**INTRODUCTION TO PROCESS EVALUATION**

**by Simon Moss**

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| **Introduction** |

Many studies explore the outcome of some intervention or program, such as an exercise program that is designed to prevent diabetes. Yet, research should not only assess outcomes but should evaluate the process as well—that is, how the intervention or program was applied. If studies report outcomes but do not evaluate the process, other practitioners might implement the intervention or program differently, generating diverse outcomes.

**Specific aims of program evaluations**

Moore et al. (2014) published a comprehensive paper that delineates how researchers should apply process evaluations when interventions are complex. This paper is endorsed by the UK Medical Research Council and also includes many examples of process evaluation. According to these guidelines, process evaluation is usually conducted to explore and characterize three facets of intervention studies: implementation, mechanism of impact, and context. The following table outlines the key questions that correspond to these three facets.

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| Facet | Main questions |
| **Implementation**: How the intervention was delivered | * To what degree were implementers—the individuals who implemented the intervention—able to comply with the recommended practices or activities in this intervention, called fidelity? * What was the duration, frequency, or magnitude of this intervention, called dose? * What other adjustments did the implementers need to introduce, called adaptations? * To what extent did the intended targets receive this intervention, called reach |
| **Mechanism of impact**: Why the intervention was effective | * How did participants respond to features of the intervention, including their perceptions and behavior? * Which changes mediate the association between the intervention and the outcomes? * What were the unanticipated effects or correlates of this intervention? |
| **Context**: Which conditions or circumstances may have affected the results | * Which features of the setting or circumstances could affect the intervention—and specifically affect that theoretical mechanisms that purportedly explain the benefits of this intervention * Which features of the setting or circumstances might affect how the intervention is implemented? |

**When are process interventions useful**

Whenever researchers investigate an intervention—that is, some practice or program that is designed to enhance the health of individuals or fulfil some other goal—process evaluation may be considered. However, process evaluation is primarily useful when the interventions are complex. Interventions are deemed as complex if

* to implement the intervention, the implementer needs to initiate many behaviours or apply many skills—unlike, for example, merely prescribing one drug, for example
* the intervention is applied to many distinct clusters of individuals
* the intervention is designed to influence a range of distinct outcome, such as mood, weight, and sleep
* the implementer is granted some discretion over how to implement the intervention

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| **Planning the evaluation** |

Before you conduct an evaluation, you need to plan this project carefully. Specifically, you need to reach some nuanced decisions about which individuals should contribute and the relationships between these individuals. The first column of the following table outlines the issues you need to consider. The second column illustrates these issues—with reference to an intervention that was designed to explore whether a mental health program, in which participants receive daily questions about their life and corresponding advice on how to improve their mood, enhances the wellbeing of research candidates.

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| Issues to consider | Example |
| **Closeness.** How close should you be to the individuals who develop or implement the intervention. In particular   * if you develop a very close friendship with these individuals, you may not be able to evaluate their behavior objectively * but, if your relationship is not close enough, your capacity to work effectively with these individuals might deteriorate | * Your interactions with these individuals should be warm and genuine * However, you could perhaps refrain from attending social events with these individuals |
| **Conflicts of interest**. Consider whether a conflict of interest could arise from the relationships between the researchers and stakeholders, such as policy makers. If so   * The authors need to clarify how they will manage these conflicts of interest and ensure the evaluations are objective and independent | * For example, a policy maker, invested in the intervention, might be a family member or supervisor of a researcher. The researcher might feel obliged to depict the process favourably |
| **Corrections**. Consider whether you should intervene if you feel the implementers have diverged considerably from the recommended practices. That is   * if an implementer does not apply the intervention correctly, you might decide to offer advice at an opportune time * alternatively, you might decide this intervention could skew the findings | * Perhaps you should intervene only if the actions of these implementers could harm participants |
| **Expertise in research methods**. If you need to organize a research team, at least one person should have developed expertise in the research methods. | * At least one person should be an expert in quantitative methods * At least one person should be an expert in qualitative methods * That is, process evaluation tends to entail both quantitative and qualitative methods |
| **Expertise in theory**. At least one person should have developed inter-disciplinary theoretical expertise |  |
| **Oversight of outcome and process evaluation**. Usually, process evaluations are conducted in parallel to an outcome evaluation—in which researchers investigate whether the intervention was effective. If so, at least one person should be granted oversight of both the process evaluation and outcome evaluation. | * One person should be granted the role to coordinate the process evaluation and outcome evaluation * For example, this person might uncover opportunities to integrate some features of these evaluation studies to converse resources and to share key insights * This person would also examine whether these two evaluation studies might impede or affect one another * To illustrate, this person would coordinate the roles carefully to guarantee that anyone who is assessing the process data is unaware of the outcomes and vice versa. * Otherwise, knowledge of the outcomes could bias evaluations of the processes. Similarly, after evaluating the processes, individuals are not blind to the conditions. * Plans to separate or integrate these studies should, if possible, be formulated before the research begins |

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| **Designing and conducting the process evaluation** |

Once you have established the role of contributors, you need to design the methods you will utilise to collect data in more detail as well as plan the possible analyses of data. To achieve this goal, apply the guidelines that appear in the following table.

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| Guidelines on how to collect data | Example |
| **Delineate the mechanisms in this context**. That is, clarify the mechanisms or reasons why the intervention might be effective in the setting or circumstances you plan to implement this initiative | For example, a program in which participants receive daily questions about their life and mental health could be effective because   * the questions are designed to engage participants; they become more likely to apply the advice they receive * the answers to these questions gradually accrue over time and instil a sense of growth * some questions are designed to prompt individuals to contemplate future aspirations—and these reflections distract attention from immediate concerns and foster a sense of hope * some questions are designed to elicit feelings of nostalgia—a feeling that can diminish a sense of loneliness * the questions help individuals clarify their goals and enhance their motivation   Ideally, you would integrate these mechanisms into a cohesive theoretical framework. |
| **Identify and assess the assumptions of this intervention**. That is, what are the major sources of uncertainty you want to explore? | This program assumes that   * participants believe the questions and advice might be helpful; otherwise, they will not persist * participants who experience distress are still motivated enough to persist on this program and to apply the advice they receive   To assess these assumptions, participants should be asked   * “To what extent do you feel this program is likely to improve your mental health?” * “When feeling anxious, are you as likely to follow the advice? If not, how do your interactions change when you feel anxious?” |
| **Consult with stakeholders to refine the questions**. | You might, for example, seek feedback from   * the other researchers who are contributing to the evaluation * the individuals who are implementing the evaluation * managers who might need to decide whether to extend this evaluation to other services * policy makers who might need to adjust policies to facilitate this intervention |
| **Identity similar process evaluations in the past**. Decide whether you might   * replicate parts of these evaluations * extend and validate the results of these evaluations | You could, for instance   * utilize some of the protocols and measures of a previous evaluation that investigated a similar intervention * include some of the data in your analysis—such as comparing fidelity in your research to the fidelity of this previous evaluation |
| **Select your quantitative methods**. Decide which statistical or numerical methods will be used to assess hypothesised mechanisms or moderators. Attempt to measure all key processes or mechanisms. | To illustrate   * ANCOVAs could be utilized to assess whether a sense of meaning and purpose mediates the association between the intervention and wellbeing * Moderated regression could be used to gauge whether the diagnosis of participants affects their motivation to persist on this program as well as their beliefs about the efficacy of this program   You might need to seek advice on which techniques to utilise |
| **Select your qualitative methods**. Decide which qualitative methods, such as thematic analysis, will be applied to   * characterize adjustments to the intervention * characterize the perspective and experience of participants—partly to explore other causal pathways and theories   You should also include some detailed case studies to depict the experience of specific participants as vividly as possible | Interviews and focus groups with implementers and participants might uncover some vital insights. These individuals might reveal that   * implementers decided to offer more advice and fewer questions in response to feedback they received from participants * participants sometimes abandoned the intervention because they did not want to contemplate their life |
| **Consider the timing of data collection**. Data should be collected at several times before, during, and after the interventions |  |

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| **Analysing the data** |

After you have designed the process evaluation and collected the data, you need to analyse the data and report the results. The following table offers some insights on how to achieve this goal.

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| Guidelines on how to collect and analyse data | Example |
| **Present descriptive stats on fidelity, dose, and reach**. To illustrate, you could indicate   * the proportion of time that specific protocols were followed * the duration, frequency, or magnitude of specific practices or behaviours * the number of participants from various sub-categories who began or completed the intervention | For example, the report might indicate that   * when encouraging participants to utilize this program, on average, implementers conveyed 74% of the messages, with a standard deviation of 5 * on average, participants answered 40% of the questions; the mean length of these answers was 25 words, with a standard deviation of 10 * 25% of the depressed participants completed more than 50% of the questions; in contrast, 47% of the anxious participants completed more than 50% of the questions |
| **Identify characteristics or circumstances that were related to these statistics**. To illustrate   * which characteristics of participants affected these measures of fidelity, dose, and reach * which characteristics of the setting, such as location, affected these measures * which characteristics of the implementers, such as their experience, affected these measures | As an example   * a t-test revealed that implementers who were registered health practitioners were more likely to convey the key messages than other implementers. Specifically, health practitioners conveyed 82% of the messages, whereas other implementers conveyed only 68% |
| **Integrate outcome data and process data.** You might   * assess how variations in the processes moderate the association between interventions and outcomes * assess whether specific processes mediate the association between interventions and outcomes | To illustrate, various analyses, such as moderated regression, hierarchical regression, and ANOVAs, might reveal that   * when implementers conveyed all the messages to participants, the intervention was more likely to enhance wellbeing. Thus, the degree to which implementers follow the script moderates the effect of this intervention * the number of words that participants wrote—a measure of engagement—mediated the association between the intervention and wellbeing. Therefore, the intervention is effective because the program engages participants |
| **Collect and analyse qualitative data iteratively**. That is,   * perhaps interview participants during the early phases of the intervention * code the data and extract themes or insights * interview some of these participants again to explore and assess these themes or insights |  |
| **Coordinate the use of quantitative and qualitative data**. In particular   * quantitative data could be used to test some of the insights that emanate from qualitative data, such as interviews, focus groups, or transcripts * qualitative data could be used to explain some of the finding that emanate from the quantitative analyses | For example   * interviews revealed that participants tended to feel better a day after writing about positive facets of their life. Consistent with this perspective, regression analyses showed that mood one day was positively associated with the number of positive words written the previous day after controlling mood during this previous day * moderated regression showed that parents were more likely to benefit from the intervention than other participants. As Interviews with a subset of parents showed, the intervention was useful because participants could discuss the questions with their children, facilitating their relationship. |
| **Usually, report some of the qualitative data before the outcomes are revealed.** Otherwise, the outcomes might bias the interpretations. | * Furthermore, whenever you report process data, indicate whether the outcomes had been communicated before or after the data were analysed * That is, you need to acknowledge whether your interpretations could be biased. |

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| **Reporting the data** |

After analysing the data, you need to report the results. To some extent, you should follow the guidelines of other reports that have applied similar methods, such as regression analysis or thematic analysis. Nevertheless, you should also be mindful of a few principles that are quite specific to process evaluations, as outlined in the following tables.

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| Guidelines on how to collect and analyse data | Example |
| **Clarify how the theory guided the research methods**. That is, you need to show how the questions you explored and asked correspond to the mechanisms that you purport underlie the outcomes |  |
| **Consider multiple articles**. Often, researchers will publish more than one publication, such as several journal articles, to report the process evaluation. If so,   * each publication should clarify how this subset of the research is related to the overall process evaluation * typically, publish a protocol paper that delineates the entire evaluation or a summary paper. The other publications should refer to this paper * disseminate findings to relevant stakeholders, including decision makers | * This research is embedded within a broader process evaluation. In particular, as Figure 1 shows, this paper explores the perspectives of participants during the first phase of this evaluation. |

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