

The Case for the Medical Conservative

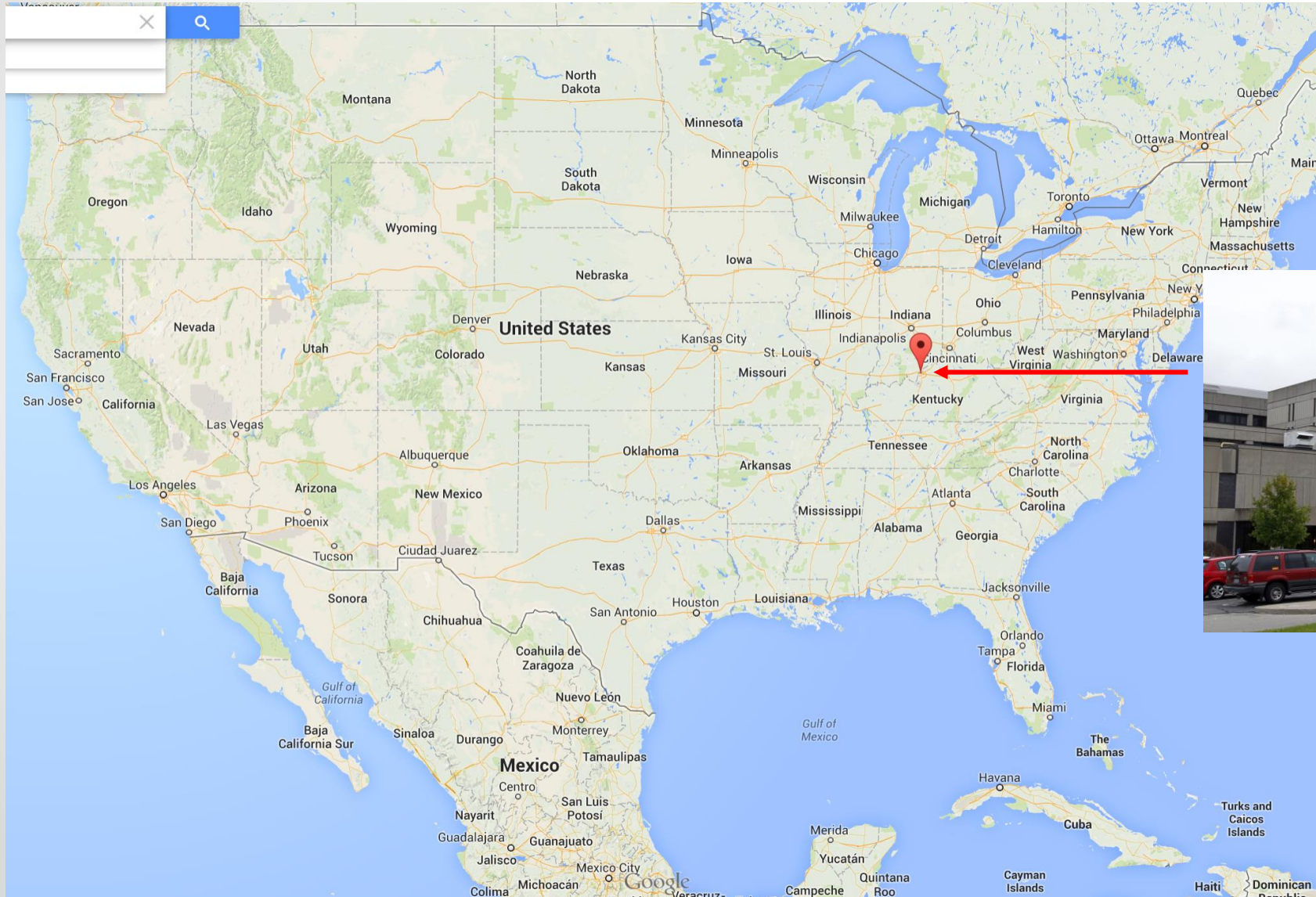
MEDS Conference

Winnipeg, Canada
2020

John Mandrola, MD
Baptist Health Louisville
@drjohnm



Disclosures – None



Baptist Health Louisville





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August 2019 Volume 132, Issue 8, Pages 900–901

The Case for Being a Medical Conservative

[John Mandrola, MD^{a,*}](#), [Adam Cifu, MD^b](#), [Vinay Prasad, MD, MPH^c](#), [Andrew Foy, MD^d](#)

 PlumX Metrics

DOI: <https://doi.org/10.1016/j.amjmed.2019.02.005> |

 Check for updates

- A 95-year-old man who lives independently presents to the hospital with shortness of breath.
- *He has not seen a doctor in 6 decades.*

Q: Why did he live to 95 years?



- **Magic Bullets**
- Mortality
- Uncertainty
- Problems with Fear
- Medicalization/Social Expectations
- Big business
- State of the Evidence
 - Reproducibility
 - Harms reporting
- Decision Quality

Antibiotics

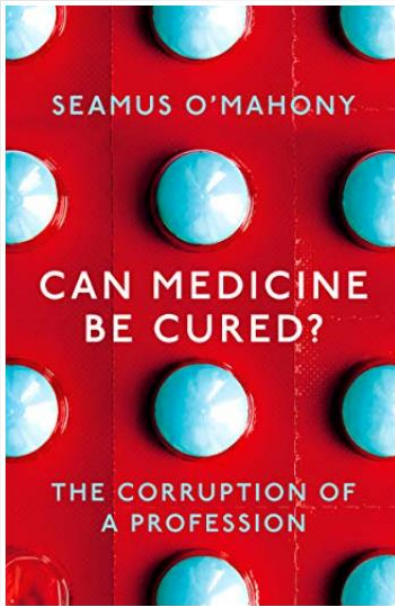
*Childhood
Vaccines*

Insulin

*Pacemaker
s*

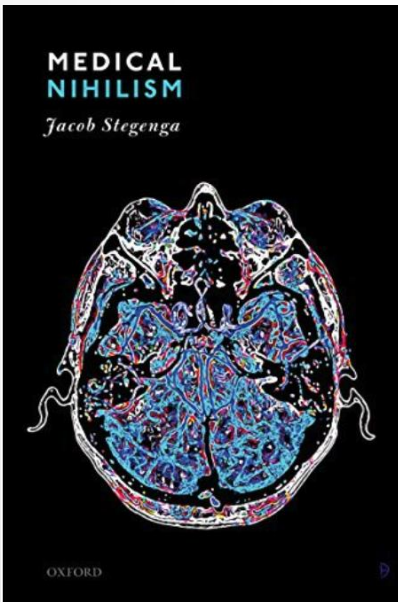
HIV Meds

Transplants



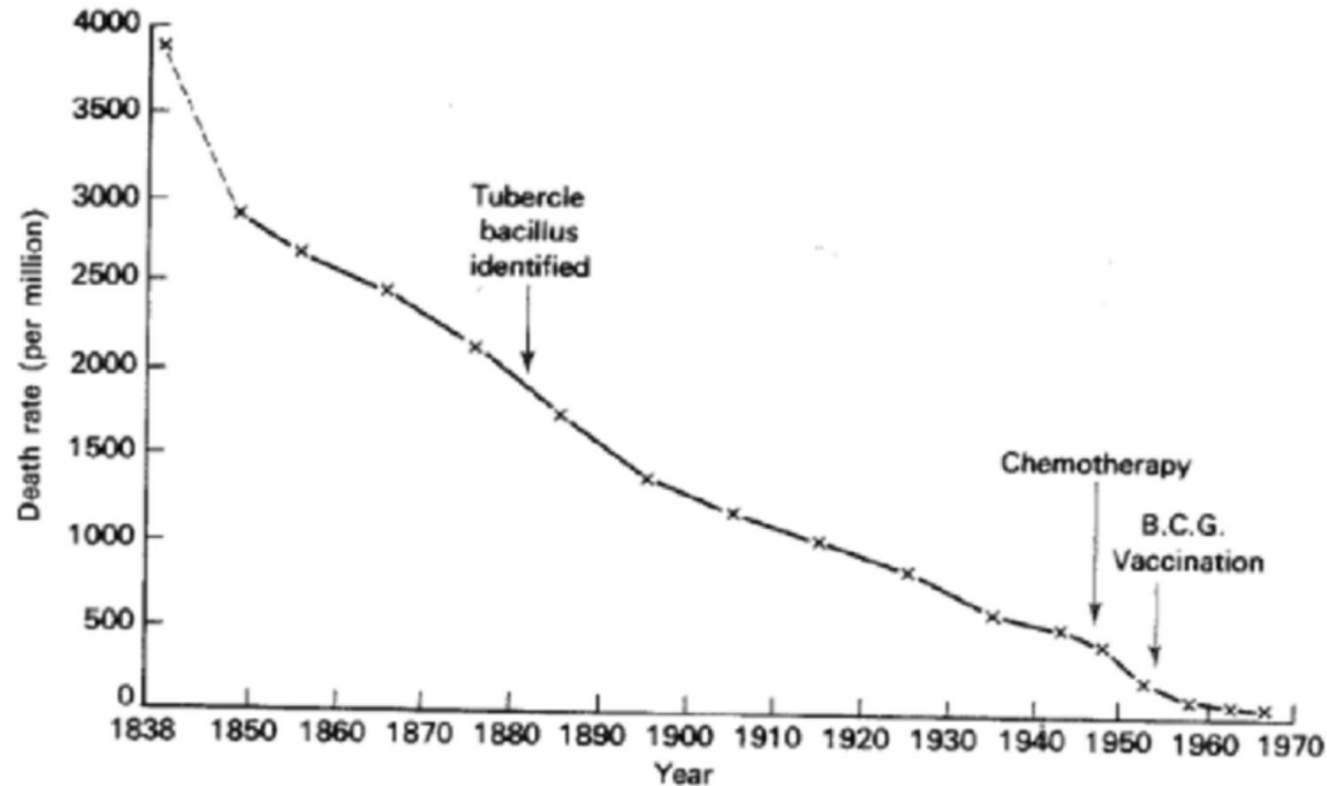
1930s - 2000

*The Golden Age of
Medicine*



*"Magic Bullet" model of
medical science*

Medical Innovations Compared With Sanitation and Relief of Overcrowding?



5.1 Respiratory tuberculosis: death rates, England and Wales.

- h/t Saurabh Jha MD @roguerad

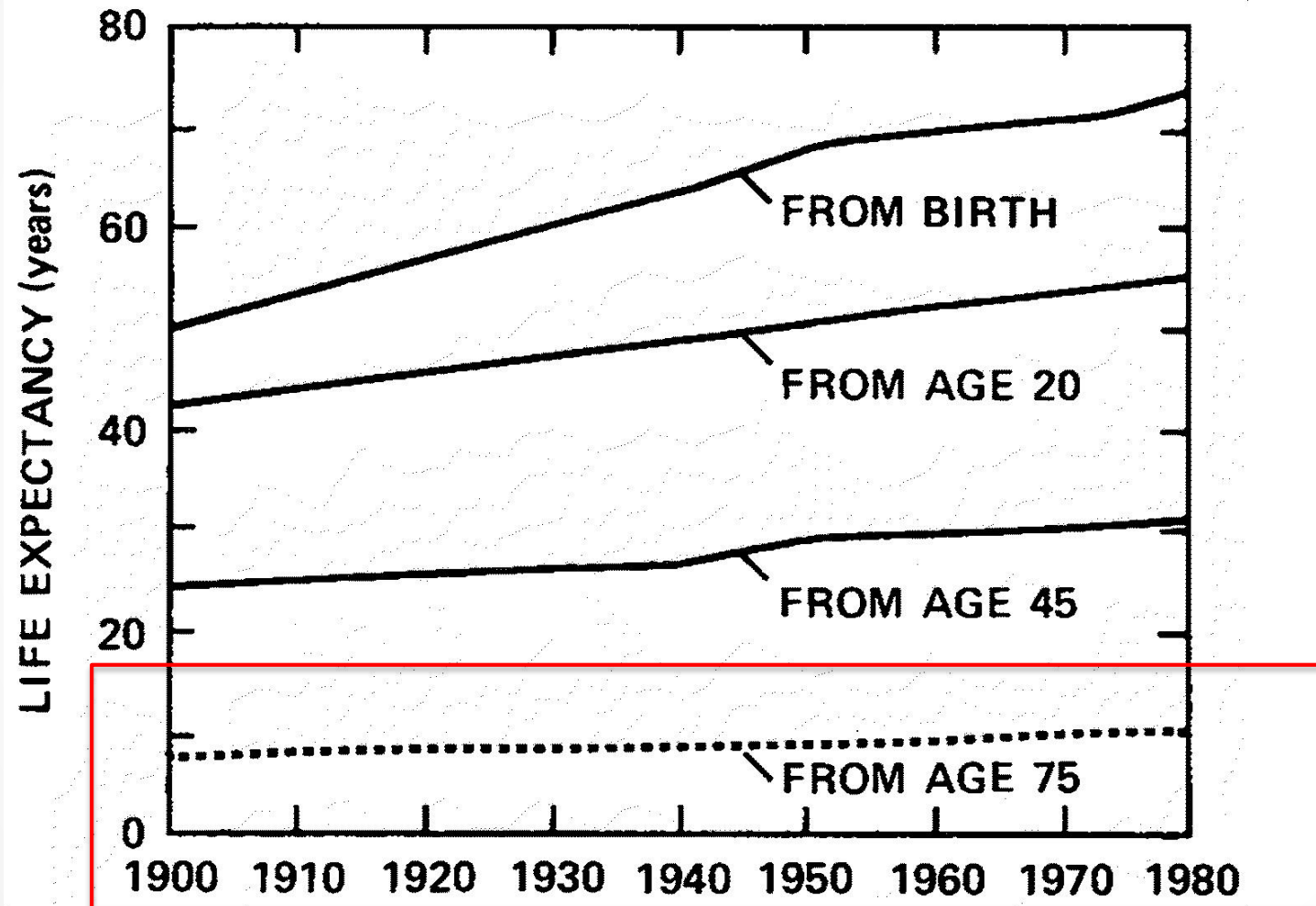
- Magic Bullets
- **Mortality**
- Uncertainty
- Problems with Fear
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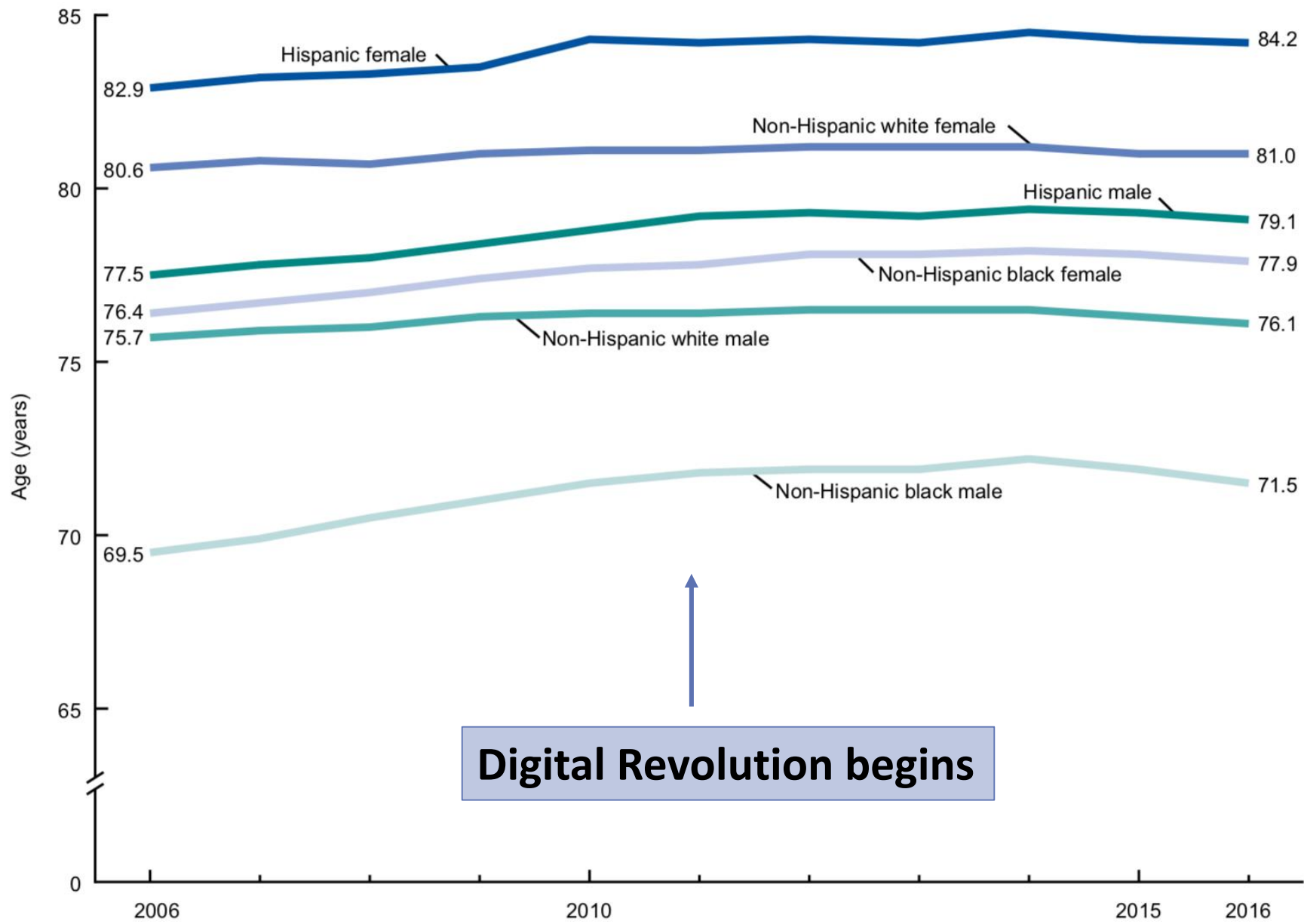
II -- Death is not optional

Aging, Natural Death, and the Compression of Morbidity

James F. Fries, M.D.

N Engl J Med 1980; 303:130-135 | July 17, 1980 | DOI: 10.1056/NEJM198007173030304





Digital Revolution begins

SOURCE: NCHS, National Vital Statistics System, Mortality.

FRONTLINE

WATCH | SCHEDULE | TOPICS | ABOUT FRONTLINE | SHOP | TEACHER CENTER

FACING DEATH

HOME / WATCH » INTERVIEWS | THE BIG ISSUES | EDUCATIONAL GUIDES 8

Recommend 35

Tweet 8

Facts & Figures



HOW WE DIE | COST OF CARE AT THE END OF LIFE | INTENSIVE CARE | BONE MARROW TRANSPLANTS

How We Die

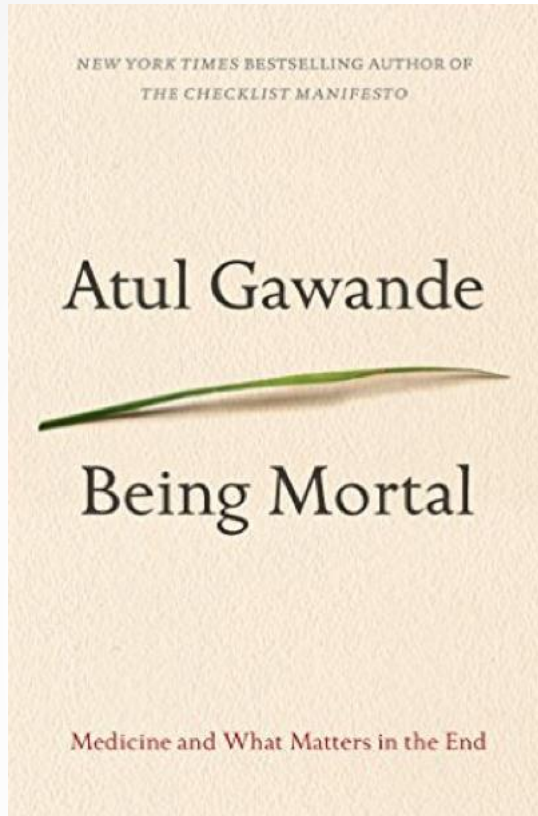
- Nearly half of all Americans die in a hospital.
Source: Centers for Disease Control (2005) [PDF]
- Nearly 70 percent of Americans die in a hospital, nursing home or long-term-care facility.
Source: Centers for Disease Control (2005) [PDF]

- 7 out of 10 Americans say they would prefer to die at home.
Source: Time/CNN Poll (2000)

7 out of 10 Americans say they would prefer to die at home

- Only 25 percent of Americans actually die at home.
Source: Centers for Disease Control (2005) [PDF]

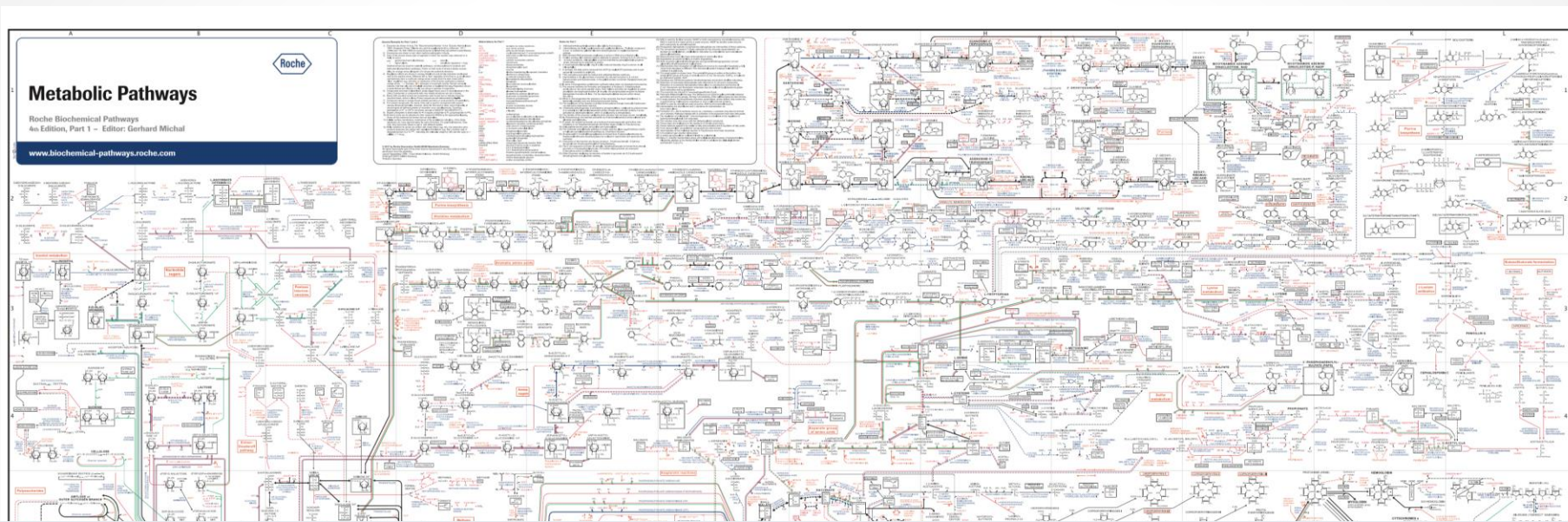
Only 1 in 4 do die at home



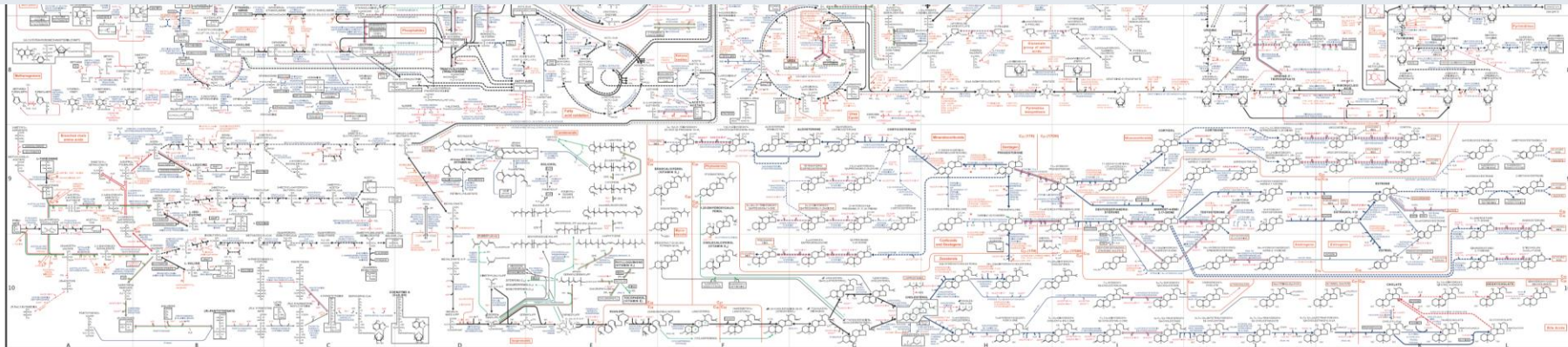
“Hope is not a
plan.”

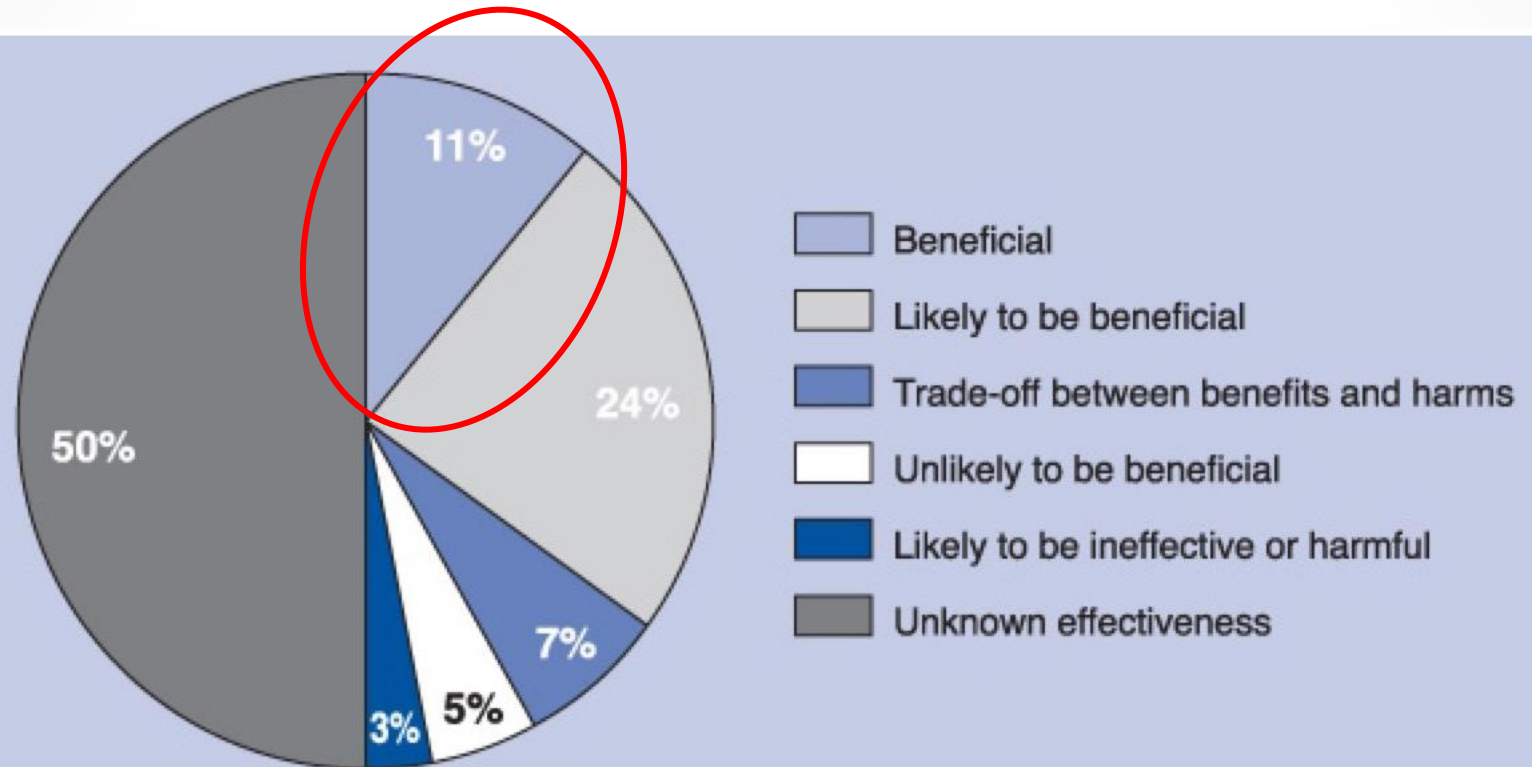
-- Atul Gawande, MD

- Magic Bullets
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The Human Body is Complex
Easy Fixes – Magic Bullets -- are Rare






Effectiveness of 3000 treatments as reported in randomised controlled trials selected by Clinical Evidence. This does **not** indicate how oftentreatments are used in healthcare settings or their effectiveness in individual patients.

Meta-Research: A comprehensive review of randomized clinical trials in three medical journals reveals 396 medical reversals



Diana Herrera-Perez, Alyson Haslam, Tyler Crain, Jennifer Gill, Catherine Livingston, Victoria Kaestner, Michael Hayes, Dan Morgan, Adam S Cifu, Vinay Prasad  [« see less](#)

Oregon Health & Science University, United States; University of Maryland School of Medicine, United States; University of Chicago, United States

- 3000 RCTs
- *Lancet, JAMA, NEJM*
- 2003-2017

Medical Reversal – RCT shows that an accepted practice is not better than a prior or lesser standard

- 396 or 13% of RCTs reversed an accepted practice
 - (often codified in guidelines)

ORIGINAL ARTICLE

Mortality and Morbidity in Patients Receiving Encainide, Flecainide, or Placebo — The Cardiac Arrhythmia Suppression Trial

Debra S. Echt, M.D., Philip R. Liebson, M.D., L. Brent Mitchell, M.D., Robert W. Peters, M.D., Dulce Obias-Manno, R.N., Allan H. Barker, M.D., Daniel Arensberg, M.D., Andrea Baker, R.N., Lawrence Friedman, M.D., H. Leon Greene, M.D., Melissa L. Huther, and David W. Richardson, M.D. the CAST Investigators*

Original Contribution

FREE

July 17, 2002

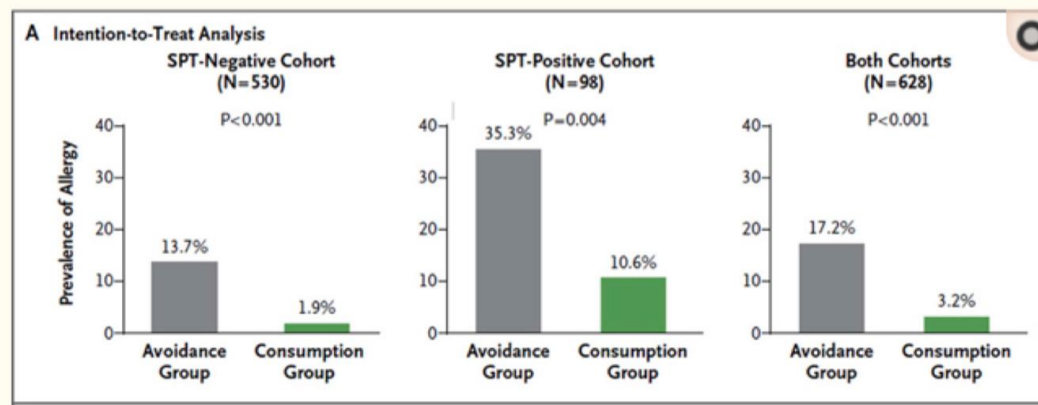
Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women Principal Results From the Women's Health Initiative Randomized Controlled Trial

Writing Group for the Women's Health Initiative Investigators

ORIGINAL ARTICLE

Randomized Trial of Introduction of Allergenic Foods in Breast-Fed Infants

Michael R. Perkin, Ph.D., Kirsty Logan, Ph.D., Anna Tseng, R.D., Bunmi Raji, R.D., Salma Ayis, Ph.D., Janet Peacock, Ph.D., Helen Brough, Ph.D., Tom Marrs, B.M., B.S., Suzana Radulovic, M.D., Joanna Craven, M.P.H., Carsten Flohr, Ph.D., and Gideon Lack, M.B., B.Ch. for the EAT Study Team*



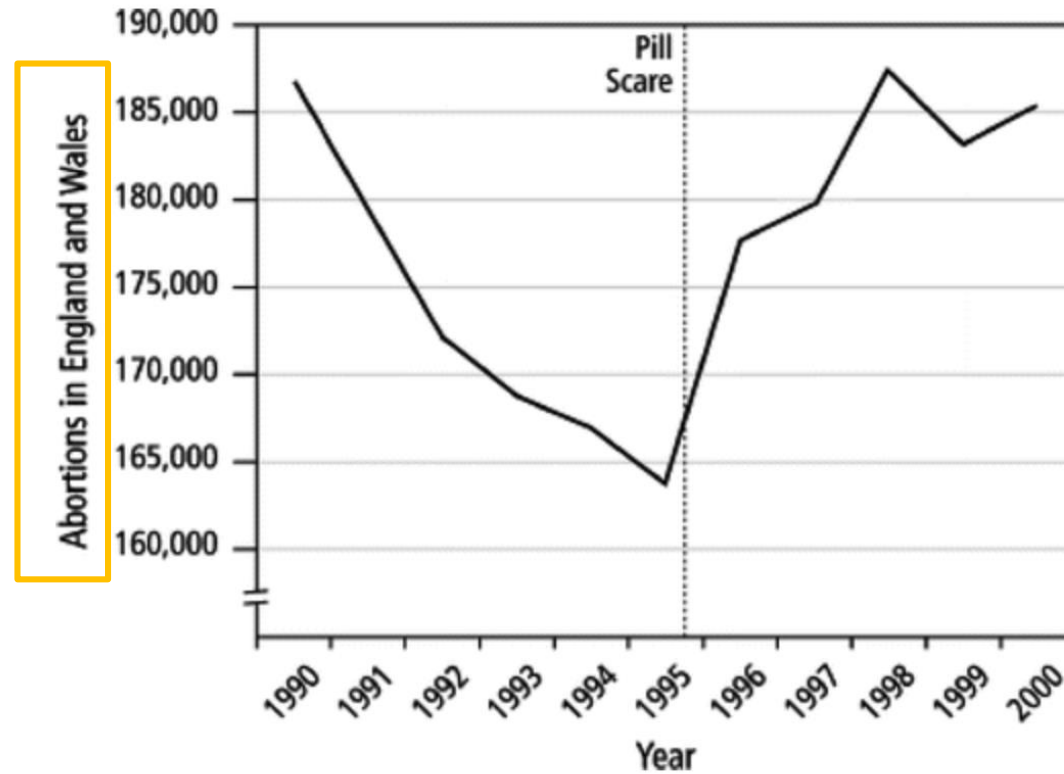
- Magic Bullets
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- **Problems with Fear**
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IV – Fear – Destroys Decision Quality

October 1995

- UK Committee on Safety of Medicines issued a warning:
- Third-generation OCP increased the risk of venous thrombosis by 100%
- Risk increased from
 - 1/7000 to 2/7000 = 100%

Abortions in England and Wales



- $\approx 13,000$ additional abortions in the following year
- Cost ≈ 46 million pounds
- Risk of VTE with abortion/pregnancy $>$ 3rd generation OCP

Commentary

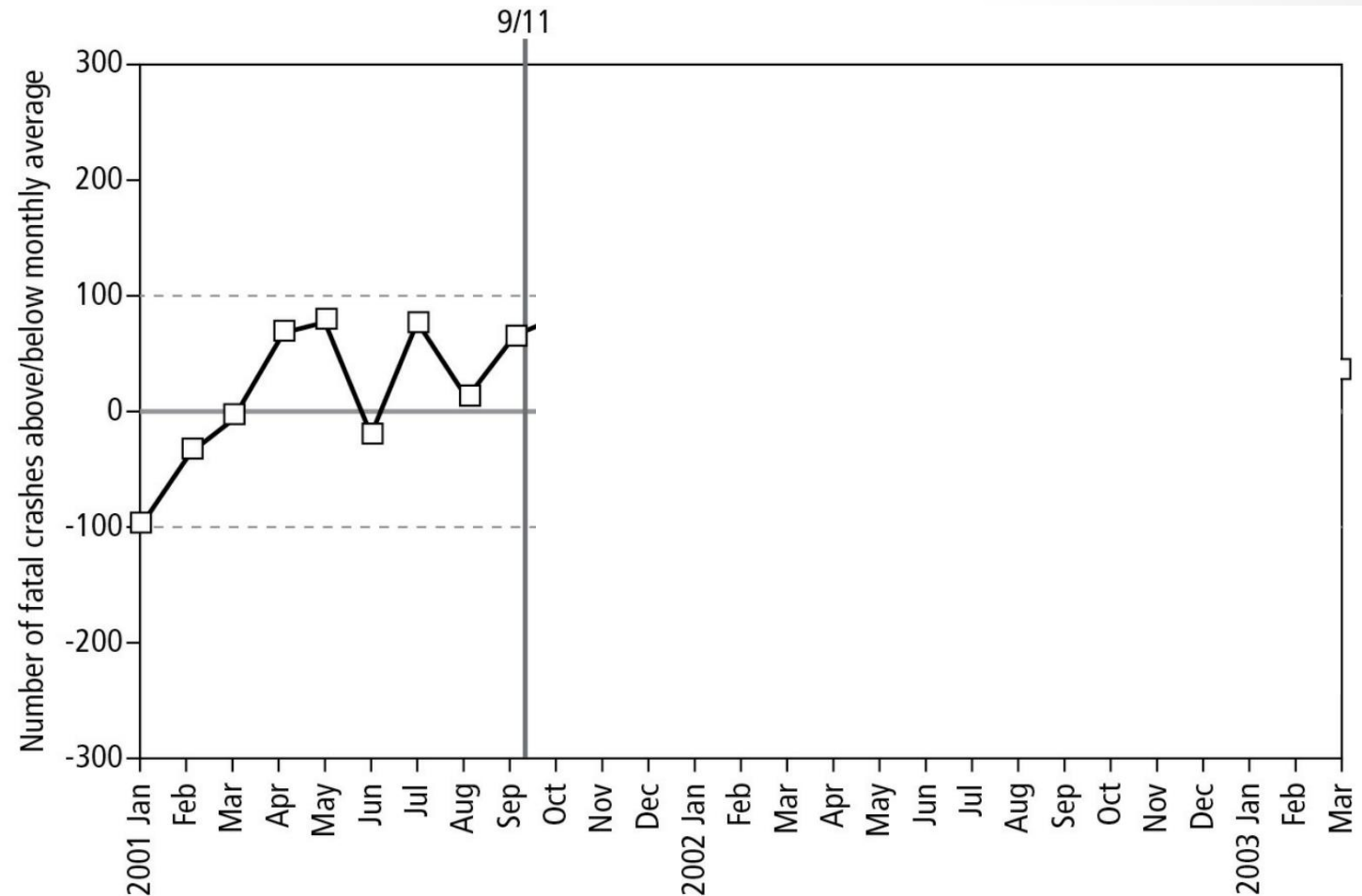
Dread Risk, September 11, and Fatal Traffic Accidents

Gerd Gigerenzer

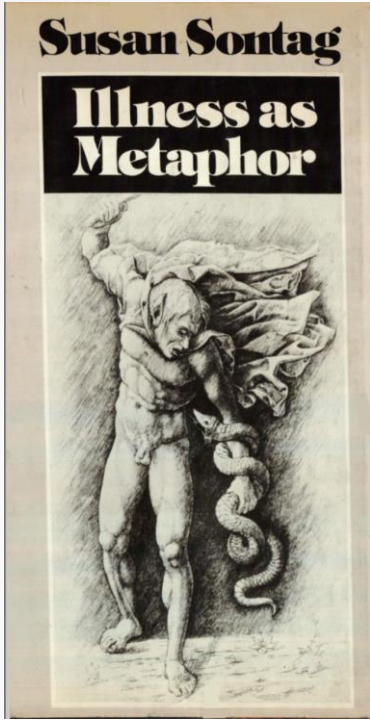
Max Planck Institute for Human Development, Berlin, Germany

Fear – Dread Risk

Fear of flying led to ≈ 1600 extra traffic-deaths in months after 9/11



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Sontag's Dual Citizenship

Kingdom of the Well



Kingdom of the Sick



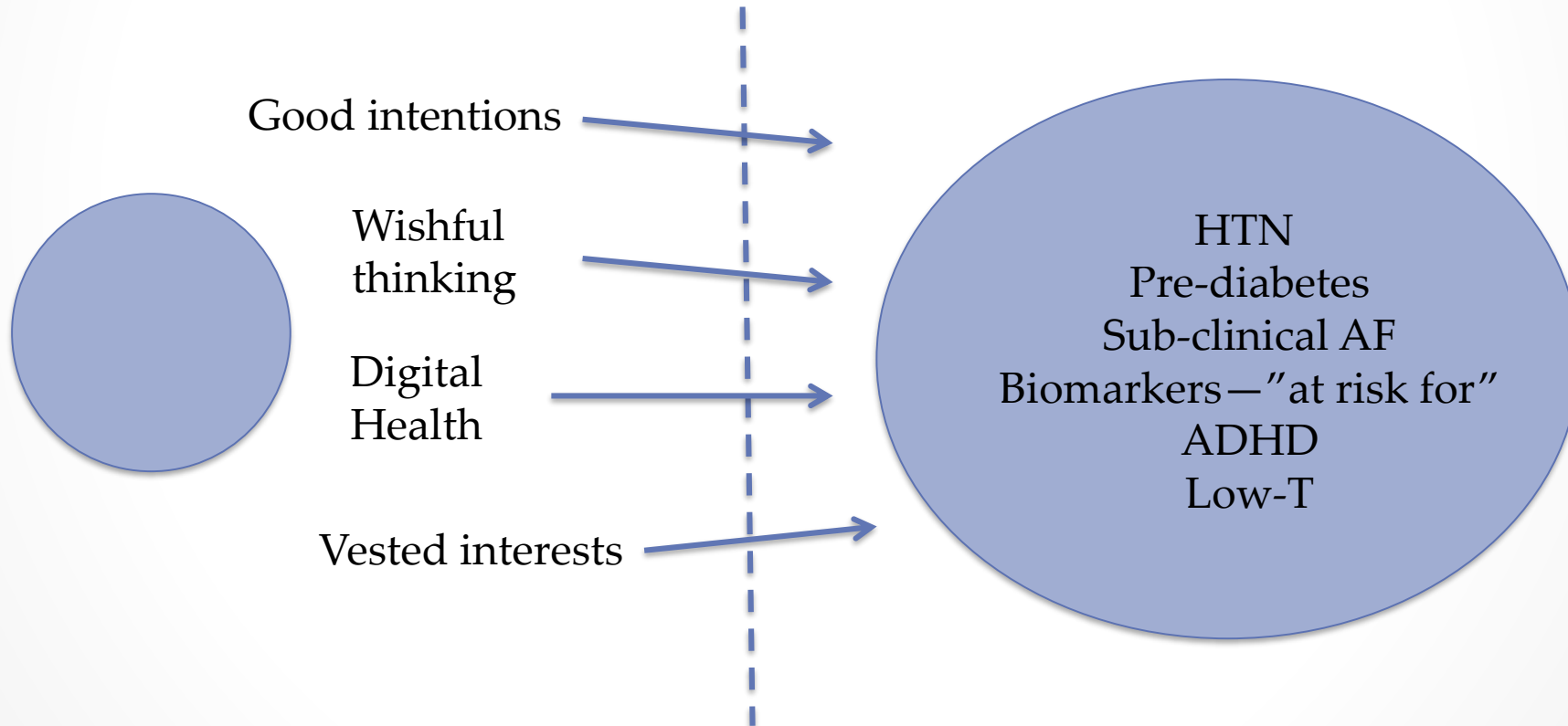
Circa 1978

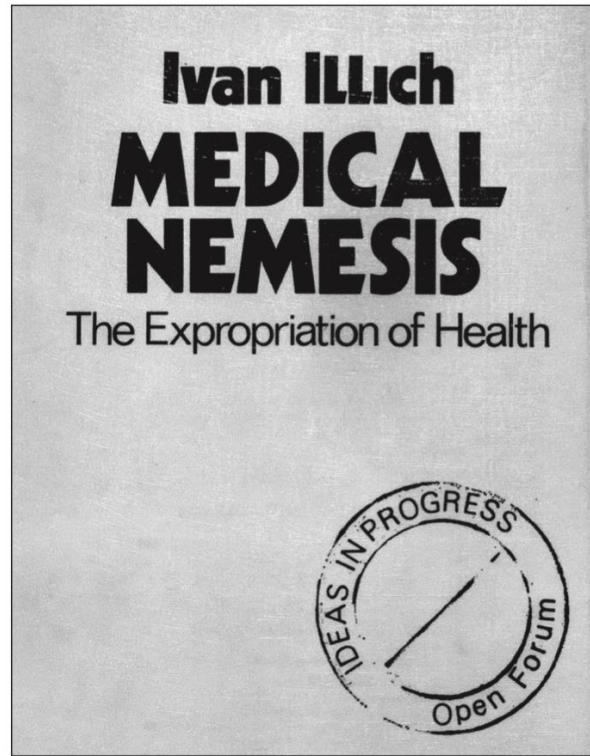
Sontag's Kingdoms

circa 2018

Kingdom of the Well

Kingdom of the Sick





Circa 1976

Social Iatrogenesis

Clinicians / Hospitals / Pharma

- Sponsor sickness
- Reinforce morbid society
- Encourage consumerism for preventive therapies



Anticipatory Medicine



You are sick -- You need us to fix you

AF screening (ECG specificity – 95%)



Screened population 1,000,000

AF prevalence 2%

Number of people w/ AF $0.02 \times 1,000,000 = 20,000$ people

Number without AF $1,000,000 - 20,000 = 980,000$ people

True Negative $0.95 \times 980,000 = 931,000$ reassured they do not have AF

False Positive $0.05 \times 980,000 = 49,000$ people falsely diagnosed with AF

List of RCTs showing benefit from oral AC in short-duration screen-detected AF

- Click to add text

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AHA JOURNALS ▼

ORIGINAL RESEARCH ARTICLE

Wide Variation in Reported Rates of Stroke Across Cohorts of Patients With Atrial Fibrillation

Gene R. Quinn, Olivia N. Severdija, Yuchiao Chang, Daniel E. Singer



Download PDF

DOI <https://doi.org/10.1161/CIRCULATIONAHA.116.024057>

Circulation. 2017;135:208-219

Originally published October 31, 2016

Review of 34 studies of AF cohorts NOT treated with AC



2 CHA₂DS₂-VASc
High risk

0.8 SCr
mg/dL

113.8 CrCl
mL/min

3 Evaluate Therapy

Standard Dose (clinical trials)

Not applicable

Stroke Risk/Benefit

Bleed Risk

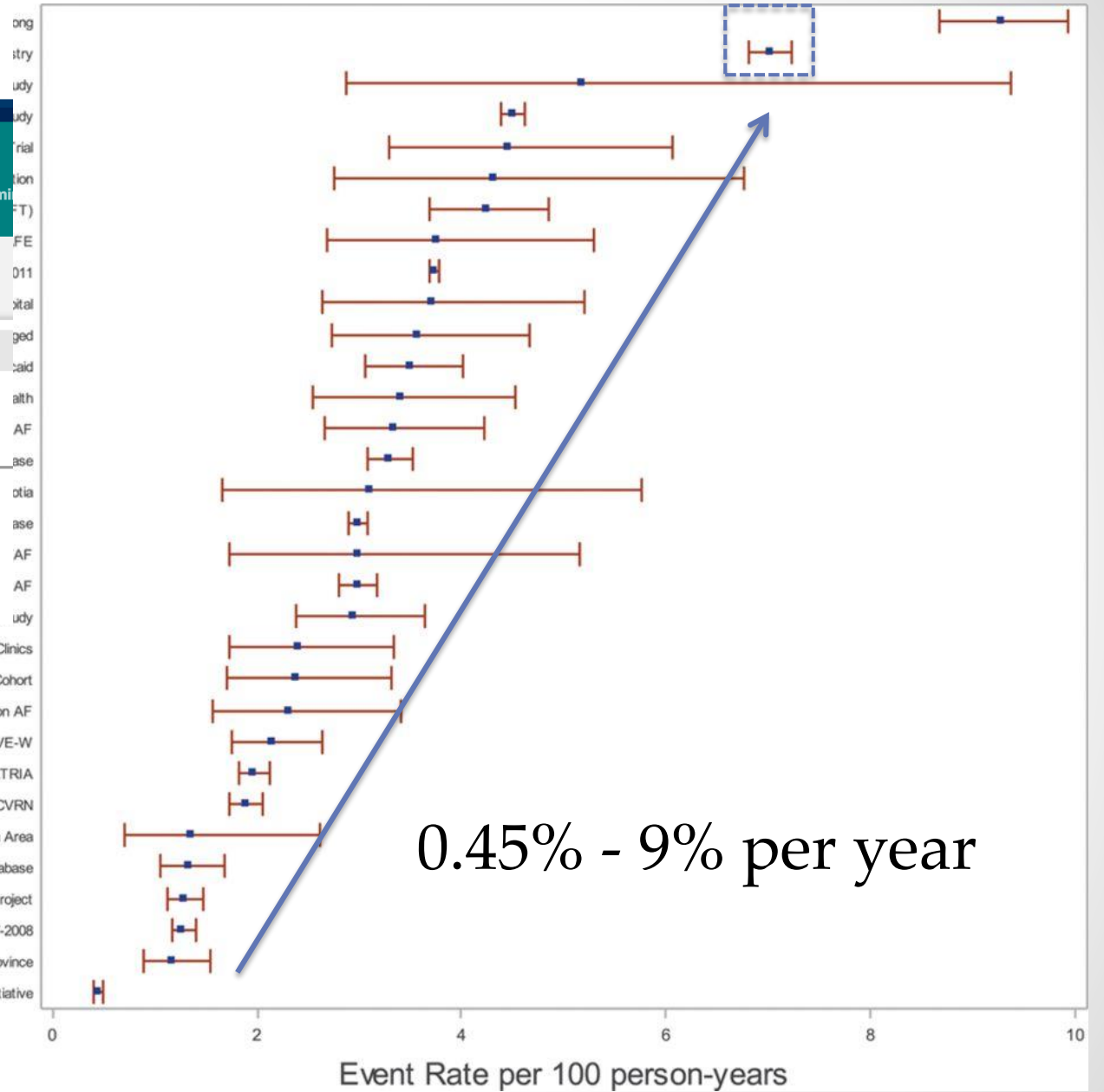
Safety Info

Risk/Benefit Information*

Patient's ADJUSTED ANNUAL risk of stroke with No Therapy**

2.2%

- Japanese Multi-Arrhythmia Clinics
- Japan - Iwate Cohort
- Euro Heart Survey on AF
- ACTIVE-W
- ATRIA
- ATRIA CVRN
- Spain - Atrial Fibrillation in the Barbanza Area
- Japan - Shinken Database
- Loire Valley AF Project
- Taiwan - National Health Insurance Database 1997-2008
- China - Yunnan Province
- Women's Health Initiative



Do we know the untreated stroke risk?

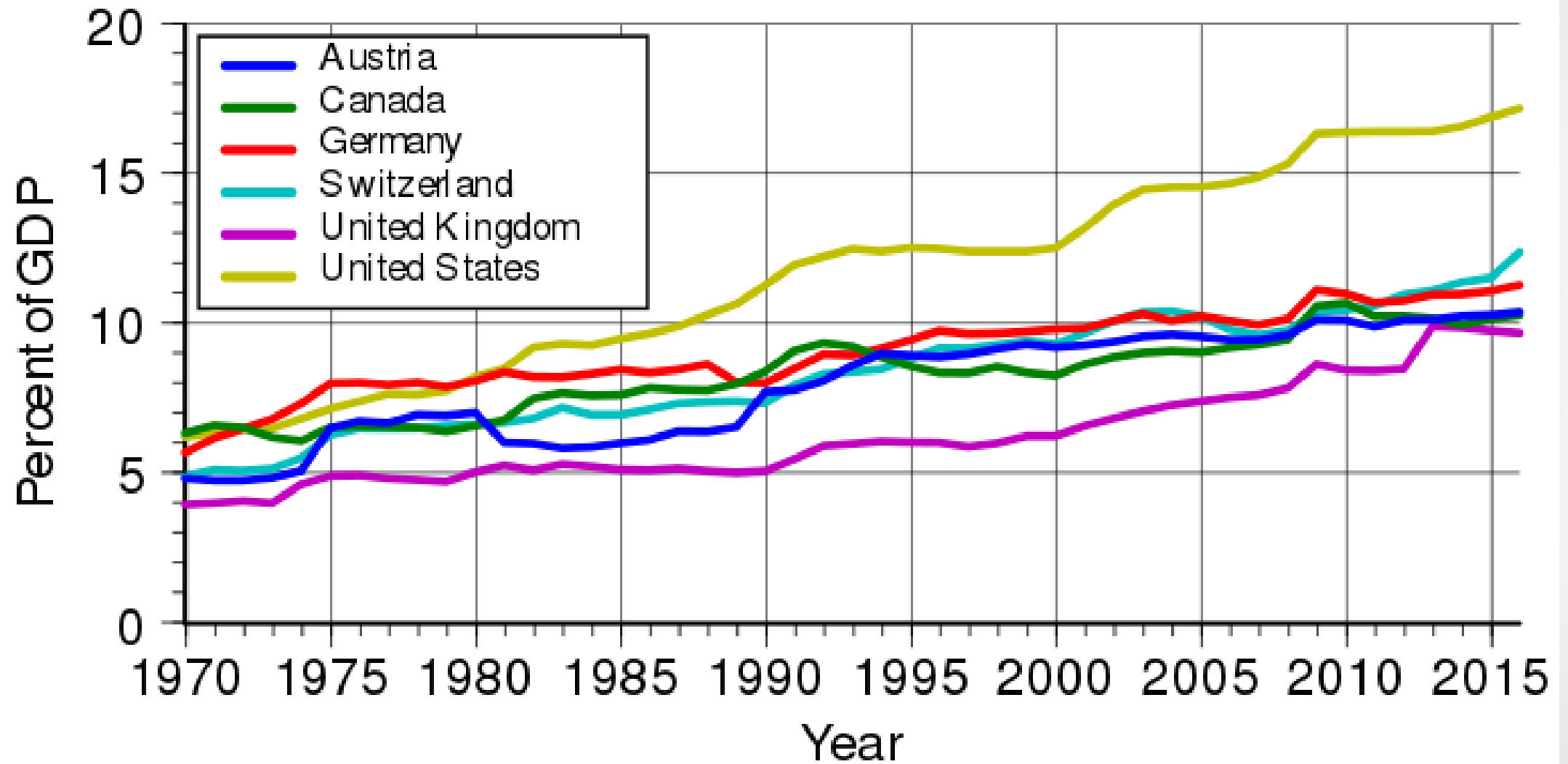
	Women's Health Initiative (17)	Stockholm Area Database (20)	Taiwan NHI Database (15)	ATRIA (18)	Iwate Cohort (30)	J-Rhythm, Shinken, Fushimi (32)	Euro Heart Survey on AF (8)	Swedish AF Study (22)	General Practice Research Database (28)	Clalit Health Services AF (34)	PLA General Hospital AF (25)	J-Rhythm (44)	AVERROES ACTIVE-A, and ACTIVE-W* (45)	Alberta AF Cohort † (46)	Taiwan NHIRD - 1996-2011 (14)	Danish National Patient Registry (6)	Queen Mary Hospital (35)
CHA₂DS₂-VASc Score																	
0	--	0.3	0.35	0.04	0	0.53	0	0.2	0.38	0.42	0	0.7	--	--	1.15	0.78	2.41
1	0.2	0.5	0.5	0.55	0.6	0.55	0.6	0.6	0.78	0.82	0.9	0.9	1.1	1.3	2.11	2.01	6.64
2	0.48		0.91	0.83	0.95	1.11	1.6	2.2	1.92	1.81	1.7	1.9	2.3	6.5‡	3.39	3.71	7.84
3	0.82		1.35	1.66	1.96	1.38	3.9	3.2	2.84	2.57	2.7	1.2	3.3‡		3.89	5.92	9.56
4	1.3		2.12	2.8	5.45	1.52	1.9	4.8	3.7	3.71	1.8	2.3			4.61	9.27	11.58

Quinn et al Circ 2017

<http://circ.ahajournals.org/content/135/3/208?download=true>

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Health Care Cost (1970-2016)





Christina Farr ✓
@chrissyfarr



For tech companies, heart disease is the “holy grail of disease management.”



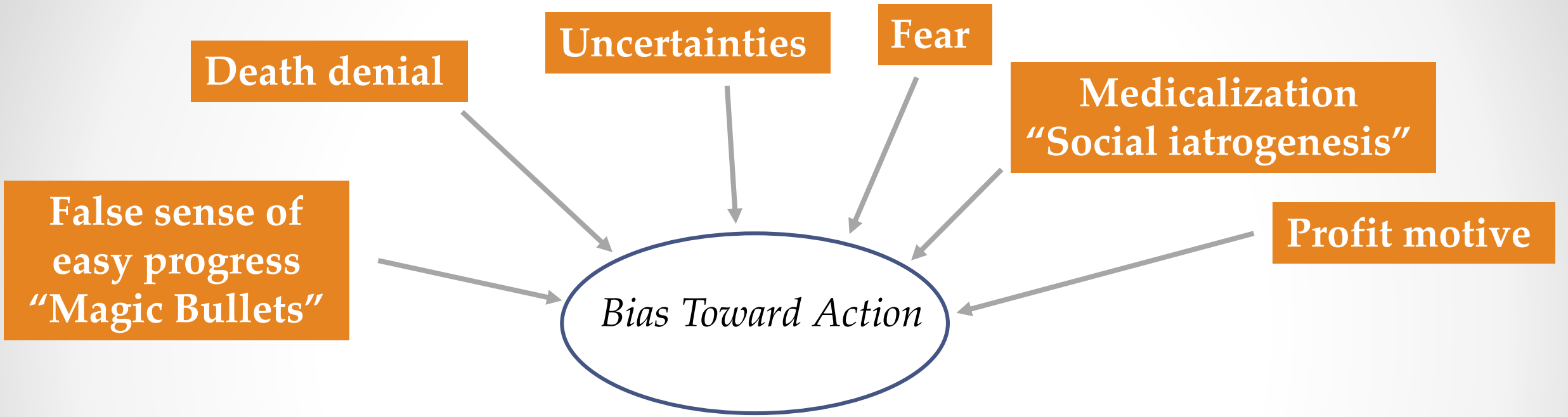
Apple hires another prominent cardiologist as it makes heart health a big ar...

CommonSpirit Health By The Numbers

Operations in 21 States		Over 20 million patients treated last year	
Care Provided Highlights		Financial Highlights	
146 hospitals	1,100+ non-acute care facilities	\$38 billion in assets	\$30 billion in total annual operating revenue
\$4.2 billion charitable care and services		Employee Count: 150,000 Including approximately 100,000 advanced practice nurses	
Largest Not-For-Profit Health System			

More revenue, and expense, than many well-known companies

Companies with less than \$30 Billion in annual revenues based on FY18 financials.



“A (medical) conservative is someone who stands athwart history, yelling Stop, at a time when no one is inclined to do so, or to have much patience with those who so urge it.”

William Buckley Jr

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 - Reproducibility
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[August 2019](#) Volume 132, Issue 8, Pages 900–901

The Case for Being a Medical Conservative

[John Mandrola, MD^{a,*}](#),  [Adam Cifu, MD^b](#), [Vinay Prasad, MD, MPH^c](#), [Andrew Foy, MD^d](#)

 PlumX Metrics

DOI: <https://doi.org/10.1016/j.amjmed.2019.02.005> |

 Check for updates

The medical conservative adopts new therapies
when the benefit is clear and the evidence
strong and unbiased.

What About Guidelines?

March 19, 2019

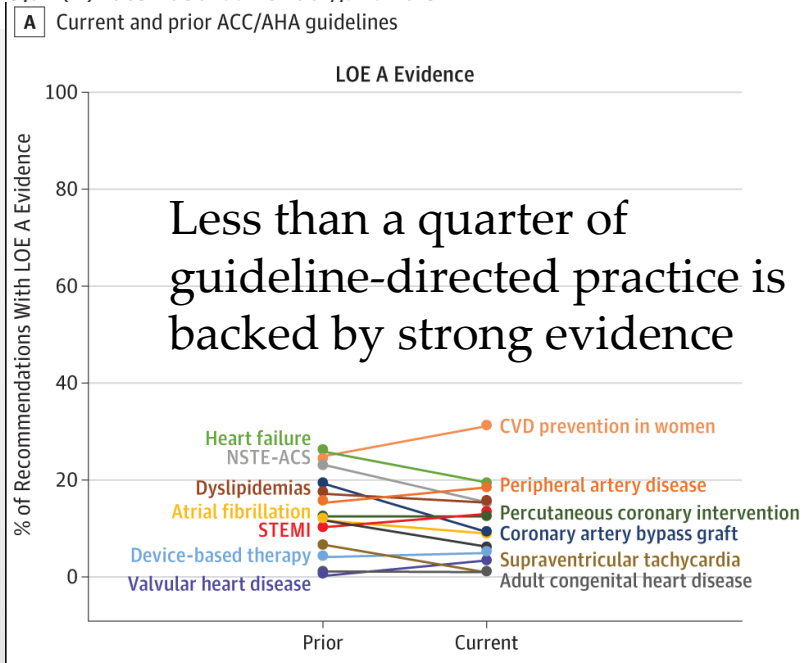
Levels of Evidence Supporting American College of Cardiology/American Heart Association and European Society of Cardiology Guidelines, 2008-2018

Alexander C. Fanaroff, MD, MHS¹; Robert M. Califf, MD^{2,3,4}; Stephan Windecker, MD⁵; et al

» Author Affiliations | Article Information

JAMA. 2019;321(11):1069-1080. doi:10.1001/jama.2019.1122

- N = 26 guidelines
- > 2600 recommendations



Most recs = no RCT evidence

Dualities of Interest in Guidelines

Research article | [Open Access](#) | Open Peer Review | Published: 03 May 2013

Underreporting of conflicts of interest in clinical practice guidelines: cross sectional study

[Julie Bolette Brix Bindslev](#), [Jeppe Schroll](#), [Peter C Gøtzsche](#) & [Andreas Lundh](#) ✉

BMC Medical Ethics 14, Article number: 19 (2013) | [Cite this article](#)

N = 45 guidelines from 14 specialties

- 53% of authors had COI
- But
- 2% guidelines disclosed COI

- Bindslev BMC Ethics 2013

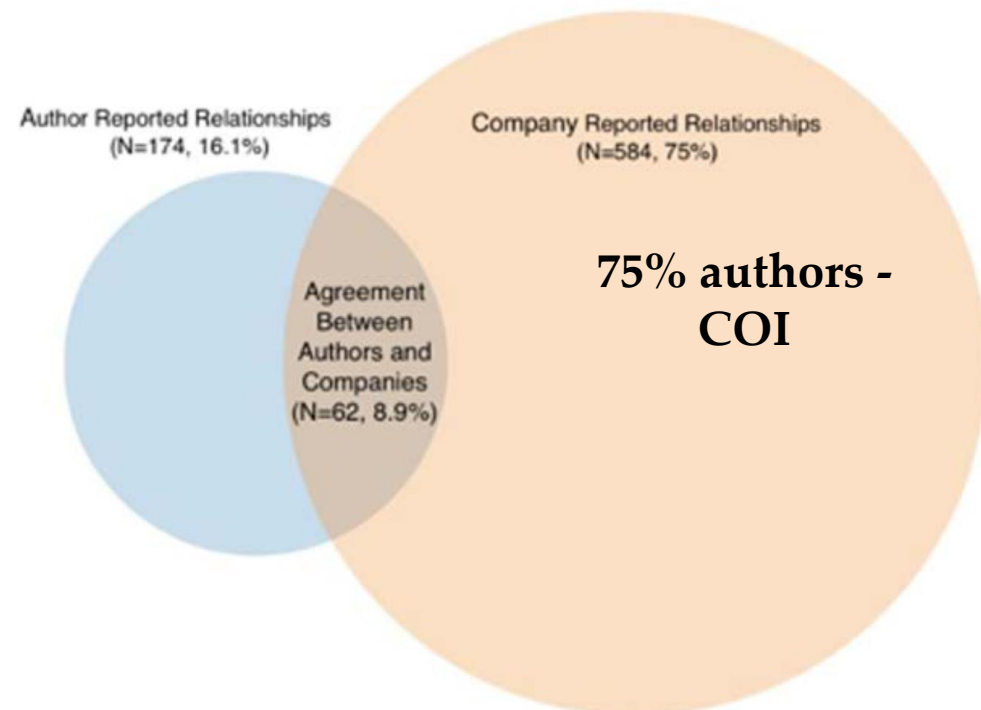
[Circulation: Cardiovascular Quality and Outcomes](#)

DATA REPORT

Analysis of American College of Cardiology/
American Heart Association Guideline
Author Self-Disclosure Compared With Open
Payments Industry Disclosure

Can We Trust the Independence of Cardiovascular Guidelines?

Steven E. Nissen ✉



Dudum Circ OQ 2019
Nissen Circ OQ 2019

Reproducibility and Transparency

Reproducible the Biomedic

Shareen A. Iqbal Joshua

Published: January 4, 2016

Five-Year Outcomes after PCI or CABG for Left Main Coronary Disease

Gregg W. Stone, M.D., A. Pieter Kappetein, M.D., Ph.D., Joseph F. Sabik, M.D., Stuart J. Pocock, Ph.D., Marie-Claude Morice, M.D., John Puskas, M.D., David E. Kandzari, M.D., Dimitri Karpaliotis, M.D., W. Morris Brown, III, M.D., Nicholas J. Lembo, M.D., Adrian Banning, M.D., Béla Merkely, M.D., et al., for the EXCEL Trial Investigators*

Random biomedicine

Article

Figures/Media

Metrics

November 7, 2019

- Number with published protocol → 1

Question	Authors' Response
Will the data collected for your study be made available to others?	No

Original Investigation

FREE

September 10, 2014

Reanalyses of Randomized Clinical Trial Data

Published reanalyses of RCTs of
the same question

N = 37 (32 by the same authors)

Shanil Ebrahim, PhD^{1,2,3,4}; Zahra N. Sohani, MSc^{2,5}; Luis Montoya, DDS⁶; Arnav Agarwal, BSc⁷; Kristian Thorlund, PhD^{1,2}; Edward J. Mills, PhD^{1,2,8}; John P. A. Ioannidis, MD, DSc^{1,9,10,11}

Thirteen reanalyses (35%) led to interpretations *different* from that of the original article

- 3 (8%) different patients should be treated
- 1 (3%) fewer patients should be treated
- **9 (24%) more patients should be treated**

Many Analysts, One Data Set: Making Transparent How Variations in Analytic Choices Affect Results

R. Silberzahn, E. L. Uhlmann, D. P. Martin, more...

Show all authors ▾

First Published August 23, 2018 | Research Article |



<https://doi.org/10.1177/2515245917747646>

Perspective > Medscape > Mandrola on Medscape

COMMENTARY

The Year's Most Important Study Adds to Uncertainty in Science

John M. Mandrola, MD

DISCLOSURES | November 02, 2018

29 teams of data scientists/statisticians

Used the same dataset

To answer one question:

Are soccer refs more likely to give red cards to dark-skinned players?

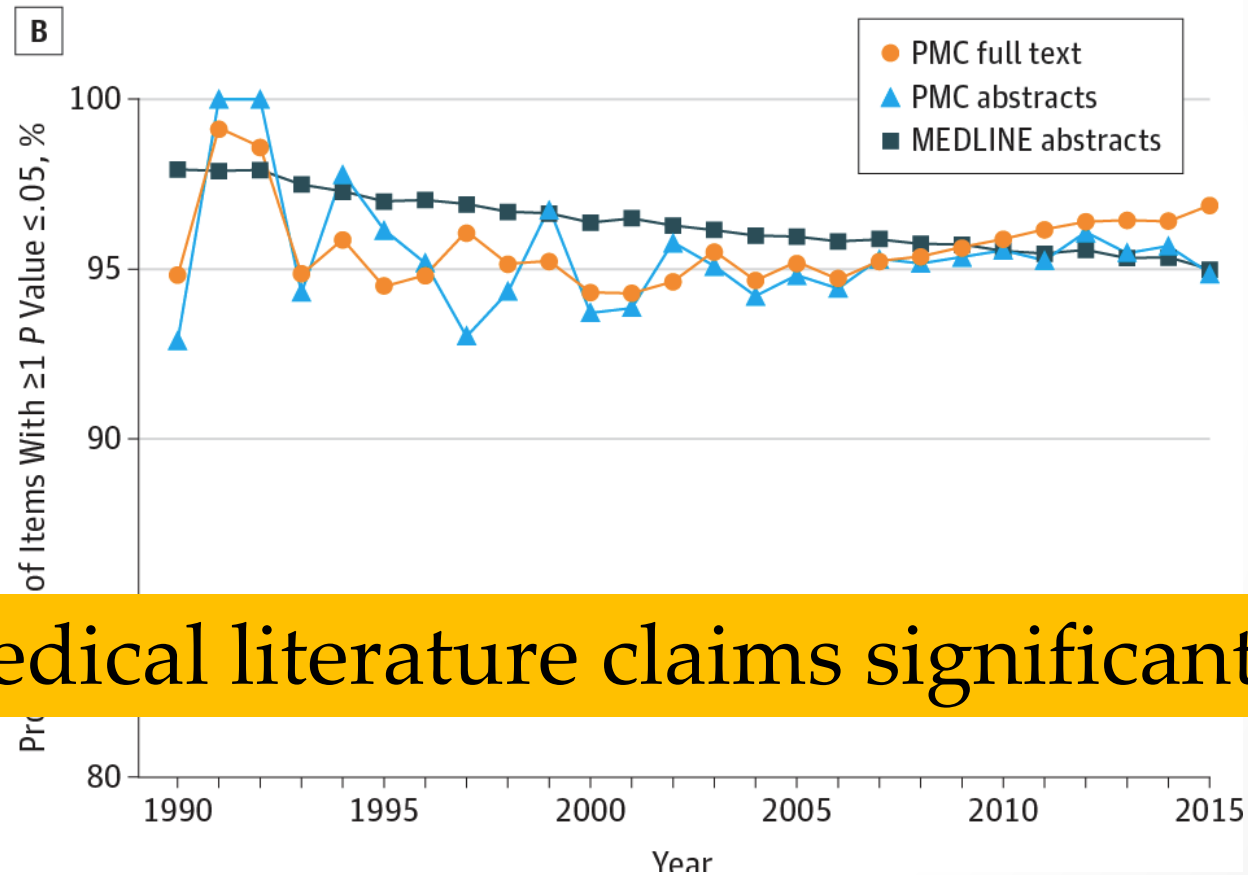
Team	Analytic Approach
12	Zero-Inflated Poisson Regression
17	Bayesian Logistic Regression
15	Hierarchical Log-Linear Modeling
10	Multilevel Regression and Logistic Regression
18	Hierarchical Bayes Model
31	Logistic Regression
1	OLS Regression With Robust Standard Errors, Logistic Regression
4	Spearman Correlation
14	WLS Regression With Clustered Standard Errors
11	Multiple Linear Regression
30	Clustered Robust Binomial Logistic Regression
6	Linear Probability Model
26	Hierarchical Generalized Linear Modeling With Poisson Sampling
3	Multilevel Logistic Regression Using Bayesian Inference
23	Mixed-Model Logistic Regression
16	Hierarchical Poisson Regression
2	Linear Probability Model, Logistic Regression
5	Generalized Linear Mixed Models
24	Multilevel Logistic Regression
28	Mixed-Effects Logistic Regression
32	Generalized Linear Models for Binary Data
8	Negative Binomial Regression With a Log Link
20	Cross-Classified Multilevel Negative Binomial Model
13	Poisson Multilevel Modeling
25	Multilevel Logistic Binomial Regression
9	Generalized Linear Mixed-Effects Models With a Logit Link
7	Dirichlet-Process Bayesian Clustering
21	Tobit Regression
27	Poisson Regression

March 15, 2016

Evolution of Reporting P Values in the Biomedical Literature, 1990-2015

David Chavalarias, PhD¹; Joshua David Wallach, BA²; Alvin Ho Ting Li, BHSc³; John P. A. Ioannidis, MD, DSc⁴

N - 16 million abstracts from Medline and Pubmed



96% of the Biomedical literature claims significant results



OPEN ACCESS

ESSAY

Why Most Published Research Findings Are False

John P. A. Ioannidis

Published: August 30, 2005 • <https://doi.org/10.1371/journal.pmed.0020124>

68,436
Save

3,458
Citation

2,909,608
View

10,484
Share



- Bias
 - Design
 - Study question
 - Selective reporting
- Low power
- Small effect size
- Multiple comparisons
- COI



May 3, 2019

Level and Prevalence of Spin in Published Cardiovascular Randomized Clinical Trial Reports With Statistically Nonsignificant Primary Outcomes

A Systematic Review

Muhammad Shahzeb Khan, MD¹; Noman Lateef, MD²; Tariq Jamal Siddiqi, MBBS³; Karim Abdur Rehman, MD⁴; Saed Alnaimat, MD⁵; Safi U. Khan, MD⁶; Haris Riaz, MD⁴; M. Hassan Murad, MD⁷; John Mandrola, MD⁸; Rami Doukky, MD⁹; Richard A. Krasuski, MD¹⁰

[» Author Affiliations](#) | [Article Information](#)

JAMA Netw Open. 2019;2(5):e192622. doi:10.1001/jamanetworkopen.2019.2622

- SR of 6 major journals in 3-year period
- RCTs with non-signif primary endpoints
- 587 studies identified
- 93 RCT (16%) – NS results

Spin = Language designed to distract from the non-sig primary endpoint

- 57% of abstracts
- 67% of main paper
- 11% in title

Even if reproducible and real

Effect Sizes ??

ARR vs RRR

P values

Jupiter Trial

Rosuvastatin to Prevent Vascular Events in Men and Women with Elevated C-Reactive Protein

Paul M Ridker, M.D., Eleanor Danielson, M.I.A., Francisco A.H. Fonseca, M.D., Jacques Genest, M.D., Antonio M. Gotto, Jr., M.D., John J.P. Kastelein, M.D., Wolfgang Koenig, M.D., Peter Libby, M.D., Alberto J. Lorenzatti, M.D., Jean G. MacFadyen, B.A., Børge G. Nordestgaard, M.D., James Shepherd, M.D., *et al.*, for the JUPITER Study Group*

- ≈ 18,000 patients w/ LDL > 130 and CRP > 2
- Rosuvastatin vs Placebo
- PEP = MI, Stroke, Revasc, UA, CV death

End Point	Rosuvastatin (N=8901)		Placebo (N=8901)		Hazard Ratio (95% CI)	P Value
	No. of Patients	Rate per 100 person-yr	No. of Patients	Rate per 100 person-yr		
Primary end point	142	0.77	251	1.36	0.56 (0.46–0.69)	<0.00001

Relative Risk Reduction → 44% with a super-small P value

Absolute Risk Reduction → 1.6% vs 2.8% = **1.2%**

NNT → 82

ARR vs RRR

Cost

**MOVING
CLOSER TO
ZERO RISK
OF DEVICE
INFECTION**

With the TYRX[®]
Antibacterial Envelope

Medtronic
Further. Together.

The advertisement is a square graphic divided into four quadrants. The top-left quadrant is dark blue with white text. The top-right quadrant is a close-up photograph of a copper-colored, mesh-like envelope. The bottom-left quadrant is a solid blue bar. The bottom-right quadrant is a dark blue bar with the Medtronic logo and tagline.

Antibacterial Envelope to Prevent Cardiac Implantable Device Infection

Khaldoun G. Tarakji, M.D., M.P.H., Suneet Mittal, M.D., Charles Kennergren, M.D., Ph.D., Ralph Corey, M.D., Jeanne E. Poole, M.D., Edward Schloss, M.D., Jose Gallastegui, M.D., Robert A. Pickett, M.D., Rudolph Evonich, M.D., François Philippon, M.D., Janet M. McComb, M.D., Steven F. Roark, M.D., *et al.*, for the WRAP-IT Investigators*

WRAP-IT Trial

≈ 7000 patients w/ high-risk CIED surgery
 TYRX Envelope vs Control
 PEP – Serious device infection

Table 2. Summary of Initial Major CIED Infections within 12 Months.

End Point	Envelope (N = 3495)	Control (N = 3488)	Total (N = 6983)	Hazard Ratio (95% CI)
	<i>number of patients (percent)</i>			
Primary end point: major CIED infection within 12 mo	25 (0.7)	42 (1.2)	67 (1.0)	0.60 (0.36–0.98)*

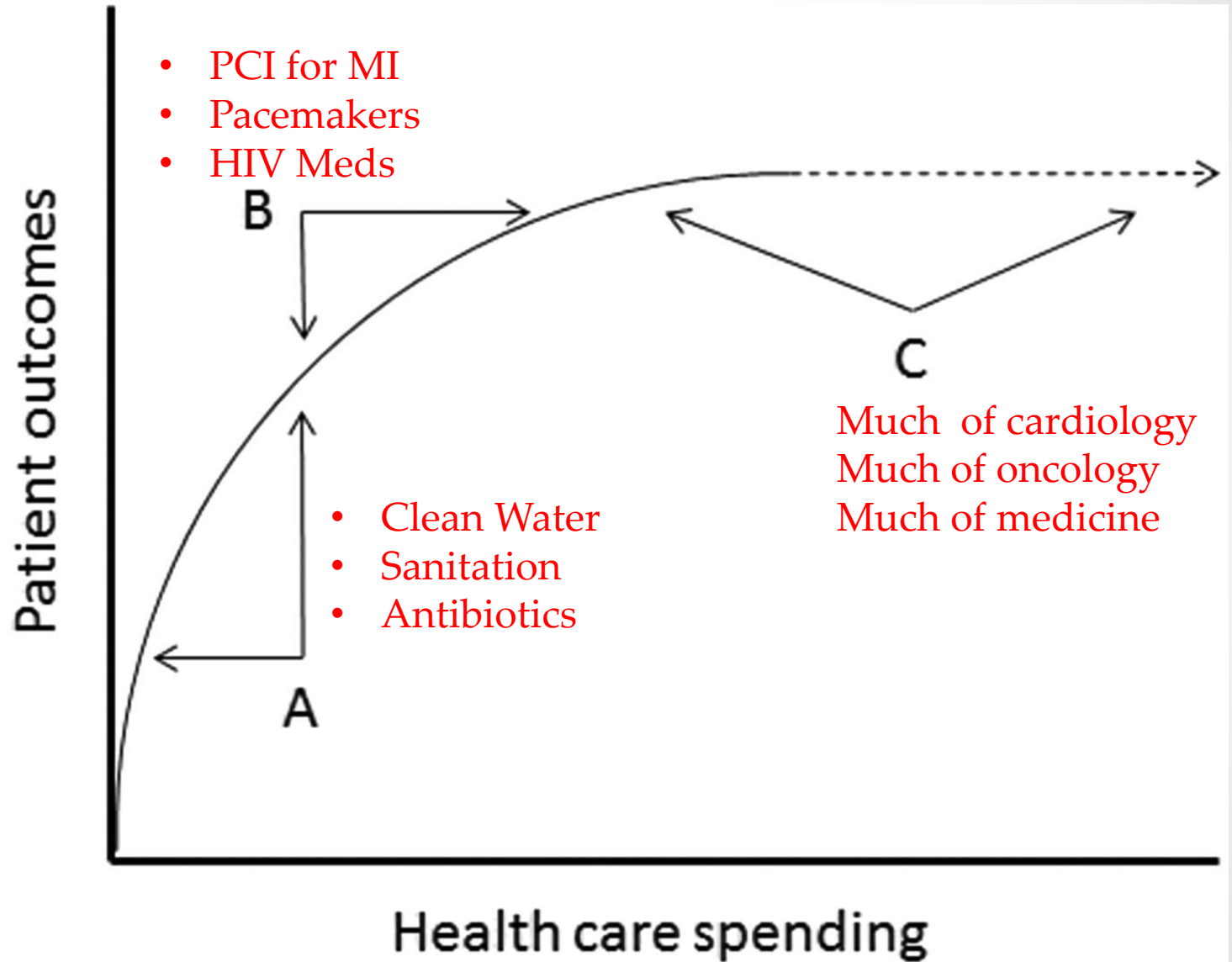
Heavy Heart: The Economic Burden of Heart Disease in the United States Now and in the Future

Andrew J. Foy MD^a, John M. Mandrola MD^b

Show more

<https://doi.org/10.1016/j.pop.2017.11.002>



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[August 2019](#) Volume 132, Issue 8, Pages 900–901

The Case for Being a Medical Conservative

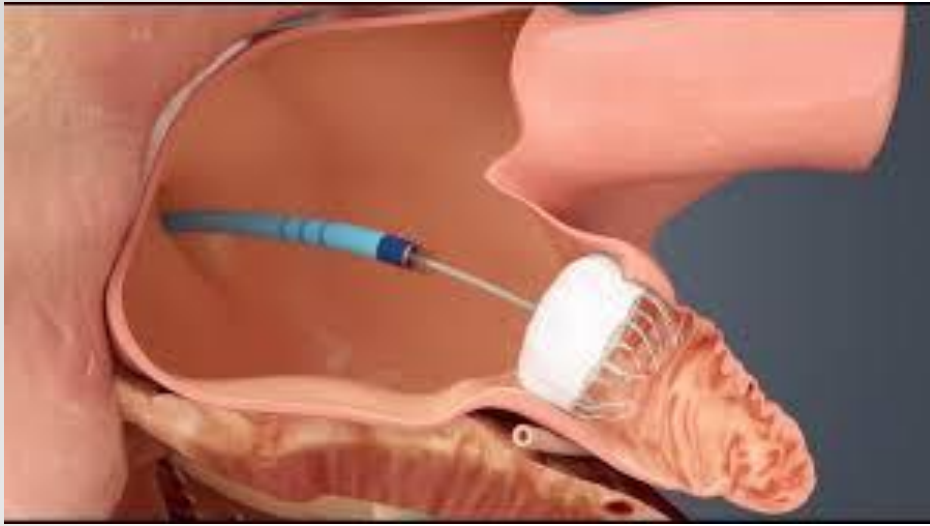
[John Mandrola, MD^{a,*}](#)  , [Adam Cifu, MD^b](#), [Vinay Prasad, MD, MPH^c](#), [Andrew Foy, MD^d](#)

 PlumX Metrics

DOI: <https://doi.org/10.1016/j.amjmed.2019.02.005> |

 Check for updates

...content experts are often enthusiasts for whatever content they are expert in...



Left Atrial Appendage Occlusion

- 100,000 devices have been implanted in the last 2 years in the US
- LAAO has been done in Europe for > 10 years
- Regulators allowed non-inferiority margin of 1.75

5-Year Outcomes After Left Atrial Appendage Closure

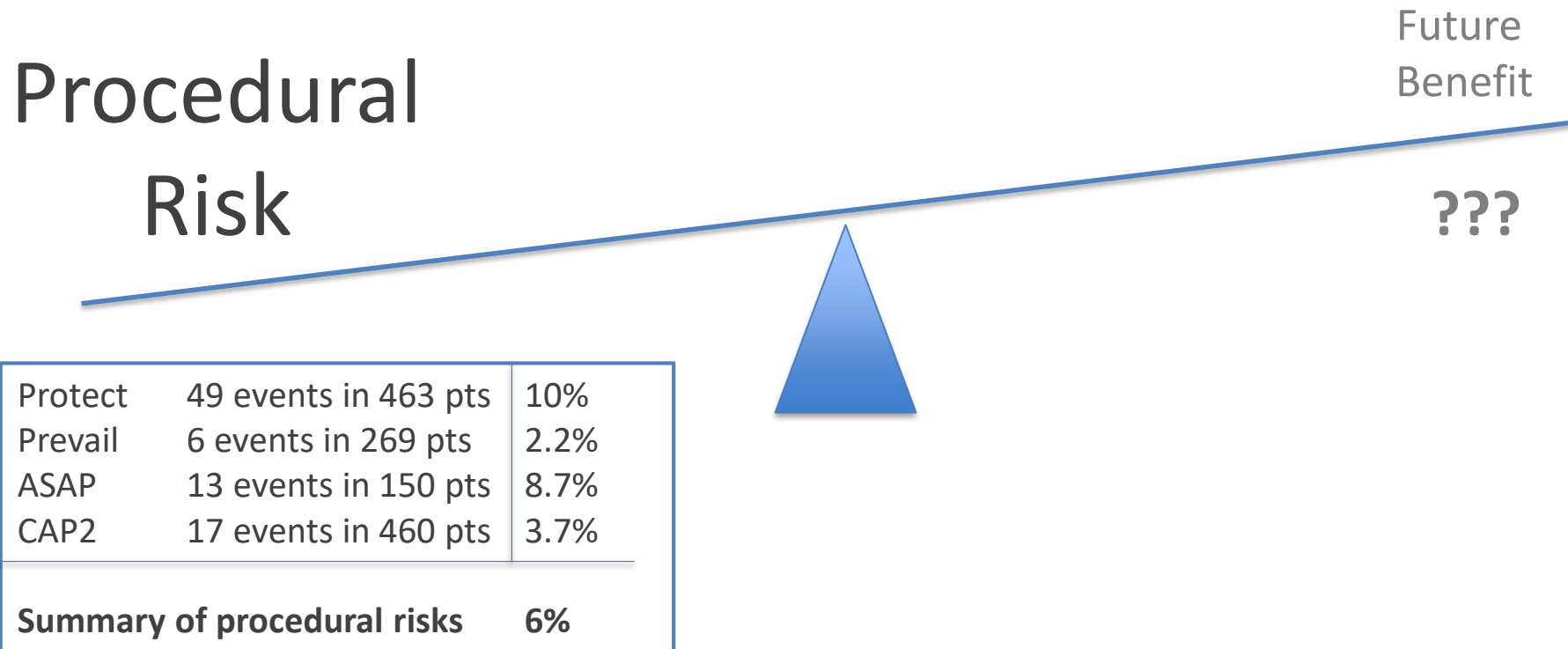
From the PREVAIL and PROTECT AF Trials

Vivek Y. Reddy, MD,^{a,b} Shephal K. Doshi, MD,^c Saibal Kar, MD,^d Douglas N. Gibson, MD,^e Matthew J. Price, MD,^e
Kenneth Huber, MD,^f Rodney P. Horton, MD,^g Maurice Buchbinder, MD,^h Petr Neuzil, MD, PhD,^b
Nicole T. Gordon, BSEE,ⁱ David R. Holmes, Jr, MD,^j on behalf of the PREVAIL and PROTECT AF Investigators

“LAAC with Watchman provides stroke prevention in atrial fibrillation comparable to warfarin...”

Device	Warfarin	18-month	NI Criteria Met?
18-month	18-month	Rate Ratio	95% CrI
rate	rate	95% CrI	Upper Bound <1.75

Watchman Procedural risks also alter net clinical benefit



Holmes Lancet 2009
Holmes JACC 2013
Reddy Circ 2011
Reddy JACC 2013

Reporting of Harms

Assessing the quality of reporting of harms in randomized controlled trials published in high impact cardiovascular journals

Muhammad Shahzeb Khan ✉, Rohan Kumar Ochani, Asim Shaikh, Muthiah Vaduganathan, Safi U Khan, Kaneez Fatima, Naser Yamani, John Mandrola, Rami Doukky, Richard A Krasuski

European Heart Journal - Quality of Care and Clinical Outcomes, qcz050,
<https://doi.org/10.1093/ehjqcco/qcz050>

Published: 03 September 2019 **Article history** ▼

- SR of RCTs over 6 years
 - *Circ*, *EHJ*, *JACC*
 - N = 153 RCTs
- CONsolidated Standards Of Reporting Trials.



<http://www.consort-statement.org/extensions?ContentWidgetId=561>

Adherence to CONSORT harm extension checklist = 59% of RCT

No improvement over the 6-year period

- Magic Bullets
- Mortality
- Uncertainty
- Problems with Fear
- Medicalization/Social Expectations
- Big business
- State of the Evidence
 - Reproducibility
 - Harms reporting
- **Decision Quality**

The Case for Being a Medical Conservative

[John Mandrola, MD^{a*}](#)  , [Adam Cifu, MD^b](#), [Vinay Prasad, MD, MPH^c](#), [Andrew Foy, MD^d](#)



DOI: <https://doi.org/10.1016/j.amjmed.2019.02.005> |



Decision Quality

The question we ask is simple:

“would an unbiased patient, who had perfect knowledge of an intervention’s tradeoffs, voluntarily choose to adopt it, and taking into account differing patient resources, pay for it?”

Cardiologists' and patients' views about the informed consent process and their understanding of the anticipated treatment benefits of coronary angioplasty: a survey study

Felicity Astin, John Stephenson, Joy Probyn, Janet Holt, Keith Marshall, Dwayne Conway

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First Published November 27, 2019

Research Article

[Find in PubMed](#)

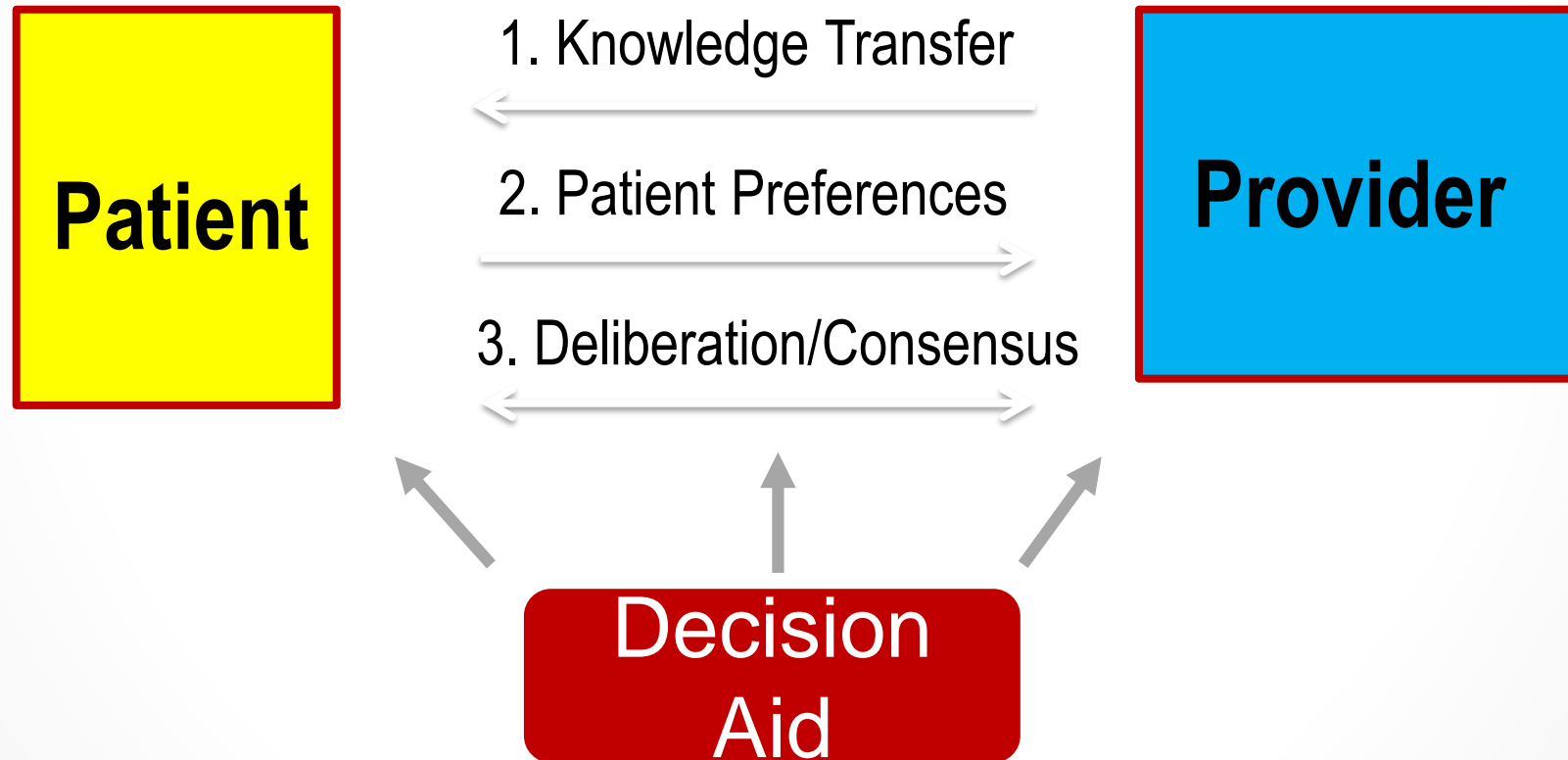
 Check for updates

<https://doi.org/10.1177/1474515119879050>

- Survey of patients having PCI (stent)
- 118 cardiologists; 326 patients

- 40% of patients did not understand or remember information they received on PCI
- 60% of patients believed the PCI was curative

Shared decision making is not just patient education



Intervention Review

Decision aids for people facing health treatment or screening decisions

Dawn Stacey^{1,*}, France Légaré², Nananda F Col³, Carol L Bennett⁴, Michael J Barry⁵, Karen B Eden⁶, Margaret Holmes-Rovner⁷, Hilary Llewellyn-Thomas⁸, Anne Lyddiatt⁹, Richard Thomson¹⁰, Lyndal Trevena¹¹, Julie HC Wu⁴

Database Title

The Cochrane Library

- Improved patient knowledge
- Decreased decision conflict
- Made decisions less practitioner-controlled

IX – Moving Beyond SDM to SUM

Shared Understanding of Medicine



Following

Richard Lehman
@RichardLehman1 Follows you

Ancient English GP turned Professor of the Shared Understanding of Medicine.

202 Following **11.1K** Followers

Viewpoint | Sharing Medicine

September 2017

Sharing as the Future of Medicine

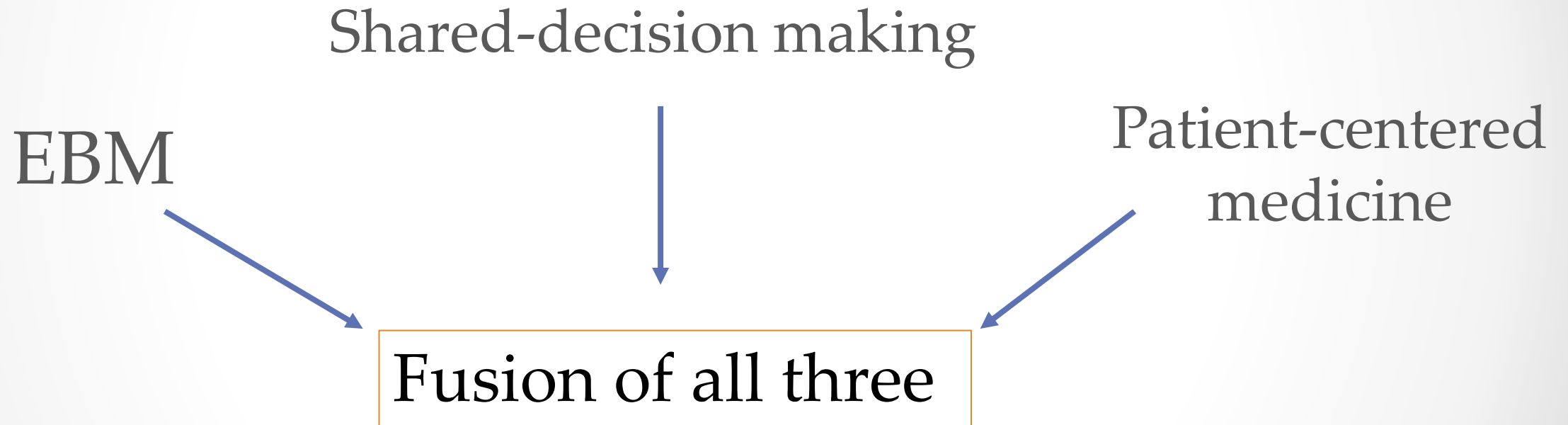
Richard Lehman, BM, BCh, MRCGP¹

» Author Affiliations | Article Information

JAMA Intern Med. 2017;177(9):1237-1238. doi:10.1001/jamainternmed.2017.2371

• <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2635331>

SUM –Shared Understanding of Medicine



X- Conclusion

- “In the end, the medical conservative stands in awe of the human body.”
- “We see true medical progress as slow and hard in large part because nature has provided the human body inherent healing properties.”

“The wisest of conservative physicians understand and embrace how little effect the clinician has on outcomes.”

“While many may call this frame of reference nihilistic, the conservative clinician sees it as protective against our greatest foe — hubris.”



- A 95-year-old man who lives independently presents to the hospital with shortness of breath
- *He has not seen a doctor in 6 decades.*

Q: Why did he live to 95 years?



Thank You

- John.Mandrola@gmail.com
- Twitter -- @drjohnm

- True Progress (magic bullets) -
-false sense of progress
- Death denial culture
- Uncertainty/Complexity
- Fear
- Medicalization / Social
latrogenesis
- Healthcare Profit Motive



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The Case for Being a Medical Conservative

[John Mandrola, MD^a](#), [Adam Cifu, MD^b](#), [Vinay Prasad, MD, MPH^c](#), [Andrew Foy, MD^d](#)

PlumX Metrics

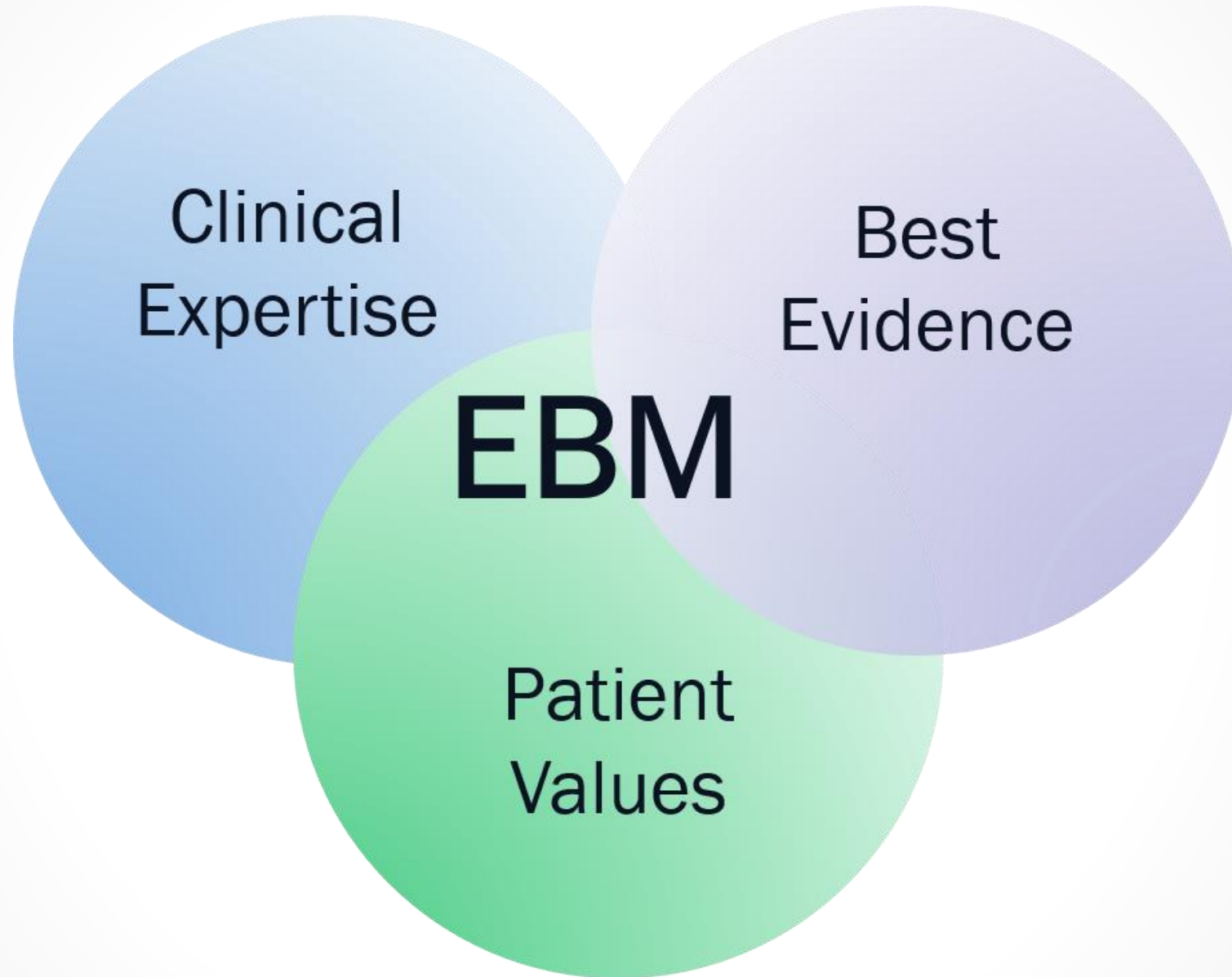
DOI: <https://doi.org/10.1016/j.amjmed.2019.02.005> | Check for updates

“A conservative is someone who stands athwart history, yelling Stop, at a time when no one is inclined to do so, or to have much patience with those who so urge it.”

William Buckley Jr

How about the digital revolution?

I - We must appreciate true progress



Fear Destroys Decision Making

- One of the first tasks of a clinician is to remove un-necessary fear.

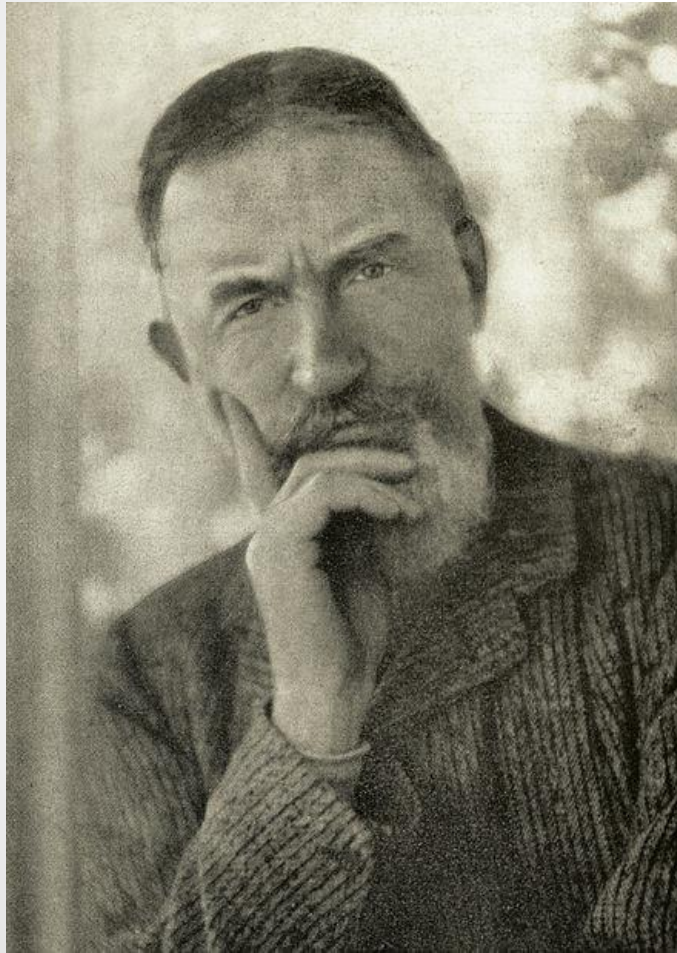
- True Progress (magic bullets)
- Human Mortality (unchanged)
- Uncertainty/Complexity
- Fear of Disease/Dying
- Medicalization / Social Iatrogenesis
- Healthcare Profit Motive



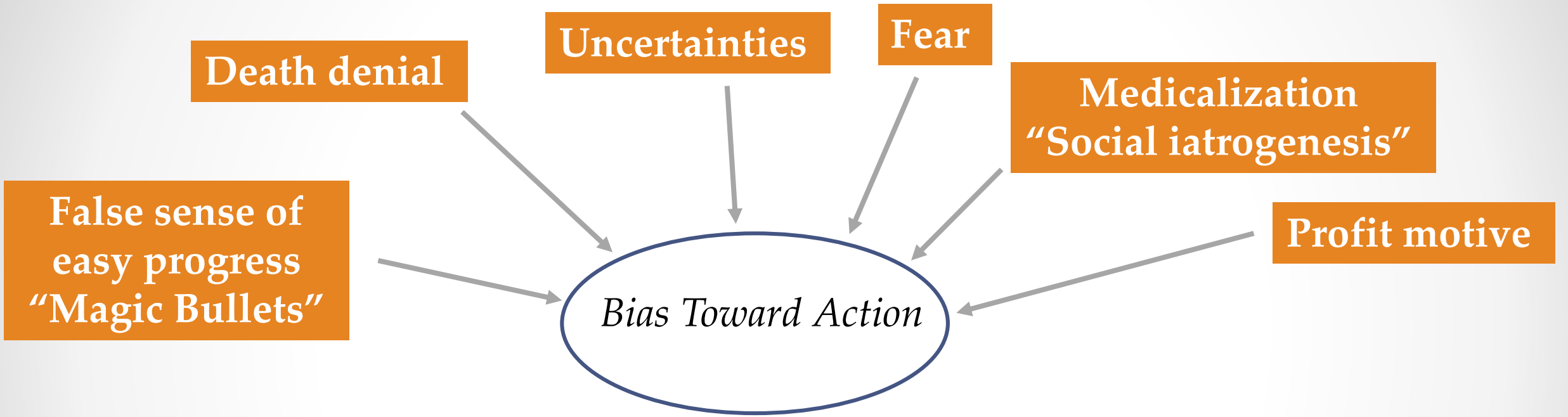
Current Model

- Keep Spending
- Keep Testing
- Keep Treating

Even Doctors Have Conflicts



- George Bernard Shaw – (an Irish playwright and polemicist)
-compared doctors to tradesmen and shopkeepers, with a pecuniary interest in people being ill.



“A (medical) conservative is someone who stands athwart history, yelling Stop, at a time when no one is inclined to do so, or to have much patience with those who so urge it.”

William Buckley Jr

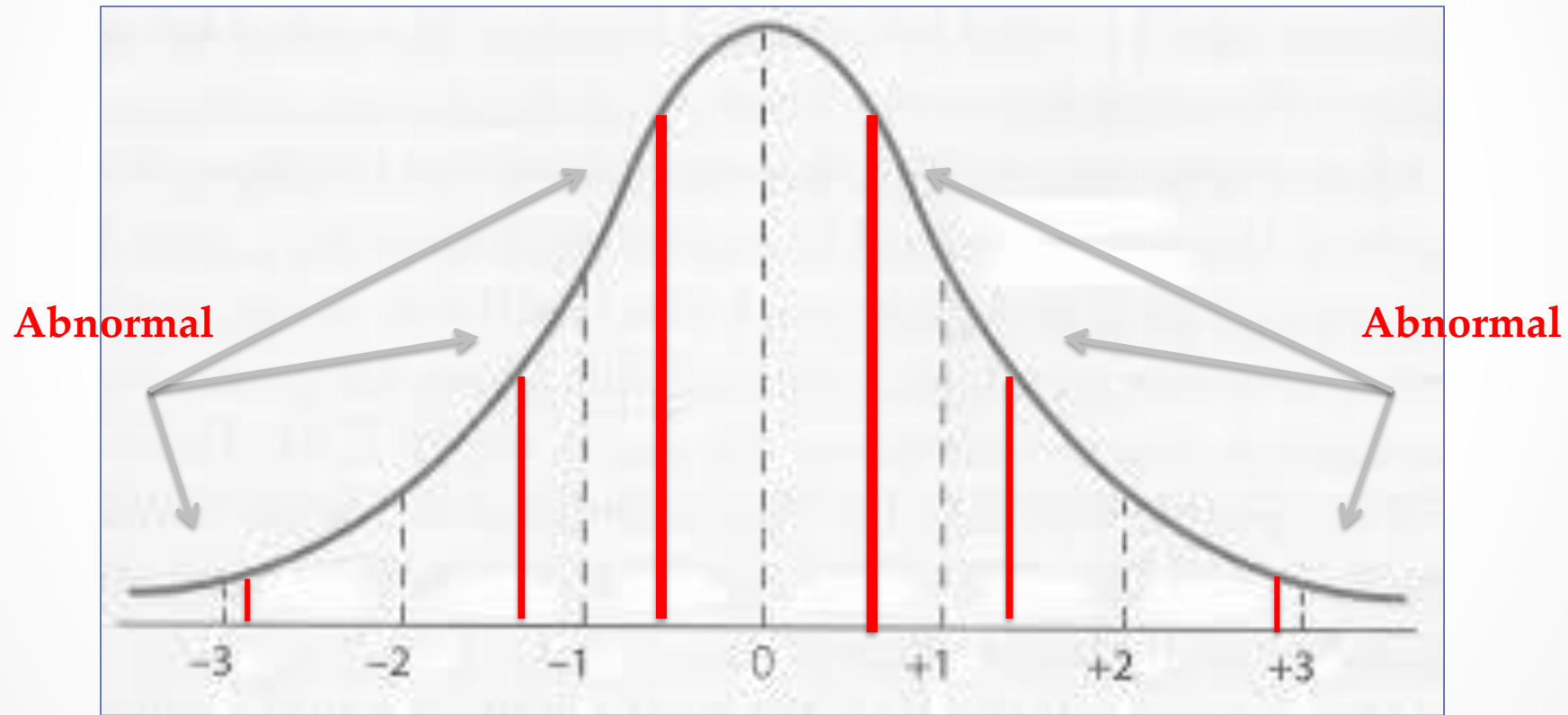
- True progress
- Complexity of the Human Body
- Uncertainty of most interventions
- Power of fear / Human Mortality



Profit motive

Business of medicine

Medicalization -- Can Normal be Saved?



Cultural Iatrogenesis

- Healthy people adapt to ageing, to healing when damaged, to suffering and then to the peaceful expectation of death.
- But medicine's metastasis into culture has dire consequences:
- *By transforming pain, illness, and death from a personal challenge into a technical problem, medical practice steals the potential of people to deal with their human condition in an autonomous way*

How do we do that?

- We must understand how little we control outcomes?



John Ioannidis has dedicated his life to quantifying how science is

OPEN ACCESS

ESSAY

Why Most Published Research Findings Are False

John P. A. Ioannidis

Published: August 30, 2005 • <https://doi.org/10.1371/journal.pmed.0020124>

Article	Authors	Metrics	Comments	Media Coverage
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68,436 Save	3,411 Citation
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- My wife Staci and I were talking recently about practicing medicine in 2020. She is a physician too.
- She said something that was seemingly paradoxical:
- Practice was easier when we started in the 1990s.
- What I hope to explain is why, despite the progress, the technology, the AI, and even the gene risk scores this is.
- I also want to make the case that the best way to approach medical practice in 2020 is to be a medical conservative.

Biases/Frame

- My wife Staci Mandrola is a hospice and palliative care MD
- Assistant Prof of Medicine at University of Louisville
 - In-patient palliative care



Another Story:



- Gaya – a medical resident I met at a small conference tells me about Staci.
- They both work at a safety-net and trauma hospital
- Gaya: Staci swoops in to any situation and no matter how bad it is, she makes people feel better.
- (remember: Staci does not order tests; she does not use catheters; she does not do surgery)
- Ladies and gentlemen, Gaya made me think.
- The wonderful tools (catheters, meds, surgeries) that we have does indeed make it harder to truly care for people.

- In days of old, all a physician could offer was caring, comforting words and a presence.
- But now, caregiver and patient alike have come to expect medical or procedural "fixes."
- The Magic bullets.

The other fact that must be recognized

- Humans are not immortal.

CANCER CARE: THE DECEPTIVE MARKETING OF HOPE

October 22nd, 2018

ATYPICAL vs. TYPICAL

"You can survive Stage 4 cancer. I'm living proof of that."
- Florida Cancer Specialists Cancer Center

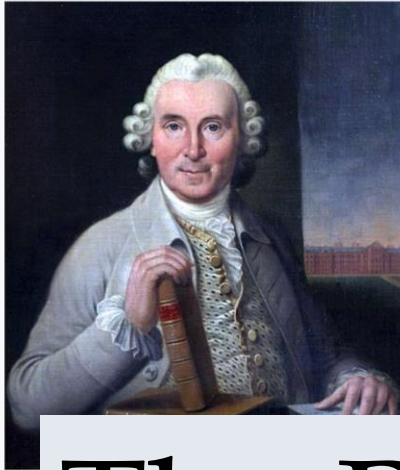
Lung Cancer Stage 4
4.7%
5 Year Survival Rate

TOP ADVERTISING SPENDERS

1. Cancer Treatment Centers of America
2. MD Anderson Cancer Center
3. Memorial Sloan-Kettering Cancer Center
4. Dana-Farber Cancer Institute
5. Moffitt Cancer Center
6. Texas Oncology
7. Fox Chase Cancer Center
8. NYU Langone Health Perlmutter Cancer Center
9. Siteman Cancer Center
10. Florida Cancer Specialists & Research Institute

Perhaps the greatest medical innovation of the last 100 years

James Lind



- Medicine's first RCT in 1747
- Citrus (Vit C) in Scurvy
- Published in 1753

42 years

The Randomized Controlled Trial

https://en.wikipedia.org/wiki/James_Lind

We can't rely on guidelines ...

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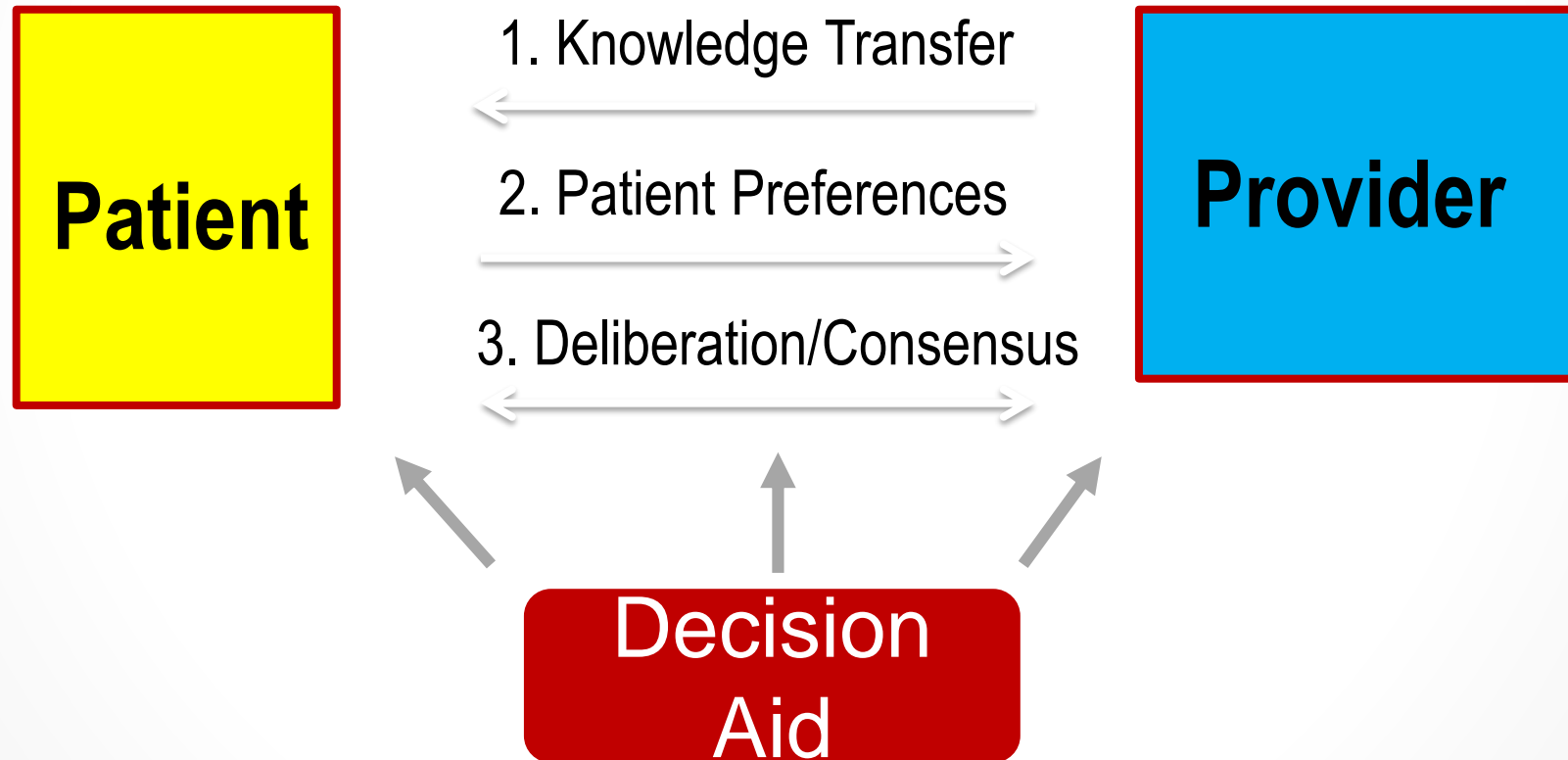
 PlumX Metrics

DOI: <https://doi.org/10.1016/j.amjmed.2019.02.005> |

Here is a story about our times

- It was ten years ago—about the time I first started thinking about conservative practice,
- I was running on a trail and got a scratch on my leg from a bush.
- It barely broke the skin. I thought nothing of it.
- A few days later, the spot started aching a bit. I ignored it—b.c it wasn't that bad.
- The ache did not go away. The red line got wider, deeper,
- It will heal on its own, I thought. I am a strong athlete. Heck I am part Dutch.
- Then the streaking started. I showed it to a surgeon in the doctor's lounge.
- He shook his head and said you are the dumbest doctor I have ever seen.
- I'm like, people healed infections before antibiotics.
- Yes, he said, and people died too.
- Literally hours after taking a dose of abx, the pain eased. The wound opened up and healed slowly over the next week.
- The scar on my leg reminds me that modern medicine can be amazing.

Shared decision making is not just patient education



Intervention Review

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Database Title

The Cochrane Library

- Improved patient knowledge
- Decreased decision conflict
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DECIDE-ICD Trial

A Multicenter Trial of a Shared DECision Support Intervention for Patients Offered Implantable Cardioverter-DEfibrillators

ClinicalTrials.gov Identifier: [NCT03374891](https://clinicaltrials.gov/ct2/show/study/NCT03374891)

Study Design

Study Type ⓘ : Interventional (Clinical Trial)

Estimated Enrollment ⓘ : 1000 participants

Allocation: Randomized

Intervention Model: Parallel Assignment

Intervention Model Description: Step-wedge design. 6 groups will begin recruiting participants as control participants. begin intervention.

Masking: None (Open Label)

Primary Purpose: Supportive Care

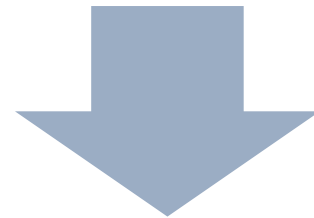
VII – Courage to Resist

**The duty of being a medical conservative.
When in doubt, for the patient**

CAMILLA ALDERIGHI¹, STEFANO DEL PACE², RAFFAELE RASOINI¹

in dubio pro reo principle - “[when] in doubt, for the accused”

Uncertain Benefits / Possible Harm



Favor caution over action (precautionary principle)



Edward J Schloss MD

@EJSMD



Replying to [@EJSMD](#) [@Toaster_Pastry](#) and [@SergioPinski](#)

Here's how I work. In gray area, choose least invasive/expensive option. This isn't even gray.

- <https://twitter.com/EJSMD/status/845007273751728128>

V- Medicalization / Social Expectations

CommonSpirit Health By The Numbers

Operations in 21 States		Over 20 million patients treated last year	
Care Provided Highlights		Financial Highlights	
146 hospitals	1,100+ non-acute care facilities	\$38 billion in assets	\$30 billion in total annual operating revenue
\$4.2 billion charitable care and services		Employee Count: 150,000	
Largest Not-For-Profit Health System		Including approximately 100 advanced practice nurses	

More revenue, and expense, than many well-known companies

Companies with less than \$30 Billion in annual revenues based on FY18 financials.