



Ethical limits of medical technology

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Medical technology

- Overall: significant benefit for patients
⇒ life expectancy↑ + quality of life↑
- Ambivalence ⇒ wanted and unwanted effects
 - **Individual level**: side-effects, might prolong suffering ⇒ benefit for the patient??
 - **Societal level**: major cost-driving factor in health care ⇒ limits of affordability??
- Requires setting ethical limits
 - Micro-level: individual patient care
 - Policy level: limits for health care system
- Normative ethics ⇒ ethical justification



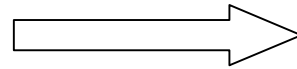
Ethical limits: justification

- Problem: plurality of normative ethical theories
- Alternative: coherence theory of justification
- John Rawls: considered judgments \Leftrightarrow (wide) reflective equilibrium of ethical norms, principles (& theories)
- Principles of biomedical ethics (Beauchamp & Childress ⁵2001)
 - Beneficence
 - Nonmaleficence
 - Respect for autonomy
 - Justice
- Specification & balancing
 - Example: Clinical decision support systems (CDSS)

Ethical principles

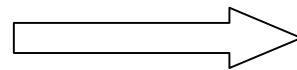
Ethical criteria

Beneficence



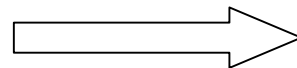
- Functionality: efficacy, effectiveness, feasibility (**instrumental reasoning**)
- Utility \Rightarrow benefit for the patient
- (Better) alternatives?
- Integrity of physician-patient relationship

Nonmaleficence



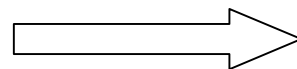
- Safety, robustness (malfunctioning↓)
- Data protection & security
- No diffusion of responsibility

Autonomy



- Respecting patient preferences
- Privacy protection

Justice



- Cost-effectiveness (efficiency)
- Access to CDSS

\Rightarrow Criteria for ethically appropriate use: www.medscape.com/viewarticle/408143



Societal level: basic assumptions

- (1) It is unethical not to consider cost-effectiveness in allocating scarce health care resources.
 - Justification: **Utility maximization**
We have an obligation to achieve the greatest possible medical benefit with the scarce hc resources
 - Consideration of opportunity costs!
- (2) It is likewise unethical to allocate scarce hc resources only according to cost-effectiveness.
 - Justification: **Distributive justice**
Sick people should not be left untreated just for cost reasons.
 - Challenge: “appropriate” application of cost-effectiveness
 - **Utility maximization with fairness constraints!**



Cost-effectiveness approach

- Goal: maximizing health benefits with available resources
- Utilitarian principle of utility maximization:
“greatest good for the greatest number”
- Ethical challenges:
 - Application problems ([internal critique](#))
 - Quantified measure of health benefits
 - Evaluation of quality of life
 - Intra-/intersubjective comparison & aggregation of benefits
 - Limits of cost-benefit calculus / discounting
 - Distributive consequences ([external critique](#))
 - Compatible with concepts of distributive justice?
 - Compatible with societal preferences about allocating hc resources?



QALY – distributive consequences

- Health benefits are maximized with the available resources 😊
- Distribution of benefits does not matter 😞
- Severity of disease is neglected
 - 0,1 → 0,2 is equivalent to 0,8 → 0,9
 - Undervalues life-saving interventions
- Positive or negative age discrimination?
 - Negative: Age ↑ → possible QALY gain ↓
 - Positive: age does not matter
 - 3 QALYs [50 year old] ≈ 9 QALYs [70 year old]
- Discrimination of disabled persons
 - Lower gain of QALYs in comparable conditions



Cost-effectiveness: application levels

- Across different indications (**Macro level**)
 - QALY-League-Tables
 - e.g. Oregon's first priority list
 - **Health care system**
- Within one indication (**Meso level**)
 - Comparison of interventions for the same indication (disease)
 - **Patient group**
- Individual case (**Micro level**)
 - Assessment of benefits and cost for one single patient
 - **Individual patient**



Oregon Health Plan (OHP)

- Initial priority list according to cost-effectiveness ⇒ comparison across indications ⇒ counter-intuitive ranking, did not reflect severity of disease
- Multiple revisions of the priority list, cost was eliminated
- Major criterion: probability to prevent death
- List in operation since 1994, regular updates, 566 of 736 interventions are covered
- OHP – lessons
 - Pure cost-effectiveness approach ethically unacceptable
 - Expansion of services instead of rationing!! („political paradox of rationing“)
 - No significant savings from priority list (instead: tax funding + managed care!)
 - Priority list of services problematic: guidelines defining indications as necessary supplement!
 - Goal of universal access in Oregon still not yet realized!



Allocation: public preferences

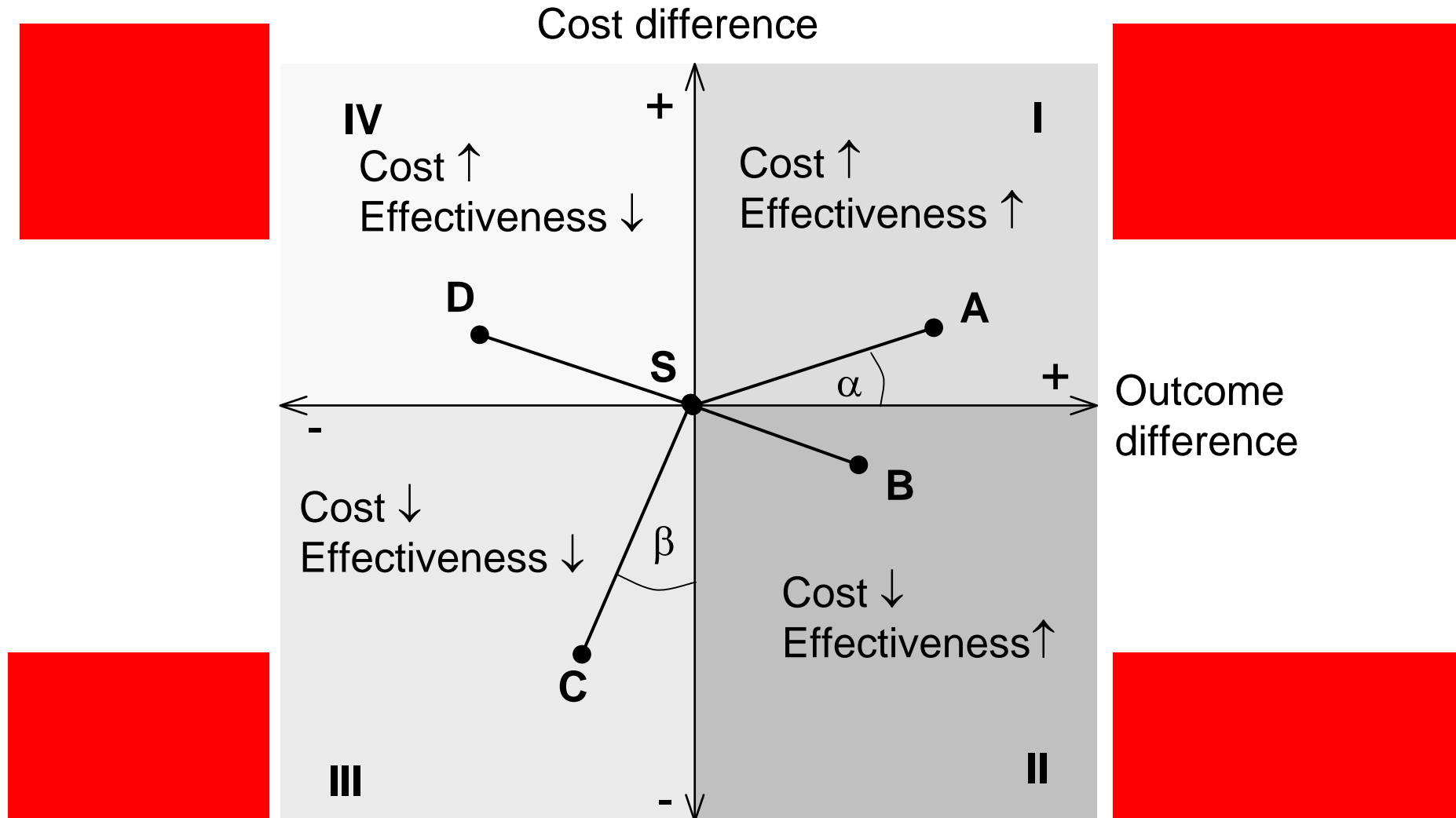
- Maximizing utilities does not reflect public rationing preferences (e.g. Ubel, Nord):
 - (1) Priority to severely ill patients (even if less cost-effective)
 - (2) Avoid discrimination against people with chronic illness or disability
 - (3) Fair distribution of health care services or health care outcomes
- QALY-maximization is not the sole goal of health care spending!
- Challenge: Find the right balance between equity and efficiency
⇒ „equity-efficiency trade-off“
- QALY-modification
 - Person Trade-Off (PTO) method
 - „equity weights“
 - „sliding scale C/E-ratio“



Meso level: application within one indication

- Comparison of cost-effectiveness of interventions for **one specific** disease
 - Distributive consequences less problematic!
- Implementation within cost-sensitive guidelines
 - equal treatment of patients ⇒ justice↑
- Ranking of interventions according to incremental cost-effectiveness ratio
 - Selection of intervention which is within the maximum societal willingness to pay
 - Challenge: determine threshold for maximum cost per outcome unit ⇒ \$50.000/QALY ??
- Absolute threshold: ethically not acceptable
 - No scientific basis for threshold
 - Efficiency would dominate all other ethical values
 - Good reasons to ignore the threshold in some cases (⇒ fairness!)

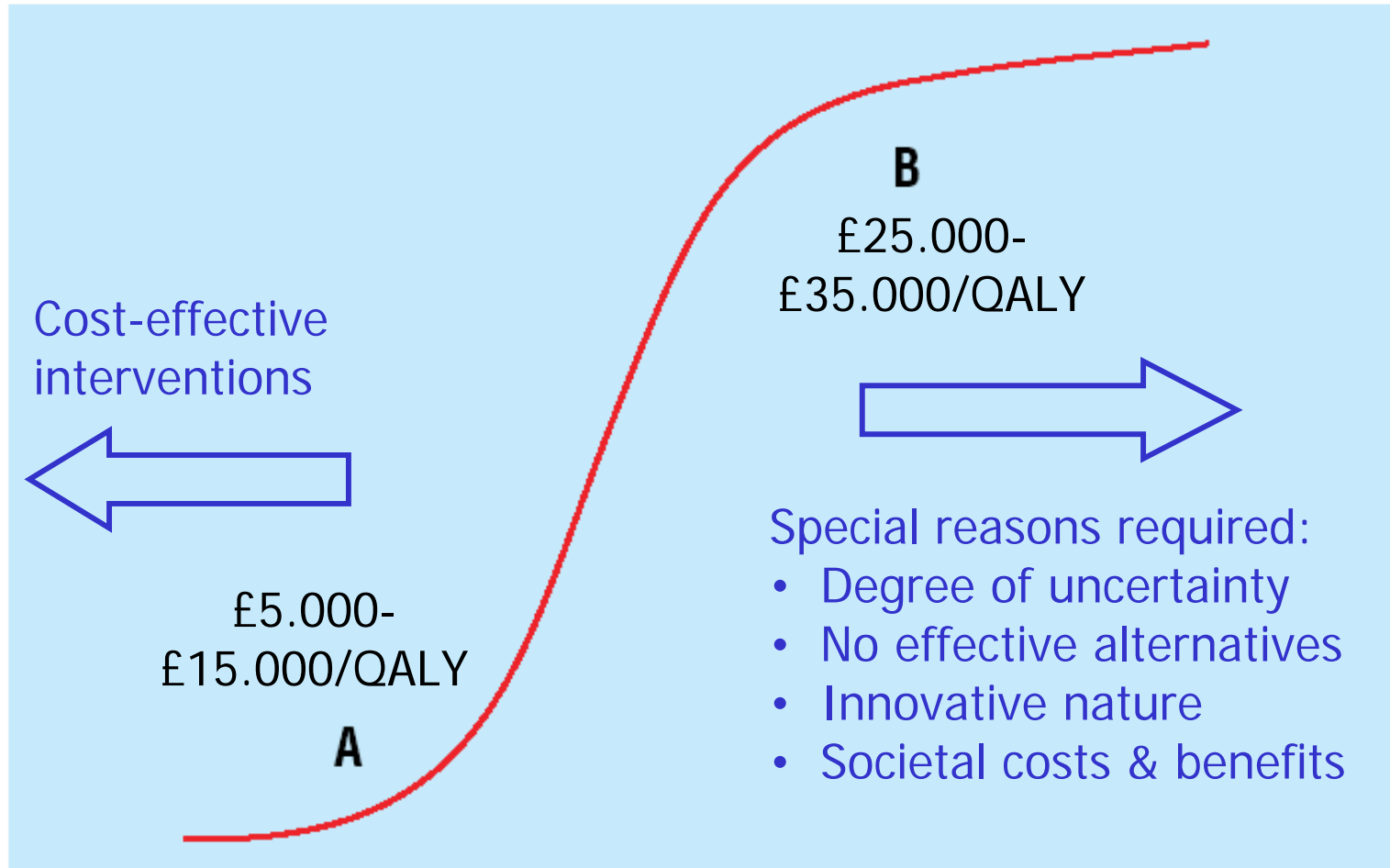
Cost-effectiveness plane



Cf. Drummond et al. (1997)

National Institute of Clinical Excellence

Probability of rejection on grounds of cost ineffectiveness



Increasing cost/QALY (log scale)



Micro level: individual patient

- Selecting the intervention that achieves a certain health state with the least amount of resources
 - ethically mandated! (= rationalization)
 - Withholding interventions with a high (=bad) cost-effectiveness ratio
 - no universally accepted threshold
 - individual patients are treated unequally ⇒ unfair!
 - Distribution of scarce resources according to cost-effectiveness (e.g. organs: EUROTRANSPLANT)
 - Most cases: no formal QALY-calculation
 - Not acceptable as sole allocation criterion!
- Application of cost-effectiveness on the micro level is ethically rather problematic!



Conclusions

- Ethical limits of medical technology \Leftrightarrow societal & individual level
- Normative basis: coherence theory of justification
- 4 principles \Leftrightarrow specification & balancing
- Cost-effectiveness approach – with fairness constraints:
 - Macro level (league-tables, health care system, e.g. Oregon):
 - Comparing outcomes across different indications problematic
 - Combination with severity of disease & distribution of benefits!
 - Meso level (indication, group of patients):
 - Distributive consequences less problematic, equal treatment of pts.
 - No absolute, rather relative threshold (cf. NICE)!
 - Start with big α , burden of proof increases with α !
 - Micro level (individual patient):
 - Universally accepted threshold procedure missing
 - Unequal treatment of patients \Leftrightarrow ethically problematic
- Application on the meso level ethically most acceptable!