

The following relationships exist related to this presentation:

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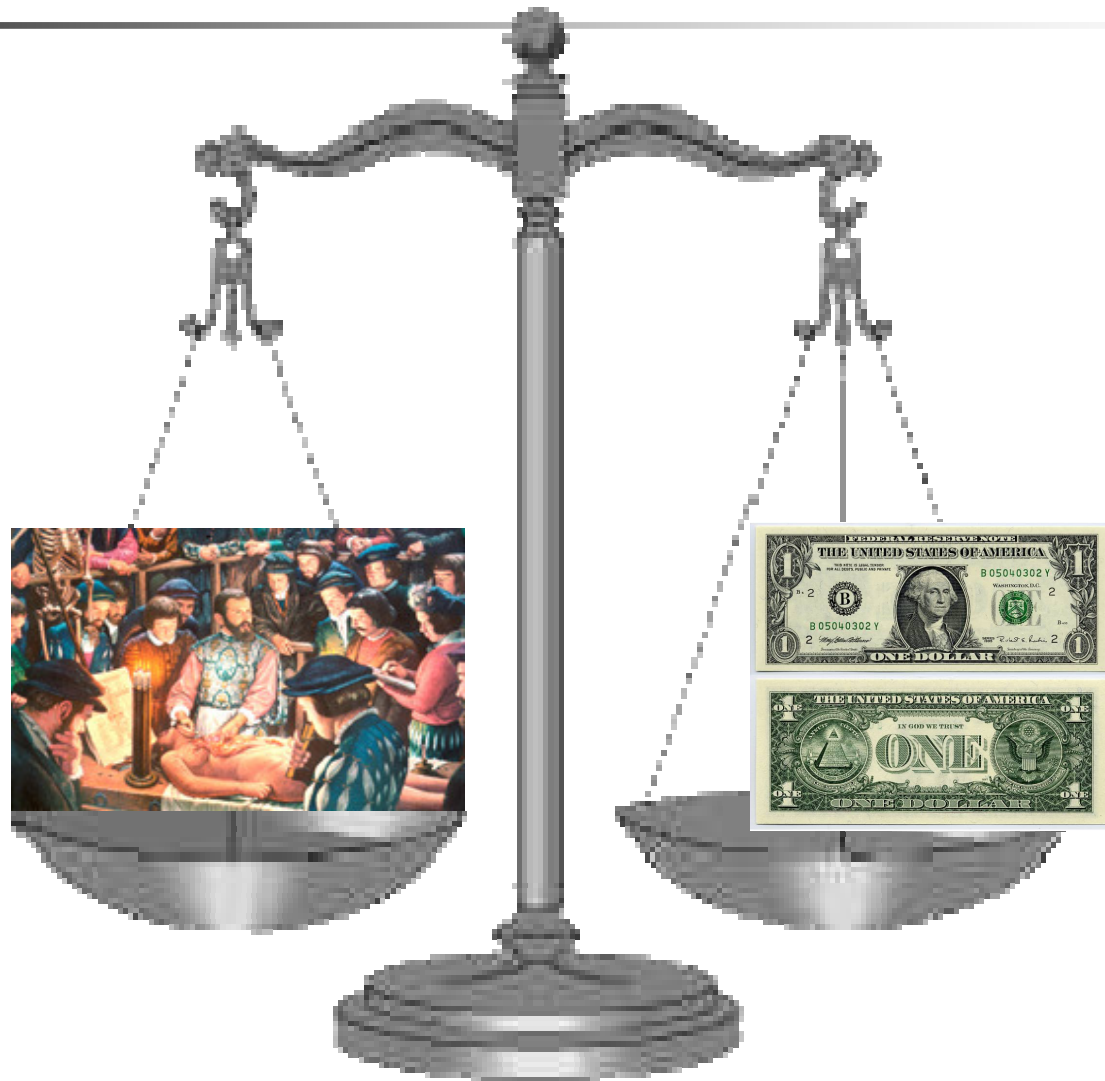


How Changes in Hospital and Physician Reimbursement Lead to Changes in Medical Practice

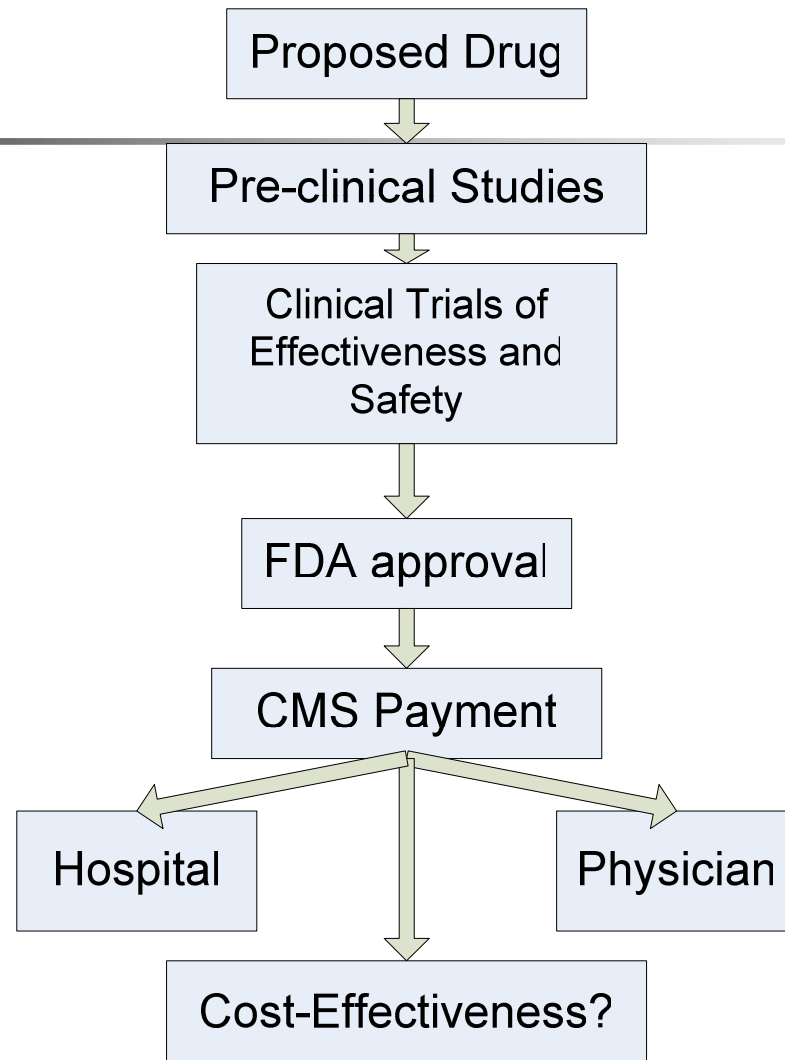
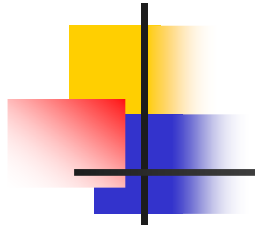
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University of Cincinnati College of
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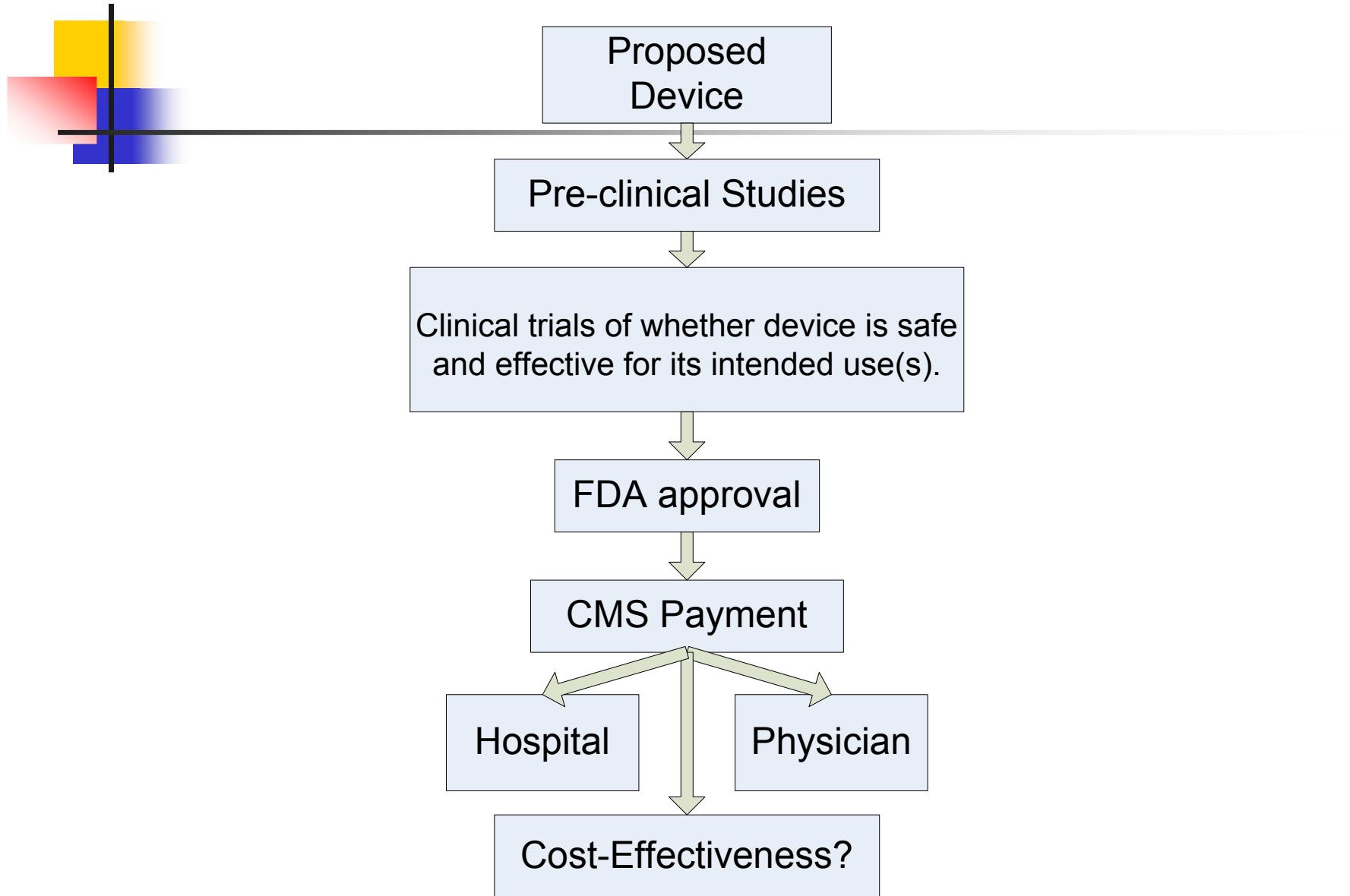
Science and Reimbursement Are The Two Major Influences Upon Medical Practice



Process of Drug Approval and Reimbursement



Process of Device Approval and Reimbursement



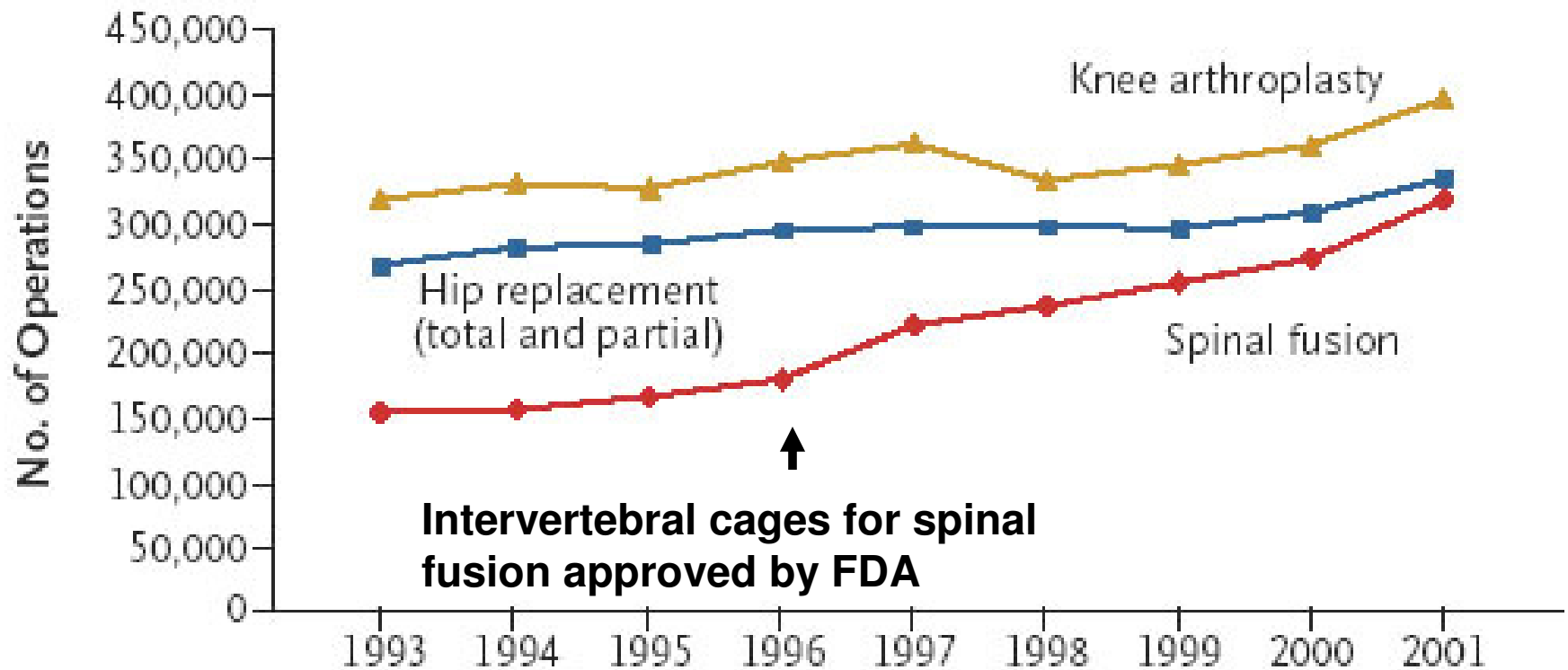


Figure 1. Annual Number of Knee-Arthroplasty, Hip-Replacement, and Spinal-Fusion Operations in the United States, on the Basis of the National Inpatient Sample.

Data are from the Agency for Healthcare Research and Quality.¹

Science Does Not Support the Dramatic Increase in Lumbar Fusion

- “The evidence base guiding the use of lumbar back surgery with fusion, is, with few exceptions (*e.g.*, lumbar spondylolisthesis of various etiologies), particularly weak, even though it is the procedure with the most rapid increase in use over the past 10 years.”
- “There were 8 trials that showed that instrumented fusion produces a higher fusion rate, but any improvement in clinical outcomes is probably marginal.”*

*Gibson JM, Waddell G. Surgery for degenerative lumbar spondylosis: updated Cochrane Review. Spine. 2005 Oct 15;30(20):2312-20

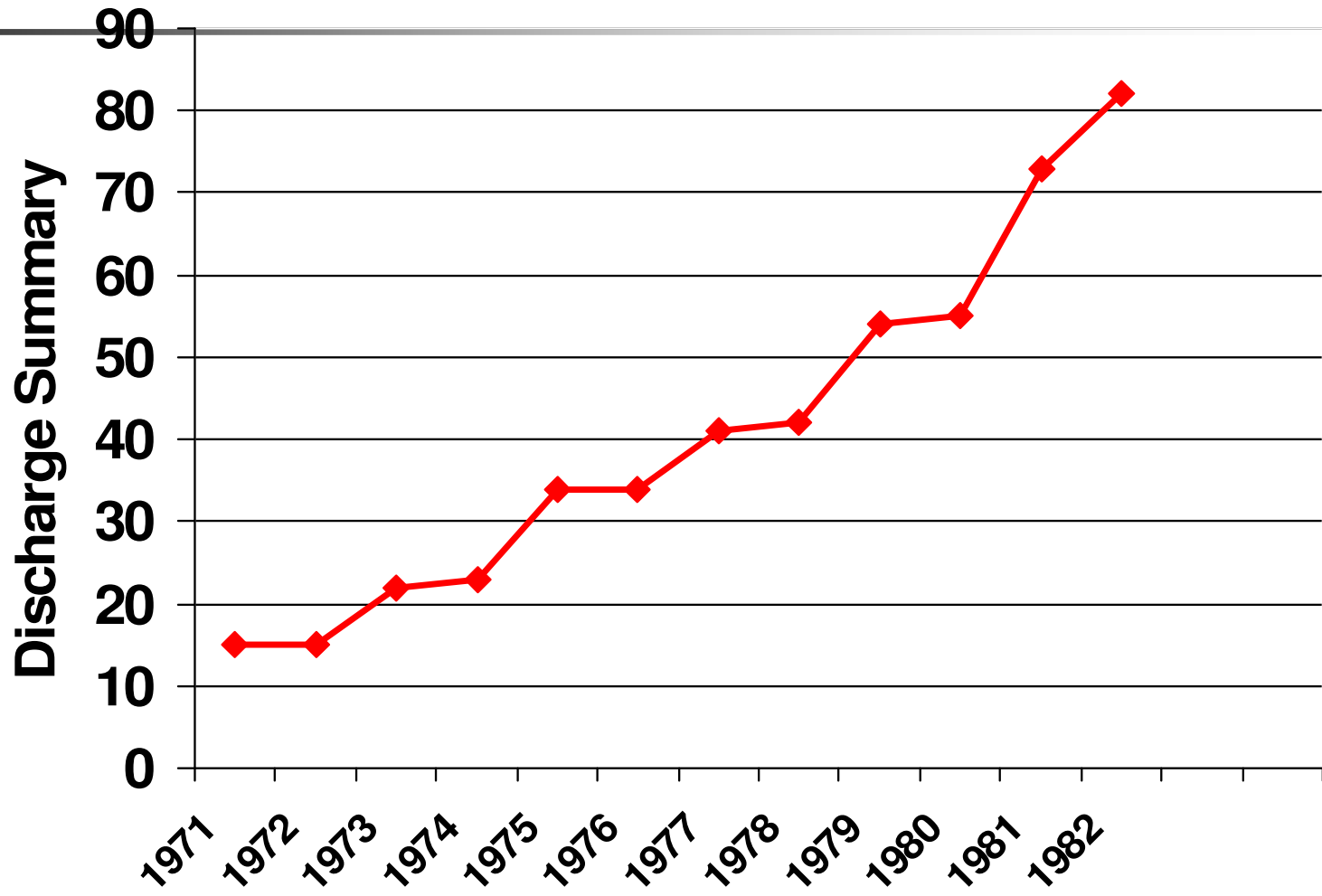
Reality

- Reimbursement for devices or procedures prior to demonstrating clinical efficacy can greatly hinder attempts to prove or disprove true efficacy and safety



Early Days of Carotid Endarterectomy

Number of CEA per National Hospital Discharge Summary





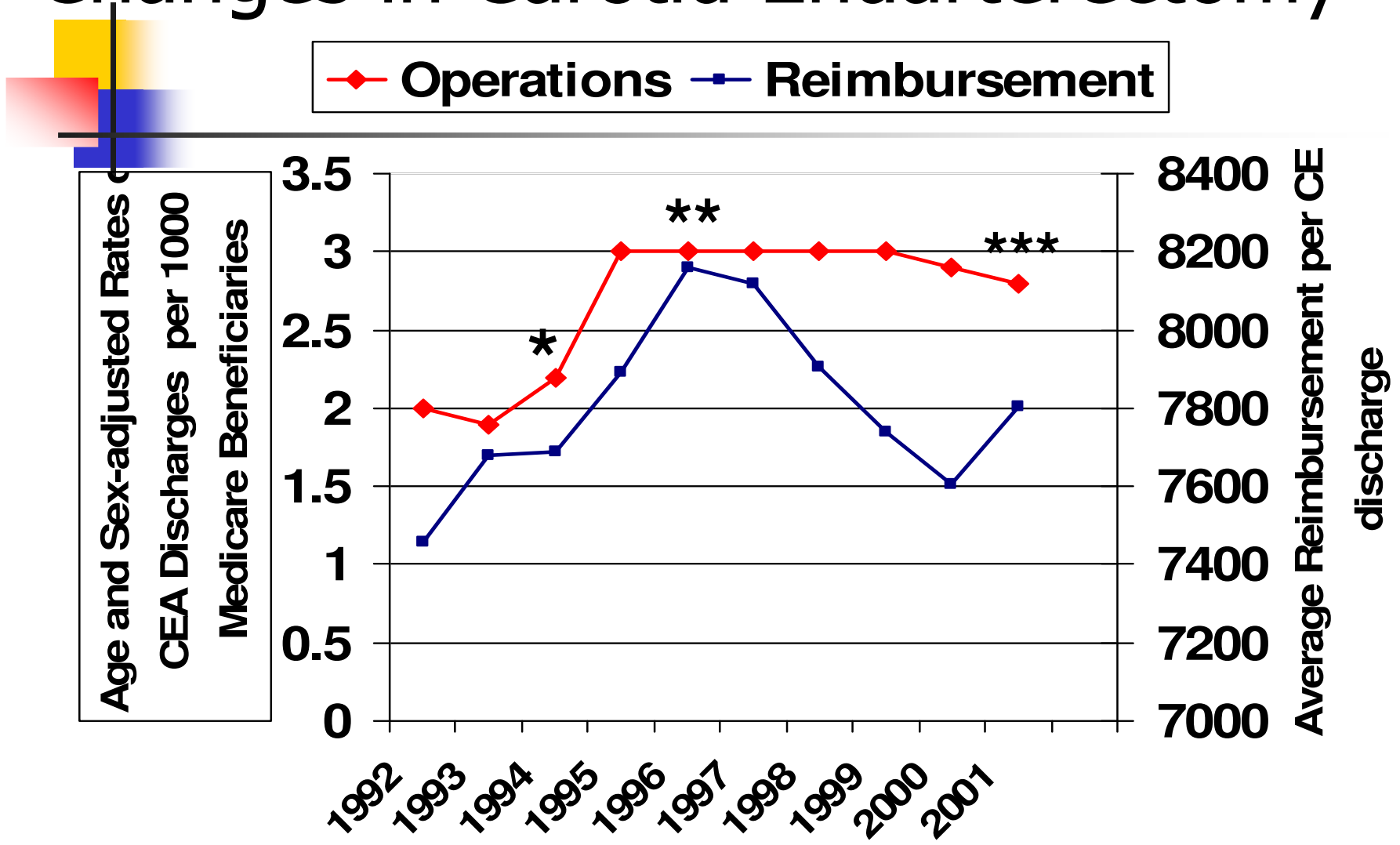
Sound Familiar?

A Proposed Method for Using a Reimbursement Moratorium to Encourage Recruitment for a Randomized Study of Carotid Endarterectomy

SARAN JONAS, M.D.

Stroke 17, No. 6, 1986.

Changes in Carotid Endarterectomy



*ACASS Clinical Advisory, NASCET results published in 1991

First reports of larger series of carotid angioplasty/stenting, *CAVATAS Trial Report



Extracranial-Intracranial Bypass

- described by Yasargil in 1969
- used with increasing frequency for
 - treatment of occlusive cerebrovascular disease
 - in combination with therapeutic CA occlusion in the treatment of unclippable intracranial aneurysms.
- In 1985, the EC-IC Bypass Study failed to demonstrate efficacy

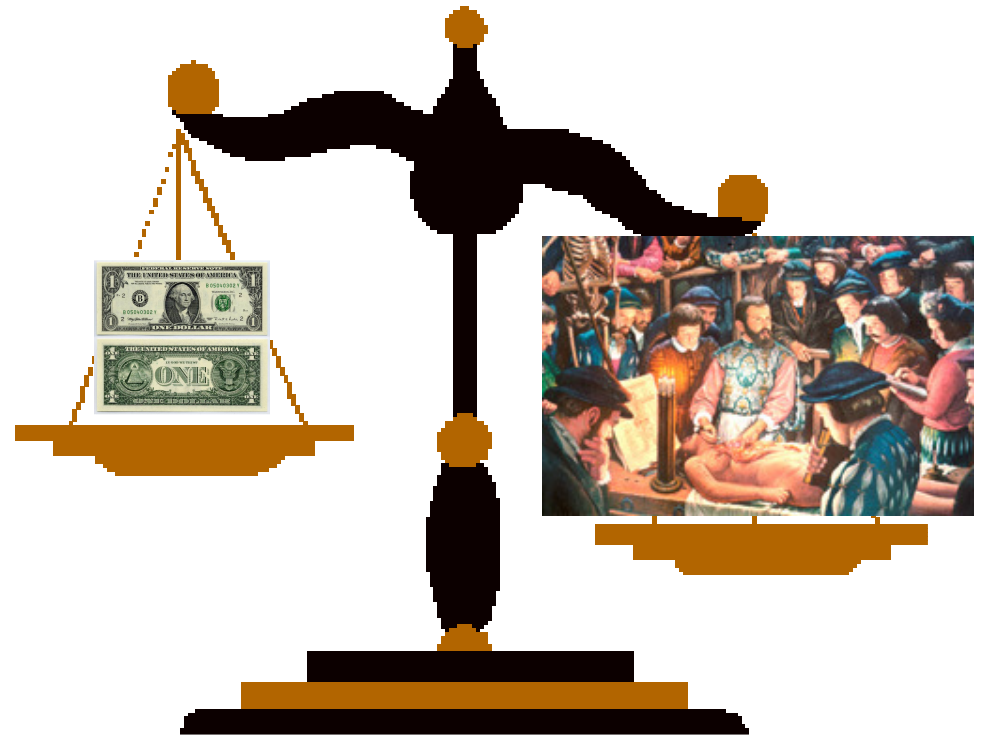
Extracranial-Intracranial Bypass



- Major change in practice in 1991: CMS announced that procedure no longer reimbursed for treatment or prevention of ischemic stroke
- Anecdotal evidence: the number of EC–IC bypass procedures subsequently performed in the US decreased sharply by as much as 75%.

Science and Reimbursement for Acute Stroke Therapy

- t-PA was approved by the FDA in 1996.
- Yet, by 2004, only 1-2% of hospitalized ischemic stroke patients were treated with t-PA across U.S.



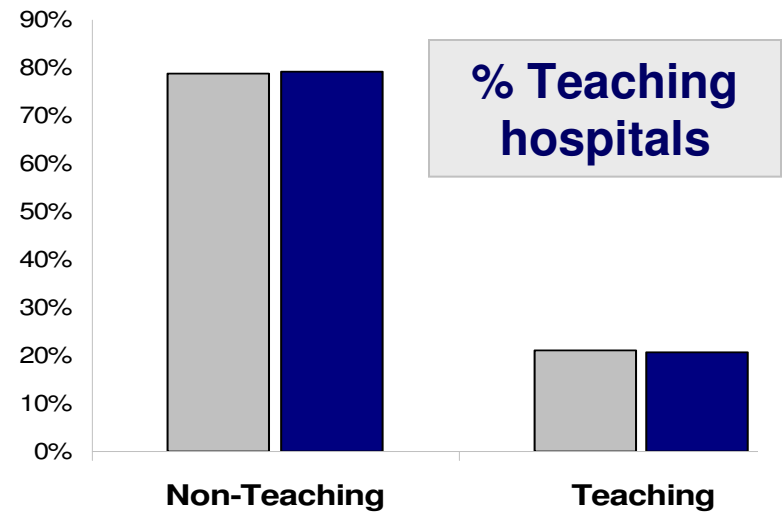
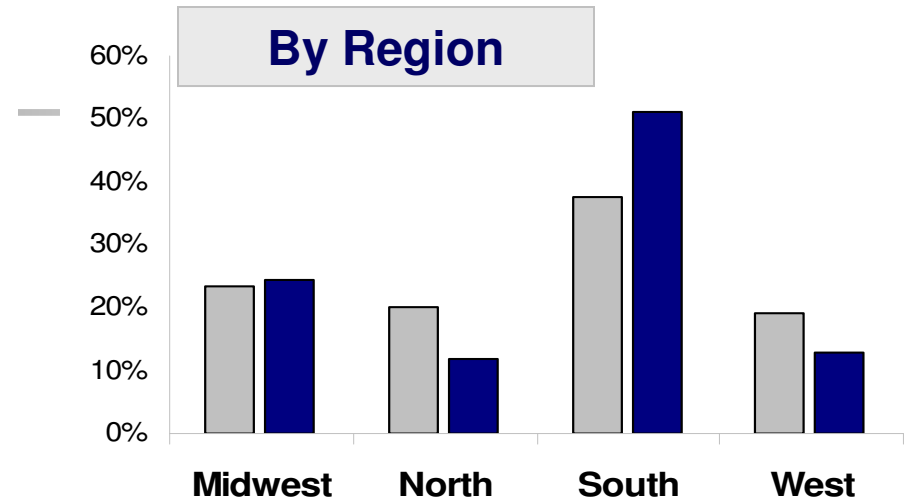
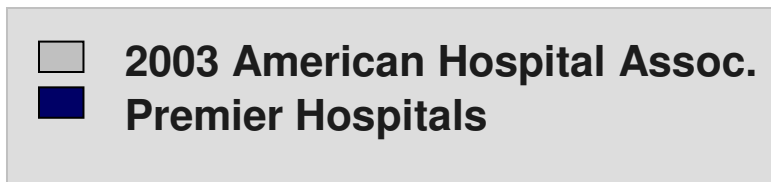
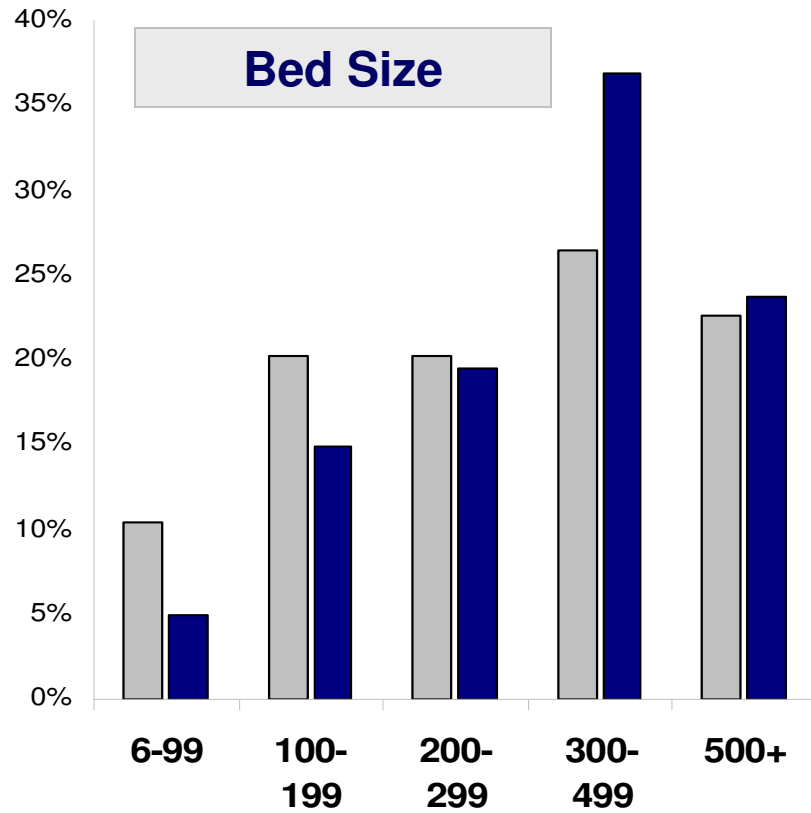


Premier Perspective Database

- Privately owned database, sampling of U.S. hospitals
- Contains approx. 1 in 6 hospital discharges in the U.S., 506 hospitals
- No age cut-off, allows cross-referencing to pharmacy billing databases

Premier Hospital Characteristics

N = 506



Slide provided by Premier Database Incorporated

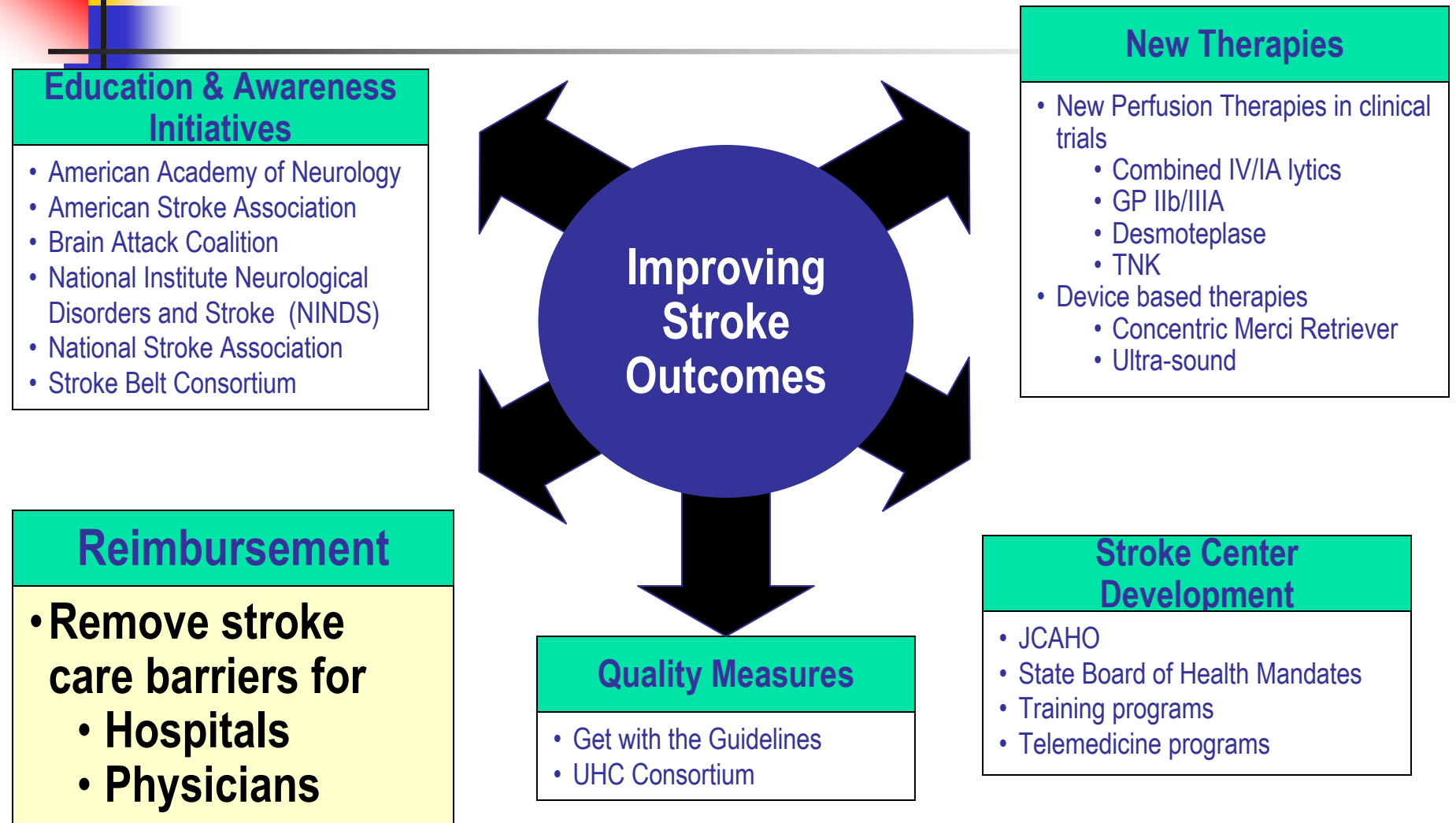


Change Over Time in Rt-PA Use, Premier Database

	FY2001	FY2002	FY2003	FY2004
Total number of cases, DRG 14/15/524, all ages	54,772	59,893	58,570	56,129
# with ICD-9 code 99.1 (%)	572 (1.04%)	632 (1.06%)	616 (1.05%)	646 (1.20%)
# with pharmacy billing for thrombolytic (%)*	875 (1.60%)	1002 (1.67%)	956 (1.63%)	1021 (1.82%)

Improving Stroke Outcomes

Multiple Prong Efforts



Health Economics

Hospital charges for Stroke Patients

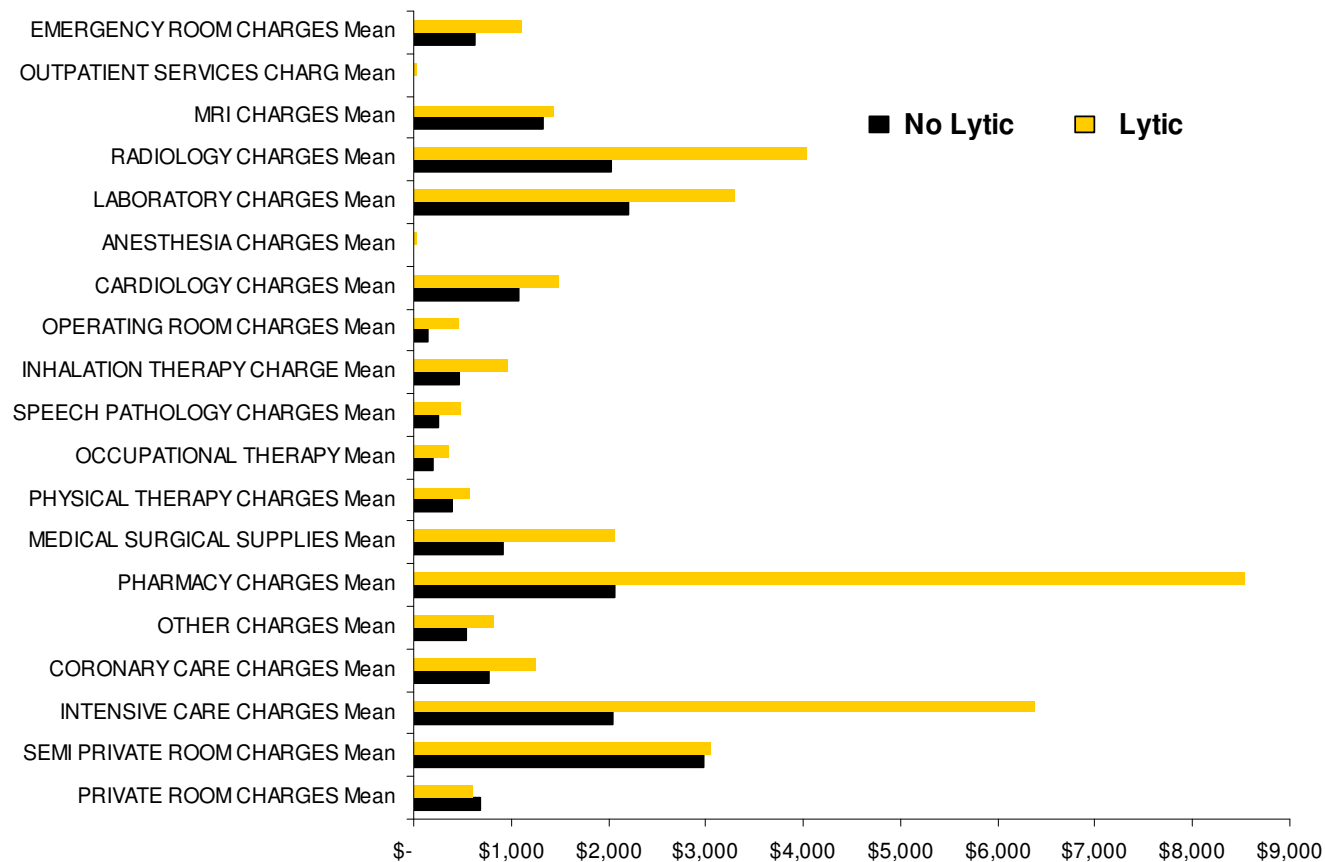
Stroke patients who receive a thrombolytic agent have significantly higher in-hospital charges but are currently small in number...

<i>Of all discharges in DRGs 14 & 15...</i>	N (% of Total)	LOS Mean	Std. Charges Mean
Patients receiving a thrombolytic identified by code 99.10	2,452 (0.76%)	7.1	\$31,765
Patients <u>not</u> receiving a thrombolytic	321,757 (99.24%)	5.6	\$16,400

Source: 2003 Medicare MedPAR data. Thrombolytic patients coded with ICD-9 code 99.10.

Hospital Costs Higher Across Every Domain for Rt-PA Treated Patients

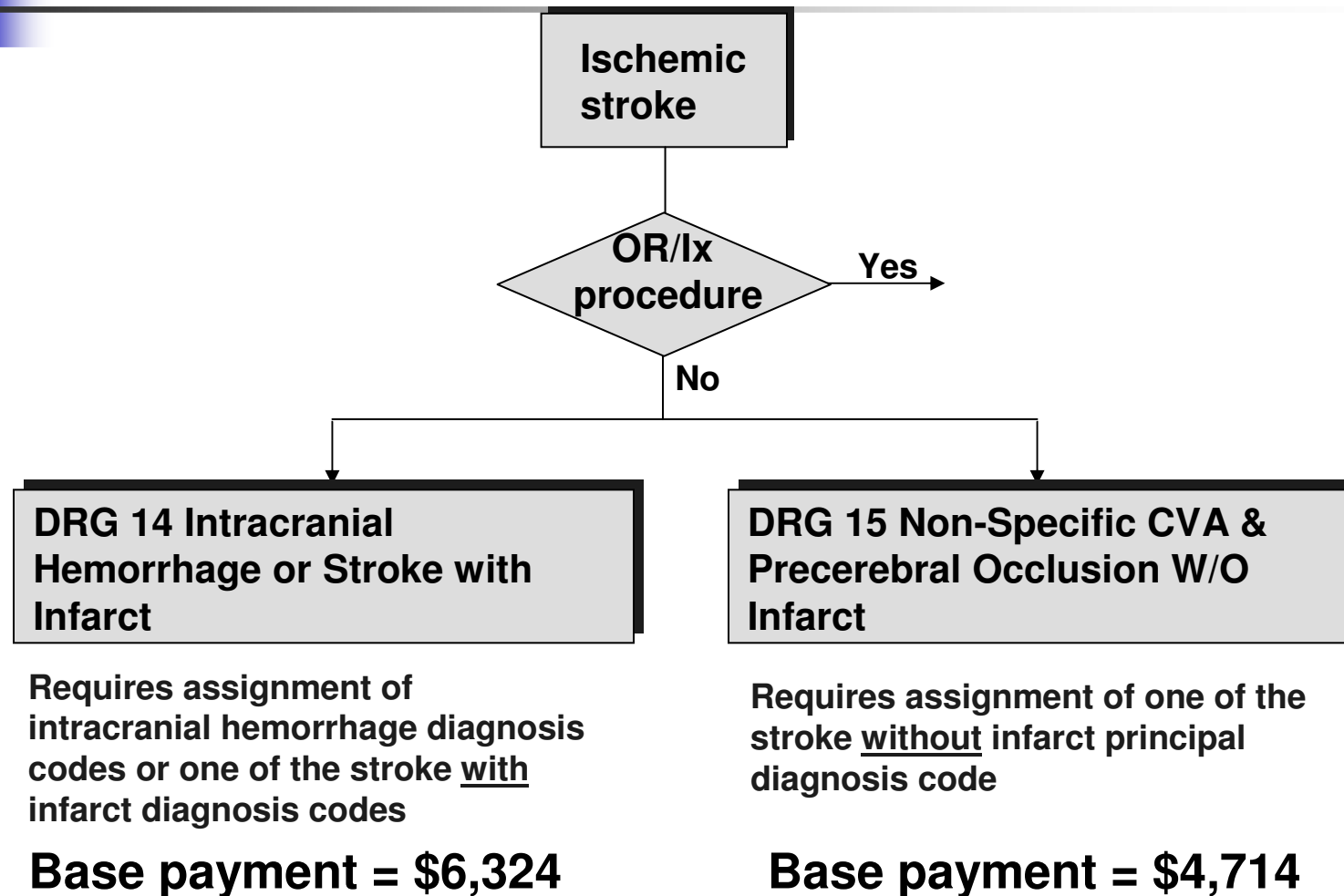
Premier Database, 2004



Health Economics

Ischemic Stroke Reimbursement * Prior to FY2005

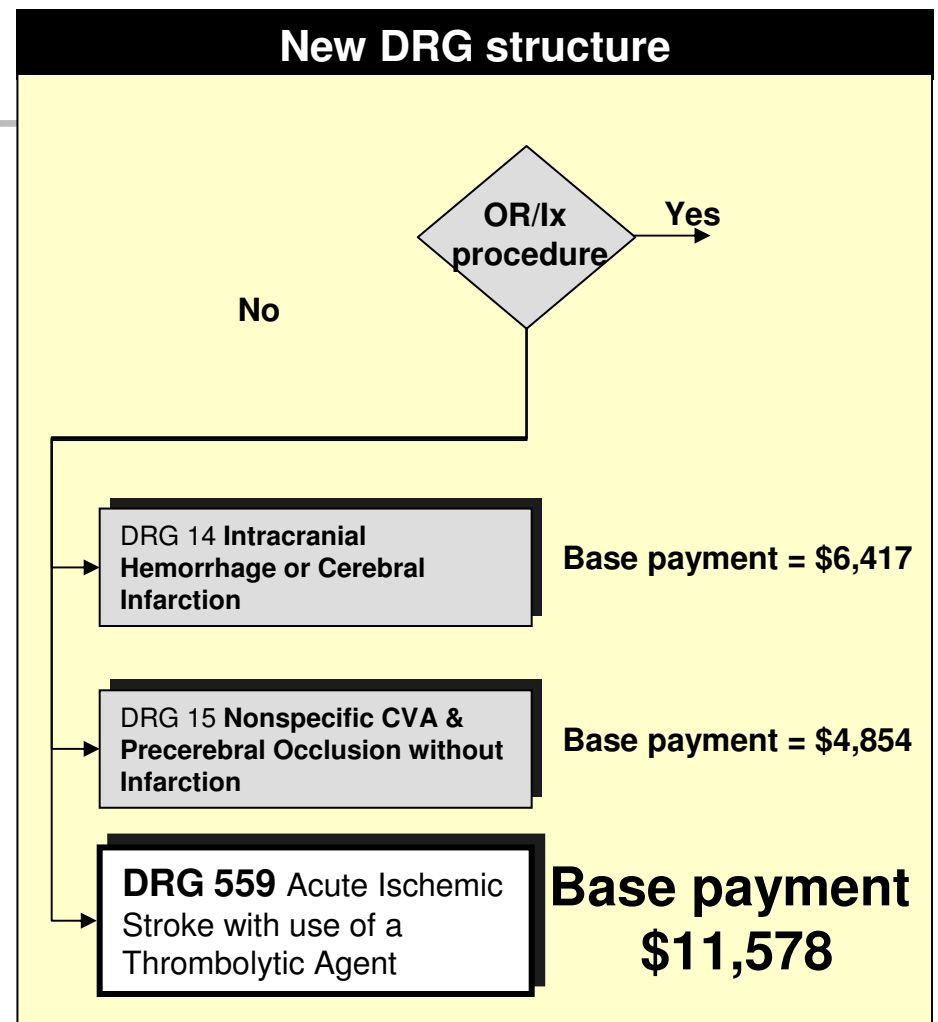
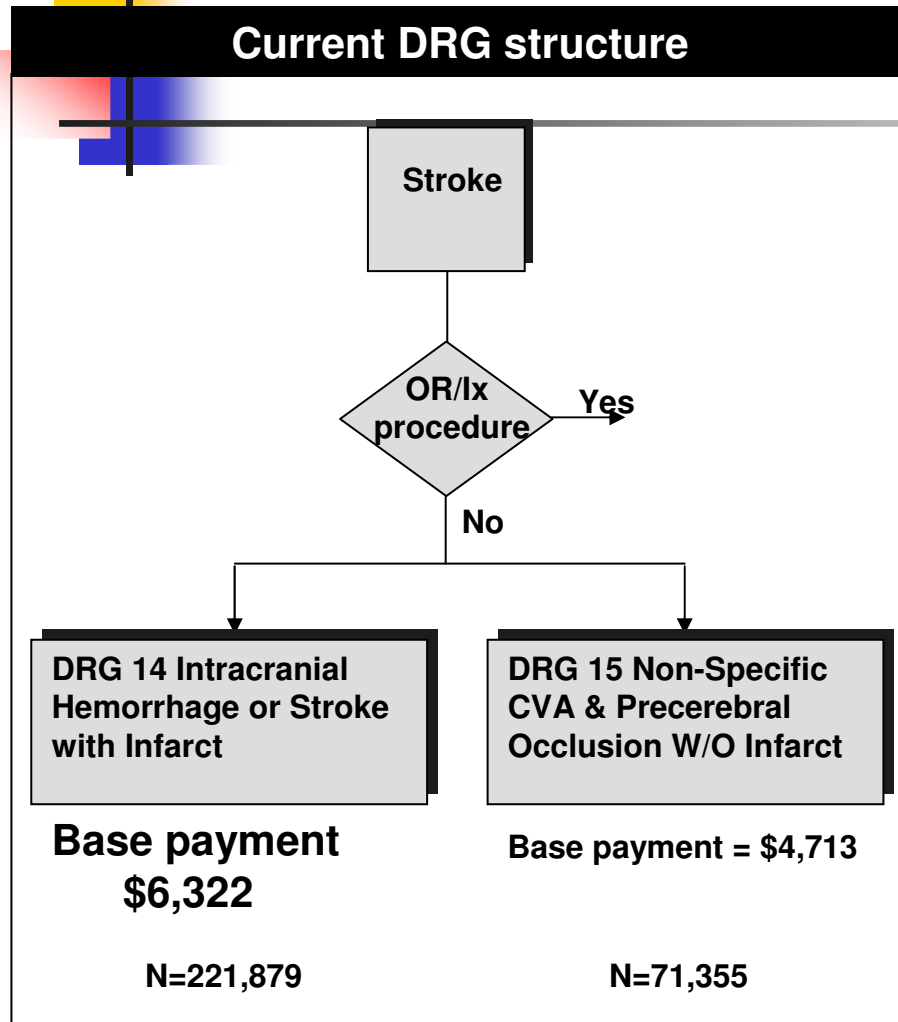
Ischemic stroke patients who do not receive a procedure were assigned to one of two possible DRGs based on principal diagnosis...



*Medicare reimbursement

CMS Final Rule – FY 2006

Stroke Reimbursement

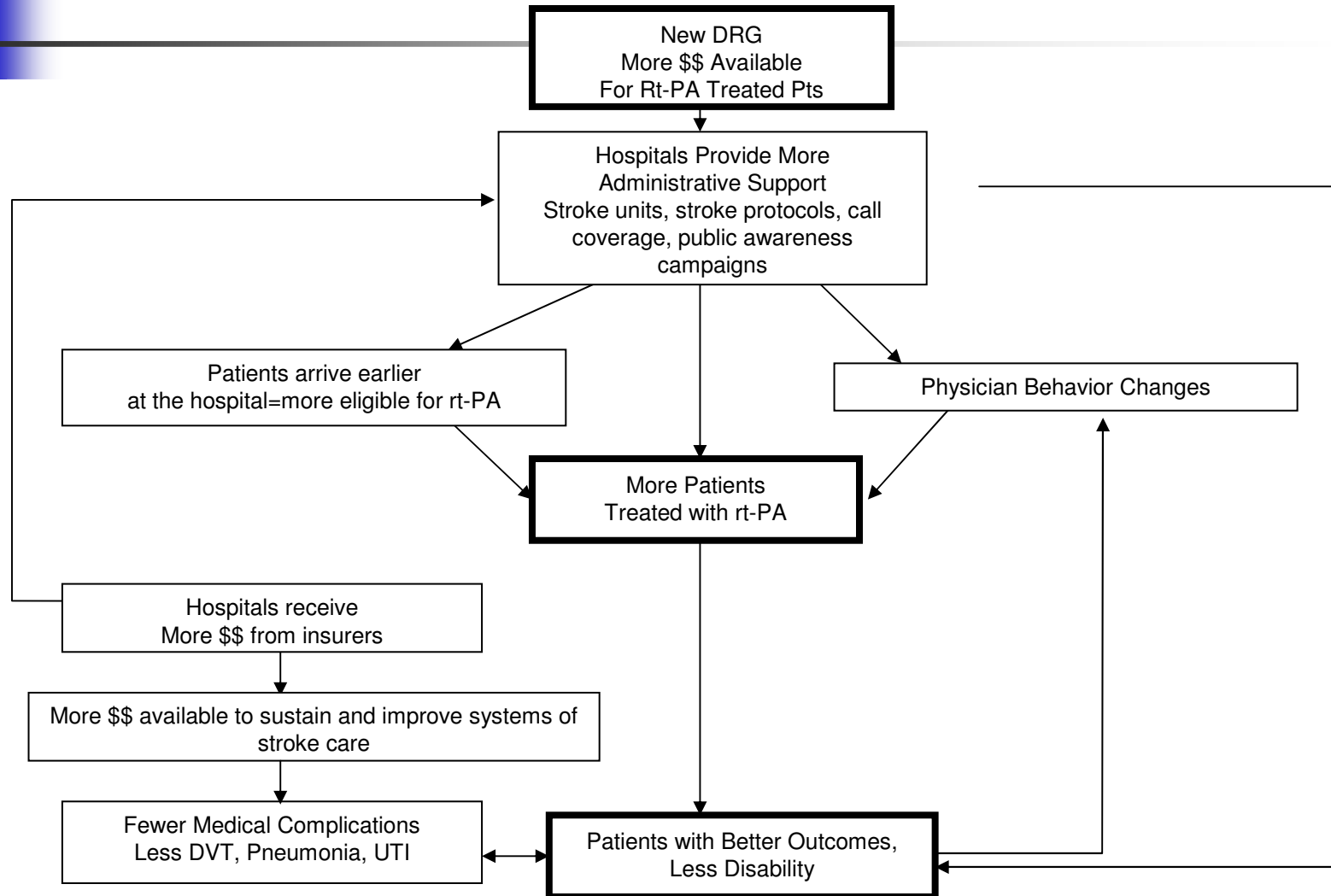




Why CMS Made New DRG 559

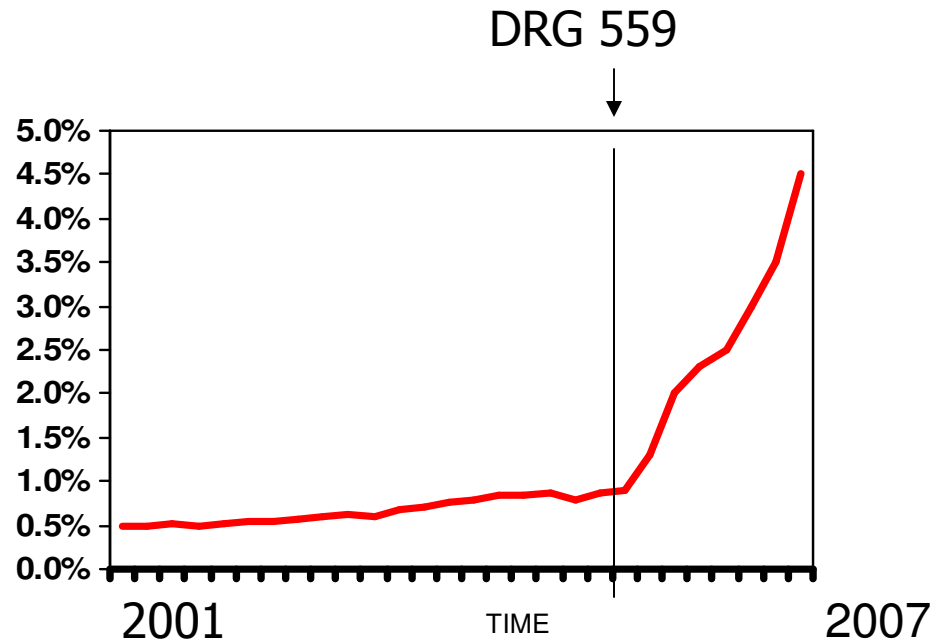
- **CMS was receptive to the proposal because proposal was specific and actionable, and it included the medical rational as well as the economic benefit for change**
 - Approximately 70% of stroke patients are over 65 years of age
 - 60% of stroke survivors are severely dependent
 - More than 20% of all stroke patients require institutional care at 3 months after onset. **t-PA decreases need for long-term care.**
 - Patients treated in DRGs 14/15 are the second leading contributor to Medicare post-acute care spending totaling **\$2.2 billion in FY 2002.**
 - Medicare **spends more on post-acute care** for these patients than what it pays for acute inpatient hospital care (~ \$1.6 Billion).

How will the new DRG Affect Quality of Care?

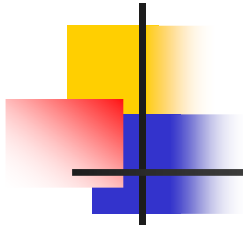


How will the new DRG affect Rt-PA Treatment Rates?

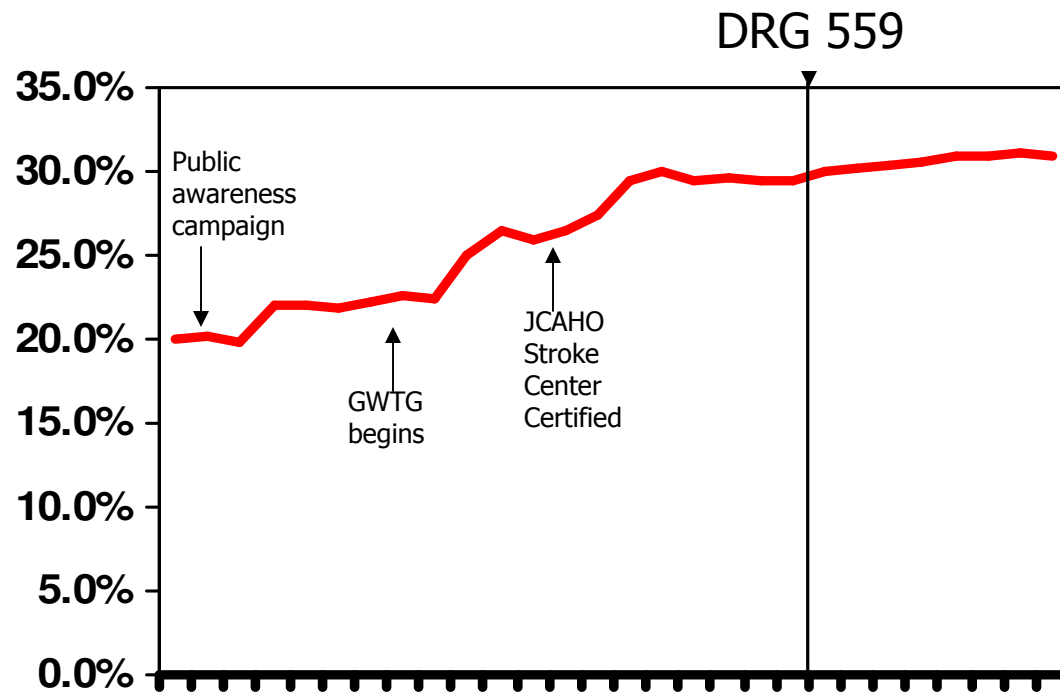
Hypothesis #1:



Maybe, for smaller hospitals not yet organized for stroke care....



Hypothesis #2



....More likely scenario for larger or more organized hospitals

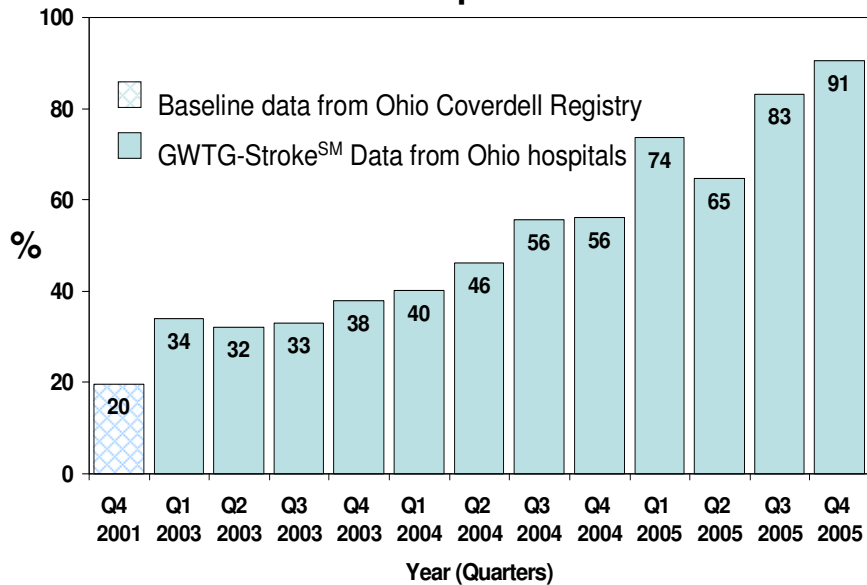


DRG 559 and Impact on Cost-Reimbursement Ratios

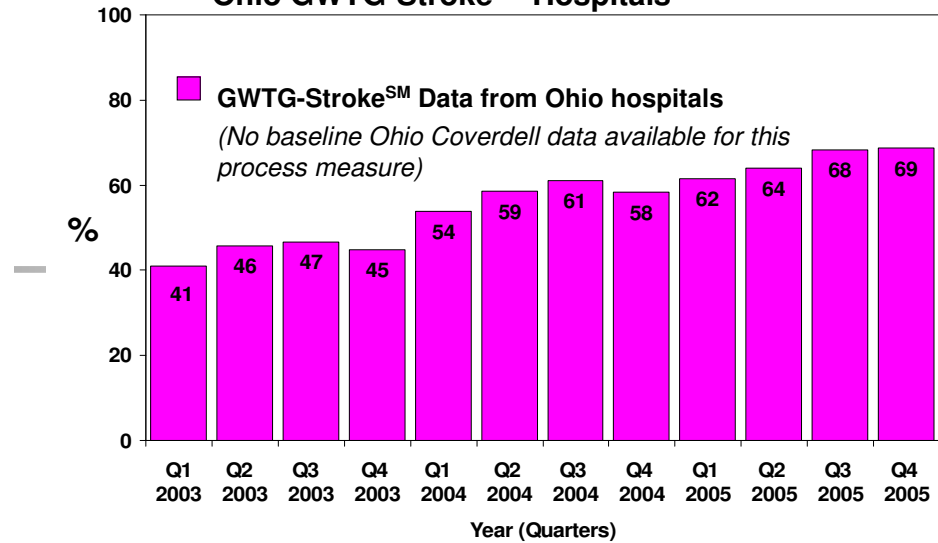
Comparison of the Hospital Cost Reimbursement Ratio for Thrombolytic Stroke Treatment Before and After DRG 559 During the Time Interval Between 2001 and 2004

	2001 CRR (N=5)	2002 CRR (N=18)	2003 CRR (N=23)	2004 CRR (N=21)	Summary CRR (95% CI) (N=67)
Before DRG 559	0.82	1.39	1.49	1.48	1.41 (0.98 to 2.28)
After DRG 559	0.91	0.91	0.85	0.69	0.82 (0.66 to 0.97)

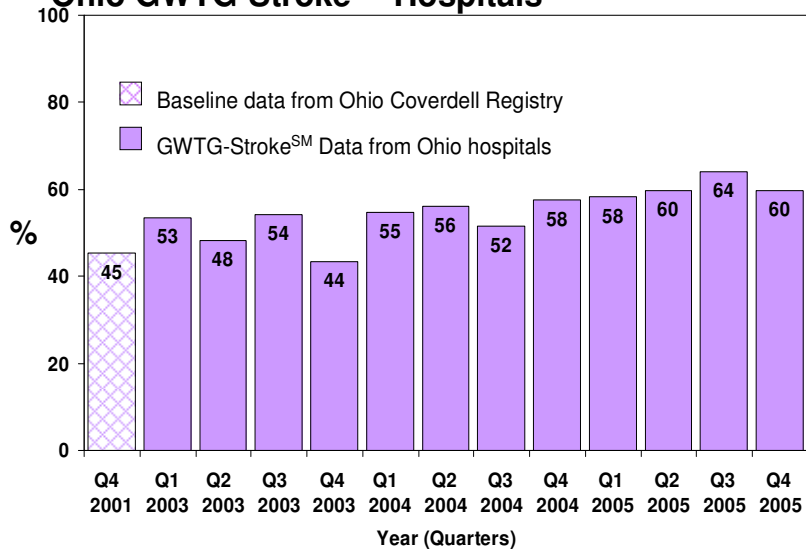
**Table 6: Documentation of Smoking Cessation Counseling Among Current Smokers
Ohio GWTG-StrokeSM Hospitals**



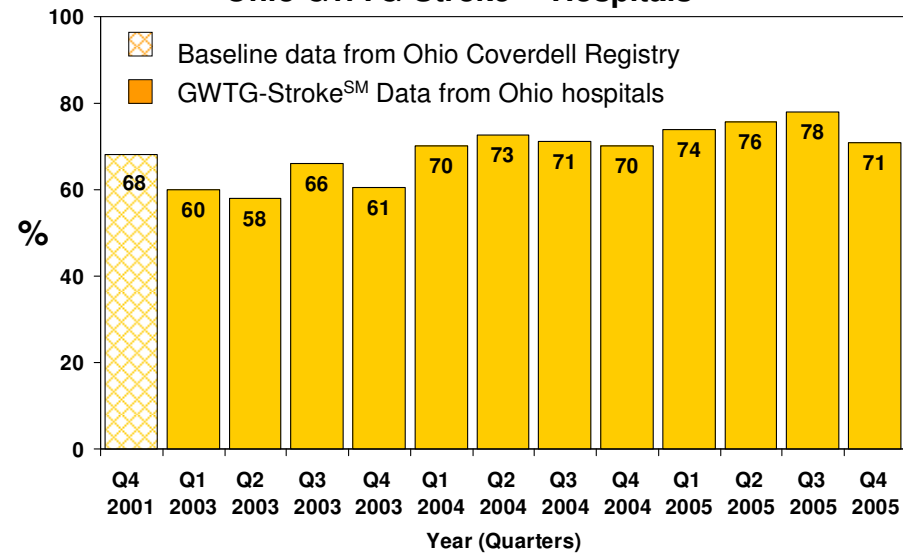
**Table 9: Ischemic Stroke or TIA Patients with Documented Lipid Profile
Ohio GWTG-StrokeSM Hospitals**

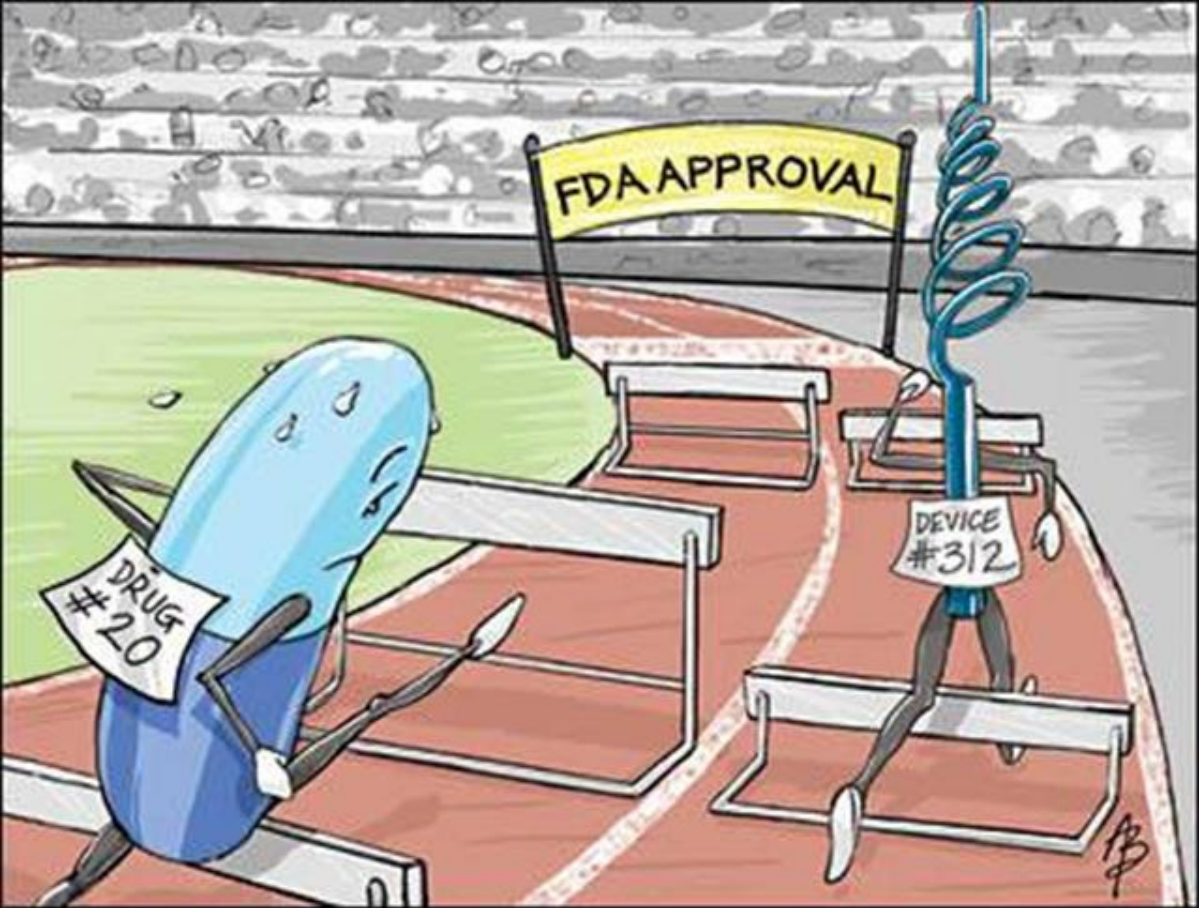
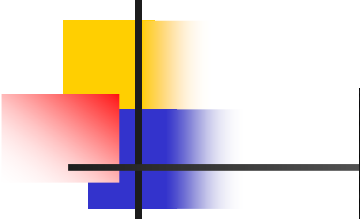


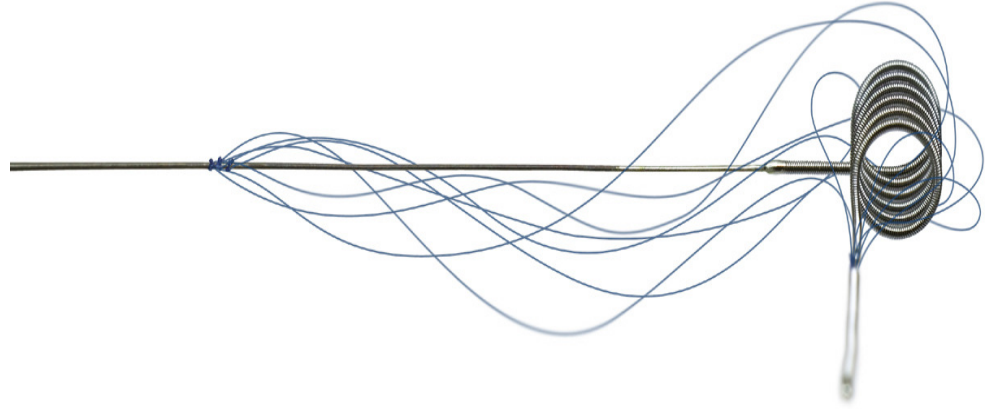
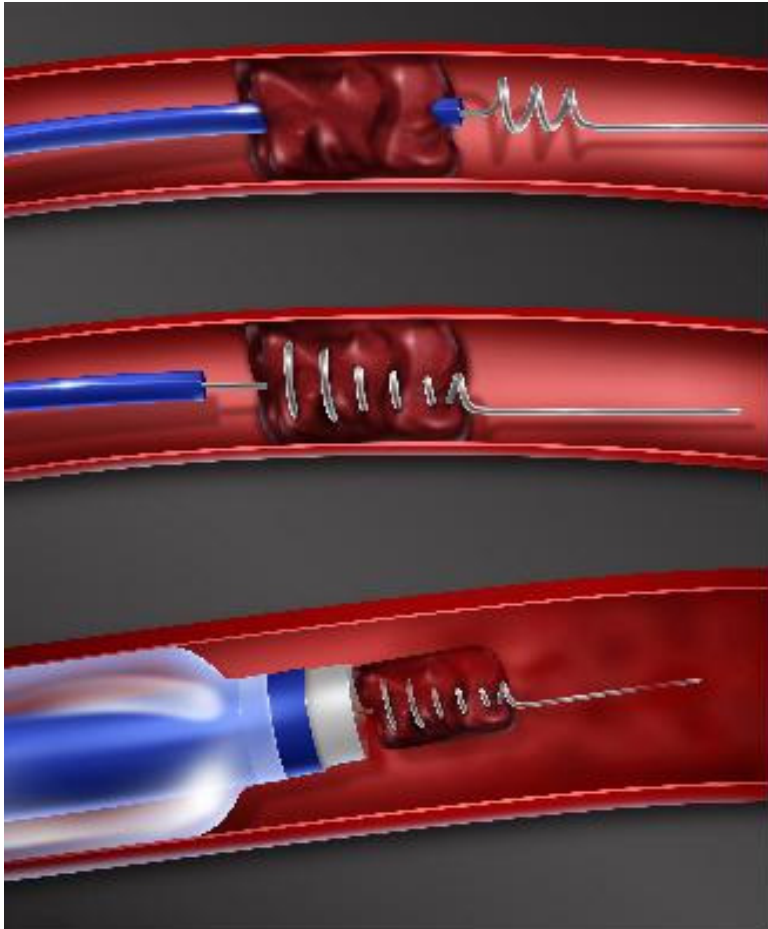
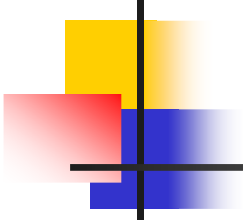
**Table 7: Dysphagia Screening Prior to Oral Intake in Ischemic Stroke Patients
Ohio GWTG-StrokeSM Hospitals**



**Table 8: Deep Venous Thrombosis Prophylaxis by Second Hospital Day in Nonambulatory Patients
Ohio GWTG-StrokeSM Hospitals**









Merci® Retriever – The First Device Approved for Clot Removal in Acute Ischemic Stroke

- **August 2004 - FDA**

The Merci Retriever is intended to restore blood flow in the neurovasculature by removing thrombus in patients experiencing ischemic stroke. Patients who are ineligible for treatment with intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

The Merci Retriever is also indicated for use in the retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vasculature.



What We Know Scientifically about Merci Retriever Device

- It reopens occluded intracranial arteries better than historical controls treated with heparin only.
- Subjects that have recanalization do better clinically than those that have no recanalization
- The rate of symptomatic ICH is similar to other acute stroke trials with severely affected patients.
- The mortality of patients treated with Merci Retriever in clinical trials is high but associated with delayed time to Rx. and severe baseline deficit.

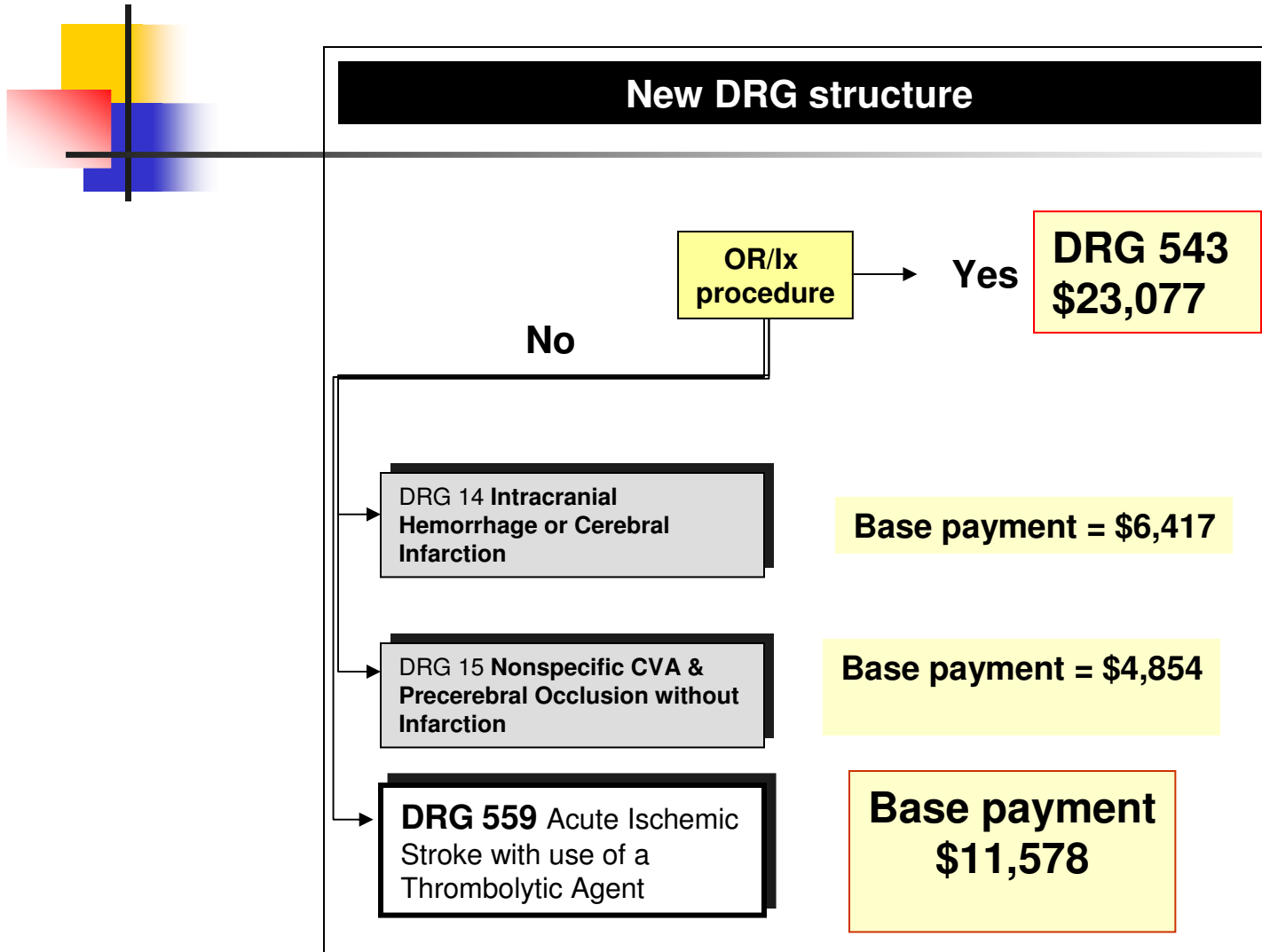


What We Don't Know Scientifically about Merci Retriever Device

- Is it efficacious and safe compared to standard therapy in patients not eligible for thrombolytic therapy (consider IV lytic trials of 3-6 hours from onset)?
- Is it more efficacious in patients treated with t-PA during the first three hours as compared to standard IV t-PA alone?
- Both of these questions are being addressed in the ongoing NINDS-funded IMS III and MR Rescue Trials – Concentric has been a very good partner in these trials.

CMS Final Rule – FY 10-2006

New Reality for Hospital Stroke Reimbursement

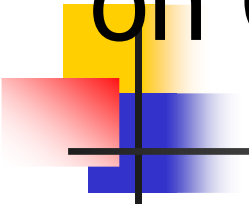


Potential Impact of Approved Devices on Clinical Trials of Acute Stroke



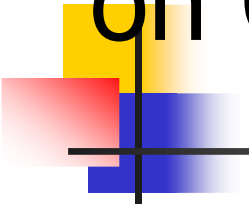
- Trials of other lytic therapies beyond 3 hours.
- Trials of other lytic therapies within 3 hours.
- Hypothermia and neuroprotection trials.

Potential Impact of Approved Devices on Clinical Trials of Acute Stroke



- **MR Rescue** – eligible subjects (not eligible for t-PA) up to 8 hours of onset treated with Merci Retriever vs. standard therapy
- Increased reimbursement to hospitals (\$23,000 for interventional stroke DRG) and interventionalists (\$1,500 and likely more) is an incentive to treat these sick patients with an approved device outside of trial

Potential Impact of Approved Devices on Clinical Trials of Acute Stroke

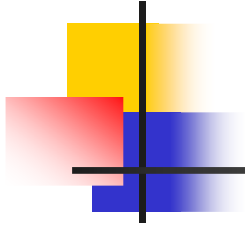


- **IMS III** – Patients with NIHSS of 10 or more within 3 hours of onset treated with standard IV t-PA or combined IV-IA approach, including use of Merci Retriever when indicated.
- Reimbursement to hospitals similar if DRG 559 is used in IMS III and catheters are supplied by study; interventionalist receives payment for study activity as well as can bill for angiogram.



Medical Devices Without Demonstration of Efficacy/Safety in Randomized Trials

- Clinical outcomes for directional coronary atherectomy appeared as good as or better than balloon angioplasty in a large registry and compared with historical controls
- While the device was embraced by the interventional cardiology community, randomized trials demonstrated either harm or no benefit in the intended patient populations.



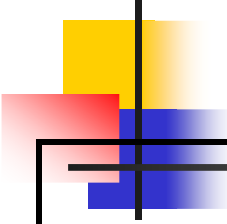
Physician Reimbursement?

Physician Reimbursement for Rt-PA Decision-Making and Treatment

	GCNK Team	Canada
Reimbursement per patient (mean for all)	\$347 (\$318)	
Reimbursement per t-PA Rx'd. patient	\$473	\$340 + \$232/call
Total time per t-PA patient	2.6 hrs	
Total time per patient not treated t-PA	1.2 hrs	
Neuro-interventionalist (n=42)	\$1484 (\$460 - IA t-PA)	\$946

Kleindorfer, et al Stroke. 2005

Physician Reimbursement for other Neuro procedures



	U.S. - Reimbursement per 30 minutes of physician time
Acute stroke evaluation	\$118
EEG	\$175
EMG + a single nerve conduction (no technical fee)	\$176
Outpatient comprehensive consult	\$143
Botox – one extremity	\$400



How to fix the physician reimbursement???

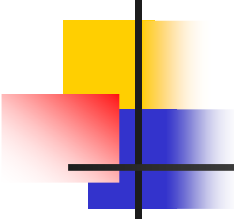
- Any proposed new code will be vigorously lobbied against by other, more powerful physician groups
- Always bill critical care when possible
- Consider lobbying the covered hospital, especially now with DRG 559

Canadian Stipends for Call Coverage

TABLE 3. Average Reimbursement for Stroke Neurologists in Canada 2002

Canadian Province	Consult Fee (1 st h)	Critical Care Fee	Weekend/After-Hours Premium	On-Call Stipend
Nova Scotia*	Alternate payment plan
New Brunswick	\$98.00	\$15.00/15 min	\$32.00	0
Quebec	\$96.75	\$75.00/15 min; first for 30 min, then \$25.00 each additional 15 min	\$31.93, 19:00–24:00 and on weekends; \$48.38, 24:00–07:00	0
Ontario	\$112.35	\$20.70	\$50.05 after-hours; 17.85 for visit from home to ER	\$500.00/d (stroke only)
Manitoba	\$130.00	\$20.00/15 min	\$39.00–\$65.00 depending on time; \$30.00 for coming in from home	\$150.00/d (neurology including acute stroke care)
Alberta*	\$140.36	\$42.32/15 min	\$72.18–\$173.74 depending on time	\$300.00/d (stroke call)
British Columbia	\$132.94	\$83.70/30 min	\$43.03–60.44 depending on time	\$740.00–\$850.00/d (neurology including acute stroke care)
Average	\$118.40	\$35.81		

Amounts are referable to 2002 when the survey was conducted. Amounts for the provinces of Saskatchewan, Newfoundland, and Prince Edward Island were not available for inclusion.



Telemedicine: Another opportunity for improved reimbursement?

- Proven feasible, reliable, and safe for helping remote sites give rt-PA
- Shown to increase rates of rt-PA
- Provides otherwise unavailable expertise to guide the decision
- May be the only way to have a primary stroke center available to the majority of U.S. citizens



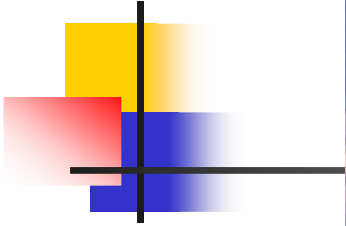
Current CMS Reimbursement for Telemedicine

- Only with two-way audio and video
- Only in “rural health professional shortage area” or “county not classified as a metropolitan statistical area”
- Yet many centers don’t meet this criteria that still need stroke neurology expertise before giving tpa

Reimbursement is A Powerful Force in Determining Medical Practice

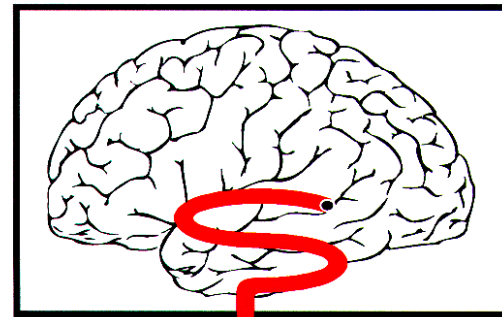


- Monitor use and reimbursement of new technology.
- Advocate for good reimbursement to hospitals and physicians for treatments proven to be cost-effective.
- Re-examine the relationship between FDA device approval and reimbursement/coverage (e.g. CREST Trial as a model).
- Better communication between FDA, CMS, and NINDS regarding approval and reimbursement for devices without proven clinical efficacy (yearly meetings new devices/drugs)



 The Neuroscience Institute
University Hospital • Cincinnati, Ohio

Stroke



T E A M
Greater Cincinnati Northern Kentucky