

Reviewer's report

Title: A new conceptual framework for implementation fidelity

Version: 1 **Date:** 5 April 2007

Reviewer: Jill Francis

Reviewer's report:

General

The authors of this manuscript have addressed a methodological issue of central importance not only for the science of implementation but for applied science in general. Although the idea of fidelity is not new, these authors highlight the importance of this issue by proposing a conceptual model that may serve as a guide to researchers in terms of the way they:

- describe interventions (i.e. develop protocols);
- develop strategies to standardise intervention delivery;
- develop strategies to optimise intervention delivery (i.e. to enhance quality);
- evaluate participant responsiveness;
- measure the fidelity with which the intervention was delivered; and
- assess the impact of fidelity as a moderator of intervention effects.

It is clearly argued that we cannot understand why an intervention works (and I would add, possibly more importantly, why an intervention may not work) unless we know whether the intervention was delivered as intended.

From the relevant literature, five components of fidelity are identified: adherence (to the intervention protocol); exposure or dose (encompassing frequency, duration and coverage); quality of delivery; participant responsiveness; and differentiation between intervention components. It is argued that all these components can and should be measured and that Programme complexity and Facilitation strategies should be added to this list.

I have found this paper extremely interesting and engaging, and I thank the editor for inviting me to review it. I think the framework presented in this manuscript will represent an important contribution to the science of implementation, but I would like to see the clarity of the argument enhanced in the following ways:

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1. It is a central principle of a cumulative science that one should assess the sufficiency of existing knowledge before proposing that one's contribution is new. The authors have cited published work on implementation fidelity, including conceptual models, but I am unclear as to whether the coverage of their literature search is comprehensive. A presentation of the search strategy and a summary of the authors' scoping of the literature would be useful. This could perhaps be presented as a brief Methods section. I am not suggesting a full systematic review, simply an indication of how papers were identified, to allay readers' concerns about adequate coverage of the literature.
2. This is related to Point 1. A simple search of Medline (Ovid; from 1950 to March Week 4 2007) demonstrates that the term "implementation fidelity" results in 15 hits. However, the term "intervention fidelity" also results in 15 hits and when the two searches are combined using 'OR' there are 29 hits in all (indicating only one duplicate). Are the authors confident that these two terms are different and that the literature on intervention fidelity is not relevant? Clarification of this point of terminology is important and is related to the question, "What is it that has (or has not) the attribute of fidelity? Is it the intervention itself or the manner in which it is delivered?" A concrete example will illustrate. Let us take a drug intervention: Pill X. Pill X has a number of components, some of which are active ingredients and some of which are 'facilitation strategies' to increase adherence (e.g. the sugar coating). But in one household, a packet of Pill X has been stored in a warm location for a long time and its active ingredients have therefore been disabled. Thus the fidelity of the intervention, Pill X, has been compromised. However, the delivery of Pill X to the patient, Augustus, has high fidelity. Augustus has taken his pills exactly as instructed, twice a day before meals.

My point is that we have two considerations here: the thing that is the intervention and the process by which it is delivered. Both the intervention and its delivery may have high or low fidelity. Given the conceptual analysis that is the foundation of the proposed model of fidelity, I think it would be useful to make this distinction. In terms of the elements of fidelity, it can be argued that Programme complexity, Facilitation strategies and Differentiation are attributes of the intervention itself, whereas Adherence and Participant responsiveness are perhaps attributes of intervention delivery. Dose/exposure and Quality of delivery are more difficult to classify but, for interventions to change behaviour, they may well be attributes of the intervention. Clarity of the terminology around these issues would not only help researchers to access the relevant literature; I think they would clarify the conceptual model itself.

3. A related point that is fairly importantly for this journal: it appears that the word “implement” is used in two senses throughout this manuscript. The first refers to the translation of research findings into practice and the second refers to the administration or presentation of an intervention in a research context. It would be clearer to readers if the first sense were retained and any reference to implementation of an intervention be replaced with ‘delivery’ of the intervention.

4. Another potentially confusing feature is the use of the term “intervention” and “model programme” interchangeably. If these are indeed two distinct types of procedures it would be useful to clarify this with examples. (Is the former to do with interventions to change individual clinicians’ behaviour and the latter to do with organisational or systemic change? Or is the former concerned with research and the latter with policy change?) Indeed, concrete examples would be helpful in any case, as the whole paper is written in abstract terms. A case study that describes an intervention, how its fidelity was assessed and how the assessment was able to inform the ‘how and why’ of intervention effects would be very useful.

5. The authors twice mention that intervention fidelity is a “process variable”. The first mention is in the Abstract; the second is in the first paragraph of the Discussion section. It would be useful to explain what is meant by “process variable” and also to explain how the issue of fidelity fits into the more general notion of process evaluation as opposed to evaluation of intervention effects.

6. As this manuscript does not report a piece of empirical research its structure is understandably non-standard. However, I think the structure could be improved to enhance readability. In particular, it would be helpful if the headings in the Discussion corresponded to the components as labelled in Figure 1.

7. On Page 6, the authors provide a critique of the component, “differentiation”. This is defined on the basis of one cited reference as “identifying unique features of different components or programs” as well as “identifying ... which elements of programmes are essential”. (Is this right? Did authors spell “programmes” in two different ways in the same paper?) The critique consists of stating that differentiation is different from fidelity because the former is about identifying the successful elements. I agree that there is a problem here but I would have thought that the problem is with the definition. On the face of it, differentiation is about distinguishing between components and would arguably fit with the concept of fidelity insofar as such distinction is a requirement of a well-specified intervention. Identifying the effectiveness of each component, however, is surely more the domain of a causal process evaluation or even of outcome assessment. The juxtaposition of (i) blind acceptance of a definition from one source and (ii) a critique that (in my opinion) correctly identifies assessment of outcome as beyond the scope of fidelity assessment - sits rather oddly here.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

8. I apologise for contesting the first sentence of this manuscript, but I think the authors have given us a definition of implementation, rather than of implementation science. The science of implementation, surely, does not rely on ‘success’ of translation. It is about the development of theories, methods and bodies of knowledge in precisely the manner that the authors have engaged in, and this will sometimes involve learning a lot from unsuccessful attempts to translate research findings into practice.

9. We need a reference to Figure 1 in the text so that the reader is tempted to view it when it is most relevant to the argument. It would be helpful if, at this point, the authors could add a brief explanation of the figure, especially the meaning of the arrows. This could perhaps link with the case study mentioned above.

10. Reference number 1: publication year is 2003.

Discretionary Revisions (which the author can choose to ignore)

11. A further central principle of science concerns the importance of replication. I feel that the authors could make more of this point. Without the strategies for maximising intervention fidelity in one study, we do not have the strategies for accurately replicating the intervention in following studies. Without these accurate replications, quantitative synthesis of findings from a group of studies is meaningless (unless fidelity data have been reported).

12. The terms 'credibility' and 'utility' are mentioned in the Abstract summary but nowhere else in the manuscript. If these are key words in the main message from this paper, it would make sense to use them in the argument.

13. The discussion of Programme complexity on Page 11 is reminiscent of Rogers' Diffusion of Innovations theory and leads me to wonder whether there are other attributes of innovations specified in this theory that would inform the articulation of the proposed model.

14. In the case of guidelines, the relationship of specificity to uptake has been well articulated by Michie and Johnston (Changing clinical behaviour by making guidelines more specific. *BMJ* 2004;328:343-345) and it may be helpful to cite this work.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of outstanding merit and interest in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.