NHS
Innovation Service

Your guide to innovation in the NHS

Evidence stage

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Evidence

Generating high quality evidence to support your innovation is needed for regulatory approval and to demonstrate the value of your innovation to payers and commissioners. You will also need to generate evidence to demonstrate that your innovation can deliver benefits for the NHS.

Where applicable, you will need to provide evidence to demonstrate how your innovation improves existing NHS standards of care.

Outcome measures

You will need to make a case for your innovation. This includes showcasing the outcomes from a variety of perspectives, such as:

- the patients or target population
- the user of your innovation, for example a clinician
- the healthcare system as a whole

For example, if you are developing an innovation for patients, it is worthwhile understanding what the current care pathway. This means mapping out the entire patient journey, and work done with a patient at different stages in the healthcare system.

It is also important to understand existing routines for clinical and care professionals, administrators, and anyone else who will be affected by your innovation.

By researching and mapping these perspectives, you will better understand whether your innovation fits into the wider healthcare system.

Questions to consider

- Would the introduction of my innovation increase the likelihood of failure or big mistakes?
- Would my innovation work with clinicians' routines, and the legal responsibility they have for a patient's safety?
- How would my innovation fit in with existing governance?
- Who is my audience? Who makes the decisions to use my innovation and who will use this?

Another consideration is to build in the involvement of patient groups, public and other stakeholders. This will ensure that you include the patient voice in your design and implementation work.

Quantitative experimental studies

Randomised control trials (RCTs) are the most rigorous approach to generating evidence. RCTs are experiments which show an outcome has occurred as a result of the innovation that has been implemented. The simplest RCT would involve a group of people who are randomised into two separate groups. One of the groups is the ‘control’ group and the other are the ‘intervention’ group. The intervention group will use the innovation, but the control group will not or will use standard care.

Measuring outcomes, or changes, in both groups enables you to directly compare and determine if the innovation provides added benefits. As well as outcome measures related to the specific disease or clinical situation, you will need to measure whether there are any negative outcomes, side effects or harms.

Quality of life is also a useful outcome measure to include. This will help to establish how your innovation affects aspects of patients' daily living. You should involve patients or users of the intervention in the design of the research to ensure their views and preferences are taken into account. For example, they may suggest that certain outcome measures are particularly important to assess.

Designing the RCT and how it will be delivered requires a lot of planning. This will be key to the success of the experiment and the strength of the evidence that it generates.

Clinical trials are the most common type of RCT. If the RCT is being used to test new treatments such as medicines, procedures, devices or any other type of therapeutic intervention then it is a clinical trial. There are four phases of clinical trials:

Phase one

- test new treatments for the first time in humans
- small group of people
- evaluate dosage or intensity of the intervention and side effects or harms associated with its use

Phase two

- test treatments which have been shown to be safe in a phase one trial
- larger group of people
- monitor any adverse side effects

Phase three

- larger group of people from different regions or countries
- demonstrates safety and effectiveness
- confirm dosage or intensity
- identifies side effects
- measures the benefits and risks of the treatment
- where applicable, the new treatment is compared with existing treatments or the current standard of care

Phase four

- approved and licensed treatments
- monitoring the safety and effectiveness
- long-term risks and benefits
- identifying rare and long-term side effects

RCTs can take years to complete, but generating evidence through these studies is often an essential requirement for a therapeutic intervention to be adopted by the NHS. You can find out more on how to design, fund and deliver clinical trials from NIHR and NICE. It may be beneficial for you to seek advice from the outset around what the evidence requirements will be for your innovation. You can do that through registering with the NHS Innovation Service.

Other types of quantitative experimental studies include:

- non-randomised control trials
- before-and-after studies

Quantitative observational studies

There are instances where an experimental study design is inappropriate, so observational studies are used instead. Observational studies do not have an experimental intervention. They rely on the observation of people without full randomisation. These types of studies can inform cause and effect associations and can be applied to existing data sets. Types of observational studies include:

- before-and-after study
- case-control study
- cohort study
- correlation study
- cross-sectional study
- interrupted time series

Visit NICE's website for more information on scientific evidence.

Qualitative studies

These types of study do not collect numerical data. They gather information on participants experiences, perceptions and behaviours. Types of qualitative studies are:

- document analysis
- focus groups
- interview studies
- observation and participant observation

Visit the NICE website for more information on qualitative studies.

Economic studies

Health economic studies investigate the cost of care. Types of analysis include:

- cost-benefit
- cost-consequence
- cost-effectiveness
- cost-utility

Visit NICE's website for more information on scientific evidence.

Real world evidence

Real world data (RWD) is used to generate real world evidence (RWE). Clinical trials demonstrate how well a treatment or intervention works under specific controlled conditions, but these studies often do not take into account the variability of the real-world application, or capture the diverse demographics of the target patient population.

RWD is collected through real life situations and can be used to generate RWE to support the uptake of the innovation. RWD may include clinical, economic and patient reported outcomes. These types of outcomes data can be derived from several sources including retrospective studies, observational studies, patient registries and anonymised electronic health records. The RWE navigator decision support tool can help you understand if and how RWE can support your innovation.

Presenting evidence

When you are preparing to present your evidence, you will need to think about what is most important to each of your user groups.

Clinical staff will care about:

- efficacy (does it work)
- accuracy (how well does it work in terms of sensitivity and specificity)
- safety
- workflows
- ease of use
- patient acceptability
- duplication of effort (overlap with existing systems or processes)

Patients will care about:

- safety
- effectiveness
- side effects
- accessibility
- usability
- involvement of patients during evidence generation

A purchaser will care about:

- cost
- safety
- training and implementation
- productive workflows
- product lifecycle (how robust is it and how often does it need to be replaced)
- failure or downtime
- software interoperability with existing core systems
- information governance, including data and cyber security

Population, intervention, comparator and outcomes framework

The population, intervention, comparator and outcomes (PICO) framework helps the formulation and answering of clinical questions. It can also be used to help you structure and present your evidence.

Population

- Who will benefit from your innovation?
- Is the population of people who will benefit similar to the population of people that the service delivers healthcare to?

Intervention

- What is the innovation?
- What is the innovation doing?
- Are there any details about pathway changes needed to accommodate the intervention?

Comparator

- What currently happens?
- What would people use if your innovation did not exist?
- What is the main alternative to the innovation in current practice?

Outcomes

- What definitive, objective improvements or changes occurred as a result of the innovation?
- How did these impact on patient care, clinicians, services and organisations?

Support services

NHS Innovation Service

The NHS Innovation Service can put you in touch with organisations that can help you with your evidence generation such as NICE and NIHR. Find out more about the organisations involved and what sort of support they can provide.

NICE Scientific Advice Service

The NICE Scientific Advice Service provides a fee-based consultancy to help develop evidence that demonstrates the clinical and cost-effectiveness for all types of technology. They provide feedback on evidence generation plans, and help companies understand health technology assessment and the perspective of decision makers. They also provide a comprehensive peer review service for economic models that helps companies optimise the model's structure, computation, coding, usability and transparency.

NICE MedTech Early Technical Assessment tool

The NICE MedTech Early Technical Assessment tool is a fee-based platform to help product developers understand what evidence they need to generate to convince healthcare commissioners of the value their technology can bring to the NHS.

NIHR Research Support Service and Clinical Research Network

The NIHR Research Support Service (RSS) and Clinical Research Network (CRN) provide support for funding applications, study design and study delivery of clinical research in applied health and social care. The RSS is a national service delivered collaboratively through eight hubs across England, each a partnership of research groups and organisations. The service provides free and confidential advice to develop funding applications within the remit of the NIHR, including clinical, applied health and social care research, and post-award advice to award holders. Find out more about the services offered by the RSS.

The CRN is made up of fifteen local clinical research networks which coordinate and support the delivery of health and care research in England. The CRN study support service can help you plan, set up, deliver and performance monitor clinical research studies. Find out more about the CRN study support service eligibility criteria and how to apply.

NHS Digital (now part of NHS England)

NHS Digital (now part of NHS England) are the statutory custodian for health and care data for England. For a fee they offer access to certain data sets through their Data Access Request service (DARS). The data may be provided in the Secure Data Environment or as an extract. For clinical trials you may also want to use the DigiTrials Service which can also provide access to this data.

The Developer Hub can help innovators learn how to build healthcare software and integrate with NHS APIs. It has resources including a step-by-step introduction on what their APIs can do and how your team can get connected, and an API catalogue.

NHS Research Secure Data Environment Network

The NHS Research Secure Data Environment Network (SDE Network) helps approved researchers by simplifying and accelerating secure access to the health and social care data they need. The SDE Network covers the whole of England and includes the NHS England SDE and 11 regional, NHS-led SDEs.