Expanding the applicability of Heallth Technology Assessments

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Expanding the applicability of HTAs

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Objective: To elucidate the potentials when incorporating pragmatic controlled trials in HTAs

Background: HTA have a policy-oriented perspective and aims at supporting health policy makers and therefore have to reflect policy applicable questions and answers. HTAs are primarily based on systematic reviews (SR) and thereby mostly on randomized controlled trials (RCT). A relevant question is whether RCTs are sufficient as inputs or it is beneficial to include pragmatic controlled trials as supplements to RCTs in HTAs.

Characteristics of RCTs and PCTs:

	Randomized controlled trial	Pragmatic controlled trial
Purpose of trial	• Test causal relationship • Aimed at explanation • Generate scientific knowledge	• Choosing between relevant technologies in daily practice • Aimed at decision making • Generate knowledge applicable to policy decisions
Setting	• Ideal experimental conditions • Tightly controlled	• Match the underlying decision-problem and context • Routine settings • Several different settings
Technology	• Exactly the same technology to all • Fully controlled technology • Often one single technology	• Complex technologies possible • Natural variations allowed • Flexible technology - adjustable to the individual patient, practitioner, setting, context etc.
Comparator	• Placebo	• The normally used technologies • High degree of flexibility
Population and sample	• Relatively small sample size • Homogenous and highly selected mix of patients • Exclusion of non-optimal patients	• Large sample size • Broad inclusion criteria • Heterogeneous mix of patients representative of the wider population
Comparison	• Control group by randomization and double blinding	• Comparison group • Randomization and double blinding sometimes possible but not always
Outcomes of interests	• Efficacy • Often very narrow; intermediate • Mainly short-term outcomes	• Effectiveness • Often a broad range of outcomes • Outcomes relevant to patients and decision makers • Reflecting the overall performance of a technology
Compliance	• Very important	• Lesser important • Non-compliance is allowed
Bias	• Selection bias is minimized	• Subjected to a variety of biases
Validity	• High internal validity • Low external validity	• Low(er) internal validity • High external validity
Generalizability	• Low	• High
Target group	• Primarily clinical decision makers	• Primarily policy decision makers, secondarily patients
Aim of study	• Which technology is technically best? • Can it work?	• Which technologies are best for a certain group of patients when adopted generally? • Does it work?

Conclusion: HTAs incorporating both RCTs and PCTs will depict both clinically efficacy measures and outcome measures pertinent for the patients reflecting a wider spectrum of outcomes for the overall performance of a technology. They will demonstrate the natural variations in implementation of a technology in different settings and contexts including variations between users of the technology and for the groups of real-life patients.

In general, including both RCTs and PCTs in HTA gives one the possibility of answering not only the question *Can it work?* but also the question *Does it work?*