Implementation and Implementation Science: the Big Disconnect

This article originally appeared in: *ARC WM News Blog. 19 Aug 2022; 4(8): 1-3.*

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The Issue

Implementation science studies adopt many different forms, but there is one point on which they converge. It is a widely accepted tenet of implementation science that the intervention should be comprehensively described.[1] This requirement is all very well, but how does the investigator know what the intervention consisted of? The obvious answer is to refer to an intervention protocol. But what if there is no protocol?

The idea that an intervention, at least if it is the subject of evaluation, must have a protocol is deeply ingrained in health service/implementation science. To suggest otherwise could open a person to an accusation that they are unscientific in their approach. However, the notion that a protocol is a prerequisite of a principled evaluation entails a corollary – interventions implemented without protocols cannot be evaluated by respectable scientists. This would be an acceptable price to pay if any of the following three conditions applied:

1. Interventions are only rarely carried out in the absence of a protocol.
2. Interventions carried out in the absence of a protocol are of a type that would not warrant evaluation.
3. Nothing of value can be learned from the evaluation of an intervention implemented without a protocol.

However, I argue here that none of these conditions are universal.

Interventions May Be Implemented Without a Protocol

It is common for service managers to implement changes without producing a formal protocol. I recently served on the board of a large NHS hospital and was a member of their quality and safety committee. A large number of initiatives were launched, task and finish groups were formed, and actions taken. However, detailed protocols describing the various actions were the exception rather than the rule. Managers just do not spend their days writing TIDieR compliant protocols. In some cases there may be a '*business case*', but that does not amount to a protocol. The SQUIRE guidelines state that "*any reasons or assumptions that were used to develop the interventions*" should be described.[2] However, these may not have been explicit at the time of the intervention. Moreover, it has been found that interventions based on an explicit theory are no more likely to be effective than those not based on an explicit theory.[3] Implementation scientists, habituated to co-production principles where researchers and service managers collaborate on producing an intervention description, might be scandalised at the very thought of intervention sans protocol. Nevertheless, real world service managers frequently intervene without a formal protocol.

An Intervention May Be Effective Even Without a Protocol

It does not follow that an intervention cannot be of interest simply because it does not have a written protocol. We conducted a study of a financial incentive to promote uptake of home haemodialysis in the West Midlands region, showing that it was effective.[4] Yet there was no protocol beyond the financial incentive itself. The fact that an intervention may be interesting and effective, even in the absence of a protocol, is exemplified by the finding that protocols for effective interventions have omitted an essential ingredient for success. This possibility is exemplified by a retrospective study of an effective intervention to reduce sepsis on intensive care wards.[5] The protocol was concerned with implementation of a checklist, while a subsequent retrospective study showed that the checklist by itself was not impactful. Leadership from the person who was overseeing its implementation was the extra, essential, ingredient.[6] The observation that an essential ingredient may be omitted from the protocol of an interesting and effective intervention vitiates the argument that it can not be worthwhile to evaluate an intervention that is implemented without a protocol.

Even Without a Protocol, an Intervention May Still Be Interesting

It could be argued that an intervention with no protocol is not worthy of evaluation. However, there are many examples of interesting evaluations of interventions that were not protocolised. For example, studies of change in the nurse-patient ratio,[7] implementation of forced functions to prevent misconnecting gas supply in the operating theatre,[8] and to increase consultant cover at weekends,[9, 10] were all based on retrospective evaluations of interventions that were not protocolised.

Absent a Pre-Implementation Protocol, It May Be Possible to Engineer a Protocol Retrospectively

Absent an explicit protocol, it may be possible to reconstruct the intervention retrospectively. For example, a recent intervention to implement guidelines to reduce hospital falls was supported by only a minimalist protocol.[11] This intervention was led by a senior nurse who was able to recreate what was done in considerable detail, even though this had not been captured prospectively in a protocol. The very act of reverse engineering a protocol may be helpful to the service. For example, we are evaluating an intervention to improve numerous aspects of leprosy care in the Chhattisgarh Province of India. When we set off on this endeavour, we were guided by a sparse business case that fell far short of the detail required of an intervention protocol. However, we are re-creating the protocol retrospectively by talking to the various actors involved immediately before and after initiation of the project. In this way, we think we may have provided a service to the policy-makers directing the programme. However, a clear line of cleavage between intervention and implementation is not available. Readers of our study results will therefore have to form a judgement about which parts of the description they wish to implement since the project began before we could finish our work.

Protocols are Highly Desirable, Just Not Essential

None of what I have said, however, should be taken as an argument against producing an intervention protocol. On the contrary, and notwithstanding the possibility that the protocol may be incomplete, producing protocols is good practice, and managers and policy-makers should be encouraged to produce such protocols. Also, the existence of a protocol enables the evaluator to draw a clear distinction between the protocol and its implementation.[12, 13] My problem is not with protocols, but with an inflexible attitude insisting that an evaluation must always be accompanied by a prospective protocol.

Conclusion

Insisting that every evaluation is coupled to a pre-standing intervention protocol might do more harm than good. The examples above show that protocols can be reconstructed retrospectively and that, as in the intensive care example, where the reconstructions were more, rather than less, accurate in terms of describing the active ingredients.

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