



## Producing Evidence of Effectiveness: A guide to the main steps

Evidence of the effectiveness of interventions is produced to identify what works. The process for producing this evidence has been standardised into 7 steps:



Describe



Design



Proceed?



Plan



Protocol



Study



Findings

The Standards of Evidence give you an approach you can follow if you want to identify the impacts of your products, services or activities. The process has been carefully defined to cover all the main things you would need to do to produce this type of evidence.

This brief guide has been developed to support the main standards by giving an easily readable summary of the steps in the process. The standards are relatively technical in style; this summary guide should help you get familiar with the overall process.

Once you are familiar with the process, if you want to follow it in detail you can refer to the Standards of Evidence. See the back page for details.



## Describe

### Describe the issue

The first step is to gain clarity over the issue that you are hoping to address, for example a problem you want to resolve. This is useful for building shared understanding. You will need to gather information about who the issue affects, why improvements would matter, and current practice in relation to the issue (if any). You will also want to think through what decisions evidence could inform.

Steps:

- Produce a description of the issue.

Resources:

- Issue description sheet.



## Design

### Design the intervention

The design stage will normally be an iterative process, as you find existing evidence, consider it, and refine your ideas about the intervention you want to test. Techniques like causal chain mapping will help you to think through the various factors that might help or hinder your intervention.

Steps:

- Search for, review, and collate existing evidence.
- Build a causal chain map.
- Prepare a detailed description of the intervention you want to test and anything you are going to test the intervention against (e.g. business as usual).

Resources:

- Study review sheet
- Intervention review sheet
- Intervention specification sheet



## Proceed?

### Decide whether to proceed to a study

Having looked at the existing evidence and thought about what intervention might be promising in your context, you should take a conscious decision about whether you need to conduct a study. You may decide that the existing evidence gives you enough information to make the decisions you are facing. If you do need to conduct a study, you will need to think about what level would be suitable. The process outlines three levels, each serving a different purpose.

#### Steps:

- Decide whether to proceed to a study or to respond to the issue based on existing evidence.
- Select the level of study that is suited to the purpose, bearing in mind the limitations of different types of study.

#### Resources:

- Information on purpose, limitations and intended usage of evidence at different levels
- Information on principal required and recommended elements of studies at each level



## Plan how the study will be conducted

It is important to get things right at the study planning stage. This is your opportunity to think through the best way of running the study to make sure you get the evidence you want at the end, including whether the intervention delivers the outcomes that you are particularly interested in. Taking a little extra time at this stage has the potential to save countless hours trying to unpick problems once the study is up and running, or in the analysis afterwards. In the worst case scenario, a mis-designed study might fail to generate any useful evidence – having gone to all that effort you may still not know whether the intervention is effective or not.

### Steps:

- Assemble a study team.
- Select and describe in detail outcome measures and other measurements that you will be making.
- Prepare a description of your study design.
- Establish your approach to recruiting participants into the study.
- Consider the ethical implications of the study.

### Potential extra steps:

- Design a process evaluation, if you are planning on conducting one.
- Design an economic evaluation, if you are planning on conducting one.

### Resources:

- Outcome measure specification sheet
- Measurement specification sheet
- Non-causal design specification sheet
- Causal design specification sheet
- Participant recruitment approach specification sheet
- Record of ethical considerations sheet
- Process evaluation design specification
- Economic evaluation design specification

**Plan**





## Protocol

### Assemble and register a protocol for the study

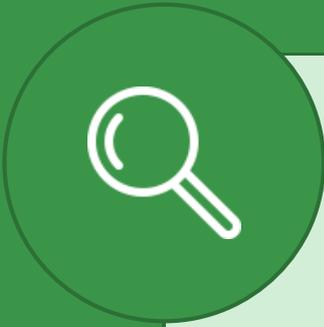
Preparing the protocol is largely just pulling together the information you will have already gathered in the earlier stages. Once you have assembled it, you should register it to increase the credibility of the study and start contributing to the wider evidence base. Registration of a protocol means making a permanent record of it on a special registry website, and doing this before the study starts means everyone will see afterwards that you made a plan and stuck to it.

#### Steps:

- Prepare a protocol.
- Register the protocol.

#### Resources:

- List of items to include in the protocol



## Study

### Conduct the study

With all the preparation work in place, conducting the study will hopefully just be a case of sticking to your plans and keeping records as you proceed. Sometimes things crop up that mean you need to change plans – do not do so lightly, but if necessary, keep a detailed record of what changes you had to make and why.

#### Steps:

- Conduct the study, sticking to the plan outlined in the protocol.
- If it becomes necessary to deviate from the protocol, keep a record of the deviations.
- Record the flow of participants through the study.
- Record any adverse events observed during the study.

#### Resources:

- Deviation recording sheet
- Records of flow of participants sheet





## Findings

### Prepare and publish findings

Once the study has been completed and the data analysed, accurate and accessible reporting will be the key to ensuring the findings are used. As well as writing reports, where possible these should be lodged in public repositories to allow others to use your findings. Remember, the findings are just as useful whether the intervention was effective or not: if it does not work, publishing that information will stop others from trying fruitless avenues in the future. Consider also making data and any analysis files accessible too (suitably anonymised) to maximise the impact of your study.

#### Steps:

- Prepare a main report.
- Prepare a summary report.
- Lodge reports in a repository so they will be accessible to potential evidence users.
- Consider publishing data and analysis files, suitably anonymised to increase the credibility and impact of the study.
- If publishing in academic journals use an open access publishing route.

#### Resources:

- Contents of main report
- Reporting checklists by study type
- List of items to include in a summary report

### For further information on producing evidence:

Full details of the standardised process for producing evidence can be found in the *Standard for Producing Evidence – Effectiveness of Interventions – Part 1: Specification (StEv2-1)*.

Explanations detailing why various elements are included in the process can be found in the *Standard for Producing Evidence – Effectiveness of Interventions – Part 2: Explanation and Elaboration (StEv2-2)*.

### Publishing information

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