for the risk of developing DVT/VTE. Utilize clinically appropriate methods to prevent DVT/VTE* and Safe Practice 18*: Utilize dedicated anti-thrombotic (anticoagulation) services that facilitate coordinated care management.*

To improve VTE prophylaxis and treatment and save patient lives, NQF formally initiated a project in 2005 to: 1) recommend a framework for measuring effective screening, prevention and treatment of VTE across the continuum of care settings; 2) endorse a statement of policy that spells out the domains of prevention and care of VTE; 3) endorse a set of preferred practices for prevention and care; and 4) develop and endorse performance measures to evaluate the quality of care for persons at risk for VTE.

In response to a call for model organizational policies and preferred practices, as well as two calls for performance measures, nine healthcare organizations submitted procedures, guidelines, or practices and 38 measures were received. No model organizational policies were received. The draft report recommends endorsement of a statement of policy identifying four specific domains of VTE prevention and care and 17 key characteristics of preferred practices that clarify an expectation of the action in each domain. It also recommends two measures of VTE prophylaxis intended for institutional public accountability; the Joint Commission on Accreditation of Healthcare Organizations is serving as a subcontractor to develop additional measures for consideration in the second phase of this project.

As the designated voting representative for your organization, the following materials are being sent to you:

- the proposed draft document being considered under the NQF Consensus Development Process;
- a general timeline for review and approval of this project; and
- the NQF Consensus Development Process, version 1.7.

Pursuant to section II.A of the Consensus Development Process, this draft document, along with the accompanying material, is being provided to you at this time *for purposes of review and*

comment only—not voting. Written comments must arrive at the NQF offices no later than 6:00 p.m. EST, March 3, 2006.

Please note that your comments must be specific. General comments directed to tone, themes, or philosophy are less useful in providing information to NQF staff and other NQF Members about what the final consensus document should state.

All comments received by the deadline will be posted on the NQF web site at regular intervals (about weekly), commensurate with the volume received. While you are free to send "marked up" documents, i.e., where the suggested changes are written directly on the draft, such material will not be posted on the web site as an official comment from your organization. Again, if you want your comments posted on the web site as the response of your organization, they should be specifically stated in your letter.

We recommend you send your comments by a method that allows you to verify delivery. Comments should be forwarded to:

National Quality Forum
ATTN: 'VTE' Project
601 Thirteenth Street, NW
Suite 500 North
Washington, DC 20005
202.783-3434 (fax)

Again, to be considered, your written comments must arrive at the NQF offices no later than the close of business (6:00 p.m. EST) on March 3, 2006. Please feel free to contact us at info@qualityforum.org or by fax 202.783.3434 if you have general questions about the document or the process (versus specific comments on the document, which we ask that you formally forward in writing, as described above).

Thank you for your interest in the NQF's work. We look forward to your review and comments.

THE NATIONAL QUALITY FORUM

Timeline for consideration of "National Voluntary Consensus Standards for Prevention and Care of Venous Thromboembolism – Deep Vein Thrombosis and Pulmonary Embolism (VTE)"

Package to NQF Members for 30-day review period	January 31, 2006
Package posted on public portion of web site and advisory regarding public comment opportunity	February 2, 2006
Public review period ends	February 24, 2006
Member review period ends	March 3, 2006
Revised document and ballot forwarded to NQF Members for initial round of voting	March 15, 2006[±]
Initial round of voting ends	April 17, 2006[±]
Board consideration	May 17, 2006[*]

[±] *Approximate*

[*] *If approved by all four Member Councils in initial round of voting.*

THE NATIONAL QUALITY FORUM

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR PREVENTION AND CARE OF VENOUS THROMBOEMBOLISM: POLICY, PREFERRED PRACTICES, AND INITIAL PERFORMANCE MEASURES

TABLE OF CONTENTS

THE NATIONAL QUALITY FORUM

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR PREVENTION AND CARE OF VENOUS THROMBOEMBOLISM: POLICY, PREFERRED PRACTICES, AND INITIAL PERFORMANCE MEASURES

INTRODUCTION

Venous thromboembolism (VTE), which encompasses deep vein thrombosis (DVT) and pulmonary embolism (PE), is the most common preventable cause of hospital death.[1,2,3] Recent estimates show that over 900,000 Americans suffer VTE each year, with about 400,000 of these being DVT and 500,000 being manifest as PE.[4] In about 300,000 persons, PE proves fatal; it is the third most common cause of hospital-related deaths in the United States.[5] Survivors are at-risk for recurrence and other serious long-term complications, including postthrombotic syndrome and chronic thromboembolic pulmonary hypertension.[6]

About two-thirds of all VTE events are related to hospitalization.[7] Although VTE is often clinically silent, with as many as 25 percent of cases presenting as sudden death from PE, needless mortality and morbidity occur due to underdiagnosis and underutilization of prophylaxis.[8] Despite the fact that several clinical interventions, including use of mechanical and pharmacologic therapies, are known to be effective in preventing and treating VTE, only one-third of all patients at risk for VTE who are appropriate candidates for prophylactic treatment actually receive such treatment.[9]

Prophylaxis is only one component in preventing DVT; however, 30 to 50 percent of patients diagnosed and hospitalized with DVT had received prophylaxis. While the improvement to 50 percent occurred with or without continuing medical education (CME), the greatest percentage of improvement occurred with CME, suggesting increasing provider education can save many lives.[10]

Improvements in the quality of VTE prevention and care—in hospitals in particular—have the potential to benefit many, given the number and variety of clinical conditions or circumstances that place individuals at risk for VTE. Most hospitalized patients have one or more risk factors for VTE.[11] Risk factors include: advancing age, recent major surgery, trauma (especially fractures of the pelvis, hip, or leg), cancer, prolonged immobilization from any cause, obesity, history of thromboembolism, hypertension, pregnancy, congestive heart failure,

acute myocardial infarction, stroke and other debilitating neurological conditions, mechanical ventilation, smoking, use of oral contraceptives or estrogen hormone therapy, and various inherited conditions.[12,13,14] Moreover, about two-thirds of VTE-related deaths are the result of hospital-acquired disease.[15]

Although preventing VTE is a significant patient safety issue, there is little public awareness of the life-threatening conditions of its components, DVT and PE. With respect to DVT, for example, a 2002 survey conducted on behalf of the American Public Health Association suggests that 75 percent of Americans have little or no awareness of DVT, and less than one-half of respondents could identify any risk factors associated with its development.[16] Recognizing the lack of public awareness, several organizations have mobilized to increase consumer knowledge of the risks, signs, and symptoms of VTE through increased media visibility. In addition to increasing public awareness, efforts to reduce the occurrence of VTE also include improved provider education. Several specialty provider organizations have developed[17,18], or are developing, guidelines to promote appropriate screening and prophylaxis of at-risk patients. Despite these efforts, however, wide variation in the prevention and care of VTE persists.

To improve VTE prophylaxis and treatment and save patient lives, this National Quality Forum (NQF) report proposes a policy, preferred practices, and an initial set of two performance measures.

RELATIONSHIP TO OTHER NQF-ENDORSED CONSENSUS STANDARDS

This report builds on previously endorsed NQF consensus standards for the prevention and care of VTE. In its 2003 report, *Safe Practices for Better Healthcare: A Consensus Report*[19], NQF endorsed 30 safe practices to improve patient safety and reduce the occurrence of preventable adverse healthcare events. In recognition of the glaring under-use of prophylaxis for VTE, one of the 30 NQF-endorsed™ safe practices specifies that upon admission to the hospital and regularly thereafter, each patient should be evaluated for the risk of developing DVT/VTE and clinically appropriate methods to prevent DVT/VTE should be utilized. Safe Practice 17 further specified that risk assessment and prevention planning should be documented in patient records and explicit organizational policies and procedures should be in place for the prevention of DVT/VTE. Safe Practice 18 further specified that organizational policies and

procedures should provide for anti-thrombotic services. It was beyond the scope of that report, however, to identify a set of model organizational policies, preferred practices, and performance measures for the prevention and care of VTE.

Box A — NQF-Endorsed™ Safe Practices 17 and 18

Safe Practice 17

Evaluate each patient upon admission and regularly thereafter, for the risk of developing DVT/VTE. Utilize clinically appropriate methods to prevent DVT/VTE.

Additional Specifications

- Document the VTE risk assessment and prevention plan in the patient's record.
- Explicit organizational policies and procedures should be in place for the prevention of VTE.

Applicable Clinical Care Settings

Acute care hospitals; long-term care facilities, and nursing homes.

Example Implementation Approaches

- Depending on the level of risk, different specific methods may be more appropriate or more effective than other methods. For example, in postoperative patients, mechanical methods such as graduate compression stockings or intermittent calf compression may be preferred to anticoagulants.

****

Safe Practice 18

Utilize dedicated anti-thrombotic (anticoagulation) services that facilitate coordinated care management.

Additional Specifications

Explicit organizational policies and procedures should be in place regarding anti-thrombotic services.

Applicable Clinical Care Settings

All care settings.

Example Implementation Approaches

- Ensure that staff are dedicated and experienced in monitoring anticoagulant therapy.
- Implement reliable patient scheduling and tracking.
- Employ accessible, accurate, and frequent PT/INR testing.
- Utilize patient-specific decision support and interaction.
- Implement ongoing patient education.

While Safe Practices 17/18 were important first steps, clearly NQF could undertake additional work to improve the quality of VTE prevention and care. There are no nationally recognized model organizational policies for the prevention of VTE. National consensus standards that identified preferred practices in VTE risk assessment, prevention, diagnosis and treatment, applicable to a variety of healthcare settings, do not exist. Likewise, there are no widely agreed upon performance measures to assess adherence to accepted guidelines for the prevention and care of VTE. Given the mortality and morbidity attributed to VTE, the need for such standards is compelling.

Recognizing that quality improvement efforts take place within a broad organizational context, NQF views organizational policies and practices as unique vehicles to advance healthcare quality. The proposed domains of VTE prevention and care and the key characteristics of preferred practices have the potential to enable improvement by providing guidance in areas where a dearth of performance measures exists while the work to identify and develop performance measures is being done. Additionally, they may drive future research and measure development, while offering healthcare organizations a framework for immediate action.

Still, while policies and practices offer a framework for early improvements in the quality and care of VTE, performance measures are critical. Given the relatively immature state of performance measurement for all aspects of VTE prevention and care and the enormous need for performance measures in this area, NQF formed a unique collaboration with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to draw upon its expertise in measure specification, development, and testing; performance measures identified through this initiative will be available for consideration under the Consensus Development Process in 2007.

This report represents the first phase of work to endorse, pursuant to the NQF Consensus Development Process (appendix F) a set of voluntary consensus standards for VTE prevention and care. It sets forth four domains of prevention and care, 17 key characteristics of preferred practices, and two surgical prophylaxis performance measures. The key characteristics of practices address elements of each domain across the continuum of VTE prevention and care, including risk assessment/ stratification, prophylaxis, diagnosis, and treatment, as well as setting forth expectations for ongoing monitoring. The domains and their attendant key

characteristics of practices are applicable across care settings and should permit each healthcare organization to adopt them in a manner consistent with the setting in which it delivers care and the scope of services provided.

PURPOSE OF THE SET

As noted, this report encompasses a framework that delineates the domains of VTE prevention and care, characteristics of preferred practices, and performance measures. Specifically:

- The statement of policy, with its four domains of prevention and care, provide a framework within which characteristics of preferred practices are explicated and a comprehensive set of performance measures to evaluate adherence to practices will be identified or developed and tested.
- The purpose of the 17 key characteristics of preferred practices for the prevention and care of VTE is to inform internal quality improvement efforts and to provide guidance to hospitals and other healthcare facilities as they strive to provide the highest quality of care to patients at risk of, and those being treated for, VTE.
- The purpose of the two performance measures for VTE surgical prophylaxis is public accountability.

IDENTIFYING THE INITIAL SET

NQF convened a Steering Committee (appendix C) to establish the initial approach to developing consensus standards for the prevention and care of VTE. A framework that demonstrates the relationship among policies, practices, and performance measures was identified, as were the purpose of the initial set of policy and practice statements and the scope and priorities of the set of voluntary consensus standards.

A FRAMEWORK FOR VTE PREVENTION AND CARE

The objectives of the VTE project framework are to ensure that:

- the endorsed set of performance measures, preferred practices, and model organizational policies is comprehensive and covers all aspects of prevention and care that impact on quality;
- needs of all stakeholders are addressed and offer knowledge that is useable by all stakeholders;
- the endorsed set of preferred practices, and model organizational policies build upon the criteria set forth in the *Safe Practices for Better Healthcare: A Consensus Report* and are generalizable (i.e., they may be applied in multiple clinical care settings and/or for multiple types of patients);
- the endorsed set of organizational policies, practices, and performance measures reflect strong evidence that they are effective in preventing and/or reducing the incidence and/or complications of VTE – DVT/PE;
- processes and criteria for the recommendation of measures, practices, and policies are standardized and precisely defined;
- reporting and implementation of the consensus standards are performed in a way that will maximize their impact; and
- the policies, practices, and measures leverage opportunities for significant improvement in the prevention and care of VTE–DVT/PE by identifying critical points in the clinical course and progression of this condition.

Criteria for Selection of Consensus Standards

Two NQF reports, *A Comprehensive Framework for Hospital Care Performance Evaluation* and *Safe Practices for Better Healthcare: A Consensus Report*, provided a framework for evaluation of the candidate practices and measures evaluated in this project. The criteria detailed in these reports were used to evaluate each candidate practice (box B) and each performance measure (box C).

149

Box B—Criteria for Inclusion of Practices in the Set

In proposing new candidate practices, as well as establishing boundaries and priorities for gaps that may exist, the following four domains, derived from earlier NQF work, were used: importance, scientific acceptability, usability, and feasibility. Further, to be included in the set, the Key Characteristics of Practices were evaluated against the specific criteria from Safe Practices for Better Healthcare: A Consensus Report, *which are.*

Specificity. The practice must be a clearly and precisely defined process or manner of providing a healthcare service. All candidate safe practices were screened according to this threshold criterion. Candidate safe practices that met the threshold criterion of specificity were then rated against four additional criteria relating to the likelihood of the practice improving patient safety.

Benefit. If the practice were more widely utilized, it would save lives endangered by healthcare delivery, reduce disability or other morbidity, or reduce the likelihood of a serious reportable event (e.g., an effective practice already in near universal use would lead to little new benefit to patients by being designated a safe practice).

Evidence of Effectiveness. There must be clear evidence that the practice would be effective in reducing patient safety events. Such evidence may take various forms, including the following:

- *research studies showing a direct connection between improved clinical outcomes (e.g., reduced mortality or morbidity) and the practice;*
- *experiential data (including broad expert agreement, widespread opinion, or professional consensus) showing the practice is "obviously beneficial" or self-evident (i.e., the practice absolutely constrains a potential problem or forces an improvement to occur, reduces reliance on memory, standardizes equipment or process steps, or promotes teamwork); or*
- *research findings or experiential data from non-healthcare industries that should be substantially transferable to healthcare (e.g., repeat-back of verbal orders or standardizing abbreviations).*

Generalizability. The safe practice must be able to be utilized in multiple applicable clinical care settings (e.g., a variety of inpatient and/or outpatient settings) and/or for multiple types of patients.

Readiness. The necessary technology and appropriately skilled staff must be available to most healthcare organizations.

149

Box C—Criteria for Evaluation and Selection of Measures

Proposed measures have been evaluated for suitability based on four standardized criteria first endorsed by NQF in 2003:[1] important, scientifically acceptable, useable, and feasible.

Important. This set addresses the extent to which a measure reflects a variation in quality, low levels of overall performance, and the extent to which it captures key aspects of the flow of care.

a. The measure addresses one or more key leverage points for improving quality.
b. Considerable variation in the quality of care exists.
c. Performance in the area (e.g., setting, procedure, condition) is suboptimal, suggesting that barriers to improvement or best practice may exist.

Scientifically acceptable. A measure is scientifically sound if it produces consistent and credible results when implemented.

a. The measure is well defined and precisely specified. Measures must be specified sufficiently to be distinguishable from other measures, and they must be implemented consistently across institutions. Measure specifications should provide detail about cohort definition, as well as the denominator and numerator for rate-based measures and categories for range-based measures.
b. The measure is reliable, producing the same results a high proportion of the time when assessed in the same population.
c. The measure is valid, accurately representing the concept being evaluated.
d. The measure is precise, adequately discriminating between real differences in provider performance.
e. The measure is adaptable to patient preferences and a variety of contexts of settings. Adaptability depends on the extent to which the measure and its specifications account for the variety of patient choices, including refusal of treatment and clinical exceptions.
f. An adequate and specified risk-adjustment strategy exists, where applicable.
g. Consistent evidence is available linking the process measures to patient outcomes.

Useable. Usability reflects the extent to which intended audiences (e.g., consumers, purchasers) can understand the results of the measure and are likely to find them useful for decision making.

a. The measure can be used by the stakeholder to make decisions.
b. The differences in performance levels are statistically meaningful.
c. The differences in performance are practically and clinically meaningful.
d. Risk stratification, risk adjustment, and other forms of recommended analyses can be applied appropriately.
e. Effective presentation and dissemination strategies exist (e.g., transparency, ability to draw conclusions, information available when needed to make decisions).
f. Information produced by the measure can/will be used by at least one healthcare stakeholder audience (e.g., public/ consumers, purchasers, clinicians and providers, policymakers, accreditors/regulators) to make a decision or take an action.
g. Information about specific conditions for which the measure is appropriate has been given.

h. Methods for aggregating the measure with other, related measures (e.g., to create a composite measure) are defined, if those related measures are determined to be more understandable and more useful in decisionmaking. Risks of such aggregation, including misrepresentation, have been evaluated.

Feasible. Feasibility is generally based on the way in which data can be obtained within the normal flow of clinical care and the extent to which an implementation plan can be achieved.

a. The point of data collection is tied to care delivery, when feasible.
b. The timing and frequency of measure collection are specified.
c. The benefit of measurement is evaluated against the financial and administrative burden of implementation and maintenance of the measure set.
d. An auditing strategy is designed and can be implemented.
e. Confidentiality concerns are addressed.

[1]National Quality Forum (NQF). *A Comprehensive Framework for Hospital Care Performance Evaluation: A Consensus Report. Washington, DC: NQF; 2003.*

Scope

The proposed voluntary consensus standards for prevention and care of VTE–DVT/PE encompass those that:

- are fully open source;
- include the entire continuum of care from prevention through diagnosis, treatment, secondary prevention, and management of high-risk populations;
- are applicable across healthcare organizations that provide care to persons at risk for VTE;
- can be used for quality improvement;
- reflect those aspects of VTE prevention and care over which healthcare organizations and providers have control, and include transitions of care between healthcare providers along the continuum of care;
- address the NQF-endorsed six aims for healthcare (safe, beneficial, patient-centered, timely, efficient, and equitable);
- address the need for education and awareness programs; and
- with respect to performance measures, are fully developed.

Priority Areas for VTE Prevention and Care Policy, Practices, and Performance Measures

In identifying the policy, practice statements, and performance measures, for prevention and care of VTE, priority was given to those that:

- are likely to lead to significant improvement in the prevention and care of VTE;
- build upon NQF-endorsed voluntary consensus standards;
- applicable to multiple levels of the healthcare system;
- address priorities for national healthcare quality;
- are suitable for accountability and efficiency;
- relate to prevention, early identification and treatment; and

- address disparities in care.

THE NQF-ENDORSED™ CONSENSUS STANDARDS

The proposed NQF-endorsed set is comprised of a broad statement of policy identifying four specific domains of VTE prevention and care, 17 key characteristics of preferred practices that clarify an expectation of the action in each domain, and two measures of VTE prophylaxis (appendix A) intended for institutional public accountability. These consensus standards are intended for hospital use and, as applicable to setting of care and scope of services, all other healthcare facilities.

The domains and key characteristics of practices also provide a framework for the development of a comprehensive set of performance measures that will be identified in the next phase of the project and supplement the two endorsed measures in this phase.

NQF endorsement of this set is intended to:

- enable early promulgation of policy that include adoption of the domains and practices into which performance measures can be integrated as they are selected, developed, and endorsed;
- facilitate assessment, prophylaxis, diagnosis and treatment services as well as patient education and organizational monitoring of VTE prevention and care services; and
- enable organizational accountability in the area of prophylaxis of surgical patients.

Statement of Policy and Domains of Care

The statement of policy below identifies four domains of VTE prevention and care and sets expectations about the approach to be taken by all organizations providing care to those at risk, or being treated for, VTE – DVT/PE.

> Recommendation 1: Every healthcare facility shall have a **written policy** appropriate for its scope, that is **evidence-based** and **drives continuous quality improvement** related to venous thromboembolism (VTE) **risk assessment**, **prophylaxis**, **diagnosis**, and **treatment**.

Key Characteristics of Preferred Practices

While the overarching statement of policy calls for specific organizational action to address four domains for VTE prevention and care, the key characteristics of preferred practices expand the policy statement by setting out general recommendations and characteristics to be addressed in each of the four domains of VTE prevention and care, as well as a monitoring function. The characteristics are arrayed across the domains and general categories as follows:

- **General Recommendations**. The five key characteristics in this area focus on use of multidisciplinary teams to establish approaches to all aspects of VTE prevention and care and provider education across all domains.
- **Risk Assessment/Stratification**. Two key characteristics of practice in this domain require that risk assessment and documentation thereof be included in an institutional policy and be carried out.
- **Prophylaxis**. Two key characteristics of practice address the requirement for risk assessment and set out the expectation that VTE prophylaxis will be based on evidence-based guidelines and include NQF-endorsed Safe Practice 17. As all domains will be, this domain is amplified by the two performance measures in this initial set.
- **Diagnosis**. Two key characteristics of practice in this domain set expectations regarding methods for establishing diagnosis, attendant documentation and provider education.
- **Treatment and Monitoring**. Six key characteristics of preferred practices speak to initiation of therapy, confirmation of VTE using institutional required testing protocols, safe administration of guideline-directed therapy, patient education, use of NQF-endorsed Safe Practice 18 and an expectation for monitoring.

Specifically, the key characteristics of preferred practices are:

With appropriate consideration to the setting of care and scope of services, organizational practices related to prevention and care of VTE should be documented in policy and include the following key characteristics:

General Recommendations

GR 1. Ensure that multidisciplinary teams develop institutions' protocols and/or "adopt" established evidence-based protocols;

GR 2. Have in place a documented system for ongoing quality improvement that demonstrates acting on evidence-based guidelines/practices (rationale for departing from guidelines should be documented unless documentation itself is for some reason contraindicated);

GR 3. Include provision for risk assessment/stratification, prophylaxis, diagnosis, and treatment;

GR 4. Include appropriate quality improvement (QI) activity/monitoring for all phases of care with periodic (as defined by institutional policy) assessment of compliance with policies and measures; and

GR 5. Provide for a system of provider education that encompasses all aspects of VTE prevention and care including primary and secondary prevention, risk assessment and stratification, prophylaxis, diagnosis, treatment and monitoring.

Risk Assessment/Stratification Recommendations

RA 1. Provide for risk assessments on all patients based on evidence-based institutional policy (institutions have the flexibility to determine how patient risks are assessed/ stratified); and

RA 2. Require documentation in the patient's health record that risk assessment/ stratification was completed.

Prophylaxis Recommendations

P 1. Provide for type and intensity of prophylaxis based on and commensurate with assessment and documentation of risk/benefit and efficacy/safety for the patient; and

P 2. Prophylaxis is based on formal risk assessment and is consistent with nationally accepted, evidence-based measures/guidelines including NQF-endorsed™ Safe Practice 17.

Diagnosis Recommendations

D 1. Include requirement to establish a diagnosis of VTE using specific objective diagnostic testing in order to justify treatment continued beyond the initial empiric treatment; and

D 2. Include institution-specific algorithm(s) for establishing diagnosis and require documentation of contraindications if the algorithm(s) is not followed.

Treatment and Monitoring Recommendations

T 1. Ensure anticoagulation is administered safely and that the setting in which anticoagulation occurs is part of the safety consideration;

T 2. Incorporate NQF-endorsed Safe Practice 18;

T 3. Provide for initiation of treatment based on empiric evidence with high degree of suspicion and assessment of safety concerns that, for continued therapy, is confirmed with objective testing based on facility policy/guidelines (also see Diagnosis);

T 4. Provide for accurate verbal and written patient education appropriate to setting and patient reading levels (that includes some assessment of understanding versus simple documentation, especially important for outpatients;

T 5. Provide for guideline-directed therapy addressing:

A. Initiation and monitoring of heparin and oral anticoagulation therapy, including timing of initial dose, dose and dose schedule, duration of heparin/oral anticoagulation overlap, and total duration of therapy;

B. Appropriate indications for placement and retrieval of an IVC filter;

C. Appropriate indications for thrombolytic therapy and venous embolectomy;

D. Prevention of postthrombotic syndrome; and

E. Monitoring for the development of and early intervention for chronic thromboembolic pulmonary hypertension.

T 6. Provide for guideline-directed therapy that addresses 'bridging' in care setting transitions.

Performance Measures

Two process measures for prophylaxis in the surgical patient are recommended for endorsement. They are:

- **Surgery Patients with Recommended Venous Thromboembolism (VTE) Prophylaxis Ordered**
- **Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery**

The developer of the measures is the Center for Medicare and Medicaid Services (CMS). As measures developed by a federal government entity, they are in the public domain.

Measure information forms that include the specifications and additional information for each of the measures are included as appendices A and B.

RELATIONSHIP AMONG ORGANIZATIONAL POLICIES, PREFERRED PRACTICES, AND PERFORMANCE MEASURES

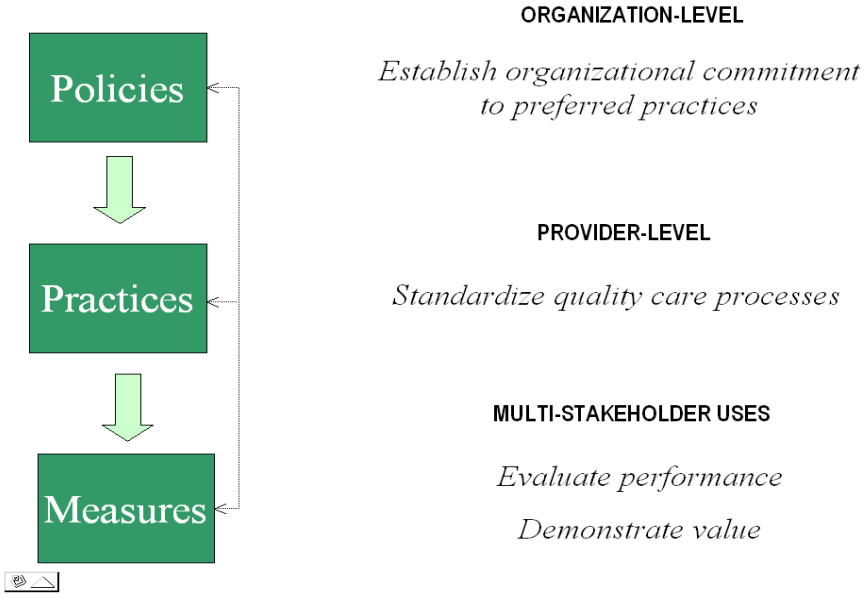
A construct was developed and implemented in this project to demonstrate the relationship among organizational policies, preferred practices, and performance measures (figure 1).

- *Organizational policies* are statements of required institutional practices or organizational regulations that are included in a standard operating manual. Model organizational policies codify preferred practices. They establish preferred practices as expected institutional behaviors and signal an organizational commitment to ensure that care processes are consistent with preferred practices. In instituting such

policies, leadership demonstrates a voluntary commitment to quality and accountability.

- *Preferred practices* encompass a broad range of clinical decisionmaking tools that guide a healthcare professional in the prevention, diagnosis, or management of DVT. They are evidence-based or represent expert consensus on quality healthcare practices. Preferred practices guide daily practice to ensure consistent, quality care. Some examples of preferred practices include risk assessment instruments, clinical protocols, and patient care guidelines.
- *Performance measures* report the degree to which care processes conform to established care standards including clinical guidelines.

Figure 1 – Relationship Among Policies, Practices, and Performance Measurement



The relationship among the three types of proposed consensus standards should be dynamic—i.e., data from performance measures should be used to inform modifications to policies and/or practices. Similarly, new evidence related to practices may well emerge and demand that the specifications for measure(s) be modified.

RELATIONSHIP TO THE FUTURE PREVENTION AND CARE OF VTE PERFORMANCE MEASURE SET

During the course of assessing the availability of model policies, preferred practices, and performance measures for prevention and care of VTE, it became clear that much work remains to be done to advance quality in this area. While many of the candidate practices addressed important aspects of VTE prevention and care, none systematically addressed each domain of care. However, taken as a whole, the candidate preferred practices informed efforts to identify the set of key characteristics of preferred practices included in this report.

Similarly, while some performance measures related to VTE prevention and care exist, a comprehensive set of performance measures that evaluates quality across each domain of care is currently lacking. However, the second phase of the NQF VTE project is underway and additional performance measures will be selected from among the candidate measures that JCAHO is developing and testing. Throughout this process, areas in which additional research is needed to improve the quality of VTE prevention and care will be identified and advanced within the framework of the key characteristics of preferred practices.

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