Process Evaluation and Adaptation in Complex Trials

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While real-world effectiveness is important, UK MRC guidance for process evaluation recognize that "effect sizes do not provide policy makers with information on how an intervention might be replicated in their specific context, or whether trial outcomes will be reproduced" (Moore et al. 2015). Hence, for evidence of effectiveness to meaningfully inform continued practice in the same context, or to inform transference to new contexts, we need to understand more than effects. We need to understand issues such as what was delivered (by whom and how), *how* did it work, and what are the contextual contingencies necessary for successful implementation and effects.

Prospectively designing process evaluations

Think about an intervention in your area of research which is going to be, or is currently being, evaluated using a randomized controlled trial, or other outcomes evaluation design.

To provide evidence to inform decisions on how this intervention should (if effective) be maintained in practice or used in other contexts, what might we need to ask about:

- Implementation/delivery
- Mechanisms
- Contextual contingencies?

What methods might we use, alongside an RCT, to understand these questions?

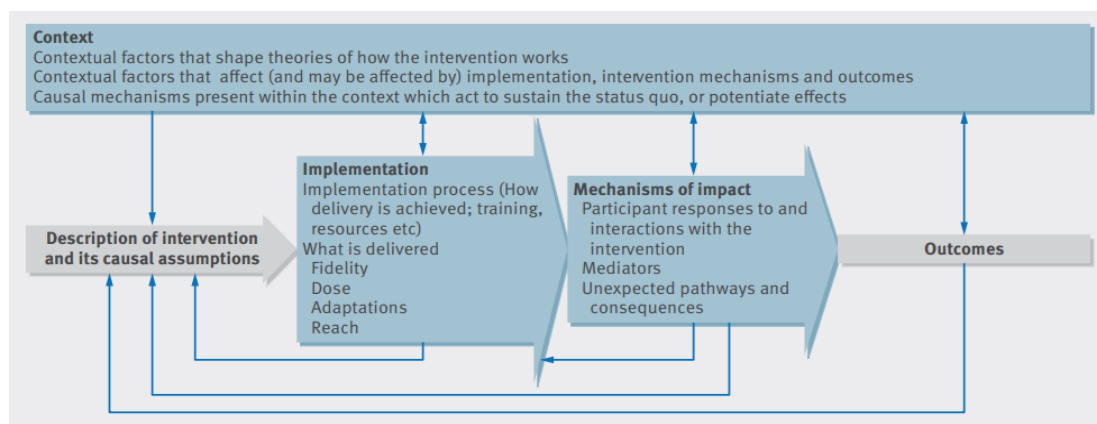Figure 1. MRC Process Evaluation Framework (Moore et al. 2015)

Fig 1 | Key functions of process evaluation and relations among them (blue boxes are the key components of a process evaluation. Investigation of these components is shaped by a clear intervention description and informs interpretation of outcomes)
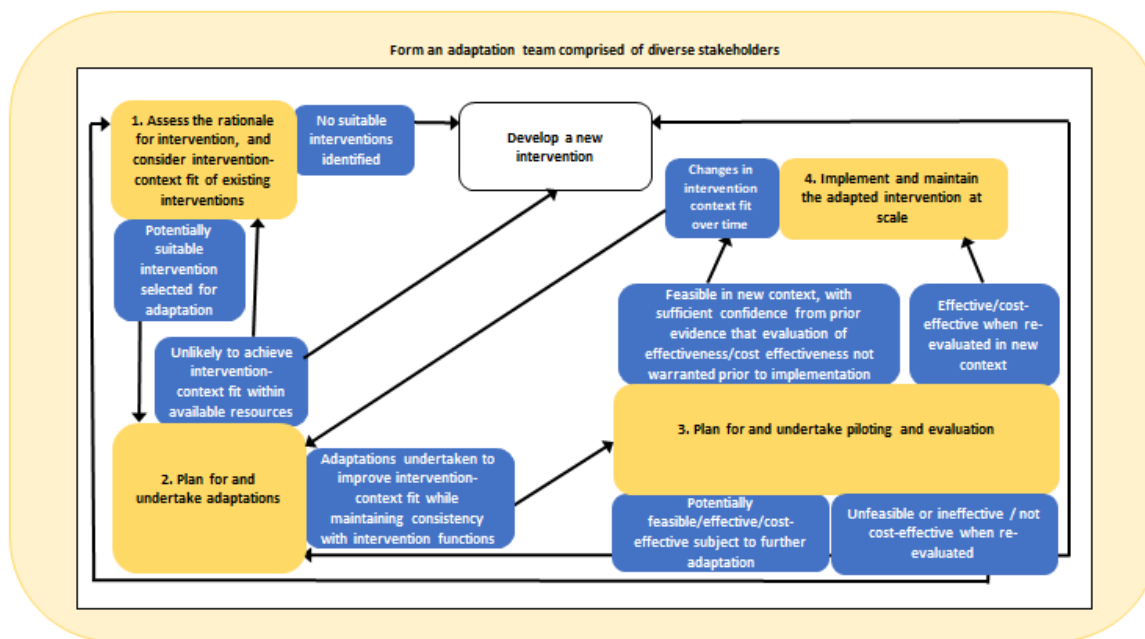
Using process evaluation data to inform adoption and adaptation decisions in a new context.

As described above, a key role for process evaluation is to provide data which enables teams in other contexts to make informed judgements on whether an 'effective' intervention might also be valuable in their context.

Looking at this from the other perspective, imagine you have identified an 'effective' intervention. What evidence would you look for (from the original evaluation, and in your own context) in order to understand:

- Are the mechanisms through which the intervention works relevant to my context?
- Are the contextual features necessary for successful implementation, and for the activation of intended mechanisms, present in my context?

Figure 2. ADAPT guidance framework (Moore et al 2020)

References

- Moore, G.F., Audrey, S., Barker, M et al.., 2015. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*, *350*.
- Moore G, Campbell M, Copeland L et al. (2020) Adaptation of interventions for implementation and/or re-evaluation in new contexts: The ADAPT Study guidance (v1.0). https://decipher.uk.net/portfolio/the-adapt-study/

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