
Good
Morning

Medical Errors

How Your Healthcare May Be Harming You

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SESSION 6
SCIENCE and TECHNOLOGY

Plan for the Course

- Session 1: Introduction and Definitions
- Session 2: Diagnostic Errors
- Session 3: Medication Errors, Surgical Errors
- Session 4: Communication Errors
- Session 5: US Healthcare System/Industry
- Session 6: Science and Technology
- Session 7: Comparison with Other Countries
- Session 8: Solutions, Reduction, Prevention

Plan for the Session

- Electronic Health Record
- Telemedicine and Digital Hospital
- Diagnostic tests
- Robotic Surgery
- Genome Analysis
- The Internet and Dr. Google
- Reversal of Medical Research and Publication

ELECTRONIC HEALTH RECORD

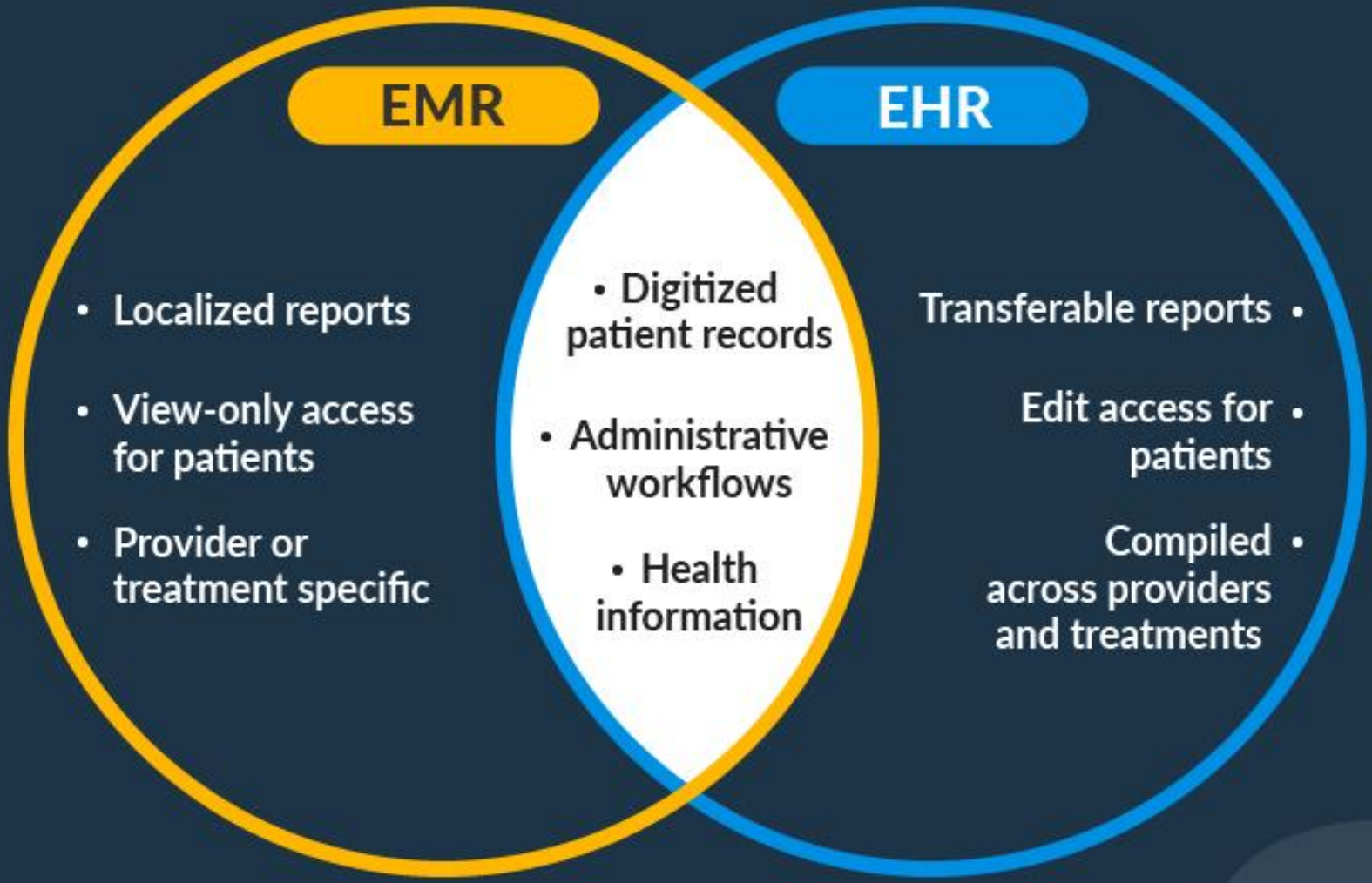
EHR/EMR/PHR

- **EHR**, Electronic Health Record, is a more longitudinal collection of the electronic health information of individual patients or populations.

- **EMR**, Electronic Medical Record, is the patient record created by providers for specific encounters in hospitals and ambulatory environments and can serve as a data source for an EHR.

- **PHR**, Personal Health Record, is an application for recording personal medical data that the individual patient controls and may make available to health providers.

EMR vs. EHR



SelectHub

Electronic Health Record

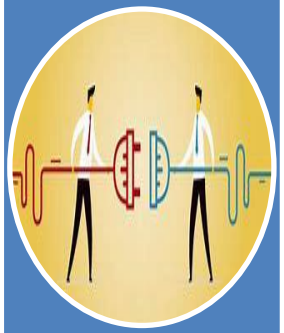
EHR

Supposed to:	But in reality:
• increase efficiency • decrease medication errors • improve quality of care • facilitate information entry • allow inter-institutional transfer of data • decrease costs • save time	• helped create and perpetuate erroneous data • increased onerous computer time for providers • never fulfilled promise of transfer and availability • created technological intrusion between Dr. and patient • created data security and confidentiality issues

Ramírez 2023

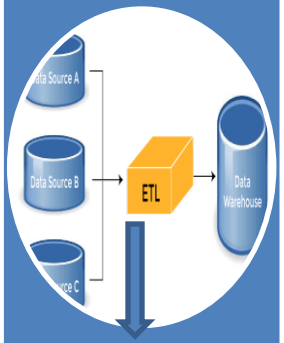
EHR Common Concerns

Usability



Interoperability

Data Security and Privacy



Extract, Transform, Load

Backup and Storage

Cost

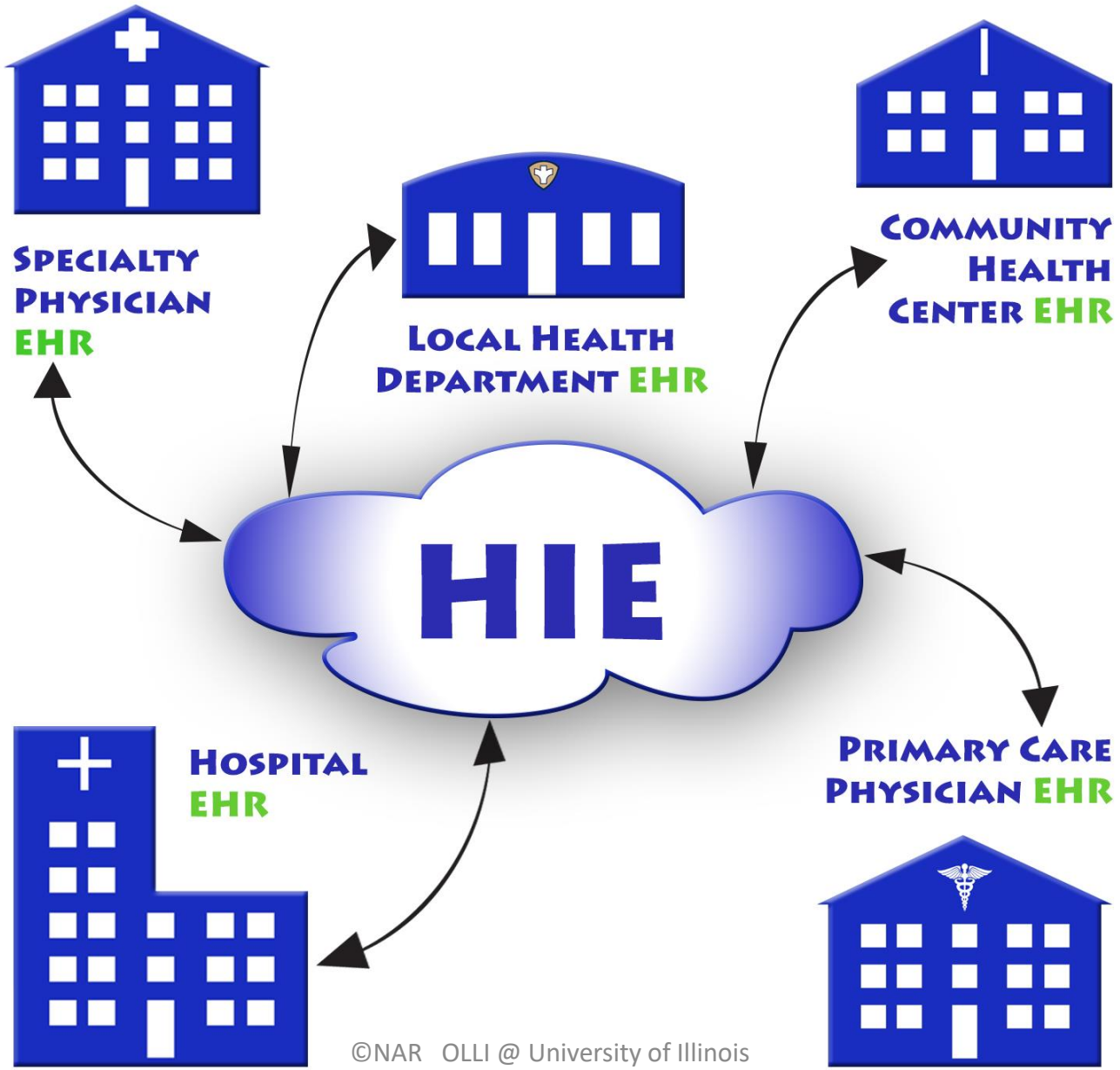
Training and Support

Health Information Exchanges

HIEs

- HIE use has grown despite challenges with standardization of EHR features and interoperability.
- In 2013–2015 some level of information was exchanged between:
  - 82% of non-federal hospitals
  - 38% of physician practices
  - 17–23% of long-term care facilities
- The major barriers to progress in Statewide HIEs have been underfunding, privacy and proprietary issues.

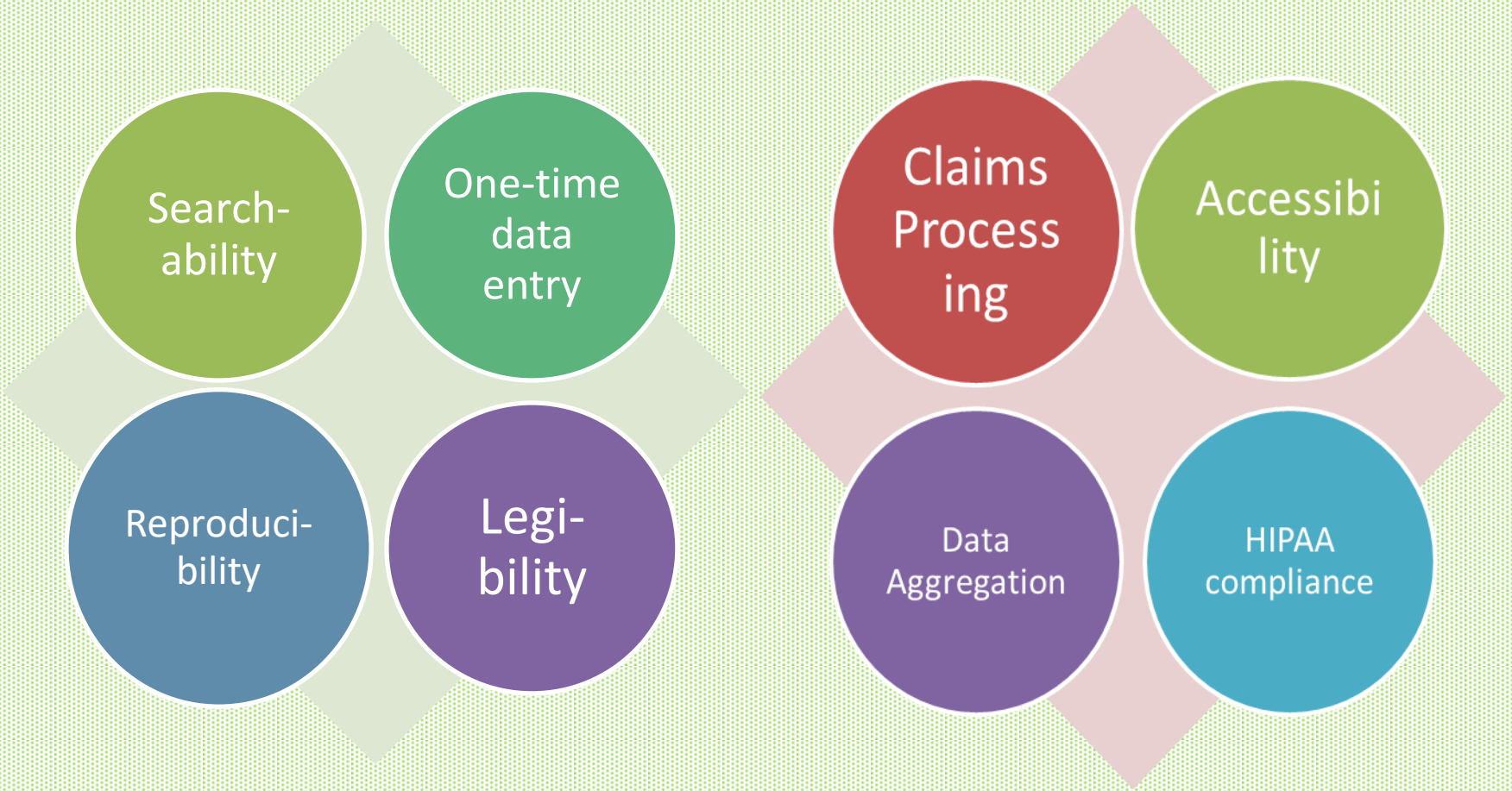
Health Information Exchange

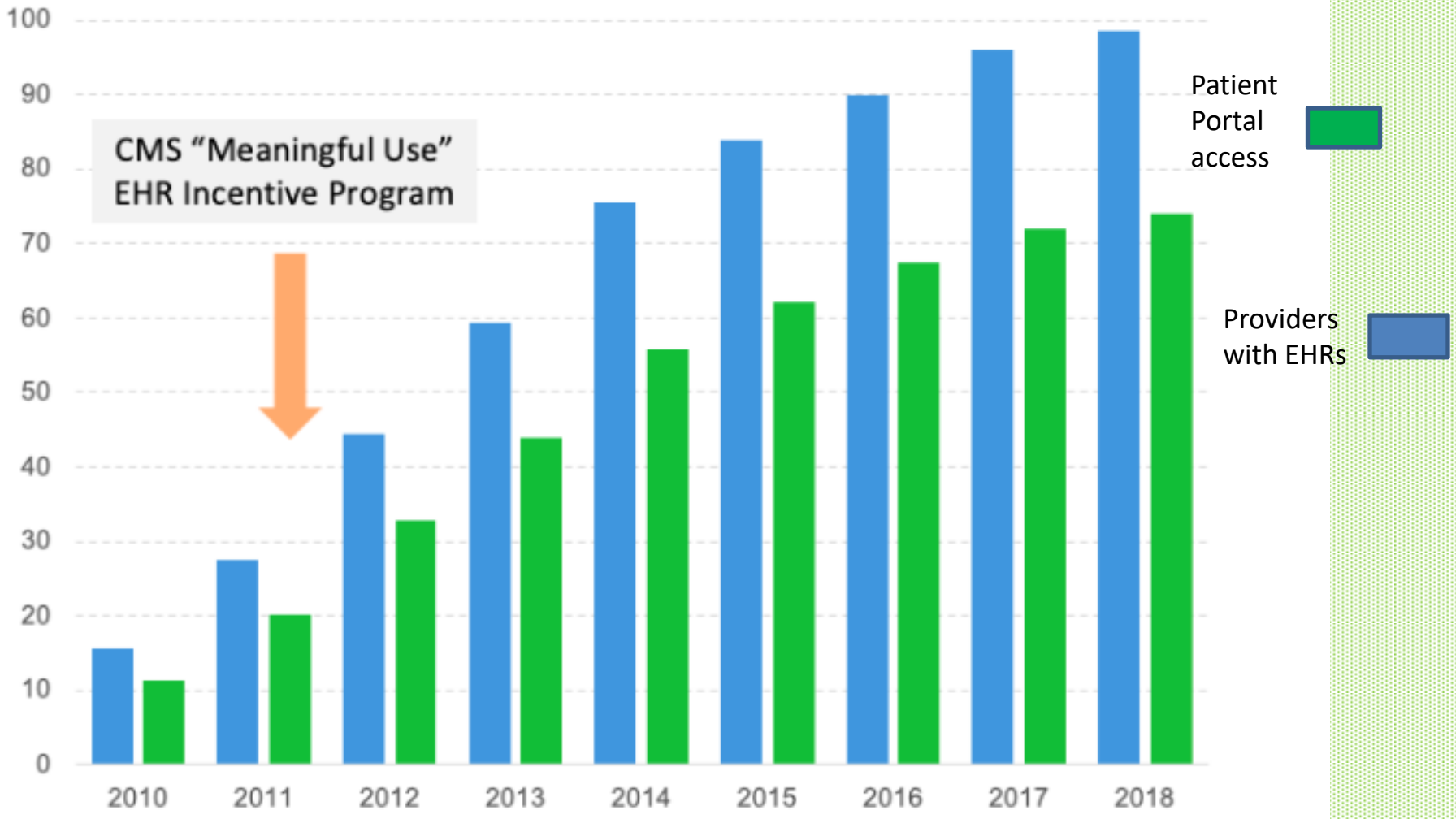


Regional Health Information Organizations
(RHIOs)

- In 2009 over 67% of Regional Health Information Organizations (RHIO's) did not reach financial viability.
- Privacy issues are the same ones that plague EHRs: how to share patient information securely.
- Providers say that by sharing patient information, with other competing companies, they could lose their competitive edge with those patients.

Definite Advantages

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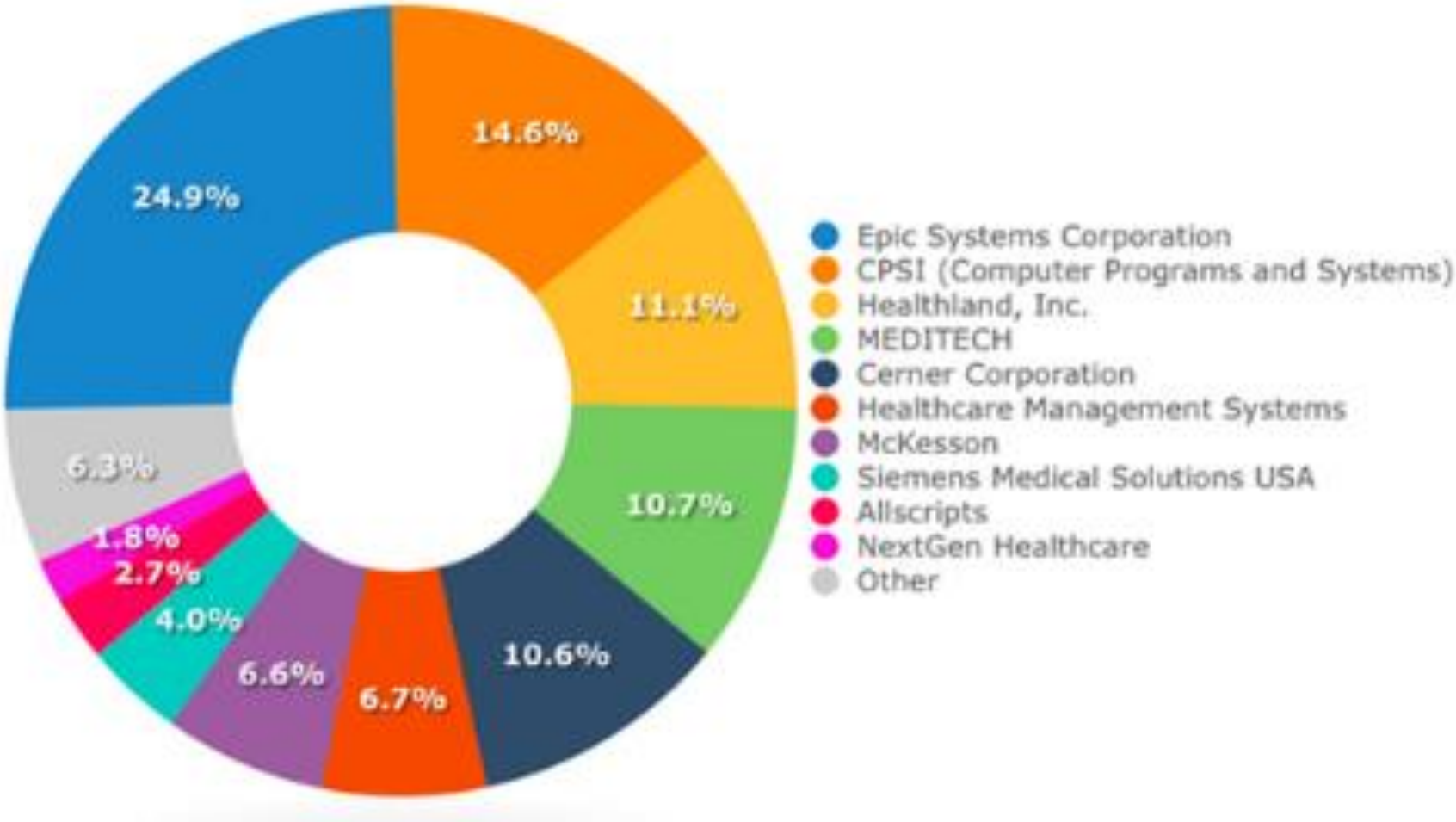
CMS "Meaningful Use"
EHR Incentive Program
2010
2011
2012
2013
2014
2015
2016
2017
2018
Patient
Portal
access
Providers
with EHRs

EHR Market Share
2019



CMS Meaningful Use

(now: Promoting Interoperability Program)

The Medicare and Medicaid EHR Incentive Programs (Meaningful Use or MU), provide financial incentives to eligible professionals who are able to demonstrate meaningful use of certified EHR technology:

- Stage 1: Eligible professionals may receive up to $44,000 through the Medicare MU program, or $63,750 through the Medicaid MU program.
- Stage 2: Eligible professionals may receive up to $44,000 through the Medicare MU program, or $63,750 through the Medicaid MU program.
- Stage 3: The financial incentives for Stage 3 have not been published by CMS

TELEHEALTH and DIGITAL HOSPITAL

Telehealth

- Use of digital information and communication technologies to access health care services remotely and manage your health care.

- Telehealth can be done primarily online with Internet access on your computer, tablet, or smartphone, with options for:
  - talking to your healthcare provider live by phone or video chat
  - sending and receiving messages from your healthcare provider using secure messaging, email, and secure file exchange
  - remote monitoring so healthcare provider can check on you at home
  - following medication changes or chronic health conditions

Telehealth

- Frequently used for mental health issues
- Cannot replace the actual physical exam
- Patients often withhold important information
- Depersonalizes the patient encounter
- Risk of insecure connection with data leaks

DIGITAL HOSPITAL

Digital Hospital

- At least 1 in 7 people are readmitted to the hospital within 30 days of being discharged.
- Providers need to deliver value-based care for acute and chronic conditions without compromising patient safety or breaking the bank.
- The solution?
- Give patients hospital-quality care without the hospital.

“Use Cases”

- Digital patient experience
- Digital workforce
- Digital operations
- Digital supply chain
- Digital ecosystem

Digital Hospital

- Patients have a digital experience with on-demand interaction and seamless processes.
- Providers have an enhanced experience and get to spend more time providing care and less time documenting it.
- Operational efficiencies through technology:
  - digital supply chains
  - automation
  - robotics
  - next-generation interoperability
  - healing and well-being designs

Digital Hospital

- Doctors and insurance companies want to keep patients out of hospitals for non-life-threatening conditions.
- Payers reward healthcare providers to keep their patients healthy at a reasonable cost and relying on inpatient treatment only when absolutely necessary.
- Failing to admit people to the hospital who do need inpatient care or discharging patients too soon can have life-threatening consequences.

Digital Hospital

- Diagnosis can be done by portable, wearable, affordable devices, and organizations will give patients the equipment needed to get hospital-level care in the home.
- Early diagnosis and preventive care for conditions such as heart disease, diabetes, and even pancreatic cancer will be done in the home during daily activities.
- Doctors and nurses will treat patients through telemedicine, digital diagnostics, and in-person visits as needed.

OSF On-Call

Digital Hospital

- "Allows you to receive hospital-level care from the comfort of your own home."

- "Imagine getting expert care and being able to sleep in your own bed, enjoy meals at your kitchen table, while surrounded by your loved ones, pets and other things you enjoy."

- "With OSF On-Call Digital Hospital, you will get the same level of care as if you were in the hospital, plus all the comfort of home and the support of your family."

From OSF Promotional brochure

OSF On-Call
Digital Hospital

- You will be provided:
  - a computer tablet for video visits and calendar reminders
  - a telephone that connects directly to your care team
  - a personal emergency response bracelet
  - equipment to monitor your vital signs
  - a device for internet access
  - a backup power supply

- "Lab tests, IV therapy, mobile ultrasounds and X-Rays can also be arranged to take place in your home, if needed."

OSF Promotional brochure

Digital Hospital

- Post-discharge care can be handled through digital devices that perform remote continuous monitoring of:
  - breathing and heart rates, blood pressure, pulse oximetry
  - blood sugar
  - early warning signs of relapse for stroke, heart failure, and other serious conditions

- A review of 9 Hospital-at-Home trials shows that people had:
  - 26% lower risk of readmission
  - a lower need for long-term care
  - lower rates of anxiety and depression
  - a cost of up to 38% less than conventional hospital inpatient care

Digital Hospital

- Patient records must be migrated into the hands (and phones) of patients themselves.
- Payers must incentivize health care providers to administer just the right amount of care.
- Doctors must relearn to classify:
  - which patients to admit to the hospital
  - which ones can receive acute or chronic care at home
  - which ones can be treated by telemedicine
  - which ones to discharge

DIAGNOSTIC TOOLS
ROBOTIC SURGERY

Diagnostic Tools

- Technology is more intrusive, less aggressive
- Procedures have shorter recovery times
- Specialists can help solve more difficult cases
- Cost of equipment has risen exponentially
- Technology's promises aren't always fulfilled.

Theranos

- Elizabeth Holmes sold the idea that its *Edison* machine could run dozens of tests on a few drops of blood.
- Promoted the test' accuracy, reliability and low cost.
- The automated, portable, system was bought by Walgreens, the Cleveland Clinic and others.
- Results were later debunked, found unreliable and invalid clinically.

Theranos

- May potentially have caused risk and harm to thousands of people whose treatments were based on the hit-or-miss results of the blood tests conducted by its labs.
- These tests produced possible misdiagnoses with incorrect treatments of patients by medical practitioners, exposing people to health risks.
- The company also neglected to notify patients who may have received inaccurate test results.
- Mike Shultz, Theranos' ex-employee and a whistleblower, said, "Fraud is not a trade secret."

Robotic Surgery

- A specially trained surgeon controls the robotic arms (a camera and very small surgical tools) from a console in the same room as the operating table, or located far away.

- The console allows surgical procedures to be performed from a seated position, while the surgeon views magnified 3-dimensional views of the patient's surgical site.

- Robotic surgery is not performed by robots, but by a surgeon who is in complete control of the robotic arms serving as tools to assist the surgeon, thus the name robotic-assisted surgery.

Robotic Surgery

- The first robot was used to perform a brain biopsy procedure in 1985
- This first innovative robot was called the PUMA 200 and it was made by Westinghouse Electric.
- Modern robotic technology has been adapted for other surgical specialties:
  - neurosurgery: brain, spinal column, and peripheral nerves
  - heart and lung procedures
  - ear, nose, and throat surgeries
  - urology and gynecology surgeries

Minimally Invasive Surgery

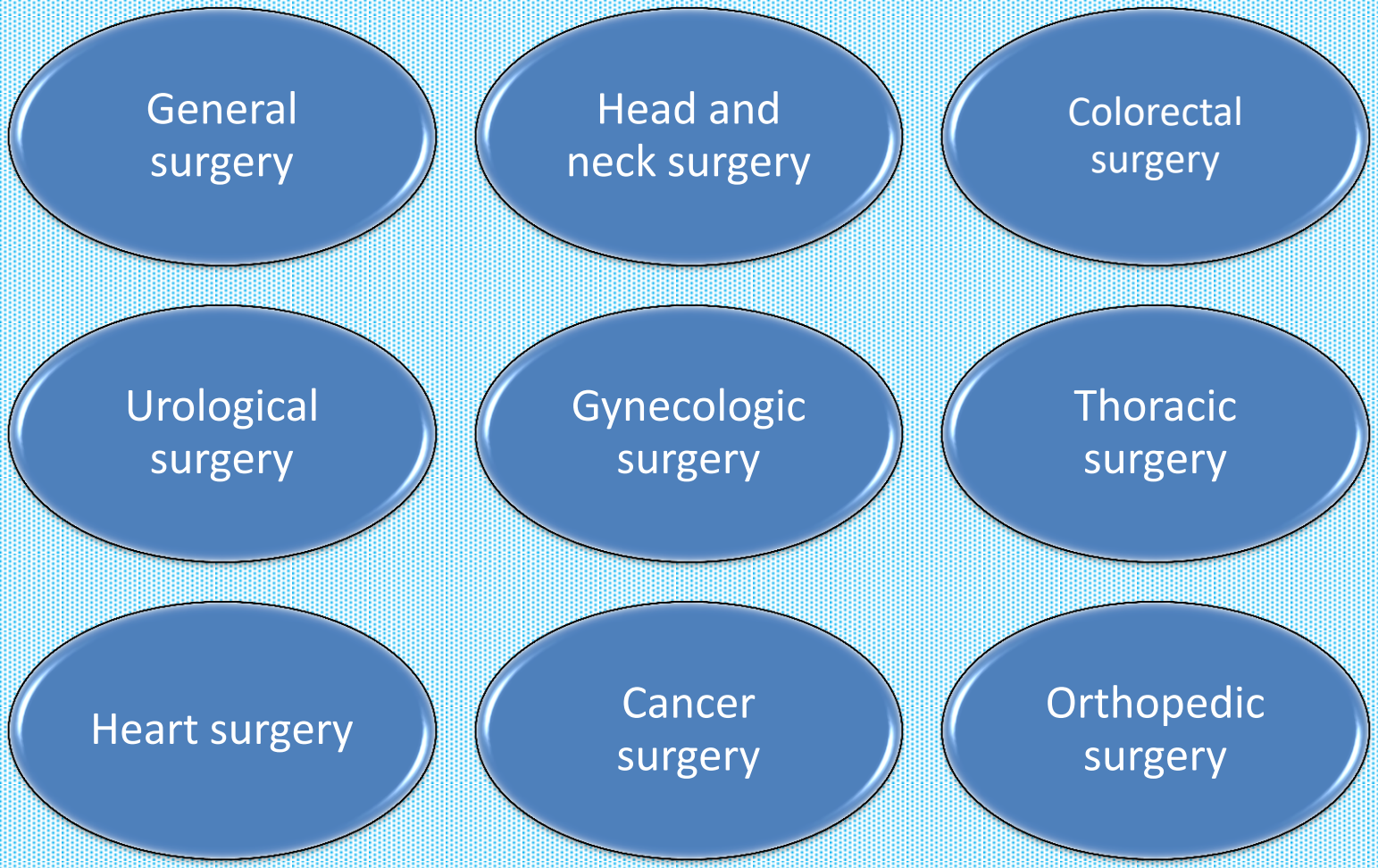
- Robotic-assisted surgery is performed using very small incisions (usually <1 inch) to insert very small tools, and the technology allows for higher range of motion and increased dexterity of movement.

- Non-robotic, minimally invasive surgery (endoscopic/laparoscopic) can be done using a narrow tube with a camera that is inserted through small incisions or through a natural opening.

- In endoscopic surgery, the surgeon directly controls the small instruments via a channel while viewing the surgical site on a computer monitor.

Robotic Surgery

Uses



Robotic Surgery

Benefits

- Improved dexterity for access to hard to reach places
- Better visualization of surgical site
- Less surgeon fatigue
- Elimination of surgeons' hand tremor
- Shorter hospital stays and faster recovery
- Less risk of infection
- Less blood loss and fewer transfusions
- Less pain and scarring
- Quicker return to normal function

Robotic Surgery

Risks

- Human error in operating the technology.
- Less experienced surgeon.
- Mechanical failure.
- Electrical arcing.
- Nerve damage.
- Computer hardware/software failure.
- Hemorrhage, structure damage.

Robotic Surgery

Complications

- Complications range from converting the surgery to open, re-operation, permanent injury, damage to viscera and nerve damage.

- From July 2005 to December 2008, 1,797 robotic surgeries were performed used 4 da Vinci surgical systems in one institution:
  - 43 cases (2.4%) of mechanical failure
    - 24 cases (1.3%) of mechanical malfunction
    - 19 cases (1.1%) of instrument malfunction
  - 3 laparoscopic conversions (0.17%) were performed

Questions? 1

GENOMIC MEDICINE

Genome

- Science has enabled genetic analysis of many cancers and tumors.
- Focused therapy can be given based on the genome of the cancer and the patient.
- Genetic testing can provide some prevention.

Genome

- Genome diagnosis is a process of examining an individual's DNA to identify changes or mutations in their genes that may cause illness or disease.

- Genome sequencing plots each of the 3 billion letters of an individual's genome, and can lead to 3 types of discoveries:
  - detecting a disease that is present but unrecognized
  - predicting a future chance of disease
  - changing the understanding of a disease that is present but misdiagnosed

Genome

- Genome sequencing can diagnose most of the > 6000 conditions for which the genetic basis is currently understood.
- Genomic testing can be used to determine what medication and dosage will be most effective and beneficial for you.
- Prenatal testing can detect some abnormalities in a baby's genes.

Genome

Reports

- Type of Clinical reports:
  - *Personalized health rep*orts show how your DNA can affect your likelihood of developing certain health conditions.
  - *Wellness reports* show how your DNA relates to your lifestyle
  - *Carrier Status reports* show carrier state for inherited conditions

- Genetic testing has limitations:
  - in a healthy person, a positive result from genetic testing doesn't always mean you will develop a disease
  - a negative result doesn't guarantee that you won't have a certain disorder

Drugs & Genetics

- Genetic variations in drug-related genes can affect their efficacy, toxicity and adverse effects.

- The FDA believes that subgroups of patients with certain genetic variants are likely to have altered drug metabolism, with risks of adverse events and differential therapeutic effects.

Clopidogrel (**Plavix**)

- *Clopidogrel* (**Plavix**)reduces the risk of heart attack and stroke.
- The CYP2C19 gene is important for the activation of *clopidogrel*, and certain polymorphisms produce *clopidogrel* resistance.
- Patients with CYP2C19 loss-of-function variant are at increased risk for clotting events, but routine genetic testing in *clopidogre*l patients may have no value.
- New guidelines recommend that people who have had a stroke or transient ischemic attack should take a genetic test to see if they can be treated with *clopidogrel* to reduce their risk of recurrence.

THE INTERNET and “DR. GOOGLE”

Online Health Infomation

- In the US, yearly, 2/3 of adults search the Internet for health information, and 1/3 of adults have used the Internet for self-diagnosis of a health problem they or family members may have.
- Use of the Internet is associated with modest but significant improvements in diagnosis, but no changes in triage or anxiety.
- The perceived harm of an Internet search for health information may be unfounded, the potential benefits are also currently minimal.

Online Health Information

- Used to learn more about your diagnosis from reputable sources than your provider has time to teach you.
- Points you toward treatments you may want to discuss with your provider.
- Find support from other people with the same condition.
- Giving your provider a huge packet of information at your appointment is unlikely to be helpful.

Online Health Information

Risks of using online medical information to diagnose or treat yourself:

- Becoming overly certain [Anchoring bias]
- Needless scares
- Unnecessary tests
- Unreliable sources
- Confirmation bias [Reinforcement bias]
- Dangerous treatments

When possible, go to websites from:

- Government agencies, such as the NIH, CDC, and the FDA.
- Respected medical centers, university medical schools, and medical organizations.
- Respected advocacy organizations.

On large health-related websites:

- At bottom of the page look for a red and blue *Health on the Net Foundation* (HON) Code badge.
- Look for citations throughout the article and/or reference lists at the bottom of the article.
- Look for publication or update dates at the top or bottom of the article.

Reputable, Reliable Sources

Online Health Information

- Scientists have warned that individuals do particularly poorly when asked to work out their own chances of having any particular ailment.

- This misdiagnosis can be:
  - self-positivity, where we overestimate the risks of falling prey to an illness
  - self-negativity, where we underestimate that risk

- People may interpret symptoms which in someone else might seem like indigestion as a sign they are having a heart attack.

Online Health Information

- For conditions whose base rate is relatively low, people are more likely to believe that they are affected than that others are.
- Individuals might underestimate their chances of suffering from relatively common illnesses.
- People are often happy to shake off seasonal flu symptoms, saying they are *under the weather,* but during an outbreak of swine flu many more people think they are affected than actually are.
- If people try to get medical help from the internet, they are limited by their own biases as well as the haphazard nature of the web.

Digital Divide

- The breach between those who do and those who don't have Internet access.

- Inequalities in access create obstacles to finding health information for the very people already likely to have problems accessing healthcare:
  - uninsured
  - underinsured
  - unemployed
  - lower incomes
  - ethnic or racial inequities

MEDICAL RESEARCH & PUBLICATION
MEDICAL REVERSAL

Inaccuracy
Invalidation
Irregularities
Inconsistency
Irresponsibility
Irreproducibility

in published Research

The Problem:

- In recent years, many published research articles have been found to have erroneous result findings.
- Some of these studies have been recalled, withdrawn or banished from the literature.
- Some authors believe that most published results are false.

Essay

Why Most Published Research Findings Are False

John P. A. Ioannidis

Summary

There is increasing concern that most current published research findings are false. The probability that a research claim is true may depend on study power and bias, the number of other studies on the same question, and, importantly, the ratio of true to no relationships among the relationships probed in each scientific field. In this framework, a research finding is less likely to be true when the studies conducted in a field are smaller; when effect sizes are smaller; when there is a greater number and lesser preselection of tested relationships; where there is greater flexibility in designs, definitions, outcomes, and analytical modes; when there is greater financial and other interest and prejudice; and when more teams are involved in a scientific field in chase of statistical significance. Simulations show that for most study designs and settings, it is more likely for a research claim to be false than true. Moreover, for many current scientific fields, claimed research findings may often be simply accurate measures of the prevailing bias. In this essay, I discuss the implications of these problems for the conduct and interpretation of research.

Published research findings are sometimes refuted by subsequent evidence, with ensuing confusion and disappointment. Refutation and controversy is seen across the range of research designs, from clinical trials and traditional epidemiological studies [1–3] to the most modern molecular research [4,5]. There is increasing concern that in modern research, false findings may be the majority or even the vast majority of published research claims [6–8]. However, this should not be surprising. It can be proven that most claimed research findings are false. Here I will examine the key factors that influence this problem and some corollaries thereof.

The Essay section contains opinion pieces on topics of broad interest to a general medical audience.

Modeling the Framework for False Positive Findings

Several methodologists have pointed out [9–11] that the high rate of nonreplication (lack of confirmation) of research discoveries is a consequence of the convenient, yet ill-founded strategy of claiming conclusive research findings solely on the basis of a single study assessed by formal statistical significance, typically for a p-value less than 0.05. Research is not most appropriately represented and summarized by p-values, but, unfortunately, there is a widespread notion that medical research articles

It can be proven that most claimed research findings are false.

should be interpreted based only on p-values. Research findings are defined here as any relationship reaching formal statistical significance, e.g., effective interventions, informative predictors, risk factors, or associations. "Negative" research is also very useful. "Negative" is actually a misnomer, and the misinterpretation is widespread. However, here we will target relationships that investigators claim exist, rather than null findings.

As has been shown previously, the probability that a research finding is indeed true depends on the prior probability of it being true (before doing the study), the statistical power of the study, and the level of statistical significance [10,11]. Consider a 2×2 table in which research findings are compared against the gold standard of true relationships in a scientific field. In a research field both true and false hypotheses can be made about the presence of relationships. Let R be the ratio of the number of "true relationships" to "no relationships" among those tested in the field. R is characteristic of the field and can vary a lot depending on whether the field targets highly likely relationships or searches for only one or a few true relationships among thousands and millions of hypotheses that may be postulated. Let us also consider, for computational simplicity, circumscribed fields where either there is only one true relationship (among many that can be hypothesized) or the power is similar to find any of the several existing true relationships. The pre-study probability of a relationship being true is $R/(R + 1)$. The probability of a study finding a true relationship reflects the power $1 - \beta$ (one minus the Type II error rate). The probability of claiming a relationship when none truly exists reflects the Type I error rate, α. Assuming that c relationships are being probed in the field, the expected values of the 2×2 table are given in Table 1. After a research finding has been claimed based on achieving formal statistical significance, the post-study probability that it is true is the positive predictive value, PPV. The PPV is also the complementary probability of what Wacholder et al. have called the false positive report probability [10]. According to the 2×2 table, one gets $\text{PPV} = (1 - \beta)R/(R - \beta R + \alpha)$. A research finding is thus

Citation: Ioannidis JPA (2005) Why most published research findings are false. PLoS Med 2(8): e124.

Abbreviation: PPV, positive predictive value

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Significance

- In 2005, John Ioannidis, professor at Stanford, wrote in PLOS Medicine “Why Most Published Research Findings Are False”.

- He said that most published medical research papers have results that cannot be replicated, and his statistical model shows that most are false positives.

- Scientists use hypothesis testing to determine whether scientific discoveries are “significant”.

Significance

Significance

- "Significance" is an expression of probability, reported in the literature as a *P value*.

- *P* is the probability that the results are due to chance and not to the item being tested.

- A *P*< 0.5 means that the chance was < 5%, and *P* < 0.1 means that chance was < 1%.

Significance

Key distinction between statistical significance versus clinical significance:

- Statistical significance determines if there is mathematical adequacy to the analysis of the results.
- Clinical significance means the difference is meaningful to the patient and the clinician.
- Two studies can have a similar statistical significance but may vastly differ in clinical significance.

A research finding is LESS likely to be true:

- when the studies conducted in a field are smaller
- when effect sizes are smaller
- when there is a greater number and lesser preselection of tested relationships
- where there is greater flexibility in designs, definitions, outcomes, and analytical modes
- when there is greater financial and other interest and prejudice
- when more teams are involved in a scientific field in chase of statistical significance

John P. Ionnanidis 2006

SURROGATE END POINTS

End Points

- Objective endpoints that we can measure:
  - life events: death, heart attacks or strokes
  - lab values
  - measureable variables: weight, blood pressure
- Subjective endpoints difficult to measure:
  - joint pain
  - shortness of breath
  - chest pain
  - headache
- Surrogate endpoints: stand-ins for things we can't measure

Surrogate Endpoints

- A laboratory value or a physical sign used as a substitute for a clinically meaningful endpoint that measures directly how a patient feels, functions, or survives.
- Changes induced by a therapy on a surrogate endpoint are expected to reflect and predict changes in a clinically meaningful endpoint.
- Therapeutic result is only valid if the effect on the surrogate leads to a real clinical benefit.

Surrogate Endpoints

- Surrogate endpoints may be used instead of clinical outcomes in some clinical trials.
- Used when the clinical outcomes, like strokes, might take a very long time to study, or in cases where the clinical benefit of improving the surrogate endpoint, is well understood.
- Also used in cases where conducing a clinical endpoint study would be unethical.

Surrogate Endpoints

- They are endpoints that we can measure easily and directly.
- They are invisible to the patient.
- It is easier to show that a treatment improves a surrogate endpoint than to show that it improves a real clinical one.

Surrogate Endpoints

Some surrogate endpoints in clinical medicine:

- Hemoglobin A1c (HbA1c) for diabetes
- Serum cholesterol profile for CV disease
- Blood pressure for strokes or heart attacks
- Bone density for osteoporosis
- Electrocardiographic elimination of PVC's

ACCORD Trial

Action to **C**ontrol **C**ardiovascular **R**isk in **D**iabetes

- 10,251 patients (mean age, 62.2 years) with a median glycated hemoglobin level of 8.1% were assigned to receive:
  - intensive therapy (targeting a HbA1c level <6.0%)
  - standard therapy (targeting a HbA1c level from 7.0 to 7.9%).
  - 38% were women
  - 35% had had a previous cardiovascular event.

- The primary outcome was a composite of nonfatal myocardial infarction, nonfatal stroke, or death from cardiovascular causes.

- Higher mortality in the intensive-therapy group led to discontinuing intensive therapy after a mean of 3.5 years of follow-up.

ACCORD Trial

Action to Control Cardiovascular Risk in Diabetes

- At 1 year, stable median HbA1c levels of 6.4% were achieved in the intensive-therapy group and 7.5% in the standard-therapy group.
- During follow-up, the primary outcome occurred in 352 patients in the intensive-therapy group, as compared with 371 in the standard-therapy group (P=0.16).
- *257 patients in the intensive-therapy group died, as compared with 203 patients in the standard-therapy group (P=0.04). *
- Hypoglycemia requiring assistance and weight gain of more than 10 kg were more frequent in the intensive-therapy group (P<0.001).

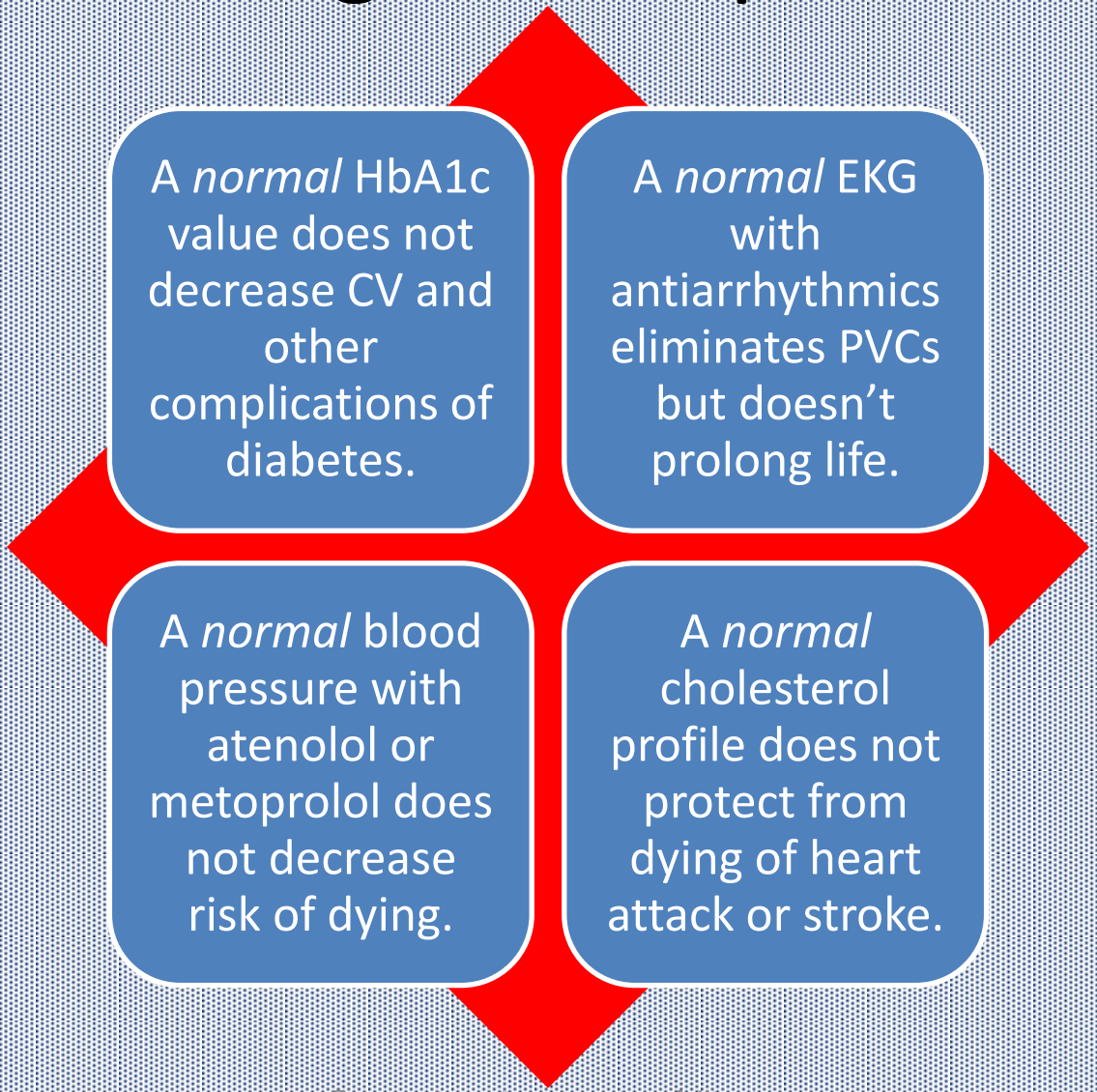
ACCORD Trial

Action to Control Cardiovascular Risk in Diabetes

- These findings suggest that for people with type 2 diabetes and additional cardiovascular risk factors, the main benefits of intensive glycemic control are non-cardiovascular.

- They also support current recommendations to tailor the degree of glucose control to the overall health status of individual patients, taking their overall frailty and burden of other illnesses into account.

Surrogate Endpoints



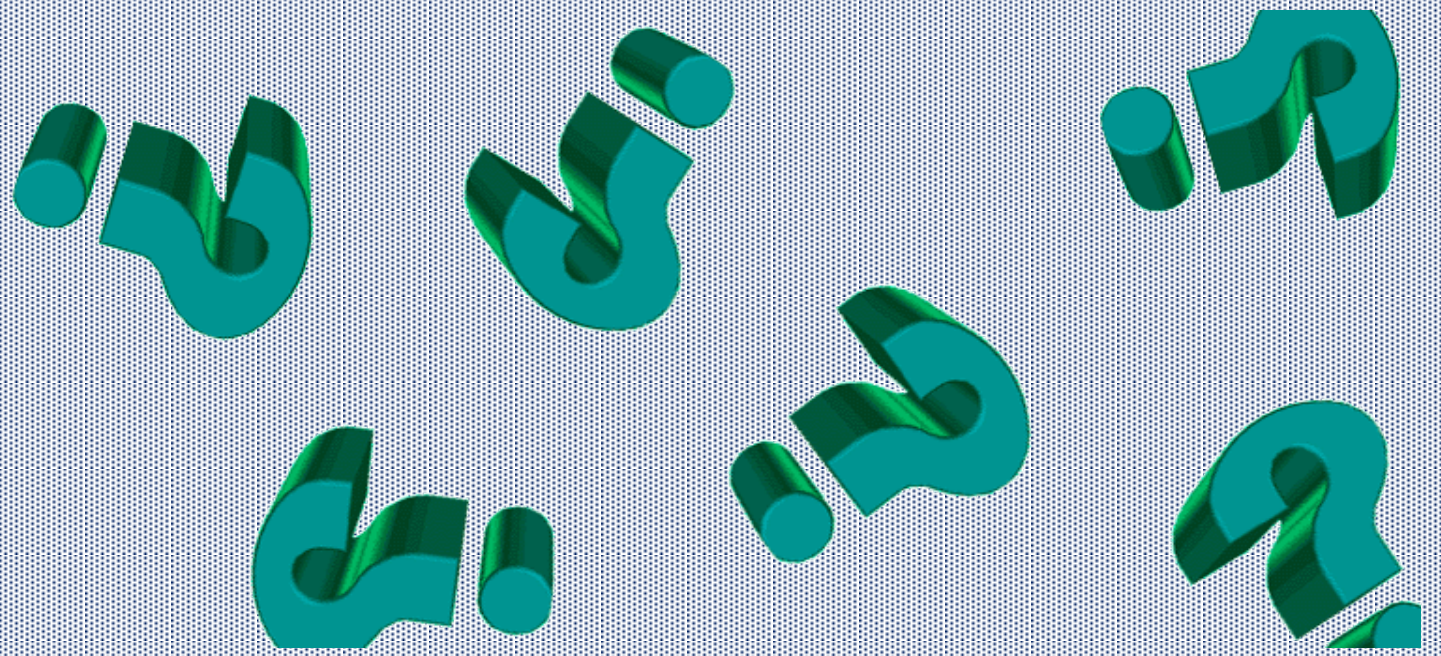
Suggestions

- Treat the patient, not the disease.
- Treat the patient, not the lab result.
- Listen to your doctor, but ASK questions.
- Check information about your illness and its treatment.

Acronyms of Some Studies

- COURAGE: **C**linical **O**utcomes **U**tilizing **R**evascularization and **Ag**gressive Drug **E**valuation
- ASTRAL: **A**ngioplasty and **St**enting for **R**enal **A**rtery **L**esions
- LIFE: ***L****osartan* **I**ntervention **F**or **E**ndpoint reduction
- CAST: Cardiac Antiarrhythmic Suppression Trial
- ESCAPE: **E**ndovascular treatment for **S**mall **C**ore and **A**nterior circulation **P**roximal occlusion with **E**mphasis on minimizing CT to recanalization times
- NICE: **N**ational **I**nstitute for Health and **C**linical **E**xcellence
- AFFIRM: **A**trial **F**ibrillation **F**ollow-up **I**nvestigation of **R**hythm **M**anagement
- AURORA: **A** study to Evaluate the **U**se Of ***Ro****suvastatin* in Subjects on **R**egular Hemodi**a**lysis

Questions? 2



MEDICAL REVERSAL
RESEARCH REVERSAL

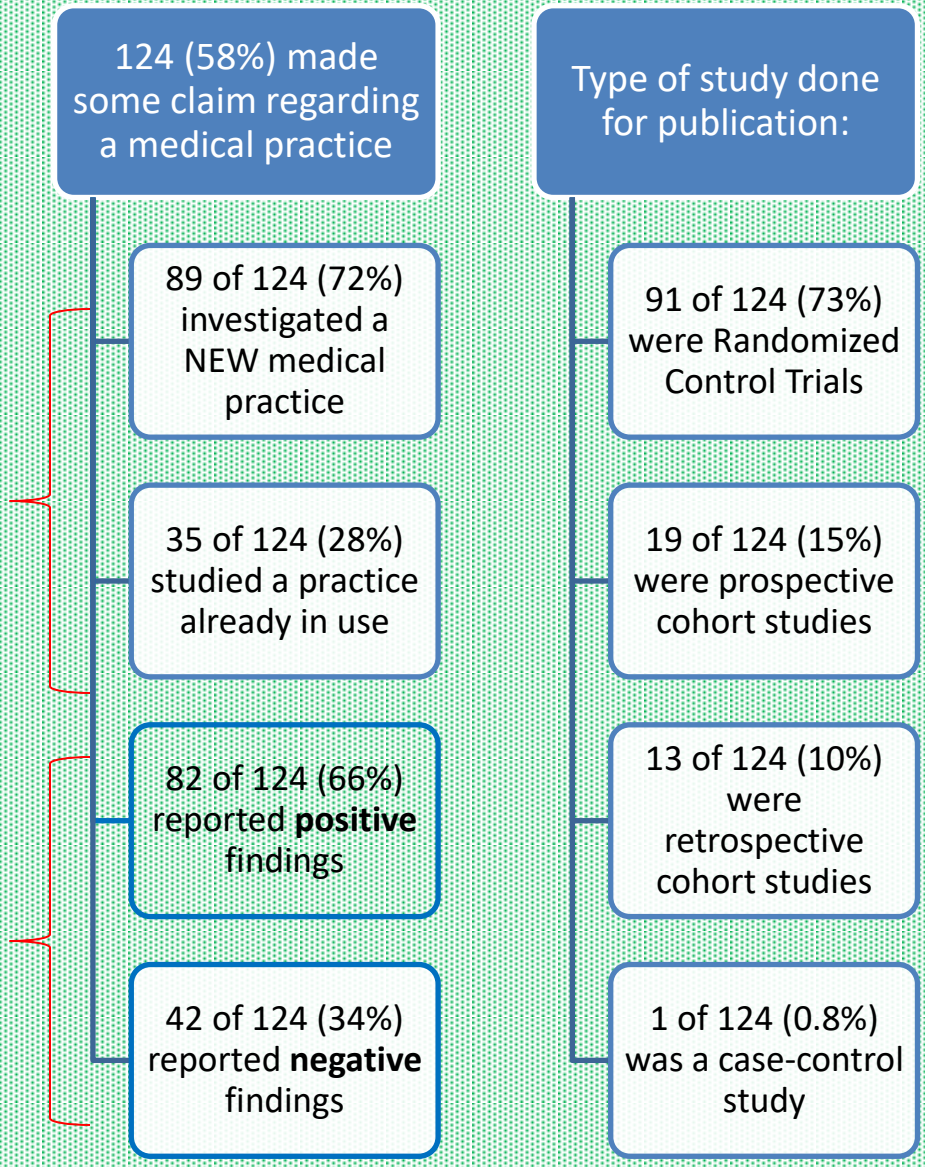
“Reversed” Research

- A study analyzed 1 year of articles in the NEJM that addressed a medical practice during 2009:
  - Practice was new
  - Practice was already in place
  - Studies were positive towards the practice
  - Studies were negative towards the practice

- 2 reviewers independently classified the articles, and a 3rd reviewer adjudicated any discrepancies.

“Reversed” Research

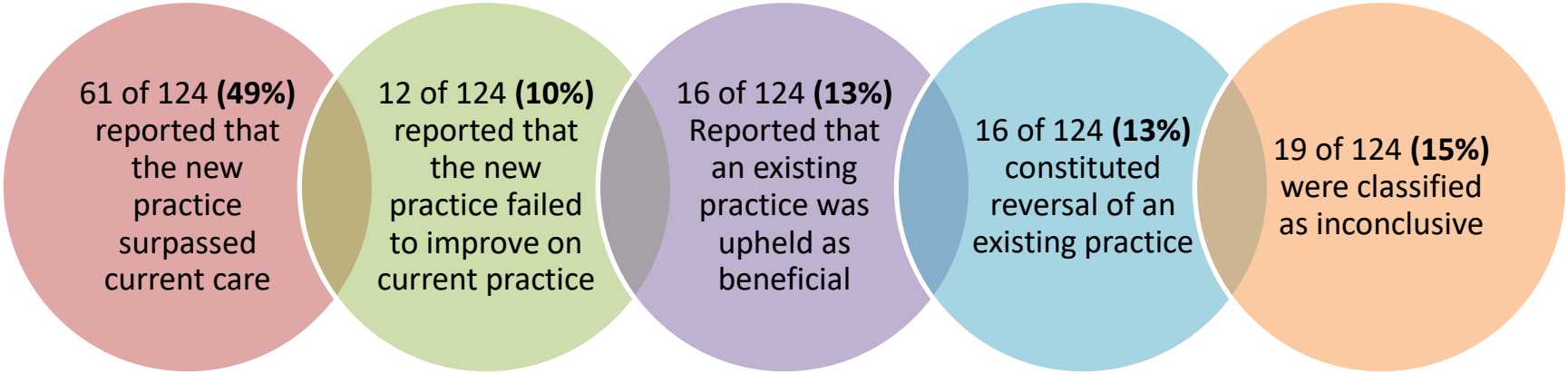
Total NEJM original articles during 2009 = 212, and 88 (42%) were descriptive molecular science studies



Ramírez 2023

“Reversed” Research

124 articles made some claim regarding a medical practice



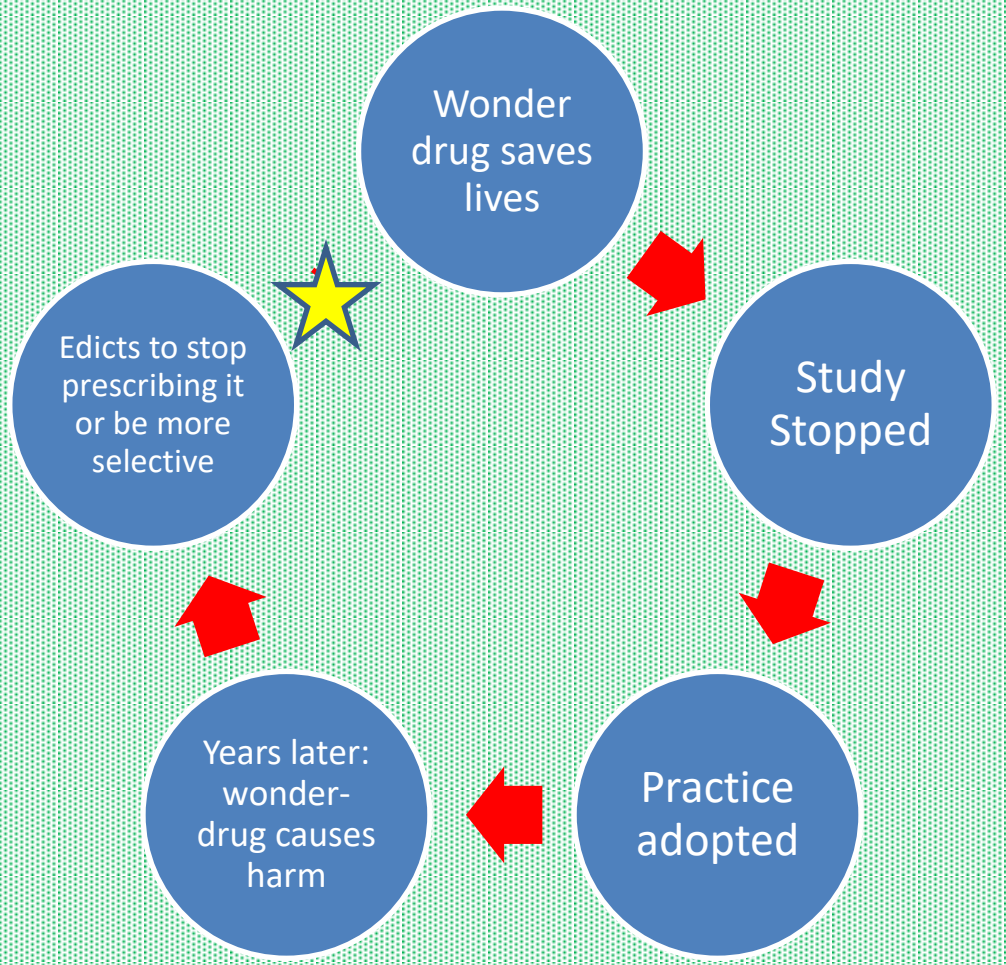
Medical Reversal

Some of the 16 Reversals:

- Prednisone in children with viral wheezing
- Tight glucose control in ICU Patients
- Routine use of statins in hemodialysis patients
- Endoscopic vein harvesting for CABG
- PCI for chronic total artery occlusions

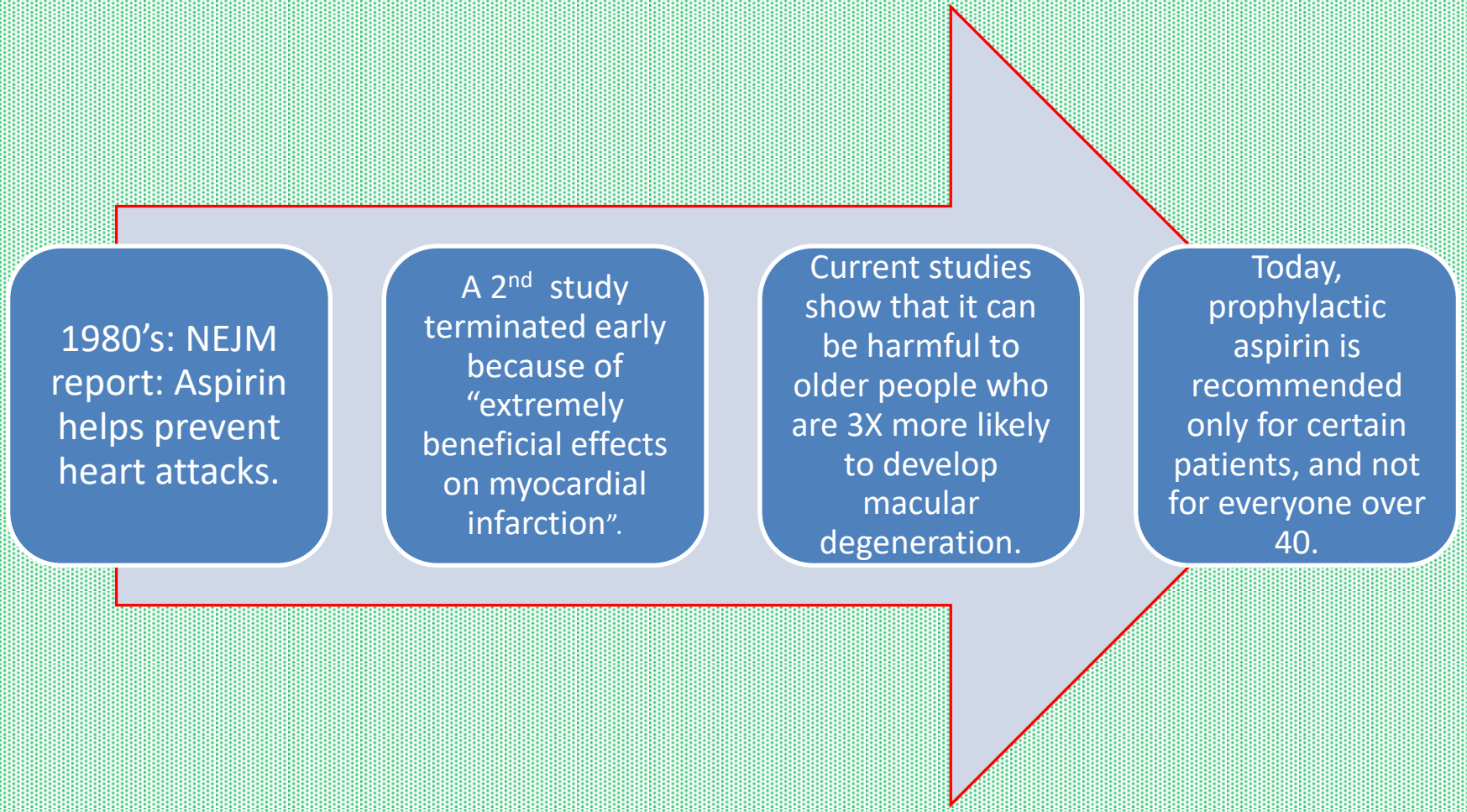
Medical About-Face, 180 degrees

The arc of modern American medical research:



Help the Heart, Hurt the Eyes

Prophylactic Aspirin



Medical Reversal

Replacement: A practice, treatment or test is supplanted by one that works better:

- Low Molecular Weight (LMW) Heparins replacing Coumadin in Deep Vein Thrombosis
- Proton Pump Inhibitors (PPI) replacing H2 receptor antagonists in Gastroesophageal Reflux Disease (GERD).

Cases of Medical Reversal

Reversal: A medical practice is changed because it either does not achieve its intended goal or causes harms that outweigh its benefits:

- Hormone Replacement Therapy (HRT) for menopause
- Class 1C antiarrhytmic agents, cardiovascular drugs (**Avandia,** *atenolol*)
- Stenting for renal artery stenosis
- Routine mammography for women 40-49 years old
- Percutaneous coronary intervention (PCI)

Other Classic Medical Reversals

- 1. Apnea as a pathophysiologic precursor of SIDS (Steinschneider, 1972). Retracted by Pediatrics 1992
- 2. Vertebroplasty (injection of polymethylmethacrylate cement into osteoporotic fractured vertebrae). Proved lack of benefit in separate RCT studies by Buchbinder and Kallmes in 2002.
- 3. Stenting for patients with coronary artery disease. (Proved to not help patients by Boden et.al 2007).

Other Classic Medical Reversals

- 4. Peptic ulcers not caused by hyperacidity of the gastric environment with the help of stress, but by infection with *Helicobacter pylori* (Tytgat 1985).

- 5. Vaccines associated with autism (1998). Refuted, retracted and publication of apology by LANCET (2010)

ISCHEMIA Study

- **I**nterntl. **S**tudy of **C**omparative **H**ealth **E**ffectiveness with **M**edical and **I**nvasive **A**pproaches, enrolled patients with moderate to severe ischemia—but who had not had a heart attack within the past 2 months, to receive either an invasive procedure (stent or coronary bypass), or medical therapy.

- It was a large, $100 M NIH study that sought to resolve a debate over which approach is best.

ISCHEMIA Study

The trial was designed to measure the time to a primary end point:

- cardiovascular death
- heart attack
- hospitalization for angina
- heart failure
- resuscitated cardiac arrest
- quality of life

ISCHEMIA Study

- Enrolled 8,518 patients and randomized 5,179: 73% of these patients had blinded CT angiography to exclude life-threatening conditions, then:
  - 2,588 received an invasive procedure
  - 2,591 received medical therapy.
  - median follow-up was 3.3 years; the full trial lasted 7 years.

- "The clinical results suggest that there is no need for invasive procedures in patients without symptoms,"

- For those with angina, the results show *it is just as safe to begin treating with medication and lifestyle change, and then if symptoms persist, discuss invasive options.*

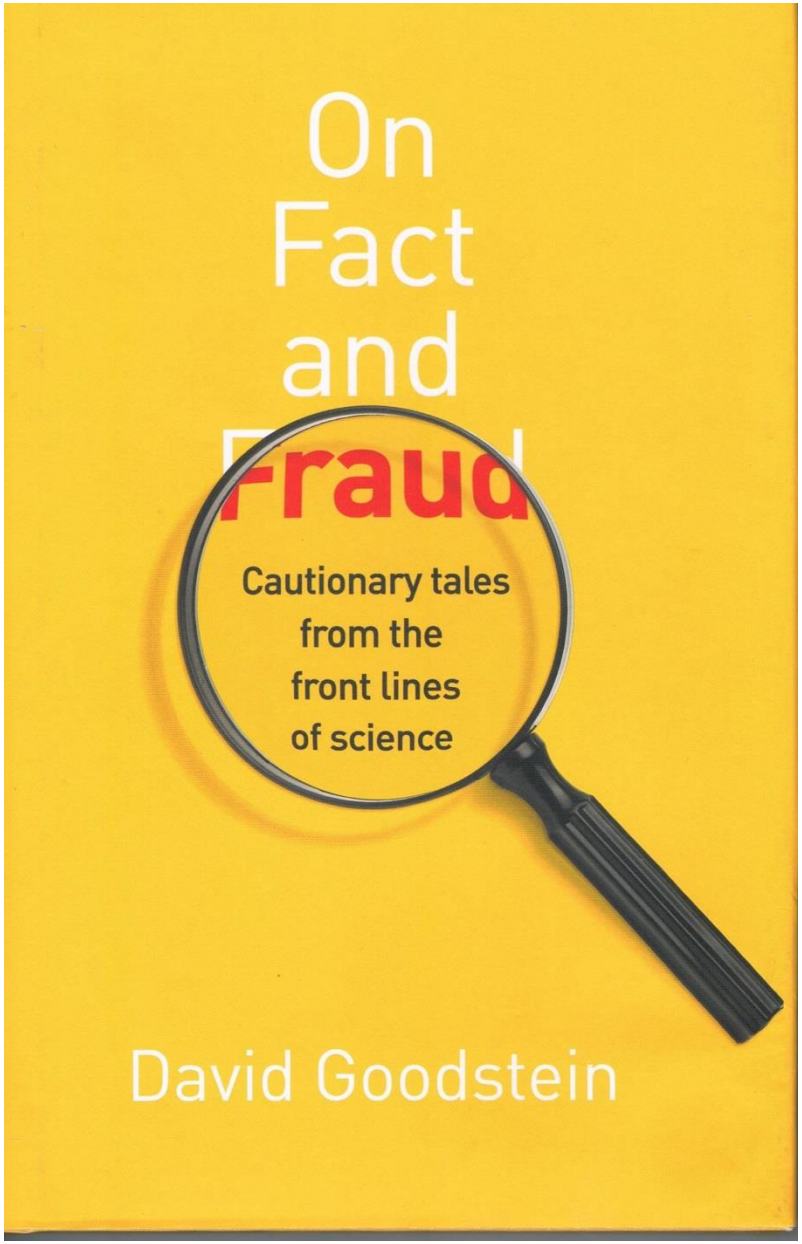
ISCHEMIA Study

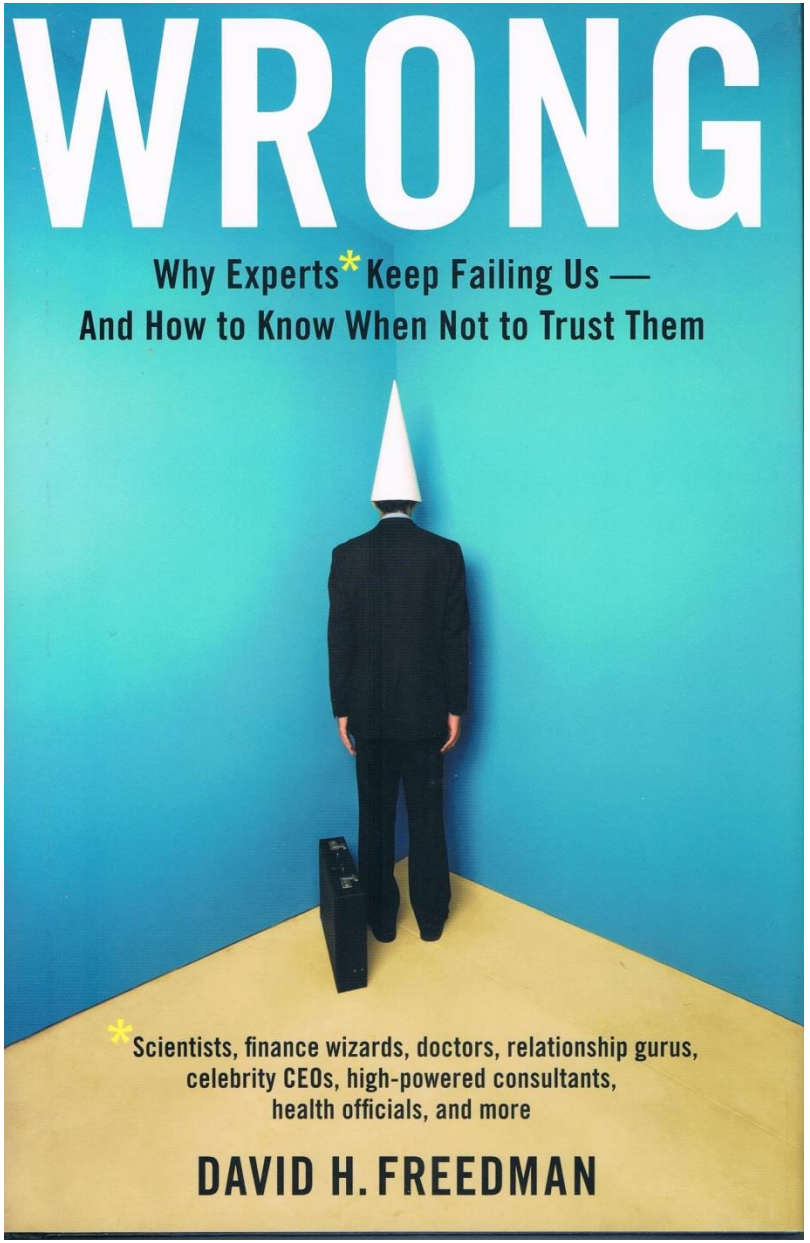
- By the end of the trial, the death rate between the two groups was essentially the same:
  - 145 participants who had invasive procedures
  - 144 who received medication alone

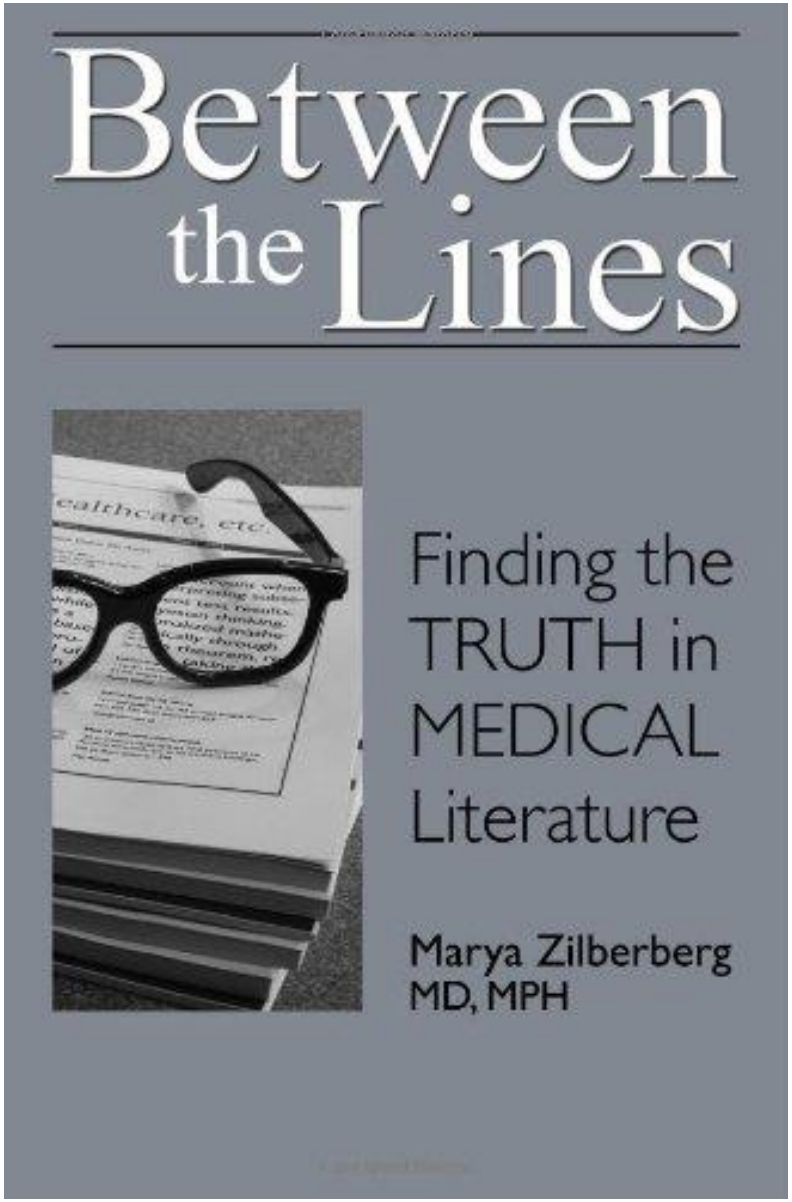
- The overall rate of disease-related events was similar:
  - 318 who had invasive procedures had a heart attack
  - 352 who took medication alone had a heart attack

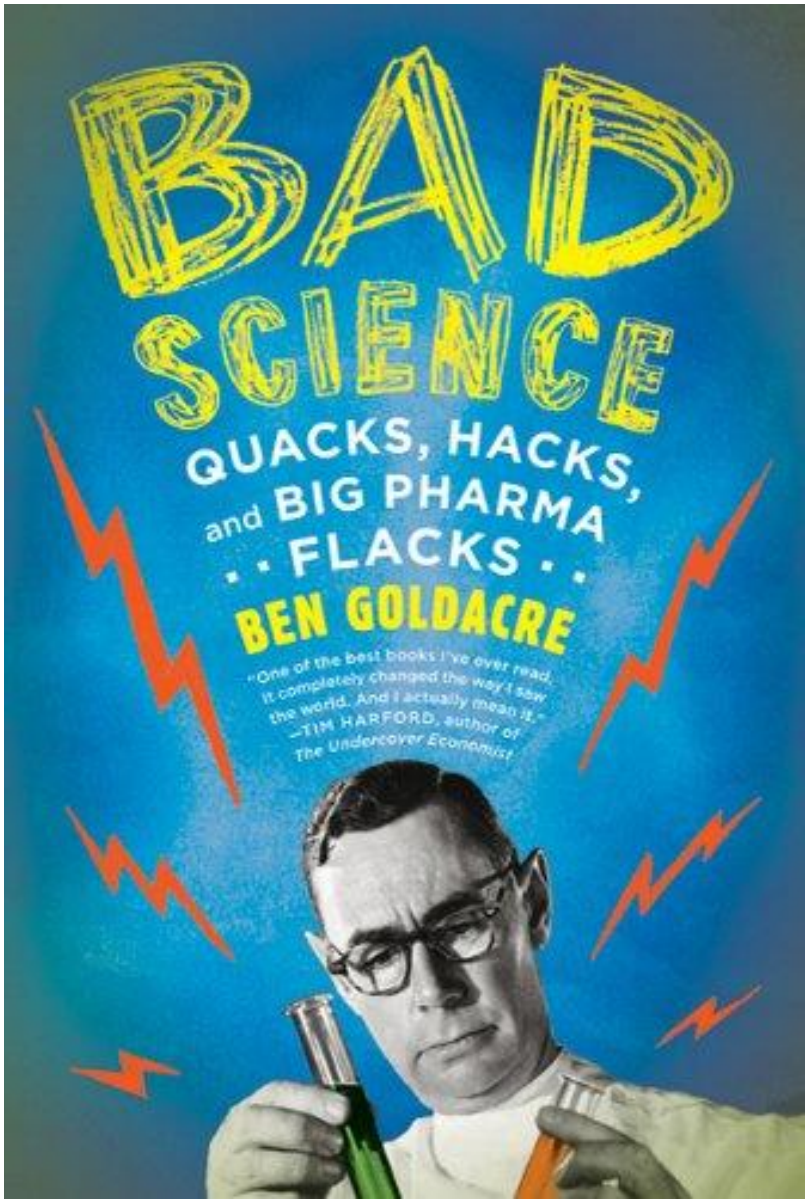
Medical Reversal Perils

- Unjustified costs.
- Undermines public's trust in the medical system, not only among patients, but also among doctors.
- Harms patients who received the intervention with no real benefit when it was considered relatively safe and effective.
- Removing a once-commonplace practice is very difficult, sometimes because of financial conflict of interest, or because of sheer obstinacy to defend one's practice, procedures, and scientific beliefs.

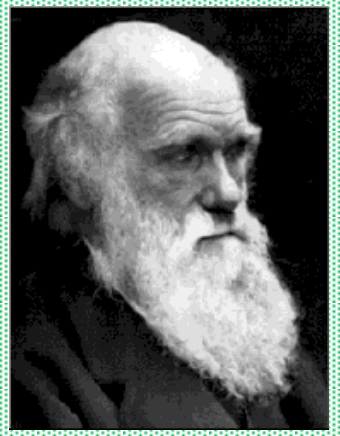

On
Fact
and
Fraud
Cautionary tales
from the
front lines
of science
David Goodstein


WRONG
Why Experts* Keep Failing Us —
And How to Know When Not to Trust Them
*Scientists, finance wizards, doctors, relationship gurus,
celebrity CEOs, high-powered consultants,
health officials, and more
DAVID H. FREEDMAN


Between
the Lines
Finding the
TRUTH in
MEDICAL
Literature
Marya Zilberberg
MD, MPH


BAD
SCIENCE
QUACKS, HACKS,
and BIG PHARMA
FLACKS
BEN GOLDACRE
"One of the best books I've ever read. It completely changed the way I saw the world. And I actually mean it."
—TIM HARFORD, author of The Undercover Economist

Charles Darwin



To kill an error is as good a service as, and sometimes even better than, the establishing of a new truth or fact.

False facts are highly injurious to the progress of science, for they often endure long; but false views, if supported by some evidence, do little harm, for every one takes a salutary pleasure in proving their falseness.

My mind seems to have become a kind of machine for grinding general laws out of large collections of facts.

I love fools' experiments. I am always making them.

Closing Thoughts

- I have little patience with scientists who take a board of wood, look for its thinnest part and drill a great number of holes where drilling is easy. (Albert Einstein)
- Two truths cannot contradict one another. (Galileo Galilei)
- Today, it is not only that our kings don't know mathematics, but our philosophers don't know mathematics and—to go a step further—our mathematicians don't know mathematics. (J. Robert Oppenheimer)
- Analogy cannot serve as proof. (Louis Pasteur)
- ***Errare humanum est: Perseverare diabolicum***.-"To err is human: To repeat error is of the Devil." (Seneca)

Final Questions?


Thank
you

Session 7 Comparison with Other Countries
October 19, 2023

- The Commonwealth Fund
- Mirror, Mirror Report
- Comparison with 10 Other Countries
- Morbidity and Mortality
- Healthcare Expenditure
- Universal Healthcare