

Safely Doing Less:

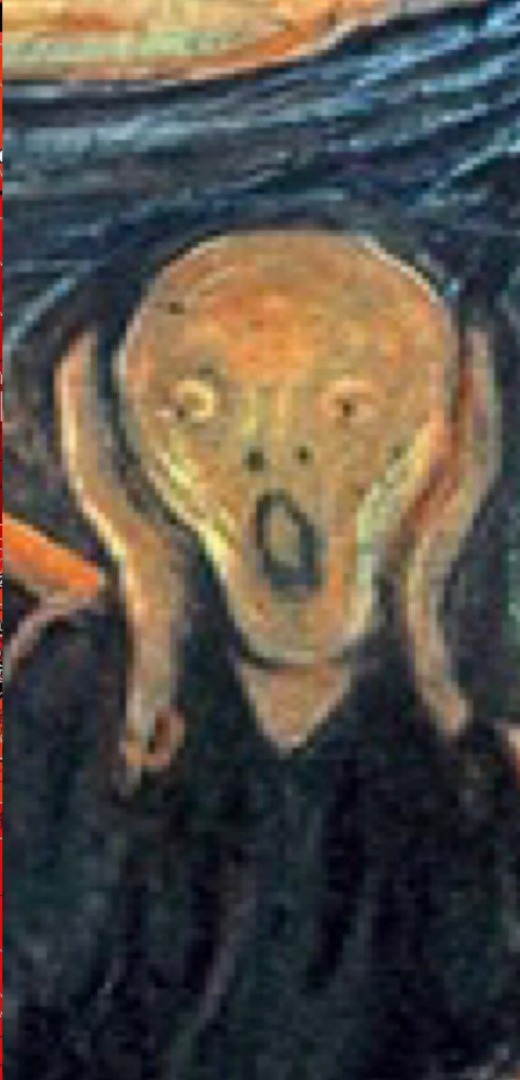
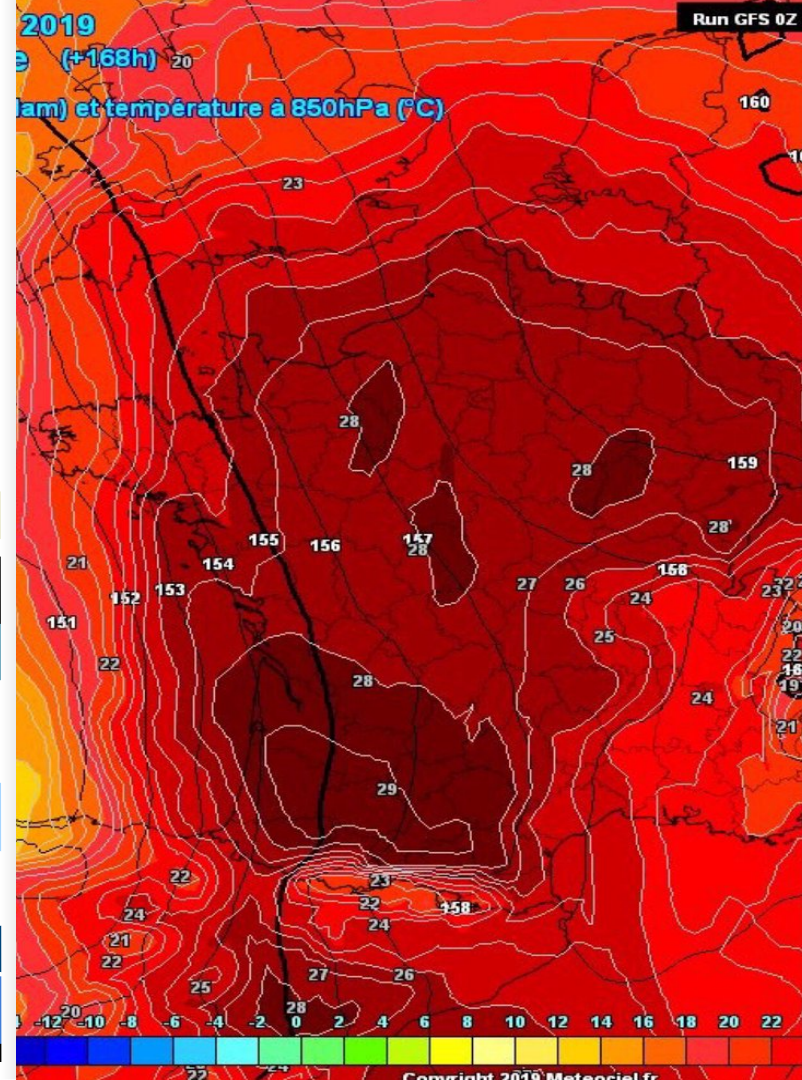
How Past Science Informs Future Practice



Tom Newman, MD, MPH

Professor Emeritus of Epidemiology & Biostatistics and Pediatrics

UCSF Mini-Medical School



**A 'screaming'
weather map
basically
captures
France's extreme
heat**

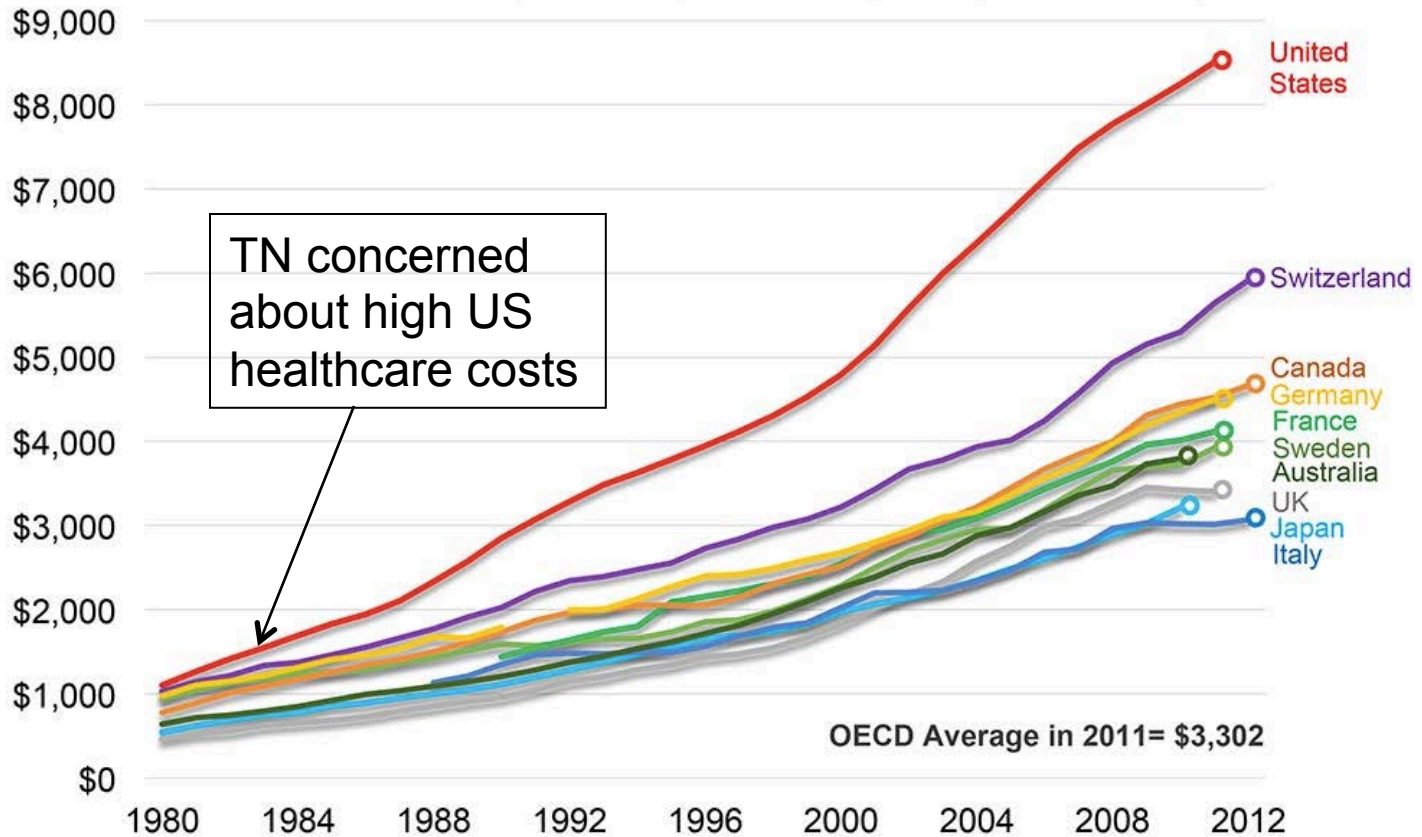
[https://www.cnn.com/
2019/06/26/europe/france-heat-
map-intl/index.html](https://www.cnn.com/2019/06/26/europe/france-heat-map-intl/index.html)



Origin of this talk

- I gave the first version of this talk to students in an "Inquiry" elective on climate change I have co-taught since 2016
- I quoted the UCSF Academic Senate Task Force on Sustainability:
 - *"Trying to reduce the carbon footprint from healthcare without examining what we do is like trying to reduce the carbon footprint from travel without examining what trips we take."*
- Much of my career has focused on critically examining what we do (and teaching others to do so)

Health Care Spending Per Capita (\$US PPP)



TN concerned about high US healthcare costs

OECD Average in 2011= \$3,302

Source: OECD Health Data 2013.
Data note: PPP = purchasing power parity.
Produced by Veronique de Rugy, Mercatus Center at George Mason University.

Waste in healthcare

Table. Estimates of Annual US Health Care Waste, by Category in Billions of \$, 2011)

Cause	Low Estimate
Overtreatment	158
Administrative complexity	107
Failures of care delivery	102
Pricing failures	84
Fraud and abuse	82
Failures of care coordination	25
Total	558
Waste as a fraction of total healthcare spending	21%

Berwick and Hackbarth, JAMA. 2012;307(14):1513-1516




Origin of the title for this talk

PEDIATRICS[®]

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Safely Doing Less: A Missing Component of the Patient Safety Dialogue



AUTHORS: Alan R. Schroeder, MD,^a Stephen J. Harris, MD,^a and Thomas B. Newman, MD, MPH^b

Published online November 28, 2011



Slide from Dr. Allan Schroeder



**Dr. Schroeder and
Packard Children's Hospital
Stanford:
Doing less for *you* today!!!**



Lucile Packard
Children's Hospital
Stanford



Alan Schroeder is @safelydoingless #safelydoingless



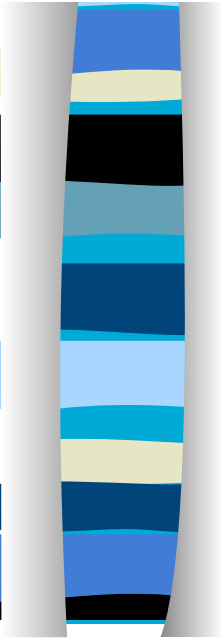
Take home message #1

- If you look for stuff, you will find it.
- This is not always a good thing.
- Examples
 - Oxygen saturation monitoring
 - Cancer screening

Impact of Pulse Oximetry and Oxygen Therapy on Length of Stay in Bronchiolitis Hospitalizations

Alan R. Schroeder, MD; Andrea K. Marmor, MD; Robert H. Pantell, MD; Thomas B. Newman, MD, MPH

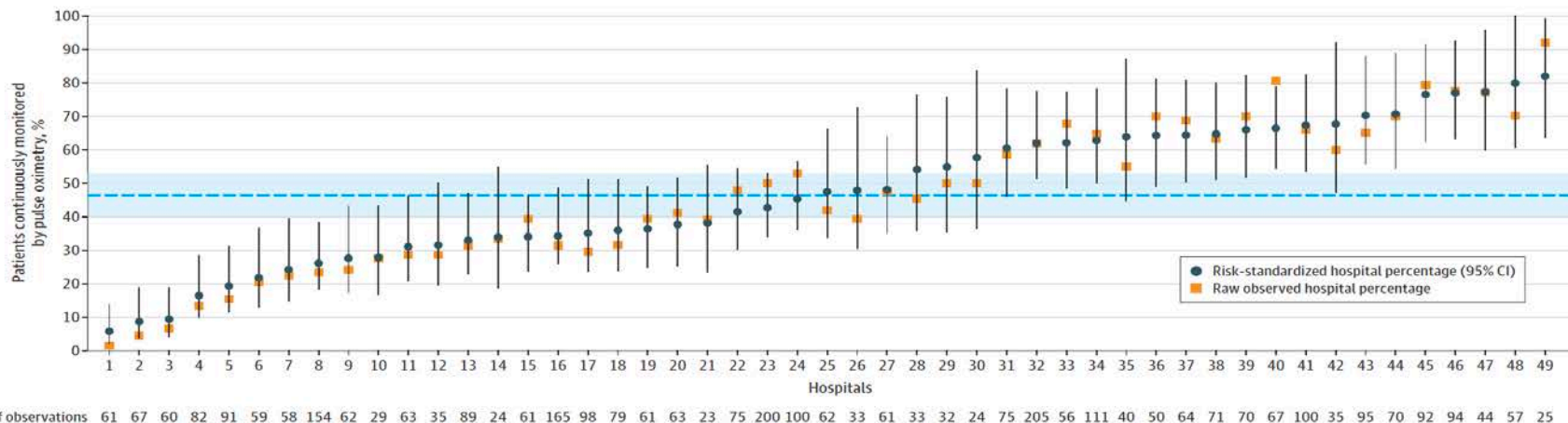
Arch Pediatr Adolesc Med. 2004;158:527-530

- 
- Low tech, low-budget chart review
 - In 16 of 62 patients (26%) length of stay was prolonged because of concerns about low oxygen saturations

Prevalence of Continuous Pulse Oximetry Monitoring in Hospitalized Children With Bronchiolitis Not Requiring Supplemental Oxygen

Christopher P. Bonafide, MD, MSCE; Rui Xiao, PhD; Patrick W. Brady, MD, MSc; Christopher P. Landrigan, MD, MPH; Canita Brent, MPH; Courtney Benjamin Wolk, PhD; Amanda P. Bettencourt, PhD, APRN, CCRN-K, ACCNS-P; Lisa McLeod, MD, MSCE; Frances Barg, PhD, MEd; Rinal S. Reidas, PhD; Amanda Schondelmeyer, MD, MSc, for the Pediatric Research in Inpatient Settings (PRIS) Network

Figure 2. Continuous Pulse Oximetry Use in Patients With Bronchiolitis Not Receiving Any Supplemental Oxygen or Nasal Cannula Flow

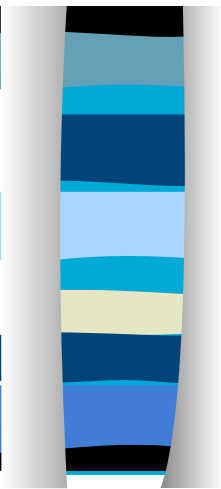


Patients were aged 8 weeks through 23 months. Points represent the percentage of patients with bronchiolitis actively monitored with continuous pulse oximetry, measured using direct observation. The dotted blue line indicates overall percentage across all hospitals and the shaded area represents the 95% CI. The risk-standardized

percentage for each hospital is the ratio of the predicted to expected use percentages multiplied by the overall percentage across all hospitals. Hospitals are ordered by risk-standardized percentage of patients monitored.

Overuse of Continuous Pulse Oximetry for Bronchiolitis The Need for Deimplementation Science

Christine C. Cheston, MD; Robert J. Vinci, MD



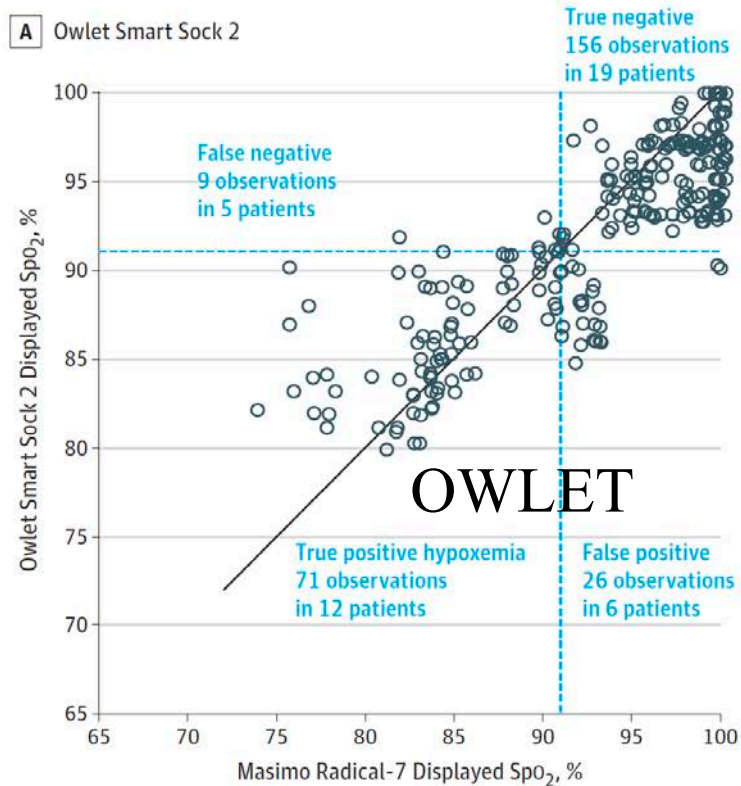
JAMA April 21, 2020 Volume 323, Number 15, p. 1449

Owlet Smart Sock 2 Baby Monitor



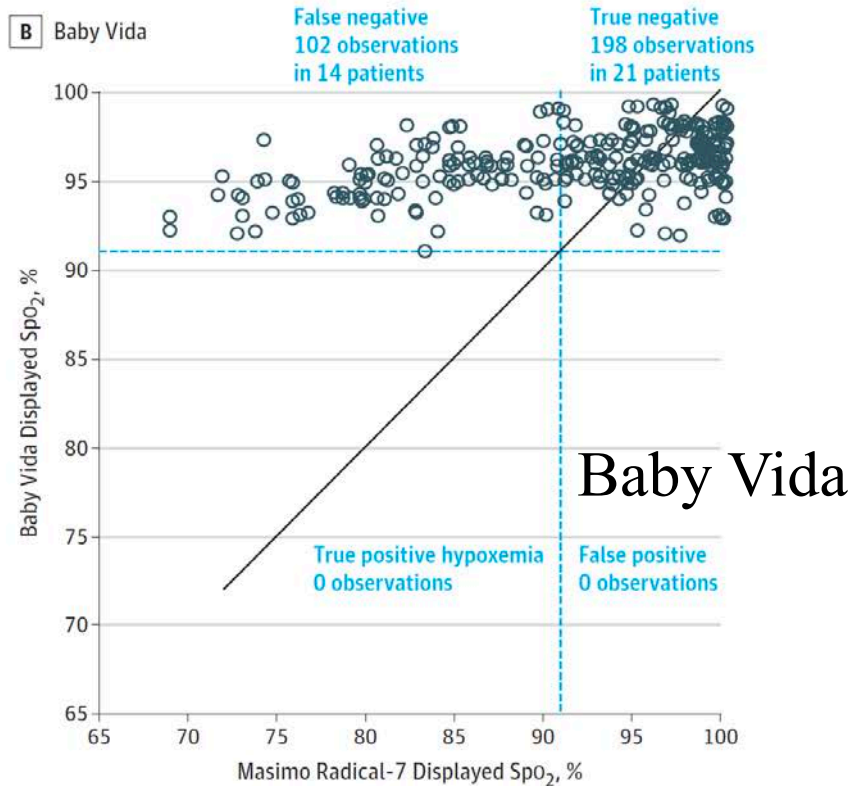
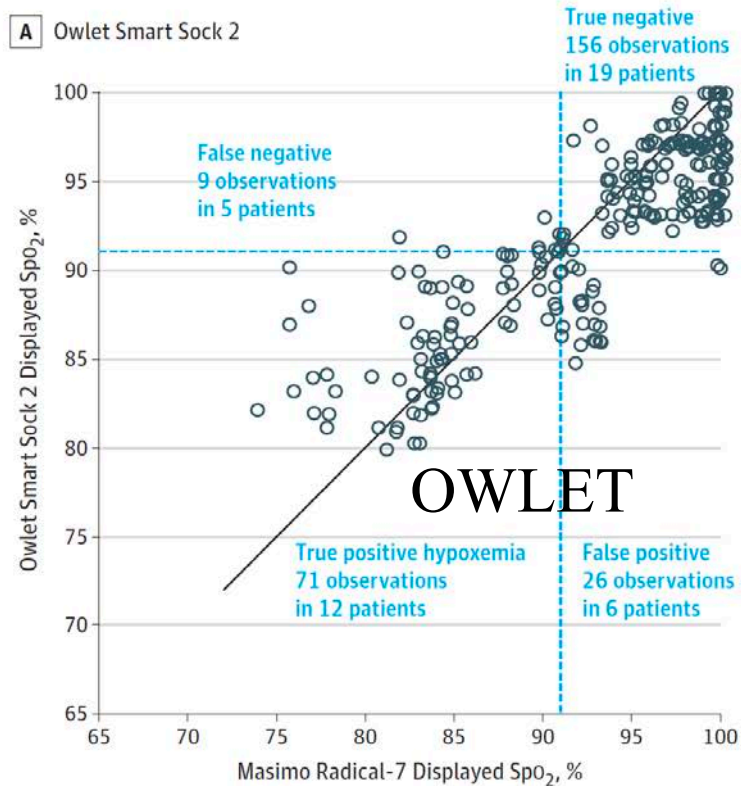
The advertisement features the "baby vida" logo at the top, which consists of two overlapping hearts (one blue, one pink) with a white heartbeat line. Below the logo, the text "oxygen monitor" is prominently displayed, followed by the tagline "GIVING YOU VITAL PEACE OF MIND". The central image shows a baby's feet with the white oxygen monitor sock on the right foot. To the left, a smartphone displays the app interface, with a Wi-Fi symbol and the text "Real-time feed to App. For Apple & Android devices." Below the baby's feet, a caption reads "Monitor fits comfortably over your baby's foot. Monitors oxygen level & heart rate. Alarms to readings outside of normal range." At the bottom, there are two icons: a green circle with "O₂" for "oxygen level" and a green heart with a white heartbeat line for "heart rate".

Figure 1. Oxygen Saturation (SpO₂) for Oxygen Baby Monitors Owlet Smart Sock 2 and Baby Vida (Consumer Monitors) vs US Food and Drug Administration–Cleared Masimo Radical-7 (Reference Monitor)



Hospitalized babies 0-6 months. One monitor on each foot.
Bonafide et al. JAMA 2018; 320:717

Figure 1. Oxygen Saturation (SpO₂) for Oxygen Baby Monitors Owlet Smart Sock 2 and Baby Vida (Consumer Monitors) vs US Food and Drug Administration–Cleared Masimo Radical-7 (Reference Monitor)



Hospitalized babies 0-6 months. One monitor on each foot.
Bonafide et al. JAMA 2018; 320:717



Arterial oxygen saturation in healthy term neonates

Christian F. Poets, Valerie A. Stebbens, Jane A. Lang, Louise M. O'Brien, Andrew W.

Boon, David P. Southall

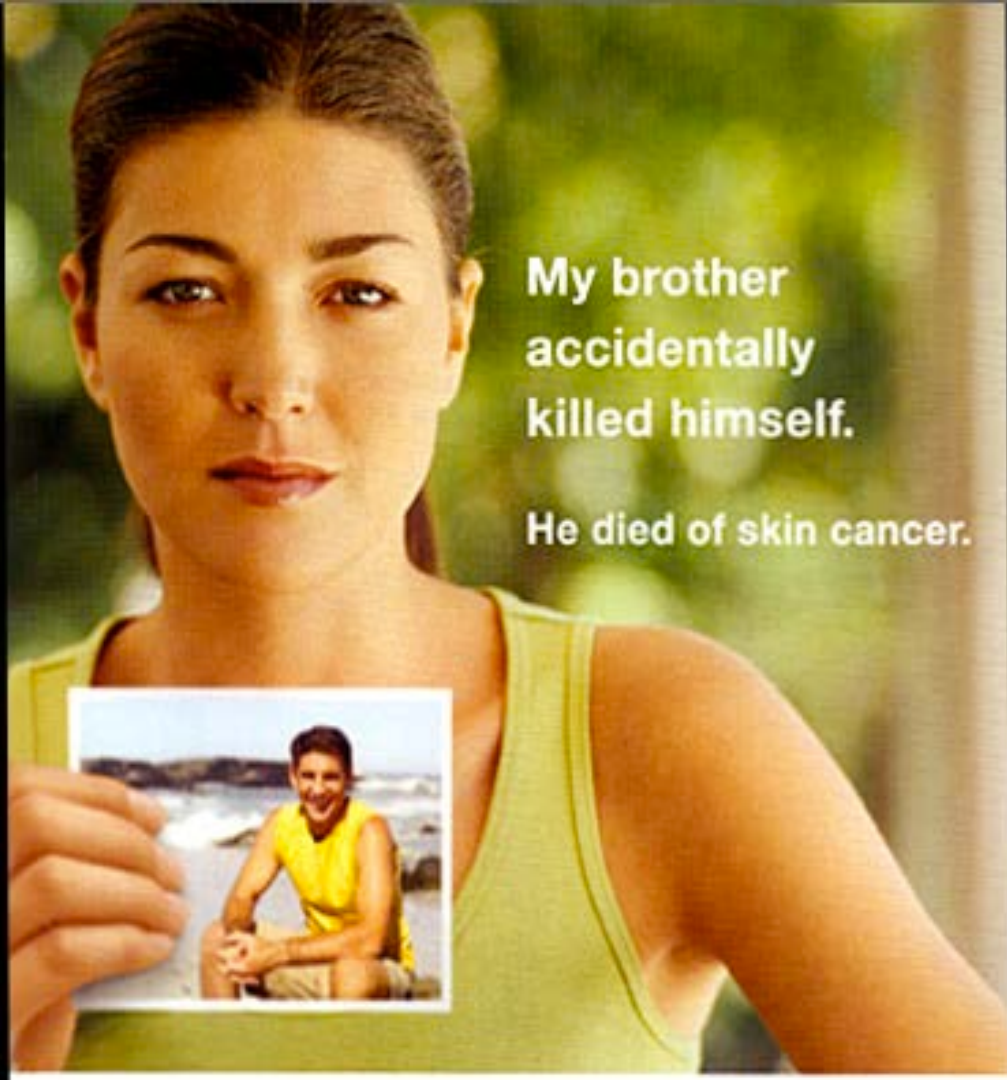
Eur J Pediatr 1996;155:219-223

- Overnight pulse oximetry recordings in 60 healthy term infants
- Episodes of desaturation ($\leq 80\%$ for > 4 seconds) were found in 35% of recordings in week 1 and 60% of recordings in weeks 2-4.
- In week 2, the median number of desaturations per 12-hour recording was 4 (range 0 to 165).
- Normal babies desat!



Summary

- If you look for desats in babies, you will find them
- In inpatients, this often prolongs hospital stays
- In outpatients, clinically important desats (and SIDS) are very rare
- So almost all alarms will be false alarms, even if the sat really was low.
- But anxiety (and hence the market for these products) is real.

A woman with dark hair pulled back, wearing a light green tank top, looks directly at the camera with a serious expression. She is holding a small, white-bordered photograph of a man in a yellow tank top sitting on a beach. The background is a soft-focus green outdoor setting.

**My brother
accidentally
killed himself.**

He died of skin cancer.

**Woloshin et al.
Cancer Screening
Campaigns —
Getting Past
Uninformative
Persuasion. NEJM
2012;
367:1677-1679**

**Professional medical
organization ad**



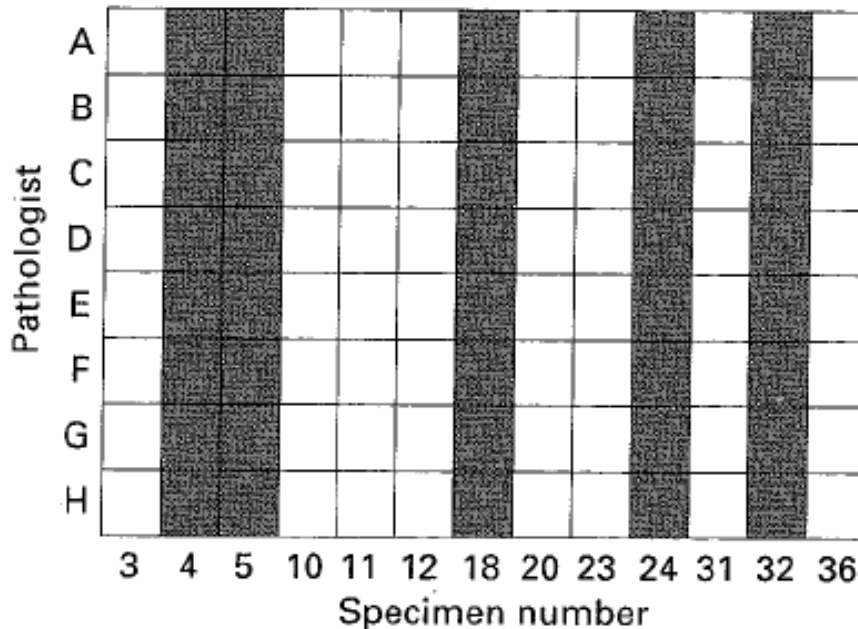
Interobserver Agreement Among Pathologists for Diagnosing Malignant Melanoma*

- Eight expert dermatopathologists selected on the basis of their reputation and publications
- Each selected 5 cases of melanomas or benign melanocytic nevi that shared histological features with melanoma
 - Had to be "classic cases" that could be published as examples
 - 37 cases selected

*Farmer ER et al. Discordance in the histopathologic diagnosis of melanoma and melanocytic nevi between expert pathologists. *Human Pathology* 1996;27:528

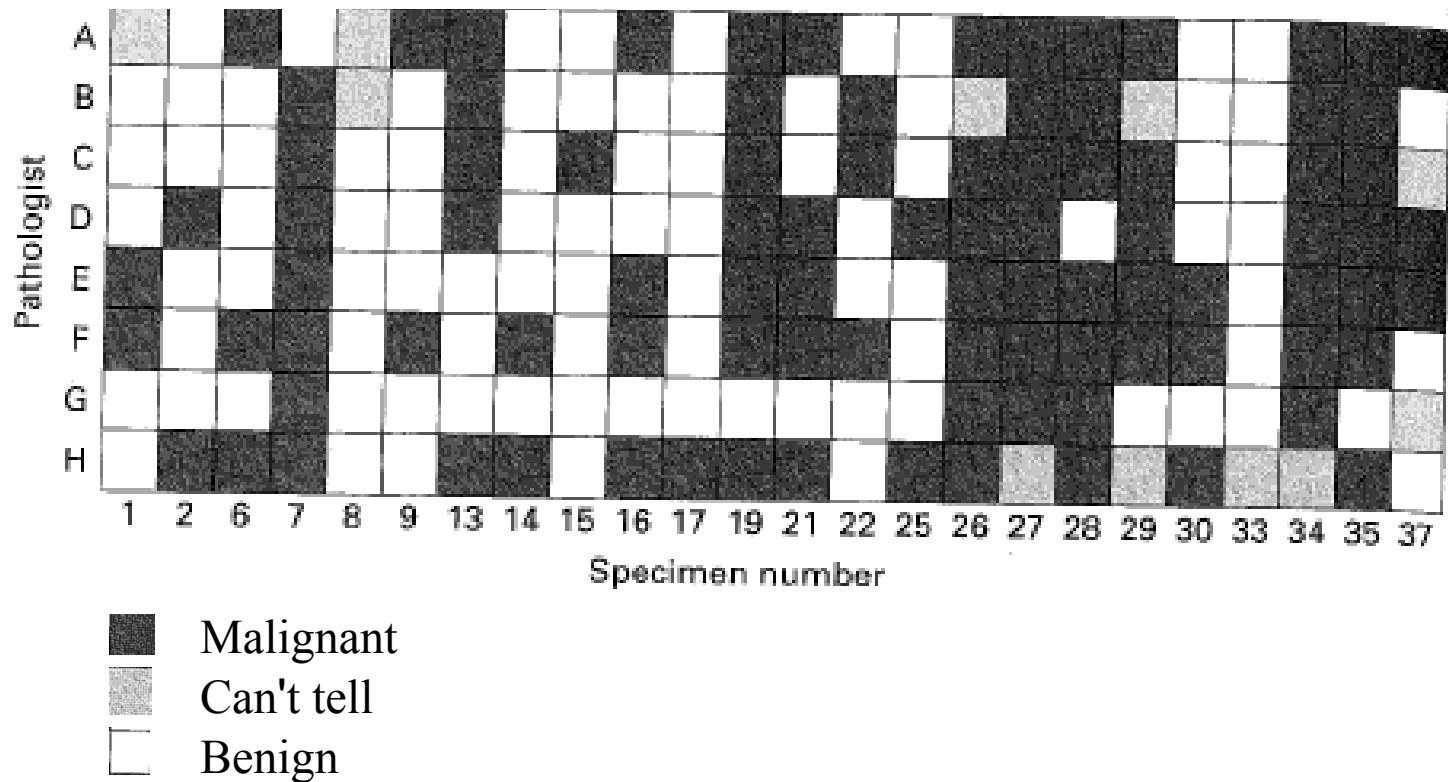
Interobserver Agreement Among Pathologists for Malignant Melanoma: 13 cases with perfect agreement

■ Malignant
□ Benign



See Welch, HG. Should I Be Tested for Cancer?: Maybe Not and Here's Why. University of California Press. 2006.

Interobserver Agreement Among Pathologists for Malignant Melanoma: 24 cases with disagreement





Concerned about lung cancer?

Lung cancer is by far the leading cause of cancer death among both men and women, and nearly half of all cases are in the most advanced stage at diagnosis. Fortunately, Carolinas Imaging Services now offers a lung cancer screening that can detect cancer before it becomes symptomatic. The National Comprehensive Cancer Network recommends the screening for individuals 55+ with a history of heavy smoking (at least 30 pack-years), and individuals 50+ with a 20-pack-year history coupled with another risk factor, such as asbestos exposure. The cost is only \$250—well worth the peace of mind that comes with finally having answers.

Schedule your lung cancer screening today at 704.442.4390.





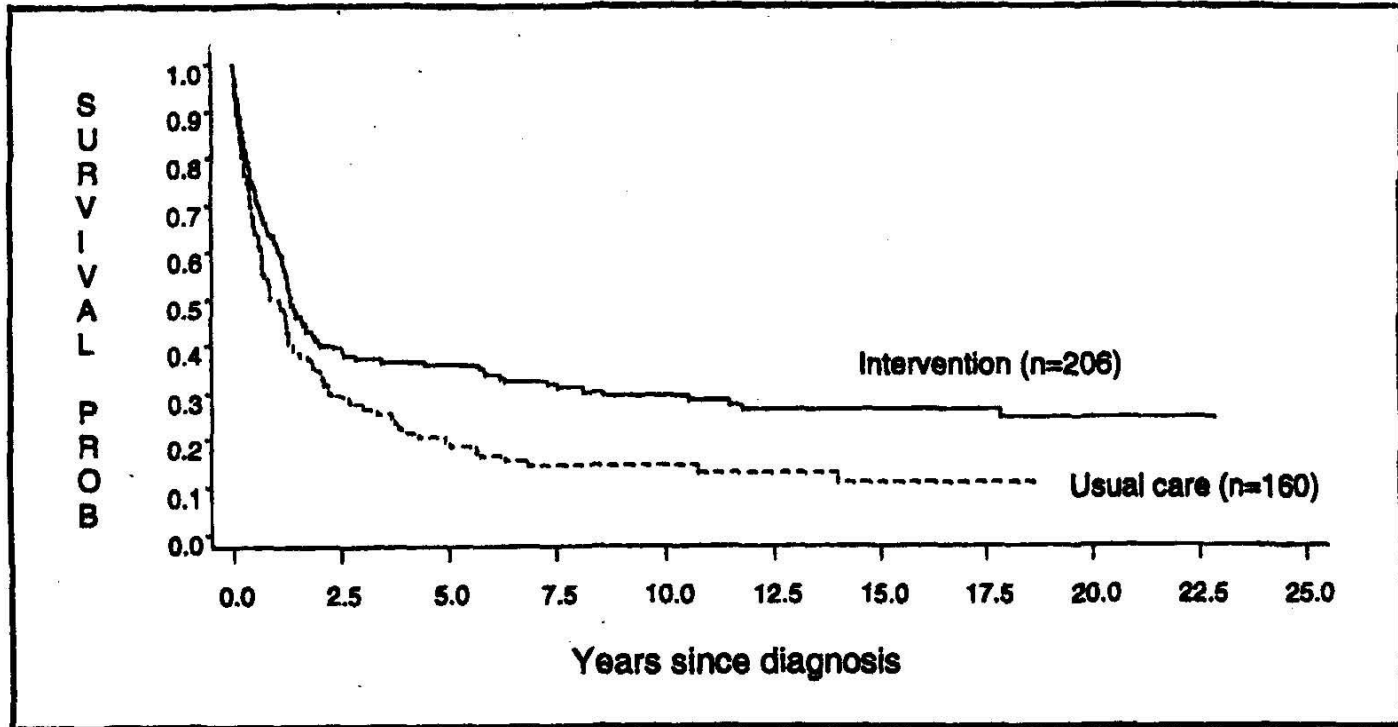
Classic Study: Mayo Lung Project

- Randomized trial of lung cancer screening
- Enrollment 1971-76
- 9,211 male smokers randomized to two study arms
 - Intervention: chest x-ray and sputum cytology every 4 months for 6 years (75% compliance)
 - Usual care (control): same tests at trial entry, then a recommendation to receive them annually

*Marcus et al., JNCI 2000;92:1308-16

Mayo Lung Project Extended Follow-up Results*

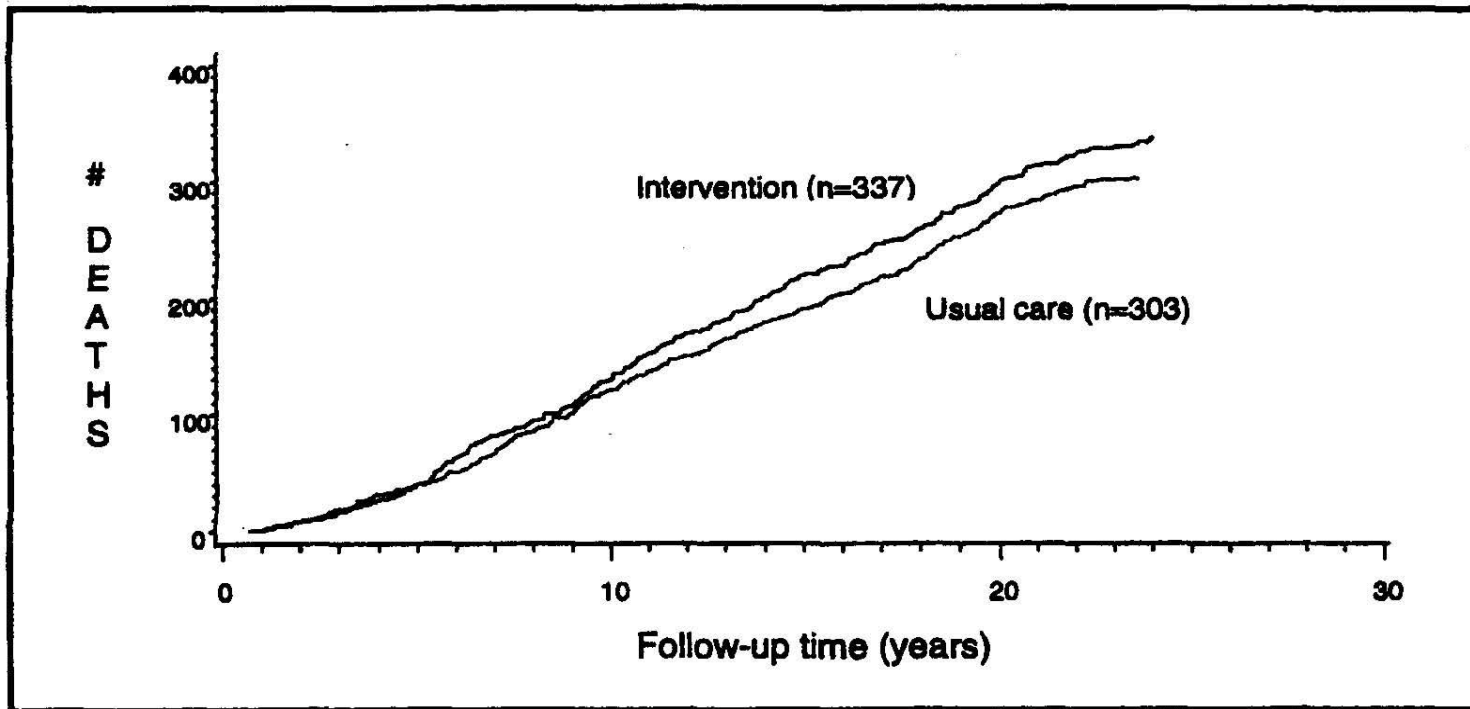
- Among those with lung cancer, intervention group had more cancers diagnosed at an early stage and better **survival**



*Marcus et al., JNCI 2000;92:1308-16

Mayo Lung Project LP Extended Follow-up*

- Intervention group: slight increase in lung-cancer mortality (P=0.09 by 1996)



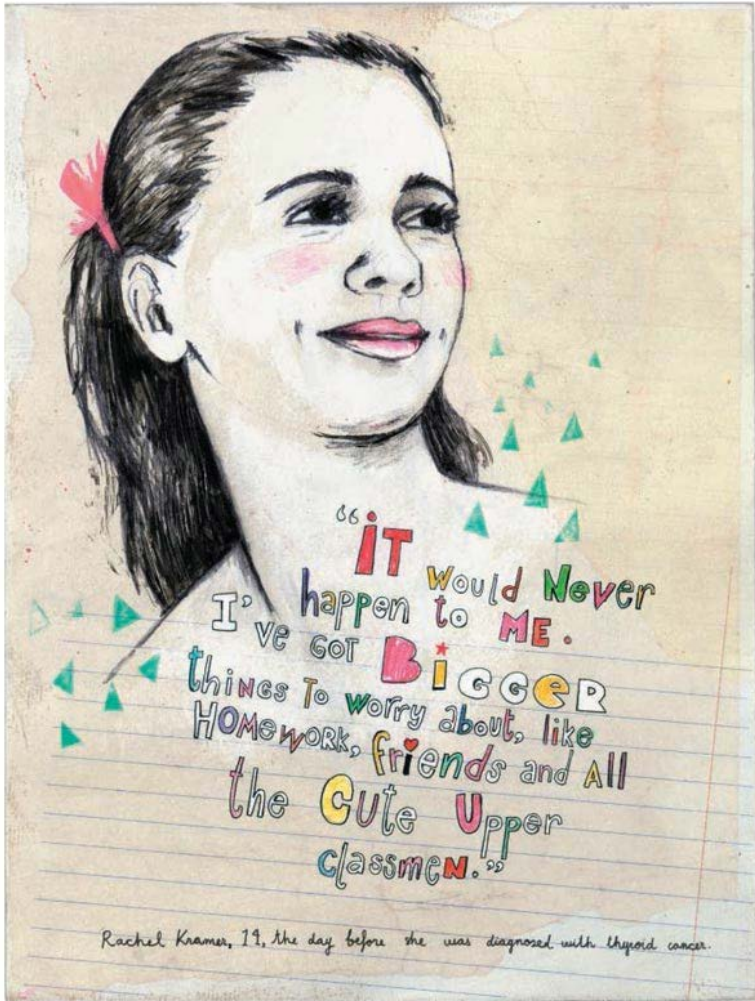
*Marcus et al., JNCI 2000;92:1308-16



What happened?

- After 20 years of follow up, there was a significant increase (29%) in the total number of lung cancers in the screened group
 - Excess of tumors in early stage
 - No decrease in late stage tumors
- Reason: Overdiagnosis
 - Some of the "cancers" diagnosed in the screened group never would have caused a problem

Black W. Overdiagnosis: an underrecognized cause of confusion and harm in cancer screening. JNCI 2000;92:1308-16



Ad from a disease advocacy group:

“Rachel Kramer, 14, the day before she was diagnosed with thyroid cancer.”

Also found at <http://www.lombardilaw.com/blog/malpractice-is-a-very-personal-type-of-claim.cfm>

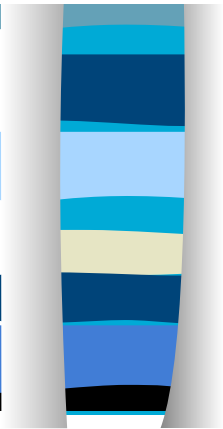
From: Woloshin et al. Cancer Screening Campaigns — Getting Past Uninformative Persuasion. NEJM 2012; 367:1677-1679

SPECIAL REPORT

Epidemiologic Signatures in Cancer

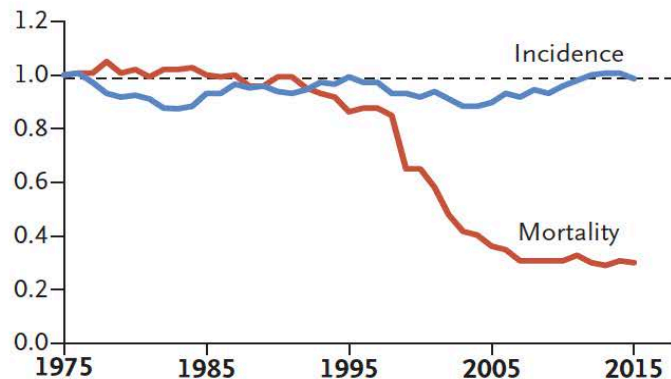
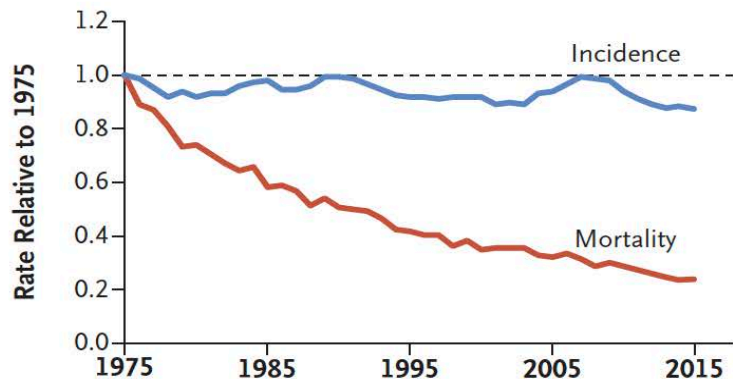
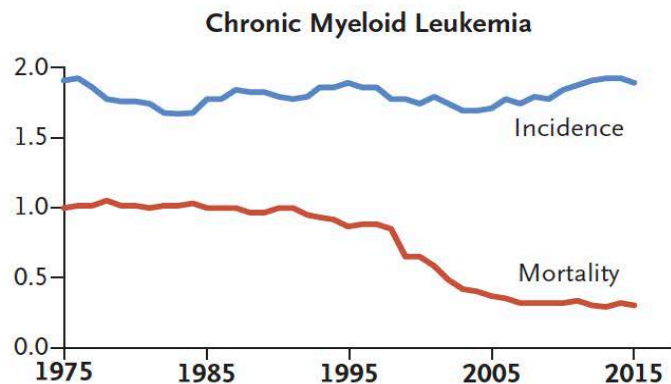
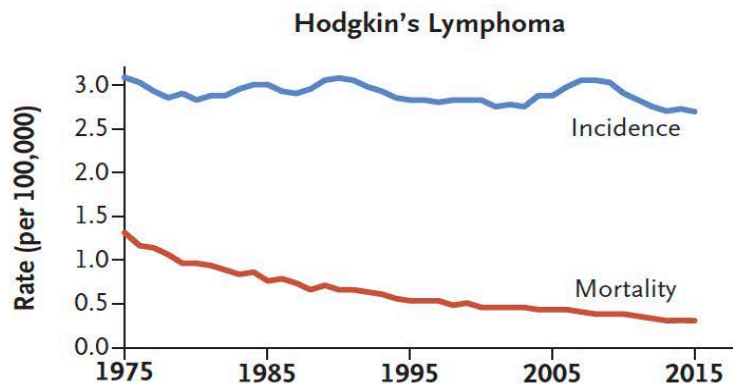
H. Gilbert Welch, M.D., M.P.H., Barnett S. Kramer, M.D., M.P.H., and William C. Black, M.D.

N Engl J Med 381;14, October 3, 2019



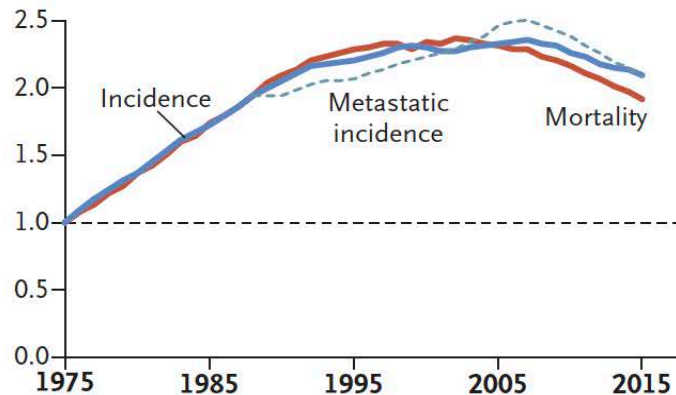
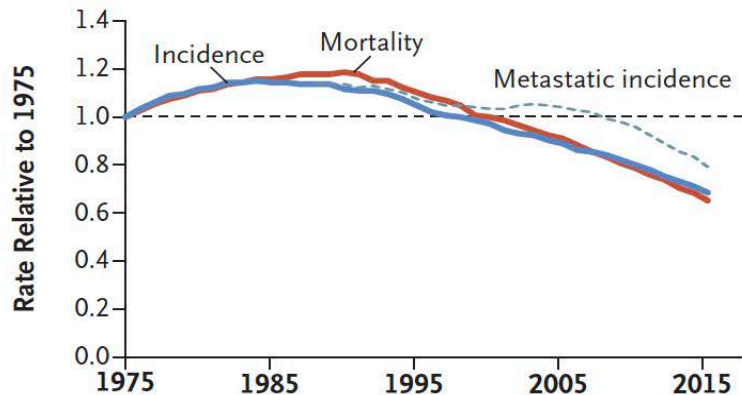
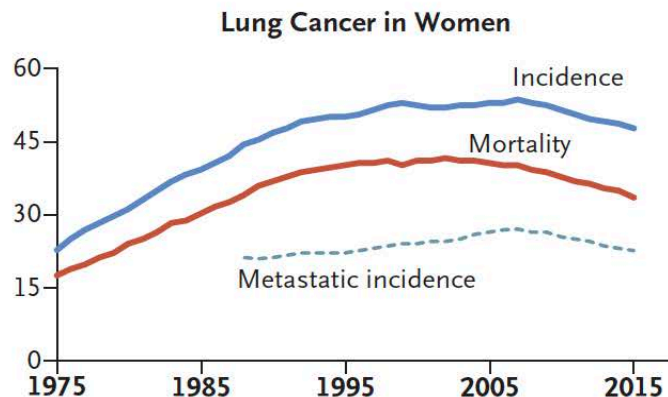
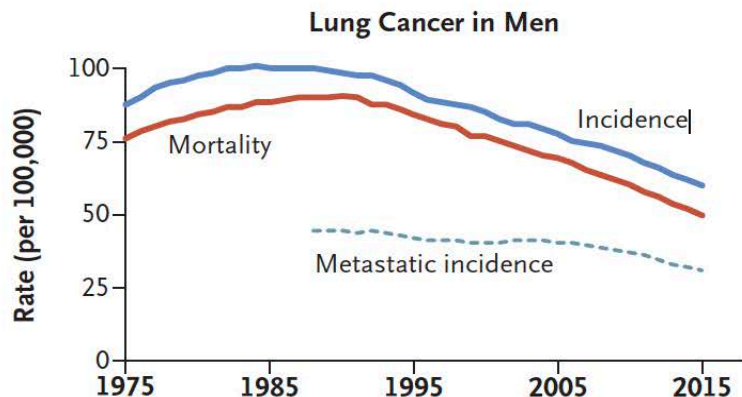
Improving treatment

A



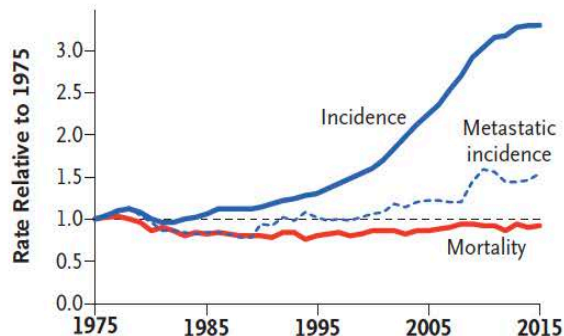
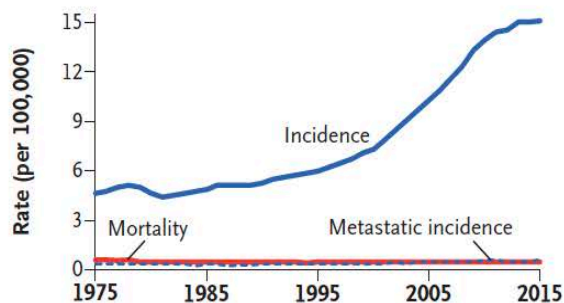
Real changes in incidence

B

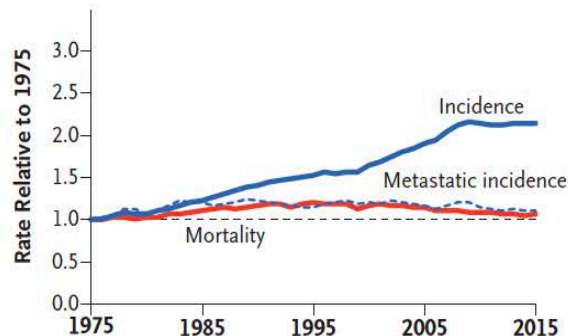
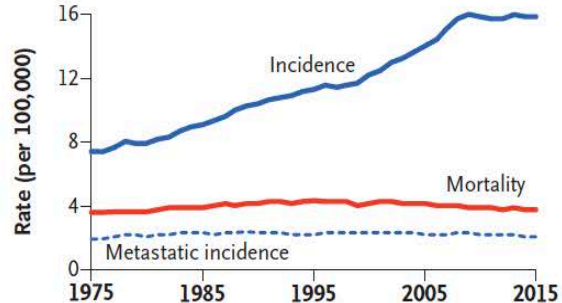


Overdiagnosis (with stable true cancer occurrence)

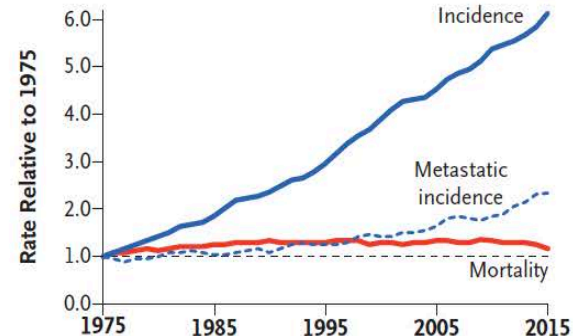
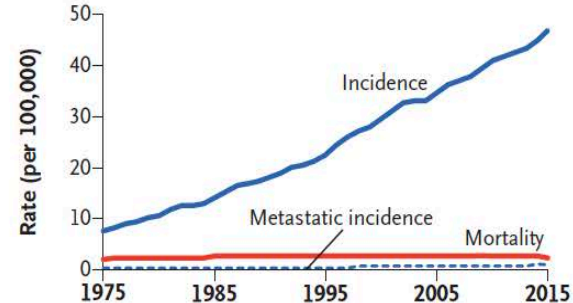
A Thyroid Cancer



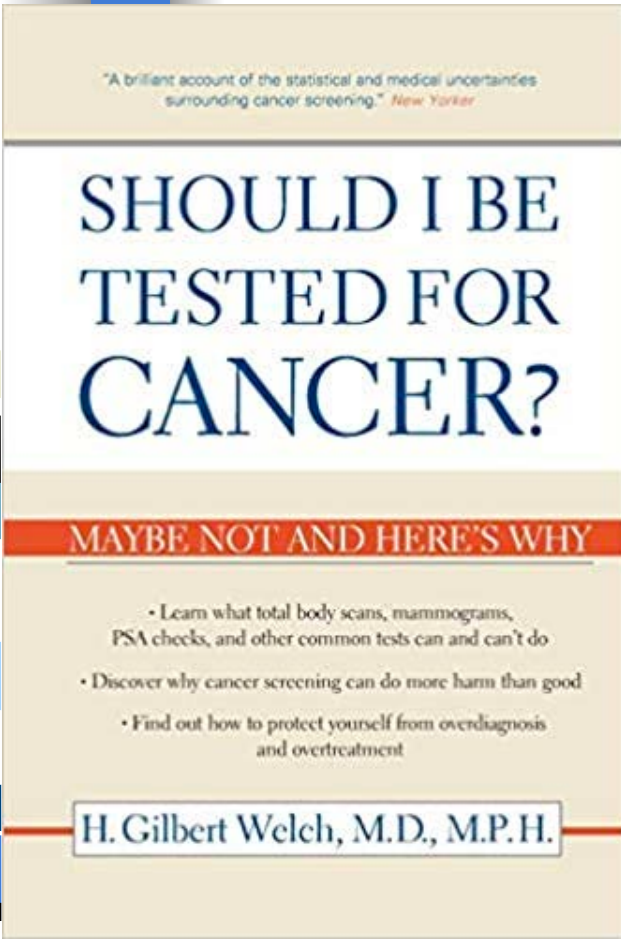
B Kidney Cancer



C Melanoma



Additional reading by Dr. Welch



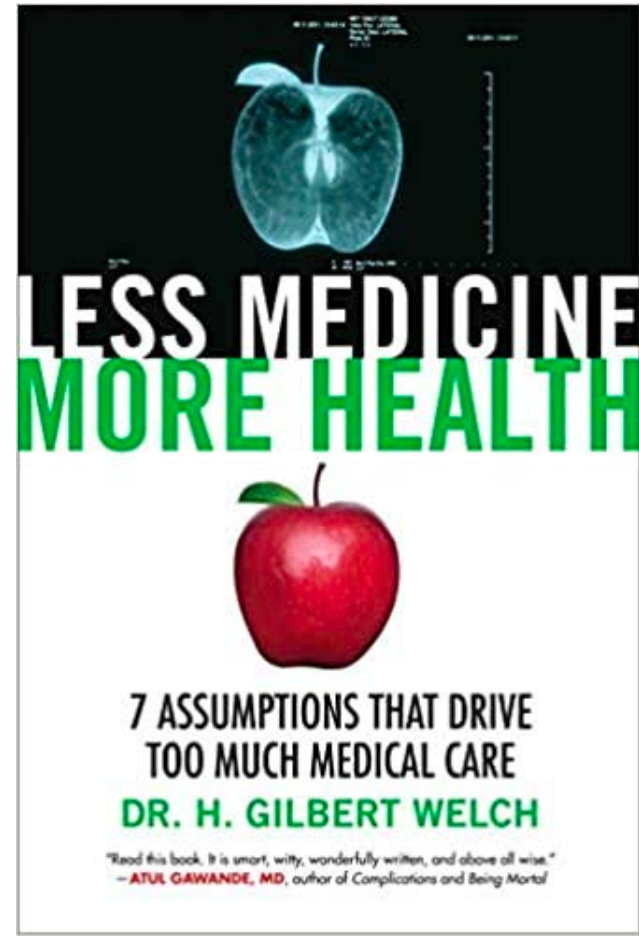
OVER-DIAGNOSED

MAKING PEOPLE SICK IN THE PURSUIT OF HEALTH

DR. H. GILBERT WELCH,
DR. LISA M. SCHWARTZ, AND DR. STEVEN WOLOSHIN

"This brilliantly researched, well-argued, and clearly written book will help us avoid the unnecessary tests, drugs, surgeries, and therapies that are the inevitable outcome of our epidemic of overdiagnosis."


—SIDNEY WOLFE, MD, author of *Worst Pills, Best Pills* and editor of *Worst Pills.org*





Take home message #2

- Compelling stories are not enough
- Need to quantify (or at least estimate) risks and benefits of interventions
- Examples
 - Infant safety seats on airplanes
 - Childhood cholesterol screening
 - Early onset sepsis



American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™



Press Release

AAP CALLS FOR AN END TO LAP TRAVEL FOR CHILDREN ON PLANES

AMERICAN ACADEMY OF PEDIATRICS

Committee on Injury and Poison Prevention

Pediatrics 2001;108:1218-1221

Ending lap travel: Background

- Children under 2 can ride on parent's lap with no ticket
- July 19, 1989: UAL #232 crash at Sioux City, Iowa. An unrestrained infant (Eric Tsao) dies.
- 1990: US National Transportation Safety Board (NTSB) recommends universal restraint
- July 12, 1994: Another “lap child” dies in crash, NTSB again urges FAA to require infant restraint



NBC News Archives





FAA Report to Congress, 1995

■ Methods

- Detailed analyses of survivability of previous crashes
- Base case assumed the extra cost for the infant's ticket would make 20% drive rather than fly

■ Results over 10 years:

- Infant restraint would prevent maximum of 5 infant deaths
- Increase of 82 motor vehicle deaths due to diversion from planes to cars

■ Rejected as “flawed” by NTSB and Congress



Congressional Testimony: Evidence

- "I think there is more than enough evidence that substantiates what we're trying to do.
- "The question, I think, Mr. Chairman, comes down to how many more children must die, how many more have to be hurt before we reach the threshold of FAA's ghoulish cost/benefit ratio?"

--Congressman Jim Lightfoot, Iowa



“Real” vs “Theoretical” Children

- “The argument in support of the FAA’s resistance to the NTSB...is unreasonable on its face and ridiculous in its justification. It protects theoretical children driving in cars at the expense of real flesh-and blood infants whose safety is unquestionably compromised when flown as a lap-baby”

Nader R, Smith WJ. Collision course: the truth about airline safety. Blue Ridge Summit, PA: TAB Books, 1994. Cited by Beshai D. Arch Ped Adol Med 2003;157:953-4



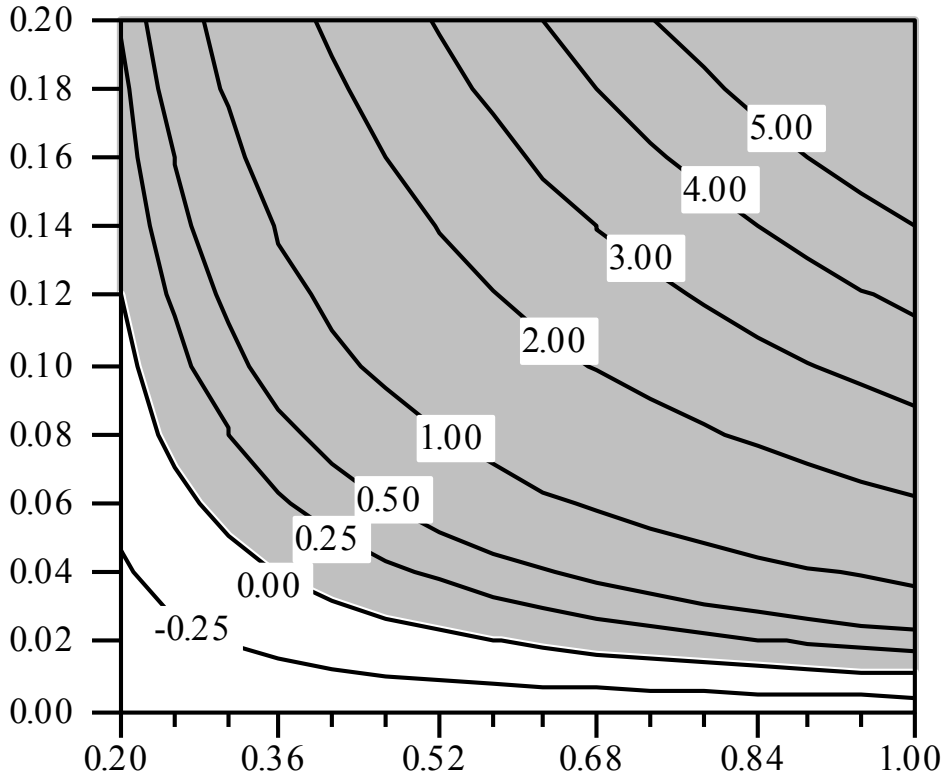
Effects and Costs of Requiring Child Restraint Systems for Infants Traveling on Commercial Airplanes*

- Benefits: similar to FAA (6 deaths in 10 years)
- Risks:
 - Did not assume 20% switching to cars
 - Did not assume vehicle miles traveled would carry average risk of deaths
 - Modeled what percent could switch to cars before net deaths increased

*Newman TB, Johnston B, Grossman D. Arch Pediatr Adol Med 2003;157:969-74

Deaths caused or prevented per year

Proportion Choosing to Drive



■ Increased deaths
□ Decreased deaths

*Newman TB, Johnston B, Grossman D. Arch Pediatr Adol Med 2003;157:969-74

Relative Risk of Auto Death for Families



Effects and Costs of Requiring Child Restraint Systems for Infants Traveling on Commercial Airplanes*

- Net increase in deaths over 10 years 0-30 vs 82
- Costs: assuming NO diversion to cars, at \$200/round trip ticket
 - ~\$1.3 Billion per life saved

*Newman TB, Johnston B, Grossman D. Arch Pediatr Adol Med 2003;157:969-74

The power of stories over statistics

Thomas B Newman

Neonatal jaundice and infant safety on aeroplanes provide two lessons on the power of narrative, rather than statistical evidence, in determining practice

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biostatistics and
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BMJ 2003;327:1424-7

BMJ,
2003.

I've always been more comfortable with numbers than with narrative, demanding data rather than accepting anecdotes. Recently, however, as a result of research in two unrelated areas—neonatal jaundice and infant safety on aeroplanes—I've been increasingly impressed with the power of stories over statistics. So I've decided to branch out from my usual publication format and tell a few stories of my own.

Treating jaundice in newborns

The jaundice story is one of me trying to treat jaundice in newborns according to the best evidence. Ironically, the more of an expert on the evidence I have become, the more difficulty I have practising according to that evidence. This is because becoming a "jaundice expert" means becoming familiar with rare but tragic stories of children with kernicterus. These stories are so powerful that it is hard to keep them from trumping other evidence in determining practice.

My neonatal jaundice story starts in the early 1980s, when I was a resident in paediatrics at the University of California, San Francisco. At that time, we treated babies with phototherapy when they had bilirubin concentrations above 14 mg/dl (239 $\mu\text{mol/l}$), and did exchange transfusions for concentrations above 20 mg/dl (342 $\mu\text{mol/l}$). Unfortunately, the early 1980s was not a good time to be transfusing blood in San Francisco. Although we did not know it then, the

blood supply was contaminated with HIV. We also did not know that most of these exchange transfusions were unnecessary.

In 1983, in an article entitled "Bilirubin 20mg/dL = vigintiphobia," Watchko and Oski questioned the "fear of twenty" that led to exchange transfusions for jaundice in healthy babies.¹ Subsequently my colleagues and I reviewed and re-analysed existing studies and came to the same conclusion: that jaundice in healthy newborns was being overtreated.^{2,3} We recom-



JAMES STEVENS/NSPIL

There's a story behind the "kinder, gentler" treatment thresholds for jaundice in newborns



Child Restraint on Airplanes: Summary

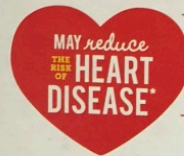
- Good data
 - Very little benefit
 - Very high cost per benefit
 - Would probably cause net harm
- Powerful stories
- Notice of Proposed Rule-Making issued by FAA in 2001
- Archives of Peds and Adol Med paper 2003
- Decision NOT to change rule 8/25/05*

*https://www.faa.gov/news/press_releases/news_story.cfm?contentKey=1966

SHE HAS
HER MOTHER'S EYES.
AND HER FATHER'S
CHOLESTEROL.



Multi-Grain Cheerios



made with **5** WHOLE GRAINS



Enlarged to
Show Detail
Serving
Suggestion

100% DAILY VALUE OF 9 VITAMINS & MINERALS

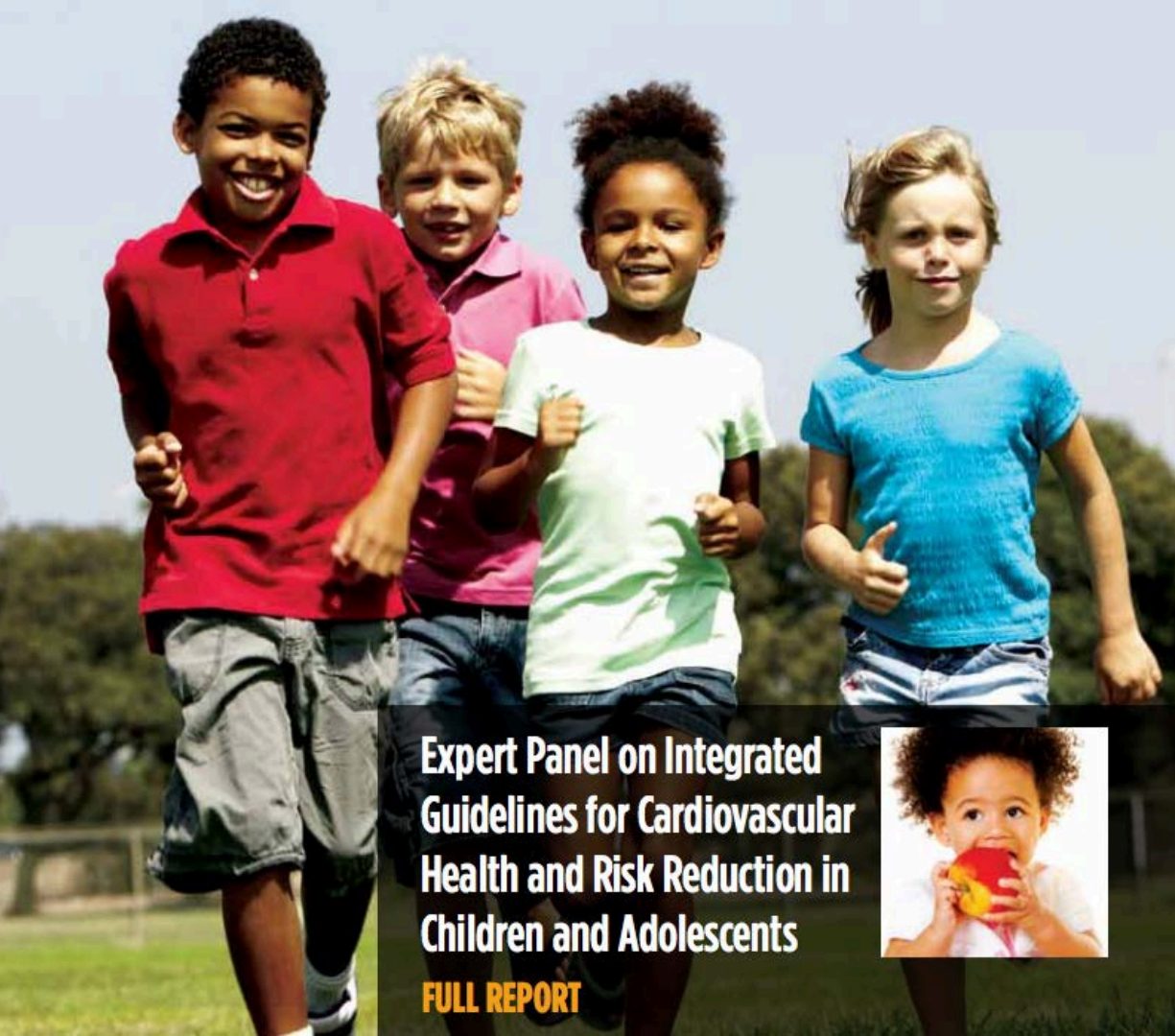
Lightly Sweetened Cereal

*DIETS LOW IN SATURATED FAT AND CHOLESTEROL MAY REDUCE THE RISK OF HEART DISEASE. MULTI GRAIN CHEERIOS® CEREAL IS LOW IN FAT (1.5g), SATURATED FAT FREE AND CHOLESTEROL FREE.

NO ARTIFICIAL FLAVORS
NO COLORS FROM

SIMPLY MADE
Gluten Free
GROWN MILLED TOASTED

Multi-Grain
Cheerios:
6 g sugar
in 29 g
serving =
20.6%
sugar



**Expert Panel on Integrated
Guidelines for Cardiovascular
Health and Risk Reduction in
Children and Adolescents**

FULL REPORT



National Heart, Lung and Blood Institute (NHLBI) 2012 Guidelines

Endorsed by the
American
Academy of
Pediatrics (AAP)

CATCH HEART DISEASE EARLY. SCREEN NOW.

Early indicators of heart disease—like high cholesterol and hypertension—can be identified as soon as age nine. Screen now to proactively manage warning signs—before they become more serious problems.

[DOWNLOAD NOW](#)

NIH GUIDELINES FOR PEDIATRIC LIPID TESTING

*Download the NIH
Guidelines for Pediatric
Lipid Testing.*

[DOWNLOAD GUIDELINES](#)

From emailed
link 10/4/18



NHLBI/AAP 2012 Guidelines

- Universal lipid screening at ages 9-11
 - Strong recommendation
- Fasting lipid panels *beginning at age 2 years* for ~40% of children
 - Strong recommendation
- Treatment with low-fat, low cholesterol diet, then statins

"Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present."

The Case Against Childhood Cholesterol Screening

JAMA, 1990

Problems With the Report of the Expert Panel on Blood Cholesterol Levels in Children and Adolescents

JAMA, 1997

Thomas
Neil

Cholesterol Screening in Children and Adolescents

Newman TB and Garber AM. Pediatrics, 2000

If It's Not Worth Doing, It's Not Worth Doing

Overly Aggressive New Guidelines for Lipid Screening in Children: Evidence of a Broken Process

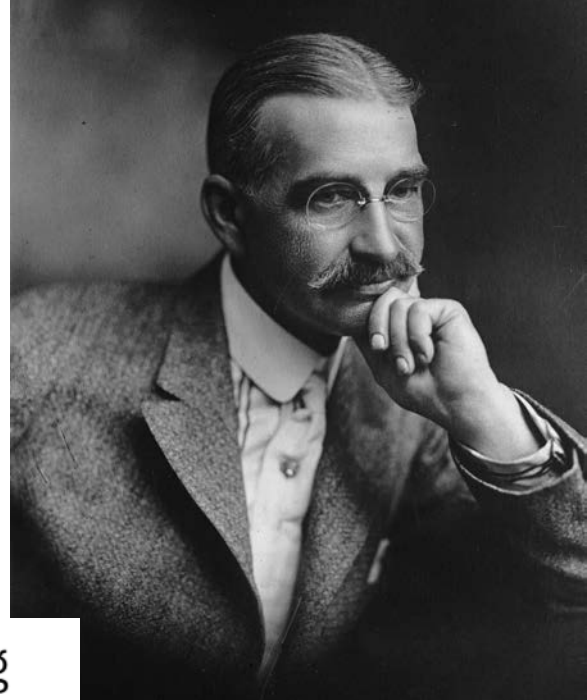
Newman TJ

LESS IS MORE

Lipid Screening in Children

Low-Value Care JAMA Internal Medicine 2016

Thomas B. Newman, MD, MPH; Alan R. Schroeder, MD; Mark J. Pletcher, MD, MPH



L. Frank Baum, 1911



What's wrong with the NHLBI/AAP Guidelines?

- Based on desire to prevent heart disease without *any* modeling of risks and benefits of treatment
- Overtreating girls
 - More preschool girls than teenaged boys qualify for treatment
- In young adults (17-21 years) call for 6 times more to be treated with statins than adult guidelines
- The recommended diet does not work
 - Failed diet could lead to unnecessary statin treatment
- Statins cause Type 2 diabetes

Net effects of statins in children and adolescents vs adults

Treat 100 people for 10 years; lower CVD risk by 30%, increase DM-2 by 1-2/1000/year

	Adults at 10% 10-year risk	Children & Adolescents
CV Events prevented	3	Close to 0
DM-2 cases caused	1 to 2	1 to 2

Wang et al. Association between reductions in low-density lipoprotein cholesterol with statin therapy and the risk of new-onset diabetes: a meta-analysis Nature Scientific Reports | 2017;7:39982

Joyce NR et al. Statin Use and the Risk of Type 2 Diabetes Mellitus in Children and Adolescents Academic Pediatrics 2017;17:515.

Who wrote the pediatric lipid guidelines?

TABLE 2 Financial Disclosures of the Expert Panel Chair and of the Members of the Subgroup Who Drafted the Lipids and Lipoproteins Chapter of the Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents¹

Panel Member	Reported Relevant Relationships
Stephen R. Daniels, MD, PhD, Panel Chair	Consultant or advisory board member: Abbott Laboratories, ^a Merck, ^b Schering-Plough ^c Funding/grant support for research: National Institutes of Health
Peter O. Kwiterovich, MD, Subgroup Leader	Consultant or advisory board member: Merck ^b , Schering-Plough, ^c Pfizer, ^d Sankyo, ^e LipoScience, ^f and Astra Zeneca ^g Speakers bureau: Merck, ^b Schering-Plough, ^c Pfizer, ^d Sankyo, ^e Kos, ^h and Astra Zeneca ^g Grant funding: Pfizer, ^d Merck, ^b GlaxoSmithKline, ⁱ Sankyo, ^e and Schering-Plough ^c
Patrick E. McBride, MD, MPH	Consultant or advisory board member: Bristol-Myers Squibb ^j and Merck ^b Speakers bureau: Kos, ^h Merck, ^b and Pfizer ^d (none since July 2007)
Brian W. McCrindle, MD, MPH	Consultant or advisory board member: Abbott Laboratories, ^a Bristol-Myers Squibb, ^j Daichii-Sankyo, ^k and Roche ^l Grant Funding: Astra Zeneca, ^g Sankyo, ^e Merck, ^b Schering-Plough, ^c and the National Institutes of Health

What their funders make

^a Abbott Laboratories produces the following **relevant medications**: ADVICOR (niacin extended-release/lovastatin), CONTROLIP (fenofibrate; not sold in the United States), NIASPAN (niacin extended release), SIMCOR (simvastatin/niacin extended-release), TriCor (fenofibrate), and TRILIPIX (fenofibric acid). Abbott Laboratories produces the following **relevant diagnostic instruments**: ARCHITECT ci16200 Integrated System, ARCHITECT ci4100 Integrated System, ARCHITECT ci8200 Integrated System, ARCHITECT i1000SR, ARCHITECT i2000SR, ARCHITECT i4000SR, and AxSYM.

^b Merck produces the following **relevant medications**: MEVACOR (lovastatin), VYTORIN (ezetimibe/simvastatin), ZETIA (ezetimibe), and ZOCOR (simvastatin).

^c Schering-Plough: see Merck.

^d Pfizer produces the following **relevant medications**: CADUET (amlodipine besylate/atorvastatin calcium), COLESTID (micronized colestipol hydrochloride), LIPITOR (atorvastatin calcium), and LOPID (gemfibrozil, USP).

^e Sankyo produces the following **relevant medication**: WELCHOL (colesevelam hydrochloride).

^f LipoScience produces the following relevant product: NMR LipoProfile.

^g Astra Zeneca produces the following **relevant medication**: CRESTOR (rosuvastatin calcium).

^h Kos: see Abbott Laboratories.

ⁱ GlaxoSmithKline produces the following **relevant medication**: LOVAZA (omega-3-acid ethyl esters).

^j Bristol-Myers Squibb produces the following relevant medication: PRAVACHOL (pravastatin sodium).

^k Daichii-Sankyo: see Sankyo.

^l Roche produces the following relevant products: ACCUTREND PLUS System, COBAS c 111 **analyzer**, COBAS INTEGRA Systems, COBAS 4000 **analyzer series**, COBAS 6000 analyzer series, COBAS 8000 **modular analyzer series**, MODULAR ANAsLYTICS EVO solution, and REFLOTRON Systems.



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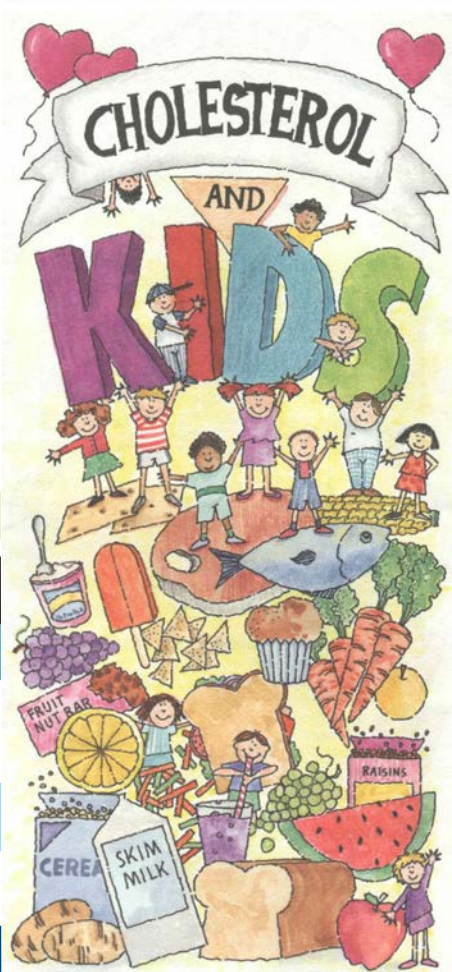
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A Parent's Guide

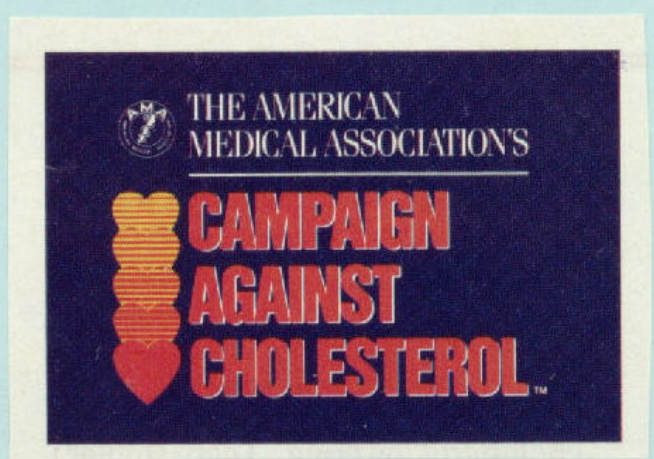
CHOLESTEROL

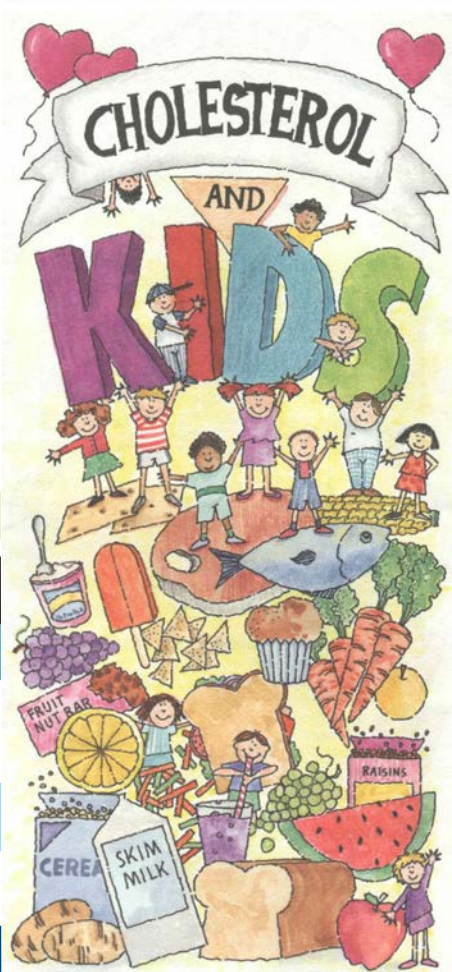
KIDS A Family Affair

You've probably heard a lot of confusing information about cholesterol and heart disease. Because hardening of the arteries (atherosclerosis) can begin in childhood, it's important for you to learn how high blood cholesterol levels contribute to the development of heart disease.

The good news for your family is that the damage done by high cholesterol levels can be prevented. The "Eating for Life" poster on the other side of this brochure can help you plan a heart healthy diet for everyone in your family. By limiting high fat foods and making good food choices all day long, you teach good eating habits. These healthy habits will help ensure that your children will live long and healthy lives.

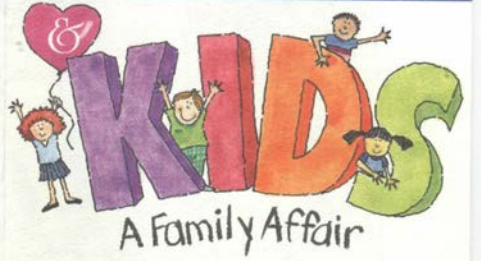
From Bristol-Myers-Squib





A Parent's Guide

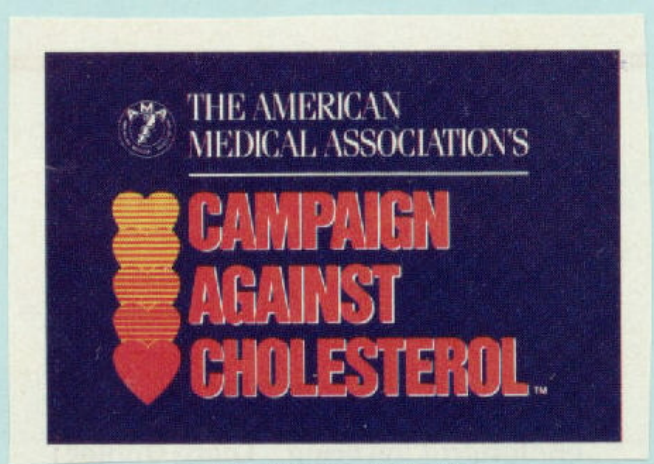
CHOLESTEROL



You've probably heard a lot of confusing information about cholesterol and heart disease. Because hardening of the arteries (atherosclerosis) can begin in childhood, it's important for you to learn how high blood cholesterol levels contribute to the development of heart disease.

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From Bristol-Myers-Squibb





Lipid Screening Conclusions

- NHLBI/AAP 2012 guidelines are an embarrassment
 - Well-intentioned effort to diagnose familial hypercholesterolemia earlier led to vast NHLBI over-reach
- New guidelines (2018) much more sensible

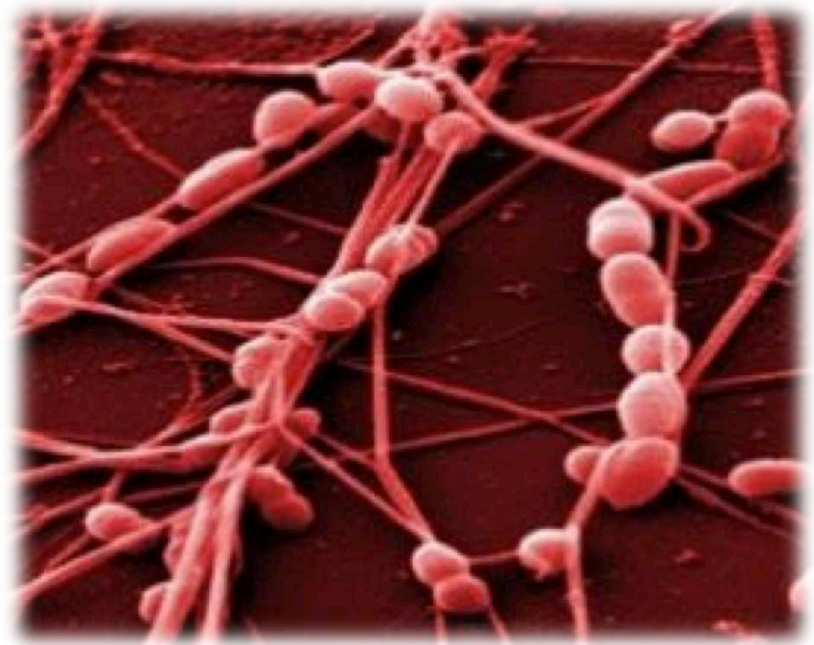
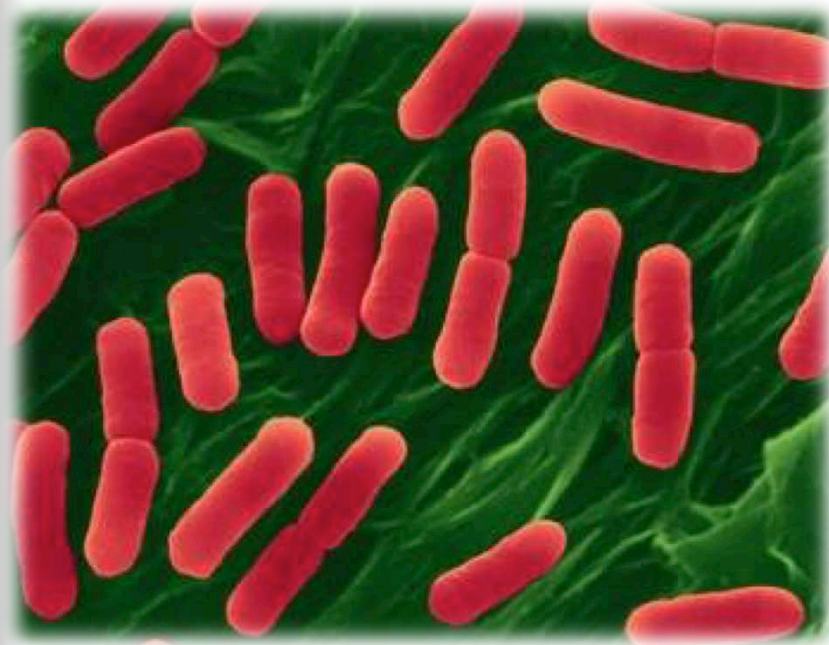
CHOLESTEROL CLINICAL PRACTICE GUIDELINES

2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/ APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: Executive Summary

**A Report of the American College of Cardiology/American Heart
Association Task Force on Clinical Practice Guidelines**

- No "Strong recommendation"!
- Lipid screening in children age 9-11 years without other risk factors "*may be reasonable.*"
- TN currently lobbying the AAP to revise its guideline

Early-Onset Sepsis in Newborns

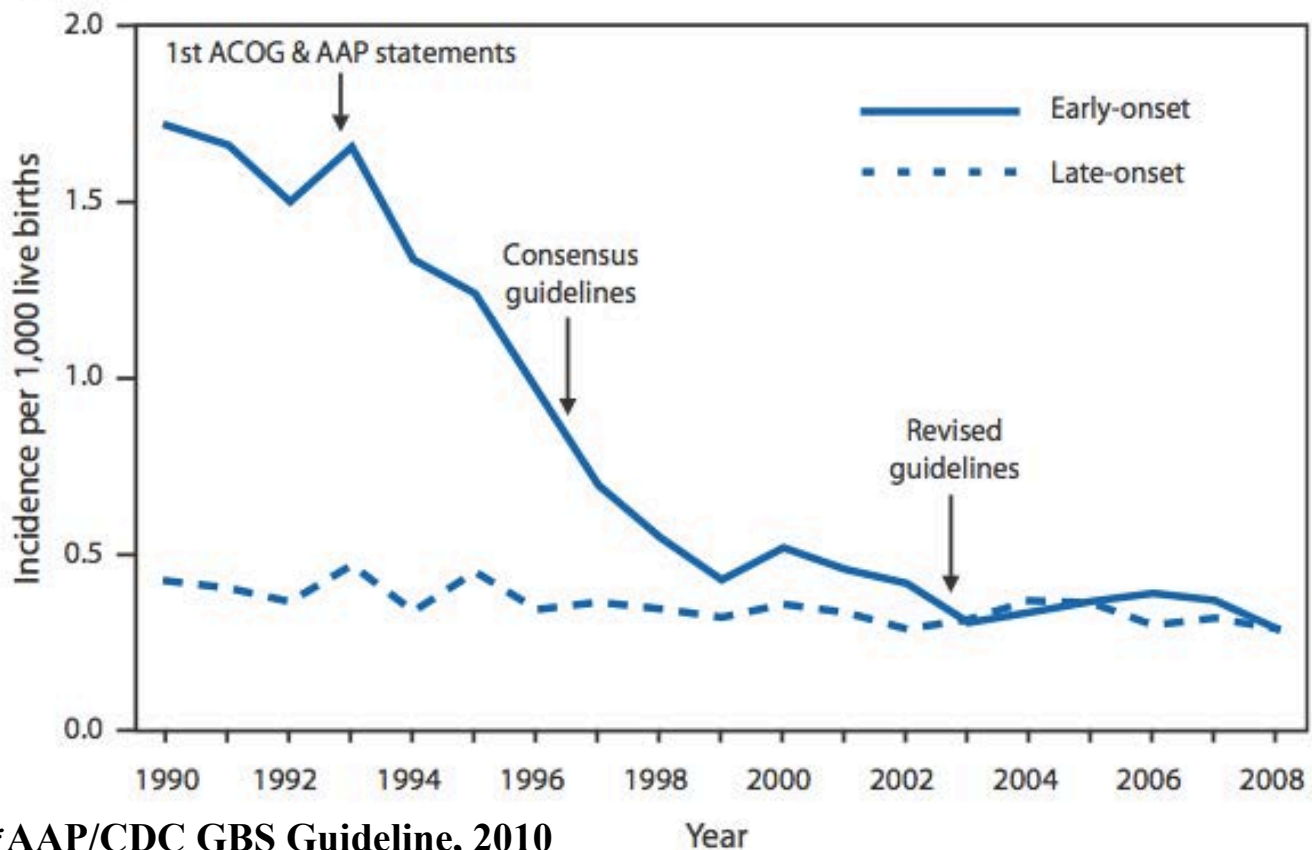




EOS Background

- Newborns with bacterial infections can become very sick very fast, sometimes dying
- For this reason, newborns with signs (or even risk factors for) infection are admitted to the NICU and treated with IV antibiotics
- A common cause: Group B Strep (GBS)
- Screening mothers for GBS started in the 1990s, and has greatly reduced the risk

FIGURE 1. Incidence of early- and late-onset invasive group B streptococcal (GBS) disease — Active Bacterial Core surveillance areas, 1990–2008, and activities for prevention of GBS disease



*AAP/CDC GBS Guideline, 2010

Abbreviations: ACOG = American College of Obstetricians and Gynecologists and AAP = American Academy of Pediatrics.



EOS Background-2

- Guidelines for treating newborns *at risk* for GBS did not change with decreasing incidence
- CDC and AAP recommended treatment of newborns with IV antibiotics if the mother was diagnosed with *chorioamnionitis* (inflammation of the membranes around the baby)
- But the "Chorio" diagnosis is subjective
- At UCSF some mothers were being treated for chorio for temperatures of as low as 37.8° C (100° F).
- Many babies treated unnecessarily



NIS-3 (Neonatal Infection Study #3)

- Collaboration between Northern California Kaiser Permanente (led by Gabriel Escobar, MD), Harvard (led by Karen Puopolo, MD, PhD), UCSC (David Draper, PhD) and UCSF (TBN)
- Retrospective study of 350 cases of EOS among 608,014 live births
- Goal: develop a quantitative risk prediction model for EOS to replace "chorio"



Relative importance of predictors in the maternal model

- Mother's highest temp 24h PTD 58%
- Gestational age 17%
- Rupture of membranes time 13%
- What antibiotics mother got and when 10%
- Whether mother Group B Strep + 2%

Summary

Neo Sepsis Ca...

Show: [Row Info](#) [Last Filed](#) [Details](#)

Values By

Predictor	Scenario
Incidence of Early-Onset Sepsis	0.3/1000=0.3/1000 live births (suggested incidence)
Gestational age	weeks: 39 days: 4
Highest maternal antepartum temp.	37.6 C
ROM (hours)	55.0
Maternal GBS status	<input type="radio"/> 0=Unknown <input type="radio"/> 1=Positive <input checked="" type="radio"/> 2=Negative
Type of intrapartum antibiotics	<input checked="" type="radio"/> 0=No antibiotics or any antibiotics < 2 hrs prior to birth <input type="radio"/> 1=GBS specific antibiotics > 2 hrs prior to birth <input type="radio"/> 2=Broad spectrum antibiotics 2-3.9 hrs prior to birth <input type="radio"/> 3=Broad spectrum antibiotics > 4 hrs prior to birth

	Risk per 1000/births
EOS Risk @ Birth	0.46

EOS Risk after Clinical Exam	Risk per 1000/births	Clinical Recommendation	Vitals
Well Appearing	0.19	No culture, no antibiotics	Routine Vitals
Equivocal	2.32	Blood culture	Vitals every 4 hours for 24 hours
Clinical Illness	9.75	Empiric antibiotics	Vitals per NICU

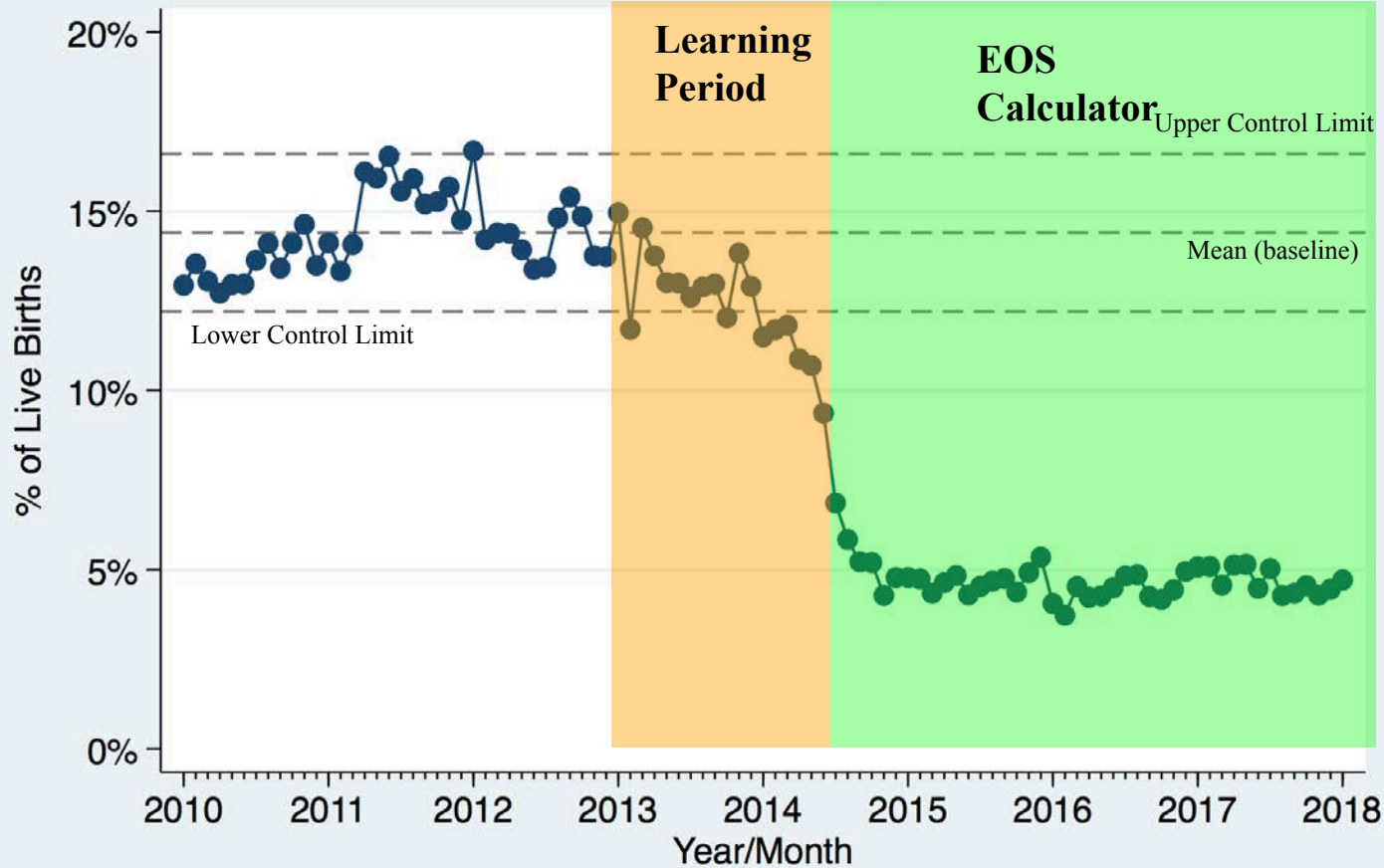
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Kaiser Sepsis Risk Calculator

Screen-shot of EPIC/APeX implementation at UCSF

Blood Cultures in the 1st 24 hours

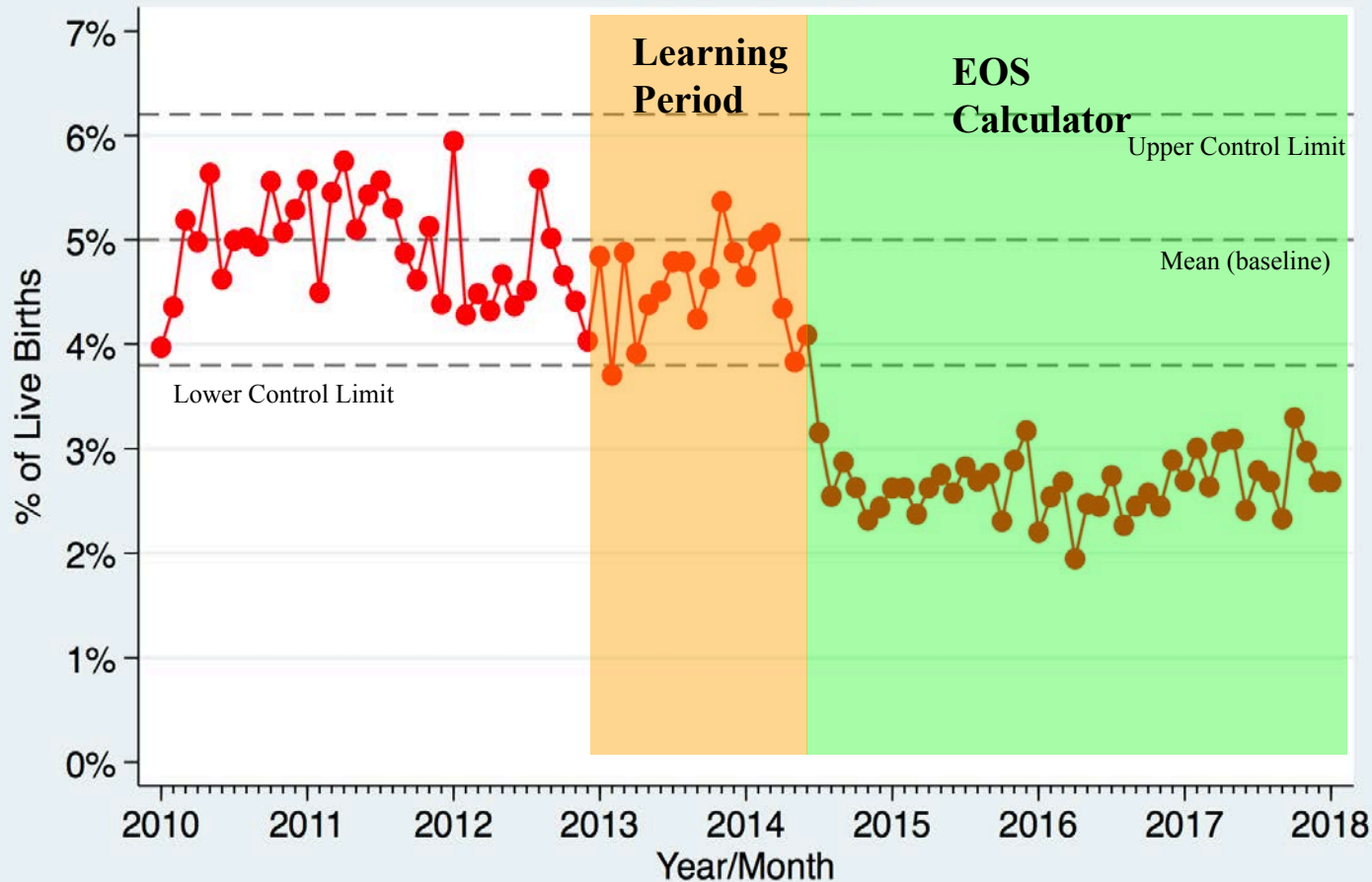
2010- Jan 2018



Further follow-up of study reported by Kuzniewicz et al. JAMA Pediatr. 2017;171(4): 365-371

Antibiotics in the 1st 24 hours

2010- Jan 2018



Further follow-up of study reported by Kuzniewicz et al. JAMA Pediatr. 2017;171(4): 365-371.

No increase in readmissions or bad outcomes from sepsis missed due to calculator.

Dec, 2018 Guideline
PEDIATRICS Volume 142, number
6, December 2018:e20182894

American Academy
of Pediatrics



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Management of Neonates Born at ≥ 35 0/7 Weeks' Gestation With Suspected or Proven Early-Onset Bacterial Sepsis

Karen M. Puopolo, MD, PhD, FAAP,^{a,b} William E. Benitz, MD, FAAP,^c Theoklis E. Zaoutis, MD, MSCE, FAAP,^{a,d}
COMMITTEE ON FETUS AND NEWBORN, COMMITTEE ON INFECTIOUS DISEASES

- Options to use a risk calculator or serial clinical examinations rather than automatic antibiotics for maternal chorioamnionitis.



Summary

- There is a huge amount of overtreatment in the US Healthcare system
- It wastes money, harms patients, and is bad for the environment
 - (But it generates a lot of income for some.)
- There is a growing need for deimplementation science: studies of how we can safely do less



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Additional Resources

- Google "Newman Document Repository" to find my website:

[http://epibiostat-supp.ucsf.edu/
newman_document_repository/index.html](http://epibiostat-supp.ucsf.edu/newman_document_repository/index.html)





Additional Slides