Evidence-Based Medicine for clinical years
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What is Evidence-Based Medicine?

Editorials

Evidence based medicine: what it is and what it isn't

BMJ 1996 ; 312 doi: http://dx.doi.org/10.1136/bmj.312.7023.71 (Published 13 January 1996)
Cite this as: *BMJ* 1996;312:71

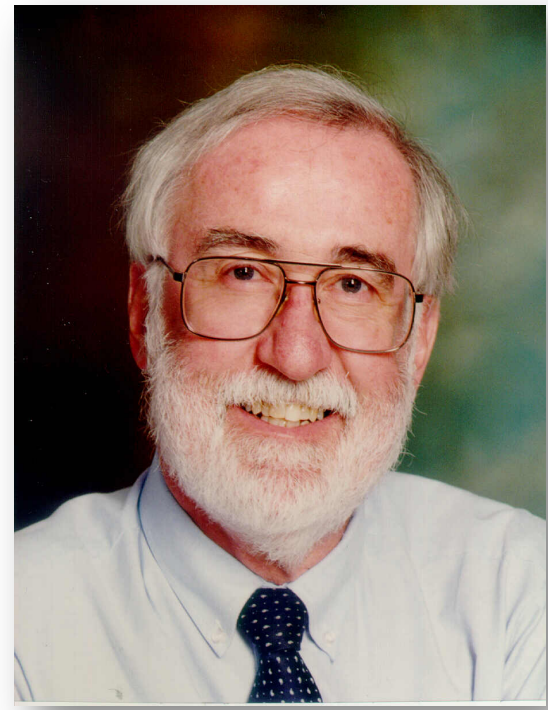
Article | Related content | Metrics | Responses

David L Sackett, William M C Rosenberg, J A Muir Gray, R Brian Haynes, W Scott Richardson

Author affiliations

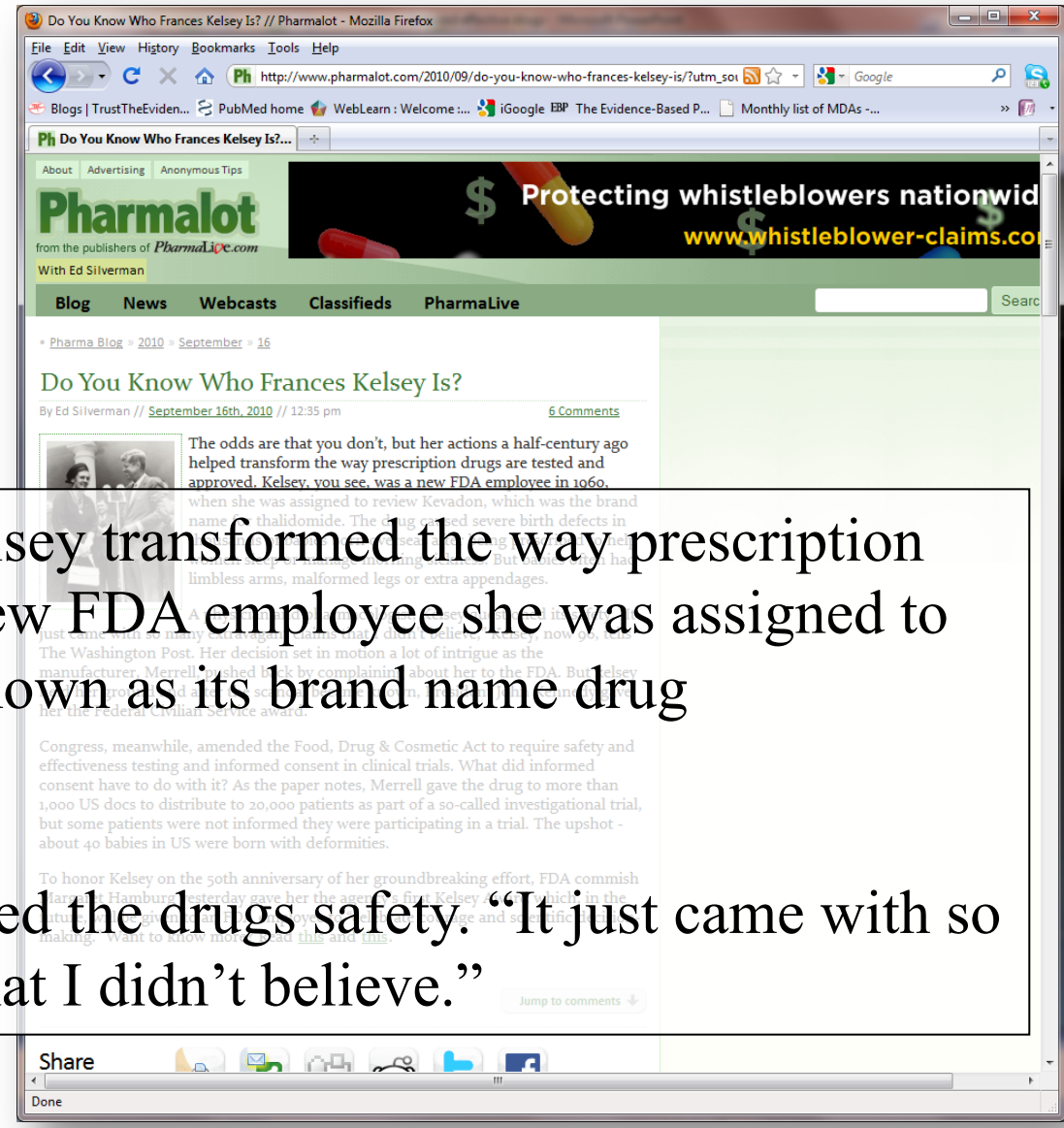
It's about integrating individual clinical expertise and the best external evidence

Evidence based medicine, whose philosophical origins extend back to mid-19th century Paris and earlier, remains a hot topic for clinicians, public health practitioners, purchasers, planners, and the public. There are now frequent workshops in how to practice and teach it (one sponsored by the BMJ



"Evidence-based medicine is the integration of best research evidence with clinical expertise and patient values"

Why do we need EBM?



Fifty years ago Frances Kelsey transformed the way prescription drugs are regulated. As a new FDA employee she was assigned to review Kevadaon, better known as its brand name drug thalidomide.

Kelsey at the time questioned the drugs safety. “It just came with so many extravagant claims that I didn’t believe.”

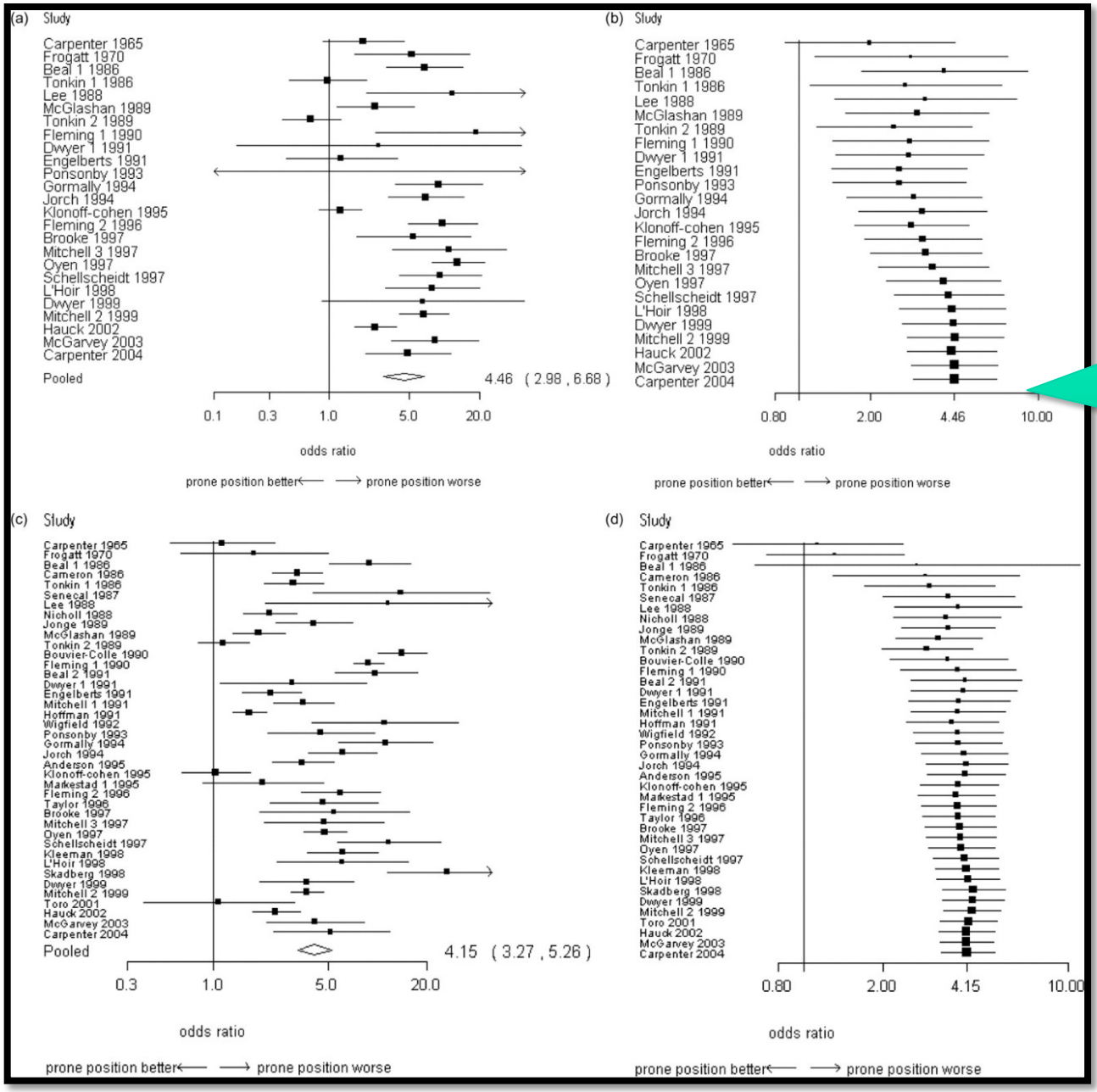
Types of study evidence affects the quality

Expert opinion- Lowest level of evidence

Would you ever have put babies to sleep on their tummies?

Expert opinion

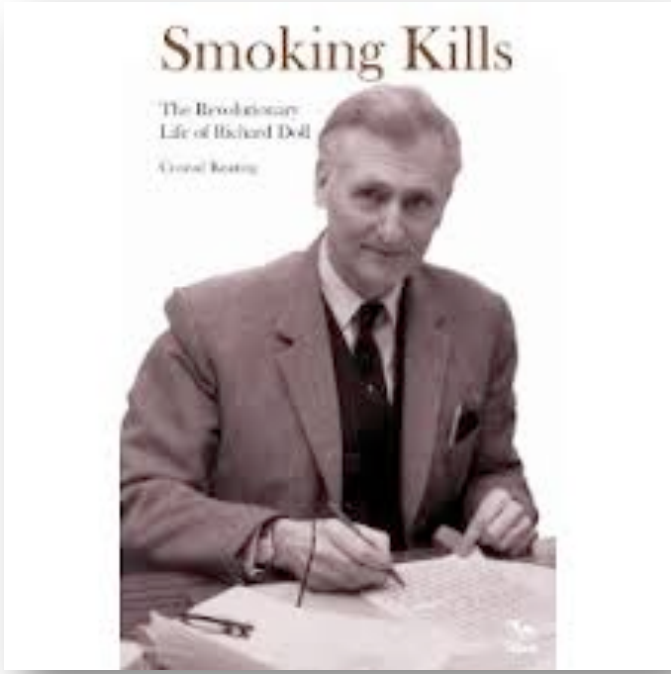
Baby and Child Care" has actually sold more that 50 million copies, only outmatched in sales by the Bible



Over four fold increase risk of sudden infant death syndrome

Ruth Gilbert et al. Int. J. Epidemiol. 2005;34:874-887

Types of study evidence affects the quality



Cite this article as: BMJ, doi:10.1136/bmj.38142.554479.AE (published 22 June 2004)

Papers

Mortality in relation to smoking: 50 years' observations on male British doctors

Richard Doll, Richard Peto, Jillian Boreham, Isabelle Sutherland

Abstract

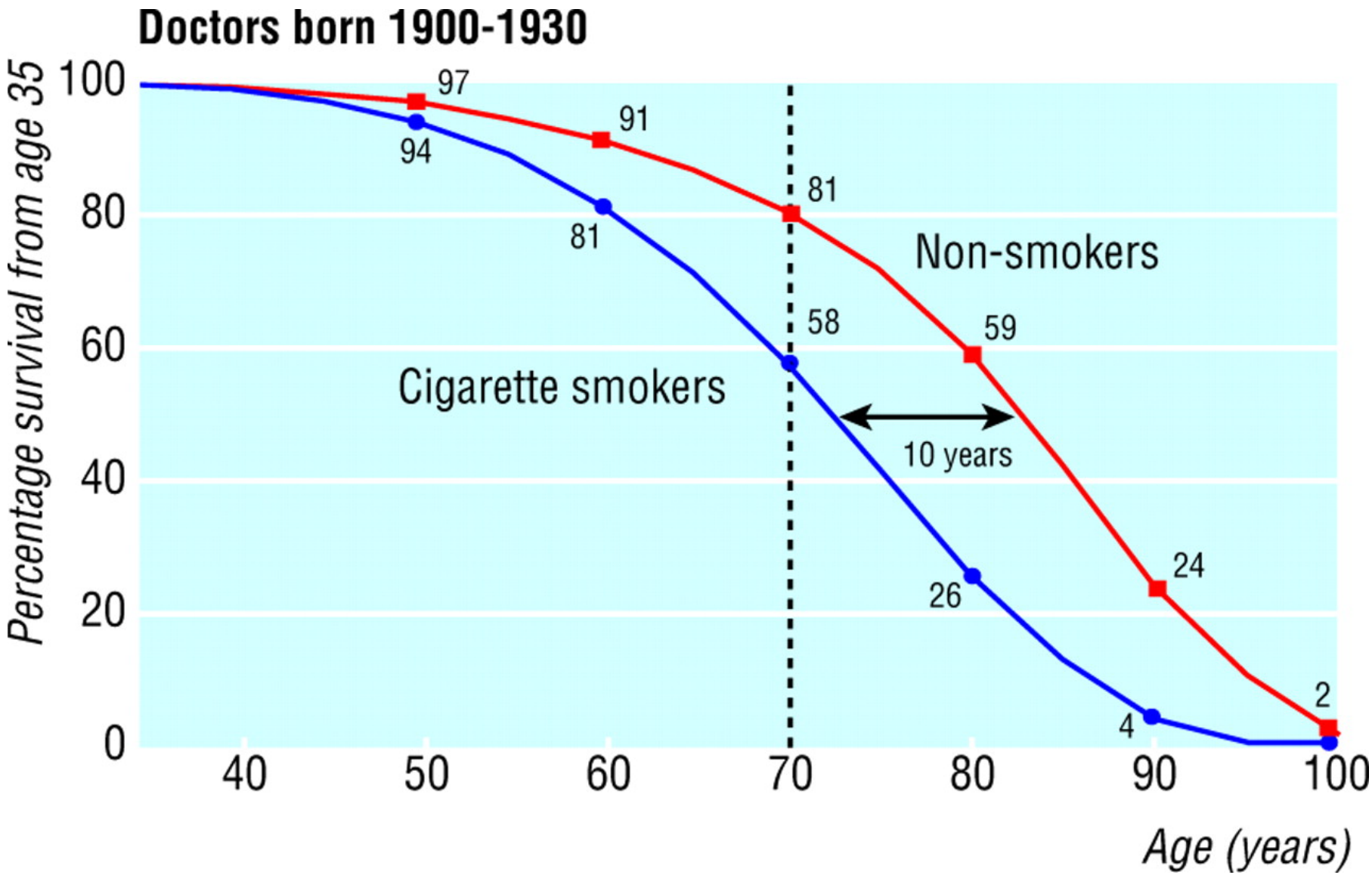
Objective To compare the hazards of cigarette smoking in men who formed their habits at different periods, and the extent of the reduction in risk when cigarette smoking is stopped at different ages.
Design Prospective study that has continued from 1951 to 2001.
Setting United Kingdom.
Participants 34 439 male British doctors. Information about their smoking habits was obtained in 1951, and periodically thereafter; cause specific mortality was monitored for 50 years.
Main outcome measures Overall mortality by smoking habit,

Kingdom (where the disease became by the 1940s a major cause of death). Throughout the first half of the 20th century the hazards of smoking had remained largely unsuspected.[1] Around the middle of the century, however, several case-control studies of lung cancer were published in Western Europe[2–6] and North America,[7–10] leading to the conclusion in 1950 that smoking was "a cause, and an important cause" of the disease.[5]

1951 prospective study

This discovery stimulated much further research into the effects of smoking (not only on lung cancer but also on many other diseases), including a UK prospective study of smoking and death

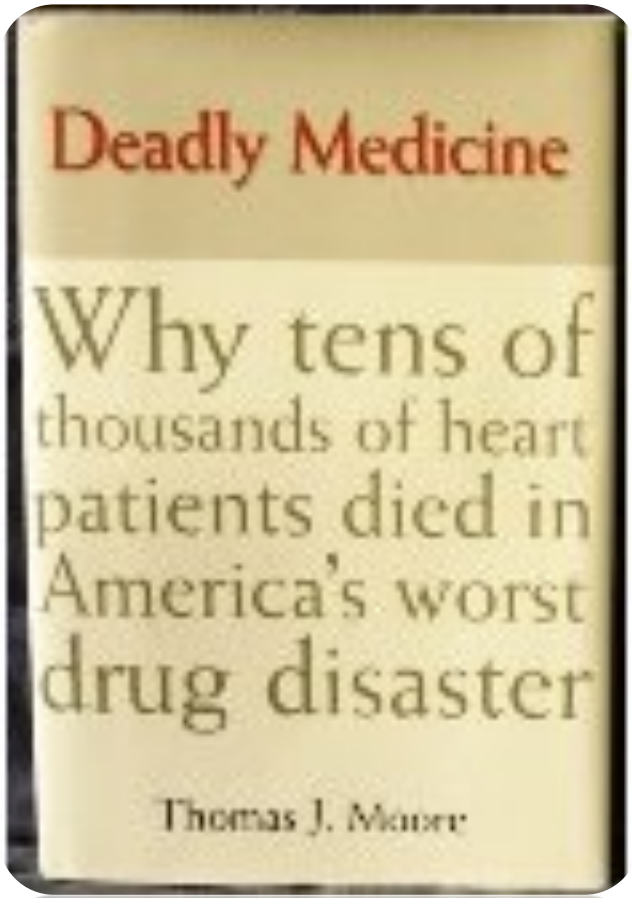
Survival from age 35 for continuing cigarette smokers and lifelong non-smokers among UK male doctors born 1900-1930, with percentages alive at each decade of age.



Doll R et al. BMJ 2004;328:1519

Types of study evidence affects the quality

Why we need RANDOMIZED CONTROLLED



In the early 1980s newly introduced antiarrhythmics were found to be highly successful at suppressing arrhythmias.

Not until a RCT was performed was it realized that, although these drugs suppressed arrhythmias, they actually increased mortality.

The CAST trial revealed Excess mortality of 56/1000.

By the time the results of this trial were published, at least 100,000 such patients had been taking these drugs.

Types of study evidence affects the quality

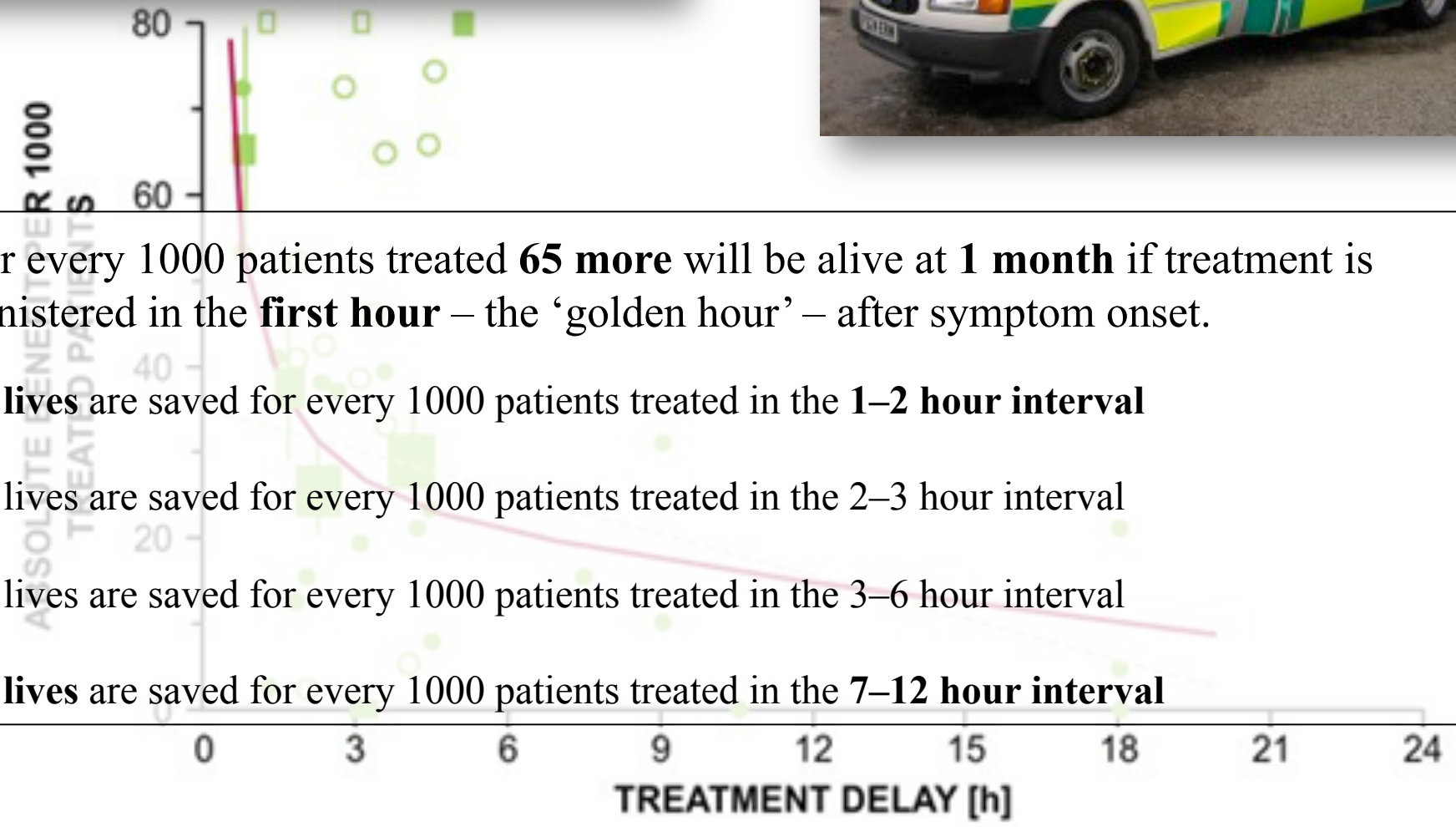
THE LANCET
Volume 348, Issue 9030, 21 September 1996, Pages 771–775

Articles

Early thrombolytic treatment in acute myocardial infarction: reappraisal of the golden hour

Eric Boersma, MSc[a], Arthur CP Maas, MD[a], Prof Jaap W Deckers, MD[a], Prof Maarten L Simoons, PhD[a,]

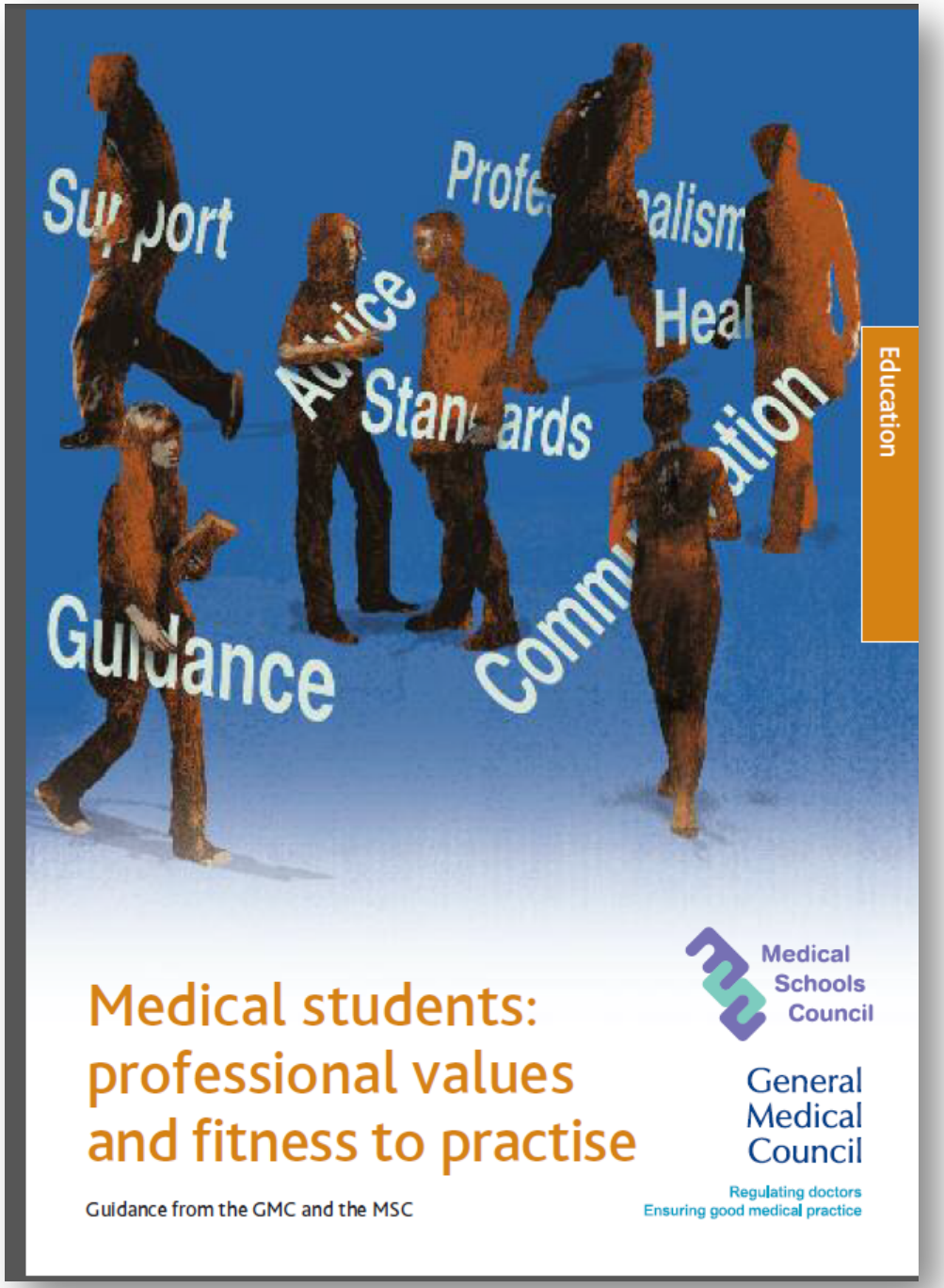
Show more



- For every 1000 patients treated **65 more** will be alive at **1 month** if treatment is administered in the **first hour** – the 'golden hour' – after symptom onset.
- **37 lives** are saved for every 1000 patients treated in the **1–2 hour interval**
- 26 lives are saved for every 1000 patients treated in the 2–3 hour interval
- 29 lives are saved for every 1000 patients treated in the 3–6 hour interval
- **20 lives** are saved for every 1000 patients treated in the **7–12 hour interval**

References: Boersma et al. Lancet 1996; 348 (9030): 771-775.

EBM
as a medical student?



Good clinical care

15 Being able to provide good clinical care is fundamental to becoming a doctor. This objective should guide a student's behaviour in both their clinical and academic work. Medical students should reflect on how they can support and promote good clinical care as part of their medical education.

16 In order to demonstrate that they are fit to practise, students should:

(a) recognise and work within the limits of their competence and ask for help when necessary
(b) accurately represent their position or abilities
(c) make sure they are supervised appropriately for any clinical task they perform
(d) respect the decisions and rights of patients
(e) be aware that treatment should be based on clinical need and the effectiveness of treatment options, and that decisions should be arrived at through assessment and discussion with the patient
(f) not unfairly discriminate against patients by allowing their personal views to affect adversely their professional relationship or the treatment they provide or arrange (this includes their views about a patient's age, colour, culture, disability, ethnic or national origin, gender, lifestyle, marital or parental status, race, religion or beliefs, sex, sexual orientation, and social or economic status)
(g) behave with courtesy
(h) report any concerns they have about patient safety to the appropriate person.[3]

Be aware that **treatment options** should be based on clinical need **and the effectiveness of treatment options**, and that decisions should be arrived at through assessment and **discussion** with the patient

Maintaining good medical practice

17 Students must be aware of their responsibility to maintain their knowledge and skills throughout their careers.

18 Students are expected to keep up to date and to apply knowledge necessary for good clinical care. They should understand that as doctors they will have to participate in audit, assessments and performance reviews throughout their careers as part of revalidation and licensing.

19 In order to demonstrate that they are fit to practise, students should:

(a) reflect regularly on standards of medical practice in accordance with *Good medical practice* and *Tomorrow's Doctors*
(b) attend compulsory teaching sessions or make other arrangements with the medical school
(c) complete and submit course work on time
(d) be responsible for their own learning
(e) reflect on feedback about their performance and achievements and respond constructively
(f) be familiar with guidance from the GMC and other organisations, such as medical schools, hospitals, trusts and health boards
(g) respect the knowledge and skills of those involved in their education
(h) make sure they can be contacted and always respond to messages in relation to care of patients or their own education.

Must be aware of their responsibility to maintain their knowledge and skills **throughout their careers**.

Students are expected to keep **up to date** and to **apply knowledge** necessary for good clinical care.

Steps of practicing EBM

1. **Ask a focused question.**
2. Track down some evidence
3. Critically appraise evidence for its validity and effect
4. Apply the evidence in practice:

1. General Questions

General knowledge about a condition such as heart attack.

These types of questions typically ask who, what, where, when

- What are the risk factors for an MI?
- What are the symptoms and sign of someone presenting with MI?
- What are the diagnostic tests for MI?
- What are the treatments of MI?
- What are the complications of an MI?

Patient presenting with MI

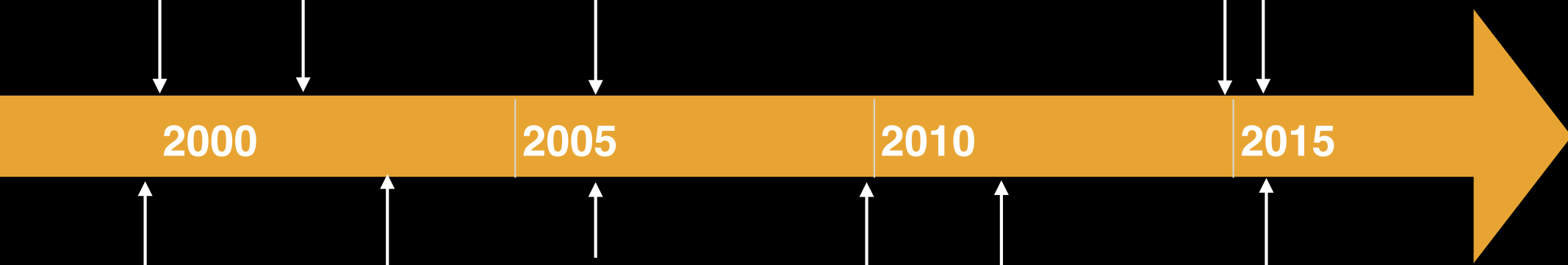
Specific Questions **about actual patient care decisions and actions**

For treatment
4 (or 3) components:

In Patients with a heart attack
Does (I) cholesterol lowering therapy
Compared to placebo
reduce mortality (O)

Types of study evidence affects the quality

Heart Attack evidence



1999

HOPE trial published on ramipril in the **NEJM**

2000

Lancet: publishes effect of low dose b-blockers in the elderly

2002

Lancet: HPS study shows benefit of statins independent of baseline level

2003

Lancet: primary PTCA more effective than thrombolysis

2005

Editorial in **BMJ** calls for aspirin for everyone

Lancet: 2005 COMMIT trial beta blocker should be withheld if the patient is unstable

Lancet: cholesterol triallist collaboration 90,056 participants in 14 RTCs

2005

Lancet: COMMIT trial of early metoprolol in 45,852 participants

2009

Lancet: aspirin is of uncertain net benefit for primary prevention

2010

In hospital mortality **5%**

2013

Routine use of Oxygen questioned in a **Cochrane** review

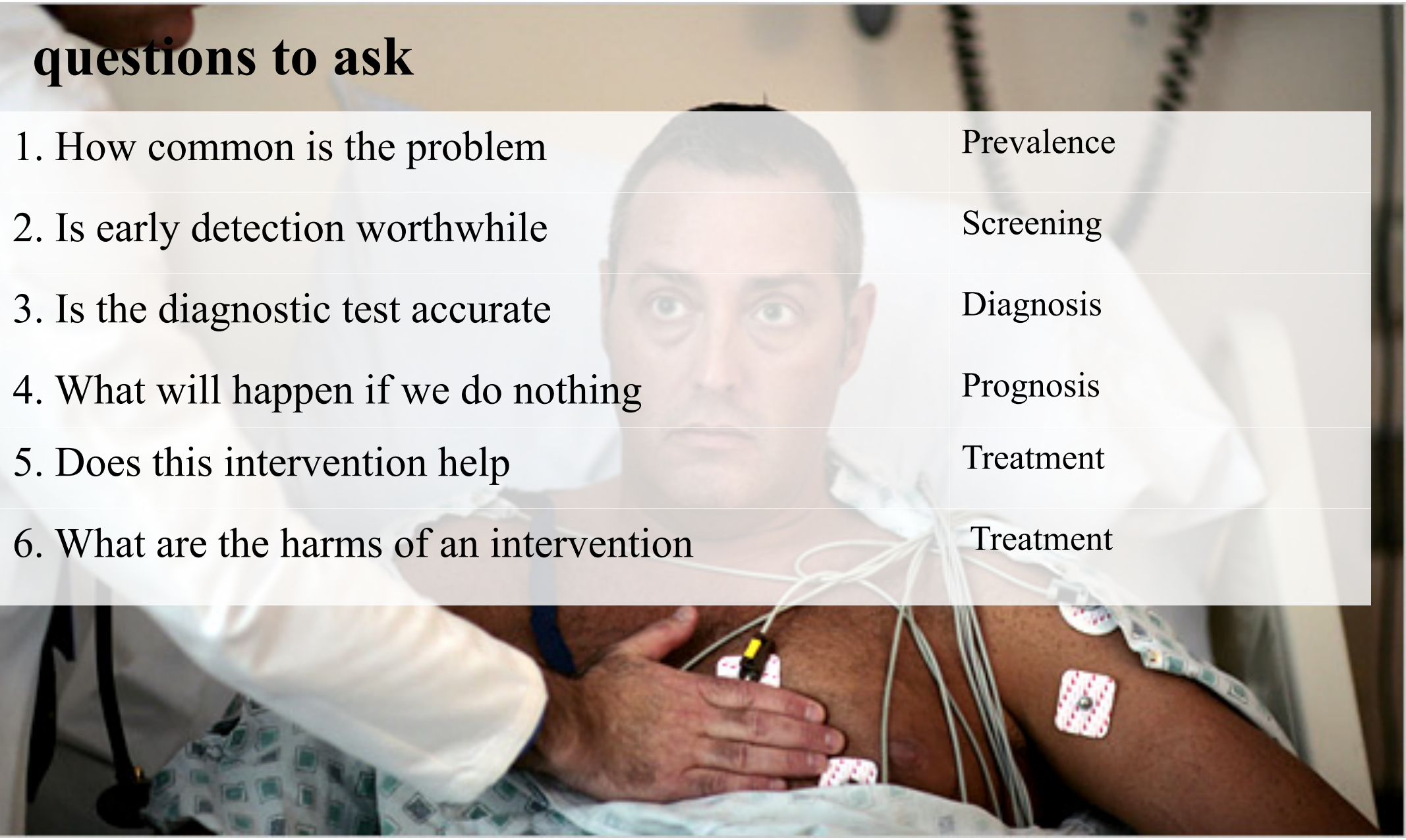
2015

American College of Physicians **guidelines** warn against screening asymptomatic individuals

2015

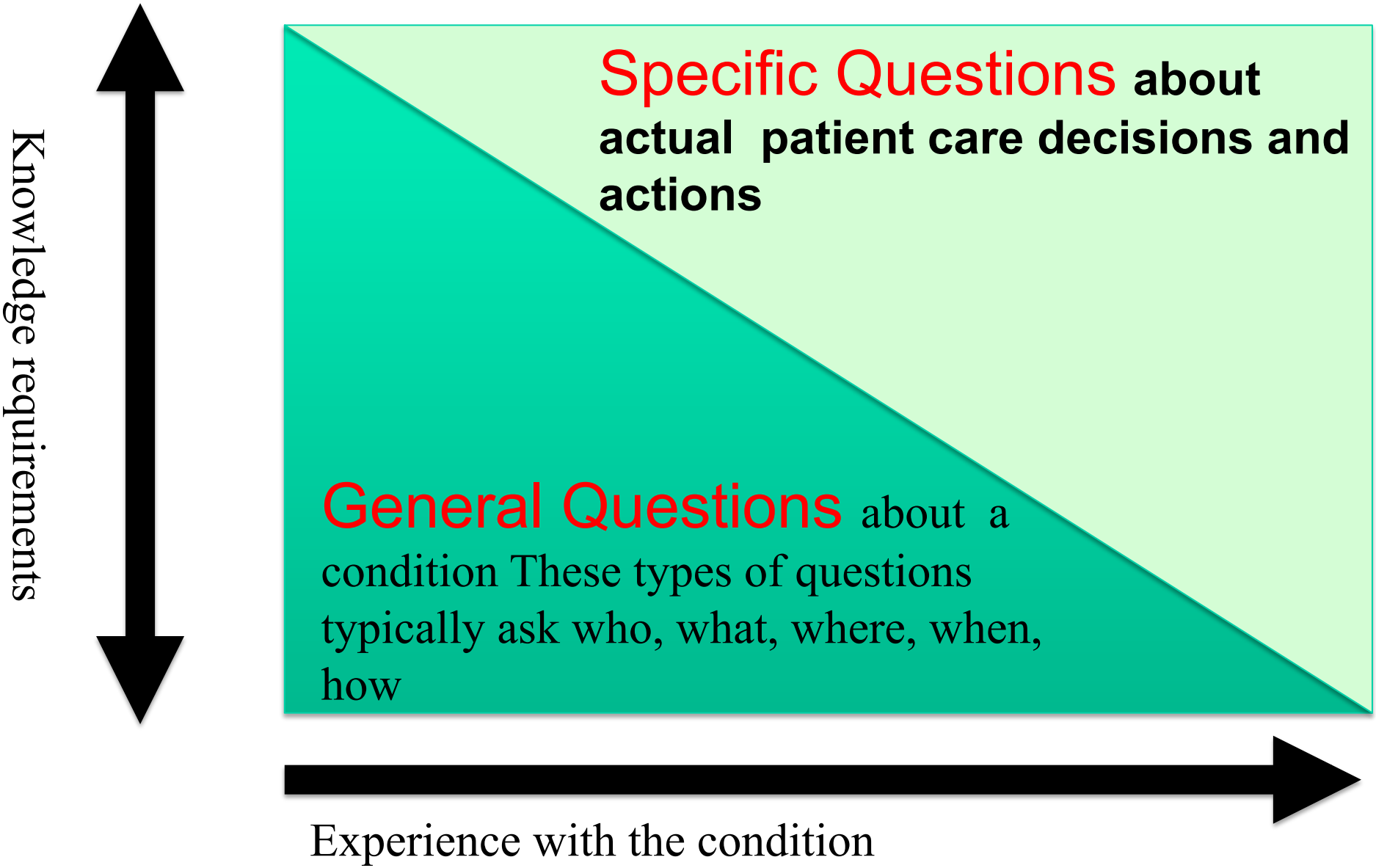
Paramedic 2 Trial tests effectiveness of adrenaline in cardiac arrest

questions to ask



1. How common is the problem	Prevalence
2. Is early detection worthwhile	Screening
3. Is the diagnostic test accurate	Diagnosis
4. What will happen if we do nothing	Prognosis
5. Does this intervention help	Treatment
6. What are the harms of an intervention	Treatment

General and Specific Questions



Keeping up to date
Size of Medical Knowledge

- NLM MetaThesaurus
  - 875,255 concepts
  - 2.14 million concept names
- Diagnosis Pro
  - 11,000 diseases
  - 30,000 abnormalities (symptoms, signs, lab, X-ray,)
  - 3,200 drugs (cf FDAs 18,283 products)

1 disease per day for 30 years

To cover the vast field of medicine in four years is an impossible task.
- William Olser

Median minutes/week spent reading about my patients

Self-reports at 17 Grand Rounds:

- Medical Students: 90 minutes
- House Officers (PGY1): 0 (up to 70%=none)
- SHOs (PGY2-4): 20 (up to 15%=none)
- Registrars: 45 (up to 40%=none)
- Sr. Registrars 30 (up to 15%=none)
- **Consultants:**
  - Grad. Post 1975: 45 (up to 30%=none)
  - Grad. Pre 1975: 30 (up to 40%=none)

Steps of practicing EBM

1. Ask a focused question.
2. Track down the evidence
3. Critically appraise evidence for its validity, effect size, precision
4. Apply the evidence in practice:

Effect of rosiglitazone on the frequency of diabetes in patients with impaired glucose tolerance or impaired fasting glucose: a randomised controlled trial

*The DREAM (Diabetes REduction Assessment with ramipril and rosiglitazone Medication) Trial Investigators**

FINDINGS:

At the end of study, 59 individuals had dropped out from the rosiglitazone group and 46 from the placebo group. 306 (11.6%) individuals given rosiglitazone and 686 (26.0%) given placebo developed the composite primary outcome (hazard ratio 0.40, 95% CI 0.35-0.46; p<0.0001); 1330 (50.5%) individuals in the rosiglitazone group and 798 (30.3%) in the placebo group became normoglycaemic (1.71, 1.57-1.87; p<0.0001). Cardiovascular event rates were much the same in both groups, although 14 (0.5%) participants in the rosiglitazone group and two (0.1%) in the placebo group developed heart failure (p=0.01).

Interpretation Rosiglitazone at 8 mg daily for 3 years substantially reduces incident type 2 diabetes and increases the likelihood of regression to normoglycaemia in adults with impaired fasting glucose or impaired glucose tolerance, or both.

Prevention of diabetes

Drug trials show promising results, but have limitations

Diabetes affects one in 20 adults worldwide and 333 million cases are projected worldwide by 2025.[1] Treatment can prevent some of the microvascular and macrovascular complications, but diagnosis is often delayed until complications present,[2] so attention has focused on prevention and early screening. Two strategies currently exist for reducing the onset of diabetes—lifestyle interventions and drugs.

study found that lifestyle interventions

similar reduction in risk was found in

ventions are labour intensive, one

achieve target weight reduction and

Although lifestyle interventions pr

results in research settings, they are dif

even in well funded healthcare system

Considerable interest has focused

tion of diabetes with drugs. For insta

Prevention Program Research Grou

31% reduction in the incidence

metformin at 2.8 years.[5] Previously

shown to be effective in controlling b

but was removed from the market be

liver toxicity.[5] In people with obesity

shown to reduce the risk of diabete

compared with placebo.[6]

More recently came the publicatio

reduction assessment with ramipril

medication (DREAM) trial.[7,8] In this

$25m (£13m; €20m), 5269 people ov

impaired fasting glucose or impaired

or both, and no previous cardiovascular

domised to receive either rosiglitazone 8 mg daily or pla-

confidence interval 0.35 to 0.46, P<0.0001). Ramipril did not reduce the risk of diabetes.

These results are promising, but they should be interpreted with caution. The mean fasting plasma concentration of glucose in both groups at baseline was 5.8 mmol/l, whereas the two hour impaired glucose tolerance test had a value of 8.7 mmol/l. The study population was therefore composed predominantly of people

onset diabetes. As in the metformin trial in 2002, this

"Furthermore, despite the population being at low risk of heart failure (10 year risk 0.33%) a significant increase (0.4%) in heart failure was seen in the rosiglitazone group compared with placebo (7.03, 1.60 to 30.9, number needed to harm at three years 250)."

BMJ 333:764 doi:10.1136/bmj.38996.709340.BE (Published 12 October 2006)

Editorial

Prevention of diabetes

Carl Heneghan (carl.heneghan@dphpc.ox.ac.uk), deputy director, **M Thompson**, clinical lecturer, **R Perera**, senior statistician

Author Affiliations

Drug trials show promising results, but have limitations

Diabetes affects one in 20 adults worldwide and 333 million cases are projected worldwide by 2025.[1] Treatment can prevent some of the microvascular and macrovascular complications, but diagnosis is often delayed until complications present,[2] so attention has focused on prevention and early screening. Two strategies currently exist for reducing the onset of diabetes—lifestyle interventions and drugs.

In the next 4 weeks

- **Try to ask for one patient you have seen:**

1. What causes the disease?
2. How was the disease diagnosed?
3. How was the patient treated?
4. What is the natural history of the disease?
5. Consider formulating a PICO

And try to find some evidence

Tracking switched outcomes in clinical trials

COMPARE
TRACKING SWITCHED OUTCOMES IN CLINICAL TRIALS
METHODS | RESULTS | TEAM | FAQ | BLOG

The team

We are a team of academics, medical students and programmers, based at the Centre for Evidence-Based Medicine, at the University of Oxford.

Thank you

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