Standards of Evidence

Standard for Producing Evidence – Effectiveness of Interventions – Part 1: Specification

Standard of Evidence 2 Part 1 (StEv 2-1:2016)

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Standard of Evidence 2 Part 1 (StEv 2-1:2016)

Published February 2016

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ISBN 978-1-911056-01-0

This standard may be indexed under the following ICS classification:

03.100.40 (Research and development)

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HACT is registered as the Housing Associations' Charitable Trust, charity number 1096829, company number 04560091.

This document may be cited as:

"Vine, Jim (2016). Standard for Producing Evidence – Effectiveness of Interventions – Part 1: Specification. HACT. London, UK."

Publication history

First published February 2016

Amendments issued since publication

Date	Text affected

Technical foreword

Information about this document

This standard is published by HACT and drafted by Jim Vine. It came into effect on 2 February 2016.

National and international standards bodies have established conventions for the drafting of standards. As far as is practicable, HACT has adopted these conventions in the drafting of this standard. For the avoidance of doubt, the adoption of these conventions does not constitute a claim that any such body has overseen the creation of this standard.

> *[REFERENCES: ISO/IEC Directives, Part 2, 2011. http://www.iec.ch/members_experts/refdocs/iec/isoiec-dir2%7Bed6.0%7Den.pdf. Rules for the structure and drafting of UK standards, 2012. http://www.bsigroup.com/Documents/standards/guide-to-standards/BSI-Guide-to-standards-2-standard-structure-UK-EN.pdf]*

This type of standard is intended to provide an agreed, repeatable way of doing something – in this case, a consistent way of producing evidence of the effectiveness of interventions. To serve this purpose, the emphasis is on ensuring that the requirements and recommendations of the standard are clear and unambiguous; consequently the style is deliberately technical rather than conversational. For a more conversational introduction to the steps defined in this standard see the accompanying guide. *[REF: Vine, 2016.]*

Use of this type of standard is normally voluntary – it is hoped that people will find it to be a useful tool to enable them to do something in a consistent way that has been carefully developed.

In line with the conventions of national and international standards, requirements and recommendations are communicated as follows:

- The verb form "**shall**" is used to express **requirements**, i.e., aspects that must be followed in order to conform to the standard.
- The verb form "**should**" is used to express **recommendations**, i.e., that a certain course of action is preferred but not necessarily required in order to conform to the standard.

Annexes are labelled as “normative” or “informative” to indicate their nature. Normative annexes are those that set out provisions or requirements. Informative annexes provide additional information that is intended to support those using the standard.

Acknowledgements

The work to develop this standard would not have been possible without the kind support of Bromford, Look Ahead Care and Support, Metropolitan, Sanctuary Supported Living, Trafford Housing Trust and Public Health England.

Great thanks are also due to all of those who have acted as a Correspondence Group for the project of developing the standard, contributing their thoughts in ways that have very much improved the final output, and to Peter Molyneux, who chaired meetings of the working group that led to the standard. Any errors that remain are, of course, the responsibility of the author.

The Correspondence Group included representatives of the following organisations: Academy of Medical Royal Colleges; Alliance for Useful Evidence; Care and Repair England; Centre for Mental Health; Chartered Institute of Housing; Children and Young People's Mental Health Coalition; Department for Communities and Local Government (DCLG); EDF; Economic and Social Research Council (ESRC); Homeless Link; Housing LIN; Joseph Rowntree Foundation (JRF); London School of Hygiene and Tropical Medicine; MDRC; National Housing Federation; National Institute for Health and Care Excellence (NICE); Place2Be; Royal College of Psychiatrists; University College London; University of Chicago; University of Durham; University of Glasgow; University of Stirling; University of Warwick; University of York; and Youth Access.

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a standard cannot confer immunity from legal obligations.

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Foreword

The growth of the evidence agenda has come at a crucial time for the housing sector. Factors such as demographic changes and resource constraints mean that the sector needs to ensure it maximises its impact. The robust use evidence will ensure we understand more about the people we house so that we are putting resources into those things that really make a differences to their lives.

It is important that the creation of this standard was supported not just by housing providers but also by Public Health England, reflecting the powerful potential contribution that good housing can make to people's health and wellbeing. We know that the health sector demands robust evidence – and rightly so – and as housing providers seek to work more closely with health partners the use of this standard will ensure that they are able to talk the same evidence-based language to achieve better outcomes.

Beyond producing evidence of the health impacts of our work, this standard can also be used to investigate a wide range of other activities. Which of our employment projects are most successful at getting people into work? Which forms of support are most effective at supporting tenants to be able to pay their rent? Which forms of communication are best for building engagement with hard-to-reach groups?

Housing associations work with people and communities that have experienced disadvantage and have a great track record of making meaningful differences in people's lives. By producing and using robust evidence we can ensure that the case for this work continues to be made and that it makes the difference that really matters.

So it is with great pleasure that I am able to introduce this Standard of Evidence. It is a valuable tool that will support many more people to produce evidence of the effectiveness of their interventions. It does this through a set of relatively simple steps, from working out what problem you are trying to address and thinking about how you might resolve it to ultimately identifying the outcomes that you are trying to achieve.

I hope this new standard will be adopted widely, not just by social housing providers but by all those looking to drive innovation and produce evidence of the effectiveness of their interventions. Creativity on its own will not be enough, we need to marry up the evidence with creative new ideas to harness the potential and make the difference.

Gavin Cansfield
Chair, HACT

Introduction

The aim of producing evidence of the effectiveness of interventions is to enable decisions to be informed by knowledge of what works. This requires decision makers to have access to evidence that establishes whether an intervention contributes, in a causal sense, to the achievement of particular outcomes. Consequently, the objectives of evidence produced in conformity with this standard are to increase the degree of certainty about whether an intervention is effective at achieving its intended outcomes, and to make that knowledge accessible to those who might use it.

Establishing the effectiveness or otherwise of an intervention requires a careful approach, in part because correlation does not automatically imply causation: simply observing an outcome after an intervention is not sufficient to prove that the intervention caused the outcome. Furthermore, people receiving one intervention may also be in receipt of others, so approaches that robustly establish the effectiveness of an intervention need to be designed to detect the part of any outcomes that are attributable to the intervention being studied. Evidence of correlation (as might be produced by evidence at level 1 in this standard) may increase the degree of certainty about the effectiveness of the intervention from 'unknown' to 'might be working'. Producing this type of evidence can often be a useful and relatively simple first step in understanding the potential effectiveness of an intervention. Evidence of a causal link (levels 2 and 3) can take that further, towards 'reasonably confident this works (at least in this context)'.

Open publishing of details of studies investigating the effectiveness of interventions, both before commencing a study and reporting its findings, increases the potential impact of the evidence. It can do this both by enhancing the credibility of evidence findings and by making them more accessible to more decision makers.

This standard specifies a process that supports those producing evidence to do so in a way that is robust and transparent. The process also includes steps such as reviewing existing evidence to support decisions about what type of evidence it would be most suitable to produce. In doing so, it will increase the potential for decisions to be made based upon accurate and credible evidence of the effectiveness of interventions.

1 Scope

This Standard of Evidence specifies a process for producing evidence of the effectiveness of interventions. It is intended to establish a common process for the production of evidence of effectiveness, to provide confidence in the robustness of evidence produced, and to support the increased use of evidence that has been produced.

This part of the standard (part 1) only provides the specification of the process and does not attempt to justify why the various elements of the process are required or recommended. Explanations of the rationale behind the elements of the process are provided separately, in part 2 of the standard. *[SEE: Vine, 2016a.]*

Detailed requirements and recommendations are provided in relation to producing evidence through new primary studies.

Detailed processes for producing evidence through the use of systematic reviews, economic evaluations, and process evaluations are outside of the scope of this standard. Instead, high-level approaches to producing each of these three types of evidence are provided, with additional details specified through the use of references where available.

The standard is intended to be used by those responsible for designing and assessing the effectiveness of interventions. It is also intended that those commissioning external studies of the effectiveness of their interventions could specify that they require evidence to be produced in line with the requirements and recommendations of this standard.

This standard is for use by those who wish to investigate the effectiveness of interventions in any sector. It was designed with particular reference to the needs of organisations in the housing sector.

2 Terms and definitions

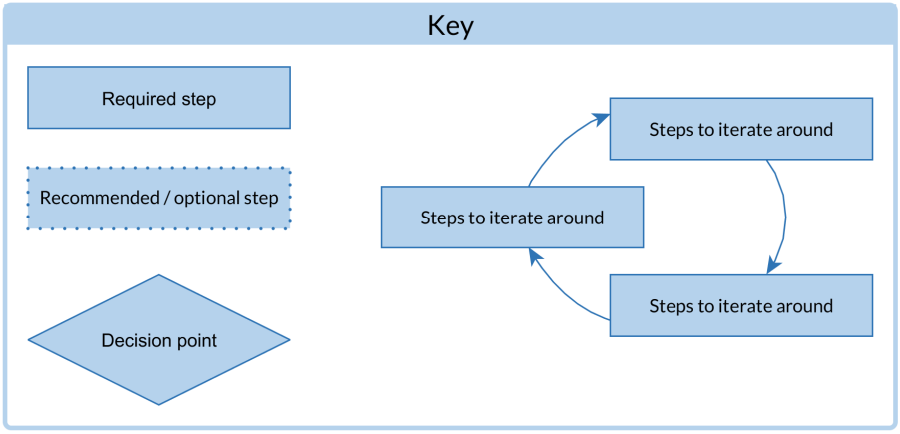
For the purposes of this standard, the terms and definitions given in StEv1-1 (General Requirements for Evidence – Part 1: Vocabulary) apply.

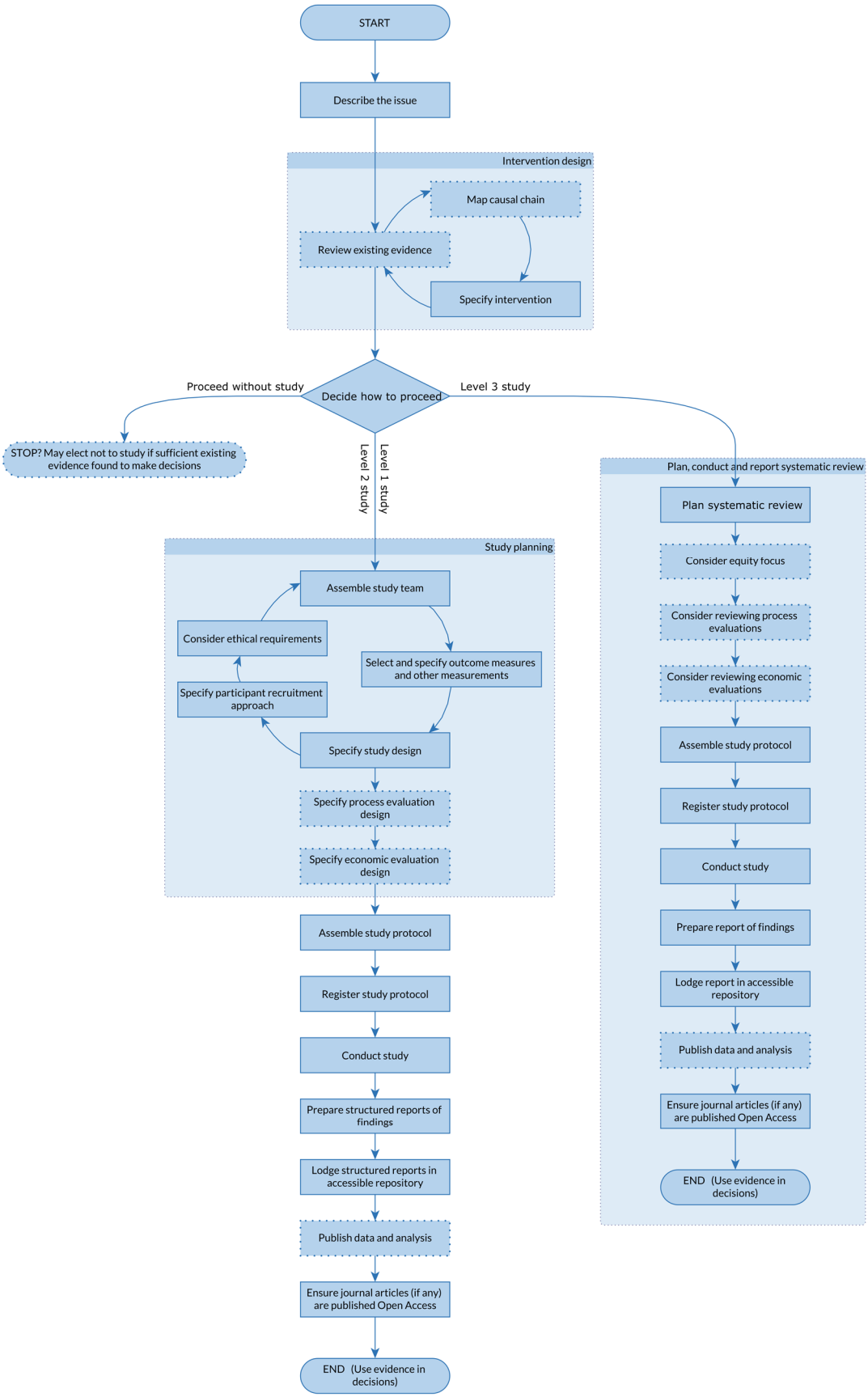
[REFERENCE: See section NR.11.]

3 Process

Figure 1 illustrates the process specified in this standard for producing evidence of the effectiveness of interventions.

Figure 1 Process for producing evidence of the effectiveness of interventions




START
Describe the issue
Intervention design
Map causal chain
Review existing evidence
Specify intervention
Decide how to proceed
Proceed without study
Level 3 study
Level 2 study
Level 1 study
STOP? May elect not to study if sufficient existing evidence found to make decisions
Study planning
Assemble study team
Consider ethical requirements
Select and specify outcome measures and other measurements
Specify participant recruitment approach
Specify study design
Specify process evaluation design
Specify economic evaluation design
Assemble study protocol
Register study protocol
Conduct study
Prepare structured reports of findings
Lodge structured reports in accessible repository
Publish data and analysis
Ensure journal articles (if any) are published Open Access
END (Use evidence in decisions)
Plan, conduct and report systematic review
Plan systematic review
Consider equity focus
Consider reviewing process evaluations
Consider reviewing economic evaluations
Assemble study protocol
Register study protocol
Conduct study
Prepare report of findings
Lodge report in accessible repository
Publish data and analysis
Ensure journal articles (if any) are published Open Access
END (Use evidence in decisions)

4 Issue description

An issue description shall be prepared that details the issue that the intervention to be studied is intended to respond to.

The issue description shall contain the information detailed in Table 1, structured in the same sections and order as provided in the table.

Table 1 Issue description

Date	Date of preparing this description.
Description of issue	The problem, circumstance or situation that it is intended that an intervention should respond to. When studying interventions to attend to particular problems this should be presented as undesirable aspects of a situation that it is hoped can be improved if an effective intervention can be identified. When studying an intervention that is untested but assumed to have a positive influence on aspects of a situation this should be presented as the aspects that it is thought that the intervention may be improving.
Who experiences the issue?	Those directly experiencing the issue.
Why would improvements in relation to this issue matter?	Why are the negative experiences a problem, or why would it be beneficial to achieve the prospective improvements?

Who does it matter to?	May be wider than those experiencing the issue.
Current practice	How is the issue currently typically attended to (if at all)?
Relevance of the study	What decisions are the results of this study intended to inform? Are there deadlines for making those decisions? How might practice be changed if an effective intervention is identified or an intervention is found to be ineffective? What information would this study need to generate to be able to affect these decisions?

5 Intervention design

5.1 General

Developing an intervention design should involve undertaking the following steps:

- Evidence review
- Causal chain mapping
- Intervention specification

These steps should be undertaken iteratively, progressively refining the outputs of each step based on the development of each of the others. For example, it may be necessary to undertake further evidence review activity once an intervention description has been developed, to ensure that evidence related to the described intervention has been searched for and reviewed.

5.2 Evidence review

[NOTE: This section specifies a non-systematic approach to reviewing evidence that does not attempt to avoid issues associated with publication bias in the evidence base. A systematic approach to reviewing evidence comprises a study type in its own right: see the information on level 3 at section 6.2.]

5.2.1 General

For a level 1 study, existing evidence should be searched for and reviewed to identify what is already known about the effectiveness of interventions related to the issue.

For a level 2 study, existing evidence shall be searched for and reviewed to identify what is already known about the effectiveness of interventions related to the issue.

[NOTE: The decision regarding what level of study to conduct is detailed in section 6.2. If an evidence review has not been conducted before deciding to conduct a level 2 study it may be conducted after that decision.]

Consideration should be given to publishing elements of the evidence review to make them available to those conducting similar reviews in the future.

5.2.2 Search for evidence

If undertaking an evidence review, the search for evidence to be reviewed should include searches of:

- the Campbell Library (http://www.campbellcollaboration.org/lib/) and the Cochrane Library (http://www.cochranelibrary.com/) for existing relevant systematic reviews;
- any subject-relevant repository of evidence findings;
- academic literature, using a specialist search engine;
- the internet, using a standard web search engine.

Other search strategies to find additional evidence may include:

- targeted searches of websites of organisations likely to have conducted studies related to the issue;
- examining references in reports that have been found;
- contacting researchers and subject experts;
- calling for evidence (e.g. on a website or via social media).

5.2.3 Review of evidence from individual studies

If undertaking an evidence review, each study identified shall be reviewed by collating the information detailed in Table 2, structured in the same sections and order as provided in the table. If more than one report is located describing the same study they shall be covered on the same study review sheet, and the information on report details shall be recorded for each.

If more than one study is identified assessing the same or similar interventions they shall each be covered on separate study review sheets.

Table 2 Study review sheet

Name of study	Name given to the study by those who conducted it, if any.
Brief description of study	Single sentence description of study covering the study design, intervention(s) studied, the primary outcome and key features of the context including the population.
Report details	
Title	Title of the report
Author(s) and affiliation(s)	Listed authors for the report and their organisational affiliations. In the absence of identifiable authors, record other relevant contacts involved in the study if possible.
Date of publication	Publication date of the report.
Source (web address or other)	Location for the report. Where possible, this should be the definitive location of the evidence where it can be found for future reference.
Study details (NB: For each item record where in the report it was found)	
Study location	Details of where the intervention was delivered. This may be either a specific place (or places) or a description of the characteristics of the place.
Dates	When the study was conducted, including when the intervention was delivered and when outcomes were measured.

Roles	Details of the organisations involved in delivering the intervention(s) and conducting the study, and their respective roles. Depending on the nature of the intervention and the study this may include organisations providing locations and/or client lists to act as study sites, those delivering the intervention, and those responsible for the study / evaluation component.
Study population	Details of the population of participants in the study, including any eligibility criteria that affected who were involved in the study.
Intervention	Description of the intervention(s). A comprehensive description would contain all of the information outlined in Table 4. When conducting an evidence review you may decide that a shorter summary covering particular features is more proportionate to your needs.
Outcomes measured	List of outcomes that were sought or measured in the study. This should include any outcome for which a result is reported in the study.
Reported results	Summary of results, especially whether a relationship was observed between the intervention and the outcome(s) of interest.
Assessment information	
Evidence level	Was the study designed such that its findings would be able to demonstrate a causal link between the intervention and the outcome or just a correlation/relationship?

Assessment of quality	Extent to which the findings appear to be robust and reliable. This should include consideration of whether there are any factors in the study design that mean that the findings might be explained by factors other than any relationship observed with the intervention.
Pragmatic attitude	Extent to which the study seems to have been designed and conducted as a pragmatic study, with participants, intervention implementers and resources appearing similar to those likely to be found in normal practice.
Assessment of applicability	Extent to which the evidence appears relevant to your situation. This should include consideration of whether the context in which the intervention was studied seems similar to the context in which you are investigating the issue. This may also include consideration of whether any eligibility criteria mean that the population studied was substantially different from your population of interest.

5.2.4 Collating evidence on interventions

If undertaking an evidence review, an intervention review shall be produced for each intervention of interest. Each intervention review sheet shall contain the information detailed in Table 3, structured in the same sections and order as provided in the table.

Table 3 Intervention review sheet

Name of intervention	
List of studies	
Summary of evidence	Where no studies are found examining a given intervention note the absence of evidence of effectiveness for the intervention. Where one study is found examining a given intervention summarise the state of evidence created by that study. Where more than one study is found examining a given intervention summarise the state of evidence collectively on that intervention.

5.3 Causal chain mapping

A causal chain map should be prepared identifying the series of processes by which it is anticipated that the intervention being designed could lead to outcomes of interest.

In preparing the causal chain map consideration should also be given to processes by which the intervention might result in adverse outcomes.

If it is intended that more than one intervention will be tested, a causal chain map should be prepared for each.

5.4 Intervention specification

An intervention specification shall be prepared that details the intervention to be studied. If more than one intervention is to be studied, a separate intervention specification shall be prepared for each.

An intervention specification shall also be prepared for any comparison groups in the study, detailing the experience of those in the group.

Each intervention specification shall contain the information detailed in Table 4, structured in the same sections and order as provided in the table.

Table 4 Intervention specification

Date	Date on which the intervention description is being prepared.
Brief name	Name or a brief phrase that describes the intervention.
Why	Rationale, theory or goals of intervention elements.
What: Materials	Description of physical or informational materials used in the intervention, including those used in intervention delivery or in training of intervention providers.
What: Procedures	Description of each of the procedures, activities and/or processes used in the intervention, including enabling or supporting activities.
Who providing	For each category of intervention provider (e.g. housing officer) description of their expertise, background and any specific training they will receive.
How	Description of modes of delivery (e.g. face-to-face, telephone) of the intervention and whether it will be provided individually or in a group.

Where	Description of the type(s) of location(s) where the intervention will occur, including necessary infrastructure or relevant features.
When and how much	Description of the number of times the intervention will be delivered and over what time period including the number of sessions, their schedule, and their duration or intensity. Number of sessions might be determined by some stopping criteria rather than a fixed number, in which case provide details.
Tailoring	If the intervention will be personalised or adapted for different participants, description of what, why, when and how.
How well (fidelity)	Description of how and by whom intervention fidelity (extent to which implementation is consistent with plan) will be assessed (if at all), and description of strategies that will be used to maintain or improve fidelity (if any). Indicate if efforts will be made to standardise the intervention or if the intervention and its delivery will be allowed to vary between participants, intervention providers, or study sites.
Resource requirements	Describe extra resources added to (or resources removed from) usual settings in order to implement intervention.

[ADAPTED FROM: TIDieR Checklist, omitting post-intervention fields and with minor amendments by author for context relevance. Additional elements from Pragmatic Extension to CONSORT. See sections NR.12 and NR.5.]

6 Decision to proceed

6.1 Proceeding to study

Having completed the intervention design steps specified in section 5, a decision shall be taken regarding how to proceed, and specifically whether to:

- proceed to a study to create evidence; or
- respond to the issue based on the existing evidence found without conducting a new study (for example by adopting an intervention that has already accrued sufficient evidence).

6.2 Study levels

If the decision is taken to proceed to a study to create evidence, the level of study shall be selected, informed by the purpose, limitations and intended usage of the evidence to be created by the study (see Table 5).

Table 5 Purpose, limitations and intended usage of evidence at different levels

	Level 1: Exploration and Development	Level 2: Effectiveness	Level 3: Scaling-up
Purpose	Testing intervention for feasibility, acceptability, ability to deliver in practice, etc. Establishing feasibility of further study. Identify promising practice that merits further investigation and gaining impression of what scale of impact might be. Studying an intervention that is inherently so small in scale that it is not possible to study with level 2 designs.	Concerted effort to assess effectiveness of an intervention. This entails seeking to establish whether any effects observed are down to the intervention being studied, as opposed to other factors.	Examining a range of effectiveness evidence on a subject to identify whether it demonstrates consistent conclusions that would merit general roll out of the approach. Where evidence points in different directions, establishing whether there are contexts in which the intervention is more or less likely to be successful.
Limitations	Where associations are identified between the intervention and an outcome of interest it will not constitute firm evidence that the intervention caused the outcome.	Depending on the context(s) in which the evidence is generated, for any single study will need to exercise a degree of caution over its generalisability to other contexts.	Will inevitably be constrained by the availability of Effectiveness evidence. Constraints of generalisability may remain, if there is contextual similarity in the relevant Effectiveness studies.
Intended usage	Inherently not designed to provide evidence of effectiveness, so will not be suitable for informing decisions for general roll-out. Findings could suggest that more work is needed at this level (e.g. amending design of the intervention) or that the intervention is sufficiently promising to merit testing at the Effectiveness Level.	Evidence generated at this level should typically be used to support decisions about whether an intervention should be delivered more broadly.	If evidence generated at this level demonstrates a consistent and generalisable effect from a particular intervention, it should normally support broader adoption of the approach.

[NOTE: Table 6 summarises the required and recommended elements for studies being conducted at each level.]

Table 6 Principal required and recommended elements of studies at each level

◆ Required ✧ Recommended

Principal elements	Level 1: Exploration and Development	Level 2: Effectiveness	Level 3: Scaling-up
Issue description	◆	◆	◆
Evidence review	✧	◆	◆
Causal chain mapping	✧	✧	✧
Intervention specification	◆	◆	◆
Assemble study team	◆	◆	◆
Selection of outcome measures Specification of outcome measures	◆	◆	◆
Specification of other measurements (if using)	◆	◆	◆
Study design specification: non-causal design	◆		
Study design specification: design that supports robust causal inference		◆	
Specification of participant recruitment approach	◆	◆	
Ethical considerations	◆	◆	◆
Process evaluation design specification	◆	✧	✧
Economic evaluation design specification		✧	✧
Systematic identification, reviewing and analysis of multiple causal studies			◆
Study protocol (prepare)	◆	◆	◆
Registration (of protocol)	✧	◆	◆
Adherence to protocol (recording deviations)	◆	◆	◆
Flow of participants (recording)	✧	✧	
Adverse events (recording)	✧	✧	
Structured reports of findings	◆	◆	◆
Lodging reports in repository	✧	◆	◆
Publication of data and analysis	✧	✧	✧
Open access publishing (where submitted to academic journals)	◆	◆	◆

If a level 1 or level 2 study is selected, the procedures specified in sections 7 to 10 shall be undertaken.

If a level 3 study is selected, the procedures specified in Annex A shall be undertaken.

7 Study planning

7.1 General

Developing a plan for a study at level 1 or level 2 shall involve undertaking the following steps:

- Assemble study team
- Selection and specification of outcome measures and other measurements
- Study design specification
- Specification of participant recruitment approach
- Ethical considerations

These steps should be undertaken iteratively, progressively refining the outputs of each step based on the development of each of the others.

Where the techniques are being used, the study planning process shall also include:

- Process evaluation design specification
- Economic evaluation design specification

After these steps have been undertaken, reference shall be made to the description of the relevance of the study prepared in the issue description (see section 4), to check that the study as planned would provide findings that would be useful in informing the relevant decisions.

7.2 Assemble study team

Consideration shall be given to the skills and expertise needed to deliver the study. A study team shall be assembled with the necessary skills.

7.3 Measurements

7.3.1 Selection of outcome measures

At least one outcome measure shall be selected for data to be collected on.

There shall be one outcome measure identified as the primary outcome measure.

If more than one outcome measure is selected, those other than the primary outcome measure shall be identified as secondary outcome measures.

As well as outcomes of direct interest to those who will be using the evidence to inform decisions about implementation of interventions, consideration should be given to selecting intermediate outcomes for measurement. Intermediate outcomes should be identified from the causal chain map, if one has been prepared (see section 5.3).

Consideration should be given to selecting adverse outcomes for measurement. Adverse outcomes should be identified from the causal chain map, if one has been prepared.

When considering potential outcome measures for selection, reference should be made to the existing evidence base to identify outcome measures that have been used in previous studies. This should include reference to studies reviewed as part of the evidence review (see section 5.2).

When selecting outcome measures, the following factors should be considered in assessing their desirability:

- Is this outcome relevant to evidence users? Relevant outcomes, such as ones that directly relate to decisions about practices to be adopted, should be favoured.
- Is there good reason to believe the outcome measure will accurately and reliably represent the underlying outcome of interest? Outcome measures with clear links to underlying outcomes should be favoured.
- Is it a direct measure of an outcome or a surrogate? Outcome measures that directly measure the underlying outcome of interest should be favoured over those that measure surrogate outcomes.

- How easy will it be to collect data on this outcome measure? Outcome measures that can be extracted from data that are already collected or that can be collected with little additional effort should be favoured.
- Has the same outcome measure been used in previous studies? Outcome measures that have been used in other studies should be favoured.

7.3.2 Specification of outcome measures

A specification shall be prepared for each outcome measure to be recorded. If more than one outcome measure is to be recorded, a separate outcome measure specification shall be prepared for each.

Each outcome measure specification shall contain the information detailed in Table 7, structured in the same sections and order as provided in the table.

Table 7 Outcome measure specification

Outcome name	Descriptive name for the measure.
Primary or secondary outcome?	Will this outcome be treated as a primary or secondary outcome in this study?
Direct or surrogate?	Is this measure intended to directly reflect an outcome of interest or is it a surrogate measure that is intended to act as a proxy for an outcome that is hard to measure directly?
Description of measure	Details of what data will be gathered and of any processing that will be applied to raw data in order to create the measure. This shall completely define the measure such that others would be able to use it based only on this information, including the format(s) the data will be collected, stored and/or presented in.

Collection procedures	How will data be collected and by whom?
Timepoint(s) of interest	When will data be collected? If specifying more than one timepoint, the primary timepoint of interest shall be specified. Specify whether this should be collected before intervention as well as after.
Minimum practically important difference	This difference is the smallest amount of difference that would matter for comparing the intervention to the alternative. A difference or change in this outcome measure below this level would be considered negligible, unimportant or irrelevant. As well as the difference itself, record how the number was arrived at.
Relevance of outcome	Explain why the outcome and timepoint for measurement are considered important to evidence users.

7.3.3 Specification of other measurements

As well as outcome measures, studies may also collect data on other factors related to participants, including characteristics that are believed to be potential predictors of an outcome (such as demographic data), or the amount or extent or the intervention received by each participant where it is subject to tailoring (see Table 4). If the study is collecting such data, a measurement specification shall be prepared that details each measurement to be recorded. If more than one measurement is to be recorded, a separate measurement specification shall be prepared for each.

Each measurement specification shall contain the information detailed in Table 8, structured in the same sections and order as provided in the table.

Table 8 Measurement specification

Measurement name	Descriptive name for the measurement.
Description of measurement	Details of what data will be gathered and of any processing that will be applied to raw data. This shall completely define the measurement such that others would be able to accurately replicate the measurement process based only on this information, including the format(s) the data will be collected, stored and/or presented in.
Collection procedures and timing	How will data be collected, by whom, and when?

7.4 Study design specification

7.4.1 Non-causal designs

For a level 1 study, a non-causal design shall be specified.

As a minimum, the design shall specify that measurements will be made of the outcome measures for the intervention group after the intervention has occurred (a **post-test only** design).

Consideration shall be given to enhancing the study by adopting one of the following designs instead of a post-test only design:

- **Pre/post**: measurement of the outcome measures before and after the intervention.

- **Post-test with comparison group**: measurement of the outcome measures for both the group receiving the intervention and some other group that does not receive it.
- **Pre/post with comparison group**: measurement of the measures outcome both before and after the intervention for the group receiving the intervention and some other group that does not receive it.

Where a design is adopted that features a comparison group, it should be selected to be as similar as possible to the intervention group in terms of characteristics that are likely to have an influence on the outcome measures.

If a comparison group features in the design, an intervention description shall be prepared for that group (see section 5.4).

The design specification shall contain the information detailed in Table 9, structured in the same sections and order as provided in the table.

Table 9 Non-causal design specification

Design name	Type of non-causal study to be conducted. The main options are: • Post-test only • Pre/post • Post-test with comparison group • Pre/post with comparison group
Description of planned design	Description providing sufficient detail that a suitably experienced person would be able to duplicate the study based on the information provided. (Ensure that plans for measurements are reflected in outcome measure specifications, including details of whether measurements will be taken before as well as after the intervention.)

Description of comparison group (if any)	Detail whether there is a comparison group, and if so, how it will be selected, and the steps taken to ensure that it is as good a match as possible for the intervention group.
Description of planned analysis	Description providing sufficient detail that a suitably experienced person would be able to duplicate the analysis based on the information provided.

7.4.2 Designs that support robust causal inference

For a level 2 study, a design shall be specified that supports robust causal inference.

The design specified shall be a randomised controlled trial (RCT) unless it is not appropriate, practical or ethical to conduct an RCT. See Annex B.

Where it is deemed that an RCT is not suitable, an alternative design shall be selected based upon its ability to generate a robust counterfactual given the specific circumstances of the study, including data availability and implementation details. See Annex C.

Where a design is adopted that features a non-random comparison group, it should be selected to be as similar as possible to the intervention group in terms of characteristics that are likely to have an influence on the outcome measures.

Consideration should be given to the use of independent study partners (i.e., not from the organisation responsible for the intervention) in the conduct of a level 2 study to ensure access to necessary skills and independence of the study.

Studies should be designed to be pragmatic in attitude, resembling the situation in normal practice as closely as possible (as opposed to explanatory attitude studies, which are delivered under tightly controlled conditions).

Consideration should be given to designing the study such that it is able to address equity issues.

The design specification shall contain the information detailed in Table 10, structured in the same sections and order as provided in the table.

Table 10 Causal design specification

Design name	
Justification for design	If an RCT design is specified, it is sufficient to note that it is appropriate, practical and ethical. If a design other than an RCT is specified, provide details of why an RCT was not appropriate.
Framework (superiority, non-inferiority or equivalence)	Whether the study is designed to test superiority (the intervention being better than the comparison), non-inferiority (the intervention being at least as good as the comparison) or equivalence (the intervention delivering the same outcomes as the comparison).
Description of planned design	Description providing sufficient detail that a suitably experienced person would be able to duplicate the study based on the information provided.
Pragmatic attitude	Record design decisions taken to make the study more pragmatic in attitude. Detail any respects in which it was necessary to adopt an approach that is more explanatory in attitude.
Equity	Which disadvantaged subgroups (if any) have been identified for particular attention in the study? Description of any design features, including data collection and analysis plans, that support the assessment of equity issues in the study.

Description of planned analysis	Description providing sufficient detail that a suitably experienced person would be able to duplicate the analysis based on the information provided.
Assumptions	Any assumptions made as part of the design.
Limitations of approach	Any limitations associated with the approach that are relevant to this study. For non-RCT designs this should include a description of any limitations of the approach's ability to support robust causal inference.

7.5 Specification of participant recruitment approach

For level 1 and level 2 studies a participant recruitment approach shall be specified.

Eligibility criteria should be specified that are as inclusive as is feasible, reflecting as far as possible the population that the intervention would be intended to be offered to if proven to be effective.

The target sample size should be established such that the study is likely to be able to detect a difference of the scale of the minimum practically important difference (see section 7.3.2) for the primary outcome measure (see section 7.3.1).

The approach specification shall contain the information detailed in Table 11, structured in the same sections and order as provided in the table.

Table 11 Participant recruitment approach specification

Target population including location(s)	Description of the target population including settings and locations where the data are planned to be collected.
Eligibility criteria	A comprehensive description of the eligibility criteria used to select the study participants. The criteria should be justified and information provided on the degree to which they reflect the typical population that the intervention would be intended to be offered to if proven effective. Potential participants at substantially elevated risk of adverse outcomes from the intervention being studied should be excluded.
Process for recruitment	Method of recruitment, such as by referral or self-selection. If recruiting by referral, where will referrals be accepted from? If recruiting by self-selection, where will the opportunity to participate be promoted?
Target sample size	The target sample size (including number per arm of the study). Details of how the sample size was determined. If a formal power calculation was used, identify the primary outcome on which the calculation was based (see section 7.3.1), all the quantities used in the calculation, and the resulting target sample size per arm. Details should be given of any allowance made for attrition or non-compliance during the study.
Intended recruitment schedule including date of first recruitment	

[ADAPTED FROM: Target sample size details adapted from item 7a of the CONSORT statement. http://www.consort-statement.org/checklists/view/32-consort/83-sample-size]

7.6 Ethical considerations

Studies shall be designed and conducted in line with good ethical practice. A record shall be kept of the ethical issues that are considered regarding the study.

The record of ethical considerations shall contain the information detailed in Table 12, structured in the same sections and order as provided in the table.

[NOTE: Table 12 has been prepared to record information on ethical practice that will be relevant in general but is not intended to cover all eventualities. Specialist situations may require special ethical considerations to be made. These may include situations where the study is working with those whose ability to give informed consent is limited; health studies that fall under certain legislation requiring to certain ethical approval processes to be followed by law; or where there are funders' requirements for particular ethical processes.]

Table 12 Record of ethical considerations

Ethics committee	Will the study be submitted to an ethics committee for approval? If so, which?
Ethical state of study given existing evidence base	Is there a state of uncertainty over which of the options being investigated is most beneficial (equipoise)? If not, are there other grounds making it ethical to offer a known-effective intervention to some and not others (e.g. natural delay)? Is there an intervention that is already known to work for the issue being studied in this context? If so, is this being used as the comparison intervention for any new intervention being studied, rather than using a no-service comparison group?

Risks to participants	Have you considered risk of harm for participants, including any discomfort or inconvenience that they might experience through participation?
Risks to study team	Have you considered risk of harm to those conducting the study?
Participant involvement	Have participants / potential participants been involved in the design of the study?
Participant consent	Will consent be obtained? If not, why not? When will consent be obtained? Who will obtain consent? How will consent be given (e.g. verbal, written)? If not written, how will records be kept? What steps will be taken to ensure that consent is informed and freely given? If using secondary data, does the primary consent cover the proposed usage (e.g. further analysis)? Attach a copy of the participant consent form, if being used.
Participant information	What information will be provided to participants about the study, its aims and procedures? Will any information be withheld? If so, why? Attach a copy of the participant information sheet, if being used.
Participant payment	Will participants be paid? If so, how much? Has consideration been given to whether this creates a conflict of interest? How is the potential for that being mitigated in the design?

Confidentiality and personal data	What steps will you take to protect the confidentiality of data of participants? Who will personally identifiable information be shared with? How will consent be obtained for use of personal data? How long will personal data be held for? How will it be disposed of?
Breaking confidentiality	Are there circumstances under which confidentiality might be broken to prevent harm? If so, under what circumstances would this be done and what procedures would be used?
Other	The headings on this record are not intended to cover all eventualities. Please record any other ethical considerations here.

7.7 Process evaluation design specification

For level 1 studies a process evaluation design shall be specified.

For level 2 studies a process evaluation design should be specified.

Where a causal chain map has been produced (see section 5.3) it should be referred to when designing the process evaluation. The process evaluation may be used to examine which of the causal links anticipated in the causal chain map appear to occur in practice.

Consideration should be given to ensuring that the design does not make excessive calls on the study participants or implementers.

[NOTE: Detailed specification of the design of process evaluations is outside of the scope of this standard. Table 13 provides an overarching framework within which the design may be specified.]

Table 13 Process evaluation design specification

Date		
	Will this be measured?	*If so, how?*
Fidelity		
Evaluation feasibility (how feasible it is to conduct evaluation of the intervention)		
Implementation feasibility (how feasible it is to implement the intervention)		
Acceptability to target population		
Acceptability to implementers		
Participation (recruitment, proportion of target population reached and representativeness)		
Participants' perceptions of relevance of intervention		
Participants' intention to use (e.g. knowledge gained from intervention)		
Impact on intermediate outcomes		

Qualitative study to explore causal processes		
Unanticipated outcomes (beneficial or adverse)		
Context: impact on implementation		
Context: impact on outcomes		

7.8 Economic evaluation design specification

For level 2 studies an economic evaluation design should be specified where it is felt that there is a reasonable likelihood of the study demonstrating effectiveness.

[NOTE: Detailed specification of the design of economic evaluations is outside of the scope of this standard. Table 14 provides an overarching framework within which the design may be specified.]

Table 14 Economic evaluation design specification

Evaluation type	Type of economic evaluation to be conducted. Main options are: • Cost minimisation • Cost-effectiveness analysis • Cost-benefit analysis • Cost-utility analysis
Design	Details of the design of the economic evaluation.

8 Study protocol

8.1 Contents

For level 1 and level 2 studies a protocol shall be prepared that details the planned approach to the study. The protocol shall contain the information detailed in Table 15.

Table 15 Protocol

Descriptive title of study	Title identifying the study design, intervention(s) studied, the primary outcome and key features of the context including the population.
Date of protocol	Date of preparing the protocol
Collation of information	Issue description
	Intervention specification (for each intervention and any comparison / control group)
	Outcome measure specification (for each outcome measure)
	Measurement specification (for each additional measure, if any)
	(For level 1 studies) Non-causal design specification
	(For level 2 studies) Causal design specification

	Participant recruitment approach specification
	Record of ethical considerations
	Process evaluation design specification (where relevant)
	Economic evaluation design specification (where relevant)
Roles	Information on the roles being played by the partners involved in delivering the intervention(s) and conducting the study.

8.2 Registration

For a level 2 study the protocol shall be published in a registry before commencing data collection.

For a level 1 study the protocol should be published in a registry before commencing data collection.

Where possible, a registry should be selected that is likely to be known by and visible to evidence users, including those who are likely to be interested in addressing the same issue through their activity.

The protocol may be published in more than one registry.

9 Study conduct

9.1 Adherence to protocol

Except where it becomes apparent that doing so would create an unacceptable risk of harm or if changing circumstances mean that continuing using the protocol would be inappropriate, the registered protocol shall be followed as closely as possible. This shall include close adherence to the planned analysis outlined in the protocol.

Any deviations from the registered protocol shall be carefully recorded.

Records of deviations from the protocol shall contain the information detailed in Table 16, structured in the same sections and order as provided in the table.

Table 16 Deviation recording sheet

Reason (type)	Record one of these categories of reasons for the deviation: • Risk of harm identified • Additional information becoming available from external studies • Resource difficulties • Problems recruiting participants • Problems with data collection • Other
Reason (details)	Description of the reason
Timing	Date on which it became necessary to make the change.

Change (type)	Which broad area changed from the protocol, for example: • Intervention (main or comparison) • Outcome measurement • Participant recruitment • Study sites • Analysis
Change (details)	Description of how the study conduct varied from the protocol.

9.2 Flow of participants

Records should be kept of the flow of participants through the study.

Records of the flow of participants should contain the information detailed in Table 17, structured in the same sections and order as provided in the table.

Table 17 Records of flow of participants

Number of participants or units approached to take part in the study	
Number meeting eligibility criteria	
Reasons for non-participation	

Deviations from planned study protocol with reasons	
For each arm	
Number of participants assigned to the group	
Number receiving intended intervention	
Number completing the study protocol	
Number analysed for primary outcome	

[ADAPTED FROM: CONSORT Statement and Pragmatic extension to CONSORT Statement (see sections NR.2 and NR.5).]

9.3 Adverse events

Records should be kept of adverse events occurring for participants during the study.

Records should be kept for all arms of a study, i.e. including any comparison arm(s) as well as intervention arm(s).

10 Findings and other study outputs

10.1 General

In all reporting of the study, whether in a form specified in this standard or an additional report, care shall be taken to accurately present the findings of the study.

Particular care shall be taken to ensure that reporting does not use language that specifies or implies that any relationship identified between an intervention and an outcome is causal in nature if the study's methods do not support such a conclusion.

Any additional reporting shall include a link or similar to allow readers to refer to the main report (see section 10.2.1).

Where, exceptionally, evidence generated by a study is not being made public (for example, due to issues of competitive advantage), main and summary reports shall still be prepared in the formats specified (see sections 10.2.1 and 10.2.2).

In any table, figure or data listing, estimated or derived values, if used, shall be identified in a conspicuous fashion. Detailed explanations shall be provided as to how such values were estimated or derived and what underlying assumptions were made.

> *[ADAPTED FROM: Requirement regarding estimated and derived values adapted from: Structure and Content of Clinical Study Reports E3, ICH.]*

Any reports should include sufficient publishing and authorship information to enable accurate citation, including: author(s); title; publisher (and/or name of organisation); place of publication; date of publication.

Where a study is conducted by an independent party, those commissioning the study should be offered a reasonable opportunity to comment on draft reports and articles to ensure clarity and accuracy, but not to alter the findings.

10.2 Structured reports of findings

10.2.1 Main report

For a level 1 or level 2 study, a main report of the study shall be prepared.

The main report shall contain the information detailed in Table 18, structured in the same sections and order as provided in the table.

Table 18 Contents of main report

Descriptive title of study	Title identifying the study design, intervention(s) studied, the primary outcome and key features of the context including the population.
Author(s) and affiliation(s)	Authors for the report and their organisational affiliations.
Date of publication	Publication date of the report
Publishing details	Publisher or name of organisation. Place of publication.
Indication of conformity	Prominent statement indicating that this standard has been conformed to in the creation of the evidence and stating the level of study conducted. Reference to this standard to include the version (year).
Protocol registration details	Registry(ies) the protocol was registered in and registration number(s).

Roles	Information on the roles played by the partners involved in delivering the intervention(s) and conducting the study. Depending on the nature of the intervention and the study this may include organisations providing locations and/or client lists to act as study sites, those delivering the intervention, and those responsible for the study / evaluation component.
Commencement date	Date of first participant joining the study.
Completion date	Date of last participant completing the study.
Sample size	Number of participants, including details of the number in each arm of the study if relevant.
Updated protocol information	Issue description
	Intervention specification (for each intervention and any comparison / control group)
	Outcome measure specification (for each outcome measure)
	Measurement specification (for each additional measure, if any)
	(For level 1 studies) Non-causal design specification
	(For level 2 studies) Causal design specification
	Participant recruitment approach specification
	Record of ethical considerations
	Process evaluation design specification (where relevant)
	Economic evaluation design specification (where relevant)

Amendments from protocol	Details of any variance between the protocol and the updated protocol information reported above, including both deviations from the protocol and clarifications where the protocol did not provide unambiguous specification on a particular issue.
Fidelity	If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.
Methods	Any further information required to fully understand the methods used in the study (including analysis), where these do not fit into any of the headings for the updated protocol information.
Results	Full reporting of the results of the study, including all recorded outcome measures and any subgroup analyses identified in the analysis as planned in the protocol. Results on primary outcome shall be given prominence and normally detailed before any secondary outcomes.
Adverse events	Harms and adverse events observed during the study, including unexpected negative consequences as well as side effects that were anticipated during the planning stages of the study. Where the risk of potential side effects was foreseen, these should normally have been measured thoroughly to check whether they are tolerable compared to the benefits.

Exploratory findings	Findings from post hoc analyses that were not planned in the protocol, including any subgroup analyses that were not originally planned. Report how many exploratory analyses were conducted to produce the findings reported. If included, this section shall start with a statement cautioning that these types of findings are particularly susceptible to not being reproduced in subsequent studies so should only be viewed as indicative of areas that may merit future study.
Conclusions	Conclusions, including implications for practice or commissioning. Should also include a discussion of the balance of harm against benefits where adverse event findings indicate negative aspects of an intervention.

[NOTE: The 'updated protocol information' should contain the information included in the protocol, updated to reflect the actual conduct of the study where this varied from the protocol or with additional clarifying information where the protocol failed to provide sufficient information on a particular issue.]

[SOURCE: "How well (actual)" item derived from TIDieR Checklist (see section NR.12).]

When preparing the main report, the checklist(s) relevant to the study type shall be completed to ensure that all required reporting items are included in the report. The relevant checklists are detailed in Table 19.

[NOTE: Most of the checklists have been developed by health-focused researchers. They are largely written in generic terms, but do contain additional health-specific references. For studies outside of the health sector simply read these as implying the nearest generic equivalent; for example, a reference to "disease" might be read as "problem".]

Table 19 Reporting checklists by study type

Study type	Checklist	Description
Randomised controlled trials	CONSORT Statement	25 item checklist and a flow diagram.
Randomised controlled trials	Pragmatic extension to the CONSORT Statement	Extends the information provided on eight of the CONSORT checklist items.
Randomised controlled trials (where applicable)	Other extensions to the CONSORT Statement	Covering particular situations such as specific study designs or particular data.
Non-randomised studies	TREND Statement	22 item checklist
Economic evaluations	CHEERS Checklist	24 item checklist
Qualitative	SPQR guidelines	Structure for reporting qualitative research.
Any	TIDieR Checklist and Guide	Template for describing interventions.

[NOTE: Full references and links to the checklists are contained in the Normative references.]

10.2.2 Summary report

For a level 1 or level 2 study, a summary report of the study shall be prepared. The summary report shall be written in plain English.

The summary report shall include:

- Publishing and authorship information: author(s); title; publisher (and/or name of organisation); place of publication; date of publication
- Indication of conformity to the standard in the creation of the evidence and stating the level of study conducted
- Description of the intervention(s) studied
- Information on the primary and any secondary outcomes
- Implications for practice
- A link or similar, to enable readers to refer to the main report (see section 10.2.1)

10.3 Lodging reports in repository

For a level 2 study the main report and summary report shall be lodged in a publicly accessible central repository within three months of the completion of the study.

For a level 1 study the main report and summary report should be lodged in a publicly accessible central repository within three months of the completion of the study.

Where possible, a repository should be selected that is likely to be known by and visible to evidence users, including those who are likely to be interested in addressing the same issue through their activity.

Where possible and appropriate, other outputs from the same study should be lodged in the same repository.

10.4 Publication of data and analysis

Anonymised participant-level data should be published within three months of the completion of the study.

The computer files used to conduct the analysis should be published within three months of the completion of the study.

Where possible and appropriate the data and analysis should be lodged in the same repository as was used to lodge the reports. Where that is not possible, steps should be taken to ensure there are links between each.

10.5 Open access publishing

Studies need not be published in academic journals. However, where any outputs arising from studies are published in academic journals these shall be published using an established open access publishing route.

Gold open access should be used when possible. Where green open access publishing is used, the open version of the article shall be archived in a suitable repository as early as possible.

Annex A (normative) Systematic identification, reviewing and analysis of multiple causal studies

[NOTE: This annex relates primarily to systematic reviews and meta-analyses of evidence of effectiveness of interventions. Systematic reviews of other types of evidence are out of the scope of this annex.]

A.1 Study planning and conduct

The study shall be planned and conducted in conformity with the mandatory standards specified in the MEC2IR Conduct Standards (see section NR.4.1).

The study should be planned and conducted in conformity with the highly desirable standards specified in the MEC2IR Conduct Standards.

A.1.1 Equity focus

Consideration should be given to designing the study such that it is able to address equity issues.

[NOTE: Equity-focused reviews are "those that can assess effects of interventions targeted at a disadvantaged population; can assess effects of interventions aimed at reducing social gradients; and can assess effects of interventions not aimed at reducing inequity but where it is important to understand the effects of the intervention on equity." (SOURCE: Equity Checklist for Systematic Review Authors. See section NR.3.).]

If the study has a focus on equity, the Equity Checklist for Systematic Review Authors shall be completed to ensure that consideration is given to all recommended items in the planning and conduct of the study (see section NR.3).

A.1.2 Reviewing process evaluations

Consideration should be given to designing the study such that it reviews process evaluations alongside evidence of effectiveness.

A.1.3 Reviewing economic evaluations

Consideration should be given to designing the study such that it reviews economic evaluations alongside evidence of effectiveness.

A.1.4 Study protocol

The study protocol shall contain all elements specified in the PRISMA-P checklist (see section NR.7).

The protocol shall be published in a registry before commencing the study.

A.2 Findings and other study outputs

A.2.1 Report of findings

The study shall be reported in conformity with the mandatory standards specified in the MEC2IR Reporting Standards (see section NR.4.2).

The study should be reported in conformity with the highly desirable standards specified in the MEC2IR Reporting Standards.

> *[NOTE: The MEC2IR Reporting Standards include many references to the PRISMA Statement (see section NR.6). Those reporting level 3 studies may find it helpful to refer to the PRISMA Statement as well as the MEC2IR Reporting Standards.]*

If the study has a focus on equity, the PRISMA-E checklist shall be completed to ensure that all required reporting items are included in the report (see section NR.7).

A.2.2 Lodging reports in repository

The main report of the study shall be lodged in a publicly accessible central repository within three months of the completion of the study.

Where possible, a repository should be selected that is likely to be known by and visible to evidence users, including those who are likely to be interested in addressing the same issue through their activity.

Where possible and appropriate, other outputs from the same study should be lodged in the same repository.

A.2.3 Publication of data and analysis

Where possible, data assembled for the study should be published within three months of the completion of the study.

The computer files used to conduct the analysis should be published within three months of the completion of the study.

Where possible and appropriate the data and analysis should be lodged in the same repository as was used to lodge the reports. Where that is not possible, steps should be taken to ensure there are links between each.

A.2.4 Open access publishing

Studies need not be published in academic journals. However, where any outputs arising from studies are published in academic journals these shall be published using an established open access publishing route.

Gold open access should be used when possible. Where green open access publishing is used, the open version of the article shall be archived in a suitable repository as early as possible.

Annex B (normative) Circumstances where randomised controlled trials may be unsuitable

In circumstances where they are feasible, RCTs invariably provide the most robust assessment of the effectiveness of an intervention that is possible from a single study. The primary benefit of RCTs is that they overcome the threat of 'selection bias': the people receiving the intervention(s) are compared to other people in a control group who are statistically the same as them for both measured and unmeasured factors. *[SOURCE: Moher et al, 2010.]* This means that what happens to the members of the control group provides a convincing counterfactual for what would have happened to the intervention group without the intervention.

There are, however, some circumstances in which an RCT is not appropriate, practical or ethical. In these circumstances, alternative methods can be deployed that have the potential to create a second-best estimate of the causal effect of an intervention. The following reasons have been identified for circumstances where RCTs may be unsuitable:

- RCTs may be unnecessary when the **effect of an intervention is dramatic**;
- RCTs may be inappropriate for measuring **infrequent adverse outcomes**;
- RCTs may be inappropriate for evaluating **interventions designed to prevent rare events**;
- RCTs may be inappropriate when the **outcomes of interest are far in the future**;
- RCTs may be inappropriate when the **effectiveness of the intervention depends on the subject's beliefs and preferences**;
- RCTs may be impossible if the **intended implementers refuse to participate**;
- RCTs may be unethical if one option is already known to be **more effective than another**;
- RCTs may be politically impossible where **policy-makers do not want the impacts of their policies to be studied**;
- RCTs may (rarely) face **legal barriers**;
- RCTs may be impossible where an **intervention simply cannot be randomly allocated**;

- RCTs may be impossible where **contamination cannot be prevented** (i.e., where members of the control group unavoidably receive some of the benefit of the intervention);
- RCTs may be inadequate if they are **conducted in circumstances that do not reflect normal practice** due to unrepresentative service providers or an unrepresentative level of service;
- RCTs may be inadequate if the **participants are not representative of the target population**, whether due to constraints on trial eligibility or low rates of participant recruitment.

[ADAPTED FROM: List by the author, paraphrasing Black, 1996.]

Several variant RCT designs exist, increasing the situations in which they can be deployed. Cluster randomisation designs, for example, involve randomisation at the level of a social unit rather than an individual (for example, randomising different neighbourhoods into the assignment groups), which can address some concerns of contamination. Waiting list based designs exist in which all of the participants will eventually get the intervention, but the order is randomised so some get it immediately and other have to wait, which may overcome ethical concerns in situations where roll-out of a known-effective intervention would have to be phased anyway. Some challenges caused by studies being unrepresentative may be overcome by designing them to be more pragmatic in attitude.

Annex C (informative) Quasi-experimental methods

Outside of RCTs, the methods often identified as having the potential to generate causal evidence include:

- **Difference-in-Differences**: Through analysis of data from a pre/post with comparison group method (which would ordinarily be a non-causal study), the difference-in-differences approach can sometimes generate causal evidence if certain assumptions can convincingly be shown to hold.
- **Instrumental Variables**: Analysis can be undertaken to identify the effect of an intervention if there is a variable that affects the probability of an individual receiving that intervention, and acts on the outcome only via the intervention.
- **Interrupted Time Series**: If a long time series dataset exists for the outcome of interest, extending significantly before and after the intervention was introduced, examination of the trends before and after the intervention can identify any interruption in those trends, which can be attributable to the effect of the intervention.
- **Regression Discontinuity Design**: Where allocation to an intervention occurs on one side of a threshold, the identification of a discontinuity of outcomes at that threshold can provide evidence that the intervention has an impact.
- **Propensity Score Matching**: Those receiving the intervention are matched to other individuals, not on the basis of specific characteristics directly but based on how the various characteristics affected each individual's likelihood that they would have received the intervention.

Each of these techniques has its benefits and limitations. They all share the need for fairly technical skills to be conducted, and have data requirements that will affect the situations in which they are usable. They also leave open the possibility of various sources of bias (principally selection bias) that can render their estimates of effectiveness less accurate; consequently, non-randomised studies should only be conducted where RCTs are infeasible or unethical. *[SOURCE: Deeks et al, 2003.]* Where used, they should be conducted as robustly as possible, with constraints, limitations and assumptions clearly documented.

Normative references

The following documents are referenced within this standard.

NR.1 CHEERS Checklist

http://www.ispor.org/taskforces/EconomicPubGuidelines.asp

Husereau D, Drummond M, Petrou S, et al. Consolidated health economic evaluation reporting standards (CHEERS)—Explanation and elaboration: A report of the ISPOR health economic evaluations publication guidelines good reporting practices task force. Value Health 2013;16:231-50.

NR.2 CONSORT Statement

http://www.consort-statement.org/

Schulz, K.F., Altman, D.G., Moher, D., 2010. CONSORT 2010 Statement: Updated Guidelines for Reporting Parallel Group Randomised Trials. PLoS Med 7. doi:10.1371/journal.pmed.1000251

NR.3 Equity Checklist for Systematic Review Authors

http://equity.cochrane.org/sites/equity.cochrane.org/files/uploads/EquityChecklist2012.pdf

Ueffing, E., Tugwell, P., Welch, V., Petticrew, M., Kristjansson, E., 2012. Equity Checklist for Systematic Review Authors - Version 2012-10-02.

NR.4 MEC2IR (Methodological Expectations of Campbell Collaboration (C2) Intervention Reviews)

http://www.campbellcollaboration.org/Methods_Resources/MEC2IR.php

NR.4.1 Conduct standards

http://www.campbellcollaboration.org/artman2/uploads/1/MEC2IR_conduct_standards_v1_0_Updated_September_2014.docx

Adaptations on MECIR Version 2.2 Conduct Standards (Chandler, Churchill, Higgins, Lasserson, & Tovey, 2012)

NR.4.2 Reporting standards

http://www.campbellcollaboration.org/artman2/uploads/1/MEC2IR_reporting_standards_v1_0_Updated_September_2014.docx

Adaptations on MECIR Version 1.1 Reporting Standards (Chandler, Churchill, Higgins, Lasserson, & Tovey, 2012)

NR.5 Pragmatic extension to CONSORT Statement

http://www.consort-statement.org/extensions?ContentWidgetId=556

Zwarenstein, M., Treweek, S., Gagnier, J.J., Altman, D.G., Tunis, S., Haynes, B., Oxman, A.D., Moher, D., 2008. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ 337, a2390. doi:10.1136/bmj.a2390

NR.6 PRISMA Statement

http://www.prisma-statement.org

Moher, D., Liberati, A., Tetzlaff, J., Altman, D.G., 2009. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6. doi:10.1371/journal.pmed.1000097

NR.7 PRISMA-E

http://equity.cochrane.org/equity-extension-prisma

Welch, V., Petticrew, M., Tugwell, P., Moher, D., O'Neill, J., Waters, E., White, H., the PRISMA-Equity Bellagio group, 2012. PRISMA-Equity 2012 Extension: Reporting Guidelines for Systematic Reviews with a Focus on Health Equity. PLoS Med 9, e1001333. doi:10.1371/journal.pmed.1001333

NR.8 PRISMA-P

http://www.equator-network.org/reporting-guidelines/prisma-protocols/

Shamseer, L., Moher, D., Clarke, M., Ghersi, D., Liberati, A., Petticrew, M., Shekelle, P., Stewart, L.A., 2015. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. The BMJ 349, g7647. doi:10.1136/bmj.g7647

NR.9 SPIRIT Statement

http://www.spirit-statement.org/

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ISBN 978-1-911056-01-0

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