Chapter 17. Reviewing diverse types of implementation evidence

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Key points

- Implementation refers to efforts to put interventions into practice.
- Research on intervention implementation should be reviewed in a systematic way to support interpretation and application of effectiveness review findings in practice.
- Implementation reviews have varied objectives including to understand: implementation strategy effectiveness; implementation integrity; implementation experiences; and implementation mechanisms.
- These varied objectives mean that diverse types of evidence and methods of synthesis are needed to fully understand implementation.

17.1 Introduction

This chapter provides guidance on synthesising diverse types of evidence to address review questions relating to intervention implementation. Evidence on implementation is vital for decision-makers when interpreting and applying evidence about intervention effectiveness in policy-making and practice. For example, suppose a new practice such as a surgical procedure (i.e. an 'intervention') that had been shown to be effective was going to be implemented. What would the implementers need to know in order to decide how best to implement it:

- What needs to happen to make the intervention work in this context?
- How important is it to stick to implementing the intervention in the form in which it was originally tested?
- What is it like to be on the receiving end of the intervention and for the staff to deliver?
- What exactly is it about the intervention, or the context in which it was delivered, that makes it work/not work?

This chapter differs from most other chapters in the book, which focus on a specific method for qualitative evidence synthesis (QES) or methods for mixed-methods reviews with a qualitative component. As the chapters explain, these methods can be used to address diverse review objectives. In contrast, this chapter is focused on the specific objective of understanding whether and how the way an intervention is implemented affects observed outcomes. The chapter illustrates that there are various ways of examining implementation and covers four broad implementation review objectives, categorised as follows:

- to measure implementation strategy effectiveness
- to verify implementation integrity
- to understand implementation experiences and
- to examine implementation mechanisms.

The four types of objective help structure the chapter and introduce methods covering the wide landscape of implementation reviews. Diverse types of evidence, both qualitative and

quantitative, may be used to understand these different facets of intervention implementation. In addition, when including qualitative evidence, any of the QES methods and mixed-methods with a qualitative component described elsewhere in the handbook may be employed.

This chapter begins by examining in more detail what implementation means and, in particular, exploring the relationship between implementation and the interventions that are being implemented. Formulation of reviews and selection of methods for each of the four broad implementation review objectives are outlined. Any given review may have additional objectives and / or address multiple implementation objectives. As with all of the methods described in this handbook, methodological and conceptual developments mean that the choice of available methods will continue to be refined and expanded. Each of the methods and approaches described in this chapter aim to provide decision-makers with vital evidence to enable them to apply evidence on intervention effectiveness practically in real world settings.

Given that the primary audience for implementation reviews is not researchers but practitioners and policy-makers, and given the complexity of reviews on implementation, work to develop methods for implementation reviews should consider not only the purpose and rigour of the work conducted, but also how to communicate these complex findings in an accessible way.

17.1.1. What is meant by implementation?

Implementation has been defined as “a planned and deliberately initiated effort with the intention to put an intervention into practice” (Pfadenhauer et al 2015) p.104. Whilst implementation has been found to be a relatively mature concept with largely consensual definitions and relatively well-defined boundaries (Pfadenhauer et al 2015), researchers and practitioners continue to hold different understandings of what implementation means. Different perspectives and how these underpin the diversity of approaches to studying implementation in systematic reviews are considered below.

17.1.2. Interventions and implementation as separate entities

In the definition of implementation noted above a clear distinction is made between the intervention itself and the process of implementation. It is easy to see how many clinical interventions such as vaccines can be seen as distinct from implementation efforts. Clinical trials are able to verify the efficacy of a given vaccine (i.e. whether it works under ideal conditions), but its effectiveness in patients (i.e. whether it works in the real world) is also dependent on appropriate administration by healthcare workers. If a healthcare worker does not administer the correct dose, then an individual's protection against disease may be diminished. Implementation strategies to ensure appropriate administration, such as service delivery protocols and provider training, are needed for vaccination roll-out. Further, effectiveness at a population level is dependent on uptake. Implementation strategies to enable access to vaccines, public health messaging to support awareness, or efforts to address vaccine hesitancy are also of importance (Glenton et al 2021; Sutcliffe et al 2022). An implementation strategy may therefore be considered an intervention in its own right, that is distinct from the clinical intervention, such that, as illustrated in Figure 1, systematic reviews are able to study the effectiveness of implementation strategies (Jacobson Vann et al 2018; Lapkin et al 2016) separately from the underlying clinical interventions (Di Pietrantonj et al 2021). The Cochrane Library contains many reviews on implementation strategy interventions, for example interventions to increase vaccine uptake by reminding people when their vaccinations are due (Jacobson Vann et al 2018).

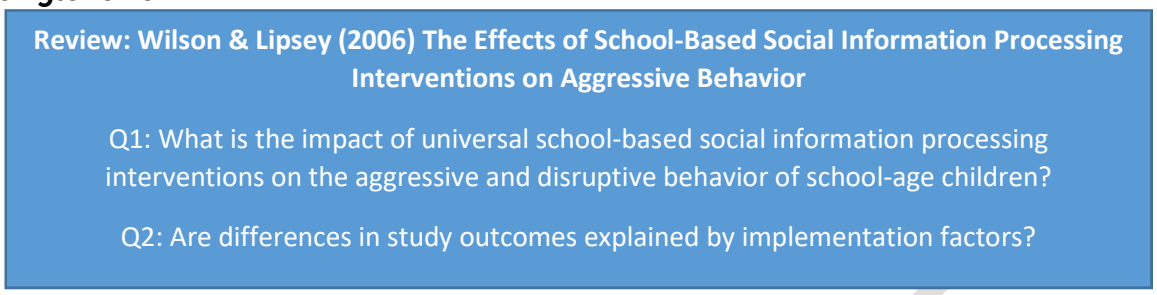
Figure 1: Effectiveness of intervention and effectiveness of implementation studied as separate entities

Review 1: Vaccine efficacy: *Di Pietrantonj et al (2021)*	**Review 2: Implementation strategies to support administration:** *Lapkin et al (2016)*	**Review 3: Implementation strategies to increase uptake:** *Jacobson Vann et al (2018)*
Vaccines for measles, mumps, rubella, and varicella in children	The effectiveness of interventions designed to reduce medication administration errors	Patient reminder and recall interventions to improve immunization rates

17.1.3. Interventions and implementation as intertwined

The distinction between intervention and implementation is less clear cut for many non-clinical interventions. This is especially true for interventions that by definition must be implemented and evaluated in real-world settings such as school-based interventions. Thus, whilst in theory the intervention is a separate entity from implementation, it is not possible to study the efficacy of such interventions separately from the process of implementation as they are not able to be undertaken under the highly controlled conditions of a clinical trial. This means that implementation is less likely to be standardised (Hawe et al 2004). Many pragmatic and less tightly controlled trial designs that better represent routine clinical practice or the non-clinical context now commonly incorporate a process evaluation to explore implementation processes and outcomes alongside the main trial to determine intervention effects. If intervention activities are not implemented according to the specified standards, guidelines, or intervention design strategy, theorized intervention mechanisms may not be realized (see also Chapter 4 on logic models). If an evaluation reveals discrepancies between the expected and observed outcomes, this may be due either to a failure of the intervention itself (e.g. reminders are not a useful tool to encourage vaccine uptake) or failure of implementation (e.g. reminders are a useful intervention but did not work because the intervention was not implemented as intended). Conversely, positive effects may be attributed to an intervention with no consideration of how much those outcomes are actually the result of efforts or enhancements made during implementation. As Moncher & Prinz argue “the cost of inadequate fidelity can be rejection of powerful treatment programmes or acceptance of powerless programmes (Moncher and Prinz 1991) p.250. Thus, by synthesising evidence on the integrity of implementation, review authors can rule out the possibility of implementation failure (See also Chapter 4 logic models and Chapter 15 Realist methods) (Cargo et al 2018). As illustrated in Figure 2, review authors may wish to examine the potential influence of implementation factors on the overall success of interventions (Wilson and Lipsey 2006).

Figure 2: Intertwined intervention and implementation studied in separate analyses in a single review



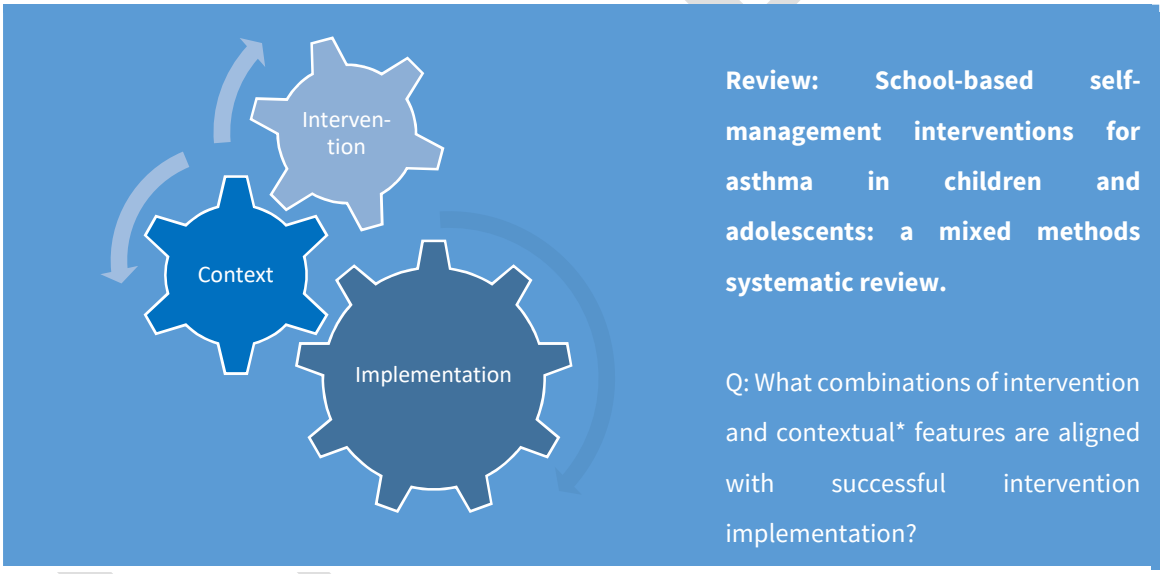
17.1.4. Interventions and implementation as interacting

Recent work on intervention complexity goes one step further and suggests that the relationship between implementation and outcomes may not be straightforward or linear, as in the conception outlined in 16.1.3, but that an intervention and its implementation can interact in complex and unpredictable ways (Pfadenhauer 2021; Thomas et al 2019). Interventions may be considered inherently complex if they involve multiple components, target multiple behaviours and / or are targeted at multiple groups or levels (Skivington et al 2021). Whilst the increased complexity of multi-component interventions inevitably makes standardized implementation challenging, a critical feature of interventions from a complexity perspective is that the different intervention components and implementation procedures interact in synergistic or dis-synergistic ways to produce non-linear effects (Petticrew et al 2019).

Another critical feature of the complexity perspective is that interventions are seen as context-sensitive in that they often interact with and sometimes adapt to the context within which they are implemented (Moore et al 2015; Petticrew et al 2019). Context is broadly defined as the "set of characteristics and circumstances that surround the implementation effort" including geographical, organisational and cultural settings and the roles, interactions and relationships of people in those settings (Pfadenhauer et al 2015). The ADAPT guidance provides a framework of things to consider when adapting an existing intervention to better fit a new context (Moore et al 2021).

Thinking of intervention and implementation as discrete entities implies that it is possible and desirable to study the respective parts of a system (intervention, implementation, context, outcomes) as distinct components (Pfadenhauer 2021). From a complexity perspective however the potential interactions between this vast array of factors means it is not only challenging to distinguish between intervention, implementation and context, it is not desirable. Because the interaction between context, implementation and intervention is likely to affect delivery in most real-world settings the segregated approach "may not produce valuable insights into why some interventions achieve effects and others do not" (Pfadenhauer 2021) p.3. As illustrated in Figure 3, reviews may therefore make a holistic examination of how interactions between implementation, intervention and context impact on outcomes.

Figure 3: Interacting intervention, implementation and contextual dimensions



*The original review question has been amended to include reference to 'contextual' factors, which were considered in the review, but were not made explicit in the original review question.

17.2. Formulation of review

Naturally then, these contrasting understandings of interventions and implementation have led to different approaches for reviewing implementation, which can be broadly categorized as addressing the following four objectives:-

1. **'Evaluation of implementation strategy effectiveness'** (i.e. synthesis of studies evaluating the impact of implementation strategies, which are viewed as interventions in their own right)
2. **'Verification of implementation integrity'** (i.e. synthesis of studies to measure the influence of individual process measures on outcomes e.g. dose, reach, fidelity etc)
3. **'Understanding implementation experiences'** (i.e. QES to understand experiences with delivering or receiving the intervention, including factors that create barriers and enablers to implementation)
4. **'Identification of implementation mechanisms'** (i.e. use of analytical techniques such as intervention component analysis (ICA) or qualitative comparative analysis (QCA) to explore how implementation interacts with intervention and contextual factors)

The first two objectives lend themselves to meta-analysis and synthesis without meta-analysis methods in that they are about testing or verifying pre-defined concepts relating to implementation. By contrast, objectives three and four require a more interpretive approach to synthesis (such as qualitative evidence synthesis or mixed-methods synthesis with a qualitative component) as they seek to develop new understandings of what implementation means and how it manifests (Gough et al 2012; Gough et al 2019). The four categories are intended as broad types of implementation review objectives, highlighted to help structure this chapter and introduce methods for the diverse landscape of implementation reviews. However, any given review may have additional objectives and / or address multiple implementation objectives. The remaining chapter provides guidance on how review teams may decide which implementation review objectives to address, how stakeholder engagement and involvement can support implementation reviews, the opportunities for addressing equity, diversity and inclusion issues in implementation reviews, and the formulation of reviews for each of the four broad implementation review objectives.

17.2.1. Determining which implementation objectives to address

Given different understandings of implementation issues, review authors may need to consider which approach is appropriate for their review. Table 2 sets out the considerations pertinent for each implementation review type. A combination of approaches may also be appropriate – e.g. a review of implementation experiences may inform a review of implementation integrity or a review of implementation mechanisms. Scoping work and engagement with diverse stakeholders, including patients and the public, may help to identify the most appropriate approach.

Table 2: Considerations for determining which implementation objectives to address

The issue / problem	Review objective	Type of evidence needed	Type of review
Intervention efficacy is established but knowledge is needed about how to implement in real-world contexts.	To identify effective implementation strategies.	Evaluations of implementation strategies.	Implementation effectiveness review – see Cochrane Handbook for Systematic Reviews of interventions (Higgins et al 2021)
An effectiveness synthesis shows unexpectedly poor (or strong) outcomes in some studies and it is anticipated that implementation factors (such as dose and reach) may have contributed.	To understand whether poor implementation, or enhancements made during implementation, explain the unexpected outcomes.	Process evaluations measuring and explaining implementation	Implementation integrity using a mixed-methods design
There is uncertainty about which implementation issues may be important and how they impact on outcomes.	To explore which factors are experienced as affecting implementation and how.	Qualitative evidence on the experience of receiving or delivering an intervention.	Implementation experiences using a QES method

Intervention complexity is evident and there is a need for guidance on which implementation features are critical.	To identify how critical intervention, contextual and implementation features interact to achieve outcomes.	Evidence on contexts, mechanisms and outcomes.	Implementation mechanisms See also Chapter 15 on Realist synthesis and Chapter 17 on QCA.

17.2.2. Stakeholder engagement and involvement

Since the purpose of implementation research is to enhance the uptake of research in practice, stakeholder engagement and involvement is considered to be particularly important (Brocklehurst et al 2017). As noted above stakeholders can provide their perspectives to determine which of the four approaches (or which combination of them) may be most helpful for reviewing implementation evidence. Stakeholders may also be important in refining the selected approach. For example, policy-makers and practitioners may have vital insights about the need for a review of implementation effectiveness and the context in which understanding is needed. Public stakeholders and practitioners may be pivotal in identifying key implementation factors to examine or prioritize in a review of implementation integrity or a review of implementation mechanisms. Likewise, the insights of patients or other public stakeholders may be critical for identifying important populations or contexts for a review of implementation experiences. Stakeholders may also provide important contributions when interpreting the findings of reviews of implementation, for example whether review findings resonate with the experiences of specific groups practitioners or patients, or in specific contexts.

17.2.3. Equity, diversity and inclusion

A lack of health equity considerations in systematic reviews limits their usefulness for decision making. Review authors are urged to consider the social, cultural and political contexts in which interventions are planned and implemented (Welch et al 2019). Implementation reviews are therefore an important tool for examining whether and how

interventions may address or exacerbate health inequalities. For example, by exploring implementation in different contexts a review of implementation effectiveness can reveal whether an intervention shown to be effective under clinical conditions might exacerbate inequalities because of barriers to uptake in socially disadvantaged groups. Equally, if barriers to uptake in specific contexts are known, a review on the effectiveness of implementation strategies to address such barriers may be warranted. A review of intervention experiences might shed light on the existence of barriers or opportunities for addressing them. Any such findings might also be tested in a review of implementation mechanisms. An equity, diversity and inclusion perspective should also be incorporated into the selection of stakeholders given their important role in shaping the implementation review scope, design, objectives and articulating equity considerations.

17.2.4. Reviews to evaluate implementation strategies

The first broad objective *'Evaluation of implementation strategy effectiveness',* refers to reviews which seek to evaluate whether specific implementation strategies support practitioners to adopt an established intervention in routine practice – i.e. implementation is the intervention being studied (Pfadenhauer et al 2015). Implementation strategies are diverse. They include interventions directed at service providers, such as audit and feedback processes to assess performance with the intervention or educational materials or sessions to support understanding. Implementation strategies may also include interventions directed at service users, such as local opinion leaders to promote uptake or mass-media interventions to increase awareness of the intervention, and interventions targeted at organisations such as strategies to change organisational culture (Effective Practice and Organisation of Care (EPOC) 2015). It is appropriate to review implementation strategy effectiveness where the efficacy of the intervention itself is already established – i.e. under ideal conditions the intervention is able to produce the desired outcome – but evidence is needed to understand whether and how similar benefits can be achieved in real-world settings. Box 1 provides an example of a review to evaluate the effectiveness of implementation strategies.

Box 1: Example of a review to evaluate implementation strategies

Review: Pantoja et al (2017) Implementation strategies for health systems in low-income countries.

Background: Coverage of essential health interventions remains low in low-income countries.

Aim: To provide a broad summary of what is known about the effects of strategies for implementing interventions to improve health in low-income countries.

Evidence: An overview based on 39 relevant systematic reviews.

Findings: Moderate- or high-certainty evidence of desirable effects of strategies targeted at healthcare workers included: - educational meetings, nutrition training of health workers, educational outreach, practice facilitation, local opinion leaders, audit and feedback, and tailored interventions. Moderate- or high-certainty evidence of desirable effects of strategies targeted at healthcare recipients included: - mass media interventions to increase uptake of HIV testing; intensive self-management and adherence, intensive disease management programmes to improve health literacy; behavioural interventions and mobile phone text messages for adherence to antiretroviral therapy. *(Note: Example findings only see review for comprehensive findings.)*

Conclusion: Reliable systematic reviews have evaluated a wide range of strategies for implementing evidence-based interventions in low-income countries. Most of the available evidence is focused on strategies targeted at healthcare workers and healthcare recipients and relates to process-based outcomes. Evidence of the effects of strategies targeting healthcare organisations is scarce.

Although this type of review focuses on implementation, methods for this type of review are not outlined in this chapter. Since the implementation strategy is evaluated as an intervention in itself, those interested in undertaking a review of implementation strategy effectiveness should follow guidance on study identification, appraisal and synthesis provided in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins et al 2021) in addition to resources on the legacy Cochrane Effective Practice and Organisation of Care Group website (https://epoc.cochrane.org/resources/epoc-resources-review-authors).

17.2.5. Reviews to verify implementation integrity

Many reviews which focus on implementation are concerned with evidence of intervention integrity as a means to understand and interpret evidence of intervention effectiveness. The effectiveness of numerous interventions, particularly those delivered face-to-face, depends both on providers delivering the intervention as intended (Carroll et al 2007) and on participants engaging with the intervention (Effective Practice and Organisation of Care (EPOC) 2015). Cargo and colleagues (2018) identified and defined numerous

implementation dimensions that may be considered in reviews of implementation integrity as listed in Table 1.

Table 1: Dimensions of implementation (Reproduced with permission by Cargo et al).

Dimension	Quantitative	Qualitative
Dose Delivered: Amount of a program delivered to participants (i.e., frequency, duration, intensity) by staff and/or implementing agency.	• Total # contact hours • # water fountains installed	• How did participants feel about the format and time commitment of the program?
Dose Received: Characteristic of the target population's utilisation or interaction with program strategies or resources ('active participation').	• Dosage of medicine ingested • # people drinking water from fountain	• What factors influenced whether clients read the take home educational materials?
Reach: Degree to which target group participates by their presence.	• # of patients served by eligible clinics	• What motivated clients to attend the clinic?
Recruitment: Specific information on procedures used to recruit or attract participants to the intervention.	• % of clients recruited by type of recruitment strategy	• How did participants feel about the methods used to recruit them?
Fidelity: Reflects implementation integrity, adherence, extent to which a program is implemented as intended.	• % of activities critical to behaviour change completed	• What factors enabled clinical staff to adhere to practice guidelines?
Adaptation: Whether aspects of a program were intentionally changed during delivery to enhance outcomes.	• % of activities that changed during intervention period	• What factors influenced staff adaptation of intervention activities?
Co-intervention: When interventions other than the treatment are applied differently to intervention conditions.	• % of control group participants getting other treatments	• Why did participants engage in other activities related to the outcome?
Contamination: Unintentional delivery of intervention to the control group or inadvertent failure to deliver intervention to experimental group.	• % of control group participants exposed to the treatment	• How did the control group come to receive the treatment?
Participant Engagement: Participant's interaction with or receptivity to a program i.e., what they think or how they feel about the intervention	• On a scale of 1 to 5, rate the extent to which the program met your needs	• Was the program culturally appropriate and acceptable to clients?
Implementer Engagement: Subjective staff attributes that influence programme delivery (i.e. what they think/feel about the intervention and their interpersonal style)	• On a scale of 1 to 5, rate your level of enthusiasm to use the practice guidelines	• How would you characterise your motivations and interests to implement the practice guidelines?
Intervention Quality: Quality of intervention materials / resources (e.g. curriculum, training and policy)	• On a scale of 1 to 5, rate the quality of the training	• Please comment on training materials and facilitation of the training
Context: Social, built and political factors (e.g., partnerships) and external to the intervention environment (e.g., social norms) that shape implementation.	• On a scale of 1 to 5, to what extent did community agencies support the intervention?	• In what ways did community agencies support the health service to deliver the intervention?

Review authors seeking to understand whether implementation integrity impacts on intervention outcomes typically draw on formal process evaluations associated with intervention evaluations to extract quantitative measures of the different implementation dimensions, as indicated in column 2 in Table 1. Analysis of these different indicators of implementation can be used to understand whether worse than expected outcomes may result from poor implementation practices rather than a failure of the intervention itself (Cargo et al 2018). Box 2 contains an example of a review designed to examine implementation integrity. The review examined school-based social information processing programs to reduce aggressive behaviour and found that the frequency of sessions per week and the quality of program implementation were both associated with programme effectiveness (Wilson and Lipsey 2006). The review team performed a regression analysis to identify the relative influence of different moderators, including the two implementation moderators identified above. This analysis was able to verify that poorly implemented programs were less effective, regardless of whether they were delivered as research or routine practice, and that programmes with more frequent treatment sessions per week tended to be more effective at producing reductions in aggressive and disruptive behaviour (Wilson and Lipsey 2006). Qualitative indicators of implementation (as shown in column 3 in Table 1) may also be used to guide sub-group analyses in effectiveness reviews or to conduct a less formal assessment of the potential for implementation failure, however qualitative evidence for establishing implementation integrity has not yet been widely used in Cochrane Reviews (Cargo et al 2018).

Box 2: Example of a review to explore implementation integrity

Review: Wilson and Lipsey (2002) The Effects of School-Based Social Information Processing Interventions on Aggressive Behaviour.

Background: For some children, the inability to process social information results in inappropriate behavioural responses and aggressive children tend to differ from non-aggressive children in various stages of social information processing. Social information processing programs involve training in one or more social information processing steps, emphasizes cognitive skills or thinking processes and involves the use of structured tasks and activities through which the cognitive skills are learned and applied to actual social situations.

Aim: To examine the effects of school-based social information processing programs to reduce aggressive behaviour. Program effects are examined overall and in relation to methodological and substantive differences across studies.

Evidence: 47 unique research studies most of which (74%) were randomized controlled trials were included in the review.

Findings: The review team found that those who participated in social information processing programs showed less aggressive and disruptive behavior after treatment than students who did not receive a program. The review found that intervention effectiveness was impacted upon by (i) the dose delivered and (ii) the quality of implementation.

Conclusion: Programs with high quality implementation and those with more frequent treatment sessions per week tended to be more effective at producing reductions in aggressive and disruptive behaviour.

17.2.6. Reviews to explore implementation experiences

Qualitative evidence is used by Cochrane (Thomas et al 2020), Campbell (Keenan et al 2021) and other review teams seeking to understand implementation experiences. For example, a 2013 Cochrane Review employed QES to examine the factors that create barriers and facilitators to the implementation of lay health worker programmes to improve access to maternal and child health (Glenton et al 2013). Described in Box 3, this review focused on understanding the experiences of both those delivering and receiving lay delivered maternal and child health interventions.

Box 3: Example of a review to explore implementation experiences

Review: Glenton et al (2013) Barriers and facilitators to the implementation of lay health worker programmes to improve access to maternal and child health: qualitative evidence synthesis.

Background: Lay health workers (LHWs) perform functions related to healthcare delivery, receive some level of training, but have no formal professional or paraprofessional certificate or tertiary education degree. They provide care for a range of issues, including maternal and child health.

Aim: To explore factors affecting the implementation of LHW programmes for maternal and child health.

Evidence: 53 qualitative studies from diverse settings and countries describing the experiences of LHWs, programme recipients, and other health workers.

Findings: The synthesis identified moderate and low certainty findings about potential barriers and facilitators to the successful implementation of lay health worker (LHW) programmes, including factors tied to the relationship between LHWs and community members, and between these two groups and health professionals. Other identified implementation barriers and facilitators included factors tied to LHW

training, supervision, working conditions, incentives and selection criteria, and the integration of the programmes into the health system.

Conclusion: The often close relationship between LHWs and their recipients is a strength of such programmes. However, programme planners must consider how to achieve the benefits of closeness while avoiding the problems. It may also be important to offer services that recipients perceive as relevant; to ensure regular and visible support from other health workers and community leaders; and to offer appropriate training, supervision and incentives.

Reviews of implementation integrity examine, for example, whether those implementing an intervention or programme achieved fidelity to pre-planned implementation approaches, whether they delivered a sufficiently high dose was delivered, or whether they reached sufficient numbers of service users. By contrast, reviews of implementation experiences such as the one described in Box 3 provide useful evidence about how such issues might be tackled, for example by identifying why the intervention was not implemented as originally intended, why a sufficient dose was not able to be delivered, or why people engaged (or not) with the intervention. For example, the QES described in Box 3 identified how appropriate training and supervision supported successful implementation of LHW programmes. Another distinguishing feature of QESs exploring implementation experiences is the emergent, flexible and open-ended nature of analyses, which enables such reviews to identify implementation issues that are particularly pertinent or issues that are unanticipated. As exemplified in the review described in Box 3, the qualitative evidence revealed potentially unmeasurable or intangible reasons for engagement, such as the close relationship between LHWs and their recipients. This open-ended approach is also amenable to providing insight into whether, or the extent to which, it is more important to achieve standardized implementation or to adapt implementation to preserve the intended outcomes. Hawe et al 2004 describe this as a focus on integrity of function over integrity of form; the aim being to preserve the function or goals of the intervention, either by tailoring an intervention to meet individual participant needs or by tinkering with an intervention to fine-tune it to fit a specific context, rather than standardising the precise form of an intervention (Hawe et al 2004). The findings of reviews of implementation experiences may therefore complement a review of implementation

integrity if conducted in advance to inform the selection of variables for sub-group analysis, or if conducted alongside or after an integrity analysis to explain reasons for observed implementation failure. See Chapter 14 for further information on integrating qualitative evidence with effectiveness synthesis evidence. Reviews of implementation experiences may also be useful in supporting decision-makers using the review to inform policy and practice by enabling understanding of pitfalls to avoid, or opportunities to secure, as illustrated in the review described in Box 3.

17.2.7. Reviews to understand implementation mechanisms

Reviews seeking to understand implementation mechanisms blend a rich understanding of how implementation factors interact with intervention and contextual features with a formal and systematic analysis of the relationship between these factors and intervention effects. As illustrated by the review of implementation mechanisms described in Box 4, reviews to understand implementation mechanisms often involve a two-stage process. Given the array of intervention, implementation and contextual factors that could interact to affect outcomes, the first step of such reviews involves identifying potentially important factors to analyse, which is much like the work undertaken for an implementation experiences review. However, what distinguishes a review of implementation mechanisms from a review of implementation experiences is that it also includes a formal analysis of the relationship between implementation and outcomes. And what distinguishes a review of implementation mechanisms from a review of implementation integrity is that it accounts for interactions between multiple intervention, implementation or contextual factors.

Box 4: Example of a review to explore implementation mechanisms

Review: Sutcliffe et al (2022) 'Leading from the front' implementation increases the success of influenza vaccination drives among healthcare workers: A reanalysis of Systematic Review evidence using Intervention Component Analysis (ICA) and Qualitative Comparative Analysis (QCA)

Background: A previous systematic review examined interventions to encourage uptake of the flu vaccine uptake among healthcare workers (HCW), finding that hard mandates, such as loss of employment for non-vaccination, were more effective than soft mandates, such as signing a declination form, or other interventions such as incentives. Despite these overarching patterns the review authors concluded that 'substantial heterogeneity' remained requiring further analysis.

Aim: To examine whether the strategies used to implement interventions explain the residual heterogeneity.

Evidence: Trials were selected from the previous review to conduct two QCA analyses – one for hard mandates (11 cases) and another for soft mandates and other intervention types (20 cases).

Findings: Both analyses revealed that an overarching 'leading from the front' implementation approach was associated with greater effectiveness. The approach was underpinned by four key features: providing education prior to implementation; two-way engagement so HCW can voice concerns prior to implementation; previous use of other strategies so that institutions 'don't-go-in-cold' with mandates; and support from institutional leadership.

Conclusion: A 'leading from the front' rather than a 'top-down' approach enhances the effectiveness of flu vaccination drives to increase uptake among HCW. Interestingly, this approach seems to enhance the effectiveness of both hard-mandate approaches and soft-mandates or other approaches.

In the example in Box 4 above, Intervention Component Analysis was employed in the first stage to inductively code study authors' informal reflections on implementing vaccine uptake interventions. Qualitative Comparative Analysis (QCA) was employed in the second stage to systematically identify how the identified factors interact to affect outcomes. Reviews of implementation mechanisms have variously used logic models (Harris et al 2019) (see also Chapter 4), QES (Burchett et al 2018; Sutcliffe et al 2018), realist synthesis (Whitaker et al 2016) and as described in Box 4, Intervention Component Analysis (Sutcliffe et al 2022) to identify potentially important features and mechanisms in the first stage. The integration of implementation mechanism evidence with effectiveness evidence in the second stage may use approaches similar to those described in Chapter 14, and examples have involved realist synthesis (Whitaker et al 2016) and qualitative comparative analysis (QCA) (Thomas et al 2014) (see Chapter 17 for detailed guidance on QCA methods).

By bringing together a rich understanding of interactions between intervention, implementation and contextual factors with an analytic synthesis method that is both systematic and able to cope with such complexity, reviews of implementation mechanisms can provide clear guidance about how to implement interventions for maximum effectiveness.

17.3. Identification of evidence

Numerous sources of evidence can be used to address the different implementation review objectives (Cargo et al 2018). These include:-

- Implementation evidence reported in effectiveness studies
- Quantitative process evaluations conducted alongside trials and published as a separate report.
- Qualitative 'trial sibling' studies– i.e. qualitative process evaluations conducted alongside trials and published as a separate report.
- Qualitative studies with no relationship to included trials.
- Evidence about implementation reported in trials / process evaluations.

Trial reports are the predominant source of quantitative implementation evidence for many reviews as they often contain information about key quantitative implementation measures such as dose delivered and reach (French et al 2020). This source of implementation evidence will therefore be retrieved by the search for effectiveness evidence.

However, implementation data is often reported in separate reports of process evaluations conducted alongside trials (Moore et al 2015). This increases the challenge of identifying implementation evidence, not only because it requires searching for a separate set of studies, but because it is more challenging to search for process evaluations than for trials. Process evaluations are often not clearly labelled as such (French et al 2020; Grant et al 2013; Liu et al 2019) making search strings complex to design. Process evaluations are often unpublished (Lewin et al 2009) making supplementary grey literature searches, which can be particularly challenging and time consuming (Stansfield et al 2016) essential. Pilot and feasibility studies, which are often rich sources of information on implementation which may be picked up through searches for trials, but they may also suffer from the same challenges of identification as process evaluations (Whitehead et al 2014). Qualitative implementation evidence may be drawn from mixed-methods process evaluations and 'trial sibling' studies or from unrelated qualitative studies, both of which present the usual challenges of searching for qualitative evidence (Stansfield et al 2014). The Cochrane Qualitative and Implementation Methods Group recommend four approaches for searching

for implementation literature (Cargo et al 2018) as described in Table 3, along with appropriate use scenarios and their strengths and limitations. See Chapter 5 on searching for more detailed guidance on searching for qualitative studies. Exacerbating the challenges of searching is a general lack of implementation evidence (Cargo et al 2018). If searches do not unearth sufficient implementation evidence, or where the additional time required for implementation searches is prohibitive, review methodologists have developed methods to gather 'informal' implementation from trials (Sutcliffe et al 2015). Inclusion of this 'informal' implementation evidence is considered in Table 3.

Table 3: Methods for searching for implementation literature

Method	Details	Considerations
1. Transfer identification from the search process to the sift process	Develop a sensitive search string with no publication type restrictions.	**Strengths**: Useful when multiple publication types are used in the review – e.g. RCTs, quantitative process evaluations, and qualitative studies. **Limitations:** Increased number of citations to screen means screening may take longer. Qualitative non-sibling studies may cover diverse issues, not just implementation, and therefore require screening at full-text to check if data on implementation is available. **Mitigations:** Automated screening tools, such as the priority screening function in EPPI-Reviewer can help to streamline screening for large reviews.
2. Retrieve process evaluations reported within randomized control trials	Use the highly sensitive Cochrane search strategy filter for trials.	**Strengths:** Useful for identifying published quantitative process evaluations and trial sibling studies via database searches. **Limitations:** Dependent on publications mentioning the trial with which they are associated in the abstract. Not suitable for identifying non-sibling qualitative studies. **Mitigations:** Supplementary strategies such as citation chasing.

3. Use unevaluated filter terms to retrieve process evaluations or implementation data	Include publication type or data type filter terms to search strings to identify process evaluations or implementation data.	**Strengths:** Increases the specificity of the search compared to approach #1, thereby reducing the time required for screening. **Limitations:** No validated implementation filters exist, use of such filter terms is considered experimental. Given the non-standard approaches to reporting process evaluations, qualitative studies and the inconsistent terminology used to describe implementation a sufficiently sensitive filter may be challenging. **Mitigations:** An iterative approach to searching may be used where the terminology used by initially identified implementation studies is fed into subsequent searches.
4. Citation-based searches	Seek out all accounts, published or unpublished, of a particular study.	**Strengths:** Particularly useful when seeking out quantitative process evaluations and qualitative trial sibling studies. Multiple accounts of the same study may provide rich understanding. **Limitations:** Time consuming - may require contacting study authors and conducting web-searches in addition to forwards and backwards citation chasing. **Mitigations:** Tech solutions available for forwards and backwards citation chasing (e.g.citation chaser).
5. Use informal evidence	Intervention Component Analysis (ICA) uses an inductive approach to analyse trialists' informally reported reflections on implementing an intervention – often reported in the discussion sections of trials.	**Strengths:** Useful when limited process data is available and / or when there is insufficient time to undertake extensive searches for implementation data using the above approaches. Uses an often rich and underutilized source of experiential evidence. **Limitations:** The evidence is not gathered using formal research methods and may thus be biased or self-justifying. It may not be as complete as achieved from a formal study, because not all trial authors report implementation experiences.

In addition to the study design a second key consideration when searching for and including evidence for implementation reviews is the numerous types of study participants who can provide insights into implementation. Individuals include those implementing interventions at the organisational level, those providing interventions directly to recipients, and those receiving interventions. Valuable insights about reach and engagement can also be obtained from individuals who were unable to, or chose not to, engage with or take up an intervention. For example, a QES on factors that impact on recruitment to randomized trials in healthcare sought the views of individuals who had been invited to participate in trials including both those who declined and those who accepted the invitation (Houghton et al 2020). Those who would be eligible for an intervention but who have not actually been exposed to or offered such an intervention may offer hypothetical as opposed to experience-based views. Whilst providing some useful insights, a synthesis based purely on hypothetical evidence is limited by an inability to elicit unanticipated or unforeseen issues, in contrast to syntheses based on experience. The QES on factors that impact on recruitment to randomized trials in healthcare excluded such hypothetical studies, including only studies where participants had direct experience of being recruited to trials. The review authors concluded that experience-based views were particularly valuable for illuminating unanticipated perspectives that hypothetical studies could not have uncovered (Houghton et al 2020).

A third consideration is whether to include only implementation evidence from trial 'sibling' studies, i.e. studies that collect implementation data from participants in trials included in the effectiveness synthesis or whether to include evidence from 'non-sibling studies' i.e. additional studies where participants provide implementation evidence about the same type of intervention although not associated with a trial included in the effectiveness synthesis. A key strength of including non trial sibling studies is having a larger pool of available evidence to draw on which, in turn, offers more opportunities to produce transferable findings with greater confidence (Noyes et al 2016). This approach may therefore be particularly important where process evaluations have not been routinely conducted alongside trials (although conducting a process evaluation alongside a trial has become normative in the last decade). It also avoids waste of historical learnings on

implementation which are not connected to trials. However, a weakness of this approach is that implementation findings from non-trial sibling studies may not accurately reflect implementation in the included trials (Noyes et al 2016).

A fourth consideration for study identification is whether or not to pre-specify implementation dimensions of interest in the inclusion criteria, or whether to include all dimensions. For example, if a review of implementation experiences is conducted prior to a review of implementation integrity, the findings of the review of implementation experiences may inform the selection of specific dimensions to include for the review of integrity. However, given the diversity and scarcity of implementation evidence, review authors may consider it pragmatic to seek and include any available implementation evidence at this stage.

17.4. Appraisal of evidence

Given the diversity of implementation approaches and evidence it is perhaps unsurprising that few assessment tools are specifically designed to assess the rigor or risk-of-bias of process evaluation or implementation evidence (Cargo et al 2018). Chapter 7 provides guidance on assessing methodological limitations of qualitative studies; reviews where the evidence is exclusively qualitative may follow this guidance. However, the EPPI-Centre has designed a flexible and appropriate tool for both qualitative and quantitative implementation studies for implementation reviews which include either or both types of evidence (Shepherd et al 2010). The first three questions in the eight-question tool direct review teams to consider whether the core steps in a research study, including recruitment, data collection and data analysis, are appropriate. Two questions (4 and 5) encourage review teams to reflect on the reported findings to consider whether the study authors' conclusions reflect the data reported and the breadth and depth of findings. The sixth question encourages review teams to consider whether the researchers took appropriate steps to privilege the target population's views. This is a counterbalance to the often top-down approach to the development and implementation of interventions – many are based on expert opinion rather than the expressed need of those targeted by the intervention or those expected to deliver it. How participants experience the intervention is crucial to implementation issues. A process evaluation that does not attend to participant experience

would only give a partial picture or miss key challenges or successes. The final two questions encourage review teams to provide an overall assessment of the rigour or 'trustworthiness' of the findings and of the 'usefulness' of the study in terms of how well it was able to illuminate why or how the intervention worked or did not work. Table 4 lists the eight core questions in the tool and examples of relevant considerations when appraising quantitative or qualitative implementation evidence.

Table 4: Adaptation of EPPI-Centre tool for appraising implementation evidence

Item	Considerations for quantitative data	Considerations for qualitative data
1. Steps were taken to minimize bias and error/ increase rigour in sampling.	Was the sampling strategy appropriate to the questions being asked? Were all stakeholders included?	Was the sampling strategy appropriate to the questions being asked? Were all stakeholders included?
2. Steps were taken to minimize bias and error/ increase rigour in data collection.	Were data collection tools validated or piloted?	Was data collection comprehensive, flexible and/or sensitive to provide a rich description of processes?
3. Steps were taken to minimize bias and error/ increase rigour in data analysis.	Were analysis methods systematic? Was diversity in perspective explored?	Were analysis methods systematic? Was diversity in perspective explored?
4. Findings were grounded in/supported by the data.	Were enough data presented to show how the study authors arrived at their findings? Do the data presented fit the interpretation provided?	Were enough data presented to show how the study authors arrived at their findings? Do the data presented fit the interpretation provided?
5. There was good breadth and/or depth achieved in the findings.	Were a range of processes issues covered in the evaluation?	Were the perspectives of participants fully explored in terms of breadth – contrast of two or more perspectives – and depth – insight into a single perspective?

6. The perspectives of the target population receiving the intervention (e.g. young people) were privileged.	Was feedback collected from the intervention recipients – e.g. measures of satisfaction? Was there a balance between open-ended and fixed-response options such that unanticipated issues can be discussed?	Was feedback collected from the intervention recipients? Was there a balance between open-ended and fixed-response options such that unanticipated issues can be discussed?
7. Rate the reliability or trustworthiness of the findings (high, medium or low)	Consider the extent to which the methods employed were able to minimize bias and error in the findings.	Consider the extent to which the methods employed were rigorous.
8. Rate the usefulness of the findings (high, medium or low)	Consider how well / comprehensively the intervention processes were described.	Consider the extent to which the process data could illuminate why or how the intervention worked or did not work.

Figure 4 provides an illustration of the overview of trustworthiness and usefulness of nine process evaluations included in a review on behavioural interventions for the prevention of sexually transmitted infections based on Questions 7 and 8 in Table 4 (Shepherd et al 2010). This transparent account enables readers of the review to understand and interpret the body of implementation evidence. Evidence appraisals have also been used in implementation reviews as a condition for analysis in QCA, see Chapter 17.

Figure 4: Example of weight of evidence based on assessments of trustworthiness and usefulness of implementation evidence. **Permission needed (Shepherd et al 2010)**

Weight of evidence judgements for (1) trustworthiness of findings and (2) usefulness of findings

	Weight of evidence					
	Trustworthiness of findings			Usefulness of findings		
	Low	Medium	High	Low	Medium	High
Borgia *et al.*[51]	✓			✓		
Jemmott *et al.*[43]	✓			✓		
Jemmott *et al.*[62]	✓			✓		
Karnell *et al.*[63]		✓		✓		
Levy *et al.*[65]	✓			✓		
Roberto *et al.*[66]	✓			✓		
Stephenson *et al.*[50]			✓		✓	
Wight *et al.*[70]			✓			✓
Zimmerman *et al.*[71]		✓			✓	
TOTAL	5	2	2	6	2	1

17.5. Data extraction and synthesis

The spectrum of implementation review types naturally means that different considerations for data extraction and different synthesis approaches are required for each type.

17.5.1. Extracting and synthesising data for reviews of implementation integrity

As indicated in Table 1 a large number of potentially important implementation dimensions relate to implementation integrity. Guidance suggests that, as a minimum, process evaluations should include information on reach, dose delivered/received, fidelity, cointervention and contamination (Armstrong et al 2008; Cargo et al 2018). However, review authors often find that process evidence is lacking (O'Toole et al 2018; Shinohara et al 2013). Even when processes are measured they are often poorly reported (Cargo et al 2015). Interventions themselves are also often poorly reported (Hoffmann et al 2014) such that assessment of implementation of complex interventions is challenging because measures of implementation (e.g. dose, reach etc) may pertain to different intervention elements (Cargo et al 2018). Thus review authors may need to develop a coding framework that is flexible enough to support comparison of similar dimensions of implementation, rather than using existing frameworks. A narrative method for synthesising the evidence may also be required (see also Chapter 18). In Box 5 the example incorporated a narrative

method of synthesis in a review on behavioural interventions for the prevention of sexually transmitted infections in young people (Shepherd et al 2010). As the example illustrates, this type of flexible and interpretive, yet transparent and systematic approach, may enable review teams to make best use of often scarce and diverse implementation evidence.

Box 5: Example of a review of implementation integrity synthesis approach

Review: Shepherd et al (2010) The effectiveness and cost-effectiveness of behavioural interventions for the prevention of sexually transmitted infections in young people aged 13-19: a systematic review and economic evaluation

Review questions: What factors facilitate or hinder the implementation of skills-based behavioural interventions in schools? What factors impact on student engagement and intervention acceptability?

Synthesis steps:

1. Preparation of detailed evidence tables describing the methodological quality, contextual details and findings of each process evaluation.
2. Findings assigned to one of eight broad pre-defined categories of implementation (accessibility/programme reach; collaboration and partnerships; content of the intervention; intervention implementation; acceptability; quality of intervention materials; skills and training of intervention providers; and 'other').
3. Two researchers independently read and re-read the tabulated details and then compared and discussed these to agree main themes to emerge from the findings.
4. Narrative written to describe and elaborate on themes.
5. Narrative reviewed and discussed by the wider team.
6. Narrative and input from the wider team translated to address directly the two synthesis questions.

Whilst the above review team used a narrative approach to synthesise the implementation data, the findings from a synthesis of process data may also be used to conduct sub-group analyses of the effectiveness evidence, in order to illustrate how the implementation issues are associated with outcomes. For example, the review described in Box 2, enabled the review authors to identify that high quality implementation and frequent treatment sessions were associated with greater intervention effectiveness (Wilson and Lipsey 2006).

17.5.2. Extracting and synthesising data for reviews of implementation experiences

Chapter 8 provides detailed guidance on extracting and synthesising evidence for QES. Additional considerations specific to QES focused on implementation experiences are discussed below.

Review teams examining implementation may face the challenge of needing to synthesize evidence from mixed-methods primary studies. Some review authors have recommended an 'integrated' (Sandelowski et al 2006) or 'data-based convergent' (Hong et al 2017) synthesis. This requires the transformation of data into a single type to enable a single method of synthesis; either 'qualitizing' or transforming quantitative data into a qualitative format, or 'quantitizing' to transform qualitative data into a quantitative format (Sandelowski et al 2006). However, for many reasons, researchers have argued that is not methodologically robust to transform data in this way and if attempted should be done in a considered way (Sandelowski et al 2009). An alternative approach to mixed-methods implementation evidence is to use mixed-methods framework synthesis (Chapter 9) which can easily accommodate both qualitative and quantitative evidence without the need for transformation (Brunton et al 2020). See further information on integrating qualitative and quantitative evidence in Chapter 14. Another challenge encountered with QES examining implementation experiences is that few qualitative studies focus exclusively on implementation. Thus, review teams face the challenge of identifying which data are relevant, and interpreting how data might relate to implementation. Review teams may find a 'framework' synthesis approach (Chapter 9) useful (Brunton et al 2020) for seeking out evidence on specific pre-identified implementation dimensions. However, the open-ended and emergent nature of qualitative research means that it may be difficult to identify data on specific dimensions. An alternative approach is to develop implementation themes iteratively, rather than employing pre-defined categories, in order to encapsulate related or interacting implementation dimensions (Chapter 10 Thematic Synthesis). If each of the studies in the synthesis addresses different implementation dimensions a 'line-of-argument' synthesis approach, consistent with meta-ethnography (Chapter 11), may be appropriate (Britten et al 2002; France et al 2019; Garside et al 2008) such that key concepts

or themes identified in different papers are linked together to generate a comprehensive account of implementation issues. Box 6 contains an example of a review of implementation experiences in which the review team combined a framework synthesis approach with meta-ethnography (Downe et al 2019).

Box 6: Example of a review of implementation experiences synthesis approach

Review: Downe et al (2019) Provision and uptake of routine antenatal services: a qualitative evidence synthesis.

Implementation synthesis question: What are the factors influencing the provision of antenatal care arising from the accounts of women and healthcare providers?

Synthesis steps:

1. Extracted data using a framework based on the theory of planned behaviour. Read each included study in detail, and extracted the relevant verbatim text, adding new categories to the framework as they emerged and merging others where conceptual similarities were identified.
2. Descriptive account of findings expressed in a detailed table of studies alongside GRADE-CERQual gradings.
3. 'Higher-level' thematic synthesis to generate domains for two line of argument syntheses; one to explain service user data and one to explain provider data. This higher-level analysis enabled the development of theoretical explanations of what might underpin perceived factors influencing women's intended and actual use of local antenatal care, or providers' capacity to provide good-quality care.
4. Developed logic models to express the findings.

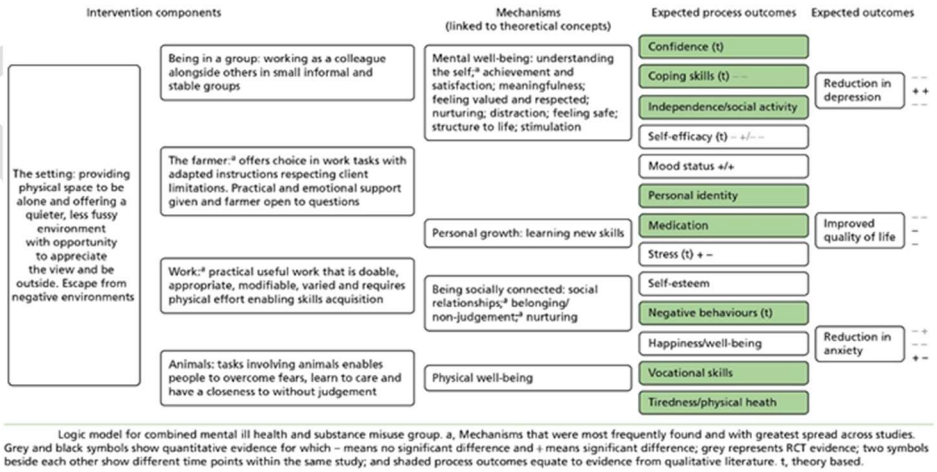
An implementation experiences QES may be conducted as a stand-alone review. However, many are conducted to inform or interpret effectiveness review findings. For example, in the review described in Box 6, the review team examined the findings of six relevant Cochrane effectiveness reviews to see if the authors paid attention to possible underlying theories or mechanisms identified in the QES. Whilst some of the effectiveness reviews noted relevant factors in the 'how the intervention might work' section, 29 of the QES findings were not represented in any of the effectiveness reviews (Downe et al 2019). Alternatively, review teams may conduct a review of implementation experiences QES as an initial step in order to inform and structure a review of effectiveness, implementation integrity or implementation mechanisms. See Chapter 14 for a discussion of available approaches for integrating QES with effectiveness evidence.

17.5.3. Extracting and synthesising data for reviews of implementation mechanisms

As described above a review of implementation mechanisms will consist of two key stages. First, potentially important implementation, contextual and intervention factors are identified. This may be achieved through an implementation experiences QES or through an analysis of theory (see Chapter 3) as in many realist reviews (Chapter 15) (Rycroft-Malone et al 2012), or through Intervention Component Analysis (Sutcliffe et al 2015).

The second key stage requires a formal analysis of how identified factors are associated with intervention outcomes. Again, a diversity of approaches may be used to conduct this second stage of analysis and synthesis. For example, in a Campbell review on the impact of Care Farms on quality of life, depression and anxiety among different population groups (Murray et al 2019), the review authors first produced a logic model from a QES to illustrate the mechanisms through which different elements of Care Farms achieved outcomes (Chapter 4). The review authors then tested this logic model against quantitative effectiveness data. The team annotated the logic model with the outcomes from the effectiveness studies to illustrate whether and how the mechanisms identified in the QES were supported by the effectiveness evidence, as illustrated in Figure 5 below.

Figure 5: Annotated Care Farms logic model. **Require permission to use (Murray et al 2019)**



Logic model for combined mental ill health and substance misuse group. a, Mechanisms that were most frequently found and with greatest spread across studies. Grey and black symbols show quantitative evidence for which – means no significant difference and + means significant difference; grey represents RCT evidence; two symbols beside each other show different time points within the same study; and shaded process outcomes equate to evidence from qualitative literature. t, theory based.

A different approach was employed in the review of implementation mechanisms described in Box 4 above. The review team first employed Intervention Component Analysis (Sutcliffe

et al 2015), drawing on the informal reflections of trial report authors about the experience of implementing flu vaccination uptake interventions for healthcare workers to identify potentially important implementation factors. The review team then used QCA to test the association between the identified factors and intervention outcomes. Chapter 17 details the data extraction and synthesis procedures required for QCA.

17.6. Reflexivity

Given the interpretive nature of many of methods for reviewing implementation, reviewer reflexivity is an important consideration. Review authors and stakeholders may have individual perspectives and biases that influence the choice of objectives and methods and preferred ways to implement interventions in any given context. Some review authors may also have developed implementation theories or implementation synthesis methods that they want to use in the review. Reflexivity may also be particularly pertinent in relation to seeking out and being sensitive to possible equity, diversity and inclusion issues which are likely to be underreported in the literature and of which review authors may be unaware. For example, review teams may need to consider the potential negative impacts of implementation strategies for disadvantaged groups, or whether marginalized voices are sufficiently well represented in implementation experiences reviews (see also section 16.2.3).

17.7 Chapter information

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Declarations of interest

Sutcliffe, Harden and Noyes are Cochrane Qualitative and Implementation Methods Group Convenors. Noyes is a member of the Cochrane Methods Executive and Editorial Board.

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