Risk and Statistics

Risk Assessment in Clinical Decision Making

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Risk

Definition:

The probability that a particular adverse event occurs during a stated period of time as result from a particular challenge.

Focus:

Risks to patients in the clinical setting
Events of occurring physical harm due to therapeutic interventions
Not of interest

• Risk to caregivers
• Risk to a health system
• Risk to an insurance company
Facts that modulate risk assessment and clinical decisions

Clinical decisions are made because it is believed that the actions that follow them will do more good than harm.

Risk assessment depends on the circumstances or the context in which decisions are made:

- values
- preferences
- information available
Ability to assess risk efficiently

in different circumstances, in conjunction with values

• Aware of relevant information
• Access to relevant information
• Availability of information in an intellectually accessible way
• Ability to interpret information
• Skills to incorporate information into decision making
Balancing risks and benefits

• Consider alternative actions (including doing nothing)
• Knowledge of beneficial effects
  - RCT
• Knowledge of risks:
  - RCT may be not appropriate
  - comes from other types of studies:
    Cohort Studies
    Case-Control Studies
    other sources (usually less valid)
Components of Risk Assessment

• Risk estimation
• Risk communication
• Risk perspective
• Risk acceptance
• Formal decision making procedures
Risk estimation

• Quantification of risks:
  - measures of risks

• Sources of risks:
  - patient related
  - disease related
  - treatment related
Risk Estimation: Measures of Risk

- Absolute risk
- Relative risk
- NNT (number needed to treat)
- Number of treatment years to produce an adverse event
Risk Estimation: Measures of Risk

• Precision → sample size
• Validity (unbiased) → study design
• Reliability → study design

• Limitations in definition, attribution, recording, identification, classification, reporting, measurement, and analysis of risk information.
Example: Helsinki Heart Study

Cardiac event within 5 years

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td>84</td>
<td>1946</td>
</tr>
<tr>
<td>Gemfibrozil</td>
<td>56</td>
<td>1995</td>
</tr>
</tbody>
</table>

Risk Placebo : \(\frac{84}{2030} \sim 4.14\%\) \(RR = \frac{2.73}{4.14} = 0.66\)

Risk Gemfibrozil : \(\frac{56}{2051} \sim 2.73\%\)

Absolute risk reduction: \(4.14\% - 2.73\% = 1.41\%\)

Relative risk reduction: \(\frac{1.41\%}{4.14\%} = 0.34\% (34\%)\)

NNT: 100 treated \(\rightarrow\) 1.41 prevented, 71 treated \(\rightarrow\) 1 prevented

Yearly risks: Placebo: \(\frac{0.0414}{5} = 0.0083\) (0.83%)

Gemfibrozil: \(\frac{0.0273}{5} = 0.0055\) (0.55%)
Risk communication

• The type of risk estimates presented to decision makers affects their assessment of risk.
  absolute risk reduction versus relative risk reduction

• How risk estimates are described influences the reaction of those given the information.
  Describing the effect of an anti-cancer drug in terms of survivors or in terms of deaths (HDT for breast cancer)
Risk communication
Graphical Displays

- Do they facilitate data interpretation?
- Patients and clinicians interpret the same display differently.
- No guidance for the selection of graphical displays to communicate risk information.
- There is no simple best method to present information to decision makers.
Risk communication

Graphical Displays: KM curves

Comparison of embolized and morphologically controlled patients with natural history

- Crawford data
- Confidence bounds of observed data

clinicians

patients

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Risk perception

Even if decision makers are presented with accurate estimates in multiple forms, their perception may be influenced by:

- probability associated with the event
- decision weights
- prior beliefs, experience
- ability to interpret
- intuitive rule of thumb
- suspicion of vested interest
Risk perception
probability value

Survival rate of cancer patient

Quantity of live

> 50%

< 50%

Quality of live
Risk perception
prior beliefs and experience

• Quick decisions, usually in the absence of strong supporting evidence.
• Opinions once formed are slow to change in response to new evidence.
• Evidence is handled in an asymmetric way by clinicians as well as patients.
Risk perception
ability to interpret probabilistic information

- Exaggerated reliance on vivid experiences or anecdotes.
- Lack of formal training in statistics.
- Patients have limited ability to interpret scientific evidence.
- Studies show: physicians overestimate risk.
- Training in judgments on disease probabilities results in no change in treatment decisions.
Risk perception
heuristics

- Situations with full informations from RCTs or observational studies do seldom exist.
- Despite lack of evidence clinicians are forced to make decisions.
- Patients use heuristics to reduce complexity of the problem.
- Needed: Studies on heuristics.
Risk perception
additional factors

• Implications of the decision
• Type of Outcome
• Timing between decision and outcome
• Circumstances
• Role
Formal decision making procedures

Helping a patient to reach a decision by attempting to incorporate risks, benefits, but also values, and preferences of the patient.

- Standard gamble
- Time trade off
- Utilities
- Willingness to pay
Conclusions

- Medical statistics is primarily concerned with providing accurate estimates of risks in clinical situations.
- Decision making following the estimates of risks depends on more than just the risks (benefits) involved.
- Research needed on: Risk communication, perception, and acceptance.
- Necessary to harmonize the decision making process between patients and clinicians.
Final Remark

Human values, different for each of us, influence our perceptions in such complex ways that at no time will all of us agree on a single level of acceptable risk.

But if people can agree upon the way risks are measured, and on the relevance of the levels of risk thus represented to the choices we must make, then the scope of disagreement and dissent is hereby limited.
Slides available:

http://www.biometrie.uni-hd.de/mb/techrep.htm