Can we prospectively estimate the economic returns of clinical trials?

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Disclosure

The presenter has advised that the following presentation is subject to no conflicts of interest and has nothing to disclose.

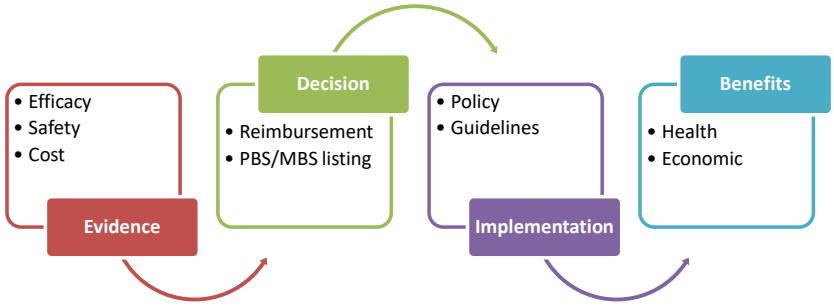
Background

- Clinical trials are important to generate knowledge, inform decision making and improve health.
- Limited budgets
- Considering the value for money of clinical trials will allow efficient utilisation of research budgets and maximise return on research investments.

Value of Information Analysis

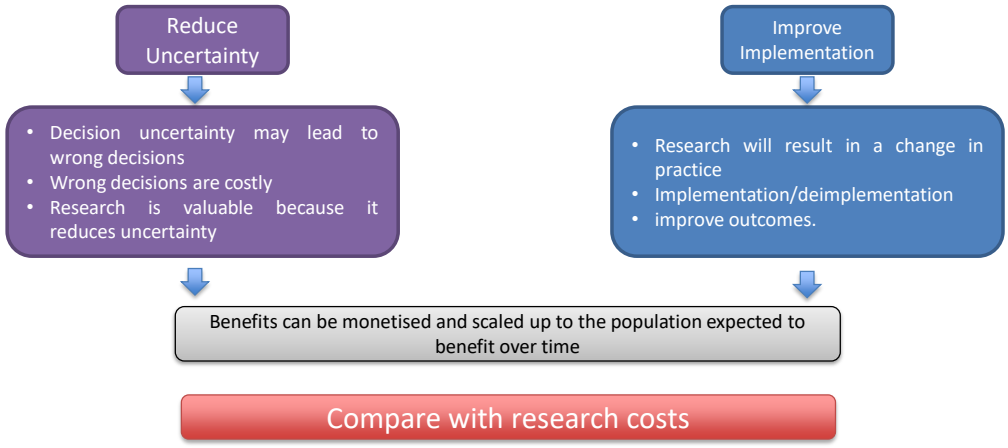
- Value of Information (VOI) analysis prospectively estimates the expected value of clinical trials
- A Bayesian approach that is deeply rooted in decision theory
- It is based on the notion that research is valuable because it reduces decision uncertainty and improves implementation

Value of Information Analysis

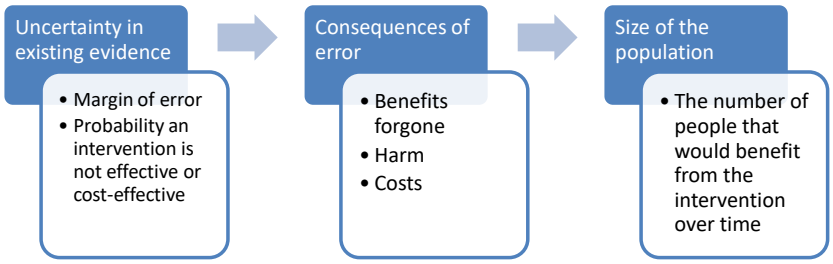


The value of a new research is the difference in health/economic benefits of two states: 1) a factual state in which research takes place and 2) a counterfactual state in which research is not conducted

Value of Information Analysis



Value of Information Analysis



- Full economic modelling
- Minimal or no modelling

Negative Pressure Wound Therapy in high-risk caesarean section wounds

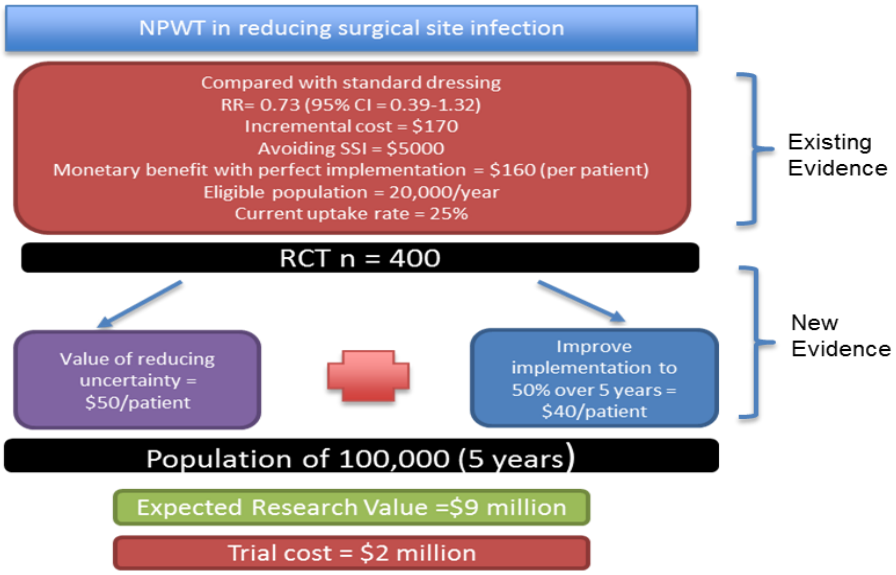
- Obese women undergoing cesarean section are at increased risk of postoperative complications.
- NPWT may prevent closed surgical incision complications (surgical site infection)
- The evidence on the effectiveness and cost-effectiveness of this technology is limited (1 RCT (n = 81) and 1 pilot study (n=92))
- An RCT of 400 patients was proposed at a budget of $2 million
- Is this trial value for money?

Methods

- We followed a minimal modeling approach in calculating value of research (proposed by Meltzer and Hoomans).
- Required the research team to provide certain information (commonly provided in grant applications).
- Simple simulations using Microsoft Excel
- Compared expected benefits with research budget

Domains	Inputs	Clarifying statements
Value of resolving uncertainty	Primary outcome(s) of the new research	The primary outcome in the research proposal (e.g., survival, quality of life, event avoided)
	Existing evidence	The source of current evidence (e.g. Meta-analysis, systematic review, clinical studies or expert opinion)
	Effectiveness of the comparator/control	The effectiveness of the comparator (e.g., baseline probability or mean estimate of the outcome of evaluated), with standard error or confidence interval
	Relative effectiveness of the intervention	The relative effectiveness of the intervention (e.g., relative risk or risk difference), with standard error or confidence interval
	Cost of the comparator	The expected cost of the comparator
	Cost of the intervention	The expected cost of the intervention or incremental cost
	Willingness-to-pay	Indicate the monetary value of one unit of effectiveness
Value of improved implementation	Current level of implementation/uptake	The current level of implementation/uptake based on existing evidence
	Expected level of implementation/uptake	The expected level of implementation/uptake with the new research
Population benefiting from research findings	Annual incidence	Incidence of the condition being researched
	Prevalence	Prevalence of the condition being researched
	Durability of information	Time in years over which the findings from the new research is useful
Other inputs	Time to report research results	Time in years for research results to report
	Discount rate	The rate of discounting future benefits and costs (e.g., 5%)
	Direct research cost	Research study budget including fixed and variable cost

Tuffaha et al 2019



Conclusions

- Value of Information analysis is a rigorous tool to prospectively quantify the value of additional research.
- Minimal modeling methods provide a practical approach for estimating the value of additional research.
- A programmable tool can be developed to further facilitate calculations
- Considering value for money of research will help research organisations prioritise and fund clinical trials with the maximum return on investment.

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Thank you