

Decision Criteria

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Content and Objectives

- To explain the consequences of bad decision making
- Understand the role and use of Health Economic tools to Decision Makers
- Understand the development of criteria for evidence based decision making
- To show that even “**good**” decisions can cause political problems
- Sources of Evidence
- Evidence Constraints
 - Rare Diseases
- Synthesising Evidence
- Value of information
- Patient Registries
- Other Real World Evidence

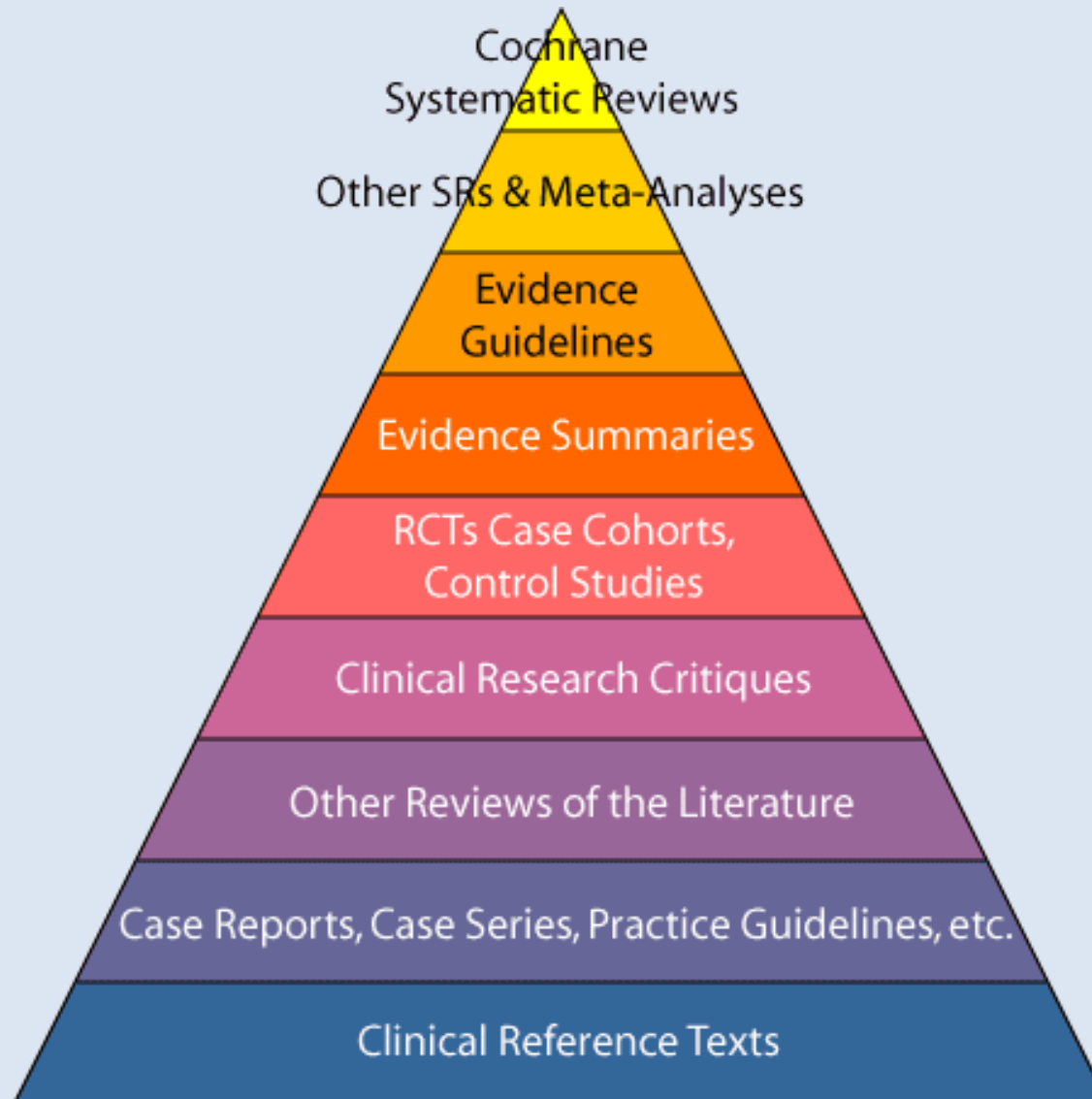
Due Care

- At what point do healthcare decisions harm patients?
- Litigation - In court - Burden Of Proof!
 - The party bringing the litigation to court can show that he/she suffered injury
 - That the injury was caused by medical care
 - The providers care deviated from due care
 - HOW!
 - Previously:
 - » customary practice by practitioners in good standing
 - Best practice - Cost Effectiveness / other decision criteria

Backdrop to NICE

- Standing Medical Advisory Committee (SMAC); a body set up under the provisions of the National Health Service Act 1977 to advise the Secretary of State and the Central Health Services Council on medical matters
- In the summer of 1998, the then UK Minister of State, Mr. Alan Milburn, made a statement in Parliament that a forthcoming drug (Sildenafil) should be limited in availability and only be prescribed by specialists
- So began a lengthy and expensive court battle for both sides, to define Sildenafil as “Due Care”
- NICE Established in 1999. To a backdrop of several ongoing high profile court cases such as this involving negligence and failure to provide quality care for patients.
 - Court System and Judges are not specialist in Healthcare

Sources of Evidence



Evidence Constraints

- Patient Population

- E.g. Rare diseases – Any disease affecting fewer than 5 in 10,000 people (WHO)

- Collecting evidence on 3,000 people would need to source patients from a population of 6,000,000 people
 - Most rare diseases are 1 in 10,000 -> 30,000,000 people

- Heterogeneity:

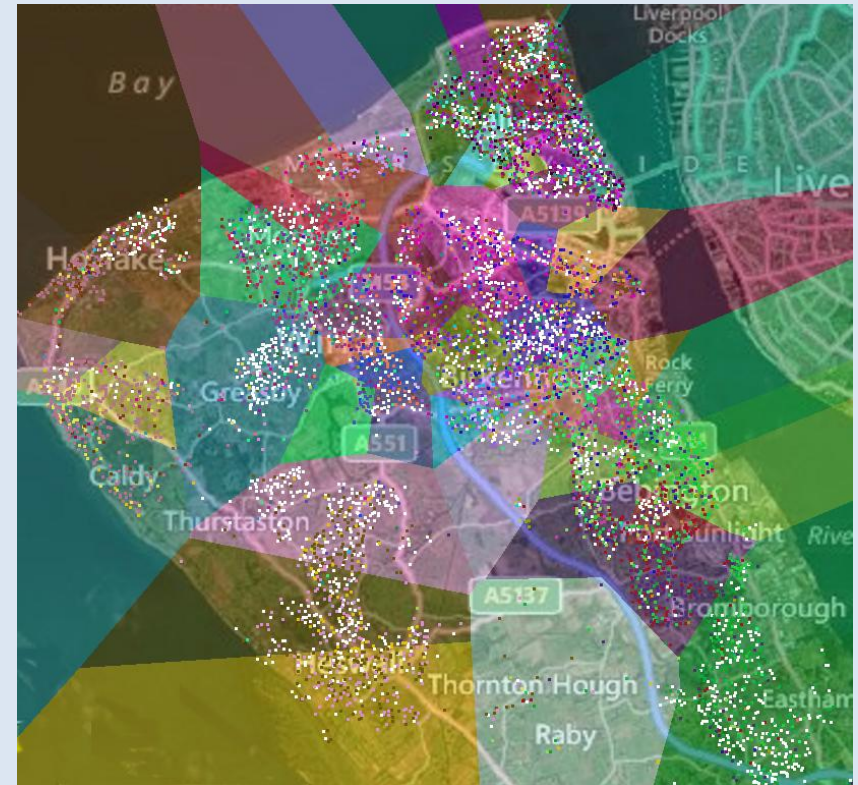
- E.g. Japan requires efficacy data on Japanese patients for decision making

Evidence Constraints

- Costs
 - Of Collection
 - Collecting evidence is an expensive, time consuming and imperfect process
 - Interpreting evidence is an even more time consuming process – peer review
 - Of Resources:
 - Many/Most Eastern European countries do not have comparable evidence on the cost, standard of care and availability of resources as countries with long established HTA programs

Synthesising Evidence

- Logical implication
 - IF (X and Y) THEN Z
- Many uses:
 - Filling in gaps when collecting evidence is not possible or prohibitively expensive
 - Validating theories (comparing with real world evidence)
- Can yield powerful results: e.g. Bariatric Surgery Discrete Event Simulation



Value of Information

- Is the cost of collecting the evidence less than the potential value of the evidence
 - Justified Research
- Is it worth improving the certainty of some parameter
 - Basing reimbursement decisions on assumptions but with data collection and reporting requirements
- Alternative perspective – what would be the costs of an incorrect decision

Transparency

- Transparency Directive Says So...
- “Many Eyes”
 - Help identify “bad decisions” or mistakes in the decision making process
 - Recent Example – UK Train service contracts awarded to company with lowest rating of service and highest price.
 - Estimated cost of reimbursing four companies for the cost of their bids was £40m
- Decide the “rules” for making the decision before making the decision
 - Follow the rules

Decision Tools

- Cost Effectiveness
- Budget Impact
- Value Based Pricing
- MCDA

Cost Effectiveness

- Willingness to pay – Cost per QALY
 - Identify Costs
 - Identify Benefits
- Adverse Events
 - Some undesirable side effects can be tolerated
 - As long as the other benefits outweigh them
 - Need to consider both the cost of managing and damage to health of undesirable side effects
- Are all health effects adequately captured by the measures?
 - VIAGRA was a failed Angina Treatment
- Cost Minimisation Analysis
 - Same as CEA, only clinical effect is assumed to be the same.
 - Biosimilars should not automatically be assumed to have equivalent clinical effect. This must be proved¹!

1. <http://www.bloodjournal.org/content/120/26/5111?sso-checked=true>

Budget Impact

- Budget Impact estimates (should) come directly from good quality Cost effectiveness models
 - Ignore benefit
 - Use expected patient population rather than sub group analysis
- Differentiate between willingness to pay (should the healthcare system pay) and ability to pay (does the healthcare system have the resources to pay – how much of a challenge will finding the resources be)
- Highly cost effective – May be anywhere between saving the healthcare system money or require resources above and beyond that available to the healthcare system as a whole

Value Based Pricing

- From this year the UK was supposed to start using Value Based Pricing.
- Instead of drug companies saying how much they are willing to accept, NICE will define how much they are willing to pay
- Brought in to avoid “no decisions” on pricing
- **Now takes a societal perspective (costs that fall outside the NHS)**
- Although NICE recommends against less than one third of the drugs it considers, these refusals have been politically difficult
 - The cost of schemes brought in by politicians to pay for drugs which NICE have said are not good value for money now account for around 1% of the entire NHS budget (~£1Bln) - drugs for multiple sclerosis (£50m-100m), The Cancer Fund (£200m) and End of Life Care (£549m)
- Main difficulty is, in economic principles, each new drug changes the value of all other drugs
 - **Only being applied to new drugs**

Multi Criteria Decision Analysis

- Defining additional Decision making Rules
 - Making decisions on more than Cost Effectiveness
 - Aspects of treatments not captured by the “QALY”
E.g.
 - Safety
 - Certainty
 - Innovation
 - Budget Impact
 - Equity

Patient Registries

- Excellent source of real world resource use and outcomes (where collected)
- Underutilised – Decision makers rarely seem to consider PR data in their decision making (**still primarily RCT focused – but this is changing slowly**)

Conclusion

- Constrained Evidence Environments require careful consideration of the value of information and alternative means of synthesising evidence
- Southern and Eastern Europe face a unique set of challenges adapting existing evidence for their healthcare service decision making which is not yet properly represented in the literature
- Transparent Decision making paves the way for “good” decision making
 - But there are different degrees of transparency, and if decisions are not transparent to the public, they may not be politically acceptable
- Complex decisions place a heavy burden on evidence synthesis
- A good decision is one that improves the deployment of healthcare resources such that population health improves
 - This requires sound quantification of the “loss” to the healthcare system when taking resources from other areas
 - Disinvestment!
- Evidence Based decision making is the process of explaining decisions in a way that can be judged