

Title: A new conceptual framework for implementation fidelity

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Abstract**Background:**

Implementation fidelity refers to the degree to which an intervention or programme is delivered as intended. Only by understanding and measuring whether an intervention has been implemented with fidelity can researchers and practitioners gain a better understanding of how and why an intervention works, and the extent to which outcomes can be improved.

Discussion:

The fidelity with which an intervention is implemented is a process variable that potentially may influence (moderate) the relationship between an intervention and its outcome. Consequently, it needs to be both understood and measured. The authors undertook a critical review of existing conceptualizations of implementation fidelity and integrated these within a conceptual framework for understanding and measuring this process variable. The resulting theoretical framework requires testing by empirical research.

Summary:

Implementation fidelity is an important source of variation affecting the credibility and utility of research. The conceptual framework presented here offers a means for measuring this variable and understanding its place in the process of programme or intervention implementation.

Background

Implementation science relates to the successful translation of research findings into practice. If an intervention of demonstrated effectiveness is to have a positive impact in practice it needs to be delivered as intended. This idea is captured by the concept of implementation fidelity, sometimes also termed “integrity”.^{i ii} Implementation fidelity is “the degree to which . . . programs are implemented . . . as intended by the program developers”.ⁱ

Implementation fidelity acts as a potential moderator of the relationship between interventions, or model programmes, and their intended outcomes. That is to say, it is a variable that may impact on the relationship between two other variables, for example, how far an intervention actually affects outcomes. This is one of the principal reasons why it needs to be measured. Indeed, a correlation has been found between the fidelity with which a model programme is implemented and how well it succeeds in its aims.^{iii iv v} For instance, two studies examining programmes to help people with mental health issues enter employment found that employment outcomes among their study groups were weakest for those in poorly implemented programmes.^{vi vii} In the same way, a study of a parent training programme found that when the programme was implemented with high fidelity to the model, the parenting practices improved significantly, but the effect was much less when implementation fidelity was low.^{viii}

Therefore, it is only by making an appropriate evaluation of the fidelity with which an intervention or model programme has been implemented that a viable assessment can be made of its contribution to outcomes, i.e, its effect on performance. Unless such an evaluation is made, it will not be known whether a lack of impact is due to poor implementation or inadequacies inherent in the programme itself, a so-called Type III error^{ix}; an issue also addressed by the thesis of comprehensiveness.^x It would also be unclear whether any positive outcomes produced by an implemented programme might be improved still further, if it was found that it had not been implemented fully. The internal validity of any study examining the relationship between an intervention and an outcome may therefore be compromised if it fails to measure the fidelity with which the intervention is implemented.

Primary research into interventions and their outcomes should therefore involve an evaluation of implementation fidelity, if the true effect of the intervention is to be discerned. However, evidence-based practitioners also need to be able to understand and quantify the fidelity with which they are implementing a model programme or intervention. Evidence-based practice assumes that a programme is being implemented in full accordance with its model. This is particularly important given the greater potential for inconsistencies in implementation of a model programme in real world rather than experimental conditions. Evidence-based practice therefore not only needs information from primary researchers about how to implement the model programme, it also needs a means of evaluating whether the programme is actually being implemented as the designers intended.

Similar issues affect secondary research: the common lack of data on implementation fidelity provided by primary research studies, known as “thinness”, prevents those working on systematic reviews and meta-analyses from gauging possible heterogeneity between studies, with the result that data may be pooled or aggregated inappropriately.^{xi xii}

Consequently, the internal validity of a review may be adversely affected.

In summary evaluation of implementation fidelity is important because this variable may not only moderate the relationship between an intervention and its outcomes, but may also prevent potentially false conclusions from being drawn about an intervention’s effectiveness. It may even help in the achievement of improved outcomes. It can give primary researchers confidence in attributing outcomes to the intervention; evidence-based practitioners can be confident they are implementing the model programme properly, if they have the tools to do so; and secondary researchers can be more confident when synthesizing studies. All the above requires a framework within which to understand and measure the concept and process of implementation fidelity. Accordingly, the objective of this paper is to review critically the literature on implementation fidelity and to propose a framework for understanding and evaluating this concept.

Discussion

This discussion begins with a brief review of the existing conceptualizations of implementation fidelity and their limitations, followed by the proposal of a framework

describing the concept and process of implementation fidelity, and recommendations for future research.

The concept of implementation fidelity is currently described and defined in the literature in terms of five elements of fidelity that need to be measured.^{i, ii, iv} These are: adherence to a model programme; exposure or dose; quality of programme delivery; participant responsiveness; and programme differentiation. Within this conceptualization adherence is defined as whether “a program service or intervention is being delivered as it was designed or written”.^{iv} Dosage or exposure refers to the amount of a programme received by participants, in other words, whether the frequency and duration of the programme is as full as prescribed by its model.^{i iv} For example, it may be that not all elements of the model programme are delivered, or are delivered but not as often as required. Coverage may also be included under this element, that is, whether all the people who should be participating or receiving the benefits of a programme do so.

Quality of delivery is defined as “the manner in which a teacher, volunteer or staff member delivers a program”.^{iv} However, it is perhaps a more ambiguous element than this suggests. An evaluation of this may require using a benchmark either within, or even beyond that stipulated by programme designers. Both ideas are accommodated by the literature. One conceptualization states that this element of fidelity could involve delivering the programme using “techniques . . . prescribed by the programme”^{iv}, while another refers to a benchmark outside of the programme: “the extent to which a provider approaches a theoretical ideal in terms of delivering program content”.ⁱ Such criteria of good practice

may therefore be external from those of the designers (although, in some cases, they may also be the same). If such a clear benchmark exists then quality of delivery may be treated, along with adherence and dosage, as one of three discrete aspects required to assess the fidelity of a programme. However, it may potentially also be viewed as a moderator of the relationship between a model programme and the fidelity with which it is implemented, a role not entertained in the literature to date. For example, if all the content of a programme is delivered badly, despite following the programme's specifications, then this may affect the degree to which high fidelity can be realized.

Participant responsiveness is "the extent to which participants are engaged by and involved in the activities and content of a program".ⁱ It involves judgments by participants or recipients about the outcomes and relevance of a programme. In this sense what is termed "reaction evaluation" in the evaluation literature may be considered an important part of any evaluation of a programme.^{xiii}

Program differentiation, the fifth aspect, is defined as "identifying unique features of different components or programs", and identifying "which elements of . . . programmes are essential", without which the programme will not have its intended effect.ⁱ Despite being viewed as an element of implementation fidelity by the literature, programme differentiation actually measures something distinct from fidelity. It is concerned with determining those elements that are essential for its success. This exercise is an important part of any evaluation of new programmes. It enables discovery of those elements that make a difference to outcomes and whether some elements are redundant. Such so-called

“essential” elements may be discovered either by canvassing the designers of the programme or, preferably, by “component analysis”, assessing the effect of the programme on outcomes and determining which components have the most impact.ⁱ It may also have implications for implementation fidelity if, for example, these essential elements are the most difficult to implement. This may then explain a lack of success afflicting the programme. Otherwise, such an exercise is independent of measurement of implementation fidelity, and is only relevant in that it may determine the content of the programme to be implemented, and therefore the model against which implementation fidelity must be measured.

Despite agreeing that implementation fidelity involves measurement of these five elements, the literature offers two distinct views on how this should be done. On the one hand, it is argued that each of these five elements represents an alternative way to measure fidelity, i.e. implementation fidelity can be measured using either adherence or dosage or quality of delivery etc..^{iv v} On the other hand, it is argued that all five elements need to be measured to capture a “comprehensive” or “more complete picture” of the process, i.e. evaluation requires the measurement of adherence and dosage and quality of delivery etc..ⁱⁱⁱ However, relationships between the various elements is far more complex than such conceptualizations allow. This paper therefore advances a third conceptual framework for implementation fidelity, which not only proposes the measurement of all of these elements, but also clarifies and explains the function of each and their relationship to one another. Programme complexity and facilitation strategies are also considered as novel elements in the framework (See Box).

Elements of implementation fidelity
Adherence
Dose / Exposure
Programme Complexity (Moderator)
Facilitation strategies (Moderator)
Quality of delivery (Moderator)
Participant responsiveness (Moderator)
Programme differentiation

This framework is described in the following way. Firstly, the basic process of measuring adherence to a model programme and its components is described. Secondly, the role of certain variables that may act as potential moderators of the relationship between a model programme and what is actually implemented is examined. In this case, moderators are those variables that may influence the relationship between a model programme and its implementation. For example, the less enthusiastic participants are about a programme, the less likely the programme is to be implemented properly and fully. Variables considered here are a programme's complexity, the use of facilitation strategies to optimize and standardize implementation, quality of delivery and participant responsiveness. Thirdly, relationships between these moderators are considered. Finally, appropriate means of measuring the various components of the framework are described.

A new conceptual framework

I. Adherence to a programme

Adherence is essentially the bottom-line measurement of implementation fidelity. If an implemented programme adheres completely to the content, frequency and coverage prescribed by its model, then fidelity to the model can be said to be high. The process of implementation and fidelity therefore begins with a model programme. This may be based on a specific item of research or a policy document. Measuring implementation fidelity means evaluating whether the result of the implementation process is an effective realization of the model programme. This means adherence to the prescribed details of the programme, i.e. the full implementation of individual components of the programme as regards coverage, frequency, duration, and any other specific details (such as the content to be delivered). Some of these elements clearly correspond to dose, which is an obvious sub-category of adherence rather than a discrete element. The measurement of adherence to a programme's predefined components may be quantifiable: an evaluation to gauge how much of the model programme has been delivered, how frequently, and whether all eligible parties have been covered.

However, adherence may not require every single component of a model programme to be implemented. A programme may also be implemented successfully, and meaningfully, if only the "essential" components of the model are implemented. However, the question remains about how to identify what is essential. One possible way to do this is to conduct a sensitivity analysis, or "component analysis", using implementation fidelity data and

performance outcomes from different studies of the same programme to determine which, if any, components or combination of components of the programme are essential, i.e. are prerequisite if the programme is to have its desired effect. However, if essential components of a model programme are not known, then fidelity to the whole programme is needed. No empirical research in any area of social policy to identify essential programme components in this way has yet been identified. Research to date has only employed the more unreliable method of canvassing the opinions of the programme designers themselves to identify essential elements, with the limitations of this approach being acknowledged.ⁱⁱⁱ

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Identifying these essential components of a programme provides scope for identifying adaptability to local conditions. Model programmes cannot always be implemented fully in the real world. Local conditions may require the programme to be flexible and adaptable. Some specifications of programmes allow for local adaptation. Even if they do not explicitly do this, local adaptations may be made to improve the “fit” of the intervention within the local context. Indeed, the proadaptation perspective implies that successful interventions are those that adapt to local needs.^{xv} However some argue that the case for local adaptation may well have been exaggerated, at least for programmes where the evidence does not necessarily support it.ⁱⁱⁱ The intermediate position is therefore that programme implementation can be flexible as long as there is fidelity to the so-called “essential” elements of the programme. The absence of these elements would have significant adverse effects on the capacity of the programme to achieve its goals. Indeed

without them it cannot meaningfully be said that the programme has achieved high implementation fidelity.

II. Moderators

A high level of adherence or fidelity to a model programme, or its essential components, is not achieved easily. Several factors may influence successful implementation. These moderators are variables that may affect the degree of fidelity with which a model programme is implemented. Each of the potential moderators of this relationship is now considered in turn.

II.1 Programme complexity

A programme's description may be simple or complex, detailed or vague. Detailed or specific model programmes have been found to be more likely to be implemented with high fidelity than programmes that are vague. For example, well-planned programmes, where all the key components are identified in advance have been found to produce higher levels of adherence than less well-structured interventions.^{i v} Specificity enhances adherence.

There is also evidence that it is easier to achieve high fidelity of simple than complex model programmes or interventions.ⁱ This may be because there are fewer “response barriers” when the model is simple.^{xvi} Complex interventions have greater scope for variation in their delivery, and so are more vulnerable to one or more components not being implemented as they should. This has led to calls in some quarters for improving the recording and reporting of complex interventions to identify and address potential sources

of heterogeneity in implementation.^{xi xii xvii} Overall research suggests that simple but specific model programmes are more likely to be implemented with high fidelity than overly complex or vague ones. As such, the comprehensiveness and nature of a programme's description may influence how far the programme successfully adheres to its model when implemented.

II.2 Facilitation strategies

Strategies may be used to help achieve the highest possible level of implementation fidelity. These include the provision of manuals, guidelines, training, monitoring and feedback, capacity building and incentives. Such strategies may be used not only to optimize but also to standardize implementation, i.e. to ensure that everyone is receiving the same training and support, with the aim that programme delivery is as uniform as possible.^{xviii}

The potential moderating role of this factor does not yet appear to have been evaluated within the literature on implementation fidelity. Yet it is possible that these strategies, like the nature of the programme description, may potentially moderate the degree of fidelity achieved in relation to the model programme: the more that is done to help implementation, through training etc., the higher the potential level of implementation fidelity to be achieved. The role of such strategies in optimizing fidelity and standardizing what is being implemented is arguably even more important in the case of complex interventions, which can be multifaceted and therefore more vulnerable to variation in their implementation.^{xvii}

More facilitation strategies do not necessarily mean better implementation. A simple model programme may require very little in terms of training or guidance to achieve high implementation fidelity. A complex model programme by contrast may require extensive support strategies. There is therefore an issue of adequacy, and this may be determined by the relationship between facilitation strategies and programme description. The relationship between these potential moderators is discussed more fully below. Empirical research has yet to demonstrate whether facilitation strategies can indeed affect how well or badly a model programme is implemented, but it should certainly be considered as a potential moderator of implementation fidelity.

II.3 Quality of delivery

Quality of delivery is an obvious potential moderator of the relationship between a model programme and the fidelity with which it is implemented. It concerns whether a programme is delivered in a way appropriate to achieving what was intended. If the content of a programme is delivered badly, then this may affect the degree to which full implementation is realized. The provision of extensive training, materials and support to those delivering a programme in studies evaluating fidelity is an implicit acknowledgement that effort is required to optimize the quality of the delivery of the programme being evaluated.^{iii xix xx xxi}

In the same way, quality assurance or improvement strategies, such as providing ongoing monitoring and feedback to those delivering the programme, provide a more explicit acknowledgement of the importance of quality of programme delivery and its potential moderating effect on implementation fidelity.^{xxi xxii}

II.4 Participant responsiveness

If participants view a programme as being of no relevance to them, then their non-engagement may be a major cause of its failure or low coverage, and thus implementation fidelity might be low. Participant responsiveness may therefore be an important moderator in any process examining implementation fidelity. In fact, participants covered by this element of implementation encompass not only individuals receiving the intervention, but also those responsible for it, and even the organization more broadly. If an organization, as represented by senior management for example, is not committed to a programme, then the responsiveness of individuals may be affected too.ⁱⁱ This is a key aspect of all organizational change literature.^{xxiii}

Participant responsiveness might be evaluated by measuring the degree to which participants accept the responsibilities required by the model programme^{xxiv}, the perceived usefulness and value of the programme being introduced^{xix} or, more broadly, the responsiveness of the environment into which the programme is introduced, the so-called “therapeutic milieu”.^{xxv} Participant responsiveness may even reach beyond attitude to actual action, for example, to gauge whether a “treatment has been . . . understood . . . and that the individual performs treatment related . . . skills and strategies”.^{xxii} In this sense, “enactment” may be considered a potential measure of participant responsiveness.^{xviii}

III. Relationships between moderators

These moderators are not necessarily discrete elements. There may be complex relationships at work between two or more moderators. An obvious example is where the

provision of training and guidelines on how to deliver the model programme may have a direct impact on the quality with which the programme is actually delivered (and this may in turn affect the fidelity with which the model programme is implemented). If the amount of training provided is small, then the quality of delivery may be poor. Facilitation strategies may also influence participant responsiveness: the provision of incentives could make both providers and participants more amenable or responsive to a new programme. Quality of delivery might function in the same way: a well-delivered programme may make participants more enthusiastic about, and committed to, a programme. One moderator might therefore predict another.

However, as noted above, these relationships are more complex than may be captured in the simple correlation of large numbers of facilitation strategies producing high quality of delivery, or by stating that small incentives produce limited participant responsiveness. One reason is the moderating role of programme complexity: a simple model programme may not require much training or guidance to achieve high quality of delivery or participant responsiveness. A small amount of training may suffice. Participants may also be enthusiastic about new programmes because of other factors, regardless of incentives or other strategies.

Thus the interaction of these moderators within the “black box” may further affect the relationship between a model programme and the fidelity with which it is implemented.

IV. Measurement

Implementation fidelity is a more holistic process of evaluation than measurement of adherence or quality of delivery alone. As a result, any evaluation needs to measure all the factors listed above that influence the degree of implementation fidelity, such as programme complexity and the adequacy of facilitation strategies. It also needs to gauge participant responsiveness or receptiveness to proposed and implemented programmes. Such measures are currently almost completely absent from the implementation fidelity research, which focuses solely on a fidelity score determined almost exclusively by adherence.^{iii viii vi vii xiv xx xxi xxii xxiv xxv xxvi} What is more, in most research, implementation fidelity falls short of the ideal and is sometimes even very poor, yet it is only by measuring the moderators described above that potential explanations for low or inadequate implementation may be apprehended or understood. It is only by identifying and controlling for the contribution of possible barriers to implementation that such issues can be addressed and higher implementation achieved.

Summary

Achievement of high implementation fidelity is one of the best ways of replicating the success with practices achieved by original research. Obviously, the successful development and implementation of policy is governed by more than the principles of evidence-based practice^{xxvii}, but the concept of implementation fidelity provides a framework for understanding why and how implementation should be evaluated.

This paper offers a new conceptual framework for implementation fidelity, which is an important moderator of the relationship between programmes and performance,

intervention and outcomes, both in research and the real world. This conceptualization provides researchers with a potential framework for implementation research. It also offers evidence-based practitioners a guide to the processes and factors at play when implementing programmes described in research. Monitoring of implementation fidelity following this framework enables better evaluation of the actual impact of an intervention on outcomes. However, much more research is needed on this topic. Empirical research is needed to clarify the moderating impact of the components described here, and to test the framework itself.

Competing Interests

The authors declare that they have no competing interests.

Author's contributions

CC drafted the paper; CC, MP and SW are responsible for the intellectual content of the paper. All authors approved the final manuscript.

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Figure 1. Conceptual framework of implementation fidelity



