



Keele University

Centre for
Medicines Optimisation

EBM Good Practice Day

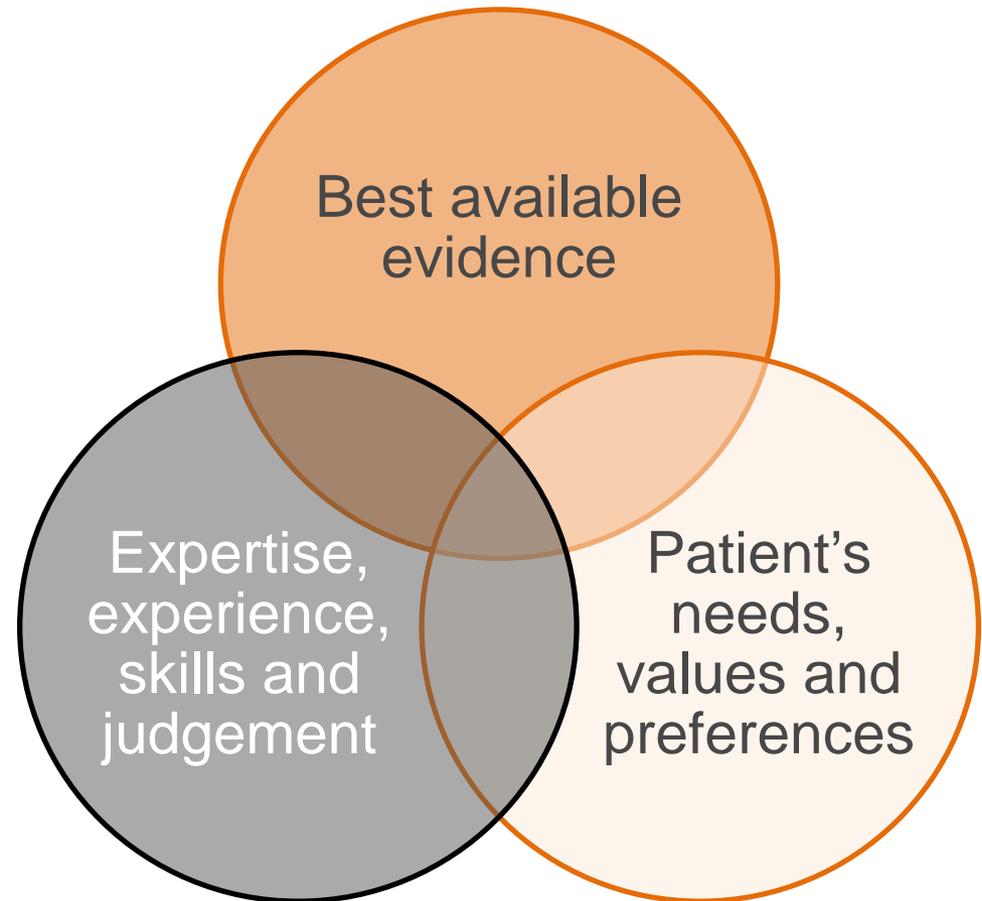


Why is this important?

Sackett D, et al. BMJ 1996; 312: 71



Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients



Why is this important?

Sackett D, et al. BMJ 1996; 312: 71

- ‘The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.’
- ‘Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care.’

Overview of the day

- We'll cover the skills you need to be better at making decisions that are **informed** by evidence
- We will look at
 - Finding the information we need, managing information overload and keeping up to date
 - What kinds of evidence are available and what meets our needs
 - Making sense of what the numbers are telling us
 - How all of us (patients and professionals) make decisions
 - How we can share decision-making with patients
- We will **not** be doing critical appraisal



Finding information (1)



- Imagine you've been asked to find out a little about the following conditions
 - Homozygous familial hypercholesterolaemia
 - Heterozygous familial hypercholesterolaemia
 - Primary non-familial hypercholesterolaemia
- Where would you look?
 - Discuss in groups of 2 or 3
 - Use whatever on-line sources you like (or imagine where you would look)



Finding information (2)

- One of your patients has been diagnosed with heterozygous familial hyperlipidaemia
- He wants you to show him the best available evidence which gives him the best chance of avoiding serious cardiovascular disease
- Where would you look?
 - Discuss in groups of 2 or 3
 - Use whatever on-line sources you like (or imagine where you would look)



Background knowledge

“I haven’t seen someone with heterozygous FH before. Even though the cardiologists and lipidologists will be the key clinicians, I need to know what it is, get an outline of the standard treatments, what complications and interactions I might need to look for, and have a rough idea about the prognosis.”

- Background knowledge is **stable**
- So it matters less where we get it from
 - Within reason!
- **Convenience** and **speed** are paramount

Foreground knowledge

“Mr Jones with heterozygous FH...
...has the evidence base changed recently? He’s only 39. He has a young family... ..He’s really worried. He needs the very best chance of avoiding a stroke or heart attack.....”

- Foreground knowledge is **not** stable; it changes
 - Sometimes these changes are important and affect people’s treatment
- Foreground knowledge is driven by the evidence
 - Therefore how it is put together and where we look for it **matters**
- We have to choose carefully where we look for it
 - Something convenient and quick might lead us astray

- Seema is 56 years old, of Pakistani family origin.
 - Life-long non-smoker, no relevant personal medical history
 - Takes no regular medication
 - Weight 72 kg and height 1.67 m (BMI 26 kg/m²)
 - TC 5.8 mmol/L, TC:HDL ratio 4.8, blood pressure 141/78 mmHg
- She has come to see you after her older brother (who lives in Scotland) had a heart attack about 3 months ago
 - He is 58 years old, has type 2 diabetes and was a smoker (but is now trying to stop)
- Seema is worried about her own cardiovascular risk and what she can do to reduce it

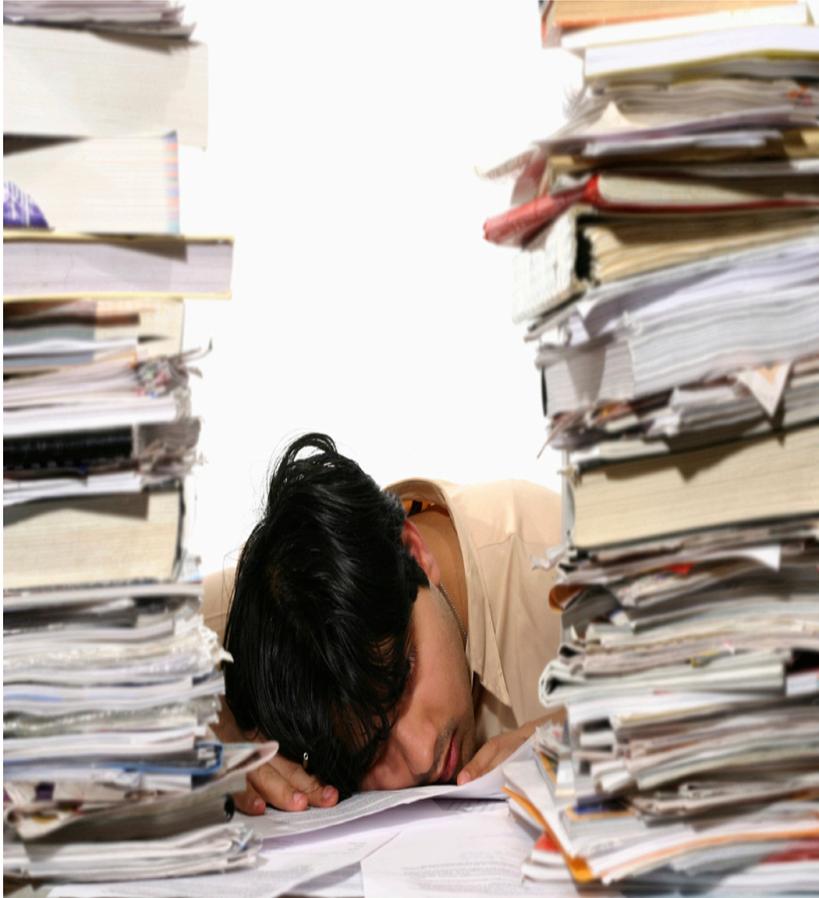


Information is crucial

“Thinking about the fact that we don’t have a lot of time, and this is the thing I feel really ashamed about, I’m in a job where people’s lives depend on the fact that I make the right decision, and sometimes I feel completely overwhelmed with the fact that I don’t know enough information about some critical decisions that I make every day.”

GPST, West Yorkshire, 2010

How can we keep up? Read more....?



- Potential journals 10,000
- New articles per week 40,000
- 97% are not relevant 1,200
- Time to read each article 15 mins
- 10h/day, 6 days/wk 240 articles
- So at the end of the first week you are about **4 weeks behind** in your reading
- At the end of the first month, you are **4 months behind** in your reading
- And at the end of the first year you are almost **5 years behind** in your reading.

Words of wisdom



Muir Gray JA: Evidence-based medicine for professionals *in* Edwards A & Elwyn G (eds) Evidence-based patient choice Oxford: OUP 2001

‘What is clear is that individuals cannot keep up to date except in the most highly restricted and specialized areas of knowledge. The job of the human being is to become skilled at locating **relevant, valid** data for their needs.

‘In the sphere of medicine, the required skill is to be able to relate the knowledge generated by the study of groups of patients or populations to that lonely and anxious individual who has come to seek help.’



How do we know what's useful?

Slawson DC and Shaughnessy AF. J Fam Pract 1994;38:505–13

Usefulness = Relevance x Validity

Work

- **Relevance**: see next slide
- **Validity**: is this trustworthy? What are the strengths and weaknesses of this evidence?
- **Work**: the effort required to find the evidence and assess its relevance and validity



Filtering for relevance

Slawson DC and Shaughnessy AF. J Fam Pract 1994;38:505–13

- F**easible: is this intervention **feasible** in my clinical practice or locality (or could it be)?
- O**utcomes: does this study report **patient-oriented outcomes**?
- C**ommon: is this condition or clinical situation **common** in my clinical practice?
- C**hange: if this evidence turns out to be valid and in keeping with the rest of the evidence base, might I have to **change** my practice?



Outcomes: what you measure matters **Slawson**

DC and Shaughnessy AF. J Fam Pract 1994;38:505–13

Patient Oriented Outcomes:

- Reduces heart attacks and strokes
- Reduces diabetic foot ulcers
- Reduces night time awakenings

Disease Oriented Outcomes:

- Reduces blood pressure
- Improves HbA1c
- Improves PEF



POOs or DOOs?

Barter J et al. *N Engl J Med* 2007;357:2109-22

- Randomised controlled trial in 15,067 people with previous CVD, or type 2 diabetes without previous CVD
- Received atorvastatin at a dose to reduce LDL to <2.6 mmol/L, plus 60 mg torcetrapib or placebo
- Originally planned for 4.5 years of follow-up
- Terminated study early (median follow-up 18 months)

DOO results

- 2.1% increase in HDL
- 24.9% decrease in LDL
- 9% decrease in triglycerides

POO results

- 25% relative increase in risk of composite of major adverse CV events
- 58% relative increase in risk of death from any cause



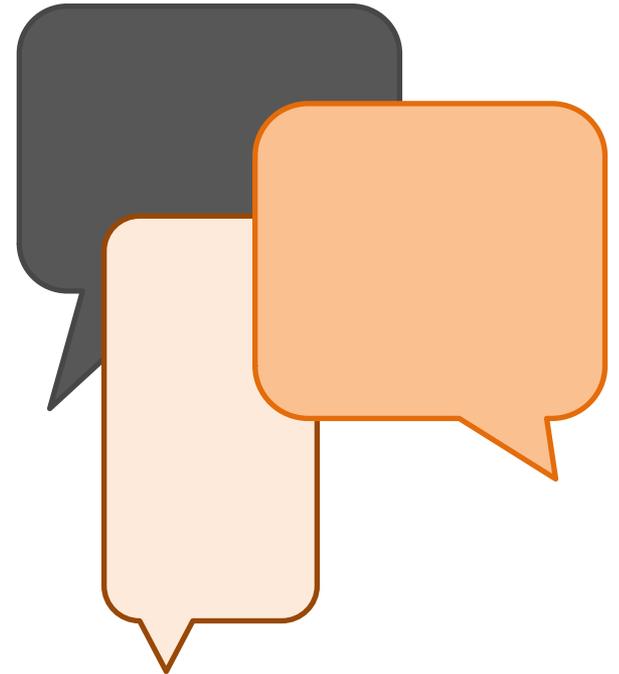
DOOs can mislead

Ebell M, et al. *Am Fam Physician* 2004; 69: 548–556

| Intervention | DOO | POO |
|--|--|--|
| Lidocaine for arrhythmia after myocardial infarction | Suppresses arrhythmias | Increases mortality |
| Finasteride for benign prostatic hypertrophy | Improves urinary flow rate | No clinically important change in patient symptom scores |
| Arthroscopic surgery for osteoarthritis of the knee | Improves appearances after debridement | No change in function or symptoms at 1 year |
| Sleeping infants on their stomach or side | From anatomy and physiology, expect a reduced risk of aspiration | Increased risk of sudden infant death syndrome |
| Beta-blockers in heart failure | Reduce force and rate of contractions | Reduce mortality |

Relevance filtering exercise

- Which of the articles on the handout look as though they might be relevant to you?
- Think:
 - **Feasible** intervention?
 - **Outcomes** patient-orientated?
 - **Common** condition?
 - **Change** in practice required?





Can *you* assess validity?

“I remember doing it as one of the things...*[at medical school]* it's a distant memory, and to do it again at that level would be just... *[sigh]*”

GPST West Yorkshire 2010

“I certainly don't do any of it, you know – don't remember the last time I really looked at a paper. I have a pile of BMJs at home this high *[gesture]* but I don't ever read them. I sometimes carry them around in my bag in case I kind of osmotically get the information *[ironic expression]* but you know, time-wise it's easier to look on GP Notebook.”

GPST West Yorkshire 2010

Why not get someone else to do it?

- Pre-digested sources of evidence from trusted sources:
 - Public-sector ethos
 - Published methodology of how produced
 - Translation of evidence into practice
 - Context of the rest of the evidence



Keeping up to date: what do we need?

- A way of ‘just knowing’ what to do **most** of the time
 - Because we haven’t got time to keep looking things up
- A way of finding out if something **new** and **important** has come along
 - Because we need to be up to date, but we don’t want to be swamped with irrelevant information
- A way of finding what we **need** when we’re stuck
 - Finding the best answer quickly

The 3 components of Information Mastery

Slawson DC, et al. *J Fam Pract* 1994;38:505–13

Maskrey N, et al. *InnovAiT* 2009;2:739–49

Information Mastery



```
graph TD; A[Information Mastery] --> B[Foraging]; A --> C[Hunting]; A --> D[Hot synching];
```

Foraging

a reliable system to alert you to new information that requires a change in your practice

Hunting

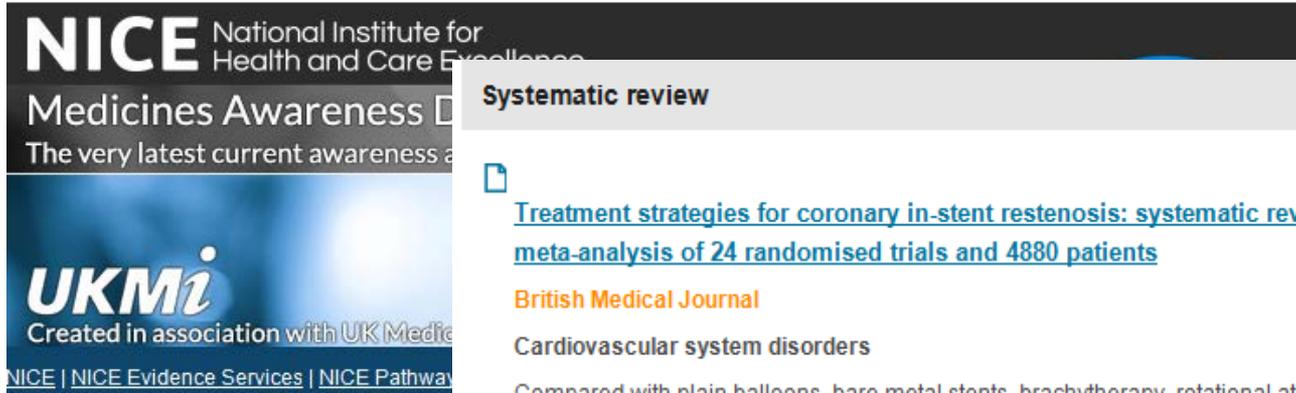
a reliable system to find the best answer to a specific question

Hot synching

purposefully checking and updating your mental map of knowledge and skills once or twice a year

Foraging

<http://www.nice.org.uk/News/NICE-newsletters-and-alerts>



NICE National Institute for Health and Care Excellence
Medicines Awareness UKMi
The very latest current awareness and information on medicines
UKMi
Created in association with UK Medicines
NICE | NICE Evidence Services | NICE Pathways

Systematic review

[Back to top](#)

[Treatment strategies for coronary in-stent restenosis: systematic review and hierarchical Bayesian network meta-analysis of 24 randomised trials and 4880 patients](#)

British Medical Journal

Cardiovascular system disorders

Compared with plain balloons, bare metal stents, brachytherapy, rotational atherectomy, and cutting balloons, drug coated balloons and drug eluting stents were linked to reduced risk of target lesion revascularisation, major adverse cardiac events, and reduced late lumen loss.

[Systemic antibiotics for treating diabetic foot infections](#)

Cochrane Database of Systematic Reviews

Diabetes | Infection and infectious diseases | Skin disorders

The evidence for the relative effects of different systemic antibiotics for the treatment of foot infections in diabetes is very heterogeneous and generally at unclear or high risk of bias. Consequently it is not clear if any one systemic antibiotic treatment is better than

[The impact of biological interventions for ulcerative colitis on health-related quality of life](#)

Cochrane Database of Systematic Reviews

Gastrointestinal disorders

High quality evidence suggests infliximab provides a clinically meaningful improvement in quality of life in patients receiving induction therapy. Moderate quality evidence suggests the same for vedolizumab in patients receiving maintenance therapy.

KINES

Rapid Update

December 2015



Variations in Prescribing Safety in UK General Practices – Room for Improvement

This [study](#) analysed the records of almost five million patients on the UK Clinical Practice Research Datalink (CPRD) using previously validated indicators of prescribing safety. Over 5% of those 'at risk' were deemed to receive potentially unsafe prescriptions. Around 12% with an indicator for the need for blood testing had potential monitoring errors. There was a wide variation between practices. Older patients and those prescribed multiple repeat medications were at greatest risk. The researchers concluded that this variation indicates considerable potential for improvement; they advise caution when prescribing multiple drugs, particularly for older people, and emphasise the importance of regular drug reviews.

A [linked editorial](#) argues that it would not be appropriate to address these concerns using financial incentives (such as seen in the Quality and Outcomes Framework). The authors emphasise the value of clinical pharmacists working with the GP team. In particular, time, or lack of it, is an important factor, and pharmacists can provide more time with patients.

References:

- ✔ Stocks SJ, Kontopantelis E, Akbarov A et al. [Examining variations in prescribing safety in UK general practice: cross sectional study using the Clinical Practice Research Datalink](#). BMJ 2015;351:h5501
- ✔ Chapman S and Curtis T. Editorial: [Safety, trust, and money are uncomfortable bedfellows](#). BMJ 2015;351:h5750

What do we already know?

- ✔ Prescribing safety indicators have been developed to identify patients at increased risk of hazardous prescribing in primary care:
 - The [PRACTiCe study](#), which was funded by the General Medical Council, looked at a sample of 15 general practices across England and using safety indicators agreed by consensus among GPs (using a Delphi technique) did a retrospective review of the clinical records of a random sample of over 1,700 patients, and over 6,000 prescription items. This found that one in 20 (5%) prescription items was associated with one or more

| Table 1: Safety Topics covered by PINCER <i>(from PINCER audit tool 'quick guide'. See PINCER website for more details.)</i> |
|--|
| Query 1: Patients with a history of peptic ulcer who have been prescribed a non-selective nonsteroidal anti-inflammatory drug without co-prescription of a proton pump inhibitor |
| Query 2: Patients with a history of asthma who have been prescribed a β -blocker |
| Query 3: Patients 75+ yrs prescribed an ACE inhibitor or loop diuretic long-term who have not had a computer-recorded renal function and electrolytes check in the previous 15 months |
| Query 4: Women with past medical history of venous or |



Important new evidence

Some important new evidence relating to prescribing and medicines optimisation Published during July 2016

- [NICE technology appraisal and other guidance](#)
- [NICE evidence summaries and advice](#)
- [SIGN guidance, Scottish Medicines Consortium \(SMC\) and All Wales Medicines](#)

| | |
|--|---|
| <ul style="list-style-type: none"> • Prophylaxis against infective endocarditis: antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures: CG64 (March 2008) • Familial hypercholesterolaemia: identification and management: CG71 (August 2008) | <p>(on when prophylaxis is recommended).</p> <ul style="list-style-type: none"> • Familial hypercholesterolaemia (CG71): In July 2016, recommendations 1.3.1.6–1.3.1.11 were replaced and are adapted from ezetimibe for treating primary (heterozygous, familial and non-familial) hypercholesterolaemia (NICE technology appraisal guidance 385). TA385 has replaced TA132, the original source for these recommendations. |
|--|---|

| | |
|---|---|
| | different interventions to minimise medicines-related patient safety incidents. |
| Type 2 diabetes: increased risk of hypoglycaemia with combined use of dipeptidyl peptidase-4 (DPP-4) inhibitors and sulfonylureas : Medicines Evidence Commentary | <p>A systematic review and meta-analysis found that adding a dipeptidyl peptidase-4 (DPP-4) inhibitor (or gliptin) to a sulfonylurea increased the risk of hypoglycaemia by around 50%. The NICE guideline on type 2 diabetes recommends the combination of a sulfonylurea and DPP-4 inhibitor as an option for intensification of treatment in certain circumstances. The guideline recommends that the choice of medicine for managing blood glucose levels should be made following a discussion with the individual person about the benefits and risks of drug treatment, and the options available.</p> |
| Behavioural support with | <p>A Cochrane review found that using high intensity behavioural</p> |
| <p>assess when the time before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop. For children and young people, this decision should be made jointly by the clinician and the child or young person or the child or young person's parents or carers.</p> | <p>managing blood glucose levels should be made following a discussion with the individual person about the benefits and risks of drug treatment, and the options available.</p> |
| | <p>Behavioural support with pharmacotherapy for smoking cessation: Eyes on Evidence</p> <p>A Cochrane review found that using high intensity behavioural support, such as more sophisticated interventions or more frequent sessions, with smokers who were using pharmacotherapy increased their likelihood of stopping smoking compared with less intense approaches.</p> |

Research

Addition of dipeptidyl peptidase-4 of hypoglycaemia: systematic review

BMJ 2016 ; 353 doi: <http://dx.doi.org/10.1136/bmj>
 Cite this as: BMJ 2016;353:i2231

Article

Related content

Metrics

Francesco Salvo, clinical pharmacist, statistician^{1,2}, Philip Robinson, De Ponti, professor of pharmacology, professor of pharmacology^{1,2,3}

Author affiliations

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Accepted 6 April 2016

Abstract

Objective To quantify the risk of hypoglycaemia with the addition of dipeptidyl peptidase-4 (DPP-4) inhibitor to a sulfonylurea.

Design Systematic review and meta-analysis.

Data sources Medline, ISI Web of Science, Cochrane, ClinicalTrials.gov, Embase, Scopus, and ProQuest.

| Study | No with hypoglycaemia | DPP-4 inhibitors |
|-----------------------|-----------------------|------------------|
| Hermansen 2007 | 27/222 | |
| Lewin 2007 | 9/161 | |
| Garber 2008 | 8/339 | |
| Chacra 2009 | 70/501 | |
| Pratley 2009 | 51/401 | |
| Kikuchi 2010 | 2/102 | |
| Owens 2011 | 180/792 | |
| Selno 2012 | 2/209 | |
| Barnett 2013 | 29/95 | |
| White 2013 | 101/1198 | |
| Total (95% CI) | 479/4020 | |

Test for heterogeneity: $\chi^2=11.25$, $P=0.26$, $I^2=20\%$
 Test for overall effect: $z=4.90$, $P<0.0001$



Medicines Evidence Commentary

commentary on important new evidence from Medicines Awareness Weekly

Published: July 2016

Type 2 diabetes: increased risk of hypoglycaemia with combined use of dipeptidyl peptidase-4 (DPP-4) inhibitors and sulfonylureas

A systematic review and meta-analysis found that adding a dipeptidyl peptidase-4 (DPP-4) inhibitor (or gliptin) to a sulfonylurea increased the risk of hypoglycaemia by around 50%. The NICE guideline on [type 2 diabetes](#) recommends the combination of a sulfonylurea and DPP-4 inhibitor as an option for intensification of treatment in certain circumstances. The guideline recommends that the choice of medicine for managing blood glucose levels should be made following a discussion with the individual person about the benefits and risks of drug treatment, and the options available.

Overview and current advice

The management of type 2 diabetes is complex. It needs an individualised multifactorial approach addressing blood glucose, blood pressure, blood lipids and lifestyle issues (for example, smoking cessation, exercise, losing weight and a healthy diet). Controlling blood glucose needs a careful balance between the intensity of the treatment regimen and avoiding hypoglycaemia. Hypoglycaemia can be a potentially life-threatening event associated with hospital admission, cardiovascular disease, and mortality¹. A Cochrane review ([CD008143](#)) compared intensive glycaemic control with conventional glycaemic control and found that intensive control did not reduce the risk of death from any cause, cardiovascular death, nonfatal stroke, or cardiac or peripheral revascularisation. Intensive control did reduce the risk of nonfatal myocardial infarction (MI), amputation of a lower extremity, and microvascular complications (including nephropathy and retinopathy) but it also increased the risk of severe adverse events and hypoglycaemia².

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Hunting means

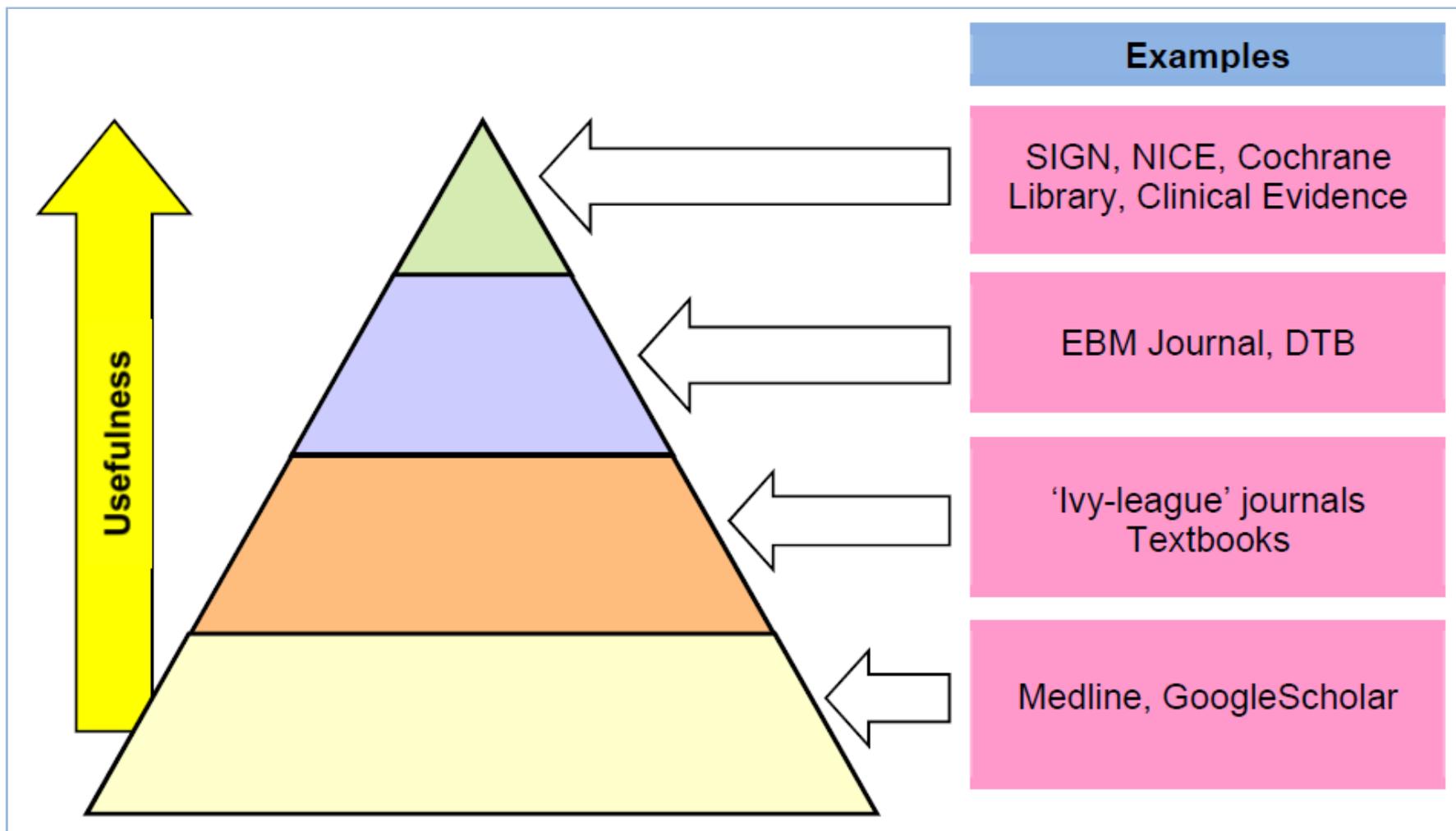
Finding the **best** answer, not just **an** answer

Finding it easily (and quickly) when we need to

Recognising it when we've found it



Drilling for the **best** information



Hot-synching



- Regularly updating yourself on the things you see/deal with commonly

Topics Specialities

A B C D E F
G H I J K L
M N O P Q R
S **T** U V W X

Tamoxifen - managing adverse effects
Teething
Tennis elbow
Threadworm
Thrombophlebitis - superficial
Tinnitus
Tiredness/fatigue in adults

TMJ disorders
Trichomoniasis
Trigeminal neuralgia
Tuberculosis

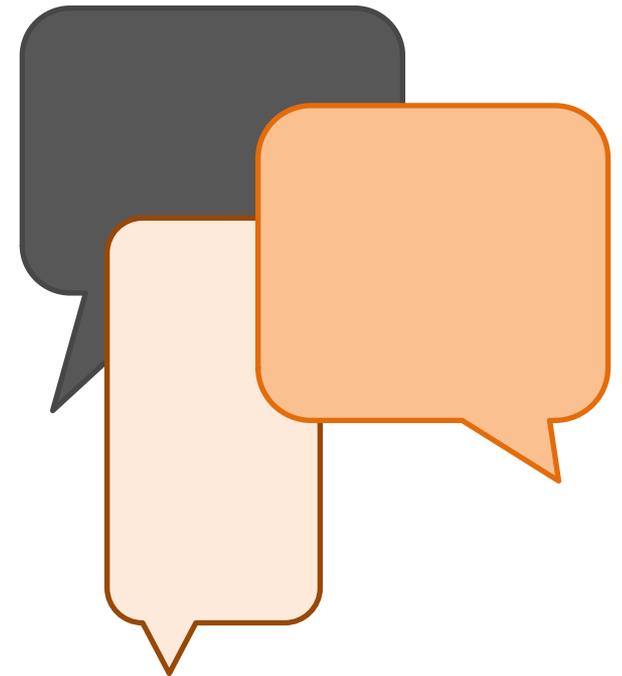
Summary

- We need to think: do I need background or foreground knowledge here?
 - We need to address these needs in different ways
- We are faced with a huge amount of information, but we need to
 - Know what to do most of the time
 - Be confident that we are up to date
 - Be able to find the best answer quickly when we are stuck
- Hunting, foraging and hot-synching can help
- We need to work out a strategy to do this



Comments?

Questions?



What evidence is out there?

Claire Stevens

Types of studies



Observational (no intervention)

- cross sectional (survey at one point in time)
 - Assesses prevalence or risk factors but takes no account of timing or duration of exposure to the risk factor
- cohort & case-control studies
 - try to link outcome with treatment or exposure over time

Experimental (with intervention)

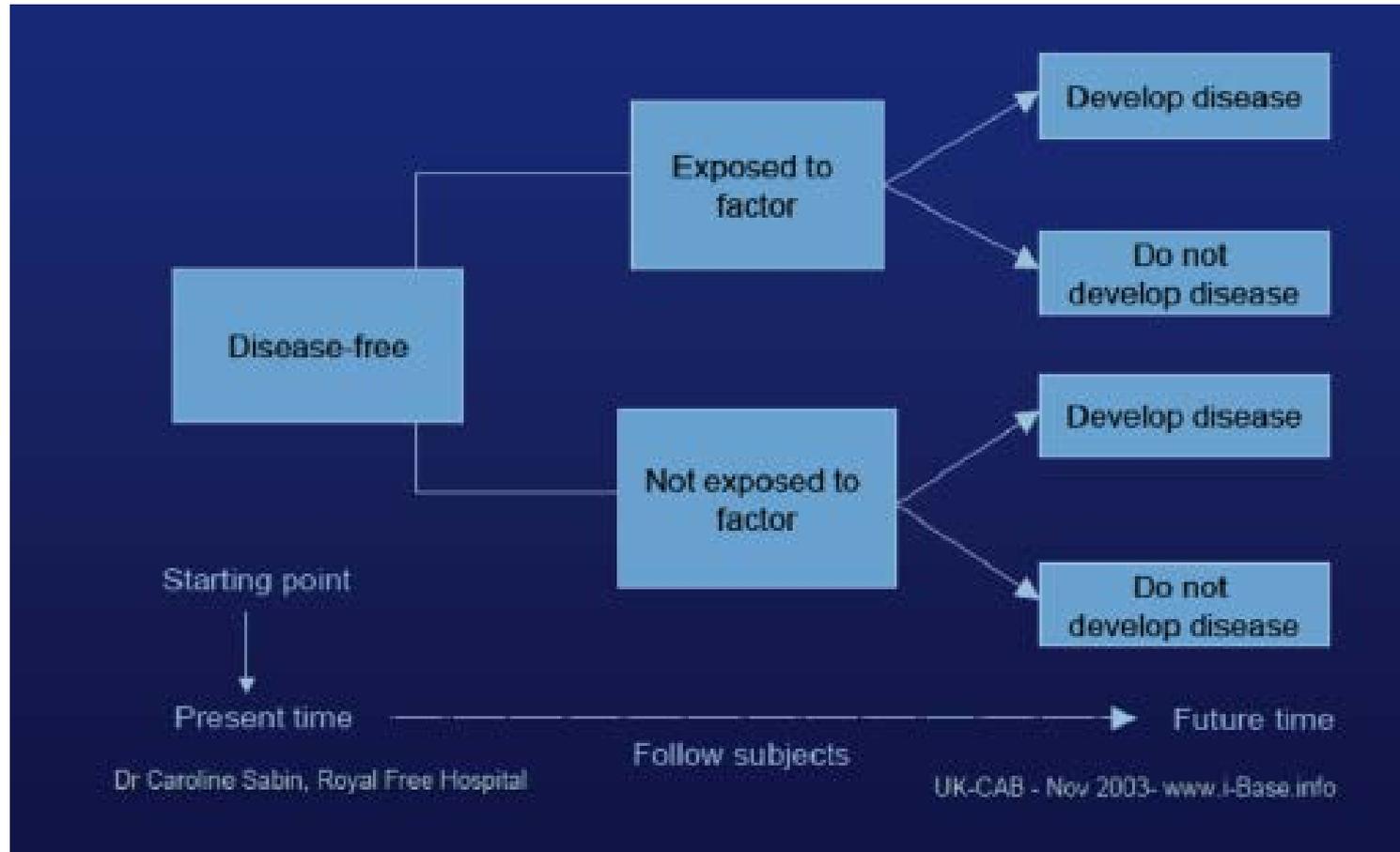
- Controlled trial (parallel, cross-over, clusters)
- randomisation (= RCT)
- Blinding
 - open, single-blind, double-blind, use of dummy interventions

Systematic Review

- Trials meeting a set of selection criteria
- May include meta-analysis (combination of results)

What evidence is out there?

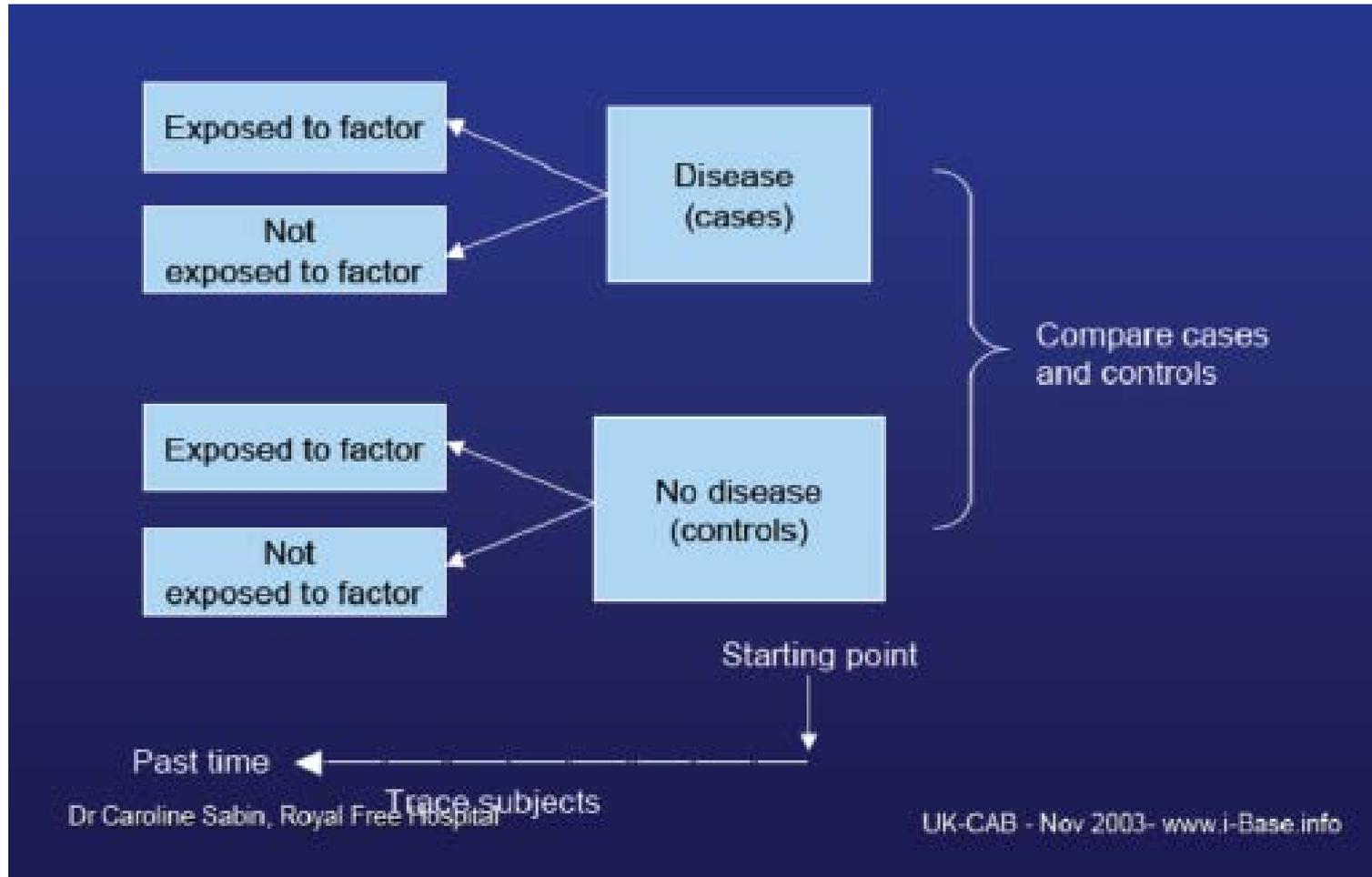
Cohort study schematic



e.g. Effectiveness of Influenza Vaccine in the Community-Dwelling Elderly;
<http://www.nejm.org/doi/pdf/10.1056/NEJMoa070844>

What evidence is out there?

Case-control study



Types of studies

Observational (no intervention)

- cross sectional (survey at one point in time)
 - Assesses prevalence or risk factors but takes no account of timing or duration of exposure to the risk factor
- cohort & case-control studies
 - try to link outcome with treatment or exposure over time

Experimental (with intervention)

- Controlled trial (parallel, cross-over, clusters)
- randomisation (= RCT; reduces selection bias)
- Blinding
 - open, single-blind, double-blind, use of dummy interventions (reduces bias in delivery of interventions and assessment of outcomes [ascertainment bias])

Systematic Review

- Trials meeting a set of selection criteria
- May include meta-analysis (combination of results)



Types of studies

What type of study would you use to answer these recent clinical questions?:

1. Randomised controlled trial
2. What effect have recent initiatives to encourage lower prescribing
Cohort study
associated with type 2
3. Randomised controlled trial
4. Case control study



Hierarchy of evidence

Table 2. Oxford Centre levels of the evidence scheme^{2,4}

| Level | Description | Recommendation Grade |
|-------|--|---|
| 1a | Systematic review with homogeneity of RCTs | A: Level 1 |
| 1b | Individual RCT with narrow CI | (provided studies are consistent) |
| 1c | All or none ^b | |
| 2a | Systematic review with homogeneity of cohort studies | B: Level 2 or 3 |
| 2b | Individual cohort study; low quality RCT (eg, < 80% follow-up) | (provided studies are consistent; |
| 2c | Outcome research; ecological studies | extrapolations from level 1 studies) |
| 3a | Systematic review with homogeneity of case-control studies | |
| 3b | Individual case-control studies | |
| 4 | Case series; poor quality cohort or case-control studies | C: Level 4 |
| | | (extrapolations from level 2/3) |
| 5 | Expert opinion omitting explicit critical appraisal (includes opinion based upon physiology, bench research, or first principles | D: Level 5 |
| | | (troublingly inconsistent or inconclusive studies from any level) |

^aFree of heterogeneity in direction and degree of results between individual studies

^bMet when all patients used to die before treatment became available, but now some survive. Or, met when some patients used to die but now all survive

<http://www.cebm.net/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/>

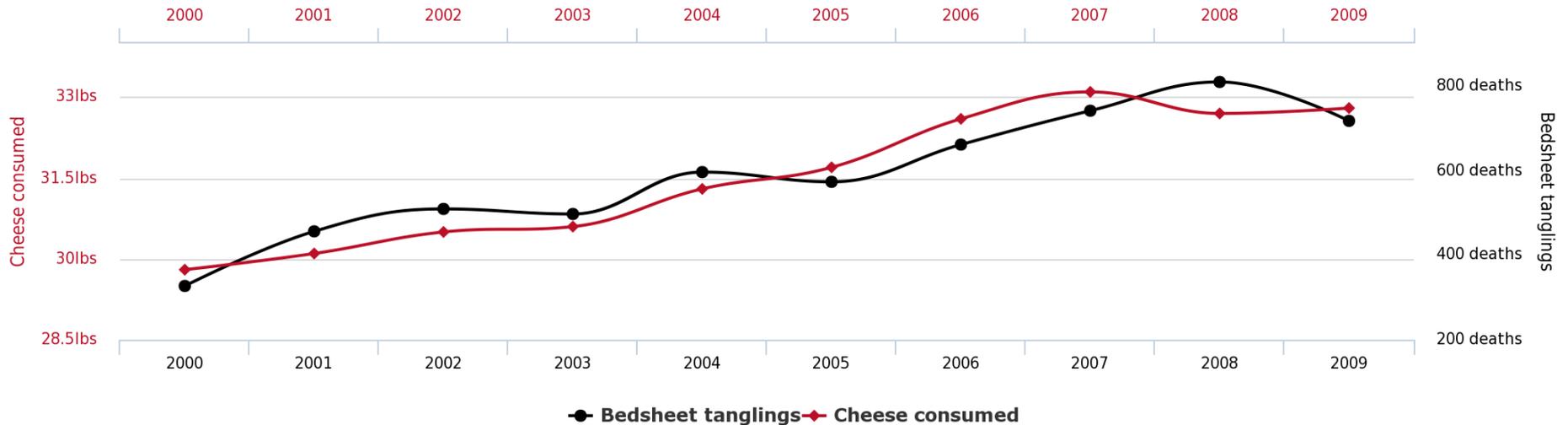
Association or causation?

www.tylervigen.com/spurious-correlations

Per capita cheese consumption

correlates with

Number of people who died by becoming tangled in their bedsheets



What does good look like?

- RCTs: well described – methods of randomisation, allocation and blinding are described, outcomes are relevant and patient oriented and assessment is blinded. Clear that sources of bias have been minimised.
- Cons:
 - RCTs: highly selected populations and models of care that may not be representative of real-world practice
 - Expensive and generally short term
- Observational trials: clear description of the selection of patient groups (with stated inclusion and exclusion criteria) or matched controls; description of the exposures and outcomes measured; description of confounding factors.
- Cons
 - Susceptible to biases – selection of the population with no randomisation, in retrospective trials there can be recall or information bias
 - Prospective cohort trials may be expensive to conduct and require a long follow up



Any questions?



Key expressions of difference

Ray Fitzpatrick & Claire
Stevens

Key expressions of difference

Absolute risk

- The absolute risk of developing a condition, establishes a baseline
- e.g.
 - the risk of getting an infection is 1 in 100,000
 - risk of being hit by a random plane falling on your house is 1 in 250,000
 - risk of winning the lottery is 1 in 14,000,000

Absolute risk reduction (risk difference)

- The amount by which an intervention can change the absolute (baseline) risk
- CER – EER

Relative risk difference

- “By how much did treatment reduce the chance of the outcome occurring in the treatment group compared with the control group?”
- $(CER - EER)/CER$

Numbers needed to treat

- Number of patients need to treat to improve the chances that one patient will benefit
- $NNT = 1/ARR$ or $100/ARR$ (if expressed as a percentage)

Key expressions of difference

Absolute and relative risk: shopping analogy

'Premium range' apples

➤ Were £4 per bag, now £3 per bag

- 'Absolute' price reduction is £1 per bag: old rate – new rate
- 'Relative' price reduction is $\frac{1}{4}$ or 25%:
 - $(\text{old rate} - \text{new rate}) / \text{old rate}$

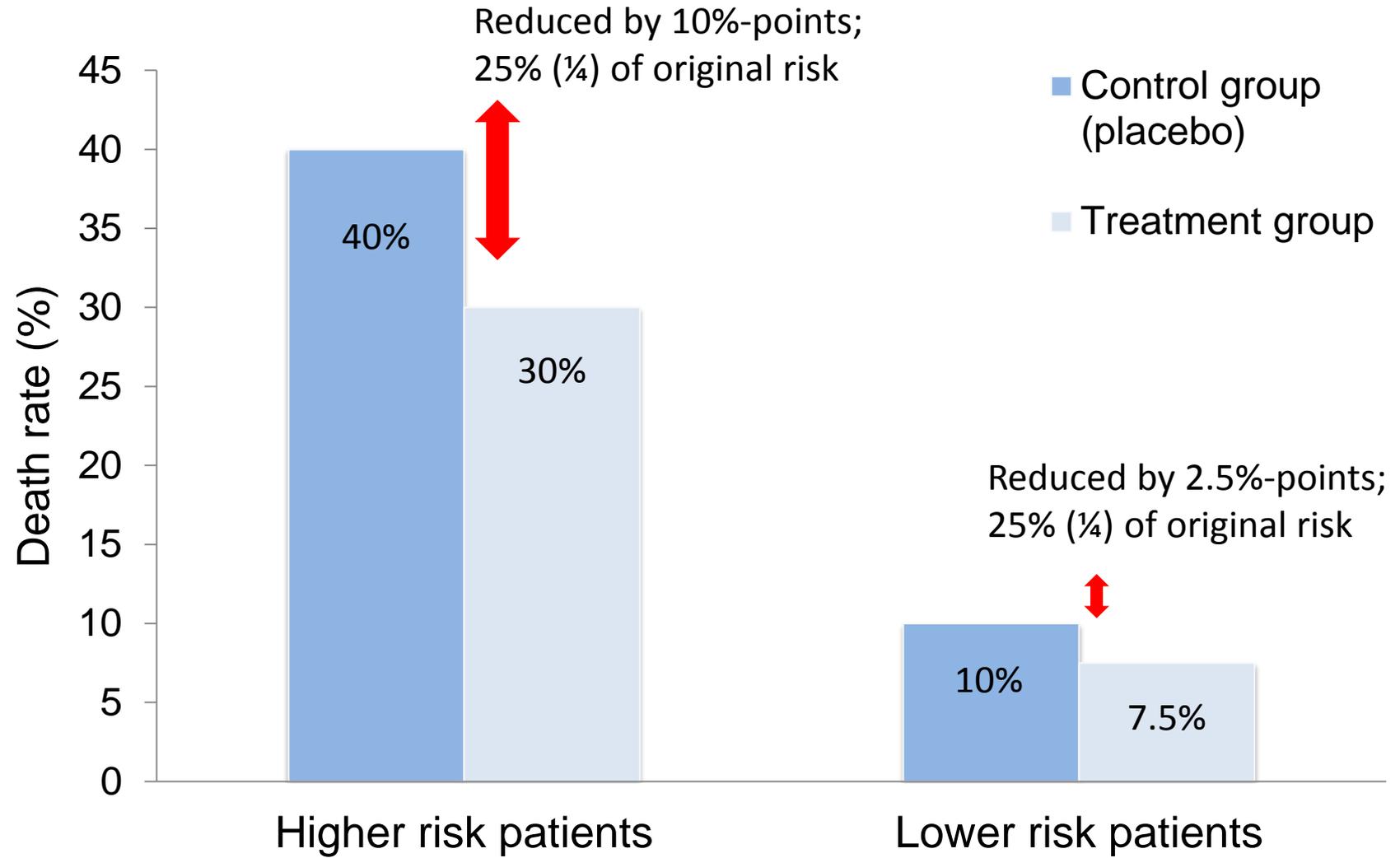
'Basics ugly' apples

➤ Were 40p per bag, now 30p per bag

- 'Absolute' price reduction is 10p per bag: old rate – new rate
- 'Relative' price reduction is **also** $\frac{1}{4}$ or 25%:
 - $(\text{old rate} - \text{new rate}) / \text{old rate}$



Same experimental treatment tested in two different trial populations: at high-risk or low-risk of a fatal event



Higher-risk patients

- 40% of people in the control group died
 - ‘control event rate’ (CER)
- 30% of people in the treatment group died
 - ‘experimental event rate’ (EER)
- The **absolute risk reduction** (ARR, risk difference) is CER–EER
 - $40\% - 30\% = 10\%$ (10 percentage points, 10 fewer people per 100)
- The **relative** risk reduction (RRR) is $(\text{CER} - \text{EER}) / \text{CER}$
 - $(40\% - 30\%) / 40\% = 0.25 = 25\%$ reduction in the risk of the control group

Number needed to treat (NNT)

Higher-risk patients

- 40% of people in the control (placebo) group died
- 30% of people in the treatment group died
- The **absolute risk reduction** is 10% (10 people per 100)
- The NNT is $100/\text{ARR}$
 - $100/10 = 10$
- On average**, for every 10 people who take the treatment, 1 doesn't die who would have done if they'd taken placebo
- The other 9 live or die, just as if they'd had placebo



Same treatment, different people

In higher risk patients:

- 40% of people taking the control died
- 30% of people taking the treatment died
- ARR 10%, RRR 25%, **NNT 10**

In the higher risk population we need to treat an average of **10** people to save 1 person

In lower risk patients:

- 10% of people taking the control died
- 7.5% of people taking the treatment died
- ARR 2.5%, RRR 25%, **NNT 40**

But in the lower risk population we need to treat an average of **40** people to save 1 person



Some practice questions

Supastatin *vs.* placebo

- Patients with cardiovascular disease.
- Outcome: rate of death, which occurs in 1,300 of 10,300 statin-treated patients and 1,500 of 10,300 patients receiving placebo
- For statin treatment *vs.* placebo, calculate the ARR, RRR, NNT**

Absolute risk reduction $CER - EER$

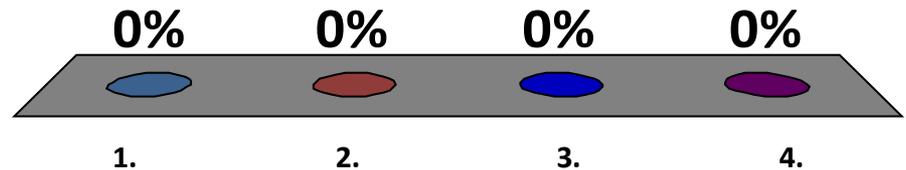
Relative risk reduction $(CER - EER) / CER \times 100$

Number needed to treat $100 / ARR$



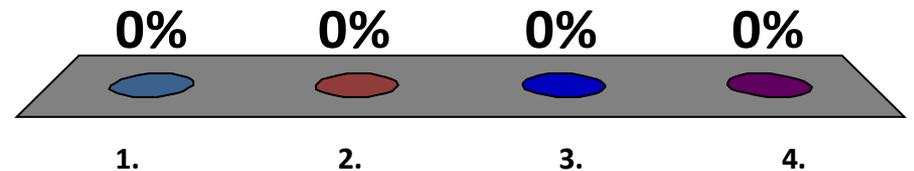
Which of the following is the ARR?

- 1. → 2%
- 2. 14%
- 3. 20%
- 4. 0.02%



Which of the following is the RRR?

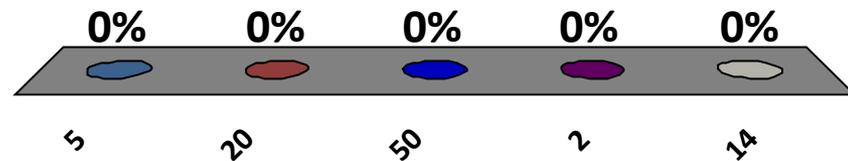
1. 2%
- 2. 14%
3. 20%
4. 0.02%





What is the NNT?

- A. 5
- B. 20
- C. 50
- D. 2
- E. 14



Nuvaparin *vs.* usual treatment

Prevention of blood clots after joint replacement surgery.
Outcome: number of patients with life-threatening clots

- 22.5% patients on nuvapararin had a life-threatening clot *vs.* 25% receiving usual treatment, what is the NNT?
- 8% of nuvapararin-treated patients had a serious adverse bleed *vs.* 3% receiving usual treatment, what is the NNH?

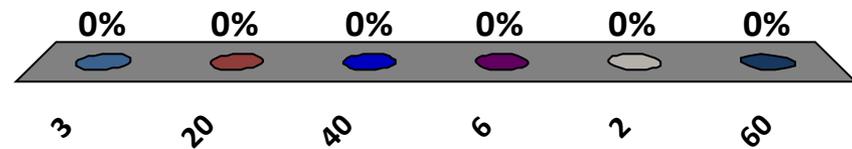
(Note: NNH is identical to the NNT, just calculated using adverse event data)

$$\text{NNT} = 100/\text{ARR}$$



What is the NNT?

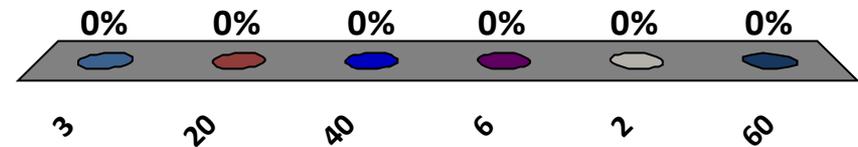
- A. 3
- B. 20
-  C. 40
- D. 6
- E. 2
- F. 60





What is the NNH?

- A. 3
- B. 20
- C. 40
- D. 6
- E. 2
- F. 60



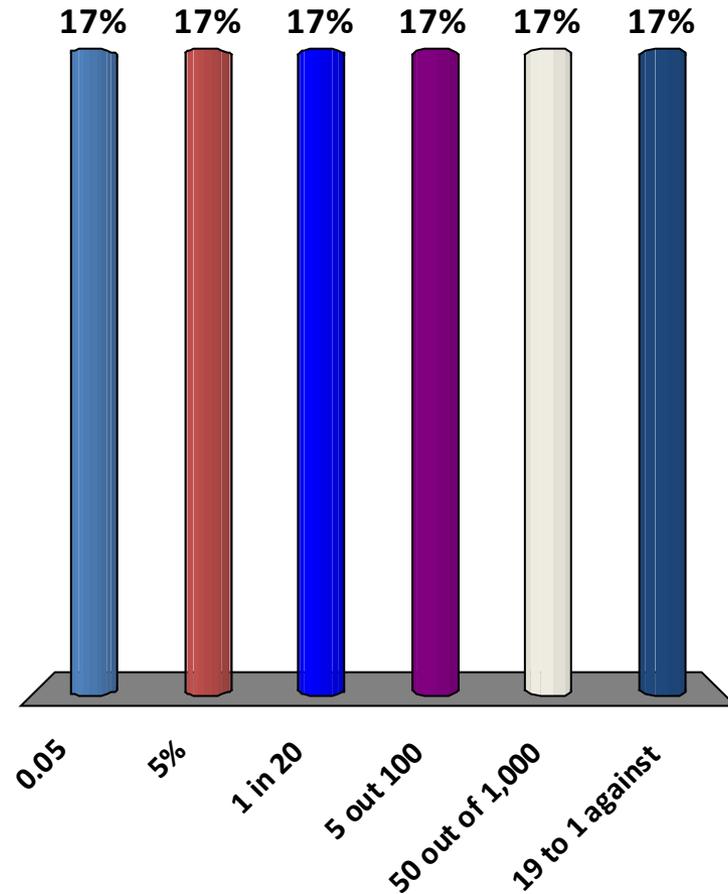
Based solely on the numbers you've just calculated...
would you add this treatment to a formulary?

1. Yes
2. No



The NNH was calculated from an absolute risk of 5%
How would you describe that risk to a colleague or patient?

- A. 0.05
- B. 5%
- C. 1 in 20
- D. 5 out 100
- E. 50 out of 1,000
- F. 19 to 1 against



What does this mean for practice?

- **Relative risk reduction** always looks more impressive, but on it's own it can be misleading.
- **Absolute risk reduction and NNTs** give the benefit in the population in the study
- So if applying evidence from a RCT to an individual patient we must consider:
 - is **my** patient at the same risk as the average patient in that trial?
 - If at lower risk (younger, fitter, etc.), the NNT would be bigger, but the person would still be at risk of side effects
 - And don't forget
 - What is the risk of harms? What are the disadvantages/inconveniences of treatment?



How reliable are the results?

The P value

How reliable are the results?:

- The probability that the observed result in a trial is due to chance



➤ If you were about to cross a bridge and were told there was a 1 in 20 chance that it would fall down - would you cross?

➤ 1 in 100?

➤ 1 in 1000?

The probability that the observed result is due to chance:

- If $p < 0.05$, there is less than a 5% (1 in 20) chance that the result is due to chance
- If $p < 0.01$ there is less than a 1% (1 in 100) chance that the result is due to chance
- If $p < 0.001$ there is less than a 0.1% (1 in 1000) chance that the result is due to chance

‘Everyday’ pragmatic interpretation of a 95% confidence interval

- The range of values within which we can be 95% certain the true population mean lies
 - It is also possible to calculate 90% or 99% CIs
- More helpful than p values because they indicate the precision of the result
 - Generally, larger studies will produce narrower CIs
- There is a relationship between CIs and p values

‘Everyday’ pragmatic interpretation of a 95% confidence interval

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Example

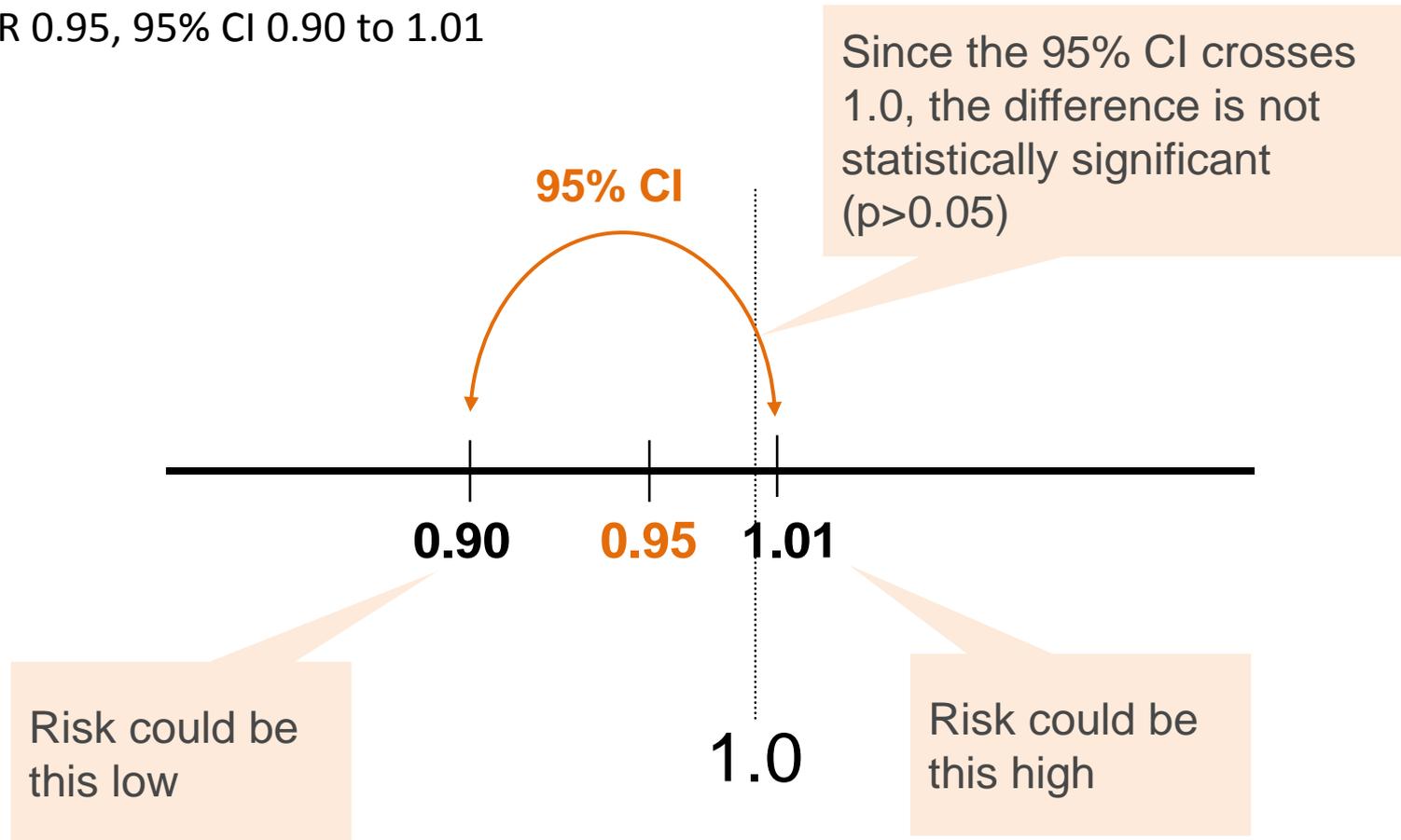
Hou W, et al (2013). *Eur Heart J* doi: [10.1093/eurheartj/ehf065](https://doi.org/10.1093/eurheartj/ehf065)

- SR and MA to assess the effects of statin therapy on CV and renal outcomes in people with CKD
 - 31 RCTs, 48,429 patients with CKD
- Risk of kidney failure
 - defined as a 25% decrease in eGFR, doubling of serum creatinine, or end-stage renal disease
 - Evidence from 6 RCTs, n=11,924
- RR 0.95, 95% CI 0.90 to 1.01

Kidney failure with statins in people with CKD

Hou W, et al (2013). Eur Heart J doi: 10.1093/eurheartj/ehs065

RR 0.95, 95% CI 0.90 to 1.01



95% confidence intervals and statistical significance

Statistically significant **reduction** in risk (upper and lower 95% CIs **both** on this side of line of no difference)



No statistically significant difference in risk (95% CIs **cross** line of no difference)



Statistically significant **increase** in risk (upper and lower 95% CIs **both** on this side of line of no difference)



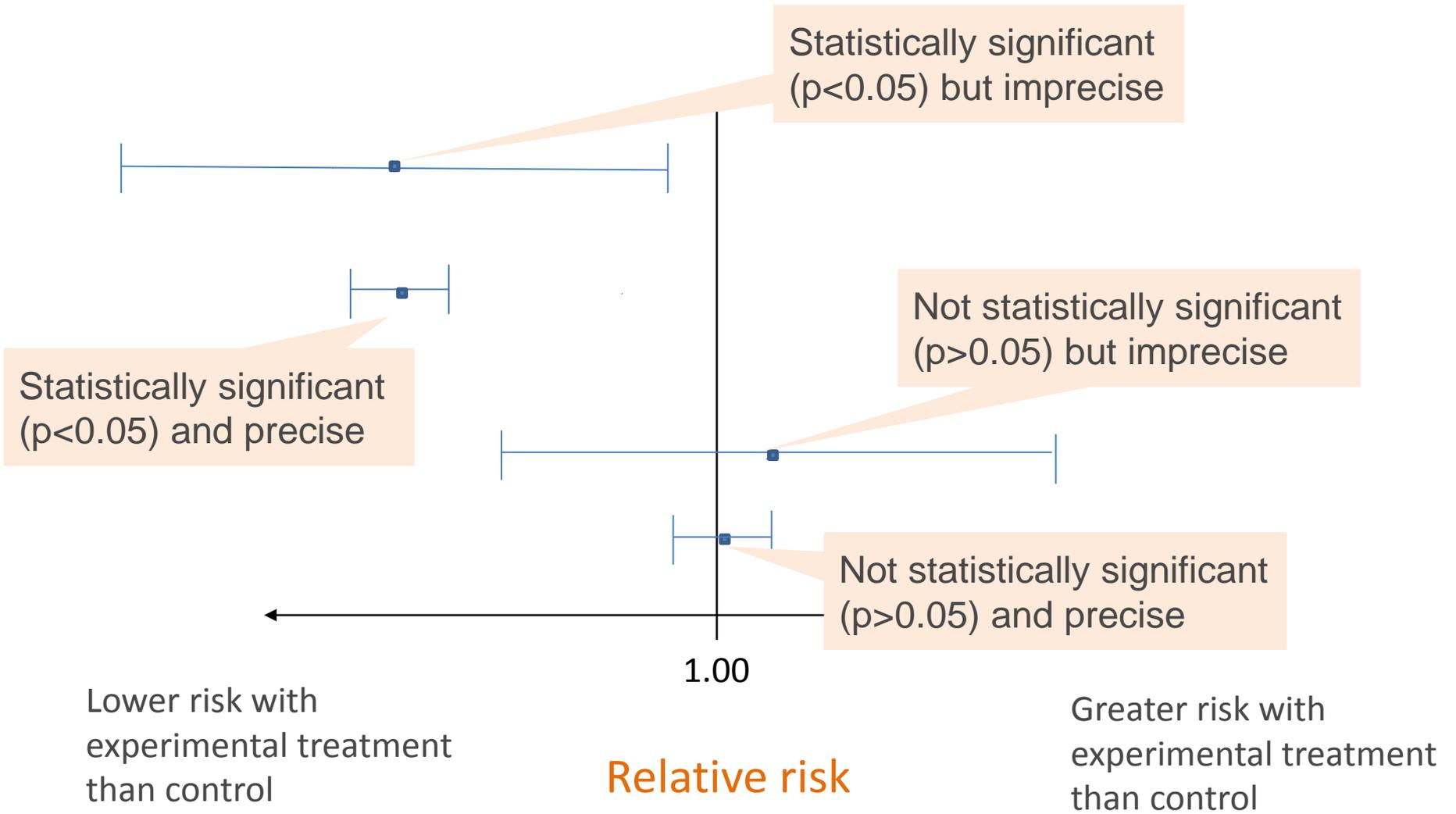
0 1.00 infinity

Lower risk with experimental treatment than control

Relative risk

Greater risk with experimental treatment than control

95% CIs give more information than p values



Sample size

How does the size of the study affect things?

- Counsell CE, et al. BMJ 1994 309: 1677-1681.
<http://www.bmj.com/content/309/6970/1677>



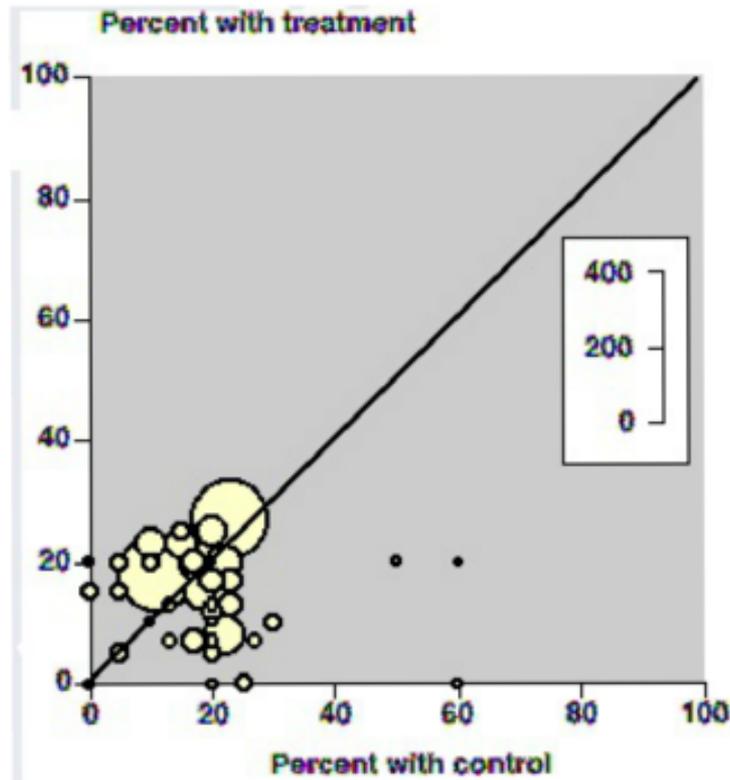
- Investigators used dice to simulate outcomes in a fictitious trial of a treatment for acute stroke
- Rolled dice to simulate results in the treatment arm compared with the control arm
- Roll of a die represented the outcome for the simulated patients in the trial:
 - 1-5 represented survival
 - 6 represented death
- Rolled for 'treatment' group then repeated for 'control' group
- Number of times the die was rolled varied from 5 to 100

Rolling the dice

Results?

– 16.7% death rate or different?

Results from BMJ study: there should be no difference between treatment arms



'L'Abbe plot (comparing trial effect size in a meta-analysis); percentage of deaths:

- Each circle is a trial result
- Bigger circles - bigger sample size
- Diagonal line of no difference

DICE therapy for acute stroke

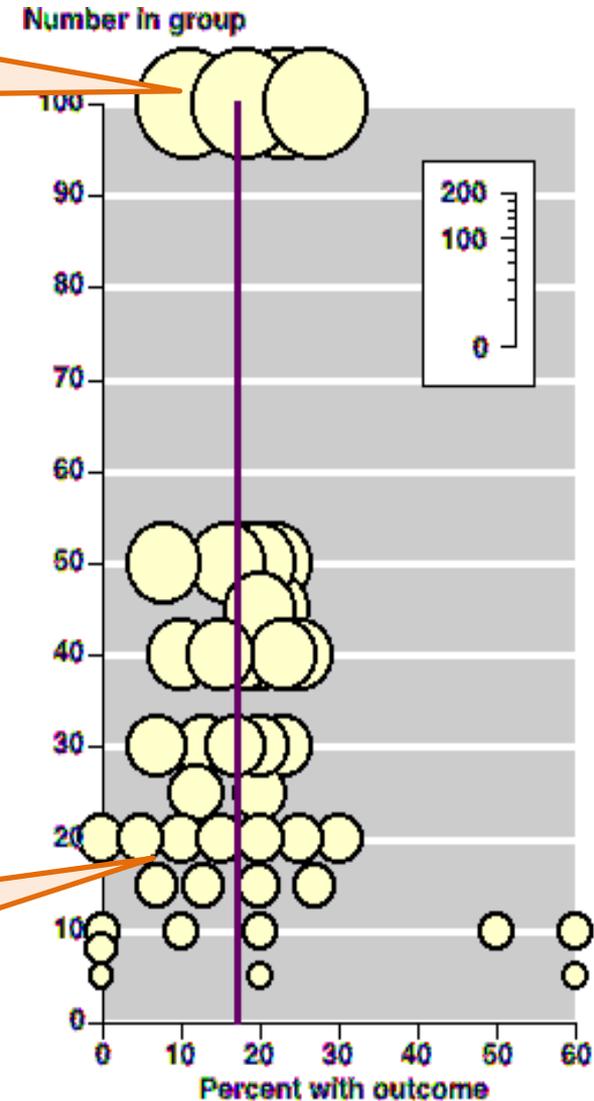
Counsell CE, et al. BMJ 1994; 309: 1677-81 [Bandolier Nov 2002]

More consistency in results

Results varied according to number of times dice was rolled:

- Variation in 'outcome' was largest in the 'smallest' studies
- The chance of a spurious result decreased with increasing numbers included in the trial

Wide variation in results

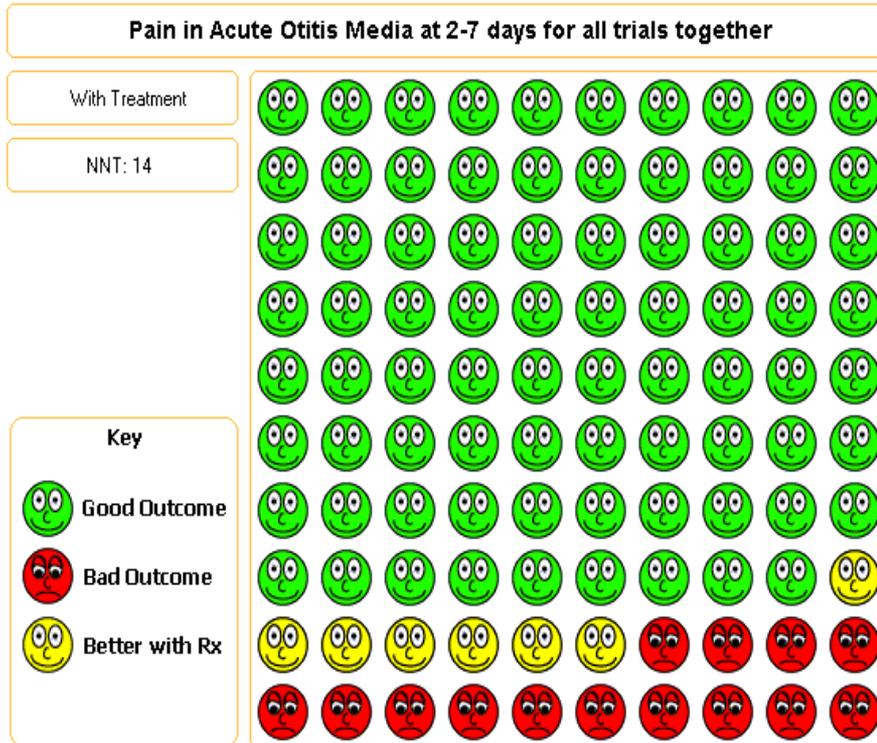


Summary

- We need to understand what the numbers are telling us
 - Relative risk and relative risk reduction are constant
 - Absolute risk reduction and NNT depend on the person's baseline risk
- P values and confidence intervals can help us interpret the result
- Remember
 - 'not statistically significant' may just mean that a true effect was not shown beyond reasonable doubt
 - 'statistically significant' does not always mean clinically significant

'Framing the risk'

Example: antibiotics for acute otitis media in children



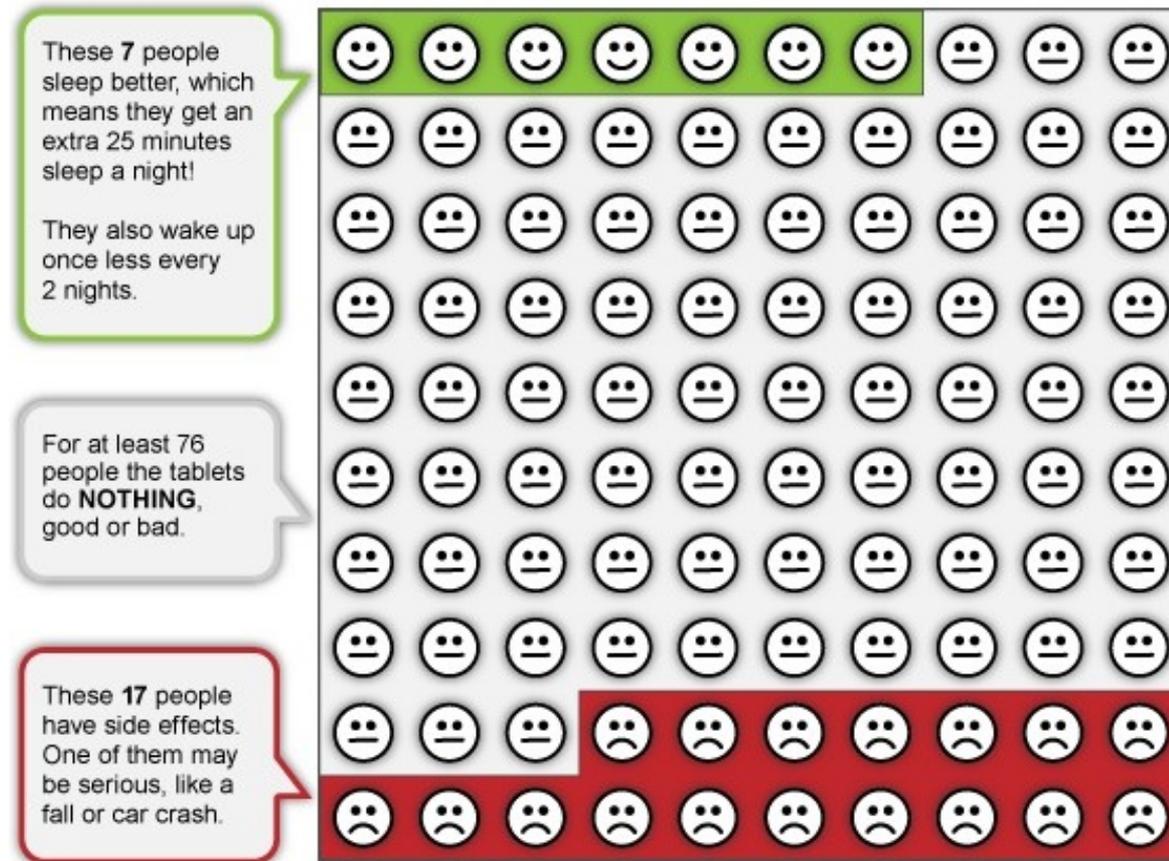


Example: sedative hypnotics in older people with insomnia

- **Sedative hypnotics in older people with insomnia: meta-analysis of risks and benefits. Glass *et al.*, *BMJ* 2005;331:1169**
- NNT to experience improved sleep quality is 13
- NNH to experience an adverse event is 6.

Effects of sleeping tablets

What would happen to 100 people like you take sleeping tablets for more than a week?



The potential benefits and harms of sleeping tablets are shown in this Cates plot, a 'smiley face' plot designed to visually communicate the risks and benefits of treatment:

[Click here for more info](#)

Note:

This is in primary insomnia vs placebo in people aged over 60 years. Adapted from Glass J, Lancot KI, Herrman N, Sproule BA, Busto UE. Sedative hypnotics in older people with insomnia: meta-analysis of risks and benefits.

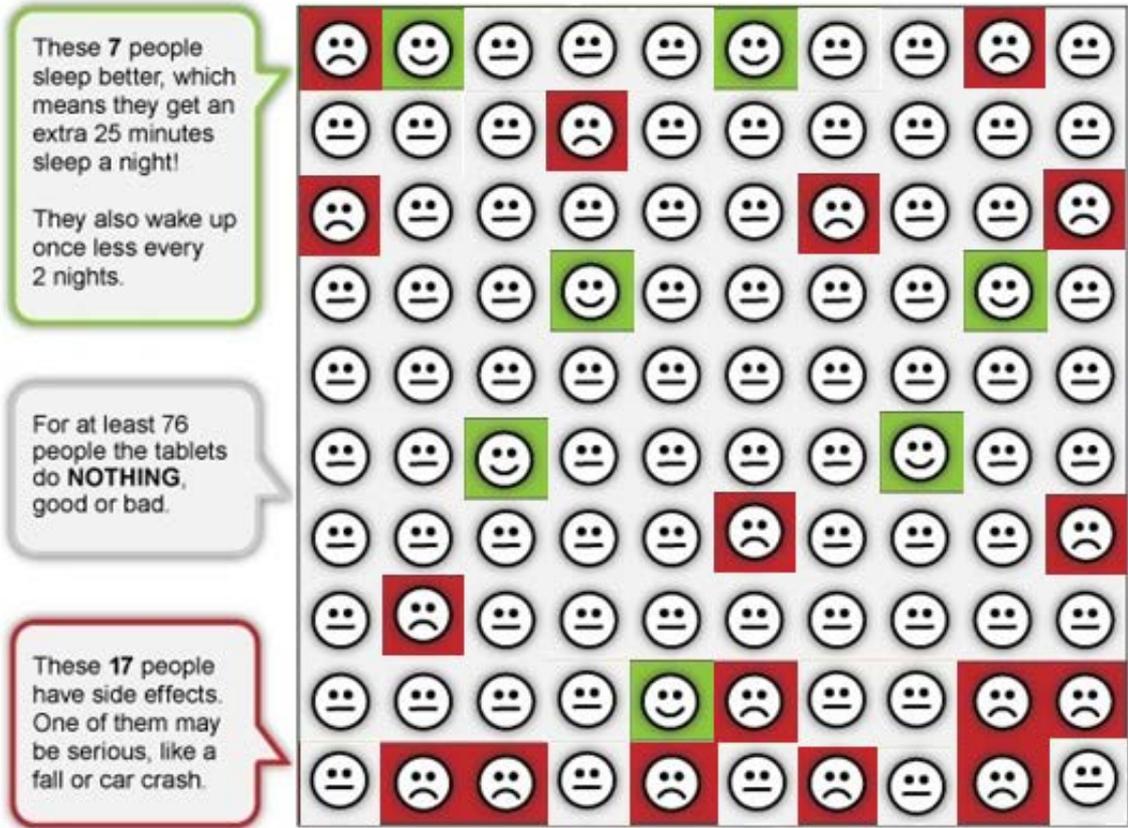
[BMJ 2005; 331:1169-75](#)

In people over 60, the benefits associated with sedative use are marginal and are outweighed by the risks, particularly if patients are at high risk for falls or cognitive impairment

<http://elearning.restproject.org.uk/#/background/hypnotic-prescribing/effects-of-sleeping-tablets>

Effects of sleeping tablets

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How people make decisions

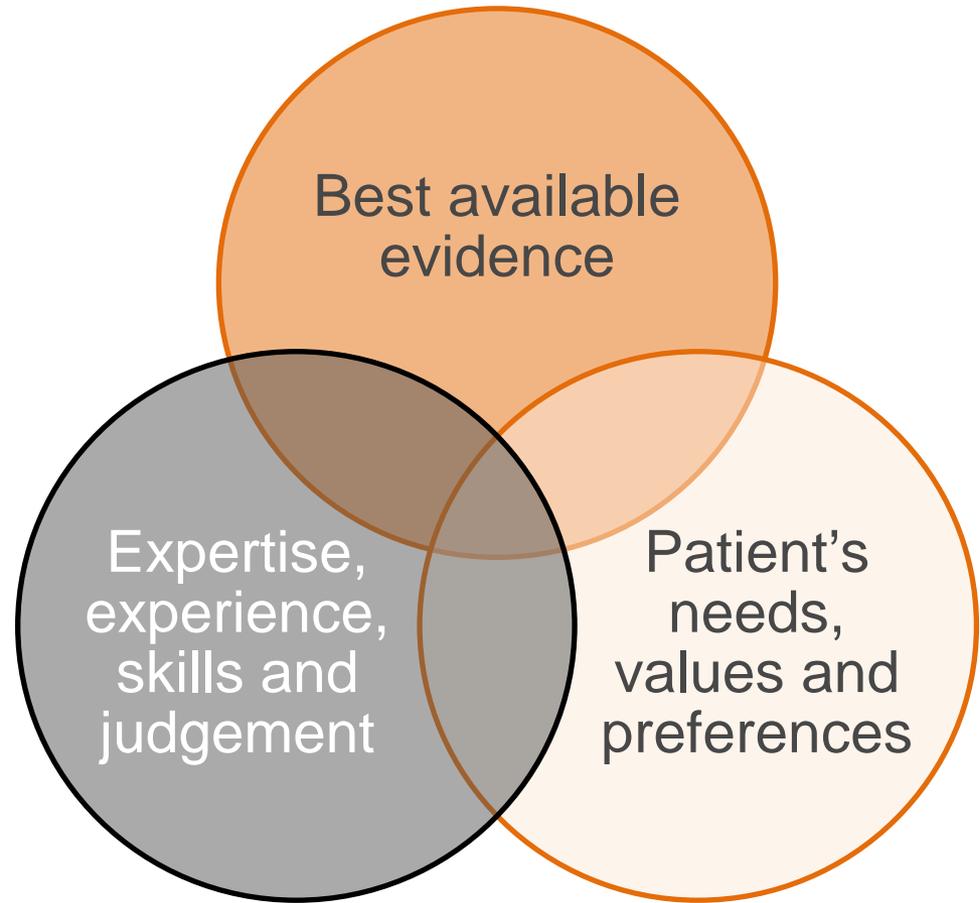
Jonathan Underhill



Why is this important?

Sackett D, et al. *BMJ* 1996; 312: 71

Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in **making decisions** about the care of **individual patients**



Have you ever thought about how you make decisions?



Please find a piece of paper and a pen

- A list of words follows
- Look at them once, do not re-read them
- When you have read the list close your eyes

Flange
Routemaster
Laggard
Sausages
Automaton
Approach
Antichrist
Research
Slipper
Haggle
Fridge
Locomotive
Bracket
Confused
Telesales
Professor
Stool pigeon
Hale
Banquet
Irrelevance

Write down as many words as you can remember

How many words
that you remembered
are in each group?

A

Flange
Routemaster
Laggard
Sausages

B

Automaton
Approach
Antichrist
Research

C

Slipper
Haggle
Fridge
Locomotive
Bracket

D

Confused
Telesales
Professor
Stool pigeon

E

Hale
Banquet
Irrelevance



RATIONAL DECISION-MAKING IN BUSINESS ORGANIZATIONS

Nobel Memorial Lecture, 8 December, 1978

by

HERBERT A. SIMON

Carnegie-Mellon University*, Pittsburgh, Pennsylvania, USA

Bounded rationality Satisficing



Choosing a car



- Imagine you are going to choose a new car
- What things will affect your decision?
- Where will you go to find that information?



The Official Site of The European New Car Assessment Programme



LATEST S



Audi A4
Large Family Car



Honda Jazz
Supermini

LEARN

- Articles
- Events
- Publications
- Standards
- Students
- Training/Education
- Webcasts/Video

SAE Standards

- Aerospace
- Automotive
- Commercial Vehicle

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SAE standards are internationally recognized for their role in helping ensure the safety, quality, and effectiveness of products and services across the mobility engineering industry. The more than 10,000 standards in the SAE database now include historical standards, and can be accessed through one of the targeted solutions below.

Get a Solution

- For:
- Enterprise
 - Small Business
 - Academia
 - Individuals

SAE Digital Library

The Digital Library is home to SAE's complete database of more than 200,000 technical papers, standards, eBooks, magazines, and related

Global Technology Libraries

Technology-focused databases of curated content from SAE and other respected publishers. Subscribers get access to the latest news and technical

Specialty Products

Specialty Products are online portfolios of SAE standards and technical papers focused on targeted technologies and industries.

JPaks

JPaks are a cost-effective way to download only as many SAE ground vehicle standards as you need. Annual subscriptions start at 10 downloads.

J1939 Standards

This convenient and cost-effective subscription provides comprehensive access to SAE's key standards and related information on the Controller

Unified Numbering System (UNS)

Unified Numbering

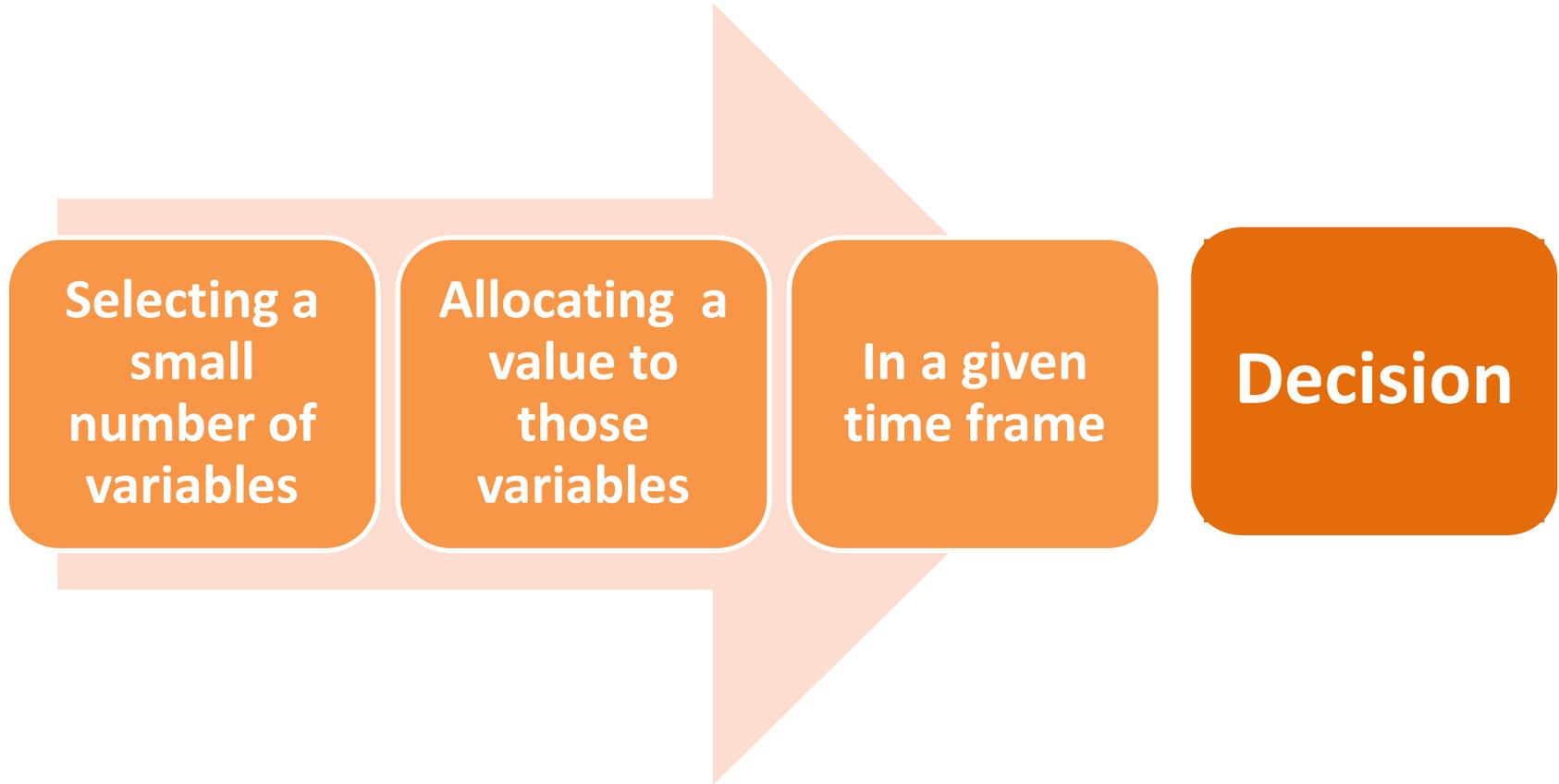
Handbook Supplements

These printed manuals compile

TechSelect

TechSelect is a cost-effective way to

Humans usually make decisions by...



Satisficing

Do clinicians make decisions like that?

Gabbay J and le May A. BMJ 2004; 329: 1013

- Not once was a guideline read
- Expert computer systems rarely used (never in real time)
- Shortcuts to evidence
 - free magazines
 - network of trusted colleagues (rarely if ever questioned)
 - Pharma reps: considerable scepticism (but not without influence)
 - Pharmaceutical adviser: highly trusted source

“Clinicians rarely accessed, appraised, and used explicit evidence directly from research or other formal sources; rare exceptions were where they might consult such sources after dealing with a case that had particularly challenged them.”

Mindlines

Gabbay J and le May A. *BMJ* 2004; 329: 1013



Keele University
Centre for
Medicines Optimisation

“Instead, they relied on what we have called ‘**mindlines**’, collectively reinforced, internalised tacit guidelines, which were informed by **brief reading**, but mainly by their **interactions with each other** and with opinion leaders, patients, and pharmaceutical representatives and by other sources of largely tacit knowledge that built on their early training and their **own and their colleagues' experience**.”

Say **out loud** who or what you see on
the screen



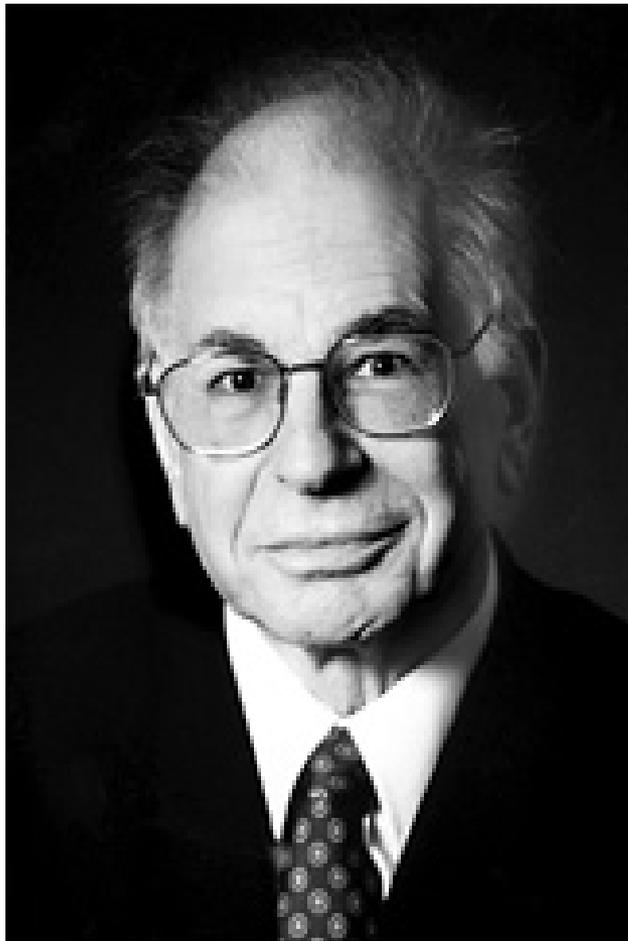
Prime Minister
4th May 1979 -
28th November 1990

What is this condition?



What treatment
does this
person need?





MAPS OF BOUNDED RATIONALITY:
A PERSPECTIVE ON INTUITIVE JUDGMENT
AND CHOICE

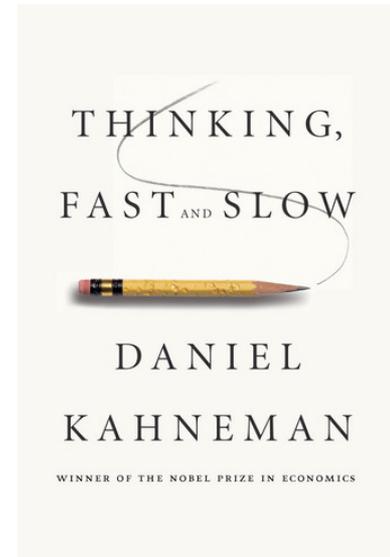
Prize Lecture, December 8, 2002

by

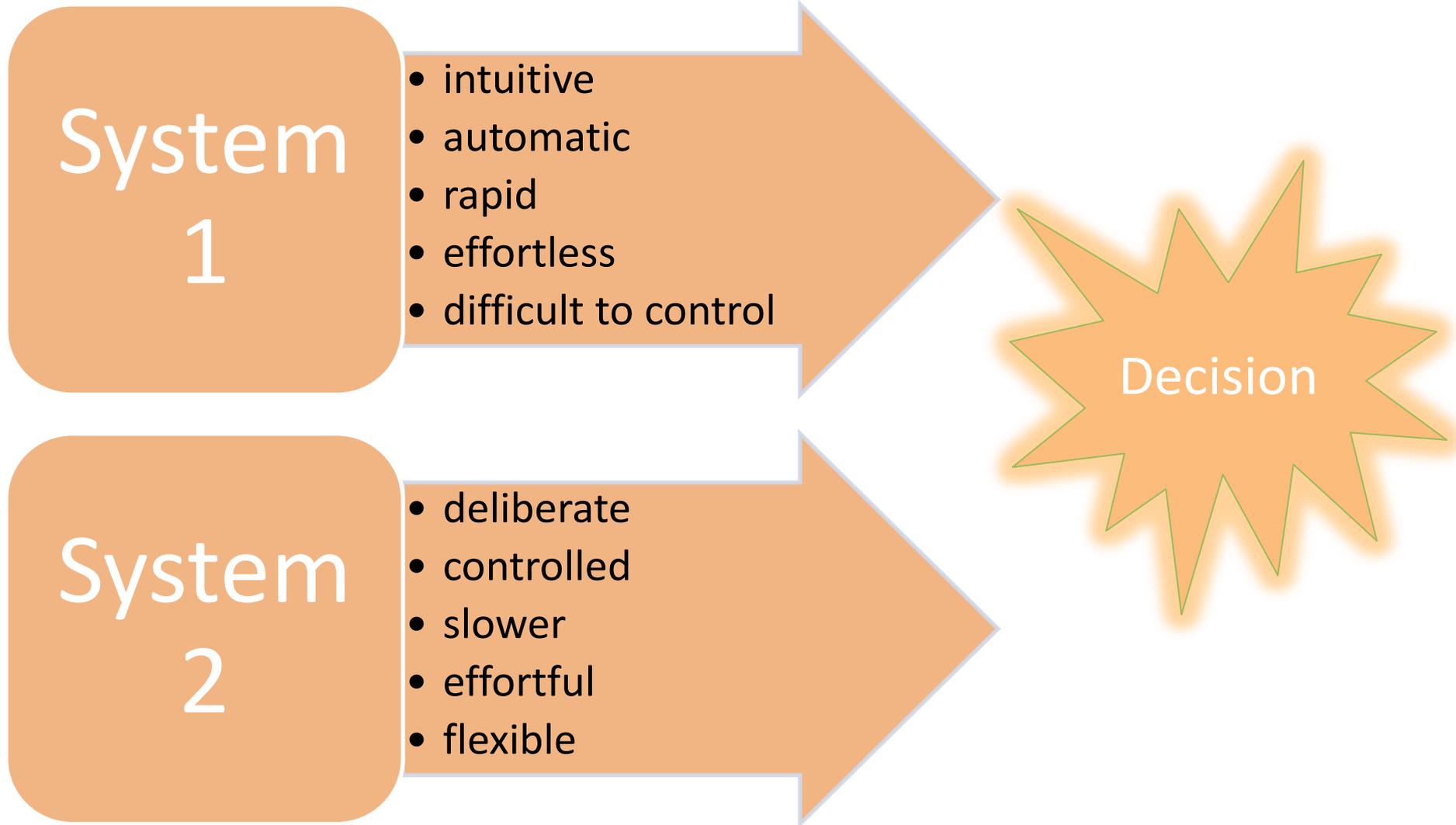
DANIEL KAHNEMAN*

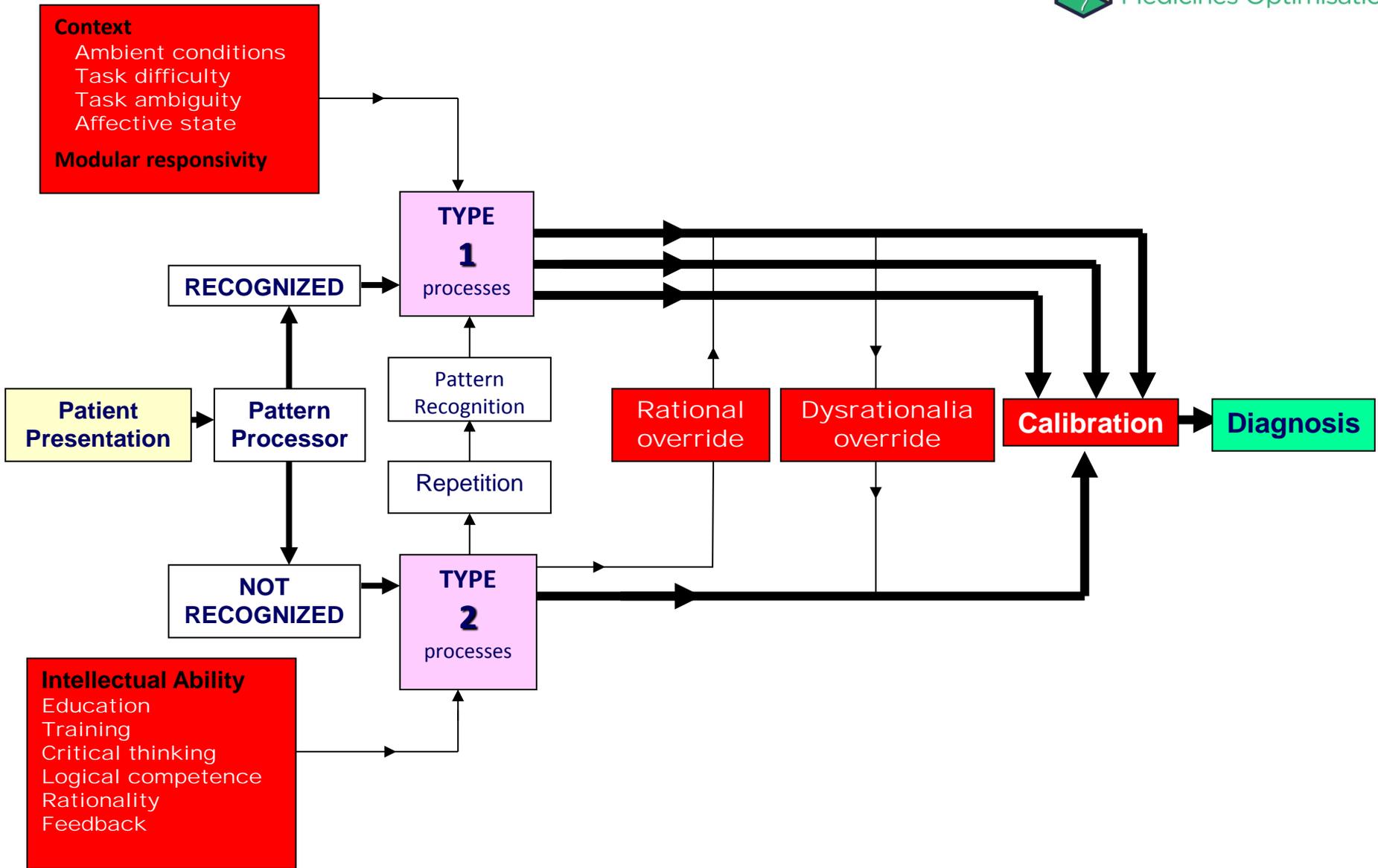
Princeton University, Department of Psychology, Princeton, NJ 08544, USA.

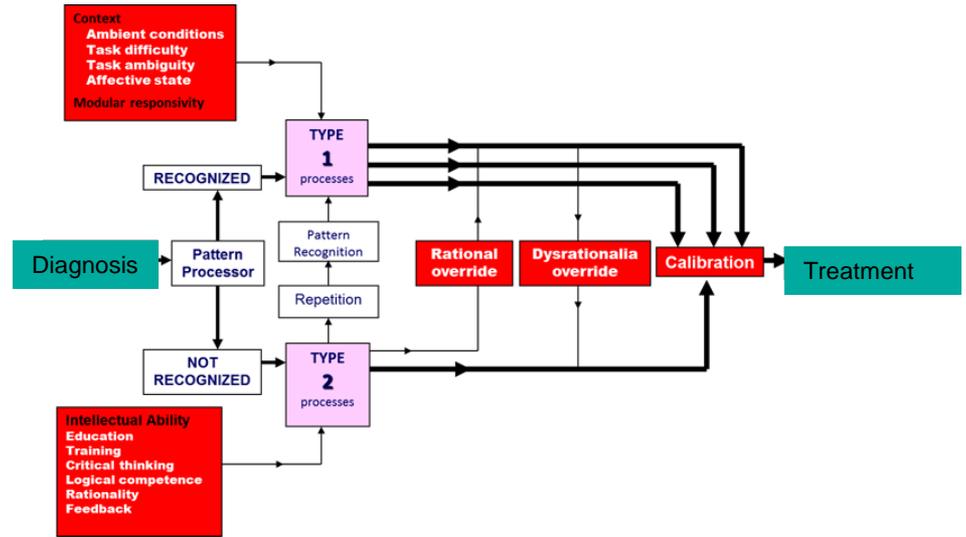
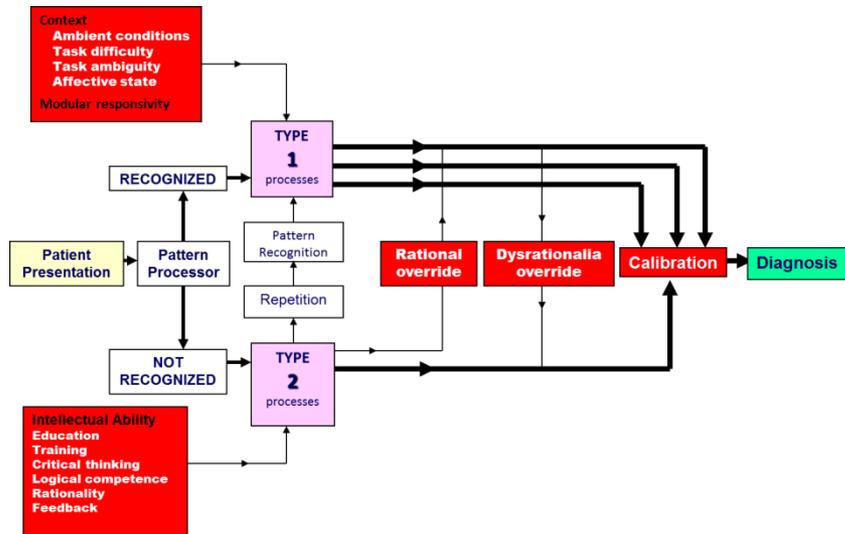
Dual-process theory
Human judgement
Heuristics & biases



Dual-process theory









Steve is very shy and withdrawn, invariably helpful, but with little interest in people. He has a need for order and structure and a passion for detail

It is most likely that Steve is a

1. Farmer or agricultural worker
2. Pharmacist
3. Disc jockey
4. Librarian
5. Member of Parliament

Who knows the story of Noah in the Bible?

- Imagine you are working as the only health care professional in a remote village
- It's the weekend
- There are no other health care professionals around
- But you do have a new piece of technology called the **Marveltron**

- The **Marveltron** will save the life of any patient you are treating
- But you have to answer correctly the question the **Marveltron** asks of the attending healthcare professional before it works its magic

- A young child is brought to you. She is seriously ill and will die imminently
- You switch on the **Marveltron** and await the question
- You must write down your answer immediately the question is asked, or the child will die
- You will be blamed for the patient's death only if you do not write down an answer. No blame will be attached to you if you get the answer wrong
- **Are you ready?**
- Have you got paper and something to write with?

In the story in the Bible, how many sheep did Noah take into the Ark?

How many sheep?

-  0
-  1
-  2
-  3
-  4
-  5
-  6
-  7
-  More than 7

The correct answer - 14

Take with you **seven pairs of every kind of clean animal**, a male and its mate, and **one pair of every kind of unclean animal**, a male and its mate, and also seven pairs of every kind of bird, male and female, to keep their various kinds alive throughout the earth.

Genesis 7: 2-3

Do not eat any detestable thing. **These are the animals you may eat**: the ox, the **sheep**, the goat, the deer, the gazelle, the roe deer, the wild goat, the ibex, the antelope and the mountain sheep. You may eat any animal that has a divided hoof and that chews the cud.

Deuteronomy 14: 3-6

- Where did you get the information to make the decision about Noah and the sheep?
- If you had had time, what would you have done to make sure you had the right answer?

All together, big breath in.....

What is the answer to this sum?

$$2 + 2 =$$

All together, big breath in.....

What is the answer to this sum?

$$75 \times 56 =$$

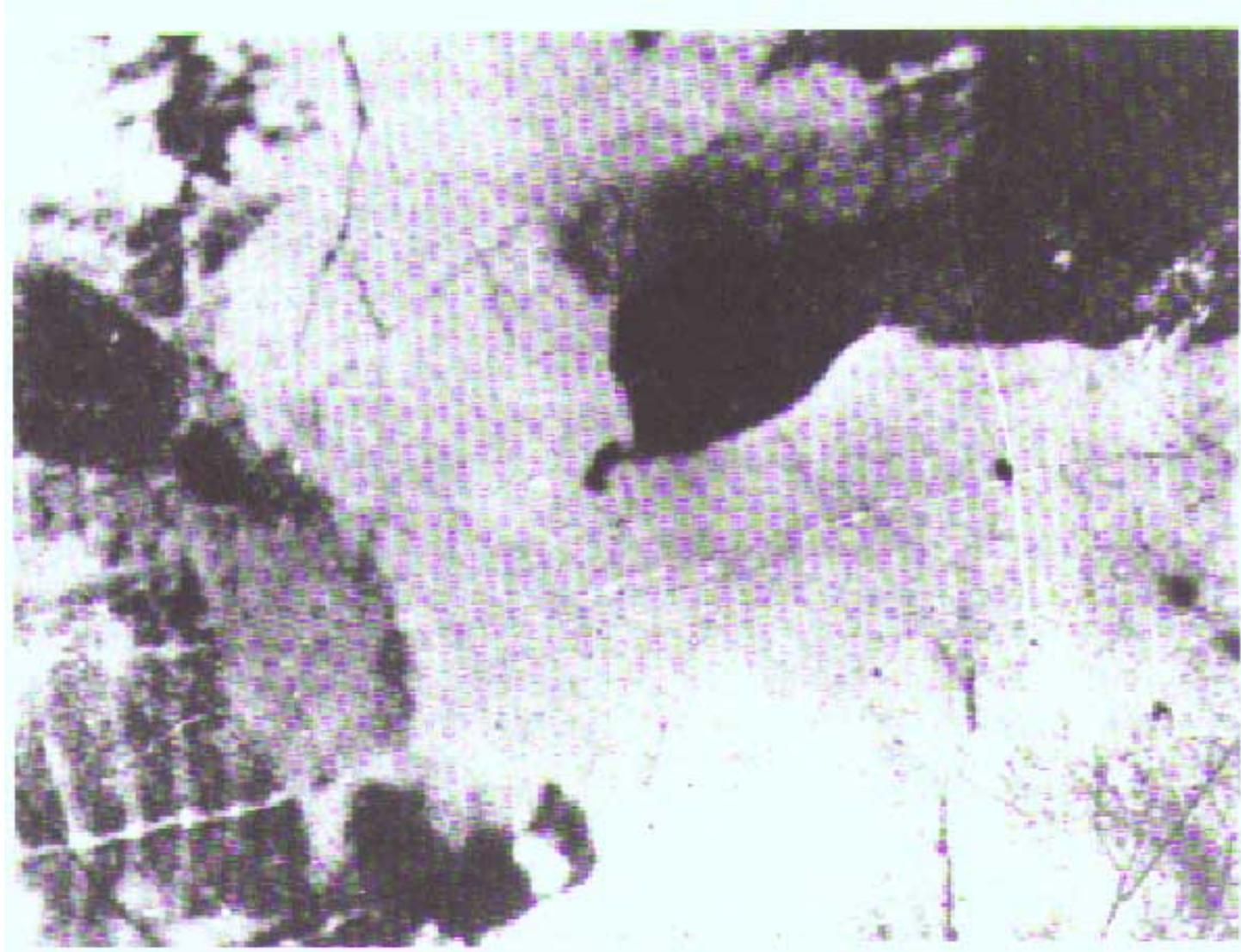
All together, big breath in.....

Is the answer to this sum right or wrong?



$$75 \times 56 = 678$$

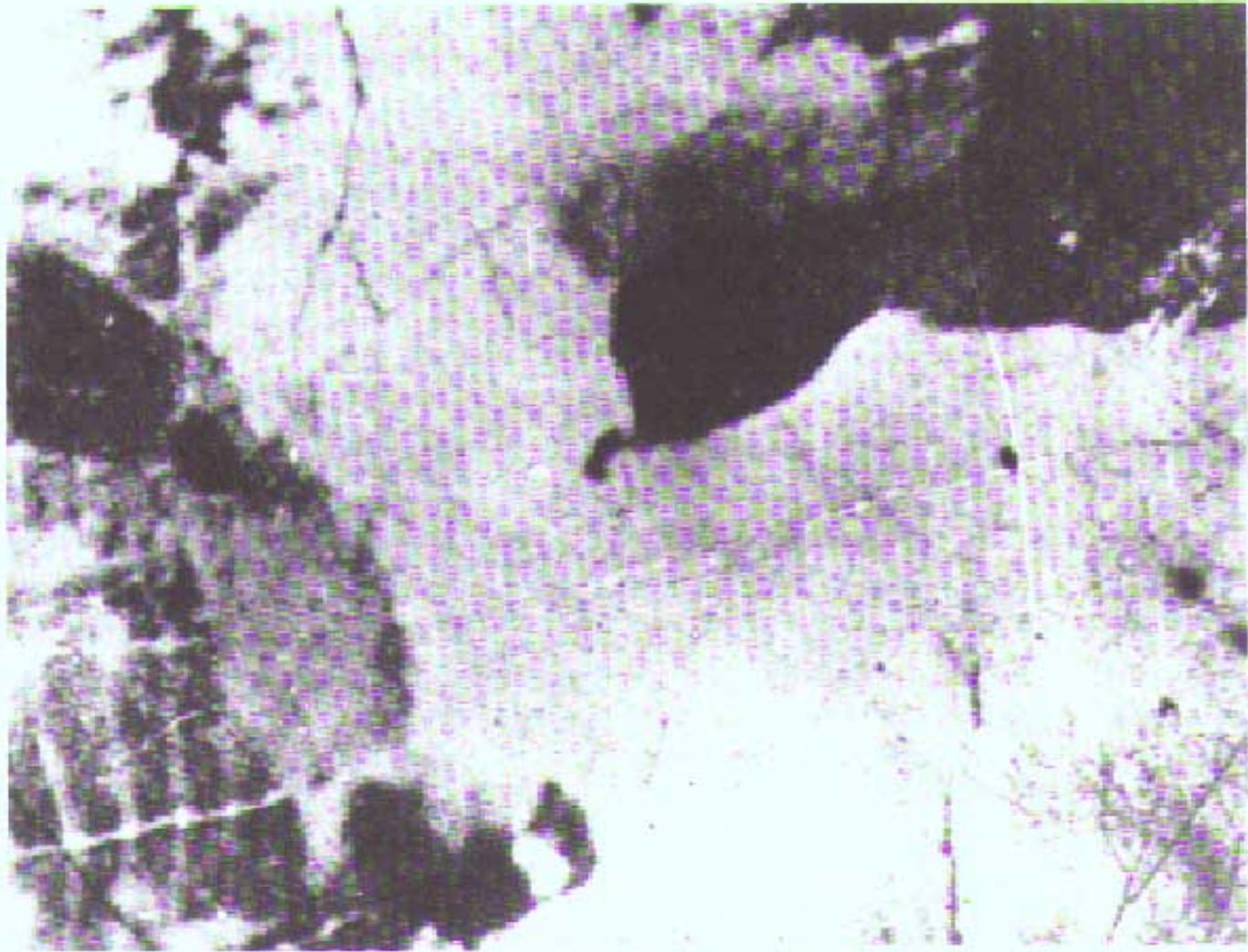
Say **out loud** who or what you see on
the screen

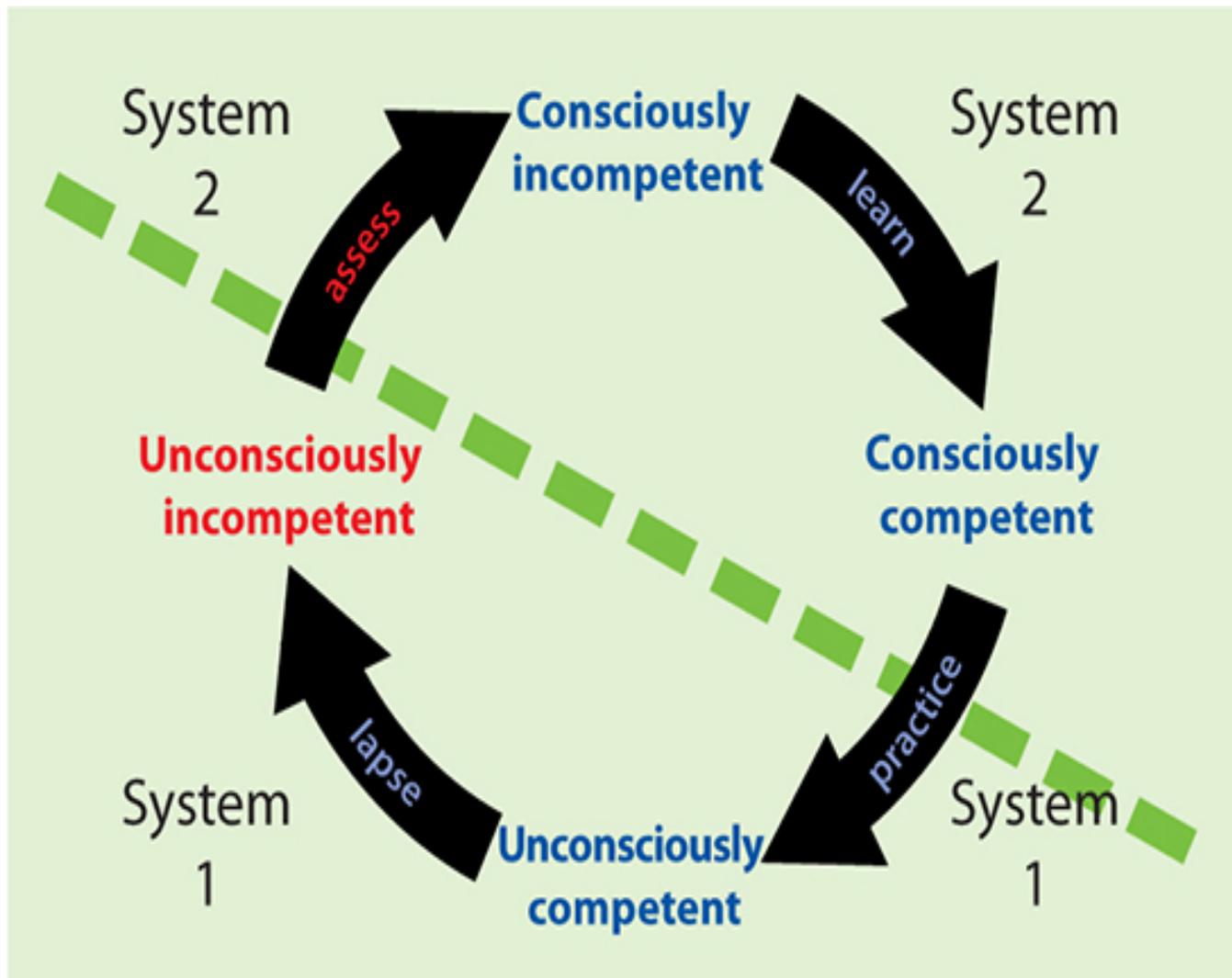














The 3 components of Information Mastery



Slawson DC, et al. J Fam Pract 1994;38:505–13

Maskrey N, et al. InnovAiT 2009;2:739–49

Information Mastery



Foraging

a reliable system to alert you to new information that requires a change in your practice

Hunting

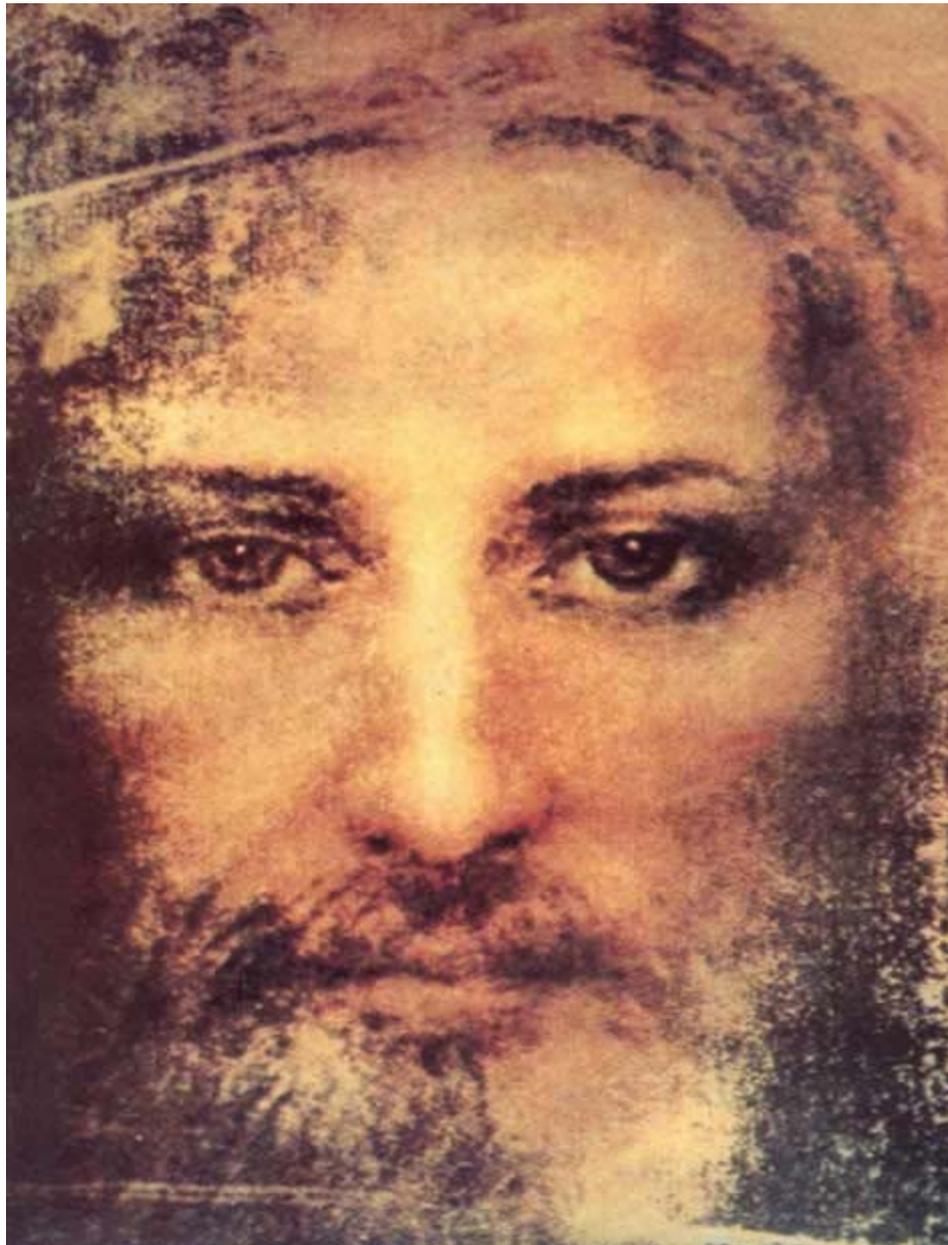
a reliable system to find the best answer to a specific question

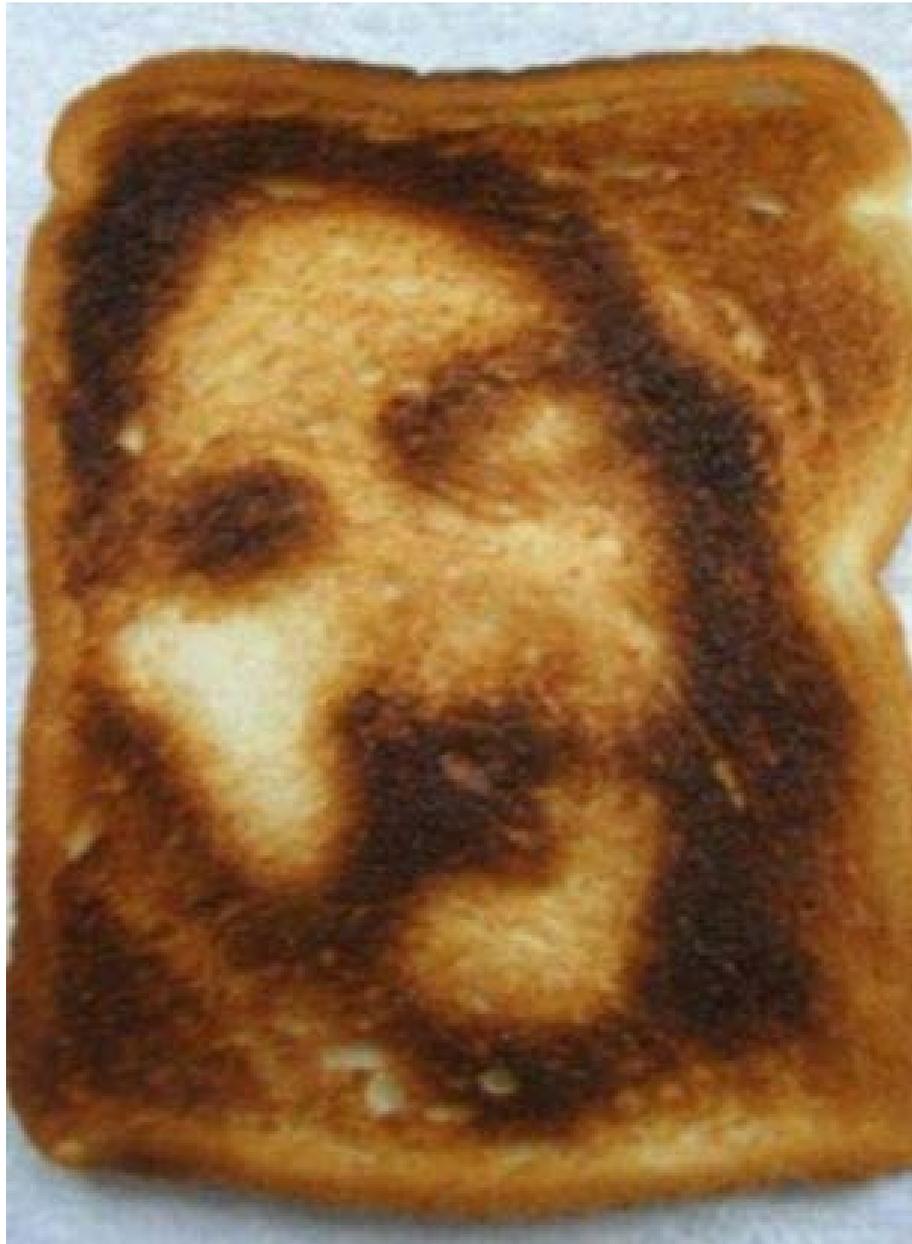
Hot synching

purposefully checking and updating your mental map of knowledge and skills once or twice a year

How dual-process theory and information mastery tie up

- We can support our **System 1** thinking with an effective **hot-synching** approach
 - Our mindlines will be in line with the evidence for the conditions we see most commonly
 - This is ‘offline’ System 2 work
- A good **foraging** service will alert us to new important information as it comes along
 - It can also help identify learning needs
- When we need to use **System 2**, a good **hunting** approach will help us find the **best** answer quickly, and know we’ve found it









>100 cognitive biases

- Anchoring bias – early salient feature
- Ascertainment bias – thinking shaped by prior expectation
- Availability bias – recent experience dominates evidence
- Bandwagon effect – we do it this way here
- Omission bias – natural disease progression preferred to those occurring due to action of physician
- Sutton's slip – going for the obvious
- Gambler's fallacy – I've seen 3 recently; this can't be a 4th
- Search satisficing – found one thing, ignore others
- Vertical line failure – routine repetitive tasks leading to thinking in silo
- **Blind spot bias – other people are susceptible to these biases but I am not**

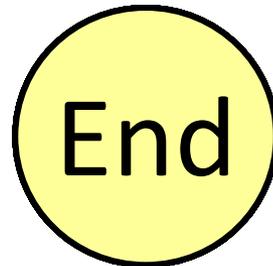
When do 'errors' occur?

Please find a piece of paper and write down your answers to each of these six questions

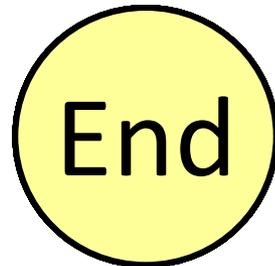
You have 10 seconds for each response

On a fire engine, there are 2 drivers up front, one at the rear and four additional fire-fighters

What is the total personnel required for standard engines? 5

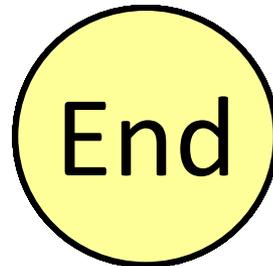


**How many turtle doves did my true love send
me on the 2nd day of Christmas?**



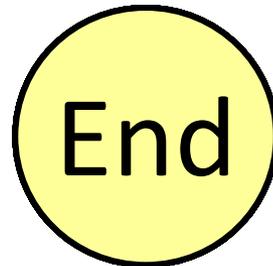
In 2015, the average time required to complete a root cause analysis was 15½ hours

How much time should be allowed for the three that are expected next month?

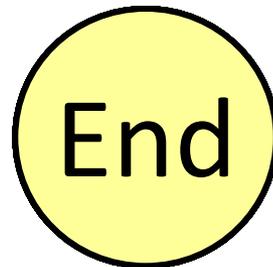


A bat and a ball cost £1.10 in total. The bat costs
£1.00 more than the ball

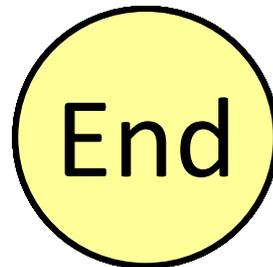
How much does the ball cost?



If it takes 5 machines 5 minutes to make 5 widgets, how long would it take 100 machines to make 100 widgets?



In a lake, there is a patch of lily pads. Every day, the patch doubles in size. If it takes 48 days for the patch to cover the entire lake, how long would it take for the patch to cover half the lake?



Answers

- A. 35 personnel on the fire engines (7×5)
 - B. 2 turtle doves
 - C. $46\frac{1}{2}$ hours ($15\frac{1}{2} \times 3$)
-

- A bat and a ball cost £1.10 in total. The bat costs £1.00 more than the ball. How much does the ball cost?
 - **The ball costs 5p (and the bat £1.05)**
- If it takes 5 machines 5 minutes to make 5 widgets, how long would it take 100 machines to make 100 widgets?
 - **5 minutes**
- In a lake, there is a patch of lily pads. Every day, the patch doubles in size. If it takes 48 days for the patch to cover the entire lake, how long would it take for the patch to cover half the lake?
 - **47 days**

Cognitive Reflective Test

Frederick S *Journal of Economic Perspectives* 2005; 19: 25



Keele University
Centre for
Medicines Optimisation

- The test measures ‘cognitive reflection’ – the ability or disposition to resist the response that first comes to mind
 - Distinguishes intuitive (system 1) from analytical (system 2) processing
- Of 3,428 people tested (mostly undergraduates) only 17% got all 3 correct
 - 33% answered all 3 incorrectly

The PRAcTICe study (1)

Avery T, et al. Report for the GMC 2012

- Study to determine the prevalence and nature of prescribing errors in general practice, explore the causes, and to identify defences against error
 - Review of 6,048 unique prescription items for 1,777 patients in 15 general practices in England
 - Interviews with 34 prescribers regarding 70 potential errors; 15 root cause analyses, and 6 focus groups involving 46 primary health care team members
- Prescribing or monitoring errors detected for 1 in 8 patients, involving around 1 in 20 of all prescription items
 - 1 in 550 items associated with a severe error

The PRAcTICe study (2)

Avery T, et al. Report for the GMC 2012

| Most commonly prescribed (% of all items) | Most commonly associated with prescribing errors (% all errors) |
|--|--|
| Amoxicillin (3.5%) | Simvastatin (10.5%) |
| Paracetamol (2.8%) | Amoxicillin (2.8%) |
| Simvastatin (2.6%) | Influenza vaccine (2.4%) |
| Aspirin (2.3%) | Diclofenac sodium (2.4%) |
| Influenza vaccine (1.8%) | Betamethasone valerate (2.0%) |
| Omeprazole (1.8%) | Ibuprofen (2.0%) |
| Ibuprofen (1.7%) | Aciclovir (1.6%) |
| Ramipril (1.5%) | Allopurinol (1.6%) |
| Flucloxacillin (1.4%) | Flucloxacillin (1.6%) |
| Levothyroxine (1.4%) | Fucibet (1.6%) |
| Lansoprazole (1.3%) | Hydrocortisone cream (1.6%) |
| Amlodipine (1.2%) | Meloxicam (1.6%) |



Prescriber

- therapeutic training, drug knowledge and experience, knowledge of the patient, perception of risk, and physical and emotional health

Pat

“While some GPs suggested that knowing their patients well

- p was helpful in terms of medication safety, **others commented on the risk of becoming blasé and not properly reviewing**

The

patients to check the safety and appropriateness of their medications.

– p

This was evident when, as part of our study, **we detected patterns of hazardous prescribing that had been going on for many years on repeat prescription** without apparent challenge.”

Personal strategies for improved performance

- Decrease reliance on memory
 - Use cognitive aids (but use them wisely)
 - Decision support, mnemonics, guidelines, algorithms etc.
- Try to make tasks easier
 - e.g. calculate drug doses on paper (not in your head)
- Be aware of own affective state
 - Especially time pressures
- Be aware of our decision mode
 - System 1 or System 2



Personal strategies for improved performance

Heighten metacognition

- Step back from the problem to:
 - reflect on the thinking
 - reflect on the affective process

Consider alternatives

- Routinely think: “If I am wrong what else might be going on?”
- Rule out worst case scenario

Seek incongruent data

- Don't be afraid to try and prove you are wrong

Reconsider dissonant facts

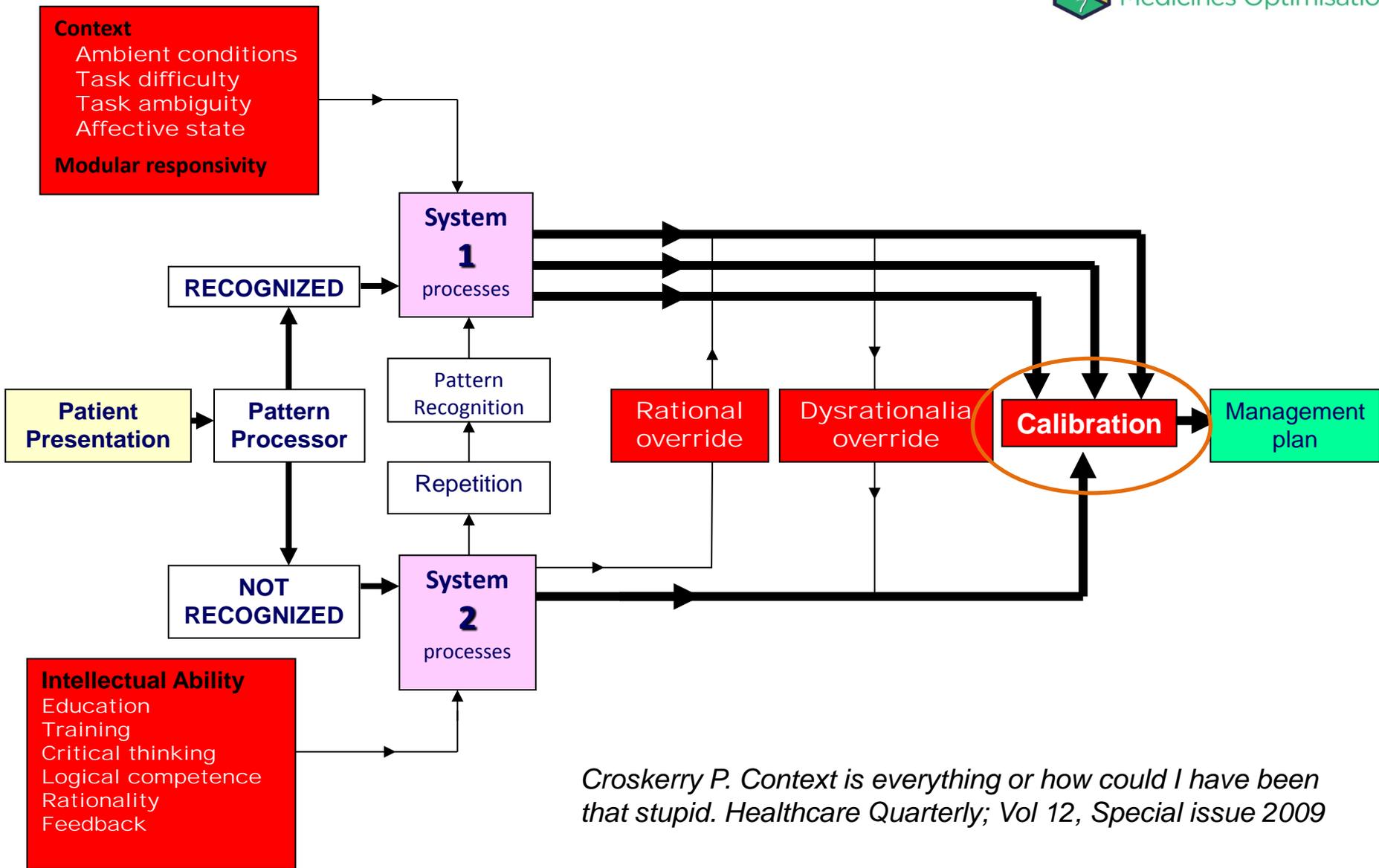
- Take a step back from the problem



Personal strategies for improved performance

- Reframe when recording
 - Mentally reconsider meaning
 - Reassess the associations you have created
- Establish accountability in a given situation
 - Who is doing what?
 - Who is responsible for what?
- Non-judgemental, constructive feedback
 - Be a giver
 - Be a welcoming receiver

**What's our single best hope for
reducing errors?**



Croskerry P. Context is everything or how could I have been that stupid. Healthcare Quarterly; Vol 12, Special issue 2009

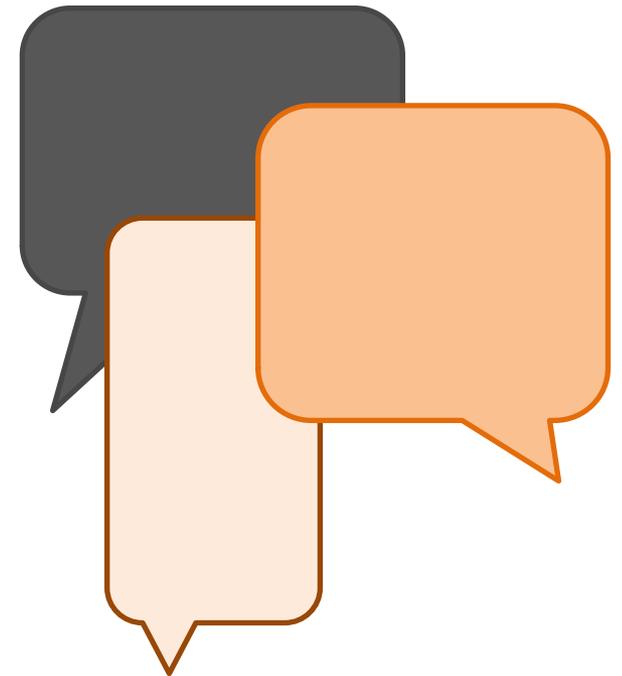
Stop

Think



Comments?

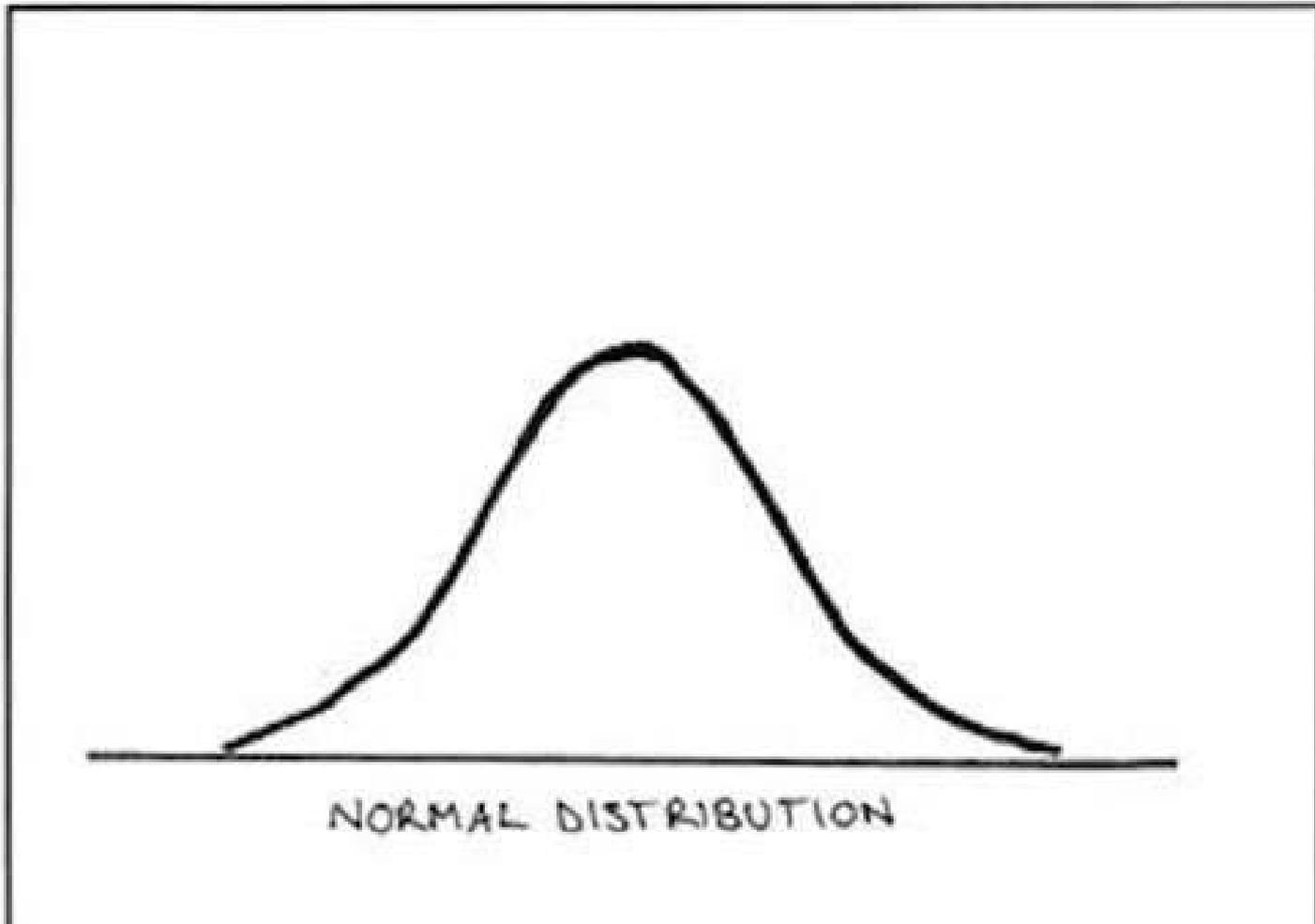
Questions?





Promotion and advertising messages

Stephen Chapman
(advert images removed due to
copyright constraints)

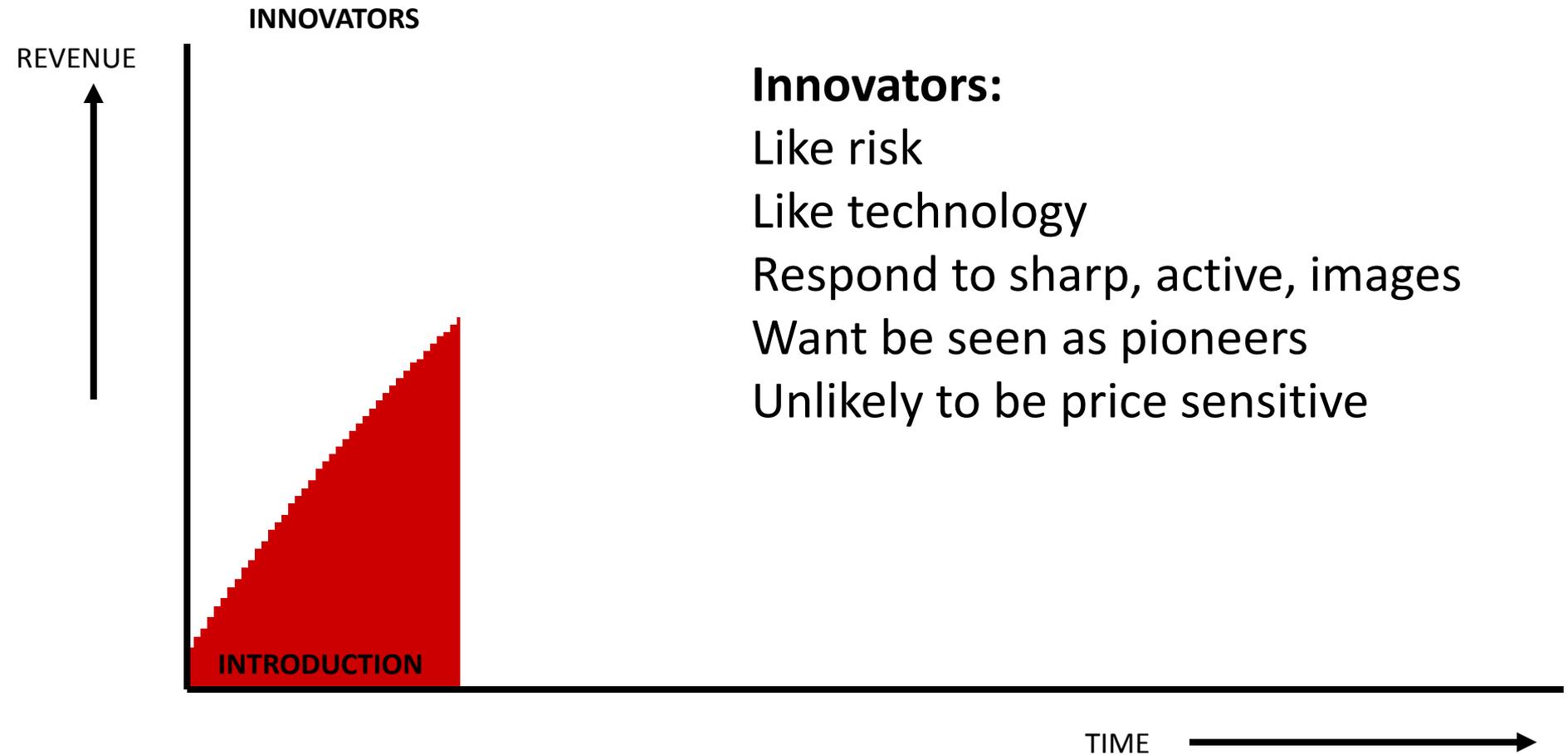




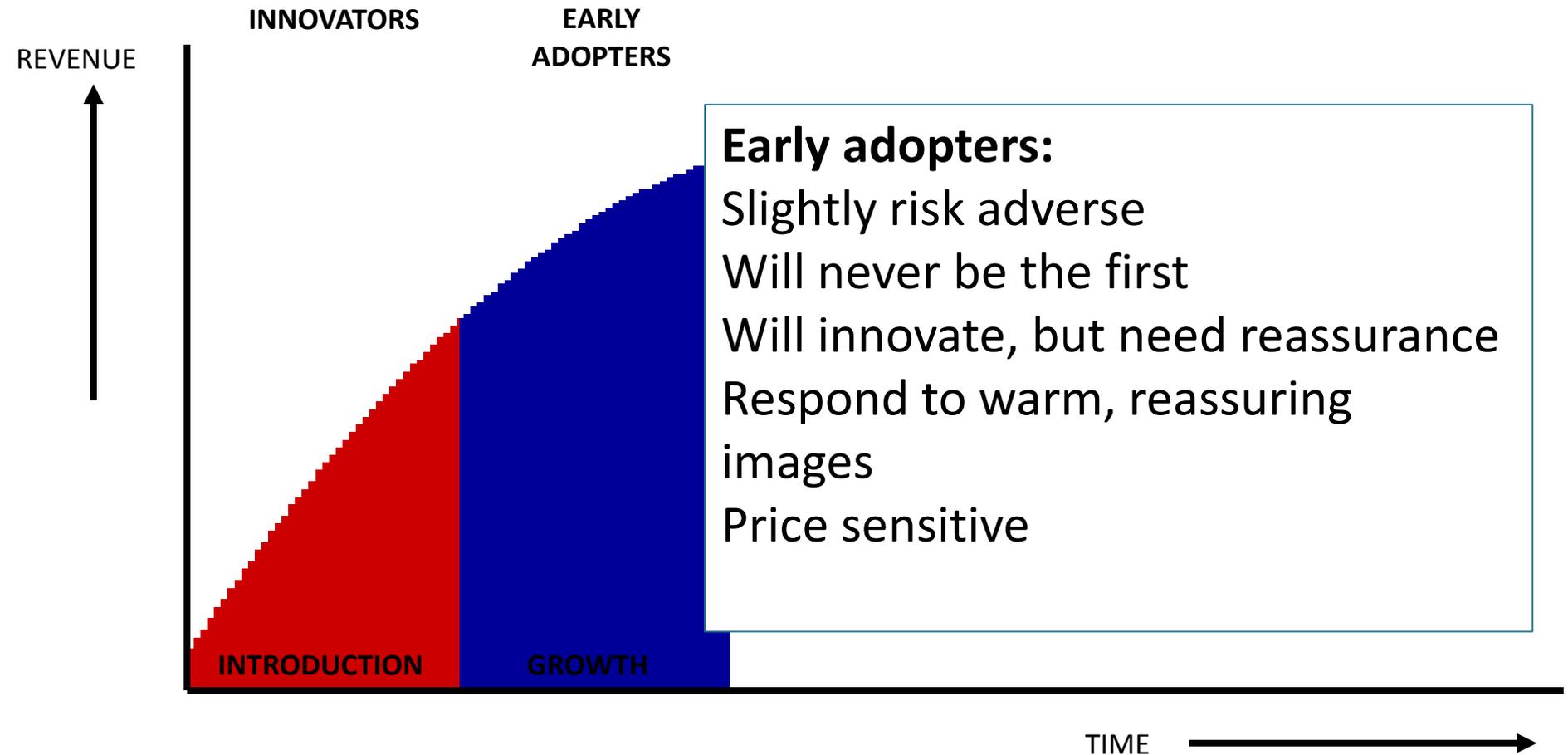
PARANORMAL DISTRIBUTION

Frenn.

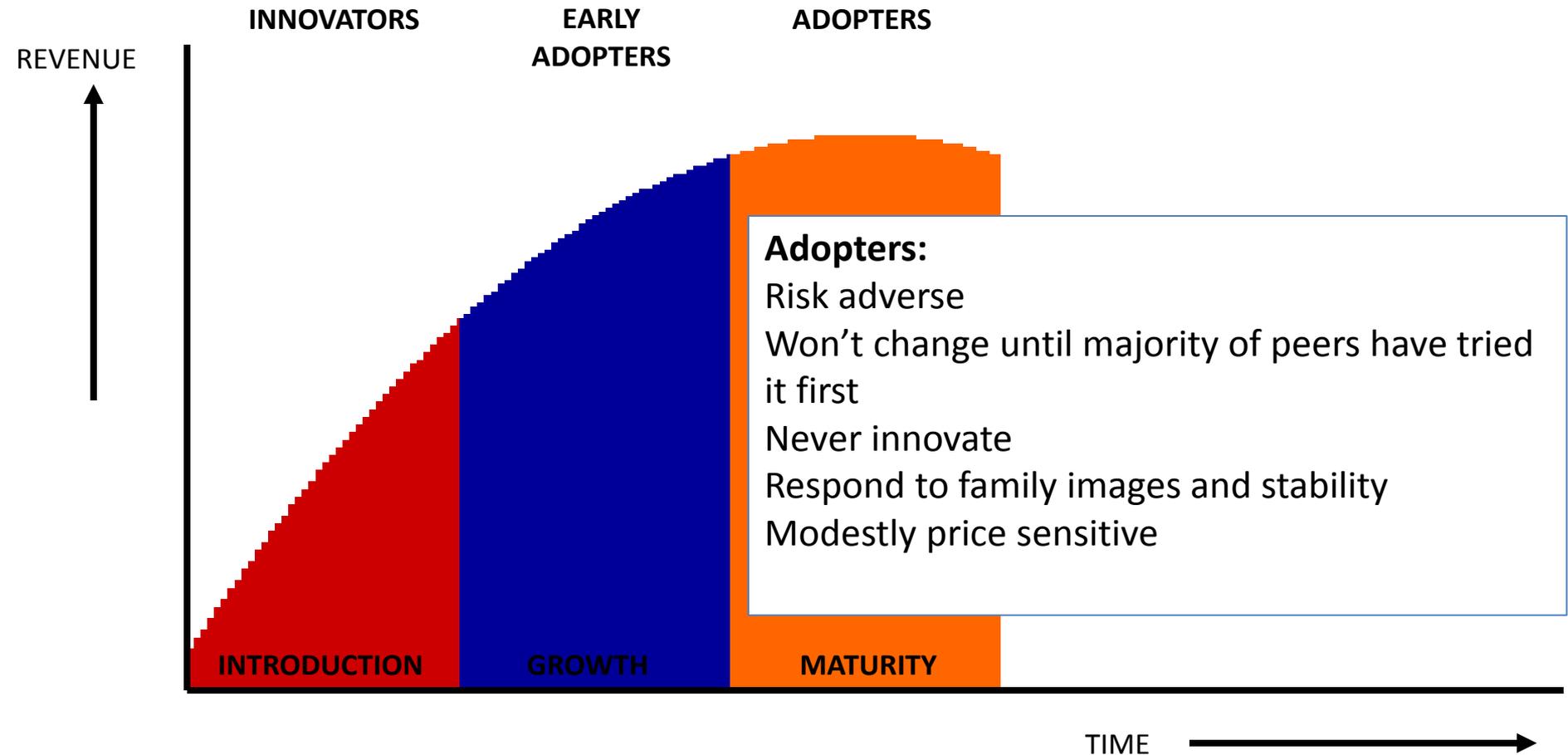
Typical Product Life Cycle; 1st year



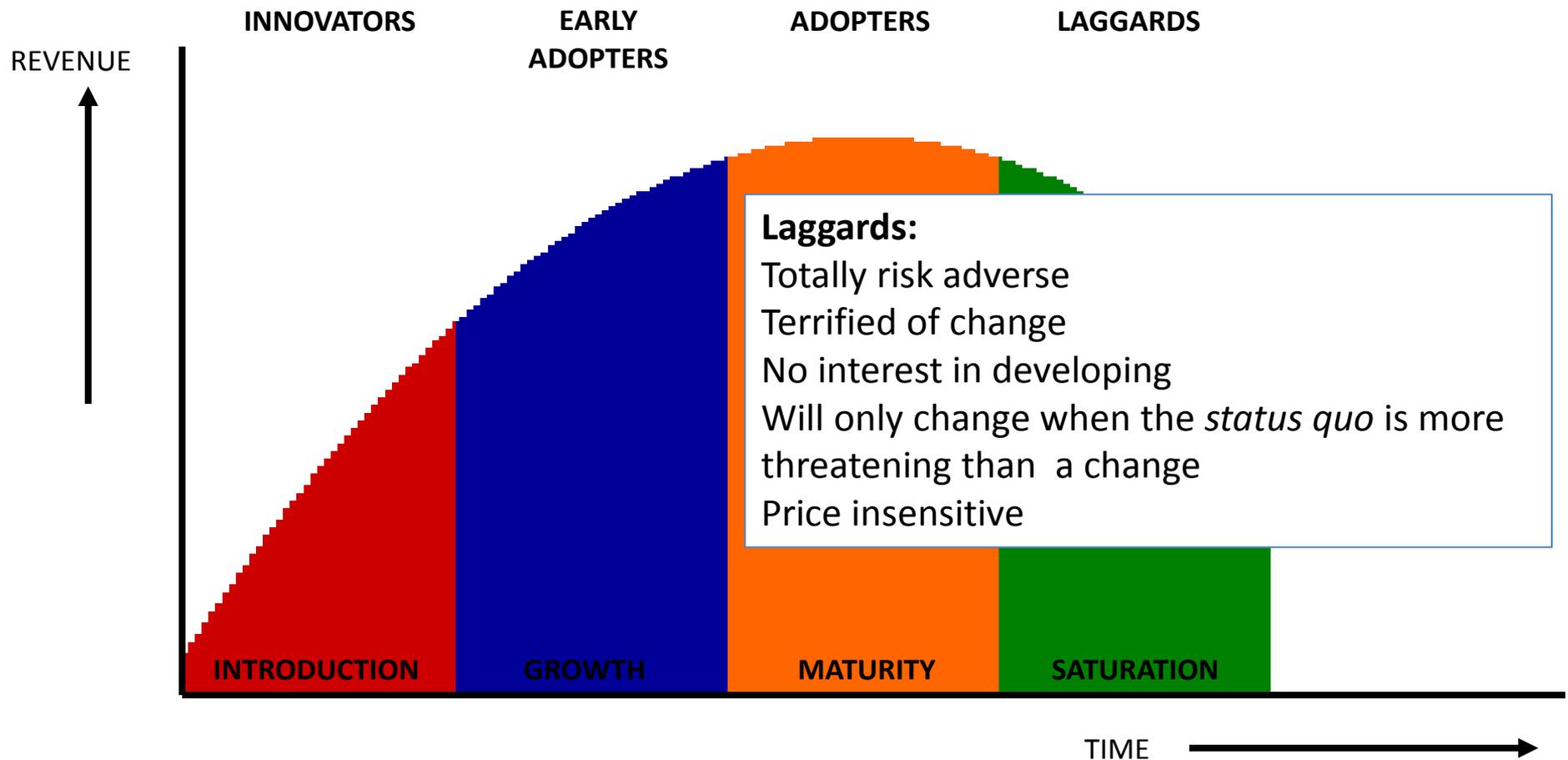
Typical Product Life Cycle; 2-4years



Typical Product Life Cycle; 4-8years



Typical Product Life Cycle; 8-10 years



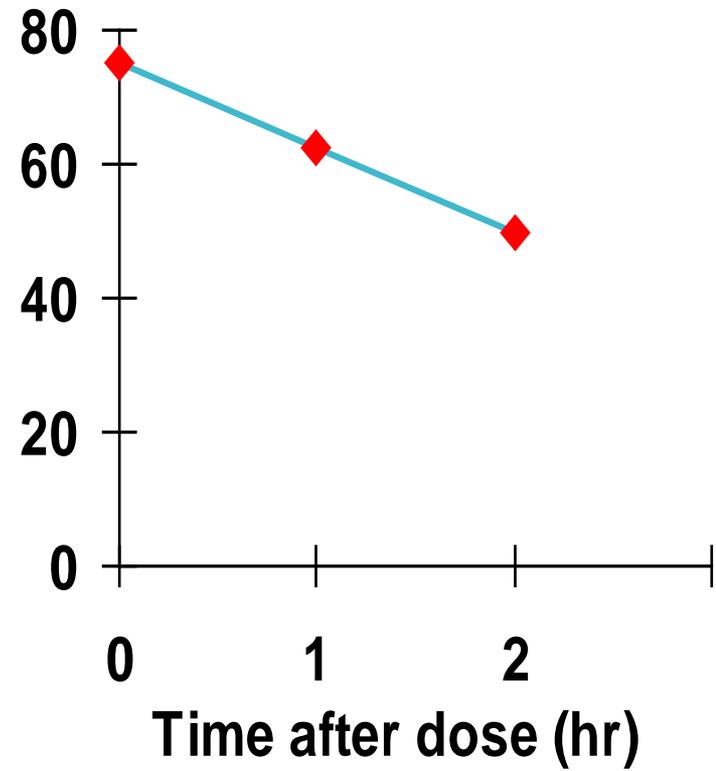
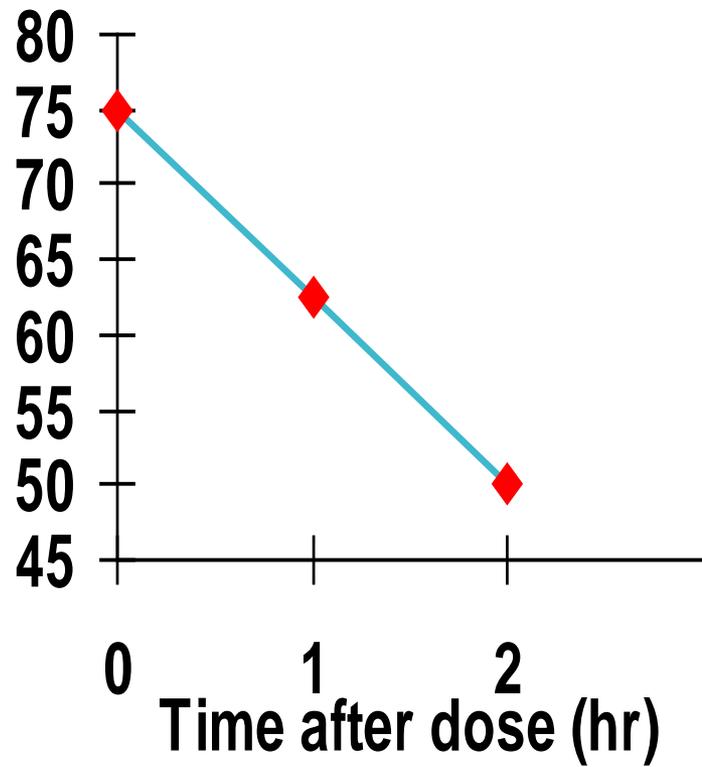


Promotional material

- advertisements
- material from industry representatives
- Often NOT a reliable source of information!
- selected results, most favourable stats
- graphical tricks
- references to unpublished sources
- unsubstantiated or misleading claims
- emotional appeal

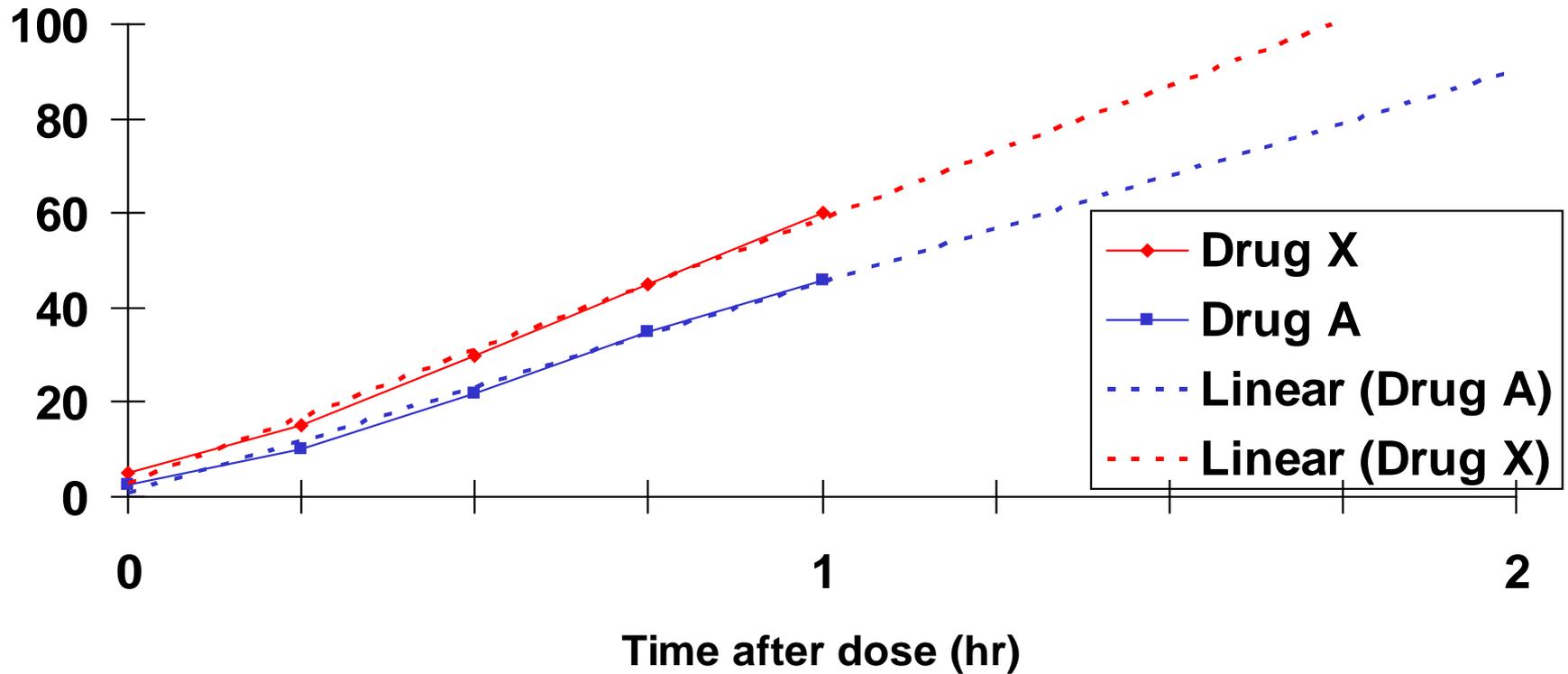


Axial distortion





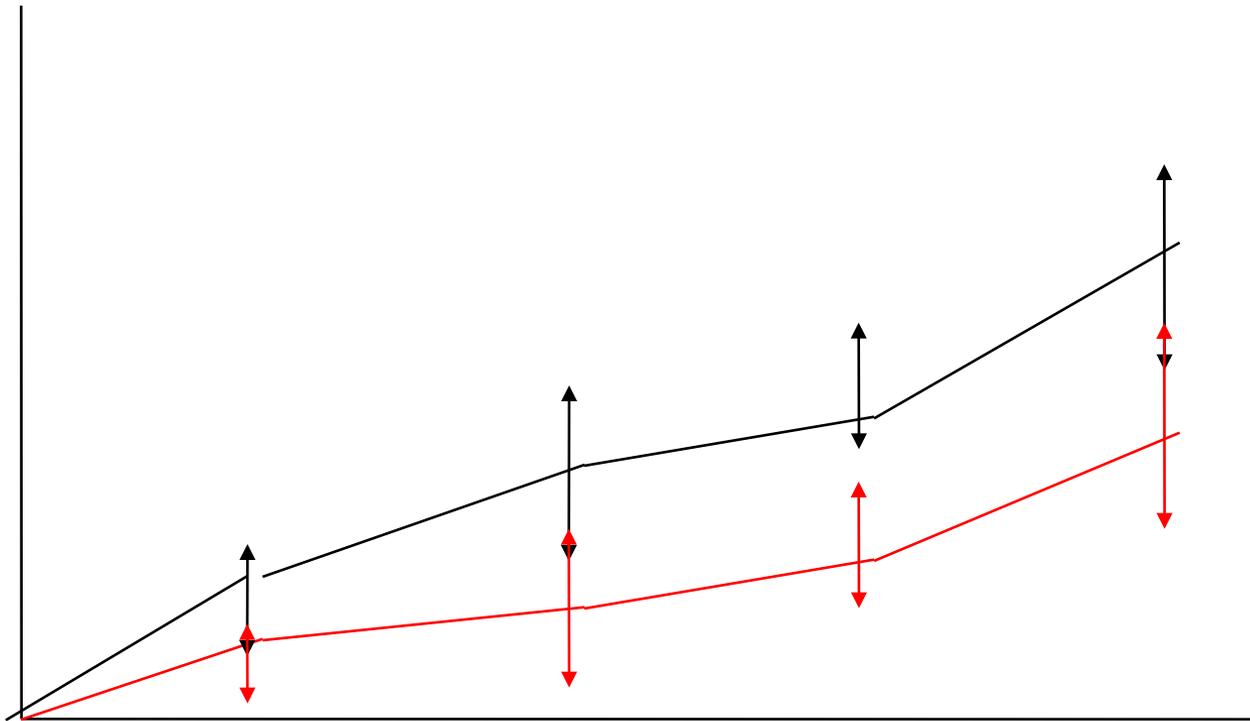
Extrapolation





Indication of variance

e.g. standard error bars





Promotional material - tricks

- Poor evidence
- Graphical tricks
- Poor references
- Unsubstantiated or misleading claims
- Emotional appeal



Group activity

- Open advertising pack on the table
 - Look at the adverts you have:
 - What claims are made?
 - Do you think it's true? What is the supporting evidence?

- If you were the editor of the BMJ or PJ would you accept these adverts?
- Justify why or why not.



"We can't find anything wrong with you,
so we're going to treat you for
Symptom Deficit Disorder."



Any questions?

What next?

Summary of the day and review/action planning