A realist understanding of programme fidelity

The RAMESES II Project

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The traditional idea of 'programme fidelity' is used in two different circumstances. One is in experimental designs which aim to assess whether X (the programme) leads to Y (a desired outcome), and to what extent it does so. The aim here is to establish that 'X causes Y'. The other is after an 'evidence-based programme' has been developed. It has already been 'established' that 'X causes Y'; the programme is now being implemented more widely. Here, the aim is to ensure that 'the same' programme is implemented, on the assumption that if the same things are done, the same outcomes will be achieved. Evaluations of this type tend to focus on detailed process evaluation: were the right things done, in the right order, with the right people, to the right extent… and so on. Traditionally, programme fidelity is the measure of the standardisation process, that is, the "extent to which delivery of an intervention adheres to the protocol or program model originally developed" (Mowbray et al, 2003).

> "Traditionally, programme fidelity is the measure of that standardisation process, that is, the "extent to which delivery of an intervention adheres to the protocol or program model originally developed"."

In experimental designs, fidelity is a holy grail. Testing the proposition that "X causes Y" requires that X is always the same; the intervention should be identical in every way and in every application. In its purest form, it also requires a closed system, so that it is possible to isolate the effects of 'X' from everything else that might impact on 'Y'. Measuring the extent of impact also requires a counterfactual – circumstances where 'X' does not apply (but that is a separate issue which is not addressed here.)

Randomised controlled trials (RCT) of medications are the usual example for this logic. The manufacturing process turns out uniform copies of the drug and so it can be assumed that X (the treatment) is always the same. To show that the medication leads to its intended outcome, people can be randomly allocated to the medication or not.

A realist evaluation approach makes different assumptions. The medication may be the same, but the same amount of the same medication does different things in different people (which is why side effects vary and medications for adults are not necessarily appropriate for children). Even more importantly for realists, implementation and effectiveness still involve human volition. Patient compliance with medication prescriptions varies considerably (Nieuwlaat et al 2014). Expectations of effectiveness may increase the likelihood of desired outcomes (the placebo effect). Staff handing out the medication may consciously or unconsciously affect the desired outcome, and so on.

People running trials respond to these potential problems with supplementary methods to ensure and check whether patients are taking the medications as prescribed and whether, for example, staff conscious and unconscious biases are eliminated. This follows the classic empirical formulation 'specify-standardise-check': precisely design and specify an intervention and take steps to ensure that the actual intervention is faithful to plan by making sure those steps are always the same and are always followed.

This 'specify-standardise-check' approach is more contentious in the evaluation of social programmes and policies, applied healthcare and psychological interventions, and so on. As with medication trials, the logic has been used both during research to test programme effectiveness and in process-fidelity evaluations. Despite the best implementation efforts, it is impossible to standardise the delivery of complex interventions. The personnel responsible for delivering the intervention (the police officers, psychologists, field staff) are diverse, as are the contexts in which they work (the crimes spots, their psychological models,

the countries they work in). There are differences among those receiving the intervention (the criminals, the people who need counselling, the communities being developed) in terms of their circumstances and capacities. And there are differences in the implementing organisations (organisational settings, culture, and resources) all of which shape how the programme is delivered and responded to (see 'Context' in this series).

> "Context is not a set of variables which can be 'controlled'."

Realists also argue that context is not a set of variables which can be 'controlled'. Rather, it is the interaction between contexts at individual and social levels and aspects of the programme that determines whether, and shapes how, the programme mechanisms work. This in turn shapes the intervention outcomes. From a realist perspective, people who share the same measurable individual characteristics can respond to the intervention in different ways and thus generate different outcomes. Furthermore, realists argue, it is impossible to equalise all aspects of context between two groups; and without understanding *what it is about the context* that matters (that is, what aspects of context affect which mechanisms), it is not possible to determine which elements of context should be equalised between trial and control groups.

Programme fidelity from a realist perspective

Realist evaluation takes a different approach to programme fidelity. Realists do not expect standardised programmes. Programmes start to change and adapt as soon as implementation begins, because of differences in local conditions, funding, programme support systems, political impetus, staff turnover, policy fashions, attempts to turn the ideal model into a feasible model on the ground, and so on.

Sometimes adaptations represent attempts to tailor the programme to specific contexts in order to enable the programme to work. Other times, adaptations reflect resource constraints, a lack of engagement or attempts to 'work around' a programme deemed 'unworkable' by key stakeholders. Realist evaluation seeks to understand when and why these adaptations occur and the nature of the adaptations. 'Fidelity failures' do not necessarily lead to programme failure (in fact, they can in some circumstances improve outcomes). Dfferences in implementation become a source of data for understanding how and why programmes do or do not work.

> "Fidelity should be re-articulated in terms of programme theory."

In summary, the concept of fidelity, as traditionally understood, is unhelpful in realist evaluation. Fidelity should instead be re-articulated in terms of programme theory: fidelity to underlying causal processes, context sensitivity, and adaptation. In other words, in a realist evaluation the goal is to understand and explain how, why, for whom, in what contexts and to what extent outcomes have occurred, compared to what might have been expected based on the programme theory. Variation is a resource that can be used to help understand what works, in what circumstances, for whom and why.

An Example

A new programme aims to implement guidelines for stroke care coordinators to improve rehabilitation outcomes. Care coordinators are expected to meet with people who have had a recent stroke and their families and go through the exact process specified in the guidelines so that the desired outcome (increased rehabilitation for people with strokes) is achieved. When these programmes are implemented in different wards, the care coordinators adapt them to their local circumstances. The standardised model may be adapted because it is impossible to follow the model strictly (e.g. if it contradicts other guidelines). Or some of the questions may be skipped or adapted (e.g. those related to sexual activity or advanced end of life decisions may not be relevant).

A realist investigation will explore how contexts affect the work done by, and outcomes from, different care coordinators in different services. For example, novice staff are more likely to engage with the new guidelines because they provide a safe tool and offer a perception of following quality professional standards. Senior care coordinators may not feel they need that safety net and continue to work according to their usual practice.

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