



Grand Rounds 2022

**Presented in Macon, GA
By Dr. Joe Sam Robinson, Jr., M.D.**

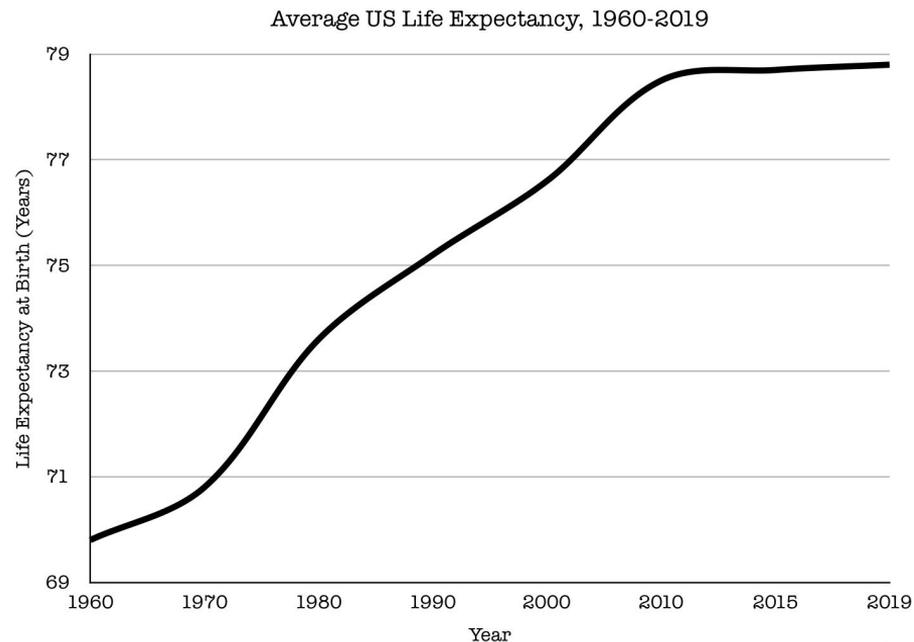


A Consideration of Clinical Guidelines, Opaque, Inefficient Healthcare Rationing, and Cost Control

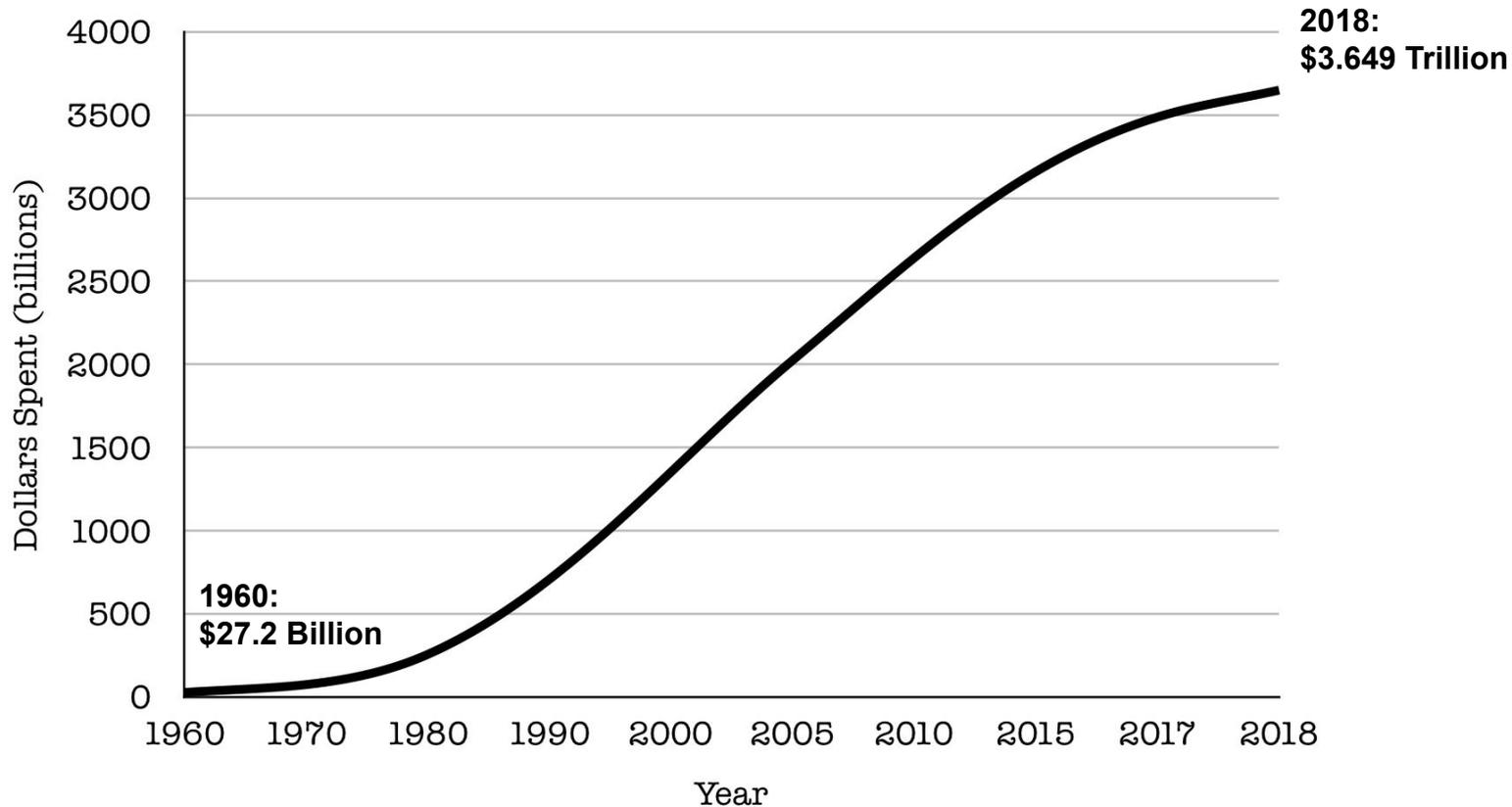
Jihyun Moon, Abdulraheem Kaimari, Zaid Al-Husein, Sara Auger, Harold Groce, MIP, and Joe Sam Robinson, Jr., M.D.

The Rising Benefits of Contemporary Healthcare

- Higher life expectancy
- Lower mortality rates
- Higher quality of life
- Less stress and worry over potential injuries or sickness



Increasing Costs: US Healthcare Expenses (1960-2018)



**Rising Healthcare
Costs**

**Increasing Benefits
of Healthcare**



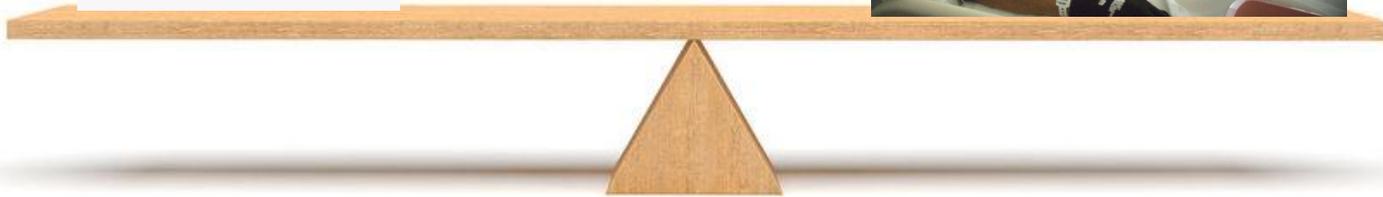


The US Healthcare System: An Amalgam of Different Political and Economic Philosophies



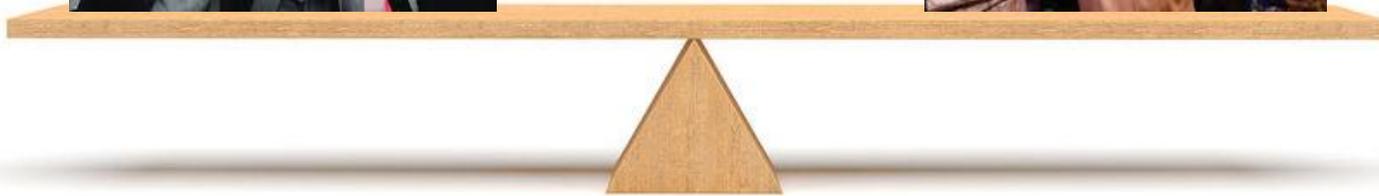


Cost vs. Care





Who Gets First Healthcare Attention? Wealth vs. Need



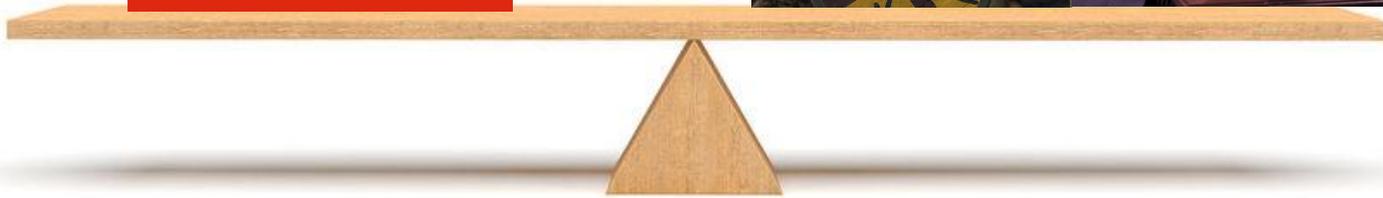


Ethical Philosophy: Two Different Roads





Treatment Imperatives Financed by Overseas Money



The Need for Myth



“What Is To Be Done?”



The Answer?

American Exceptionalism Demands A Certain Mythology In Which Every Citizen Obtains Perfect Healthcare Without Undue Individual Financial Burden (A Concept Occasionally Legally Enforced By An Estimated \$10 Million Wergild Per American Citizen).

As Healthcare Costs Have Exponentially Increased, As Have Expensive Healthcare Advances, Opaque, Ineffective Rationing Has Been Instituted By Insurance Companies and Healthcare Institutions With The Connivance Of The Government.

The Winding Path Towards This Objective



Clinical Guidelines: A Powerful Idea Towards Better Patient Care

A An Overview of Guidelines



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

A An Overview of Guidelines



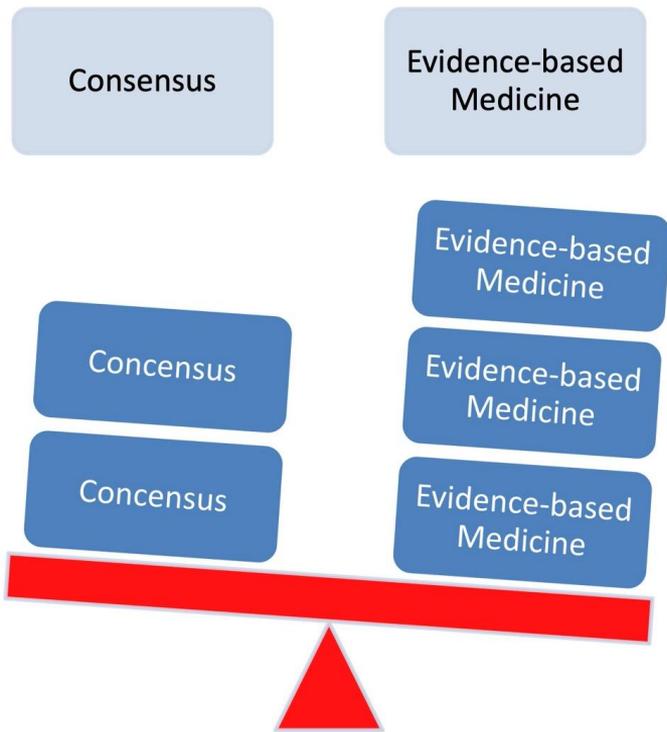
Rembrandt "The Anatomy Lesson of Doctor Tulp" (1632)

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

The scales are tipping toward EBM

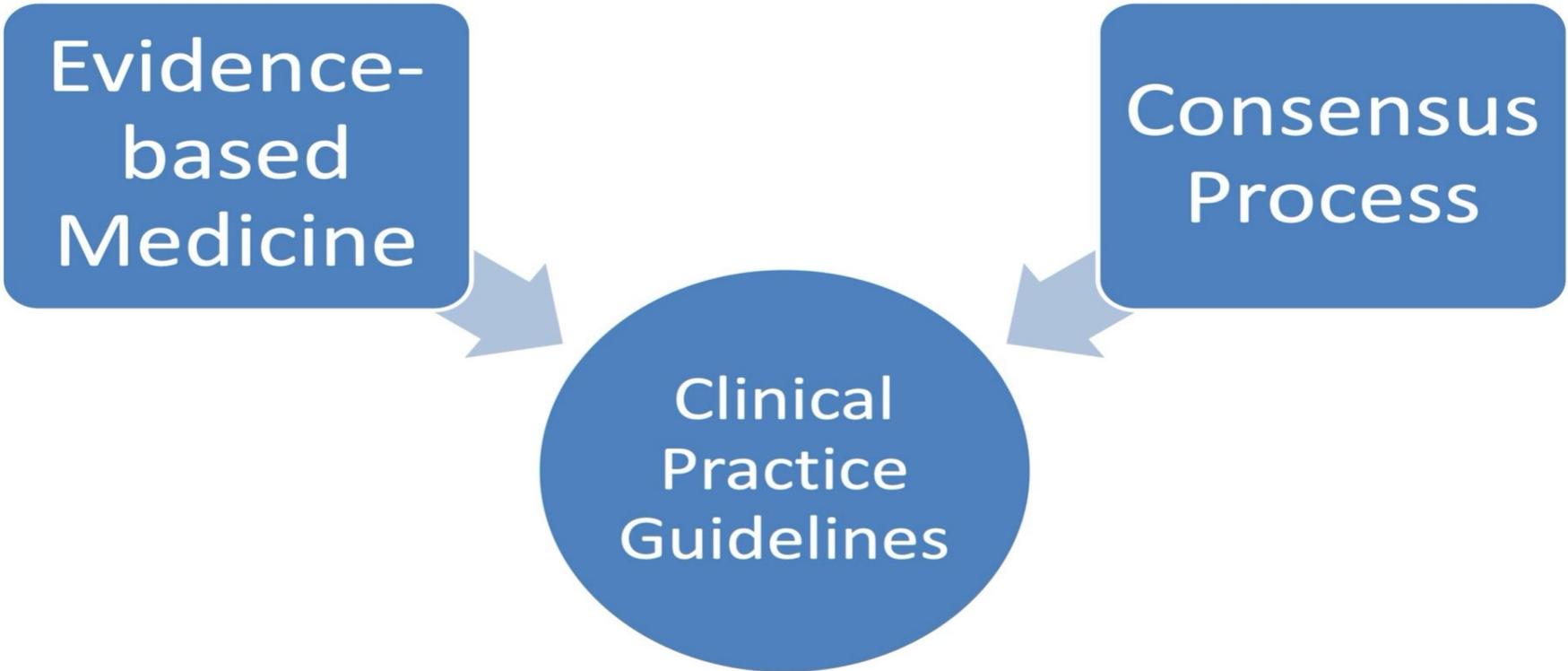


US Preventive Services Task Force Classification of Clinical Evidence

- 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.

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Clinical Practice Guidelines (CPG) Development



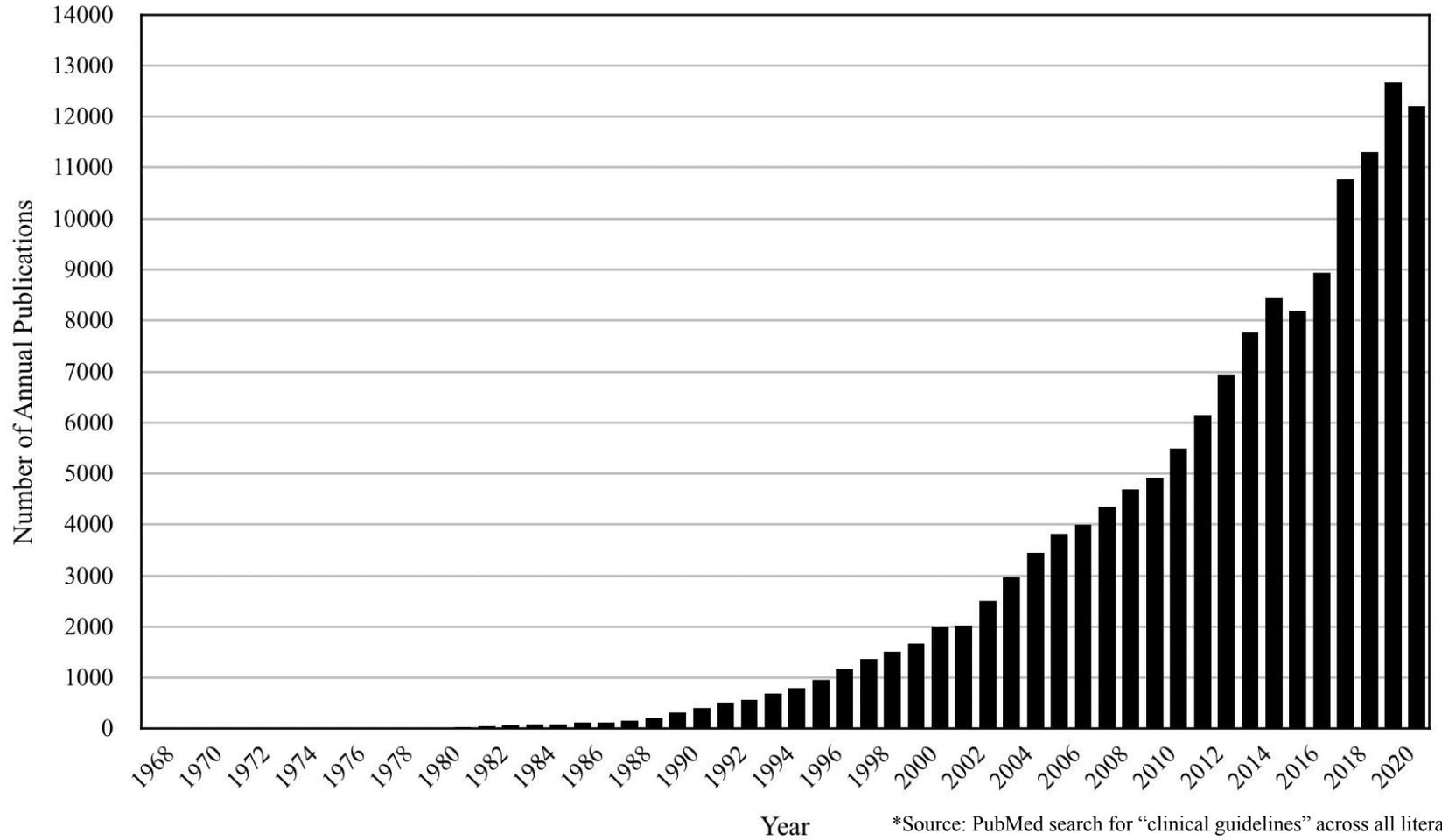
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Increasing Worldwide Clinical Dependence



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Annual Publications Mentioning Clinical Guidelines, 1968-2021

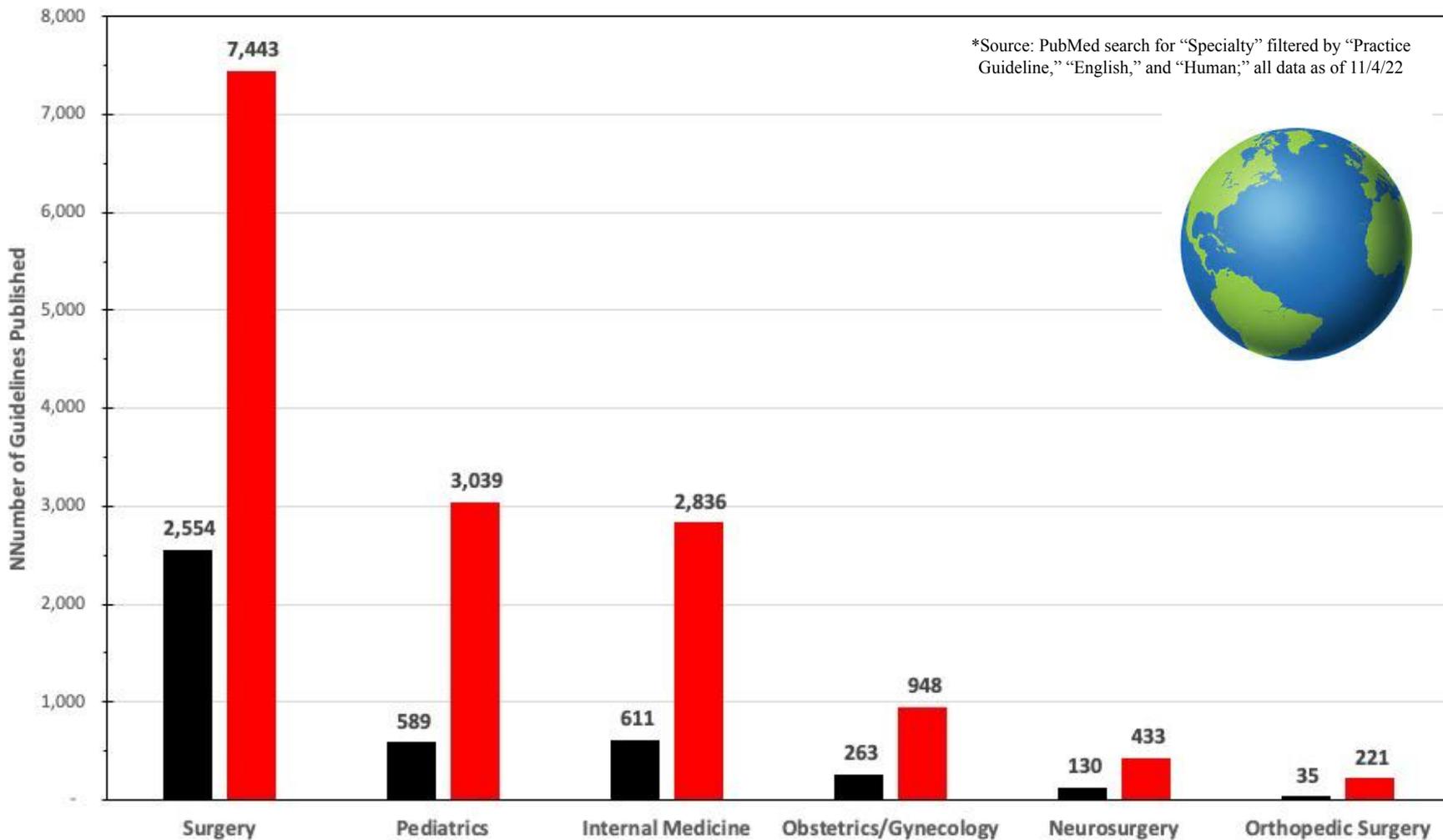


*Source: PubMed search for “clinical guidelines” across all literature types published in English, excluding practice guidelines and veterinary studies

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The Increase of Practice Guidelines by Specialty, 2010 vs 2022

*Note: Certification status unknown





Clinical Guidelines per Capita

Certified Clinical Practice Guidelines by Country, 2022

Country	Population (2022)	Number of Published Guidelines (1998-2022)	Number of Guidelines per 1,000,000 People (2022)
UK	68,713,042	381	5.545
Germany	84,402,144	376	4.455
France	65,606,008	169	2.576
US	332,403,650	271	0.815

Not All Guidelines Are the Same in Each Country

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



DANIEL K. RESNICK, M.D., TANVIR F. CHOUDHRI, M.D., ANDREW T. DAILEY, M.D.,
MICHAEL W. GROFF, M.D., LARRY KHOO, M.D., PAUL G. MATZ, M.D.,
PRAVEEN MUMMANENI, M.D., WILLIAM C. WATTERS III, M.D., JEFFREY WANG, M.D.,
BEVERLY C. WALTERS, M.D., M.P.H., AND MARK N. HADLEY, M.D.

Department of Neurosurgery, University of Wisconsin, Madison, Wisconsin; Department of Neurosurgery, Mount Sinai Medical School, New York, New York; Department of Neurosurgery, University of Washington, Seattle, Washington; Department of Neurosurgery, Indiana University, Indianapolis, Indiana; Departments of Orthopedic Surgery and Neurosurgery, University of California at Los Angeles, California; Department of Neurosurgery, University of Alabama at Birmingham, Alabama; Department of Neurosurgery, Emory University, Atlanta, Georgia; Bone and Joint Clinic of Houston, Texas; and Department of Neurosurgery, Brown University, Providence, Rhode Island

NHS

**National Institute for
Health and Clinical Excellence**

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

American	English	Criterion
∅	∅	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

Who Creates Clinical Guidelines?



How Are Clinical Guidelines Created in General?

- Creating organizations and agencies usually possess a **standing committee of experts** whose job it is to review evidence and produce clinical guidelines
 - E.g. AAFP's Subcommittee on Clinical Recommendations and Policies (SCRCP)
 - Identity of committee members not publicly available
- **When a need for a new or updated clinical guideline arises**, a topic is submitted to that committee for review
 - Need determined by service to organization's mission, suitability of current guidelines, and existence of research on the topic
- If the topic is deemed acceptable by the committee, a **systematic review of the evidence** on the topic is undertaken, usually in concert with a government research agency such as the Agency for Health Research and Quality
 - Evidence graded, with high quality evidence preferred, but ultimately **weight is given more to patient benefit than evidence quality**
- An **expert panel** is created to create guidelines based on the conclusions of the systematic review
 - Supposed to be composed of representatives from each stakeholder group, with minimal conflicts of interest
- Produced guidelines are then submitted for internal, ideally external, peer review before being published in a journal or by a certifying agency



Many Groups Produce Clinical Guidelines

Including:

- Specialty and professional groups - e.g. AANS, ATS, etc.
- Disease and patient advocacy groups - e.g. National Organization for Rare Diseases
- US Preventive Services Task Force (Overseen by US Agency for Healthcare Research and Quality)
- A variety of other international health and commercial organizations
- Government agencies
- Centers for Medicare and Medicaid Services (CMS)

- Health insurance companies - e.g. Anthem, United Healthcare



Who Certifies Clinical Guidelines? (Not All Are)





Groups Needed to Review and Certify Guidelines

Include:

- National Guidelines Clearinghouse (defunct since 2018) and the National Academy (formerly Institute) of Medicine - **USA**
- Guidelines International Network - **International**
- Cochrane Collaboration - **International**
- Agence d'évaluation des technologies et de Modes d'intervention en santé - **Canada**
- National Institute for Health and Clinical Excellence (NICE) - **UK**
- Clinical Practice Guidelines Portal - **Australia**



shutterstock.com · 1861412404

What Does Certification Mean?

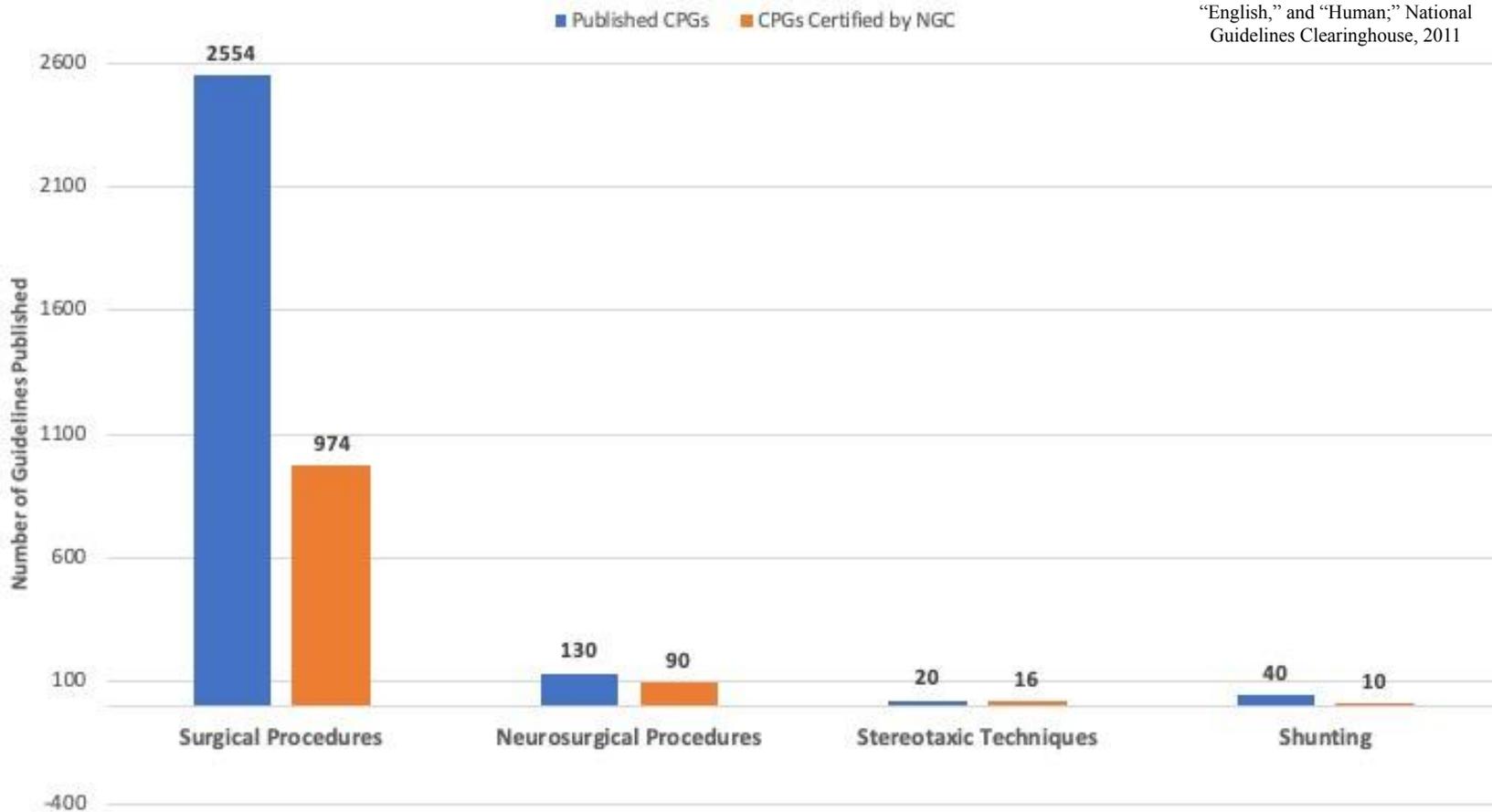
- An outside **government agency or nonprofit** has **reviewed** the guideline and found it to meet a given standard of quality.
 - E.g. Institute of Medicine's 2011 recommended framework for clinical guidelines.
 - Typically assess scope and purpose of guideline, the quality of evidence used, the degree of involvement and potential for conflict of interest in stakeholders, and the applicability of the guideline.
- **However**, certifying organizations have **no universal standard for certification**:
 - National Guidelines Clearinghouse set criteria based on IoM's 2011 recommendations.
 - Guidelines International Network uses the AGREE II rating system to determine quality.
 - Certified ~2,600 international guidelines
 - NICE has its own internal standards.
 - Certified ~200 of the ~1,800 guidelines in their database
- Lends greater authority to the clinical practice guideline and offers endorsement of its approach.

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Clinical Practice Guidelines Certified by National Guidelines Clearinghouse Compared to Total Number of Published Clinical Practice Guidelines, 2011

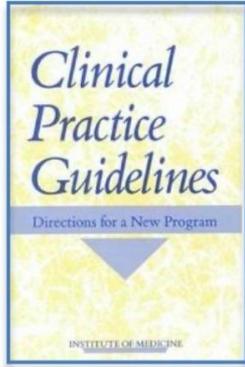
*Note: Contemporary data not findable

*Source: PubMed search for “Specialty”
filtered by “Practice Guideline,”
“English,” and “Human;” National
Guidelines Clearinghouse, 2011

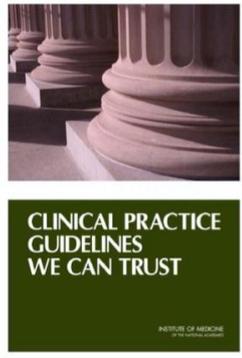




Evolving, More Insightful Standards



- Systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances (IOM 1990)



- Statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options (IOM 2011)

<http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx>

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Actual Criteria for Inclusion of Clinical Practice Guidelines in NGC

pre-2011

- 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 in 2011

The US Congress 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

2014 Additions to National Guidelines Clearinghouse Criteria for Guideline Certification

- Based on IOM's 2011 recommendations, NGC revised their certification criteria, requiring **more transparency and higher standards** when it comes to research and evidence review
- “The clinical practice guideline is based on a **systematic review of evidence** as demonstrated by documentation of each of the following features in the clinical practice guideline or its supporting documents.
 - An explicit statement that the clinical practice guideline was based on a systematic review.
 - A **description of the search strategy** that includes a list of database(s) searched, a summary of search terms used, and the specific time period covered by the literature search including the beginning date...and end date...
 - A **description of the study selection** that includes the number of studies identified, the number of studies included, and a summary of inclusion and exclusion criteria.
 - A **synthesis of evidence** from the selected studies, e.g., a detailed description or evidence tables.
 - A summary of the evidence synthesis...included in the guideline that relates the evidence to the recommendations, e.g., a descriptive summary or summary tables.”
- “The clinical practice guideline or its supporting documents contain **an assessment of the benefits and harms of recommended care** and alternative care options”



Still Not Perfect

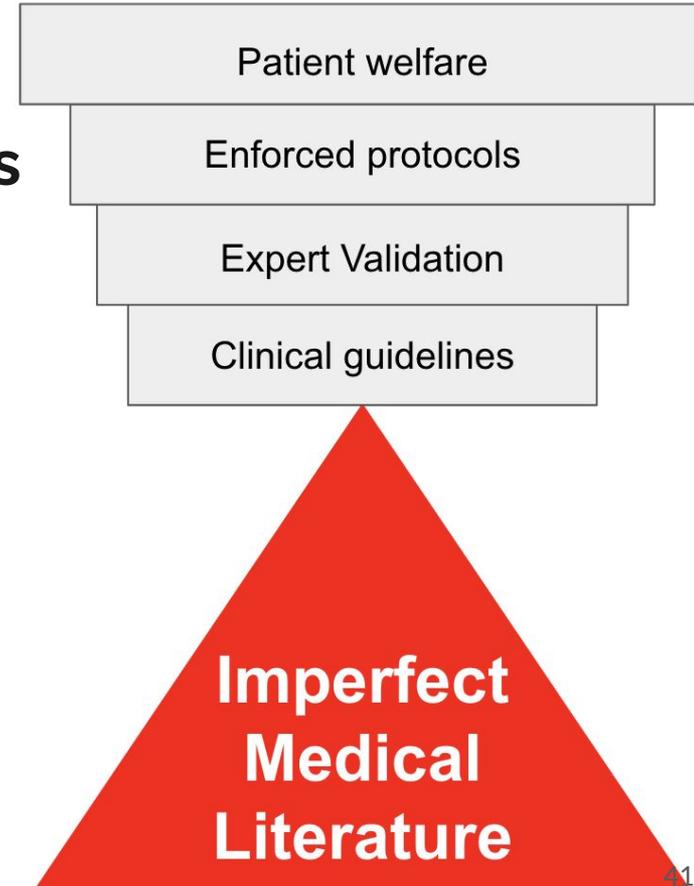
$$2+2 \neq 4?$$



General Methodological Difficulties

1. Problems with Meta-Analysis
2. Indefinite and confused clinical markers

Guidelines often based on indefinite, inadequate evidence





Examples of Clinical Guidelines in Practice Which Fail to Describe the Universal, Best Clinical Solution:

1. Cauda Equina Syndrome
2. The Use of Steroids as a Treatment for SCI

A - Specific Problems: Cauda Equina Syndrome

1. Cauda Equina Syndrome

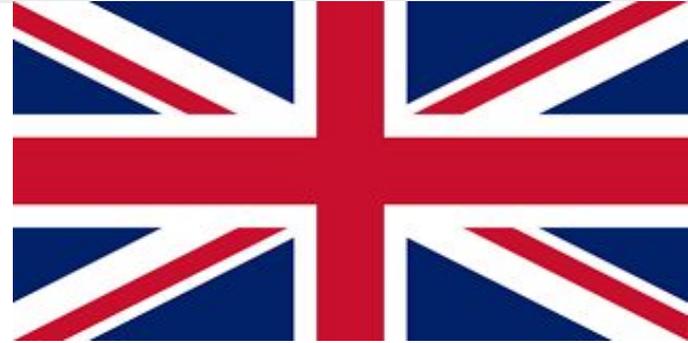


A - Specific Problems: Cauda Equina Syndrome

From the Literature, An Effort at Establishing a Clinical Guideline...

Cauda Equina Syndrome Practice Guidelines (2015 and 2019)

- From the Society of British Neurological Surgeons:
- Requires urgent investigation
- Any presentation of back and/or sciatic pain with any disturbance of bladder or bowel function, saddle or genital sensory disturbance, or bilateral leg pain.
- Clinical diagnosis has low reliability and there should be a low threshold for MRI investigation.
 - MRI should be done STAT.
- “Nothing is to be gained by delaying surgery and should be undertaken at the earliest opportunity **considering** the duration and clinical course of symptoms and signs, and the potential for increased morbidity while operating in the night.”
- Very broad, degree of injury is not stated, no statement about duration of injury or other secondary factors.



A - However...

Outcome Analysis: No Control Group

Indefinite Post-Operative Markers

- Post-operative assessment of **operative injury** often obscured by the presence of pre-operative symptoms
- Post-op improvement often obscured by impact of **natural recovery process**.
- Post-op degree of electrophysiological improvement is rarely precisely noted.
- Post-op radiological improvement is rarely noted.
- Post-op bladder, rectal, and sexual function is **generally subjectively quantitated without numerate demarcation of change**.
- Finite time of post-operative assessment is not clearly identified.



2. The Use of Steroids as a Treatment for SCI



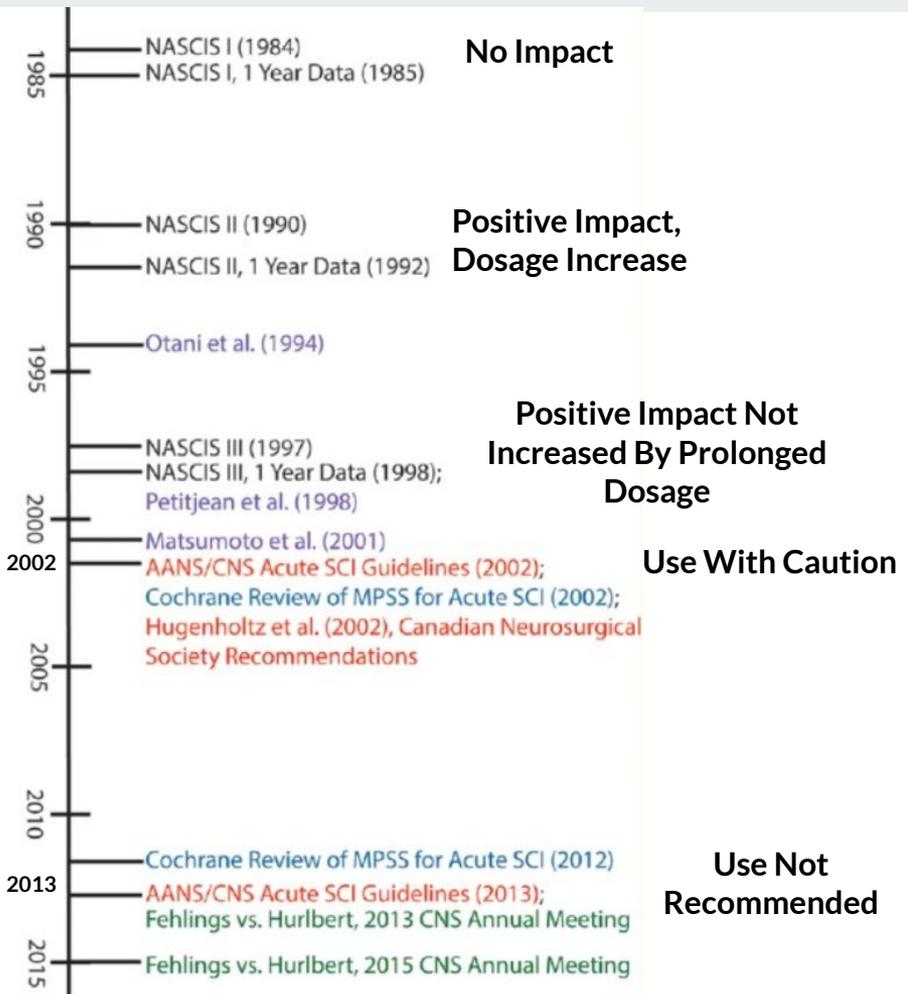
A - Specific Problems: Steroid Use in Treating SCI

Confusion Over Changing Clinical Guidelines

MPSS: A Timeline

[Methylprednisolone for acute spinal cord injury: an increasingly philosophical debate \(nih.gov\)](#)

- Legend:**
- NASCIS Publication
 - Cochrane review
 - Other trials included in the 2012 Bracken Cochrane Review
 - Guideline
 - Debate



Resulting Clinical Confusion

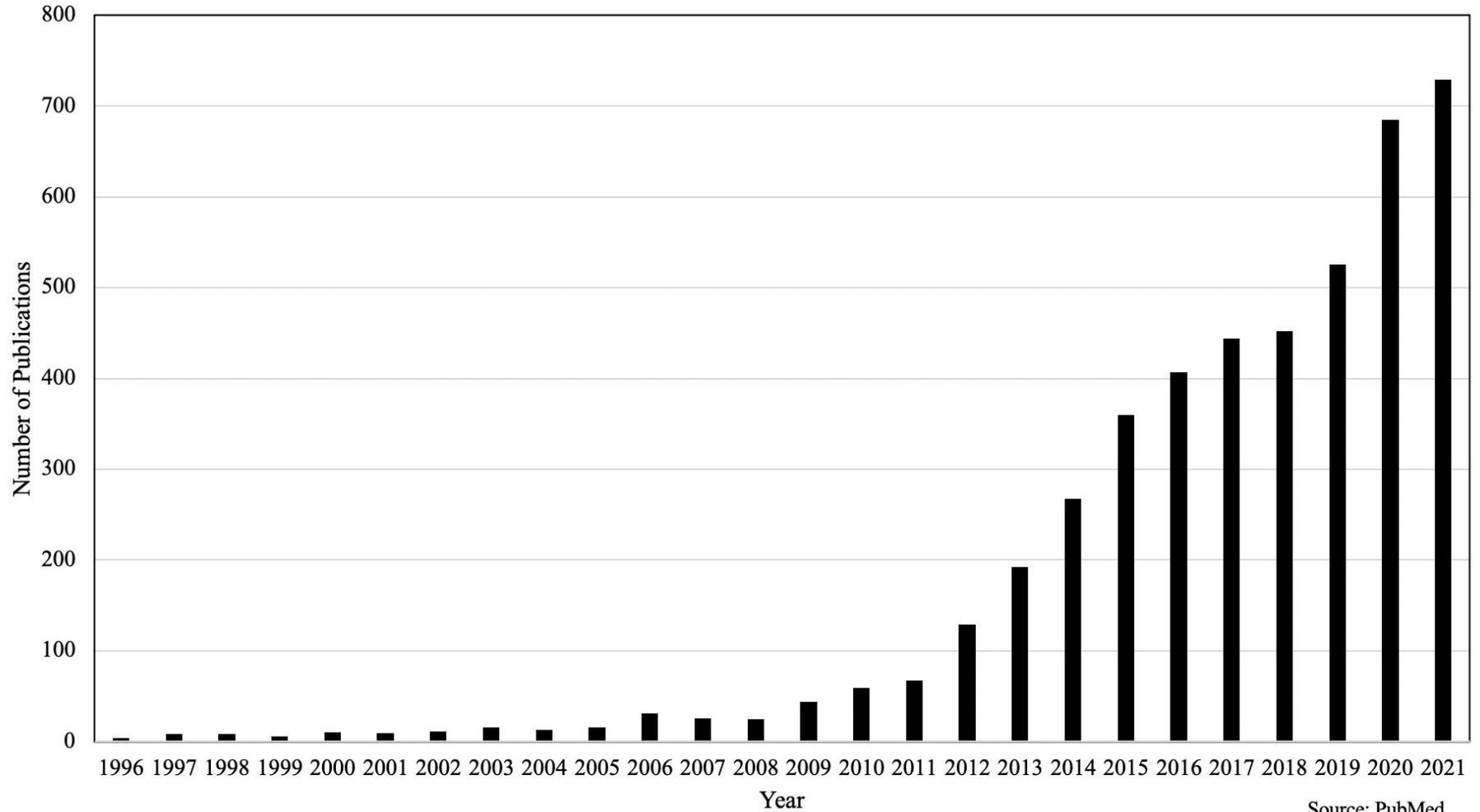
- 338 papers by title regarding methylprednisolone use for spinal cord injuries in the last 20 years (dated 2000-2021).
 - **However, 4 meta-analyses attempt to clarify clinical protocols**



Is Meta-Analysis the Answer?



Annual English Language Publications of Meta-Analyses in Neurosurgery, 1996-2021

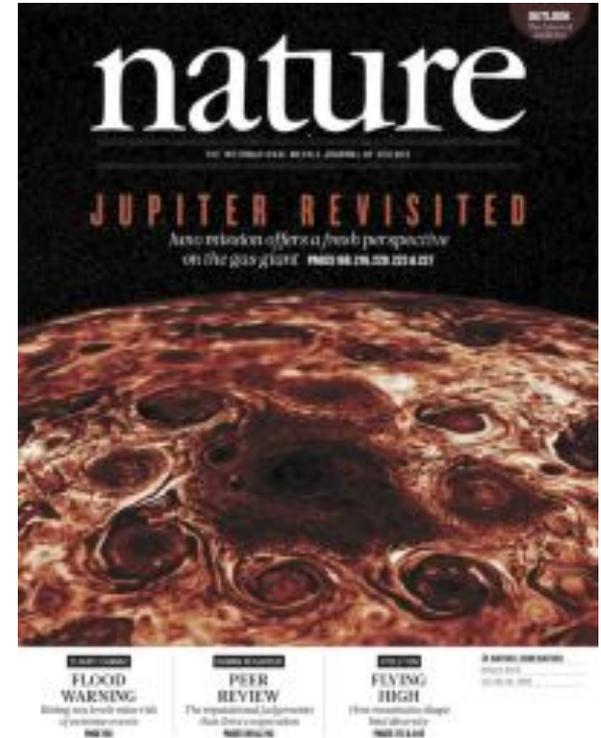


However...

8 March 2018: *Nature* Article

Volume 555, Issue 7695

- “Meta-Analysis and the Science of Research Synthesis”
 - This methodology has become central through assessing causality and therapeutic efficacy in medicine.
 - Substantial methodological difficulties often countervene study reliability.



Problems with Meta-Analysis

- 1) **Heterogeneous population** confounds conclusions for individual cohorts
- 2) **Rectitude of individual papers** can not easily be questioned
- 3) The problem of keeping all variables the same
- 4) When papers have been collected over a long period of time, old papers have less validity than more contemporary ones.
- 5) **Use of poorly constructed scales**
 - a) A problem exists when only **bimodal scales** are used
- 6) “Subtle” improvements hard to realistically measure
- 7) Clinical trials are mostly older
 - a) Not used as often as observational studies



Problems with Meta-Analysis

- 8) **Exclusion criteria** not clearly stated
- 9) When a comparison occurs between two patient cohorts, the comparison is based upon the average of each cohort which can be confused by numerical disjunctions in which **outriders are overly counted in each cohort**.
- 10) When a random effects model is used, the **conclusion is often overstated and misinterpreted as too authoritative** when it is instead the average treatment effect, meaning that more often than not the treatment effect occurs.
- 11) **Evaluated treatment markers are inadequate**; for instance, electrophysiological data is ignored and outcome analysis depends upon an often biased, self-reporting patient population.

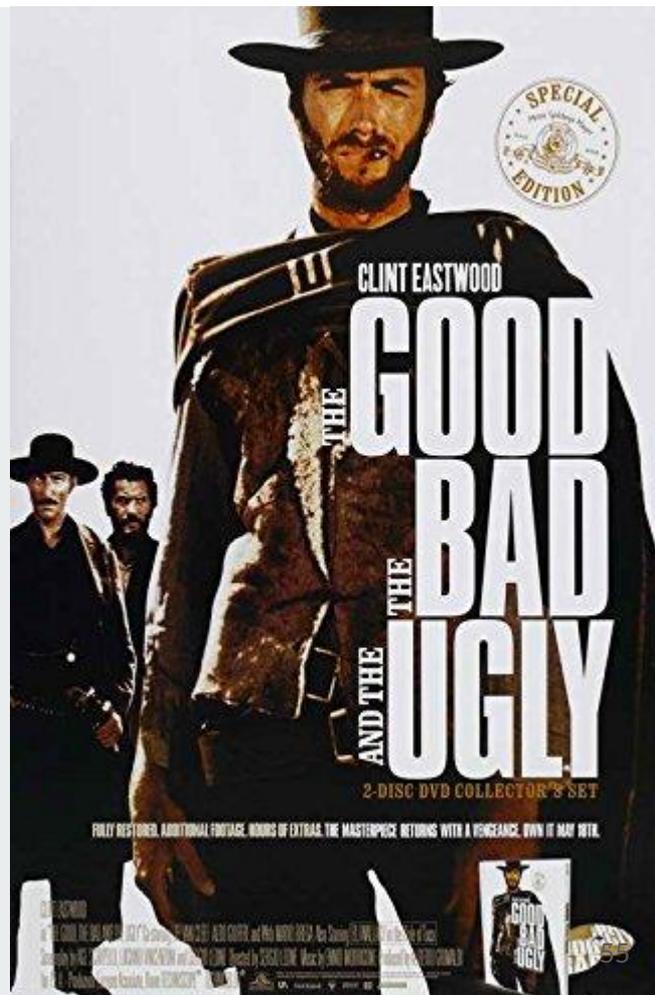


Problems with Meta-Analysis

- 12) **Outcome analysis is short-lived** and does not consider long-term assessment
- 13) **Interventions (particularly operative procedures) are considered to be the same** and that intraoperative injury is not assessed
- 14) In therapeutic time comparisons, the progressive nature of organ dysfunction is not assessed; instead an **arbitrary number is chosen for symptom onset**
- 15) Lack of consistent, coherent **definitions** for problems
- 16) **Effects of natural disease progression and recovery obscured by intervention**



The Good and the Bad





The Bright Side





Better Evidence for Clinical Decision Making

- Evidence-Based Medicine > Expert Opinion.
- “Evidence-Based Medicine and the American Thoracic Society Clinical Practice Guidelines” by Schumacher, Nguyen, Deshpande, and Makam (2019)*
 - CPGs heavily dependent on quality of evidence - most currently rely on low levels of evidence.
 - **When high quality evidence used, better recommendations produced** with better clinical applications.
- Can facilitate faster adoption of new clinical insights

*Schumacher RC, Nguyen OK, Deshpande K, Makam AN. Evidence-Based Medicine and the American Thoracic Society Clinical Practice Guidelines [published correction appears in JAMA Intern Med. 2019 May 28;:]. *JAMA Intern Med.* 2019;179(4):584-586. doi:10.1001/jamainternmed.2018.7461

A - The Bright Side

Greater Patient Well-Being

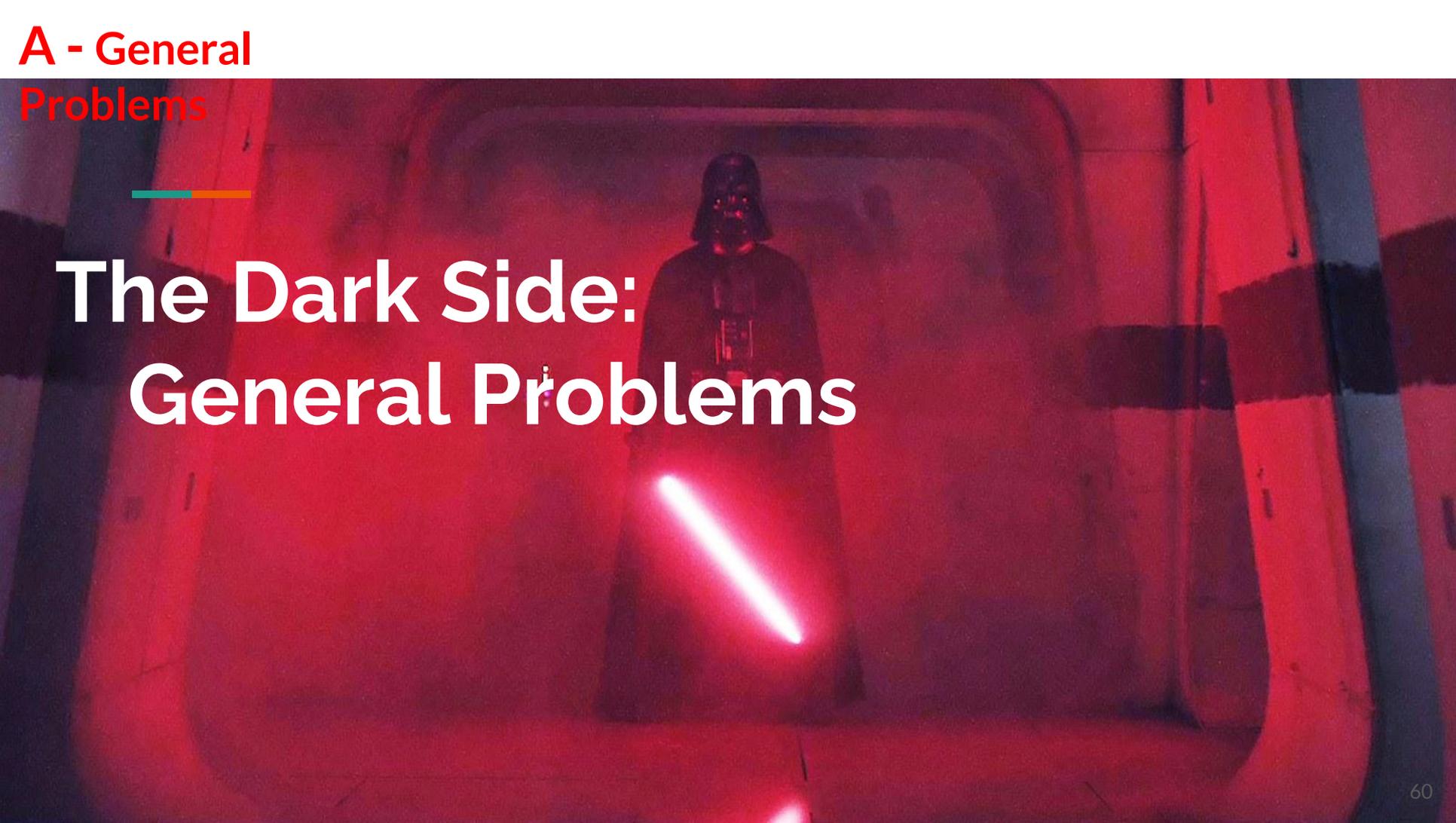


A - The Bright Side

A Path Forward



A - General Problems

A person dressed as Darth Vader stands in a dark, red-lit environment, holding a glowing red lightsaber. The scene is framed by a large, rounded rectangular opening, possibly a doorway or a tunnel. The lighting is dramatic, with the red glow of the lightsaber and the ambient red light creating a somber and menacing atmosphere.

The Dark Side: General Problems

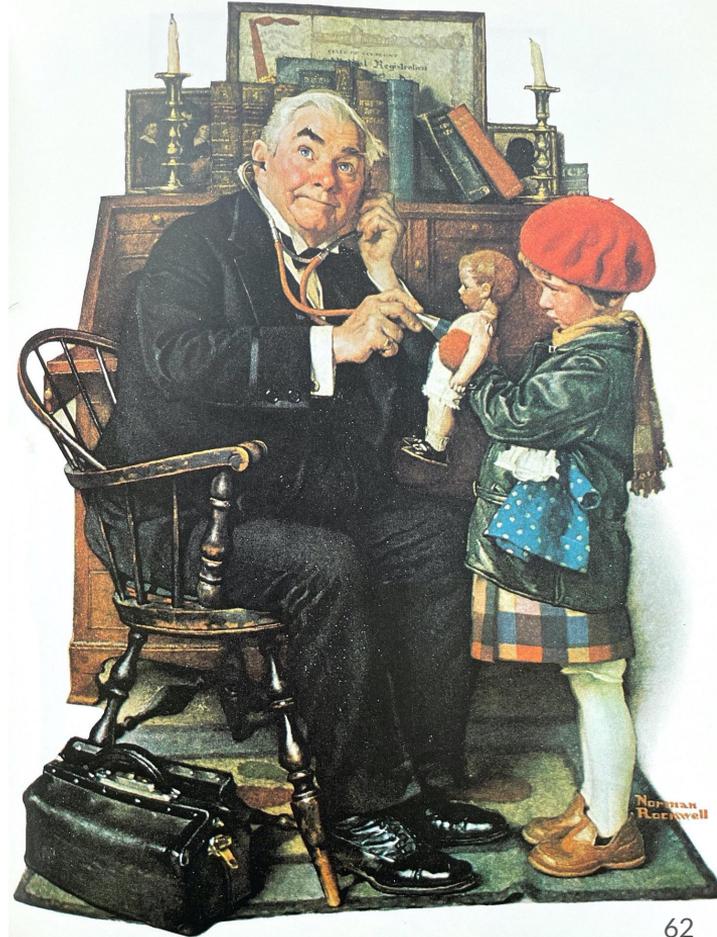
A - General Problems

Limits Innovation and Independent Inquiry



A - General Problems

Can Disturb the Doctor-Patient Relationship



A - General Problems

Alters the Protective Role of Independent Physician Opinion
Checking and Balancing Wrongful Healthcare Therapeutic Policy in Regards to the Special Circumstances of the Individual Patient



James Madison



Unregulated, Unchecked Propagation

- Can be produced at random, with **no particular regulation**, and often upon suspect data.
- Certification not required for CPGs to be propagated and implemented.
- Lack of oversight and varying quality of evidence **leads to sub-par guidelines** being used to make clinical decisions.
- Institute of Medicine standards for developing CPGs not universally followed, even in the United States.

A - General Problems


No Mention of Cost



Moreover...

**Though, Ideally, Guidelines Are
Not Meant to be Arbitrary,
Substantial Enforcement
Arrangements Exist**

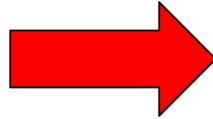


Physician Practice Control and Regulation Mechanisms are increasing

	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

— — —
Clinical Guidelines -> Standards of Care

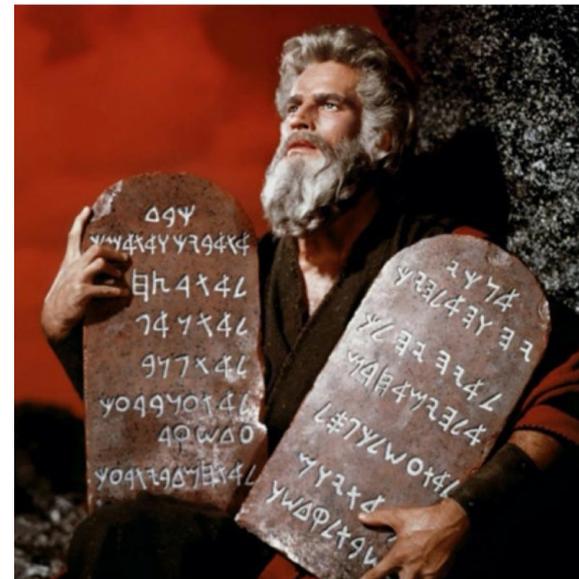


A Enforcing Guidelines



Our Suggestions for Clinical Guidelines Improvement

1. **Cost** consideration ✓
2. **Long-term** follow-up and cost-benefit analysis
3. The advantages of **biomarkers** versus actual patient outcome should be strongly considered
4. A provision to allow **new procedures that contravene practice guidelines**
5. A provision to measure **patient compliance** with the prescribed treatment
6. A mechanism for **funding high-grade studies on new technologies** for which great amount of societal benefit can be achieved
7. An easy **appeal** mechanism



And Now...An Important Segue Back To The Path Toward Opaque, Ineffective Healthcare Rationing



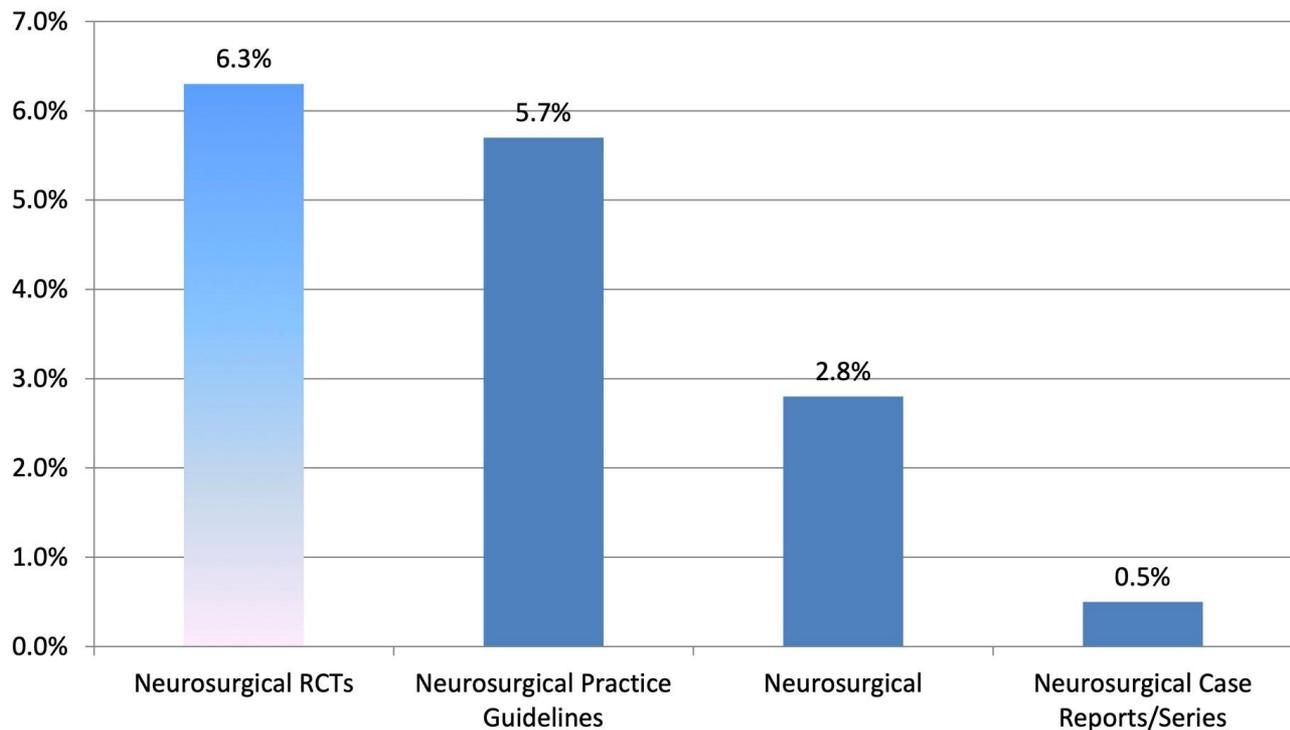
\$ The Important Missing Piece \$

Generally, **economic issues** are missing from clinical guidelines' analysis





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





Why?

- Pricing data treated as **privileged information**, and, moreover, variable by institution and geographical location
- Physicians in general would be, and are, uncomfortable with participating in any economic rationing of healthcare resources



Insurance Companies: Using Established Clinical Pathway Methodology, Into the Breach



Insurance Companies and Standards of Care



Economic Concerns Trump Clinical Guidelines

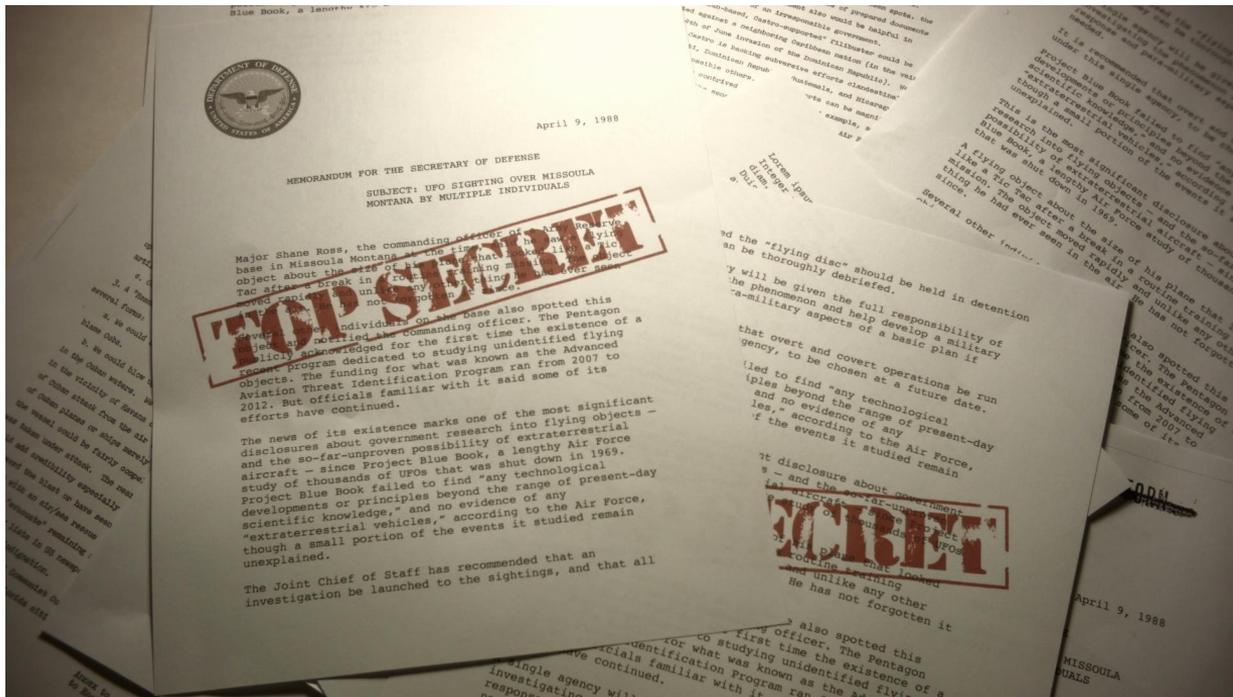
How Health Insurers Create De Facto Clinical Guidelines

- An **expert panel** is created to review evidence, existing guidelines (certified and uncertified), and expert opinions in order to develop independent treatment guidelines based upon them
 - Rarely have the resulting guidelines certified
- Appeal arrangements are present, but are very vexing and time consuming and **effectively serve to limit care access**.
- **Absence of transparency** in establishment of guidelines.
- **Potential conflict of interest** in the “experts” selected to propagate insurance-derived clinical guidelines.

Such Defects Are Not Commonly Known and Appreciated

Secret Rationing

- Hurdles established to prove “medical necessity” serve to secretly ration care for patients
- Discourage treatments until all other options exhausted



A Big Change

“Medically Necessary”

- Guidelines are designed to establish a very strict definition for treatment: is it “**medically necessary?**”
 - Hurdles put in place which must be cleared **before** a treatment can be implemented
 - e.g. months of conservative therapy, diagnostic imaging requirements, pain management requirements, etc.
 - Treatment only covered if it is the **best remaining option** to treat a patient’s injury, illness, or condition and causes more benefit than harm



Denial of Care



An Example of Rationing

Arbitrary Limitations on Spinal Fusions for Smokers

- Peer-reviewed evidence suggests **smoking is a factor that adversely affects fusion success rates**
 - Mainly retrospective cases, with a few systematic reviews and prospective RCTs
 - **Insufficient evidence to suggest cessation of smoking prior to surgery diminishes risk** (Harrop et al, 2021)
- A review of spinal fusion coverage policies from Cigna, AIM Speciality Health, Centene Corporation, Humana, and Aetna found that, despite this mixed evidence, **smokers are required to cease tobacco/nicotine consumption for at least 6 weeks prior to surgery** and encouraged to abstain for a similar number of weeks after surgery



Are Patients With A Body Mass Index Over 35 Next?



Obesity can cause increased complications, thereby costing insurance companies money

Cost Shifting By Denying Access to Care:

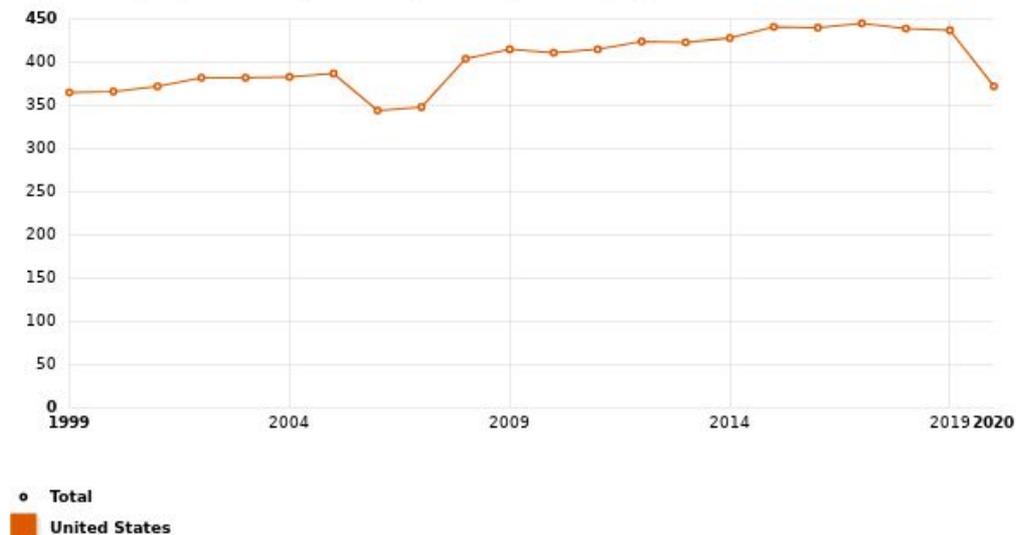
Diversion of Patient Population to Expensive Emergency Room Treatment

- The last resort - emergency rooms
- Care denial → Increase Emergency Room Utilization
- Limits on care due to insurance restrictions leads to less elective procedures and less treatment of chronic, preventable disease, creating more emergency situations
- Emergency care becomes a failsafe for patients to receive treatment and be covered by their insurance



ER Visits Annually

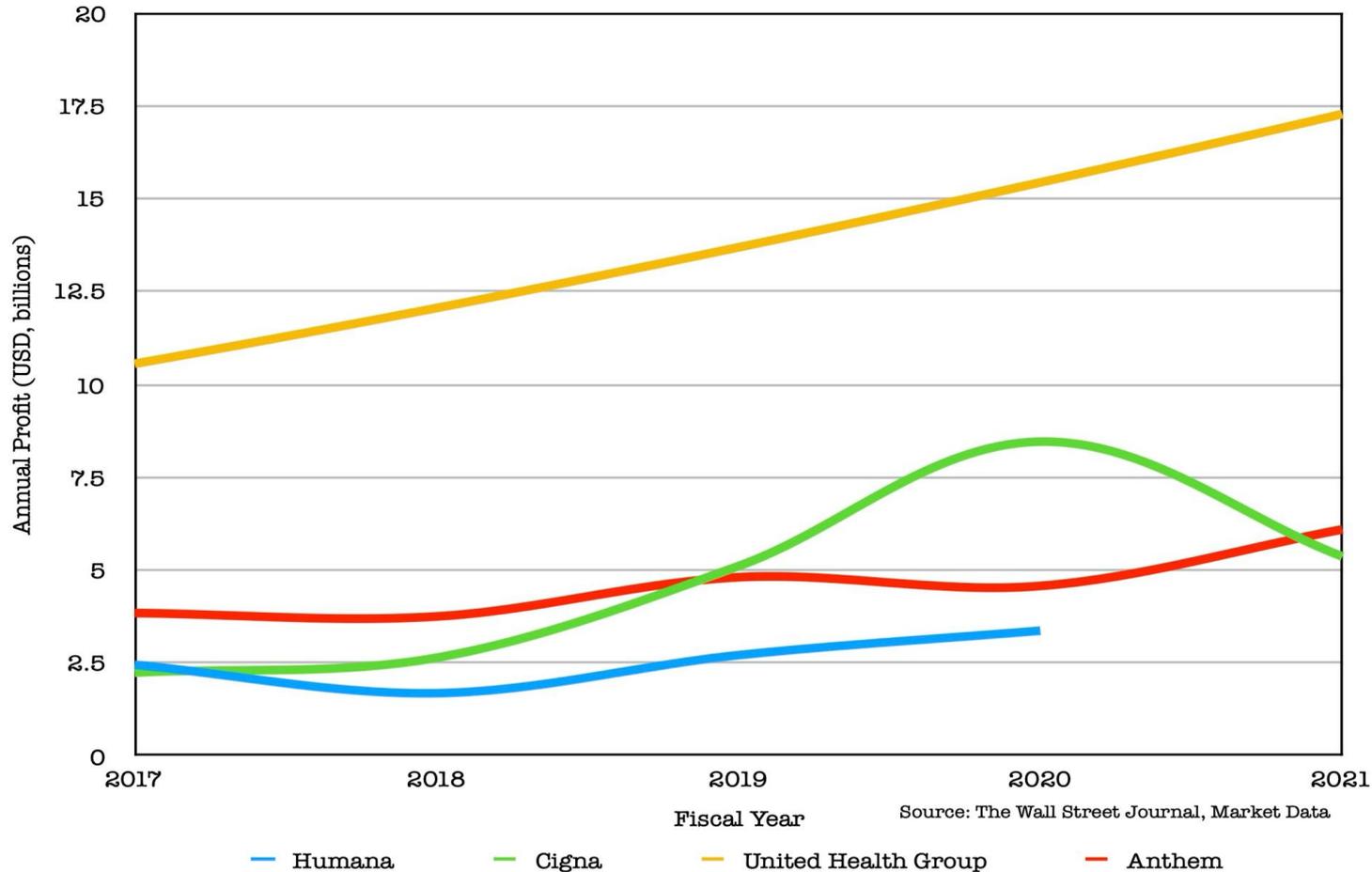
Hospital Emergency Room Visits per 1,000 Population by Ownership Type: Total, 1999 - 2020



SOURCE: Kaiser Family Foundation's State Health Facts.

B A Result: Record Profits for Insurance Companies

Health Insurance Company Profits, 2017-2021



A Primary, Rather Extraordinary Example: Medicare Advantage Plans (Medicare Part C)



Jimmie Walker
Star of *Good Times*

The Path Towards Opaque Rationing

Medicare Advantage (Medicare Part C)

- Established by the Balanced Budget Act of 1997, Medicare Part C came into force in 1999.
- Intended to offer beneficiaries greater choice in healthcare plans than standard Medicare and to cut costs and increase efficiency by outsourcing managed care to the private sector.
- Plans offer a number of additional benefits not covered by standard Medicare, such as coverage of dental care, lower premiums, and transportation to physician offices.
- Increasingly expensive and gradually privatizing Medicare writ large.
- In 2021, Medicare Advantage cost the US government an average of 4% more than a regular Medicare patient



The Hopeful, Sunlit Trail

How are Enrollees Obtained?

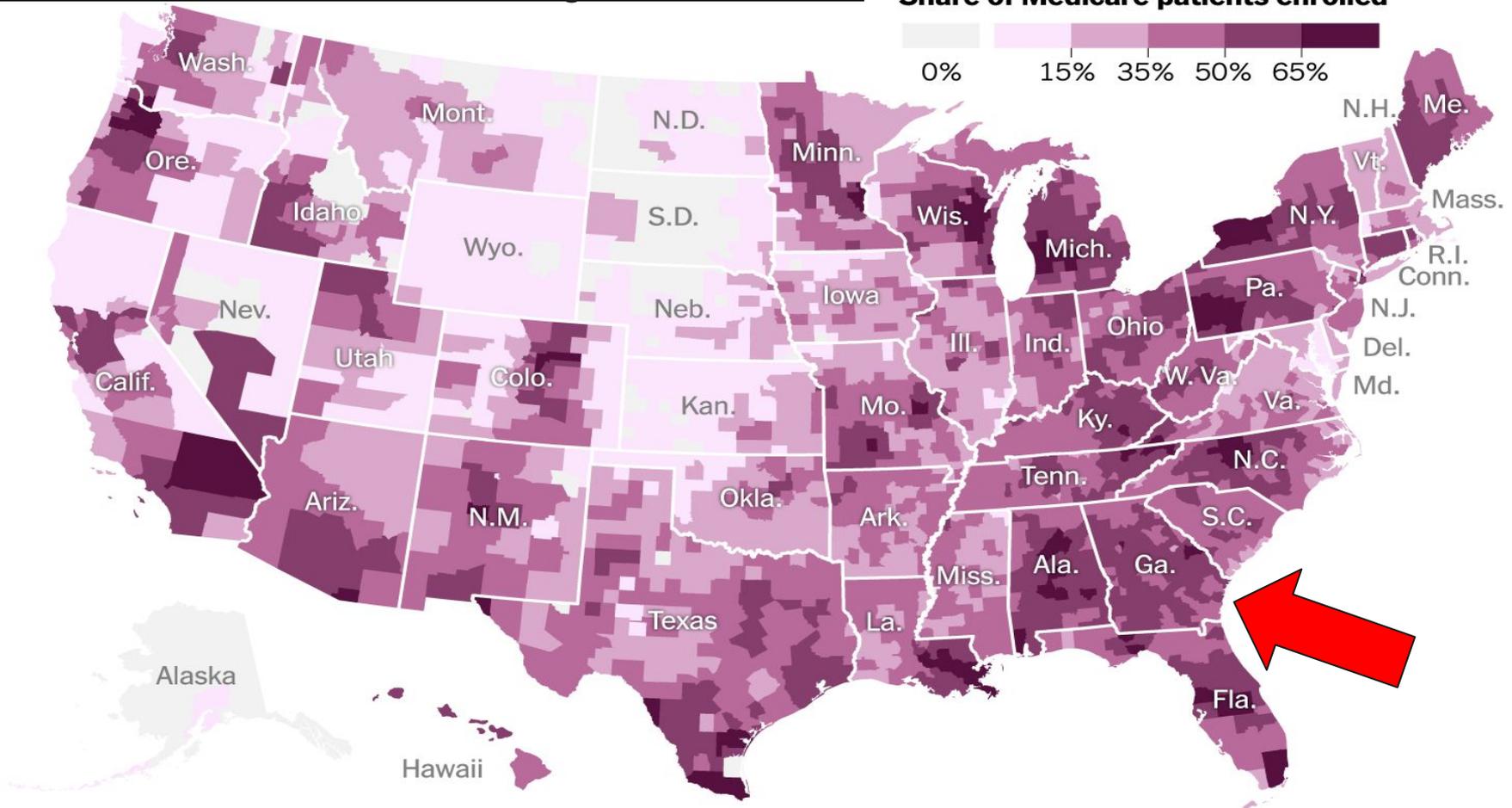
**Free Dental Care -
Insurance Companies (For Their Own Financial
Advantage) Offer Seductive Enticements**



Concentration of Medicare Advantage Patients, 2022

Share of Medicare patients enrolled

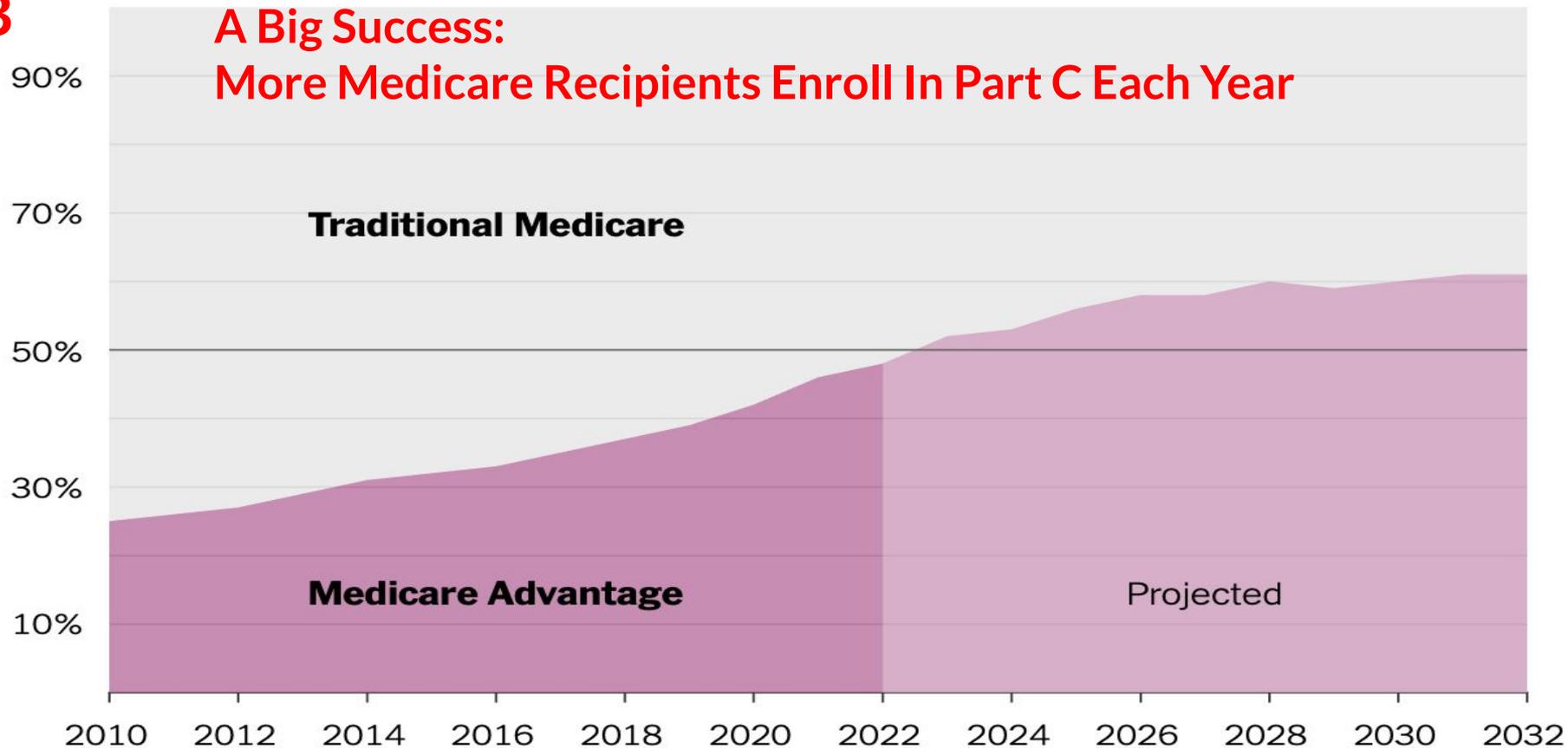
B



Source: Kaiser Family Foundation analysis of Medicare enrollment data • The New York Times

B

A Big Success: More Medicare Recipients Enroll In Part C Each Year



Note: Traditional Medicare share based on enrollment in Medicare Part B. • Source: Kaiser Family Foundation analysis of data from Medicare and the Congressional Budget Office • The New York Times

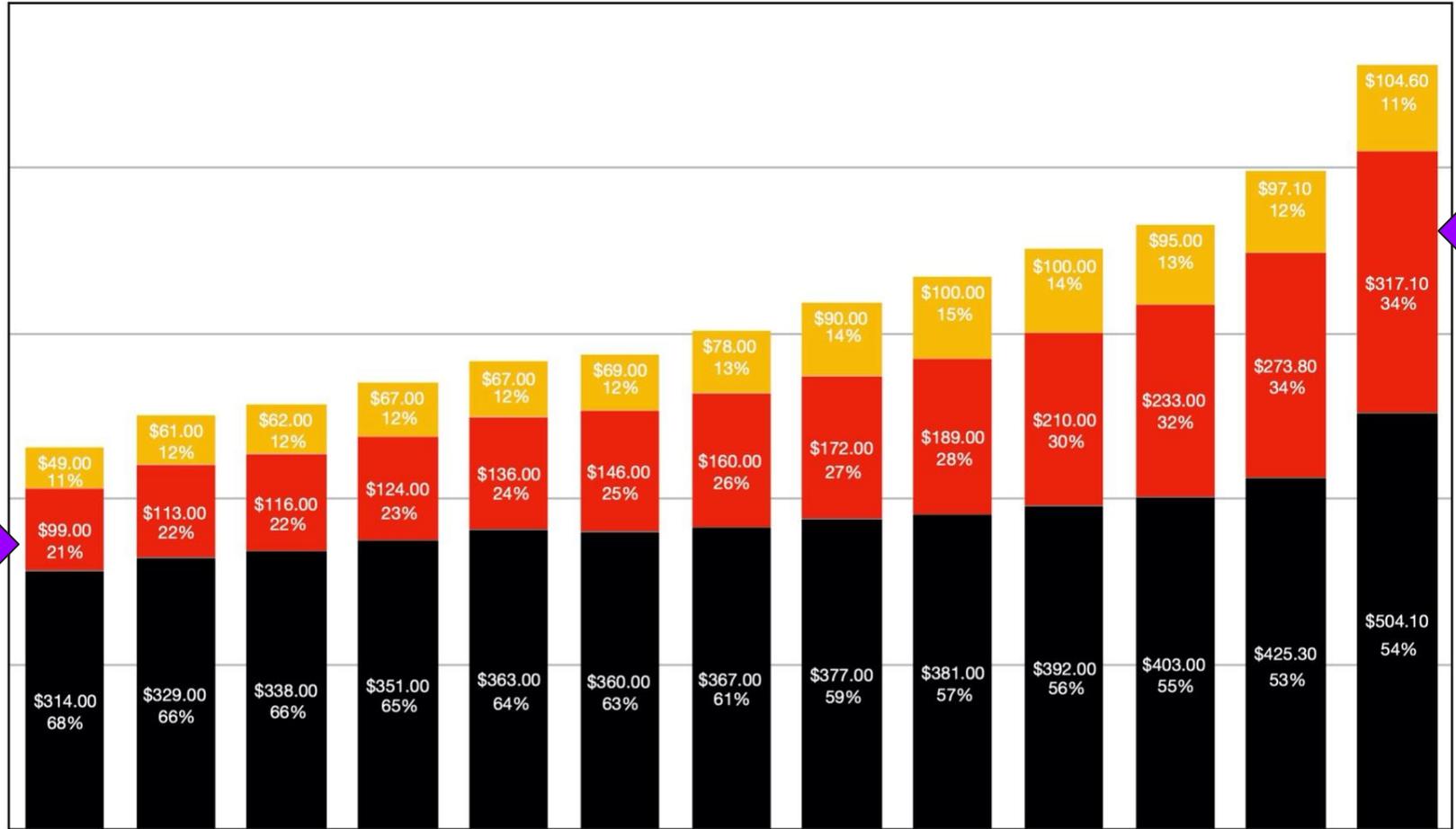
The Growth of Medicare Advantage Plans (Part C), 2008-2020

B

\$1000.00

Total Medicare Spending (USD, Billions)

\$0.00



■ Traditional Medicare Expenses

■ Part C Expenses

■ Part D Expenses

Source: CMS

Quite A Balance





How are Profits Obtained?

Extra-Tough Restrictions on Healthcare

- Medicare Advantage plans may offer additional benefits, but with **substantial limitations**.
 - Private insurance companies motivated by profit - no incentive to spend money on treatment .
- **Narrow networks** of physicians limit patients' choice of doctor.
- **Additional requirements** established before treatment is covered, not all of which are covered by the insurance plan.
 - E.g. physical therapy, second opinions, prior authorization, etc.
 - Discourages preventative medicine and early diagnosis of issues.
 - Slows pace of treatment as insurance companies must approve virtually every step.
- Insurance companies allowed to determine length of care.
- **Denials can be appealed**, and 75% of appealed denials are reversed, but the process is so complex only 1% of beneficiaries or providers ever appeal denials.
- Annual plans can be terminated by insurance companies at will, **allowing them to disenroll particularly expensive or troublesome patients** and kick them back into standard Medicare

B Medicare Advantage

(Even More)

Pulling a New, Profitable Rabbit Out of the Hat



Upcoding by Insurance Companies

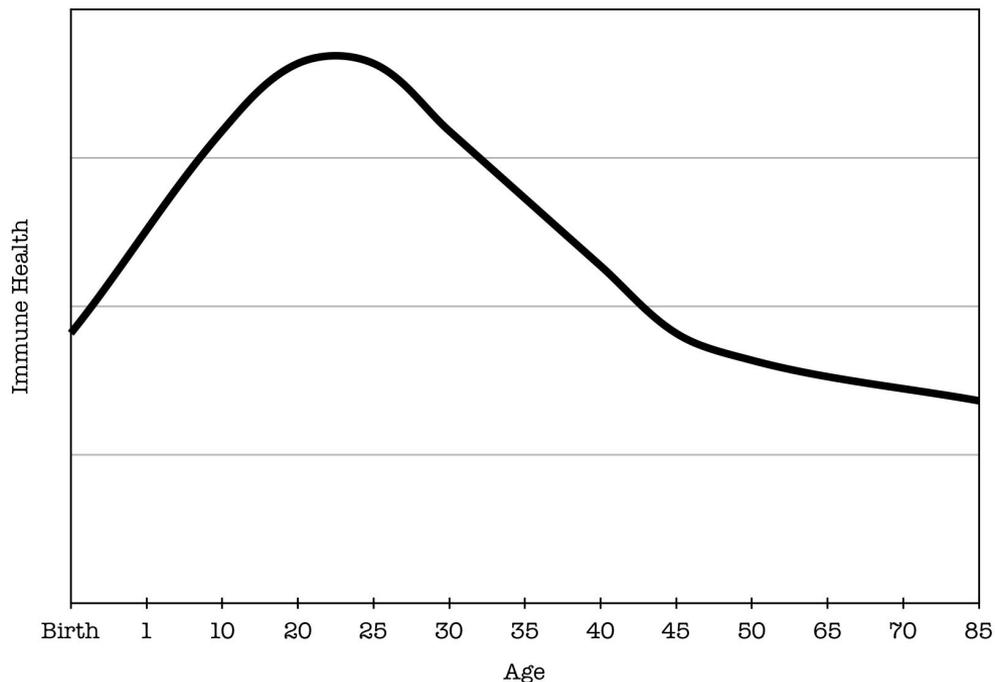
- Compensation arrangements with Part C plans incentivize the **diagnosis of all existing and potential diseases or comorbidities in a patient**, regardless of their bearing on the patient's current treatment for a given problem.
- Incredibly profitable for companies.
- Doctors and nurses **pushed to maximize diagnoses** whether they were well-founded or not and regardless of whether the proper equipment and testing for such diagnoses was available.
- **Diagnoses occasionally falsified** and some companies discouraged practitioners from treating new diagnoses, while many refuse to remove diagnoses which have been invalidated in order to continue charging the federal government for treating those diagnoses.



Naturally



- Organ Decay Over Time
- More Comorbidities Discovered in the Elderly





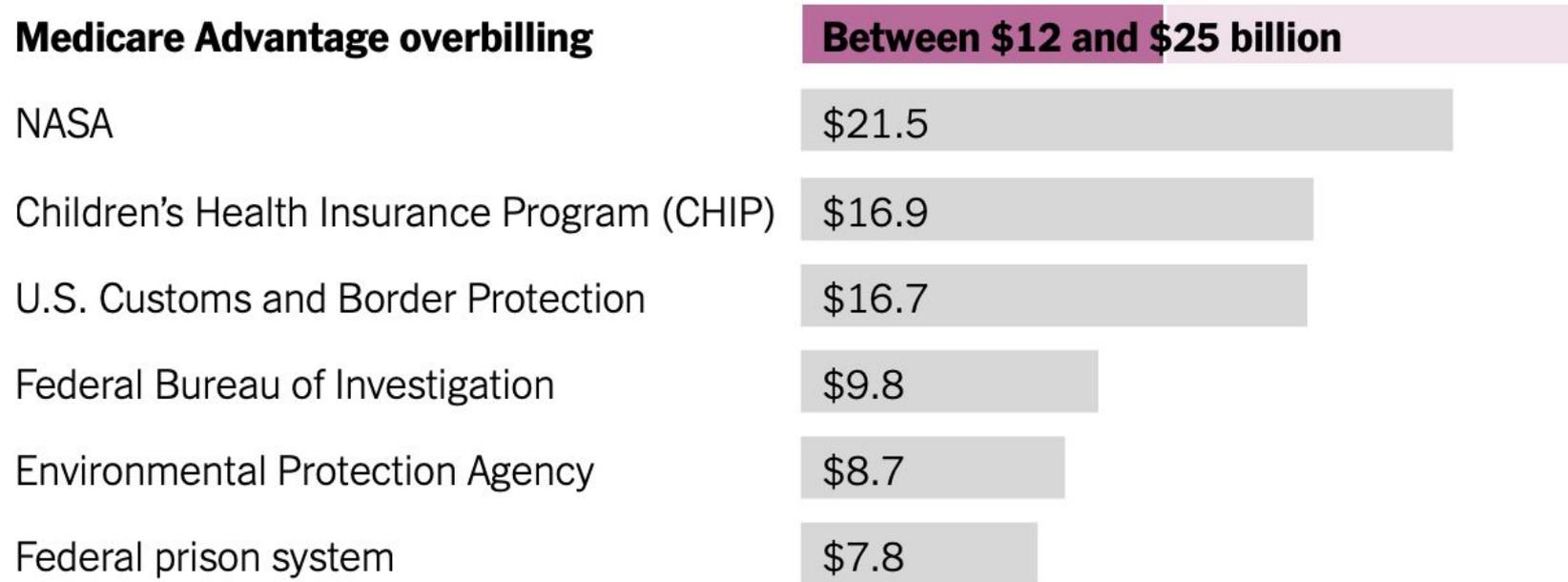
Upcoding by Insurance Companies

concern about making such changes. According to that executive, she told two of her peers in March 2016 that she was “not inclined to change” chart review in any way because “[chart review] is a cash cow” for Anthem by virtue of its having “a high ROI.”

Anthem: The Justice Department suit quotes an executive describing her reluctance to change how it mined medical records for additional diagnoses. The case is continuing.

B The Total Cost Alone of Upcoding

Medicare Advantage Overbilling Exceeds Entire Agency Budgets



Note: Figures represent outlays in the 2020 fiscal year. • Sources: White House Office of Management and Budget; Medicare Payment Advisory Commission; Richard Kronick and F. Michael Chua • The New York Times



Concerns of Predatory Behavior and Fraud

- The Government is Somewhat Watching

- Third-party insurance brokers hired by insurance companies have posed as the IRS and other government agencies, misled customers about the specifics of plans, and **focused on patients with dementia and other cognitive impairments**.
- Air-waves filled with **commercials** promising lower premiums, greater Social Security payments, and other benefits, despite the lack of universality of such benefits, and which never mentioned the restrictions on care and prescription drugs such plans entail.
 - ~7% of Medicare Advantage plan beneficiaries in 2022 actually have lower premiums than traditional Medicare.
- Complaints to the Center for Medicare and Medicaid Services about Medicare Advantage plans more than doubled between 2020 and 2021.
- 4 of the 5 largest health insurers in the US have been **sued by the US government for fraud** related to Medicare Advantage.

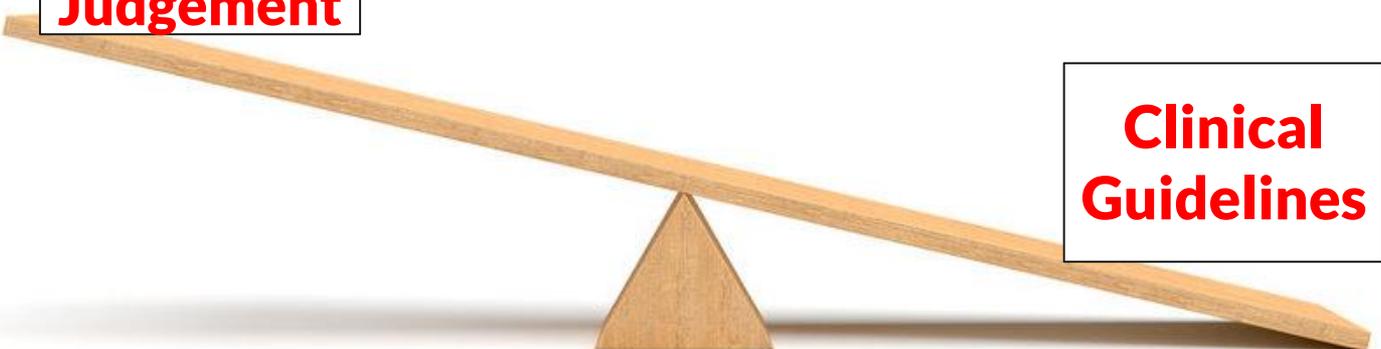


Conclusion



A New Balance Needed

**Clinical
Guidelines +
Clinical
Judgement**



**Clinical
Guidelines**

**Inefficient Cost
Restraints Are Injuring
Important Aspects of
the American
Healthcare System,
Almost at Random
(AKA Rural Hospitals)**

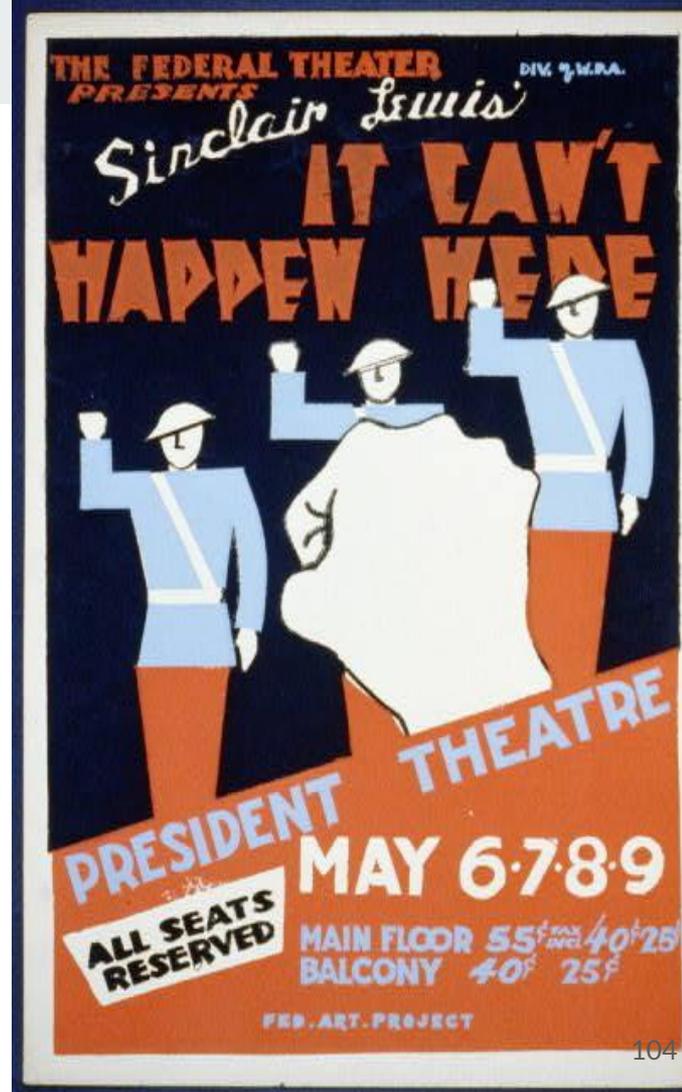


A Warning: Financial Aspirations > Physician Opinion



A Warning: *It Can't Happen Here*

- Physicians marginalized
- Opaque, inequitable healthcare rationing
- Unrestrained corporate and political control arrangements





Conclusion - The American Healthcare System Needs Reform

1. The **progressive evolution** of well-researched, though imperfect, clinical guidelines offers important possibilities for steadily improved healthcare
2. However, **substantial shortfalls** in clinical guideline methodology and implementation still exist
3. Important structural arrangements to coerce and **diminish independent physician judgement** are, arguably, not uniformly in the public's interest
4. The **great improvement** in American healthcare may have come with **unsustainable costs**
5. Moreover, **rather covertly**, insurance companies have altered established clinical guidelines for, at least in part, their economic interests
6. A particularly problematic development is embodied in **Medicare Advantage**
7. The cobbled-together, often **self-interested efforts at cost control** inefficiently damage the American healthcare system
8. The complicated, often poorly-integrated American healthcare system confronts increasing, **ill-directed cost restraints**



Thank you!

