

Assessing Risks and Benefits

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A Case

- Endemic hypothyroidism in West African nation
- Randomized trial of iodinated salt



Risks and Benefits

- Traditional attention to risk partially eclipsed by concerns of consent and benefit
- Recognized by numerous international bodies
 - Risks to subjects are minimized
 - Risks to subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may be expected to result
- Attention to welfare as well as rights



Risk

- “The possibility of suffering harm or loss”
- Risk does not mean harm!



Risks

- Types
- Quantification
- Level



Types of Risk

- Physical
- Psychological
- Social
- Economic



Quantifying Risk

- Likelihood
- Severity
- Duration



Level: Making Risk Assessments

- Empirical data
- Experts



Minimizing Risks

- ❑ Qualified personnel
- ❑ Substitution of procedures
- ❑ Monitoring
- ❑ Exclude especially susceptible subjects



Confidentiality

- Why?
 - Desire for balanced recruitment
 - Desire for “good” information
 - Protect participants from social risks: insurance, jobs, housing, and the law
- When?
 - Any research posing potential social and some economic risks
- Challenges?
 - Must be considered in the design of research
 - Strategies may be expensive



Benefits

- Types
- Quantification
- Level



Types of Benefit

- Direct
- Collateral
- Aspirational



Direct Benefit

- Arising from receiving the intervention being studied



Collateral Benefit

- Also called “indirect” benefit
- Arising from being a subject, even if one does not receive the experimental intervention
 - Medical care
 - Gratification
 - Compensation

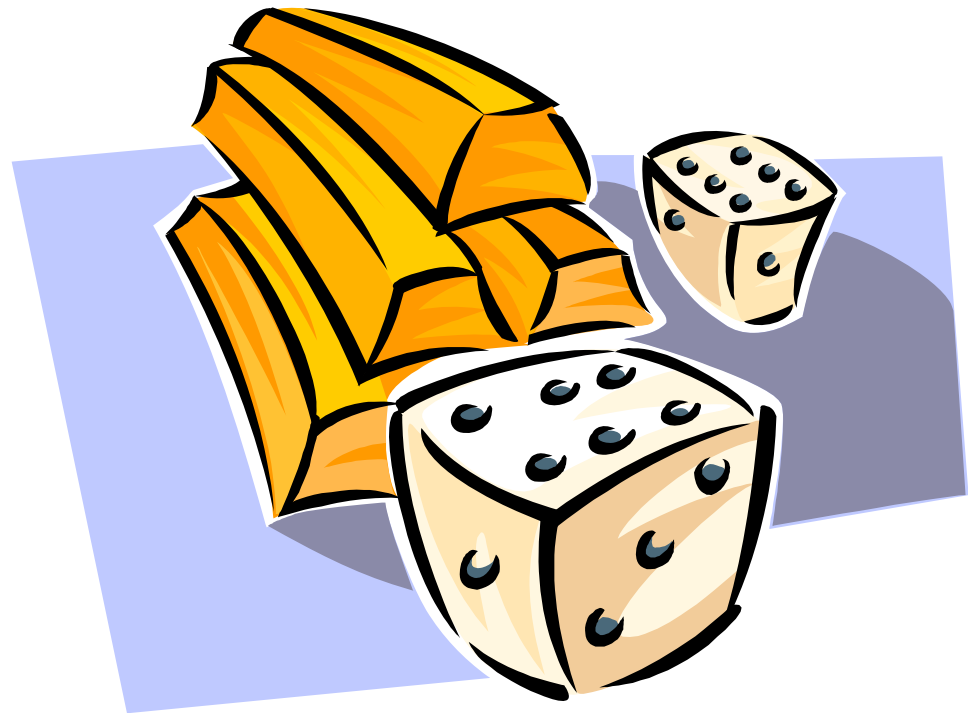


Aspirational Benefit

- Benefit to society and to future patients
- Arises from the results of the study

Quantifying Benefits

- Likelihood
- Magnitude
 - Size
 - Duration





Level of Benefit

- What is the nature of the benefit according to type of benefit?
 - Primary outcome measures
 - Secondary outcome measures



Maximizing Benefits

- Principle of beneficence
- Implications for informed consent
 - Avoid ambiguity
 - Avoid the therapeutic misconception
- Considerations with respect to justice

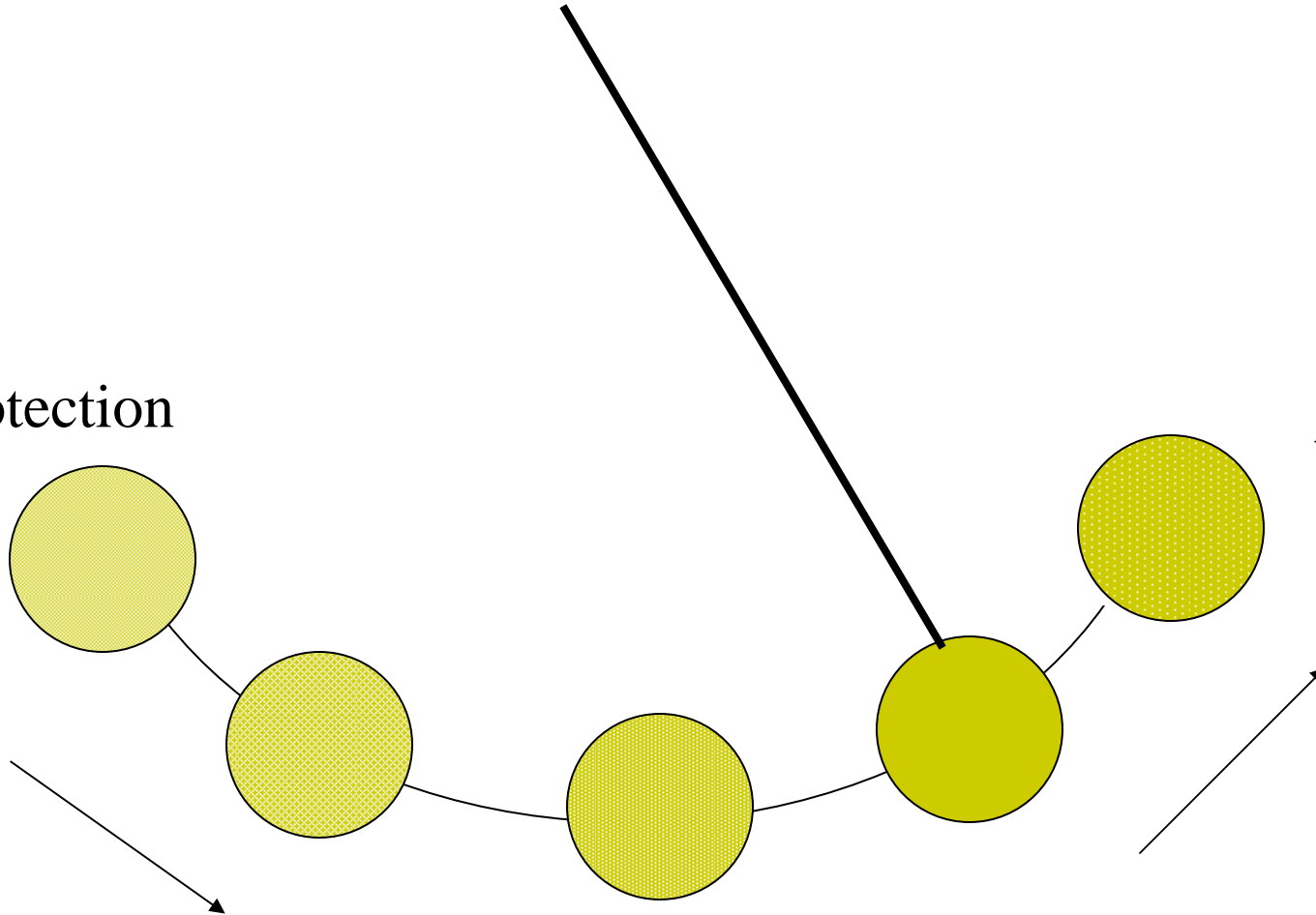


Shifting Claims about Justice and Subject Selection

- AIDS activism
- Cancer activism

Protection

Access





Justice as Access

- The ‘vulnerable sick’
- Children
- Women
- Minorities



Subject Selection

- Why?
 - Generalizability
 - Justice
- When?
 - Disease or condition is of relevance to the population or population subgroup
- Challenges?
 - Statistical power
 - Recruitment and retention



Incommensurability in Balancing Risks and Benefits

- Risks and benefits may affect different domains of health status
- Risks and benefits may affect different parties
 - Risks may be born by one individual to benefit another
 - Risks may be born by individuals to benefit society
 - Risks may be born by society to benefit individuals



Concluding Comments

- Although balancing risks and benefits can be difficult, or impossible, there is an obligation to minimize risks and maximize potential benefits in research
- To do this task well requires a nuanced evaluation of risks and benefits
- Such an evaluation not only promotes the welfare of subjects but also enhances consent and the accuracy of claims about justice