

# The assessments of three different dimensions “Efficacy”, “Effectiveness”, and “Value” require three different tools: the Randomized Controlled Trial (RCT), the Pragmatic Controlled Trial (PCT), and the Complete Economic or Cost-Effectiveness Analysis (CEA)

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## Abstract

Summarizes a lecture presented at the Evidence Life 2018 conference at Oxford.

Sir Archie Cochrane and Sir Austin Bredford Hill requested to answer three short questions before implementing a new healthcare service into daily clinical practice: CAN IT WORK? DOES IT WORK? IS IT WORTH IT? For implementation of this 3-step-CDI-strategy we propose the consecutive completion of three different types of studies.

First, a Randomized Controlled Trial (RCT) to confirm that it CAN WORK, i.e. to demonstrate efficacy under Ideal Study Conditions (ISC). Second, a Pragmatic Controlled Trial (PCT) to confirm that it DOES WORK, i.e. to demonstrate effectiveness under Real World Conditions (RWC). Third, a Complete Economic or Cost-Effectiveness-Analysis (CEA) to demonstrate that IT IS WORTH IT, i.e. to demonstrate the value [needless to say] under RWC from the patient and the societal perspectives.

Unfortunately, there is no consensus on the appropriateness of different tools (RCT, PCT, CEA) for assessment of different effects

(efficacy, effectiveness, value) under different conditions (ISC, RWC). It should be not too difficult to define ISCs and RWCs and to describe the effects that can be described under either ISC or RWC but probably not in between. Both the conditions and the interventions under these conditions can be distinguished clearly by five criteria. The goal of the intervention, the respect of patient autonomy, the legitimized application of the intervention, the application of not legitimized interventions, and finally the value generated by the intervention.

These details will be presented in four tables. First, the tree requests of Sir Archie Cochrane and Sir Austin Bredford Hill. Second, the 3-step-CDI-approach we propose. Third, the description of differences of efficacy, effectiveness, and value, and fourth, the detailed differences in the 14 steps of a RWC, PCT or RCT. The function of this 3-step-CDI-approach is a prototype of the more practicable ICE-3-step-tool that will be ready for presentation by autumn 2018.

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