Best Practice in the Ethics and Governance of Service Evaluation

Guidelines for evaluators and commissioners of evaluation in health and social care

Introduction

Mechanisms and structures for governance and ethical review of research (including evaluative research) are well established¹. For service evaluation this remains at best locally driven, variable or absent.

During 2015-16, the West of England Evaluation Strategy Group² conducted a piece of work to address this situation. Delphi consensus technique was used with stakeholders based in universities, health organisations in the West of England, and patient and public representatives to develop a framework for the governance of service evaluation and a code of good practice around ethics

The following guidance for the governance and ethical review of service evaluation has been developed from this piece of work. It is aimed at anyone conducting service evaluations within health and social care in the West of England.

The guidance provides links to available resources and includes practical examples of forms and checklists to assist with governance and ethical review.

Definition and uses of service evaluation

'A study in which the systematic collection and analysis of data is used to judge the quality or worth of a service or intervention, providing evidence that can be used to improve it.'

¹ See Healthcare Quality Improvement Partnership (HQIP), 'A Guide for Clinical Audit, Research and Service Review' http://www.hqip.org.uk/public/cms/253/625/19/190/HQIP-Guide-for-Clinical-Audit-Research-and-Service-Review-Revised%202011.pdf?realName=x5QijA.pdf and 'Guide to managing ethical issues in quality improvement or clinical audit projects' http://www.hqip.org.uk/public/cms/253/625/19/627/HQIP%20Guide%20to%20managing%20ethical%20issues%20in%20QI%20and%20CA%20projects.pdf?realName=30BCeA.pdf&v=0

² The West of England Evaluation Strategy Group is hosted by NIHR CLAHRC West to create a culture of evaluation in health and care across the region and support the spread of best practice. Its members include NHS organisations, the West or England Academic Health Science Network, Bristol Health Partners, the Avon Primary Care Research Collaborative, local universities and two public contributors. For more information visit http://clahrc-west.nihr.ac.uk/evaluation/west-england-evaluation-strategy-group/

Service evaluation is used for new and existing services across the spectrum of effectiveness, safety and experience. It is used for innovation to support the evidence base for commissioning or service development. Evaluation is crucial to ensuring that patients get the best care. Organisations should consider whether they can afford not to evaluate. Without evaluation, how will they know they are meeting the aims they set out to achieve?

It is good practice for an organisation to provide support for service evaluation. This includes having a strategy, nominated lead and register of all service evaluations in place.

The following principles should guide best practice in the governance of service evaluation:

1. Leadership, roles and responsibilities

There should be a nominated lead within each organisation with authority to provide the governance of service evaluation. Their role includes:

- Holding a register of projects to avoid duplication and to check compliance with organisation policies and procedures, including information governance and data protection. The register is a valuable source of information to the whole organisation. <u>Download</u> <u>a sample register</u>.
- Throughout the duration of the project, ensuring internal peer review for ethical issues (and risks), methodological rigour, and acceptability to stakeholders such as staff, patients and their families.
- Quality assuring the planned approach to ensure that it is proportionate, feasible, and has a clear purpose which is linked to the organisation's priorities and has an identified lead responsible for its delivery. Also to ensure that it has utility and that plans are in place to share, use and feedback to those who took part. <u>Download</u> a sample Quality Assurance Checklist.
- Checking contractual and insurance responsibilities are adequate.
- Making judgements whether the evaluator is suitable to conduct the evaluation with the population under study. For example, taking account of issues such as independence, political interest. Also whether they have one of the following: a professional registration, have had Disclosure and Barring Service (DBS) checks, hold a research passport or have suitable references.
- Convening a wider reference group (including patient/service user or public representation) to discuss and approve complex evaluations.

2. Design and Review

The Heath Research Authority (HRA) decision tool must be completed to determine if the project is a service evaluation and a record of the outcome must be kept for audit purposes. The HRA decision tool can be viewed at http://www.hra-decisiontools.org.uk/research/ and a decision-making table can be viewed at http://www.hra.nhs.uk/documents/2016/06/defining-research.pdf

Service evaluation needs to take into account the diverse nature of society and ensure that the right stakeholders, including service users and carers, are involved in the design, delivery and reporting of the evaluation.

3. Ethical Review

Any study, whether research, evaluation, quality improvement or audit should adhere to the following ethical guidelines.

Organisations, or those involved in a service evaluation, must ensure that they monitor and address ethical issues throughout the evaluation process.

All service evaluations should be reviewed to identify and address ethical issues and risks, and develop a 'risks and issues register'. This review does not need to be conducted by an external body, such as an NHS Research Ethics Committee; however we recommend this involves a peer review by an individual or committee against an agreed checklist assessing risk, ethical issues and governance arrangements. For sample checklists, see the Quality Assurance Checklist and Risk and Issues Assessment Guide and resources included in the Evaluation Works toolkit http://www.nhsevaluationtoolkit.net/checklist/

Where service evaluations involve a degree of participation (ie involvement in advisory group), ethical review should take account of matters relating to partnership, collaboration and power, community rights, ownership and dissemination of data. The UK Evaluation Society (UKES) has supported the development of a set of guidelines for patient and public involvement in evaluation. These guidelines are available on the Evaluation pages of the CLAHRC West website http://clahrc-west.nihr.ac.uk/evaluation/

4. Safeguards

All service evaluations should ensure that they have adequate safeguards in place to protect the participant, service and organisation from harm.

Where service evaluations involve human participants, this should include seeking appropriate informed consent taking into account risk, vulnerability and capacity of the participant. For example:

- Consent should be appropriate to the participant's age, learning ability, language, religious and cultural beliefs
- Consent should be explicit verbal or written consent where participants are identifiable or where their identifiable data is involved (or qualitative methods are being used)
- Consent may also be implied through the completion of activities such as surveys
- Consent may not be needed if the data is accessed in an anonymised form
- All information provided about the evaluation should be accessible to enable fair and equitable access to the study. It should take account of the potential sensitivities, emotional impact and distress that may arise from the service evaluation
- All information should make sure that it is clear that participation is voluntary and they can withdraw at any time without adverse consequences.

Examples of consent forms and participant information sheets can be viewed at http://www.hra.nhs.uk/resources/before-you-apply/consent-and-participant-information/

Service evaluations need to conduct a risk benefit analysis using their quality assurance and ethical review checklists to ensure that the benefits of conducting an evaluation outweigh the risks; ensure that risks and issues are mitigated and managed and benefits maximised.

5. Evaluator Conduct

Evaluators should adhere to a code of conduct in accordance with their own discipline³ or to specific guidelines such as:

- UKES good practice and capabilities guidance <u>https://www.evaluation.org.uk/about-us/publications</u>
- Market Research Society (MRS) Code https://www.mrs.org.uk/pdf/mrs%20code%20of%20conduct%202014.p <u>df</u>

³ For example, UK Evaluation Society *Guidelines for Good Practice in Evaluation*; British Psychological Society *Code of Ethics and Conduct*; Medical Research Council, *Good research practice: Principles and guidelines*; Social Research Association, *Ethics Guidelines*; British Association of Social Workers, *Code of Ethics*; Nursing and Midwifery Council, *The Code*; Market Research Society *Code of Conduct*

The evaluator should ensure they have the skills, experience and support to undertake the evaluation. This might require coaching, mentorship or supervision. The UK Evaluation Society (UKES) South West Evaluator Forum offers support and mentorship to those in the region working on evaluation or with evaluation evidence https://www.evaluation.org.uk/index.php/about-us/networks/49-south-west-evaluator-forum

Evaluators should declare conflicts of interest. For instance, a service manager conducting an evaluation may have a conflict of interest. While this doesn't prevent them from conducting the evaluation, they will need to declare the conflict of interest on an appropriate form for this purpose. Example 'declaration of interest' forms can be viewed at:

- NICE https://www.nice.org.uk/Media/Default/About/Who-we-are/Policies-and-procedures/declaration-form.docx
- NHS England
 https://www.england.nhs.uk/wp-content/uploads/2011/12/Paper-NHSCBA-12-2011-2B-Declaration-of-Interest-Final.pdf

Evaluators should be mindful of and respond to ethical issues throughout the whole period of evaluation.

This guidance has been produced by Emma Gibbard (Avon Primary Care Research Collaborative), Janet Brandling (Avon & Wiltshire Mental Health Partnership NHS Trust) and Trish Harding (Bristol Health Partners) in conjunction with colleagues and members of the Ethics Working Group of the West of England Evaluation Strategy Group.

Date of publication: June 2017