



Governance processes for rapid evaluation – principles, problems and preferences

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Overview

- Objectives for the session
- Case studies: **BRACE and PRUComm experience** of Primary Care Networks (PCN) research and governance
- Health Research Authority **perspective** on research and service evaluation
- **Discussion** on navigating governance processes for evaluation
- Feedback

Objectives

During this session we will explore the issues of undertaking rigorous and **well-governed evaluation** work, in the context of **HRA processes, university ethics committees, local research governance** and **GDPR**. Throughout the session we will:

- add to your understanding of the **requirements associated with information governance**;
- collectively consider the **difference between rapid evaluation and research**, and discuss the relevance of these differences with regard to the governance of studies;
- and scope out what **guidance or support** would look like in terms of ensuring a consistent approach to overseeing and obtaining permissions for rapid evaluative work.

To think about throughout the session:

- What are governance processes for?
 - Information governance?
 - Governance of the conduct of research (and what happens when something goes wrong?)
 - Ensuring staff bona fides?
 - Ensuring the organisation has capacity?
 - Why does research need governance and evaluation does not?
- Who can give permission for research or evaluation in any organisation?
- How useful is the distinction between evaluation and research, and what does it mean when academics carry out evaluations?
- How can we prove that we meet the requirements associated with GDPR?
- **Heresy – should non-clinical research OR evaluation require governance approval?**

BRACE PCN rapid evaluation

- This on-going rapid evaluation study seeks to provide clarity on the evidence available with respect to collaborations between GP practices to evaluate **the nature, functioning, potential and pitfalls** of GP collaborations.
- A particular focus on understanding issues for **rural as opposed to urban collaborations**, and the motivations and experience of collaborations that have struggled to get **going, stalled or failed**.
- Methods: **interviews** with stakeholders such as GP practitioners, practice managers, analysts, policy makers and key decision makers; **an online survey questionnaire** to all practices within each collaboration; **non-participant observation** of meetings at executive board level; and **document review**

“3.1 For the purpose of this policy framework, research is defined as the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods . This excludes audits of practice and service evaluations. It includes activities that are carried out in preparation for or as a consequence of the interventional part of the research, such as screening potential participants for eligibility, obtaining participants’ consent and publishing results. It also includes noninterventional health and social care research (i.e. projects that do not involve any change in standard treatment, care or other services), projects that aim to generate hypotheses, methodological research and descriptive research.. **Activities that are not research according to this definition should not be presented as research and need not be conducted or managed in accordance with this framework.** A decision tool that provides a definitive answer about whether a project counts as research under this policy framework is available at www.hrdecisiontools.org.uk/research.

- NB This definition involves an attempt at generalisability or transferability, i.e. the project deliberately uses methods intended to achieve quantitative or qualitative findings that can be applied to settings or contexts other than those in which they were tested.
The actual generalisability or transferability of some research findings may only become apparent once the project has been completed.

| RESEARCH | SERVICE EVALUATION | CLINICAL/ NON-FINANCIAL AUDIT |
|--|---|---|
| <p>The attempt to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods* including studies that aim to generate hypotheses as well as studies that aim to test them, in addition to simply descriptive studies.</p> | <p>Designed and conducted solely to define or judge current care.</p> | <p>Designed and conducted to produce information to inform delivery of best care.</p> |
| <p>Quantitative research – can be designed to test a hypothesis as in a randomised controlled trial or can simply be descriptive as in a postal survey. Qualitative research – can be used to generate a hypothesis, usually identifies/explores themes.</p> | <p>Designed to answer: “What standard does this service achieve?”</p> | <p>Designed to answer: “Does this service reach a predetermined standard?”</p> |

BRACE PCN: Governance

- Intention to submit UoB ethics application, which indicates the need for the researcher to **seek guidance from HRA website** to ascertain whether HRA approval is required
- Using the **HRA algorithm** to determine whether our study is categorised as research or service evaluation
- Submitting **one page outline of the study to HRA** for clarification and confirmation of whether HRA approval is necessary (study categorised as service evaluation therefore HRA approval not required)
- **Submission of UoB ethics application** for service evaluation (attaching HRA confirmation)

BRACE PCN: Governance

- PCNs unsure of what authority they have when partaking in a rapid evaluation (**i.e. can they give permission?**)
- Directed towards CCG research and development officer (**in some cases this role/person did not exist**)
- CCG directing researcher to Clinical Research Networks (CRN) who then reply clarifying that **service evaluation is not their jurisdiction**
- CCG and PCN simply request UoB approval confirmation and hold evaluation protocol '**on file**' for information purposes as part of monitoring on-going research/evaluation activity across their region

BRACE PCN: Challenges

- UoB governance still learning of HRA processes and systems **asking researchers to use algorithm** and directing them to HRA website
- **Less governed and assured process** for service evaluations although UoB accepts the role of sponsor
- Lack of guidance given to health related organisations with regard to the nature of **oversight and quality assurance required** for service evaluations (often researcher guiding the organisation)
- Differentiation of **processes and requirements** which researchers are expected to fulfil for each individual PCN/CCG

PRUComm PCN study

- PRUComm = DHSC funded cross institutional collaboration (LSHTM, University of Kent, UoM)
- Aim: understand commissioning, contracting, delivery of primary care via PCNs, and impact and outcome of these processes on care provision.
- Methods: 3 year; mixed methods; **interviews** with senior policy makers, NHS managers, GPs; **telephone survey** with Clinical Commissioning Groups; PCN case studies (interviews and observations);. **Quantitative analysis of routine data**

PRUComm Governance

- HRA Decision Tool = research. NHS REC not required.
- UoM proportionate ethical review (incl. comprehensive Digital Management Plan).
- Research Governance team approval.
- HRA 'streamlined' process for **studies with minimal impact on the NHS** where interviewees are sufficiently senior to make judgement on capacity for involvement = less sections of IRAS to complete; currently less formal submission route; quicker, proportional process for approval.
- Research Governance team sponsorship confirmation.

The HRA perspective

Paul Mills

Research Regulation Specialist



Research vs Evaluation

- Research attempts to derive **generalisable or transferable** new knowledge.
- Evaluation is designed and conducted solely **to define or judge current care.**
- If you are coming from the outside to undertake activities then your intention is to **generate generalisable new knowledge** – likely to be research
- If undertaking **within your own Trust** then likely to be evaluation

What are HRA checking for?

- Essentially, whether the research **is legal and meets NHS/HSC policy positions** on research.
- Most relevant for this type of research will be **information governance**.
- Will also provide advice in letters on working with NHS organisations, need for PI, agreements.
- Being research **may help rather than hinder** working with NHS organisations.....
- May not need NHS ethics approval, but researchers should still consider **ethical issues**.

IG requirements for research

- Primarily GDPR but also consider relevant **NHS codes of practice** etc.
- Common law duty of confidentiality
- GDPR (**personal data**) vs common law (**confidentiality full stop**)
- HRA only has a **responsibility for research**, but would consider positions to be similar for evaluations – speak to the data controller

GDPR requirements

- Legal basis for processing personal data
 - **Data subject rights**
- Transparency requirements
- Data controllership
- Agreements for processing personal data
- Data Security
 - **Data minimisation, transfer and storage of data**
- <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/>

How can you demonstrate compliance?

- **Research**

- HRA and HCRW Approval

- **Evaluation**

- Speak to the data protection officer of the data controller

- **Both**

- Well designed protocol/documentation with clear methodologies



Discussion

In small groups, discuss (15 mins):

1. How do you interpret the distinction between research and service evaluation – what are the key points of difference?
2. From your experience, what would be the **THREE** most useful things to support you/your research team when navigating governance relating to service evaluation?



Feedback

Short feedback from each group, with the aim of compiling a 'wish list' of supportive information.