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**Article:**

Cargo, M., Harris, J., Pantoja, T. et al. (7 more authors) (2018) Cochrane qualitative and implementation methods group guidance paper 4: methods for assessing evidence on intervention implementation. *Journal of Clinical Epidemiology*, 97. pp. 59-69. ISSN 0895-4356

<https://doi.org/10.1016/j.jclinepi.2017.11.028>

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# Accepted Manuscript

Cochrane Qualitative and Implementation Methods Group Guidance Paper 3:  
Methods for Assessing Evidence on Intervention Implementation

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PII: S0895-4356(17)31334-3

DOI: [10.1016/j.jclinepi.2017.11.028](https://doi.org/10.1016/j.jclinepi.2017.11.028)

Reference: JCE 9546

To appear in: *Journal of Clinical Epidemiology*

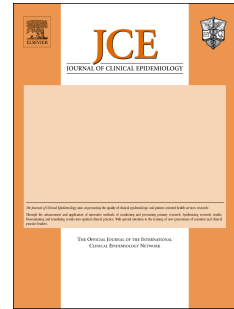
Received Date: 13 May 2016

Revised Date: 2 November 2017

Accepted Date: 9 November 2017

Please cite this article as: Cargo M, Harris J, Pantoja T, Booth A, Harden A, Hannes K, Thomas J, Flemming K, Garside R, Noyes J, Cochrane Qualitative and Implementation Methods Group Guidance Paper 3: Methods for Assessing Evidence on Intervention Implementation, *Journal of Clinical Epidemiology* (2018), doi: 10.1016/j.jclinepi.2017.11.028.

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1 **Title.** Cochrane Qualitative and Implementation Methods Group Guidance Paper 3: Methods for  
2 Assessing Evidence on Intervention Implementation

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78 **Abstract**

79 Objective: This article provides reviewers with guidance on methods for identifying and  
80 processing evidence to understand intervention implementation. Study Design and Setting:  
81 Strategies, tools and methods are applied to the systematic review process to illustrate how  
82 process and implementation can be addressed using quantitative, qualitative and other  
83 sources of evidence (i.e., descriptive textual, non-empirical). Results: Reviewers can take  
84 steps to navigate the heterogeneity and level of uncertainty present in the concepts,  
85 measures and methods used to assess implementation. Activities can be undertaken in  
86 advance of a Cochrane quantitative review to develop program theory and logic models that  
87 situate implementation in the causal chain. Four search strategies are offered to retrieve  
88 process and implementation evidence. Recommendations are made for addressing rigour or  
89 risk of bias in process evaluation or implementation evidence. Strategies are recommended  
90 for locating and extracting data from primary studies. The basic logic is presented to assist  
91 reviewers to make initial review level judgements about implementation failure and theory  
92 failure. Conclusion: Although strategies, tools and methods can assist reviewers to address  
93 process and implementation using quantitative, qualitative and other forms of evidence,  
94 few exemplar reviews exist. There is a need for further methodological development and  
95 trialling of proposed approaches.

96 **Running Title:** Methods for Assessing Evidence on Intervention Implementation

97 **Keywords:** Systematic reviews, process evaluation, implementation, Cochrane, qualitative  
98 evidence synthesis; mixed-method synthesis

99 **Funding sources**

100 This research did not receive any specific grant from funding agencies in the public,  
101 commercial, or not-for-profit sectors.

102

103

**Key findings:**

Strategies, tools and methods are available to support reviewers to address process and implementation using qualitative and process evaluation evidence and other evidence from quantitative studies included in Cochrane reviews.

**What this paper adds to what was known?**

Cochrane quantitative reviews of interventions should include steps to identify, synthesise and then integrate evidence to address reach, dose, fidelity, co-intervention, contamination and the role of contextual factors on implementation.

**What is the implication and what should change now?**

Cochrane quantitative reviews use risk of bias tools to rule out evaluation failure. This guidance suggests that systematic reviewers use complementary tools to make informed judgements about implementation failure and theory failure to strengthen internal validity and enhance the uptake of review findings by decision-makers.

104

105

106 In 2013, the Cochrane Qualitative and Implementation Methods Group (CQIMG) expanded

107 its remit to include issues related to assessing implementation in systematic reviews of

108 interventions. The CQIMG focus on implementation complements the scope of work of the

109 Cochrane Effective Practice and Organisation of Care Group which undertakes systematic

110 reviews of educational, behavioural, financial, regulatory and organisational interventions

111 designed to improve health professional practice and the organisation of health care

112 services.

113 Implementation, conceptualized as a planned and deliberately initiated effort with the

114 intention to put an intervention into practice (1), occupies the space between the 'blueprint

115 for the intervention' (i.e., assumptions articulating how and why an intervention is supposed

116 to work) and the 'outcomes observed in practice'. Process evaluation investigates the

117 activities and internal dynamics of an intervention during its implementation to determine

118 how well an intervention operates (2, 3). This article provides reviewers with guidance on

119 how to approach process and implementation in a Cochrane quantitative review of the

120 effects of an intervention. Some of the issues discussed are relevant for both qualitative  
121 and quantitative reviews. This paper should be read in conjunction with the articles in this  
122 series about question formulation (4), evidence-appropriate methods for qualitative  
123 synthesis of evidence on implementation(5) and methods for integrating findings from  
124 qualitative syntheses with intervention effectiveness reviews (6), as it provides complementary  
125 information on how to refine implementation questions, retrieve process evaluation  
126 evaluations or implementation data and rule out implementation failure and theory failure  
127 when integrating the findings from qualitative syntheses with intervention effectiveness  
128 reviews.

### 129 **Why is implementation important?**

130 Too often quantitative reviews assess intervention outcomes (i.e., does it work) without  
131 considering how the process of implementation influences observed outcomes. In these  
132 reviews, causal inferences can be undermined from limitations in the design, data collection  
133 and analysis of primary studies and lead to an under- or overestimation of the true  
134 intervention effect. To assess the internal validity of primary quantitative studies, review  
135 authors apply risk of bias tools to make judgements about a number of methodological  
136 biases (i.e., selection, performance, detection, attrition, reporting) (7). Assessing risk of bias  
137 can rule out evaluation failure due to methodological biases that compromise internal  
138 validity (2). Although risk of bias is necessary to assess the strength of causal inferences in  
139 determining whether interventions are successful, it is not sufficient. Reviewers additionally  
140 need to establish the presence of a functional relationship between intervention  
141 implementation (i.e., independent variable) and a change in the outcome (i.e., dependent  
142 variable). To draw valid conclusions both need to be defined and evaluated. At a practical  
143 level information needs to be extracted from each primary study to inform a judgement  
144 about the integrity of implementation, and to examine whether specified procedures in the  
145 primary studies were implemented as outlined in the intervention protocols.

146 Formal evaluation of implementation in a process evaluation enables reviewers to  
147 determine whether key implementation outputs were achieved (8). Synthesising this  
148 information across primary studies can enhance the internal validity of systematic reviews  
149 by ruling out implementation failure and theory failure and provide decision-makers with  
150 insights into the conditions needed to generate positive outcomes in the target population

151 (8). Implementation failure is suspect when the lack of expected outcomes is attributed to  
152 poor implementation practices. Theory failure is suspect when intervention activities are  
153 implemented according to the specified standards, guidelines or intervention design  
154 strategy but expected outcomes are not observed. This suggests that the theory, logic or set  
155 of assumptions that specify how the intervention was expected to bring about change was  
156 incorrect (9). It is additionally important to consider the important role of contextual factors  
157 as interventions can be implemented and received differently in different contexts (10).  
158 Moreover, an unfavourable context can have a significant impact on the feasibility to  
159 implement or scale-up an intervention (11).

160 The example in Box 1 illustrates how the behavioural effects of a school-based program for  
161 children are influenced by implementation.

Box 1: Example highlighting the importance of accounting for implementation in quantitative reviews of interventions.

Aspects of implementation were accounted for in a systematic review that assessed the effects of universal school-based social information processing interventions on the aggressive and disruptive behaviour of school-age children(12). Studies reporting problems with program implementation produced smaller effect sizes compared to those not reporting such problems. Moreover, programs delivering more frequent treatment sessions per week were more effective than programs delivered less frequently. Review authors hypothesise that the cognitive skills emphasised by these types of programs may be hard to master and that more frequent delivery provides children with more opportunities for practice and reinforcement. These measures of implementation provide decision-makers with useful information on the conditions under which social information programs are more likely to reduce aggressive and disruptive behaviour in children.

162

### 163 **What aspects of implementation are assessed and how?**

164 Assessing implementation is a crucial component in the systematic reviews of quantitative  
165 health and social care interventions. Lack of information on intervention implementation



166 weakens internal validity and inhibits the translation and uptake of evidence by decision-  
167 makers to inform policy and practice. Aspects of implementation can be quantitatively  
168 assessed in different types of studies. These studies include randomised trials which answer  
169 questions pertaining to “*Can this intervention work in highly controlled or ideal conditions?*”  
170 positioned at the explanatory end of the pragmatic-explanatory spectrum (10) (i.e.,  
171 ‘*efficacy*’ studies) and “*Does this intervention work in real world or usual care conditions?*”  
172 positioned at the pragmatic end of the pragmatic-explanatory spectrum (i.e., ‘*effectiveness*’  
173 studies). Dissemination studies evaluate how the targeted distribution of intervention  
174 materials to a specific audience can be successfully implemented so the increased spread of  
175 knowledge about the evidence-based achieves greater use and impact of the evidence-  
176 based interventions(13). Implementation studies evaluate how a specific set of activities and  
177 designed strategies are used to successfully integrate and sustain an evidence-based  
178 interventions within specific settings (13). Scale-up studies evaluate deliberate efforts to  
179 increase the impact of evidence-based interventions to benefit more people and to foster  
180 policy and program development on as lasting basis(13). Policy analysis, which involves  
181 identifying the possible policy options to address a health and social care problem and then  
182 using the appropriate methods to determine the most effective, feasible and efficient  
183 option, is featured in dissemination, implementation and scale-up studies. In addition, it is  
184 increasingly common that qualitative ‘sibling’ studies and mixed-method process  
185 evaluations are undertaken alongside a trial, which can be synthesised to better understand  
186 the political and operational factors associated with the implementation of health policy,  
187 health systems, behavioural, environmental or clinical interventions. A synthesis of  
188 qualitative studies that are unrelated to trials can also be helpful in understanding the  
189 factors that affect intervention implementation (14, 15).

190

191 Process evaluations focus on one or more aspects of implementation, including reach, dose  
192 delivered, dose received, fidelity, adaptation, intervention quality, recruitment, provider  
193 engagement, participant engagement and contamination, co-intervention. Contamination  
194 and co-intervention are commonly included in risk of bias assessments (10, 16, 17). Table 1  
195 provides definitions for these terms with example quantitative indicators and qualitative  
196 questions. At a minimum, it is recommended that a process evaluation includes information  
197 on reach, dose delivered/ received, fidelity and co-intervention, contamination (17) and

198 supplementary information on contextual factors (10, 17, 18). Including the latter in  
199 process evaluation aligns with the growing body of literature on complex interventions  
200 which recognises that intervention outcomes and implementation are highly influenced by  
201 contextual factors (1). The specific measures used to assess implementation in  
202 interventions will vary depending on whether reviews include efficacy, effectiveness,  
203 dissemination, implementation, policy or scale-up studies. The reason for this is that  
204 implementation is defined relative to the intervention content and as studies move from  
205 bench to bedside to population, the concepts of reach, dose and fidelity pertain to different  
206 aspects of the health and social care system. In complex reviews it is possible that these  
207 concepts may be assessed at two levels of the system (e.g., extent to which patients adhere  
208 to a treatment and the extent to which clinicians adhere to practice guidelines). In this  
209 regard, Harris (4) provides strategies for reviewers to apply in formulating review questions  
210 for complex interventions, which may include those with multiple implementation chains.  
211 We recommend review authors consider these dimensions as minimum requirements for  
212 inclusion in systematic reviews, and further consider reach, dose delivered/ received,  
213 fidelity and co-intervention, contamination as 'Other sources of bias' in the Cochrane 'Risk  
214 of bias' tool (7). When process evaluations in quantitative reviews are lacking, or results do  
215 not adequately address decision-makers concerns and qualitative perspectives on  
216 implementation are sought (Table 1) we recommend review authors collaborate with  
217 qualitative review teams to meet these minimum requirements (19).

218

## 219 **Context-dependence of implementation**

220 As a process, implementation is context-dependent and concerns the actions required to  
221 put an 'intervention blueprint' into practice (10). Context includes the immediate  
222 environment in which an intervention is implemented and broader environment that shapes  
223 the resources, political support and norms influencing engagement of the target audience  
224 (e.g., patients, practitioners). It can be difficult for reviewers to grasp these dimensions of  
225 implementation and locate them in a process evaluation. The UK Medical Research Council  
226 (MRC) Guidance on process evaluation of complex interventions provides a framework that  
227 links context, with the intervention description, implementation and the mechanisms of  
228 impact on outcomes (10). The framework in Figure 1 situates an intervention and its  
229 designated target populations in relation to the immediate and broader contexts within  
230 which the intervention is planned, implemented and evaluated (20). It can be used in  
231 conjunction with the MRC framework to help reviewers frame implementation in a formal  
232 logic model within their Cochrane review of quantitative interventions. The red line drawn  
233 around the intervention, target populations and program implementation boxes in Figure 1  
234 visually depicts how resources and the external environment in addition to factors internal  
235 to the program environment (i.e., action model), are instrumental to shaping  
236 implementation. Box 2 illustrates how intervention outcomes can vary according to  
237 contextual factors.

### Box 2: Example of contextual factors influencing program outcomes

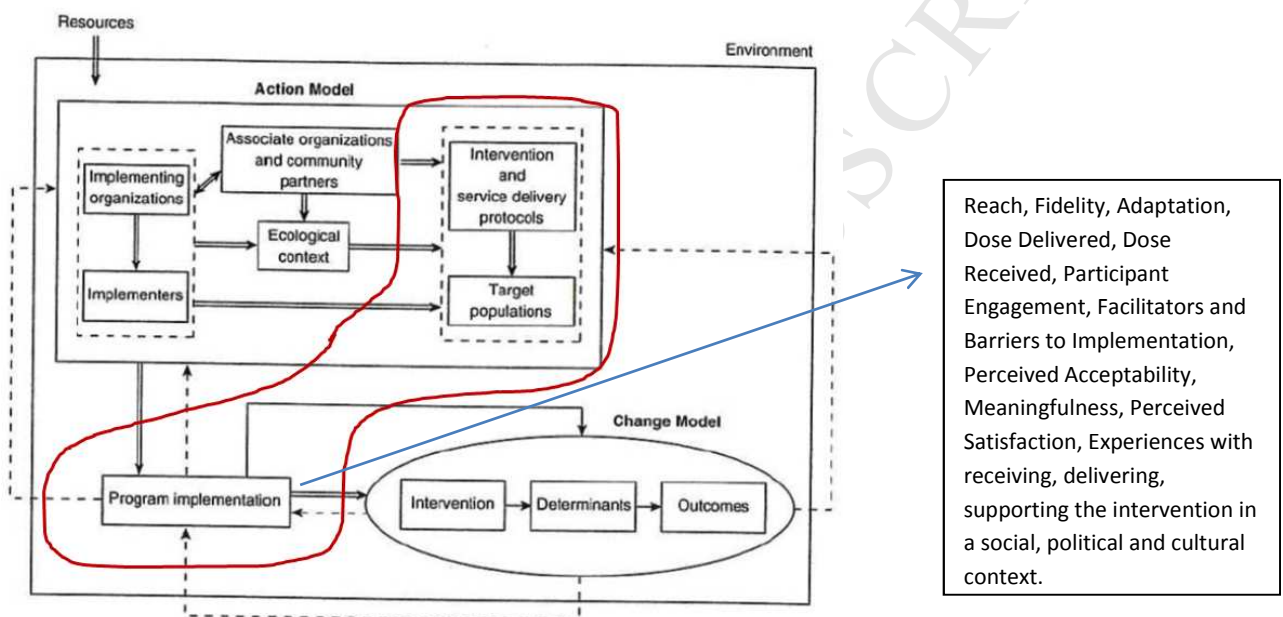
A meta-analysis of school-based programs to reduce bullying and victimisation found the impacts of these programs to vary by country of implementation (21). The programs worked better in Norway specifically and Europe more generally as compared to North America. The review authors posit that Scandinavian schools have a tradition of state intervention in social welfare and that the program context (i.e., high quality schools with small classes and well-trained teachers) may also contribute to the observed differences in outcomes.

238

239 Intervention delivery and service delivery protocols specify the nature, content and  
240 activities of an intervention, including its operating procedures, and the particular steps that

241 need to be taken to implement the intervention(20). This is the ‘blueprint for the  
 242 intervention’. What is implemented and how it is implemented to reach its designated  
 243 target populations is documented through process evaluation. Implementation can be  
 244 measured quantitatively through self-report surveys, structured observations, and  
 245 secondary analysis of routine monitoring data or qualitatively through focus groups,  
 246 individual interviews, unstructured observations (10) and open-ended survey questions.

247 Figure 1. Conceptual Framework to Situate Implementation in Relation to Context



248

249 Source: Chen H-T. Practical Program Evaluation. Thousand Oaks, CA: Sage Publications, 2005.  
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## 251 Steps of the Systematic Review Process

252 Increasingly, review authors of both quantitative and qualitative reviews are being called to  
 253 address issues relevant to context and implementation to make the findings more  
 254 applicable to decision-makers. We used the steps of the review process to illustrate how  
 255 qualitative and other sources of evidence on implementation can be synthesised and then  
 256 integrated with evidence of effect.

### 257 Step 1 - Framing the Problem and Refining Implementation Questions

258 The first step in a quantitative systematic review frames the problem and identifies which  
 259 aspects of implementation are relevant. Framing the problem is driven by a number of

260 factors including the state of knowledge on a review topic, level of resourcing, timeframe,  
 261 expertise, stakeholder input, and expectations from the review commissioners. Knowing  
 262 where to start can be challenging for review authors especially if one or more of the  
 263 following conditions is present: (a) there is considerable heterogeneity in the interventions  
 264 considered for a review; (b) there is little understanding of how interventions work to  
 265 produce outcomes for the population or context(s) of interest; (c) aspects of  
 266 implementation are not clearly understood, are poorly defined or the evidence needed to  
 267 address implementation cannot be clearly specified; (d) it is not clear how to frame the  
 268 review question from an implementation perspective; or (e) stakeholders raise questions  
 269 that are pertinent to implementation, and it is not clear how to address them. If one or  
 270 more of these situations is apparent, we recommend a scoping review or other review  
 271 activity with an implementation focus be undertaken, as outlined in Table 2, to help define  
 272 or refine implementation issues and questions of interest (22) and inform a subsequent  
 273 Cochrane systematic review of interventions. These methods align with current systematic  
 274 review practices and guidance to formulate review questions that are inclusive of process  
 275 and implementation issues (23, 24). Brief descriptions of the methods are provided in  
 276 Appendix 1, available online as supplementary material ([www.iclinepi.com](http://www.iclinepi.com)).

277 Table 2: Strategies, methods and tools to help refine the questions and scope of a Cochrane  
 278 effectiveness review.

Issue or circumstance	Review activity	Tools to assist	Product
When a broad range of interventions have been implemented to address a health issue.	Critical Review (25) Textual Narrative Synthesis(26)	Principles of simple, complicated and complex interventions (27); Template for Intervention	Classification of interventions; identification of program theory, logic model, implementation measures/ processes.
Lack of clarity in implementation concepts, definitions, measures or methods for a review.	Scoping Review [13] Concept Analysis(29)	Description and Replication (TiDIER) (28); Logic model template to situate implementation(23)	Implementation definitions for an effectiveness review; implementation concepts to assess in a qualitative synthesis.
An intervention model or framework for an effectiveness review requires adaptation to another topic or context.	Best-fit framework (30)	Logic model template to situate implementation(23)	Framework to guide the review with implementation situated in the framework.
Poor understanding of	Grounded Theory,	Logic model	Program theory and

program theory and how implementation relates to outcomes; review resources are available.	Realist Synthesis, Meta-Ethnography, Meta-Interpretation (24)	template to situate implementation (23)	logic model with implementation concepts and indicators identified.
As above, but review resources are not available.	Program theory mapping workshop	Logic model template; 'how-to' resources (27); engage consultant.	Program theory and logic model with implementation concepts identified.

279 Following Harris (4) and the Evidence for Policy and Practice Information and Co-ordinating  
 280 Centre (EPPI-Centre)(31, 32), we recommend that reviewers engage stakeholders in the  
 281 preparatory stage to ensure that the review scope is appropriate and resulting products  
 282 address the implementation inquiry questions and concerns of decision-makers. These  
 283 review activities will increase the internal validity of constructs, measures and methods  
 284 used in a quantitative review which can reduce the likelihood of evaluation failure and  
 285 strengthen the basis for making judgements that rule out implementation and theory  
 286 failure.

## 287 **Step 2 - Searching**

288 As shown in Table 1, a search for the following types of evidence may potentially help with  
 289 understanding intervention implementation:

- 290 • 'Implementation evidence' from quantitative studies (e.g. RCTs included in the effect  
 291 review) on dose and reach etc.
- 292 • 'Process evaluation evidence' - qualitative and quantitative evidence from process  
 293 evaluations conducted alongside trials
- 294 • 'Trial sibling qualitative studies' – conducted alongside trials
- 295 • 'Unrelated qualitative studies' – with no relationship to trials
- 296 • Economic evaluations – conducted alongside trials

297  
 298 Retrieval of process evaluations and implementation evidence of all types is problematic for  
 299 at least three reasons. First, process evaluations may not exist. Second, when they do exist,  
 300 they may not be clearly identifiable in terms of key terms for their retrieval. Third, process  
 301 evaluations may not be published in the peer reviewed literature (33) and, therefore, carry  
 302 the challenges associated with retrieving grey or fugitive literature (34). The CQIMG has  
 303 identified four potential approaches to identify process evaluations in a systematic review  
 304 (35). The approach that is used will be determined by factors such as the review purpose,  
 305 time and resource constraints and the perceived risk of how deficiencies in the search

306 process will impact upon the uncertainty of the review results. The first approach for  
307 retrieving process evaluations is to transfer identification from the search process to the sift  
308 process. This involves conducting a sensitive topic search without any publication  
309 restrictions (36). The review team works its way systematically through the titles and  
310 abstracts of retrieved references looking for indications of process data by using the  
311 dimensions highlighted in Table 1. This approach is feasible when a review question involves  
312 multiple publication types e.g. RCT, qualitative research and economic evaluations, which  
313 are not being searched for separately. The second approach retrieves process evaluations  
314 within randomised control trials for which the Cochrane has developed a highly sensitive  
315 search strategy (filter) (37). If a process evaluation has been published in a journal article  
316 and mentions the trial in the abstract, this method proves effective. The third option is to  
317 use unevaluated filter terms to retrieve process evaluations or implementation data.  
318 Approaches using strings of terms associated with the study type or purpose is considered  
319 experimental. There is a need to develop and test such filters. It is likely that such filters  
320 may be derived from the study type (process evaluation), the data type (process data) or the  
321 application (implementation). The last of these is likely to prove problematic because a  
322 study can describe implementation without necessarily using the word “implementation”  
323 (38). The fourth approach relies on citations-based approaches. We have proposed the  
324 identification of ‘clusters’ containing all accounts, published or unpublished, of a particular  
325 study (39). These can offer additional contextual detail but, importantly in this context, may  
326 provide implementation or process data (40).

327 At present, the CQIMG suggests that review teams either use methods 2 and 3 in  
328 conjunction with 4, most likely in a Cochrane setting, or use method 1 in conjunction with 4  
329 for a wider health technology assessment type ‘multi-review’ (35). Guidance on searching  
330 for trials can be found in the Cochrane Handbook (37) and paper 2 in this series outlines  
331 principles for searching for qualitative studies (5).

### 332 **Step 3 - Data Extraction**

333 To extract relevant information on implementation from primary studies it is crucial to have  
334 a detailed understanding of the intervention because implementation measures (e.g.,  
335 fidelity, dose) and the barriers and facilitators experienced during implementation can

336 pertain to different aspects of complex interventions (10, 17). We therefore recommend  
337 use of the 10-dimension Complexity Assessment Tool for Systematic Reviews (iCAT-SR) to  
338 assist with classifying and grouping interventions (41). For quantitative intervention  
339 reviews, this can inform sub-group or sensitivity analyses, and aid in developing logic models  
340 and identifying causal pathways that explicitly feature implementation (Lewin,  
341 forthcoming). For qualitative evidence syntheses, the ICAT-SR may facilitate comparisons of  
342 staff experiences with implementation or the construction of implementation chains for  
343 different types of programs, enhancing the theoretical and interpretive validity of the  
344 review.

345 A review of 27 systematic reviews of interventions uncovered several issues impacting the  
346 extraction of information on implementation from primary studies (42). Process evaluation  
347 terms are not always defined and reviewers may find aspects of implementation described  
348 (i.e., ‘the evaluation assessed whether the intervention was implemented as intended’) but  
349 not linked to a specific definition (i.e., fidelity). Terms or definitions are not located in the  
350 methods section which is where review authors might expect to find them; sometimes they  
351 appear in the discussion section. Aspects of implementation are defined in ways that  
352 deviate from commonly accepted definitions. For example, studies can define intervention  
353 ‘quality’ as the intervention being delivered as intended, which is the definition commonly  
354 used for fidelity (43). Like the intervention, information on program operations  
355 (‘implementation’) is often descriptive (i.e, textual) and not empirical and can appear in the  
356 background and methods section of a primary outcome evaluation paper, or in a non-  
357 empirical ‘sibling’ study. Additionally, authors often provide reflections on implementation  
358 in the discussion section. To counteract some of these limitations, following the techniques  
359 used in Intervention Component Analysis (44) we recommend that descriptive information  
360 and author reflections on the experience of implementing the intervention are used from  
361 trial and ‘sibling’ reports and further, that corresponding authors be contacted for specific  
362 information on implementation. Such information strengthens the descriptive validity of  
363 qualitative and quantitative reviews. We also recommend that review authors develop a  
364 glossary of terms and definitions supported by existing resources such as the Oxford  
365 Implementation Index (45), Checklist for Implementation (42) and the MRC Guidance on  
366 process evaluation of complex intervention (10) to reduce the likelihood of conceptual



367 slippage and inconsistent interpretation of measures of events between studies. For  
368 systematic reviews, this can guide the consistent extraction of information across studies.  
369 For a qualitative evidence synthesis, a common set of understandings of key  
370 implementation terms and processes can facilitate comparisons of experiences between  
371 studies which, again, can enhance theoretical and interpretive validity.

#### 372 **Step 4 – Assessing Rigour and Risk of Bias in the process evaluation or intervention** 373 **implementation evidence**

374 Review authors should determine if the absence of a favourable intervention effect within  
375 primary studies and at the review level is due to problems with implementation (i.e.,  
376 implementation failure) or a poorly conceptualised intervention (i.e., theory failure). Few  
377 assessment tools for primary studies or reviews explicitly address the rigour or risk of bias in  
378 process evaluation or implementation evidence. Table 1 in Noyes et al (this series (5))  
379 reports comparable terms (such as risk of bias and rigour) to describe similar domains across  
380 quantitative and qualitative research. Building on previous recommendations(46), we  
381 provide recommendations for assessing the rigour/risk of bias of process and  
382 implementation in primary studies and reviews.

383  
384 The literature was systematically searched to retrieve tools to critically appraise process and  
385 implementation. This entailed keyword searches of PubMed MEDLINE, the ISI Web of  
386 Science, the worldwide web, Google Scholar, the webpages of systematic review centres/  
387 collaborations and perusing the reference lists of relevant documents. This search was  
388 initially conducted in 2009(47) and updated periodically through CQIMG-affiliated work.  
389 One assessment tool specific to process evaluation was located. This 8-item tool developed  
390 by the EPPI-Centre is flexible and can be applied to qualitative, quantitative and mixed-  
391 method primary studies (48, 49). Six questions tap rigour related to sampling, data  
392 collection, data analysis, interpretation, breadth/scope of findings, and whether the study  
393 privileges the perspective of the target group. The last two items assess the reliability and  
394 usefulness of the findings. The question on usefulness (*'how well the intervention processes*  
395 *were described and whether or not the process data could illuminate why or how the*  
396 *interventions worked or did not work'*) offers insight into process mechanisms. Ideally  
397 process evaluation should gather both qualitative and quantitative information. Qualitative

398 data is particularly important to understand how features of context influence  
399 implementation and issues related to acceptability, meaningfulness and generalisability of  
400 the intervention. As outlined below, we recommend this 8-item tool supplement existing  
401 critical appraisal tools for primary qualitative and quantitative studies. Given that existing  
402 critical appraisal tools for systematic reviews do not address process evaluation and  
403 following recent guidance on the process evaluation of complex interventions(10) we  
404 recommend that questions be developed to supplement these tools.

405

406 For qualitative primary studies we recommend the 8-item process evaluation tool (49) be  
407 used in conjunction with a qualitative critical appraisal tool such as the Evaluation Tool for  
408 Qualitative Studies (ETQS)(50). The ETQS was the only tool of three qualitative tools  
409 reviewed to cover all forms of validity (i.e., descriptive, theoretical, evaluative, interpretive,  
410 generalisability)(51) and it additionally enquires into study context, specifically setting  
411 factors and the sampling of events, persons, times and settings both of which are important  
412 to understanding implementation. While the process evaluation specific tool captures rigour  
413 relevant to implementation, the ETQS captures rigour relevant to qualitative validity  
414 (credibility and transferability). These tools should be used in addition to tools to assess  
415 methodological strengths and limitations that feed into CERQual assessments of confidence  
416 in synthesised qualitative findings (52).

417 Assessment tools for quantitative primary studies do not address dimensions of process  
418 evaluation other than contamination, co-intervention, and participation. The Effective Public  
419 Health Practice Project Quality Assessment Tool (EPHPP) (53) is the only tool that asks a  
420 question on fidelity, operationalised as consistency of implementation. Overall integrity is  
421 judged by responses to three questions on fidelity, contamination/ co-intervention and  
422 percentage of participants receiving the allocated intervention. The Cochrane Risk of Bias  
423 Tool (CRBT) was introduced to establish consistency and avoid discrepancies in the  
424 assessment of methodological strengths and limitations. Considering that Cochrane  
425 reviewers are required to use the CRBT we recommend its use be supplemented with the 8-  
426 item process evaluation assessment tool (49). This tool is flexible and allows Cochrane  
427 reviewers to make an assessment of the methodological strengths and limitations of an

428 embedded or sibling process evaluation study that includes one or more of the dimensions  
429 in Table 1 using quantitative, qualitative or mixed methods

### 430 **Step 5 – Analysis, Synthesis and Interpreting the Evidence with an Implementation Lens**

431 Papers 2(5) and 4(6) in the series provide an overview of evidence-appropriate methods for  
432 synthesis of evidence on implementation, and paper 4 outlines methods for integrating  
433 qualitative and process evaluation evidence with evidence of intervention effect.

434 At the final stage, evidence from the qualitative and quantitative reviews need to be  
435 brought together to inform a judgement about ‘implementation success or failure’ and  
436 ‘theory success or failure’ (either partial or complete) at the integrated review level. At  
437 present no Cochrane reviews of interventions formally do this, however, information, in  
438 some reviews allows for less formal retrospective or ad-hoc judgements of theory failure  
439 and implementation failure (Box 3).

#### Box 3: Ruling out implementation failure and theory failure

Petrosino et al (54) reviewed the effects of programs comprised of organised visits to prisons by juvenile delinquents or pre-delinquents to deter them from delinquency (‘Scared Straight’). The meta-analysis found the organised prison visits to be more harmful than doing nothing. Problems with implementation were considered as a potential source of bias. All included studies were considered low risk of bias as no investigator reported problems with implementation. Since the programs were implemented with fidelity, the harmful effect suggests fault in the program’s logic that exposing at-risk juveniles to prison life would deter delinquency. The authors posit peer contagion theory as a potential explanation for the observed effect; the potential intervention benefit was offset by deviant youth interacting with each other in a group setting. This alternate causal pathway could be explored in a qualitative evidence synthesis.

440

441 We argue that reviews need to be designed at the problem description stage to address this,  
442 specifically by generating a program theory or logic model that depicts implementation  
443 outputs or measures captured quantitatively, or core processes captured qualitatively. The

444 basic logic for informing such judgements is outlined in Figure 2a-c. Implementation failure  
445 and theory failure do not operate in isolation. To determine whether theory failure is  
446 suspect in interpreting the overall intervention effect of a primary study, it is necessary to  
447 first rule out implementation failure. If a review does not systematically extract qualitative  
448 and/or quantitative evidence on implementation and finds that the primary outcome did  
449 not favour the treatment condition, reviewers do not have a basis for determining, at the  
450 interpretation stage, whether the intervention design was deficient (theory failure) or  
451 whether the outcome was marred due to implementation problems (implementation  
452 failure). This compromises the overall internal and external validity of the review. The  
453 example in Box 3 additionally highlights the need to assess implementation in order to be  
454 able to make a judgement about underlying program theory.

455 The activities in Table 2 increase the chance that reviews are guided by plausible and  
456 testable program theory. The MRC Process Evaluation Framework(10) and the framework  
457 outlined in Figure 1 provides reviewers with the conceptual building blocks to develop  
458 program theory. For any given review, program theory visually depicted in a logic model  
459 acts as a 'coat rack' of sorts to hang the most appropriate measures and methods to capture  
460 the uniqueness of intervention contexts in primary studies. Hence, context becomes  
461 'reproducible' by virtue of the conceptual frameworks, methods, measures and tools used  
462 to construct the logic that guide reviews. The synthesis methods described in papers 2(5)  
463 and 4(6) in the series provide insight into differential intervention effects, context by  
464 implementation interactions and inform judgements about partial or complete breakdowns  
465 in implementation. Methodological work is required to inform review level judgements of  
466 implementation and theory failure, whether partial or complete.

467 Figure 2a-c<sup>1</sup>. Depictions of implementation and theory failure

Implementation failure is 'diagnosed' by determining whether intervention activities produce the requisite operation outputs, depicted as the first intervening variable in Figure 2a. These outputs pertain to key implementation measures (e.g., dose delivered, reach, fidelity) and processes. If these outputs are not achieved the causal pathway has been disrupted and we wouldn't expect to see a change in the short-term goal or bridging variable, or the primary outcome.

Figure 2a. Implementation Failure



Theory failure is suspect when a process evaluation shows that an intervention achieved its key operation outputs (i.e., intervention implemented with integrity) but not its short-term goal (e.g., increase in physical activity), depicted as the intervening bridging variable in Figure 2b.

Figure 2b. Theory Failure (Case 1)



Theory failure is also suspect when an intervention achieves its operation outputs (i.e., implementation integrity) and short-term goal (e.g., increase in physical activity) but the short-term goal or bridging variable doesn't translate to a change in the primary outcome (e.g., body mass index) (Figure 2c).

Figure 2c. Theory Failure (Case 2)



468 <sup>1</sup>Adapted from (9)

## Conclusions

Assessing implementation in Cochrane systematic reviews of interventions is challenging for a number of reasons, including, but not limited to, poor reporting of intervention and implementation in primary studies, knowing the starting point to address implementation on a given topic, and pressures to accommodate knowledge translation concerns of research consumers despite reporting and review resource limitations. Depending on the review objectives, synthesis of evidence on implementation can add interpretive value to Cochrane reviews and the decision-makers who use them. This paper provides guidance for reviewers to navigate the heterogeneity and uncertainty that they are confronted with at different stages of the review process.

Table 1: Definitions of key dimensions of implementation with corresponding examples of quantitative indicators and qualitative questions.

Dimension	Quantitative	Qualitative
<b>Dose Delivered:</b> Amount of a program delivered to participants (i.e., frequency, duration, intensity) by staff and/or implementing agency.	<ul style="list-style-type: none"> <li>• Total # contact hours</li> <li>• # water fountains installed</li> </ul>	<ul style="list-style-type: none"> <li>• How did participants feel about the format and time commitment of the program?</li> </ul>
<b>Dose Received:</b> Characteristic of the target population's utilisation or interaction with program strategies or resources ('active participation').	<ul style="list-style-type: none"> <li>• Dosage of medicine ingested</li> <li>• # people drinking water from fountain</li> </ul>	<ul style="list-style-type: none"> <li>• What factors influenced whether clients read the take home educational materials?</li> </ul>
<b>Reach:</b> Degree to which target group participates by their presence.	<ul style="list-style-type: none"> <li>• # of patients served by eligible clinics</li> </ul>	<ul style="list-style-type: none"> <li>• What motivated clients to attend the clinic?</li> </ul>
<b>Recruitment:</b> Specific information on procedures used to recruit or attract participants to the intervention.	<ul style="list-style-type: none"> <li>• % of clients recruited by type of recruitment strategy</li> </ul>	<ul style="list-style-type: none"> <li>• How did participants feel about the methods used to recruit them?</li> </ul>
<b>Fidelity:</b> Reflects implementation integrity, adherence, extent to which a program is implemented as intended.	<ul style="list-style-type: none"> <li>• % of activities critical to behaviour change completed</li> </ul>	<ul style="list-style-type: none"> <li>• What factors enabled clinical staff to adhere to practice guidelines?</li> </ul>
<b>Adaptation:</b> Whether aspects of a program were intentionally changed during delivery to enhance outcomes.	<ul style="list-style-type: none"> <li>• % of activities that changed during intervention period</li> </ul>	<ul style="list-style-type: none"> <li>• What factors influenced staff adaptation of intervention activities?</li> </ul>
<b>Co-intervention:</b> When interventions other than the treatment are applied differently to intervention conditions.	<ul style="list-style-type: none"> <li>• % of control group participants getting other treatments</li> </ul>	<ul style="list-style-type: none"> <li>• Why did participants engage in other activities related to the outcome?</li> </ul>
<b>Contamination:</b> Unintentional delivery of intervention to the control group or inadvertent failure to deliver intervention to experimental group.	<ul style="list-style-type: none"> <li>• % of control group participants exposed to the treatment</li> </ul>	<ul style="list-style-type: none"> <li>• How did the control group come to receive the treatment?</li> </ul>
<b>Participant Engagement:</b> Participant's interaction with or receptivity to a program i.e., what they think or how they feel about the intervention	<ul style="list-style-type: none"> <li>• On a scale of 1 to 5, rate the extent to which the program met your needs</li> </ul>	<ul style="list-style-type: none"> <li>• Was the program culturally appropriate and acceptable to clients?</li> </ul>
<b>Implementer Engagement:</b> Subjective	<ul style="list-style-type: none"> <li>• On a scale of 1 to 5,</li> </ul>	<ul style="list-style-type: none"> <li>• How would you</li> </ul>

staff attributes that influence program delivery i.e., what they think/ feel about the intervention and their interpersonal style.	rate your level of enthusiasm to use the practice guidelines	characterise your motivations and interests to implement the practice guidelines?
<b>Intervention Quality:</b> Quality of intervention materials/ resources (e.g., curriculum, training, policy).	<ul style="list-style-type: none"> <li>On a scale of 1 – 5 rate the quality of the training</li> </ul>	<ul style="list-style-type: none"> <li>Please comment on the training materials and facilitation of the training</li> </ul>
<b>Context:</b> Social, built and political factors internal (e.g., partnerships) and external to the intervention environment (e.g., social norms) that shape implementation.	<ul style="list-style-type: none"> <li>On a scale of 1 – 5, to what extent did community agencies support the intervention?</li> </ul>	<ul style="list-style-type: none"> <li>In what ways did community agencies support the health service to deliver the intervention?</li> </ul>

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