AANS Meeting 2011

Presented by Joe Sam Robinson, Jr., M.D.

Neurosurgical Practice Guidelines & Levels of Evidence

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Astrologer diagnosing and prognosticating medical issues by studying the position of the stars (German manuscript, 1464)

Rembrandt “The Anatomy Lesson of Doctor Tulp” (1632)

Evidence-Based Medicine (EBM)

- is defined as "conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."

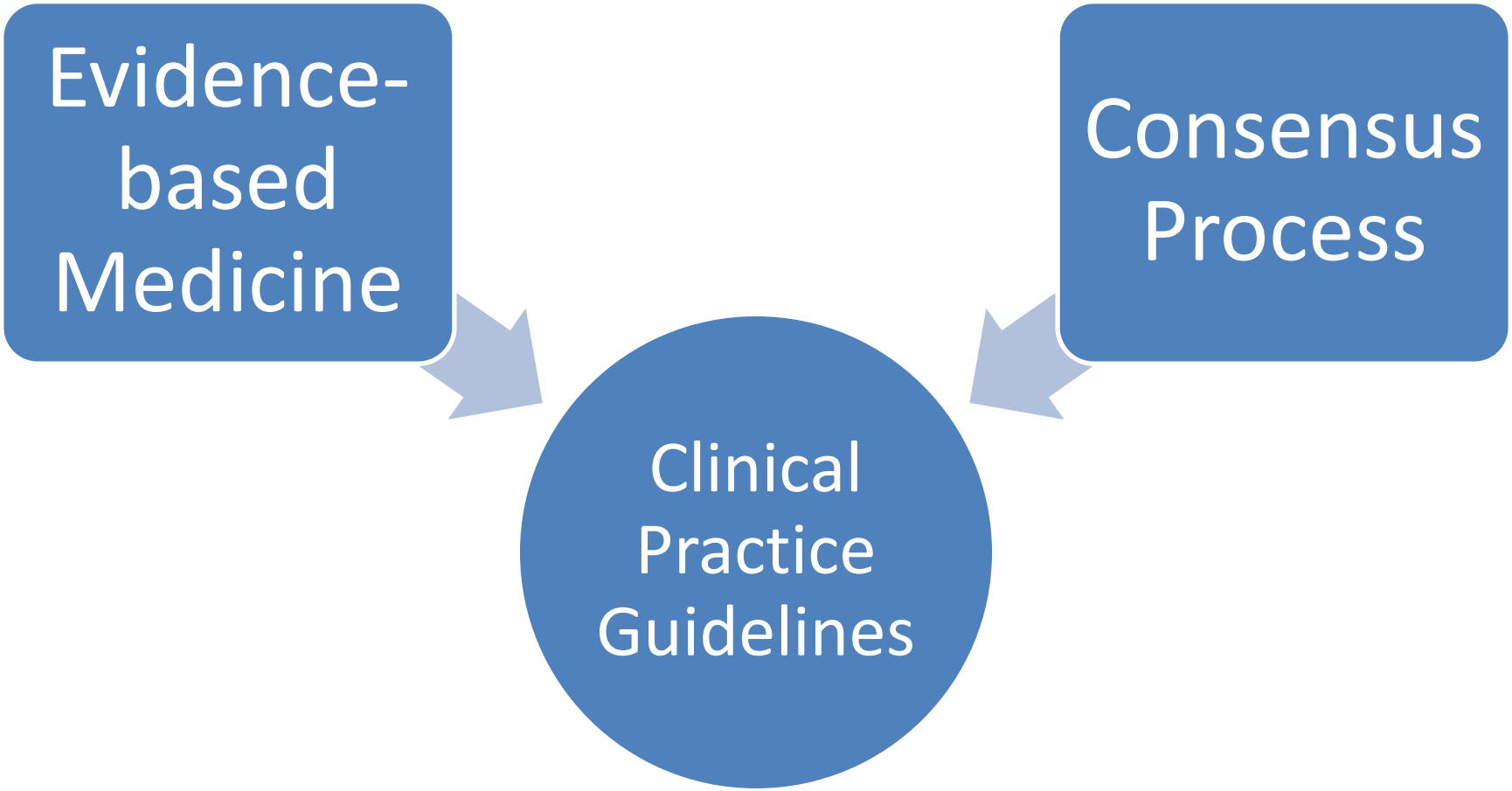
Sackett et al. 1997

Clinical Practice Guidelines (CPGs)

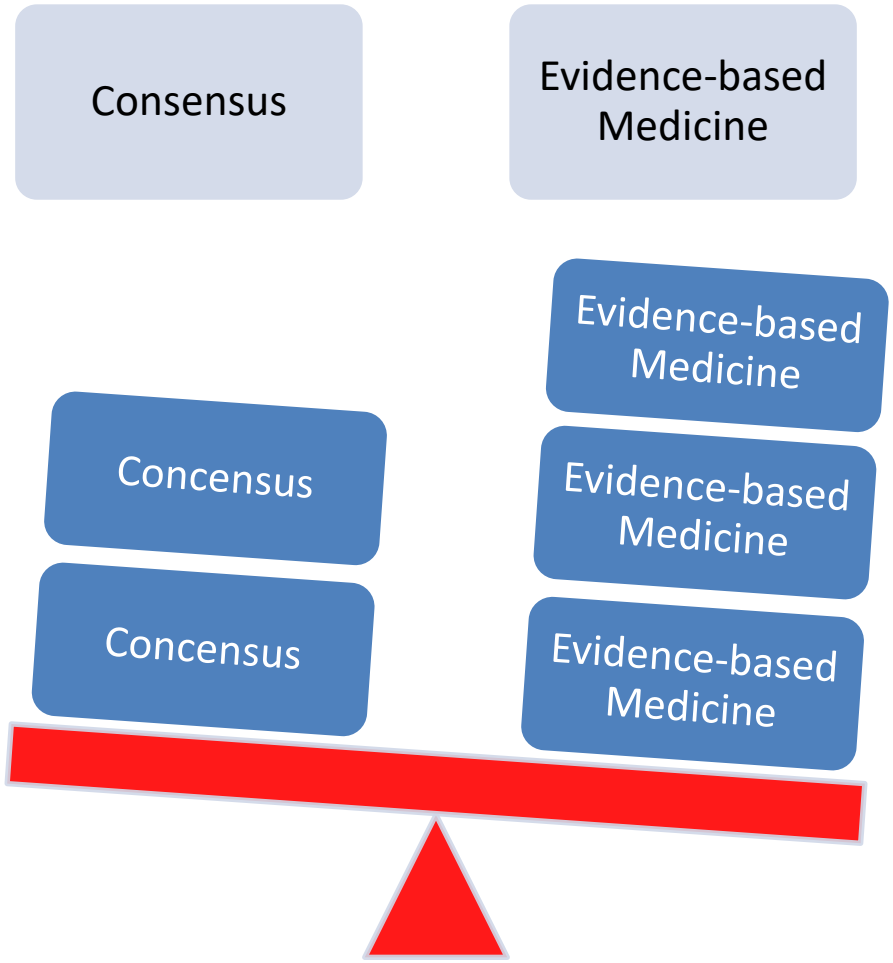
- are defined according to the Institute of Medicine (1990) as "*systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.“**
- In French - *Lignes Directrices Cliniques.*

* Field, M., and K. Lohr, eds. 1990. *Clinical Practice Guidelines: Directions for a New Program 8. Washington, DC: Institute of Medicine.*

Clinical Practice Guidelines (CPG) Development



The scales are tipping toward EBM



US Preventive Services Task Force Classification of Clinical Evidence

- Level I: Evidence obtained from at least one properly designed randomized controlled trial (RCT).
- Level II-1: Evidence obtained from well-designed controlled trials without randomization.
- Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- Level II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence.
- Level III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Study Goal

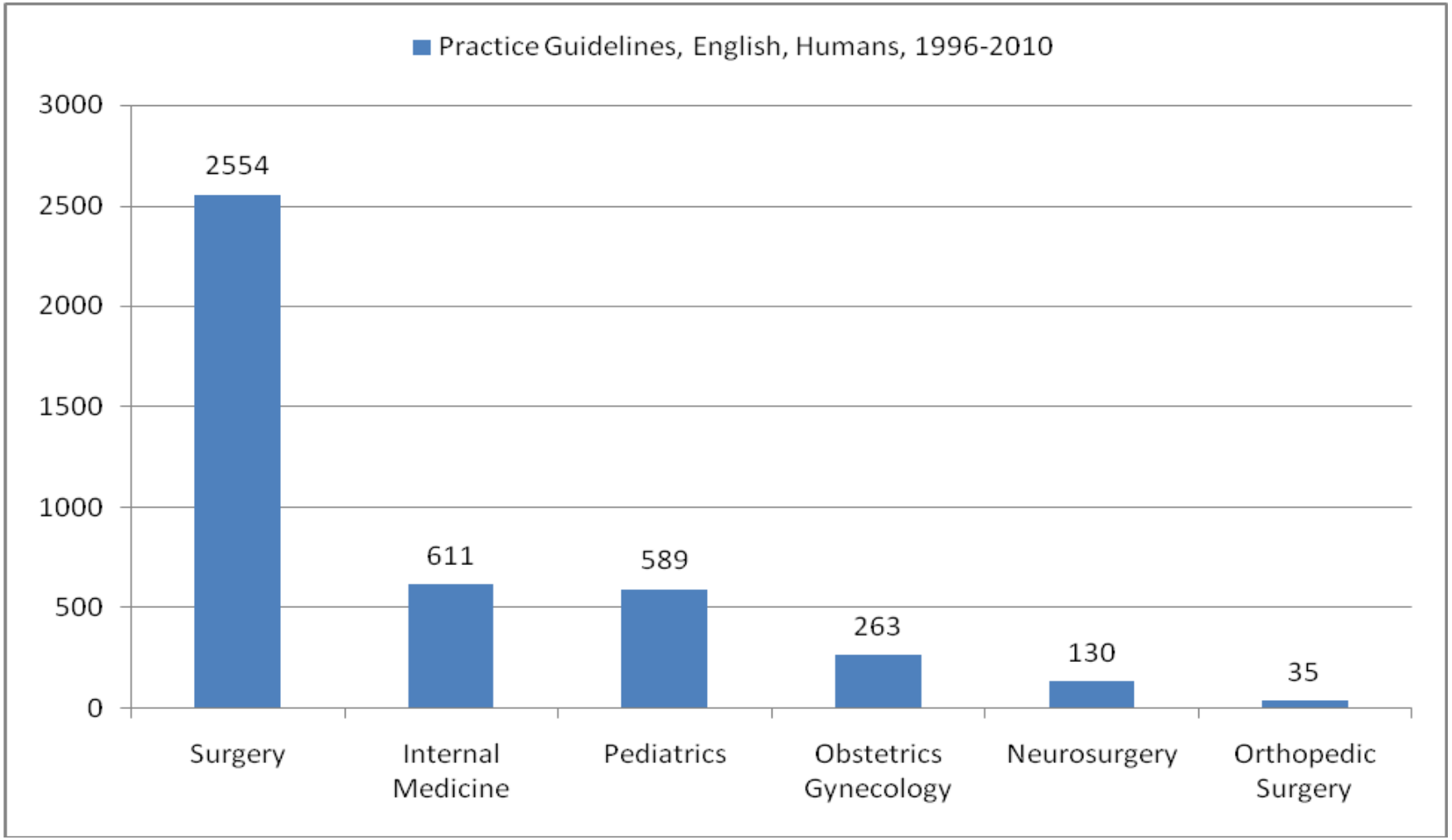
- At present, neurosurgical practice is confronted by numerous challenges related to indications for best surgical practice, basic outcomes, as well as cost of care. To explore the comprehensiveness of practice guidelines published in the field of neurosurgery we searched PubMed for practice guidelines. Special attention was devoted to spine fusion due to the exponential rise in spine fusion rates in the United States in the last two decades.

Methods

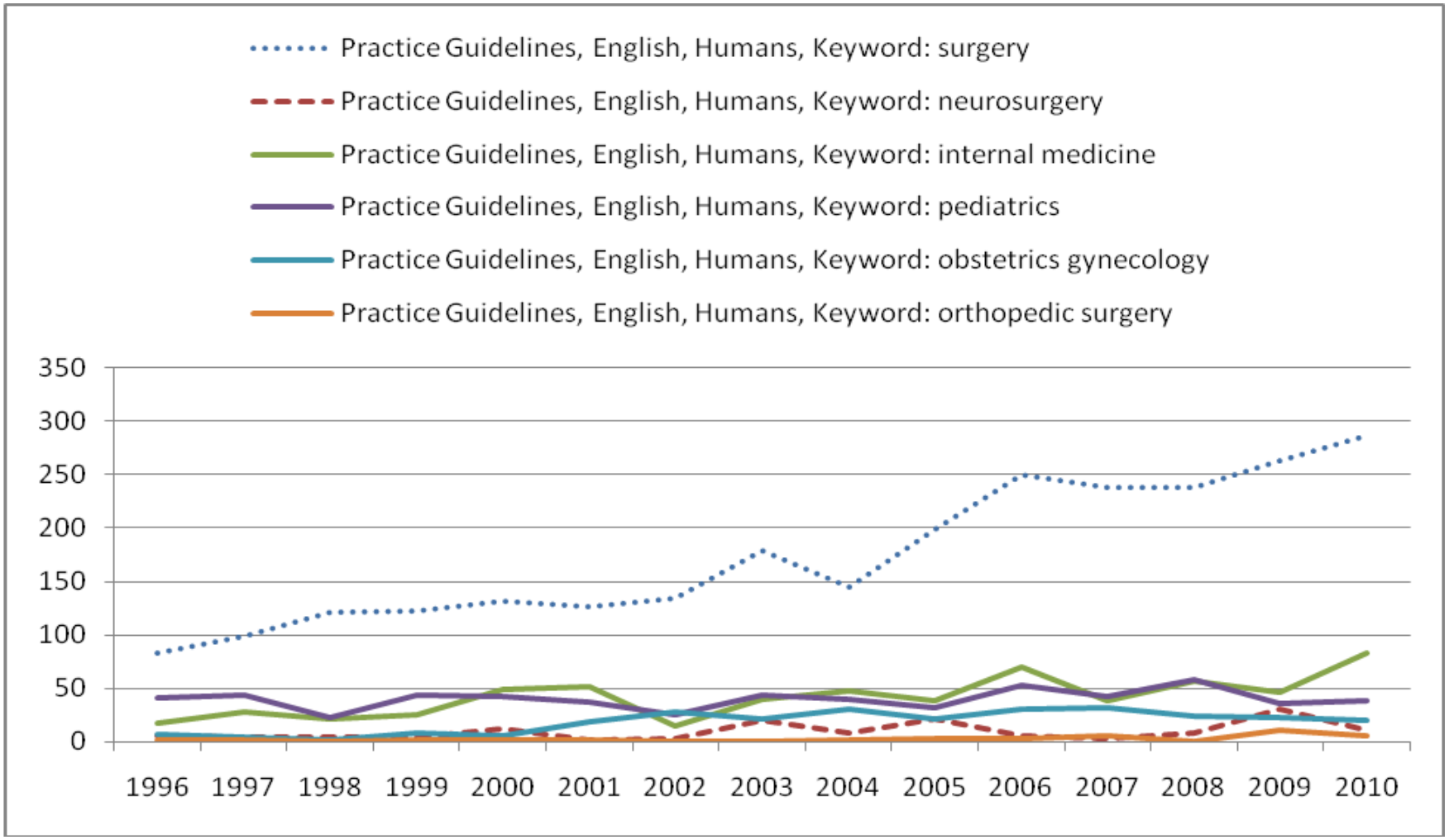
- PubMed is a free database accessing primarily the MEDLINE database of references and abstracts on life sciences and biomedical topics. The United States National Library of Medicine (NLM) at the National Institutes of Health maintains the database as part of the Entrez information retrieval system. PubMed was first released in January 1996.
- Contents of journals approved by PubMed are indexed per type of article including “Practice Guidelines.” In this study, PubMed was queried for practice guidelines published in “English” and related to “Humans.” Obviously, an article published in English does not necessarily mean it was published in an American journal.
- The following keywords were used to explore practice guidelines related to:
- “Surgery”
- “Neurosurgery”
- “Internal medicine”
- “Pediatrics”
- “Obstetrics Gynecology”
- For comparison purposes, practice guidelines pertaining to four major neurosurgical interventions were studied:
- Brain tumor surgery.
- Brain aneurysm clipping/coiling.
- Spine fusion.
- Discectomy.

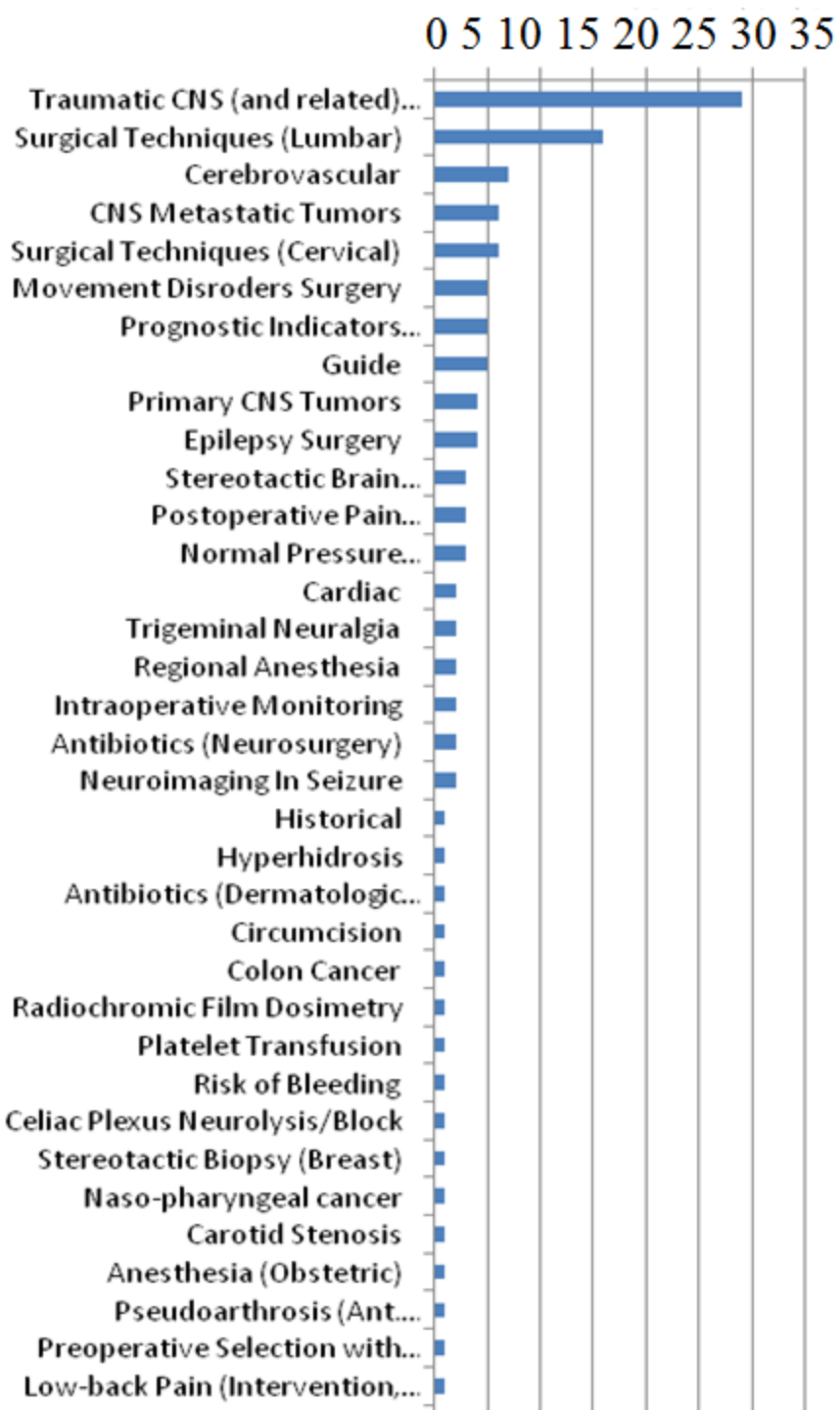
Results

Neurosurgical Practice Guidelines Compared with Different Specialties (Numbers)



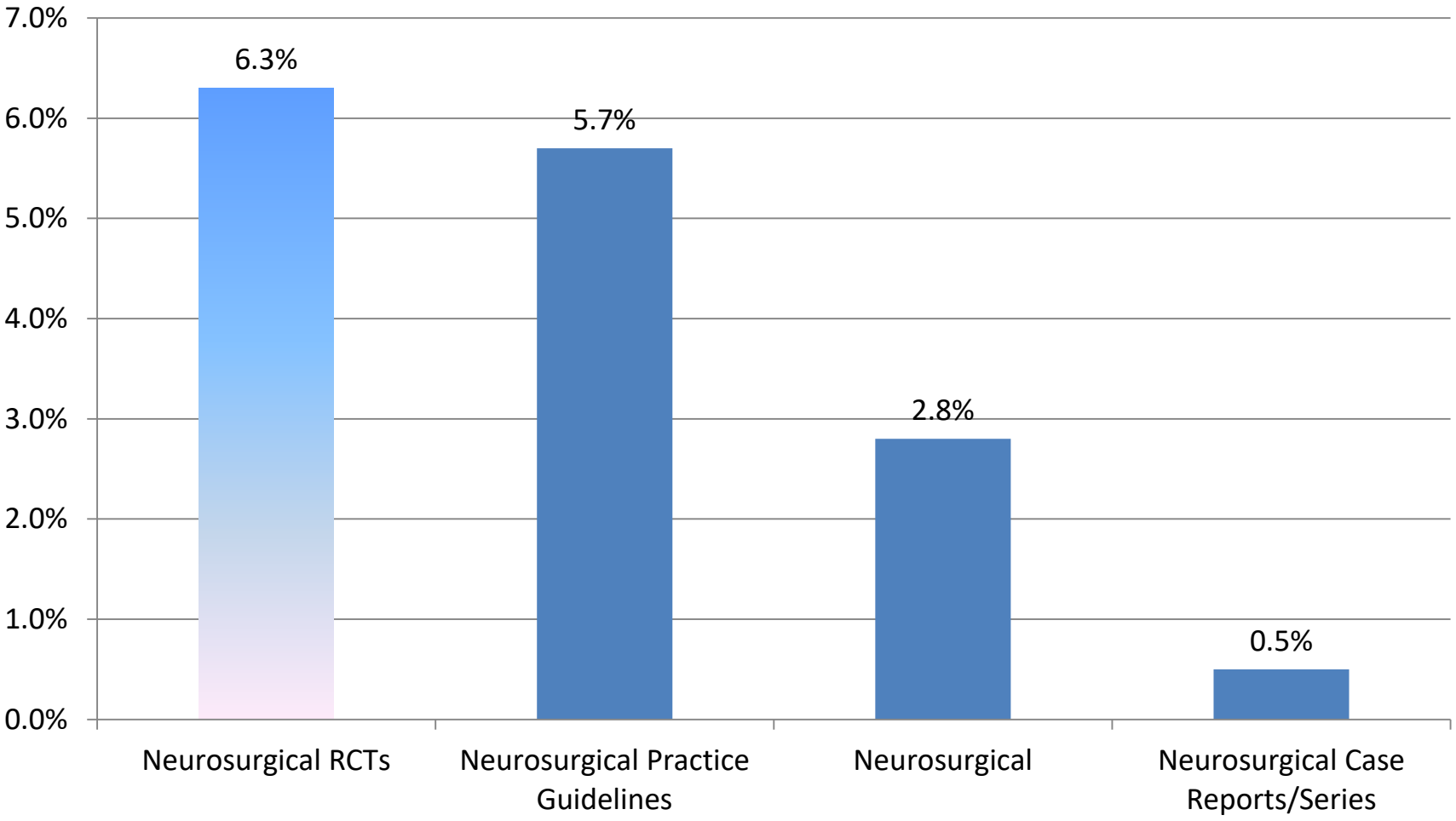
Neurosurgical Practice Guidelines compared with Different Specialties (Trends)





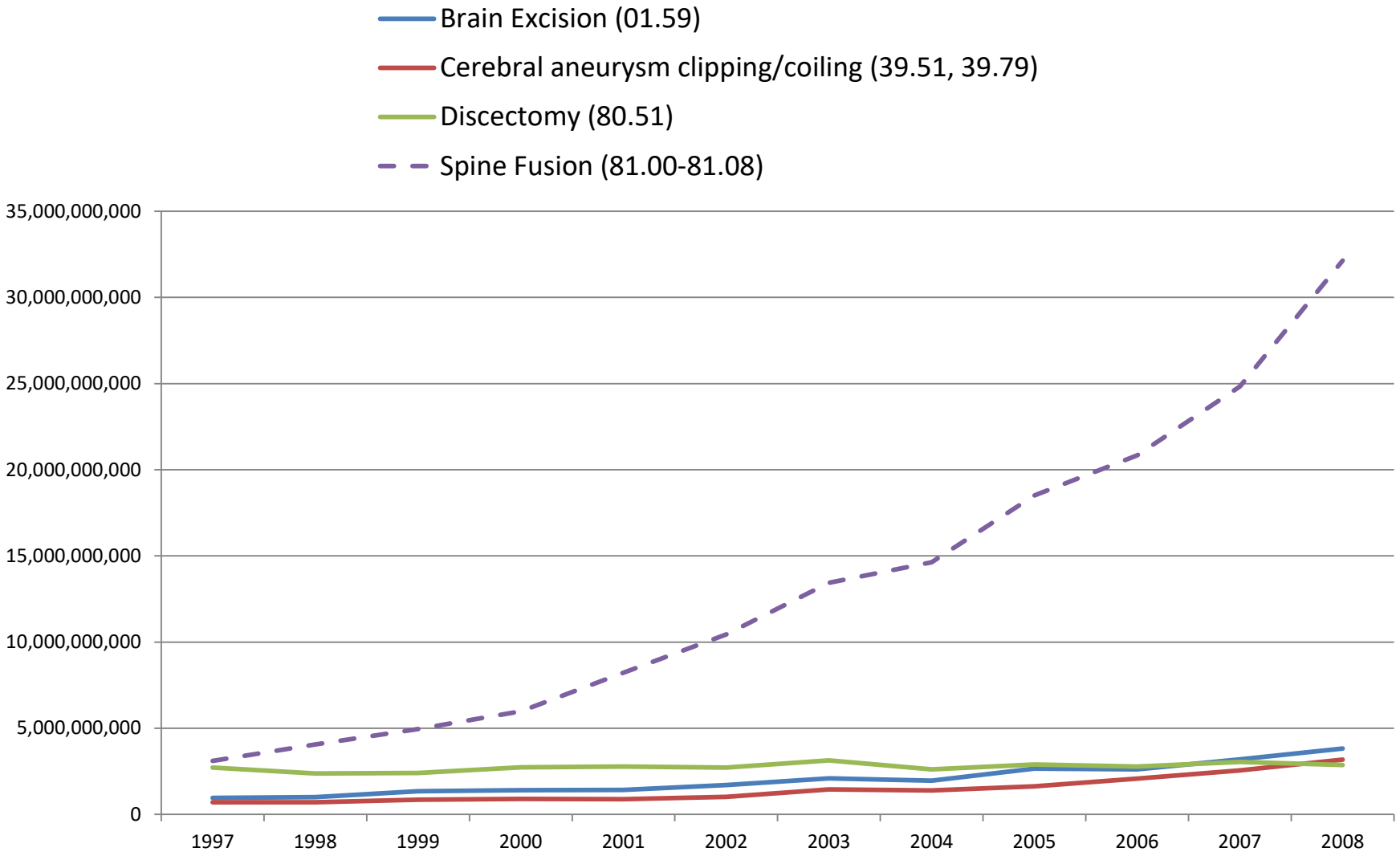
Breakdown of Neurosurgery Practice Guidelines Published in English and Indexed by PubMed 1996-2010

Percentage of cost inclusion in different types of neurosurgical literature 1996-2010



Spine Fusion Practice Guidelines As an Example

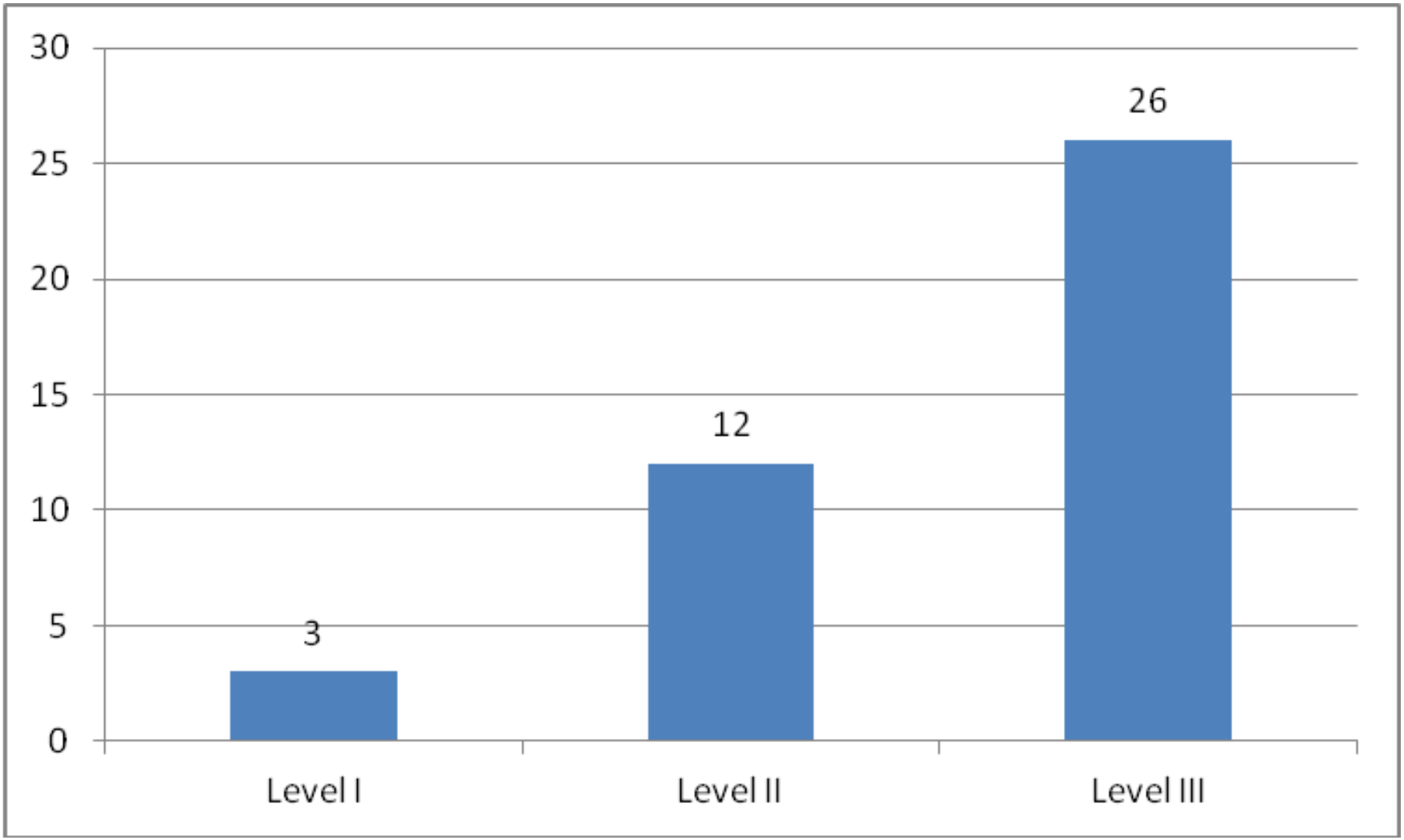
Aggregate Hospital Charges $ for Neurosurgical Procedures in the United States



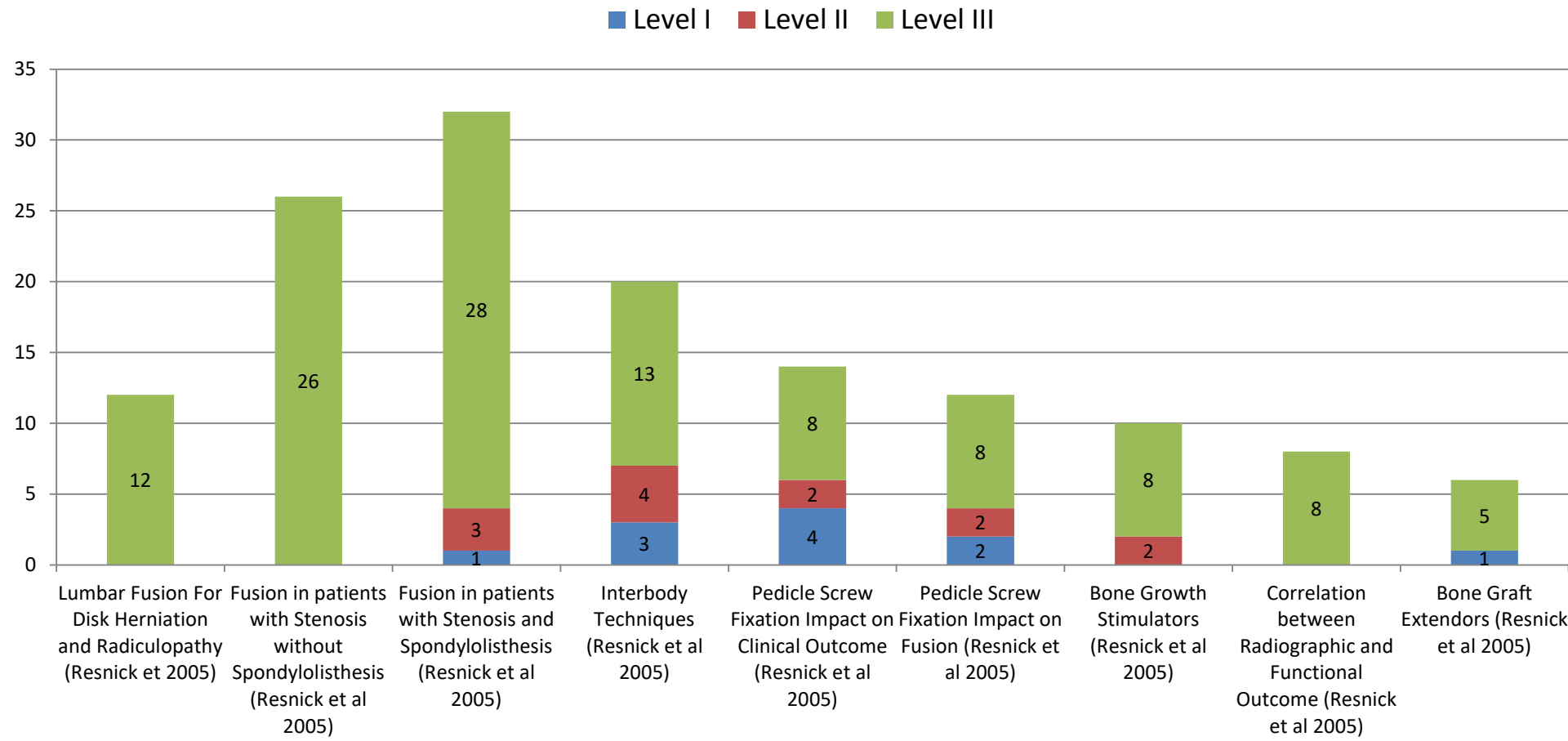
42 Recommendations: Method of Analysis

	Source	Year	Level I	Level II	Level III
Anterior cervical discectomy and ACD with fusion (ACDF) are associated with longer term (12 months) improvement in certain motor functions compared to PT. However, comparable clinical improvements with PT or cervical immobilization therapy are also present in these clinical modalities	AANS/CNS	2009	1	0	0
The addition of pedicle screw fixation to PLF increases fusion success rates when assessed based on plain x-ray films with dynamic imaging.	AANS/CNS	2005	1	1	1
The use of lumbar fusion as a treatment standard for carefully selected patients with low-back pain intractable to the best medical management.	AANS/CNS	2005	1	0	0
Association between clinical outcome and pseudarthrosis with variable incidence of symptomatic and asymptomatic pseudarthroses	AANS/CNS	2009	0	0	1
Revision of a symptomatic pseudarthrosis may be considered because arthrodesis is associated with improved clinical outcome	AANS/CNS	2009	0	0	1
Posterior approaches may be associated with higher fusion rates following repair of an anterior pseudarthrosis	AANS/CNS	2009	0	0	1
Pseudarthrosis is best assessed through the absence of motion detected between the spinous processes on dynamic radiographs	AANS/CNS	2009	0	1	0
The measurement of interspinous distance on dynamic radiographs of >or= 2 mm is a more reliable indicator for pseudarthrosis than angular motion of 2 degrees based on Cobb angle measurements	AANS/CNS	2009	0	1	0
The combination of interspinous distance measurements and identification of bone trabeculation is unreliable when performed by the treating surgeon	AANS/CNS	2009	0	1	0
Identification of bone trabeculation on static radiographs should be considered a less reliable indicator of cervical arthrodesis than dynamic films	AANS/CNS	2009	0	0	1
Autograft bone harvested from the iliac crest, allograft bone from either cadaveric iliac crest or fibula, or titanium cages and rectangular fusion devices, with or without the use of autologous graft or					

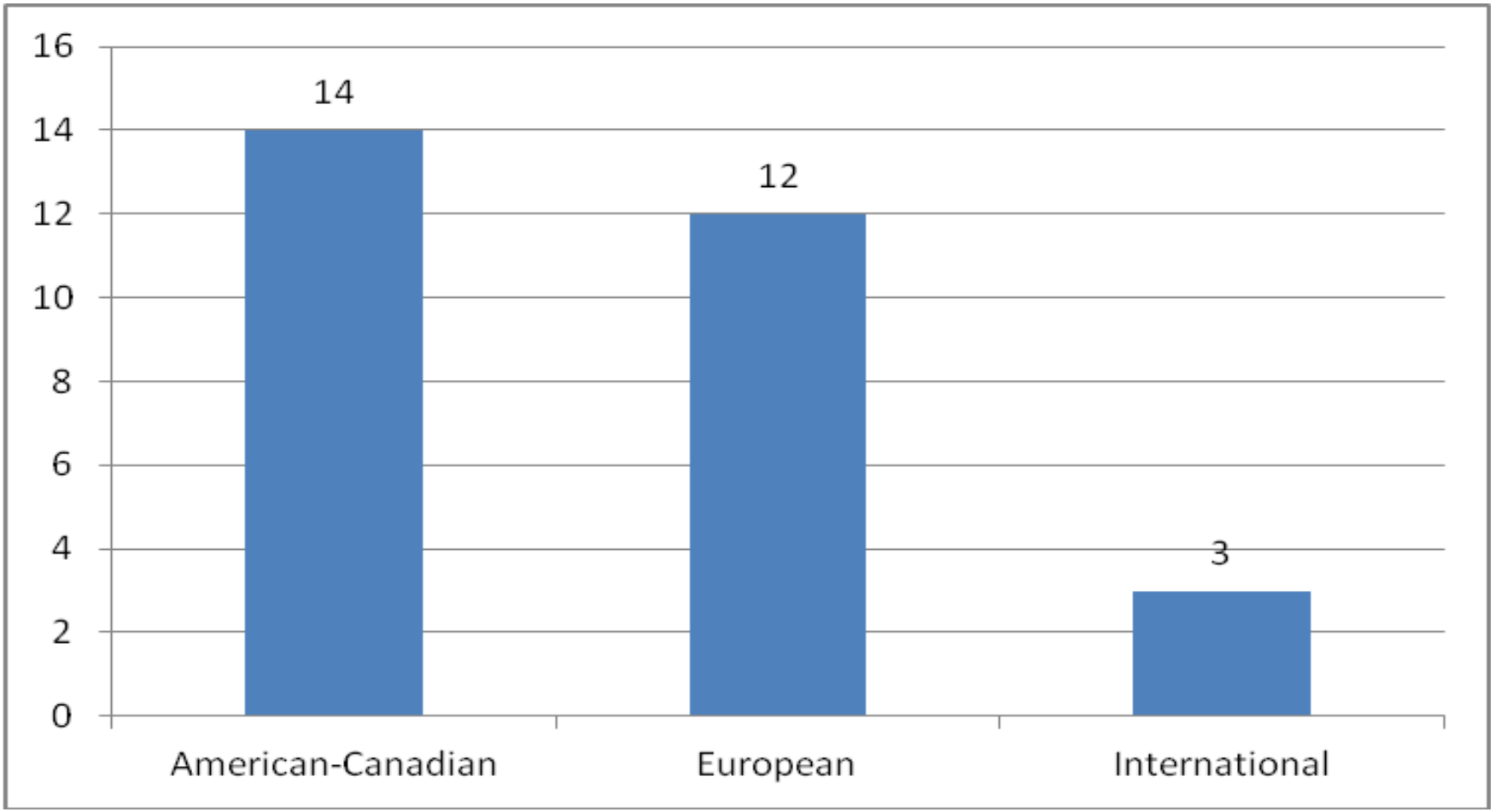
Levels of evidence for recommendations related to Spine Fusion



Topic of Practice Guidelines Papers related to Spine Fusion



A Potential Source of Conflict:
Different Sources of Practice Guideline Papers related to Spine Fusion



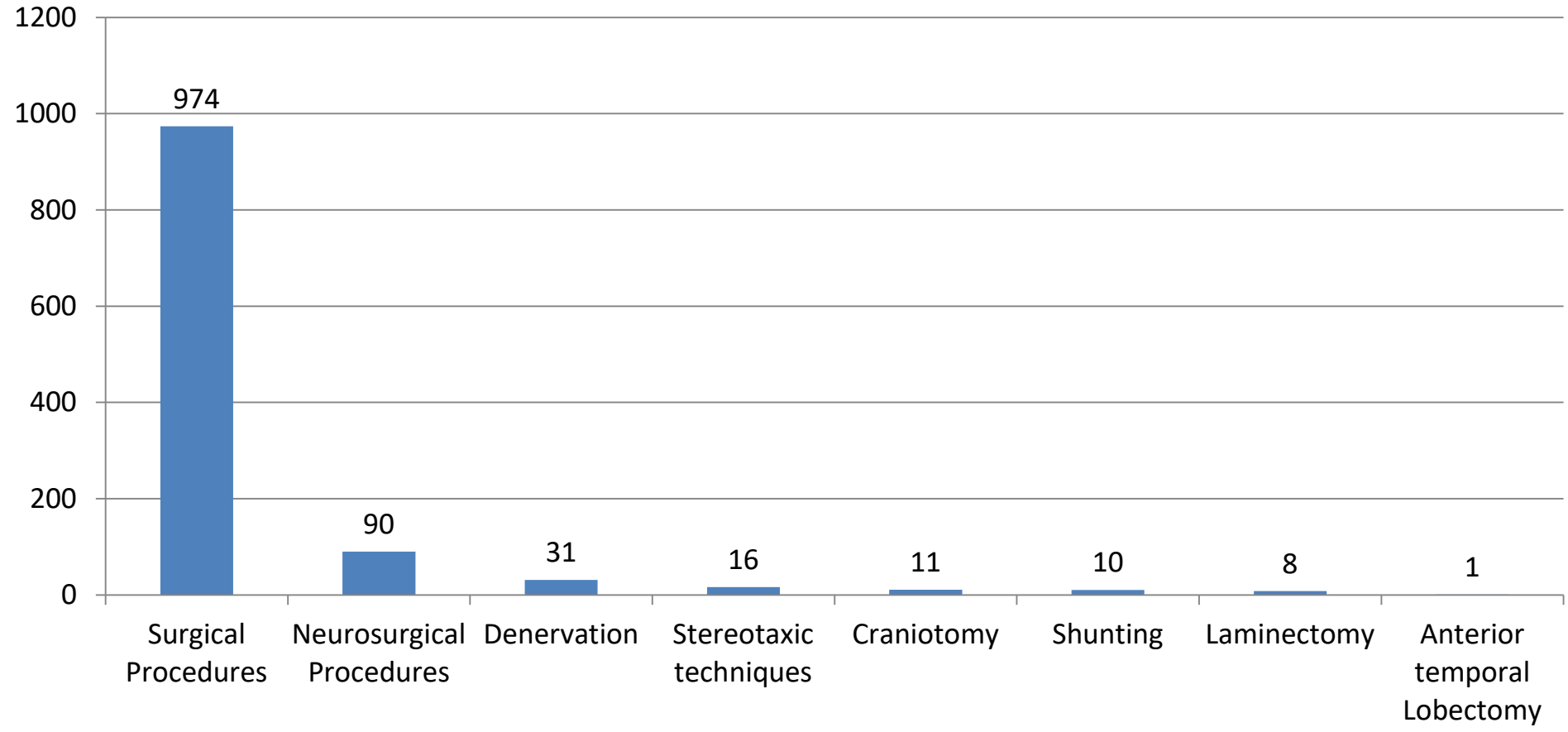
A Way to Clarification:
Clinical Practice Guideline Certification

CPG Certification Agencies

- National Guideline Clearinghouse (NGC) - USA
- Guidelines International Network - International
- Cochrane Collaboration - International
- Agence d'évaluation des technologies et des Modes d'intervention en santé - Canada.
- eGuidelines.co.uk and National Institute for Health and Clinical Excellence (NICE) - United Kingdom.
- Clinical Practice Guidelines Portal - Australia.


Congress
1989
Agency for Health Care Policy and Research
Agency for Health Care Research and Quality
National Guideline Clearinghouse

Neurosurgical Practice Guideline Certification by National Guideline Clearinghouse (NGC)



Criteria for Inclusion of Clinical Practice Guidelines in NGC

- All of the criteria below must be met for a clinical practice guideline to be included in NGC.

1. The clinical practice guideline contains systematically developed statements that include recommendations, strategies, or information that assists physicians and/or other health care practitioners and patients to make decisions about appropriate health care for specific clinical circumstances.
2. The clinical practice guideline was produced under the auspices of medical specialty associations; relevant professional societies, public or private organizations, government agencies at the Federal, State, or local level; or health care organizations or plans. A clinical practice guideline developed and issued by an individual not officially sponsored or supported by one of the above types of organizations does not meet the inclusion criteria for NGC.
3. Corroborating documentation can be produced and verified that a systematic literature search and review of existing scientific evidence published in peer reviewed journals was performed during the guideline development. A guideline is not excluded from NGC if corroborating documentation can be produced and verified detailing specific gaps in scientific evidence for some of the guideline's recommendations.
4. The full text guideline is available upon request in print or electronic format (for free or for a fee), in the English language. The guideline is current and the most recent version produced. Documented evidence can be produced or verified that the guideline was developed, reviewed, or revised within the last five years.

New Criteria

- The U.S. Congress, through the *Medicare Improvements for Patients and Providers Act of 2008*, solicited the Institute of Medicine (IOM) to undertake a study on the best methods used in developing clinical practice guidelines. The IOM developed eight standards for developing rigorous, trustworthy clinical practice guidelines

IOM Standards for Developing Trustworthy CPGs

March 2011

1. Establishing transparency
2. Management of conflict of interest (COI)*
3. Guideline development group composition
4. Clinical practice guideline–systematic review intersection
5. Establishing evidence foundations for and rating strength of recommendations
6. Articulation of recommendations
7. External review*
8. Updating

STANDARD 5
Establishing evidence foundations for and rating strength of recommendations

- For each recommendation, the following should be provided:
- An explanation of the reasoning underlying the recommendation, including:
  - A clear description of potential benefits and harms.
  - A summary of relevant available evidence (and evidentiary gaps), description of the quality (including applicability), quantity (including completeness), and consistency of the aggregate available evidence.
  - An explanation of the part played by values, opinion, theory, and clinical experience in deriving the recommendation.
- A rating of the level of confidence in (certainty regarding) the evidence underpinning the recommendation.
- A rating of the strength of the recommendation in light of the preceding bullets.
- A description and explanation of any differences of opinion regarding the recommendation.

Do Guidelines comply with these criteria?

Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 11: interbody techniques for lumbar fusion

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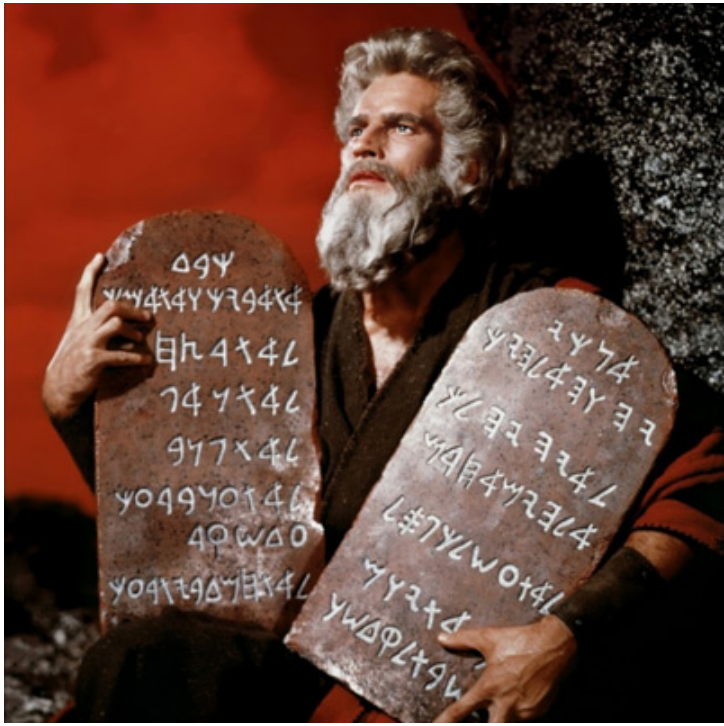
NHS
National Institute for Health and Clinical Excellence

Lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine

American	English	Criterion
Ø	Ø	1. Establishing transparency
Ø	Ø	2. Management of conflict of interest (COI)
Ø	Ø	3. Guideline development group composition
Ø	Ø	4. Clinical practice guideline–systematic review intersection
√	Ø	5. Establishing evidence foundations for and rating strength of recommendations
√	√	6. Articulation of recommendations
Ø	Ø	7. External review
Ø	Ø	8. Updating

Suggested Additions

9. Cost consideration
10. Long-term follow-up and cost-benefit analysis
11. The advantages and disadvantages of biomarkers versus actual patient outcome should be strongly considered
12. A provision to allow new procedures that contravene practice guidelines
13. A provision to measure patient compliance with the prescribed treatment
14. A mechanism for funding high-grade studies on new technologies for which great amount of societal benefit can be achieved.
15. CONSORT criteria should be used by the NGC to better grade quality of research
16. An appeal mechanism



Why is this important?

Why is this important?

I

Physician Practice Control and Regulation Mechanisms are increasing

	Government Medicare, Medicaid, Tricare coverage policies	Private Insurance Coverage Policies	InterQual evidence-based clinical decision support criteria	Joint Commission	State Board and Licensing Criteria	TORT Law	Professional Societies	FDA
Pretreatment	√	√			√			√
Posttreatment			√	√	√	√	√	√

Because of the national financial healthcare crisis coupled with improved electronic data collection, such regulation is likely to increase in the future

Why is this important?

II

When intellectually appropriate toward effectuation of a desired outcome, such control mechanisms are liberty to make use of unvalidated and incomplete practice guidelines to potentially suppress innovation and restrict appropriate access to care

Why is this important?

III

- The 8 standards advocated by IOM (let alone our 7 suggestions) are not applied at all to:

1. Present neurosurgical guidelines
2. Any of the organizations that regulate healthcare expenses
3. The committee of 15 mandated under The Patient Protection and Affordable Care Act 2010

Why is this important?

IV

- As an asset in decision making, if physicians advocate and support extensive enquiries into appropriate clinical guidelines they will be empowered to exercise their ethical responsibilities to better protect their patients against capricious and arbitrary intervention from those agencies primarily interested in short term cost savings and aggregation of institutional power.

Main Points of the Presentation

- Evidence-based medicine is important and should be used to work out clinical practice guidelines
- Relatively few clinical practice guidelines has been published
- Most clinical practice guidelines are based on low grade clinical evidence
- Cost should be considered in practice guidelines
- Practice guidelines issued by different organization with potential for confliction
- Certification process is established by the Agency for Health Care Research & Quality to resolve these issues
- 8 principles/standards are worked out by the Institute of Medicine to regulate the certification process
- Extensive revision of criteria suggested
- Present and potential importance of practice guidelines highlighted.

Thank you