Service evaluation

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Service evaluation: a grey area of research?

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Abstract:	The National Health Service in the United Kingdom categorises research and research-like activities in five ways, as 'service evaluation', 'clinical audit', 'surveillance', 'usual practice' and 'research'. Only activities classified as 'research' require review by the Research Ethics Committee (REC). It is argued in this position paper that the current governance of research and research-like activities does not provide sufficient ethical oversight for projects classified as 'service evaluation'. The distinction between the categories of 'research' and 'service evaluation' can be a grey area. A considerable percentage of studies are considered as non-research and therefore not eligible to be reviewed by the REC, which scrutinises research proposals rigorously to ensure they conform to established ethical standards; protecting research participants from harm, preserving their rights and providing reassurance to the public. This paper explores the ethical discomfort potentially inherent in the activity currently labelled service evaluation.

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Abstract

The National Health Service in the United Kingdom categorises research and research-like activities in five ways, as 'service evaluation', 'clinical audit', 'surveillance', 'usual practice' and 'research'. Only activities classified as 'research' require review by the Research Ethics Committee (REC). It is argued in this position paper that the current governance of research and research-like activities does not provide sufficient ethical oversight for projects classified as 'service evaluation'. The distinction between the categories of 'research' and 'service evaluation' can be a grey area. A considerable percentage of studies are considered as non-research and therefore not eligible to be reviewed by the REC, which scrutinises research proposals rigorously to ensure they conform to established ethical standards; protecting research participants from harm, preserving their rights and providing reassurance to the public. This paper explores the ethical discomfort potentially inherent in the activity currently labelled service evaluation.

Keywords: Research ethics, Research, Service evaluation, Ethics review, Ethics principles

Introduction

The National Health Service in the United Kingdom categorises research and research-like activities in five ways, as 'service evaluation', 'clinical audit', 'surveillance', 'usual practice' and 'research'[1]. Service evaluation is widely employed in the clinical research setting.

This paper looks to raise an important issue for ethical review in the health services; that of the ethical rigour in service evaluation. Service evaluation laudably seeks to assess how effectively a patient service is achieving its intended goals. However, a concern has been identified by the authors, that the very nature of this form of enquiry, commonly seen as not requiring specific approval from research ethics committees (REC), may also be at risk, inadvertently, of bypassing ethical principles.

Recently the authors of this paper were involved in a service evaluation to investigate patient experiences and outcomes of the care provided in two different heath care settings.

The project methods included non-participant observations and interviews, but as this

enquiry had been predefined as service evaluation, this project was not submitted for review by the relevant REC. The project was given approval by the Caldicott Guardian, responsible for reviewing the arrangements for handling patients' data[2] and also approved by the local Quality Improvement Team. This latter process focused on potential disruption to clinical areas, such as protecting participants' confidentiality but not directly the ethical conduct of the study.

Once these approvals had been received, the researchers were permitted, quite properly in service evaluation, to proceed. The particular growing disquiet as the enquiry progressed was that an ethical dimension did not appear to be addressed and questions arose as to whether this was more appropriately seen as research. If it had had been so, a full and rigorous ethical review would have been required.

Ensuring ethical behaviour and standards

There are fundamental, well understood theories underpinning and ensuring ethical behaviour and standards. Virtue ethics focuses on the role of moral character of the individual from which choices and actions follow. Principle based ethics, on the other hand, serve to guide morally right actions and is based on: respect for autonomy, non-maleficence, beneficence and justice[3-5]. From this, ethical rules, policies and guidance, are widely employed by research ethics committee to make *ethics* or *ethical*

principles more explicit[3]. Although ethical rules, policies and guidance are, indeed, derived from ethical principles, there are debates as to whether rules, policies or guidance can truly reflect morals. Accordingly, it is recognised that a more rule-based ethic in the real world of research also encompasses the ideals of virtue ethics to provide valuable guidance in establishing research integrity and the consequent accountability for the research process[5]. As indicated at the outset, five categories of research and research-like activities are identified as: 'service evaluation', 'clinical audit', 'surveillance', 'usual practice' and 'research'. Any activity collecting and/or analysing data on health or health services must be classified under one of these headings[1] (Table 1). All the above activities must adhere to ethical standards.

However, once the research like activity has been classified, different regulatory and ethical requirements are endorsed. Only activities classified as research are eligible for review by the REC. The classification of projects, at this point, therefore significantly changes the extent to which they are subject to institutional oversight and formal ethical governance.

The uncomfortable question that arises is whether the current governance of research and research-like activities provides sufficient ethical oversight for the category identified as service evaluation. Distinguishing between the categories of research and service evaluation is not always clear as the guidance and definitions might suggest; some projects could fit into either category with relatively little or no changes in focus

or content. As the experience of the researchers above illustrates, projects classified as 'service evaluation' may involve researcher-led activities and interventions that might equally be seen as research in other contexts, or by other institutions. It can be then discomforting and difficult to understand why these projects receive no ethical review from a REC, whilst other projects, involving similar types of activity, receive extensive ethical review. Current governance policy and processes require the individuals conducting projects classified as service evaluation to follow ethical principles and patient protection laws which should be trusted, virtuous and acted upon ethically. This assumption contrasts with the more principle-based ethics practised through the REC, where projects are examined in great detail, and each element of the project is expected to be defended against a pre-existing ethical framework[6]. It is argued here that it is the predetermined classification that can guide the researchers' ethical decisions and actions. However, it must be that the first imperative of any research enquiry is the ethical consequence of the activity not merely what may seem as the more obvious, and even desirable, classification.

In light of these concerns, it serves to reflect on the historical development and implementation of research enquiry in general and of service evaluation in particular, and explore the development of the ethical implications of categorising forms of research activity.

Development of the ethical milieu

Research ethics first became of critical concern at the Nuremberg trials after the second world war. Dreadful crimes against humanity were identified, following immoral human experiments on concentration camp prisoner, undertaken under the guise of research. As a result, in August 1947, the Nuremberg Code was introduced giving the set of ten ethical principles for conducting human experiments[7]. As ethical sensitivity developed, the World Medical Association developed the Declaration of Helsinki in 1964[8] seen as the cornerstone of modern human research ethics, whatever the current classification of such research that may currently exist.

The NHS Health Research Authority[1(p.4)] defines the activities as follows:

1. 'Service evaluation': designed and conducted solely to define or judge current care.
2. 'Research': the attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them. Specific questions generate a protocol driven project to derive new knowledge and understanding.
3. 'Clinical audit': designed and conducted to produce information to inform delivery of best care, which serves to identify if desired standards of

service delivery are being met.

4. 'Surveillance': designed to manage outbreak and help the public by identifying and understanding risks associated.
5. 'Usual practice': designed to investigate outbreak or incident to help in disease control and prevention.

The categories of 'research', 'service evaluation' and 'clinical audit', have consistently been present in health service guidance since the development of Research and Development (R&D) governance in the early 1990s. However, the range of terms used to classify R&D activities, and their definition, changed. A brief account of these developments can serve to identify some of the processes, motivations and definitions that have contributed to the category of *service evaluation*.

Research and Development Governance 1948-1990

With reference to Figure 1, it can be seen that initially, research and related activities were given little attention within the NHS; there was no centralised governance for research and any such research governance occurred at a local level[9]. It was not until 1989, that the British government appointed a National Director of R&D, tasked with overseeing patient based activity related to teaching and research in the clinical environment in the NHS[9]. At this time, key terms used to describe R&D activities in

governance documents included *research*, and *clinical audit*, the latter key to the quality assessment processes for clinical practice[10].

Research and Development Governance 1991-2000

Despite this movement towards research governance, progress was slow, and little central funding allocated to the R&D department[9]. However, the implementation of the European Good Clinical Practice (GCP) regulations and guidelines in 1990[11], marked a 'sea change' in the primacy of ethical behaviour in research.

In 1991, local REC were established to review the ethical quality of proposed research studies, at this time predominantly biomedical research[12]. These committees were under the aegis of local health services, with no centralised oversight of research activities in the health service as a whole[13]. Each local NHS health board established its own administrative structure and management according to the local interpretation of the latest Research Governance Framework.

In 1996, Regional Health Authorities were established, who were responsible for, amongst other things, research development[9]. For the first time, research and development activities in the NHS were incorporated into a clear framework for governance.

In 1997, the first national system for ethical review was established with the

development of the Multi-Centre REC responsible for research across different local government. However, the Multi-Centre REC did not have the authority over local RECs[13]. On a somewhat separate pathway, it was in 1997, that the idea of service evaluation emerged, with a particular focus on primary care, was put forward by Evans and Steiner[14]. Their suggestion was that this term could be used to describe a range of quality improvement studies where the specific purpose would be to judge the quality of care against existing approved standards.

In 1998, in response to the widely recognised GCP, the first national research strategy was developed[15]. A funded NHS R&D programme was established, with the aim of improving the research environment within the NHS[9]. The approach to research and development was becoming more strategic and unified, but oversight of the ethical conduct of individual projects continued to function at a local level and, arguably, activity under the umbrella of Service evaluation developed by a means of pragmatic gradualism.

Research and Development Governance 2001-2016

In 2001, the European Directive, responsible for the GCP regulation and guidelines[16], required more rigorous governance of research activities within the NHS. From this the existing system of ethical review was established under a centralised REC[17]. REC now

acted as a gatekeeper to ensure all research studies were carried out in accordance with ethical standards on their approval. Unlike previous systems, the current REC gives ethical advice and review for studies that are identified as research and, importantly, are required to be independent of any local health service[17, 18].

In 2001, the Department of Health published the *Research Governance Framework for Health and Social Care*[17], introducing a definition of research as "the attempt to derive generalizable new knowledge by addressing clearly defined questions with systematic and rigorous methods"[(p.3)]. The Research Governance Framework was central to changing the landscape for NHS research review. According to this Framework, all research was required to meet the ethical and scientific standards established by research governance requirements. Critically, for the authors' thesis, in contrast, activities such as clinical audit, service evaluation and practice development fell within a clinical governance framework, which was intended to safeguard the quality of care and health care delivery. The Research Governance Framework stated that there was no need for clinical audit, service evaluation and practice development to undergo ethical review[19]. Despite the obvious rigour identified above, it is hard to find the rationale for the essential categorising of studies into research or non-research, with service evaluation firmly in the latter. In 2006, the NHS introduced a new/revised system for classifying research and development activities under the headings of research, clinical audit and service evaluation[20]. In this guideline, service evaluation

was defined as procedures whereby medical service was judged "…by providing a systematic assessment of its aims, objectives, activities, outputs, outcomes, and costs"[21(p.9)] whilst Clinical audit was defined as a "quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change."[21(p.9)] Figure 1 serves to demonstrate the evolution of this different terminology and associated definitions. As before, only *research* required review by the REC[20]. The decision as to classification could be made according to the recommendation from the local R&D office, arguably adding considerably to their work burden if, by the same token, reducing that of the REC[22].

In 2009, the initial typology of research and development activity was increased to five categories: 'clinical audit', 'service evaluation', 'research', 'usual practice' and 'surveillance work'[23]. In 2011, this was reduced again to 'research', 'clinical audit' and 'service evaluation'. It is difficult to track these changes through government documentation, but different classifications can be found in local NHS documents such as guidelines published by NHS Wirral[24]. No explicit rationale could be located for the change of terminology but, as in previous iterations, only activities classified as *research* required review by the REC.

In 2013, there was further alteration, with a revised version of the 2009 terminology with the current five categories[1]. The same classifications are reviewed again in 2016.

In all these iterations only activities classified as *research* require, or indeed, of interest to the current debate, are permitted, review by the REC.

The Health Research Authority (HRA), established in 2011 to raise awareness of the rights of patients and the public in health and social care research, was also tasked to co-ordinate the REC and promote transparency in research. It constitutes the lead R&D office in the UK[25]. It is worth noting that, in England, the HRA is responsible for recommending which studies to go forward for review by a REC, whilst in Scotland, R&D is the decision maker[25].

In summary, governance of R&D in the UK NHS has developed significantly since the implementation of the GCP in 1991, and any activity meeting the criteria of *research* is now subject to independent review according to centralised standards. However, the definition of research, although very specific, excludes activities which might, arguably, be regarded as research in other contexts or others' views. Since the 1990s, health research has shifted from being almost entirely biomedical in focus, towards a proliferation of studies that focus on the quality of care[3, 26] and the question arises as to whether the research governance has properly responded to this significant shift. It is clear that the typology of research and development activities is intended to facilitate and clarify both the organisation of research governance and the practical and timely conduct of R&D activities within the health service. Although no rationale was found for differentiating research activities and non-research activities, the report

written by Evans and Steiner[1] was clearly influential on the activity of service evaluation as identifed currently, despite the lack of a clear mandate. It has to be pragmatically acknowledged that, by excluding certain activities from the category of research, the number of studies requiring review might be kept at a manageable level, allowing non research activities to proceed relatively untroubled. This exclusion of certain activities from ethical review can also be found in other national systems of research governance, for example New Zealand and Australia both exclude certain activities from the category of 'research' and thus from ethical review[27, 28]. However, this exclusion has been criticised. For example, Gerrish and Mawson[19] and Wade[29] suggest that every quality improvement study should be categorised as research and even studies not deemed research still require independent ethical review. Surprisingly, these critiques have not generated any real debate, which may be due to the understandable paucity in published service evaluation studies[29].

Service Evaluation in the NHS

What is indisputable is that the volume of health research being carried out in the NHS has increased enormously over the past few decades[30]. However, as alluded to above, until relatively recently, very little of this research was about the health service itself. In 2000, the newly developed Service Delivery and Organisation (SDO) encouraged the

development of research projects to investigate the quality of care, and the experiences of service users[30]. During the first five years of the SDO, its steadily increasing budget reflected the growth in the amount of commissioned research, from £167,000 in January 2000 to £7 million in July 2006. Between 2001 and 2006, a total of 23 research projects were commissioned by the SDO, with an average budget of £102,000 per project[30]. These projects, meeting pre-determined SDO themes, were identified by the SDO as 'research'[30], but arguably if they were to accord with the recent and latest definitions, they might have been classified as 'service evaluation'. At the very least there is inconsistency in decision making and subsequent ethical activity.

Recording Service Evaluation Activity

It is difficult to give any accurate statistics as to the prevalence of service evaluation in the NHS in any given year but, as an informal illustration, the South East Scotland Research Ethics Service[31] estimated that they had given advice on a total of over 1,300 studies over the past 6 years of which approximately 70% of these were classified as *not research* (see Table 2, Figure 2). While this is not representative data, it is nevertheless interesting to note the proportion of studies advised as non-research.

Service Evaluation: a distinct enquiry?

Despite the lack of rationale for clear justification for its emergence, service evaluation has become embedded as a form of service enquiry distinct from research. Gerrish and Mawson[19] and Wade[29] point out, that in the NHS R&D typology, the categories of research and service evaluation necessarily have many similarities. They both include projects that start with a question, expect the answer to change or influence clinical practice, may involve the collection and analysis of new data, or the analysis of already existing data, and both depend on using an appropriate method and design to reach sound conclusions[19, 29].

The most marked difference between the categories is that a service evaluation can only employ an intervention that has already been undertaken in the health service. Put simply, research investigates what should be done, whereas service evaluation investigates whether it is being done and to what standard[1, 23, 24].

Although guidance on making the distinction between service evaluation and research is available[1, 23, 24], the distinction can be difficult to agree or make in practice. The NHS Quality Improvement Strategy (QIS), 2011, has acknowledged that there can be a *grey area* when it can be difficult to decide where the project fits, and R&D would only *advise* the researcher of the likely classification. Casarett, Karlawish[26,] and Wade[29] agree that documents discussing the distinction between audit, service evaluation and

research, often base this distinction on the methodological 'process' of the project rather than the defined objectives. This means that projects on the border between service evaluation and research could easily be aligned to either category with relatively small, or even no, adjustments to methodology or design. For researchers facing time and resource constraints, it may be more attractive to position their project towards service evaluation, thereby avoiding the need for an in-depth ethical review. Equally, it may seem disproportionate that small changes to the design or presentation of a project may have such significant consequences for the degree of ethical oversight required for the project. These are difficult and ethical issues in themselves to confront.

The current system of research governance has evolved an 'all or nothing' approach to ethical review, arguably inadequate if it means that activities with potentially significant ethical consequences are not reviewed. Two problems are positioned here. Firstly, by adopting the absolute 'review/ no review' approach, current research governance ignores the grey areas of research ethics. This presents an absence of ethical scrutiny. Secondly, there may be an implicit assumption that the label service evaluation poses thereby less of a risk to participants than research, when this may not be the case. Challenging this, Twycross and Shorten[32] argue that the standards expected of service evaluation in terms of design, data collection, and analysis should be at least as high as for research because service evaluation or audit may "quickly

move findings to create tangible practice change"[(p.66)]. Service evaluation is often embedded within day to day practice, the latter being the very means of evaluating service provision[33].

Ethical Review

Ethical review is axiomatically beneficial for research. According to Wade[34] "Ethical concerns arise when the involved parties have different interests or values in a situation in which a potential conflict exists between the burden and risk imposed on patients or others, including society, and the likely benefit" [(p. 469)].

Ethical review provides guidance for researchers, and safeguards for participants. Although service evaluation does not require specific approval from a REC or R&D approval, ethical principles must still be adhered to in terms of such as consent, anonymity, data protection and privacy of patients[29]. However, it can be challenging for researchers, particularly novice researchers, to conduct a service evaluation in clinical settings without any ethical advice and support from an ethics committee.

It is difficult to conduct a meaningful review of studies classified as service evaluation, as, as indicated, few published studies are identified in this way[26(p. 66)]. The authors can only speculate as to why this is the case. However, based on information gathered from the South East Scotland ethics service, and the authors' own experiences, one

suggestion might be that many service evaluations are undertaken for purely pragmatic, service-led reasons, not deemed a priority for peer review journal publication. In this way, it could be argued that that most service evaluations vanish from view.

Service evaluation case studies

In light of this deficit of published service evaluations, three examples are discussed below. A detailed description will be given of the three service evaluation case studies in below to demonstrate that they easily have met the criteria for research. It is noted that this case analysis is not for punitive purposes but purely to demonstrate the dilemma and disquiet.

Evaluation of PIMA point-of-care CD4 testing in a large UK HIV service[35]

This service evaluation was undertaken to evaluate the performance and patient acceptability of a new laboratory service for patients with HIV. Capillary blood samples were collected from consented participants for the new laboratory service. The participants were asked to complete a five point Likert questionnaire, to assess their views about the laboratory service. Surprisingly, a study involving blood sampling and direct patient involvement was still classified as service evaluation not requiring ethical review from the NHS. Studies that collect participants' blood are normally defined as

research, because collecting patients' tissues or anything from their body will require the highest ethical standard. The Human Tissue Act, 2004[36], stated that all tissue collected require consent and advice from the REC. Although this study could entail risk, it had met the criteria for service evaluation. Even if not deemed research on the determined criteria, it is argued that the study carried a form of risk that should have merited closer ethical scrutiny.

The effect of anaesthetist grade and frequency of insertion on epidural failure: a service evaluation in a United Kingdom teaching hospital[37]

This service evaluation investigated prospectively all patients undergoing either intra-abdominal or thoraco-abdominal surgery who received epidural analgesia. Health records were examined to identify the reason for, and the method of care for, epidural catheter removal. Although it analysed existing data, it was interesting that neither ethical approval nor informed consent from patients concerned were required. Using patients' data often raises ethical concerns. The classification of this study allowed easy access to the relevant databases without any reference to ethical guidance.

A service evaluation of the feasibility of a community based consultant and stroke navigator review of health and social care needs in stroke survivors 6 weeks after hospital discharge[38]

In this last service evaluation, focusing on stroke survivors, all the stroke survivors took part in a joint review under the auspices of the Department of Health's National Stroke Strategy Quality Marker. The Joint review clinics were held twice a month by a stroke consultant, who completed a comprehensive and holistic assessment of the individual, alongside quality of life questionnaires and focus groups. This was in addition to the standard stroke care and constituted a new intervention whose value had yet to be proven. It is argued that such a study involving patients should perhaps have included a REC driven assessment of risk of harm.

The authors contended that those concerned in the above defined service evaluations were not encouraged to think about such ethical considerations, distracted by the comforting label of service evaluation.

As noted at the outset, the authors of this paper were also involved in a service evaluation. This service evaluation in an acute clinical setting included interview and observation with staff and patients without either ethical approval or informed consent. The study could be intrusive and key personal data was included without ethical scrutiny. At face value, it was hard to foresee risk of harm in such a defined service evaluation without the required ethical prompt axiomatic in in research. The evolving ethical concern for participants' well-being led to the evolution of this position paper.

All the above were classified as service evaluation. However, similar methods of the study and population groups, could be found in many studies classified as research required to provide extensive justification for their methods, and recruitment strategies, with detailed safeguards put in place to protect research participants. What has been established is that it can be hard to determine whether a study is research or not. Although guidance on making the distinction between service evaluation and research is available, and indeed looks superficially clear, the distinction can be difficult. However, it can be argued that the arbiter of this distinction can be the ethical review seen as a 'gatekeeper' for a study's category. This, rather the than the label, determining the route to, or away from, ethical review. Despite the fact that the process can be complicated and time-consuming, it can help the researchers to identify potential harm, which will not only protect participants, but also protect researchers. It is accepted that, at present, a service evaluation may not require specific approval from a REC or R&D, but ethical principles must still be uppermost and adhered to for the protection of participants and vulnerable[18, 29]. It is important for all undertaking research activity, however defined, of any sort to reflect on their own role in the study and critically think about the ethical issues during the study[19, 29, 34].

Discussion

Ethical principles remain at the heart of all research-like activities. The development of ethical review processes should be the guardian for all studies. Although regulation for service evaluation has been established, it has been argued that ethical dilemmas in such classification and guidance clearly exist. Fundamental is that in any research activity the researchers must do no harm[7]. Before any research activity or service evaluation, involving individuals is undertaken, the foreseeable risks and discomforts, as well as any anticipated benefit for the individual, are identified. Risk of harm can, indeed, on occasions be difficult to predict[39]. As service evaluation is commonly embedded in the practice it is evaluating, it can pose particular challenges and complexities, particularly for a novice researcher[33]. It is not an easier route. In any research activity, REC guidance is to assist decision making when encountering ethical dilemmas[3]. Inevitably, there may be gaps in a rule-based system[32, 40]. Reviews from the REC act as the default system, a safety net, that may reveal potential harm and/or minimise such harm, ensuring that the potential benefits outweigh any risk[39]. The problem identified is that in service evaluation, this vital step is not present, the choice of service evaluation even preferred to avoid the potentially complicated ethical review process.

Conclusion

The difficult debate put forward here is whether the main ethical concern is wrongly labelling enquiry as research and non-research activities. No published evidence could be found to explain fully the purpose of the current classification system. Whatever the classification, or when this is determined, the key driver of all such activity is its ethical component and this truism goes back over 70 years.

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Conflict of interest

The authors declare that there is no conflict of interest.

References

1. NHS Health Research Authority. Defining research. London 2016,

http://www.hra.nhs.uk/documents/2016/06/defining-research.pdf (accessed 11 May 2017).

2. Roch-Berry C. What is a Caldicott guardian? *Postgraduate Medical Journal* 2003; 79(935): 516-8. DOI: 10.1136/pmj.79.935.516

3. Gert B, Culver CM, Clouser KD. Common morality versus specified principlism: Reply to Richardson. *Journal of Medicine and Philosophy* 2000; 25(3): 308-22. DOI: 10.1076/0360-5310(200006)25:3;1-H;FT308

4. Sachs B. The case for evidence-based rulemaking in human subjects research. *The American Journal of Bioethics* 2010; 10(6): 3-13. DOI:10.1080/15265161003702857

5. Resnik DB. Ethical Virtues in Scientific Research. *Accountability in Research: Policies & Quality Assurance* 2012; 19(6): 329-43. DOI: 10.1080/08989621.2012.728908

6. McLean SA. *First do no harm: Law, ethics and healthcare*: Routledge; 2016.

7. Mitscherlich & F. Mielke, *Doctors of infamy: The story of the Nazi medical crimes (pp. xxiii–xxv)*. New York: Schuman, 1949.

8. Carlson RV. The revision of the Declaration of Helsinki: past, present and future. *Br*

J Clin Pharmacol 2004; 57: 695-713. DOI: 10.1111/j.1365-2125.2004.02103.x

9. Greengross P, Grant K, Collini E. The UK National Health Service, https://assets.publishing.service.gov.uk/media/57a08d91e5274a31e000192c/The-history-and-development-of-the-UK-NHS.pdf (1999, accessed 1 January 2017)

10. National Institute for Clinical Excellence. *Principles for best practice in clinical audit*. Radcliffe, 2002.

11. Commission of the European Communities. *Good Clinical Practice for Trials on Medicinal Products in the European Community*. London: HMSO; 1990.

12. Department of Health. Local research ethics committees. London, 1991.

13. NHS Scotland. Governance arrangements for NHS Research Ethics Committees in Scotland. Edinburgh, 2001.

14. Evans D, Steiner A. *Evaluation in Primary Care: A Guide*. Leeds: NHS Executive 1997.

15. Kolman J, Meng P, Scott G. *Good clinical practice : standard operating procedures for clinical researchers.* Chichester :Wiley; 1998. DOI: 10.1002/0470842520.ch26

16. Commission of the European Communities. *Official Journal of the European Communities.* Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. 2001.

17. Department of Health. *Research Governance Framework for Health and Social Care.* London: HMSO, 2001.

18. Department of Health. *Research Governance Framework for Health and Social Care.* London, 2005.

19. Gerrish K, Mawson S. Research, audit, practice development and service evaluation: Implications for research and clinical governance. *Practice Development in Health Care* 2005; 4(1): 33-9. DOI: 10.1002/pdh.29

20. Royal College of Physicians. *Guidelines on the practice of ethics committees in medical research with human participants.* 4th ed. London: Royal College of Physicians, 2007, p.136.

21. NHS Research and Development Forum. Categorising research within the Research Governance Framework for Health and Social Care, http://www.rdforum.nhs.uk/content/wp-content/uploads/2014/05/categorising_projects_guidance2006.pdf (2006, accessed 15 January 2017).

22. Department of Health. Report of the Ad Hoc Advisory Group on the Operation of NHS Research Ethics Committees. London: Department of Health, 2005.

23. Authority NHR. Defining research, http://webarchive.nationalarchives.gov.uk/20130107105354/http:/dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4112417.pdf (2009, accessed 15 January 2017).

24. NHS Wirral Research & Development. *What is the difference between research, evaluation and audit?* 2011.

25. NHS Health Research Authority. *Who we are*. 2017.

26. Casarett D, Karlawish JT, Sugarman J. Determining when quality improvement initiatives should be considered research: Proposed criteria and potential implications.

JAMA 2000; 283(17): 2275-80. DOI: 10.1001/jama.283.17.2275

27. National Health and Medical Research Council. The national statement on ethical conduct in human research Australia, https://www.nhmrc.gov.au/guidelines-publications/e72 (2007, accessed 20 January 2017).

28. National Ethics Advisory Committee. Ethical guidelines for intervention studies. https://neac.health.govt.nz/system/files/documents/publications/ethical-guidelines-for-intervention-studies-2012v2_0.pdf (2012, accessed 15 January 2017).

29. Wade DT. Ethics, audit, and research: all shades of grey. *BMJ* 2005; 330(7489): 468-71. DOI: 10.1136/bmj.330.7489.468

30. National Coordinating Centre for the Service Delivery and Organisation. *The impact of the NHS Service Delivery and Organisation Research and Development Programme.* London: National Coordinating Centre for the Service Delivery and Organisation, 2009.

31. Bailey, A. (2017). *Email on service evaluation*. [email].

32. Twycross A, Shorten A. Service evaluation, audit and research: what is the difference? *Evidence Based Nursing* 2014; 17(3): 65-6. DOI: 10.1136/eb-2014-101871

33. Moule P, Armoogum J, Douglass E, Taylor J. Evaluation: Importance for your practice. *Nursing Standard.* 2017.

34. Halpern SD. The continuing unethical conduct of underpowered clinical trials. *JAMA* 2002; 288: 358-62. DOI: 10.1001/jama.288.3.358

35. Herbert S, Edwards S, Carrick G, Copas A, Sandford C, Amphlett M, et al. Evaluation of PIMA point-of-care CD4 testing in a large UK HIV service. *Sexually Transmitted Infections* 2012; 88(6): 413-7. DOI: 10.1136/sextrans-2012-050507

36. Price D. The human tissue act 2004. *The Modern Law Review* 2005; 68(5): 798-821.

37. Heinink TP, Baker BG, Yates VF, Addison DC, Williams JP. The effect of anaesthetist grade and frequency of insertion on epidural failure: a service evaluation in a United Kingdom teaching hospital. *BMC Anesthesiology* 2015; 15(1): 1. DOI: 10.1186/1471-2253-15-5

38. Dewan B, Skrypak M, Moore J, Wainscoat R. A service evaluation of the feasibility of a community-based consultant and stroke navigator review of health and social care needs in stroke survivors 6 weeks after hospital discharge. *Clinical Medicine* 2014; 14(2): 134-40. DOI: 10.7861/clinmedicine.14-2-134

39. Israel M, Hay I. *Research Ethics for Social Scientists*. London: Sage, 2006.

40. Schauer F. *Playing by the Rules: A Philosophical Examination of Rule-based Decision-making in Law and in Life*. Oxford: Oxford University Press 1991.

Table 1. Differentiating clinical audit, service evaluation, research, usual practice and surveillance work[1].

Research	Service evaluation	Clinical audit	Surveillance	Usual practice (in public health)
The attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted solely to define or judge current care.	Designed and conducted to produce information to inform delivery of best care.	Designed to manage outbreak and help the public by identifying and understanding risks associated.	Designed to investigate outbreak or incident to help in disease control and prevention.
Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.	Designed to answer: "What standard does this service achieve?" (Service development and quality improvement may fall into this category.)	Designed to answer: "Does this service reach a predetermined standard?"	Designed to answer: "What is the cause of this outbreak?"	Designed to answer: "What is the cause of this outbreak?" and treat.
Addresses clearly defined questions, aims and objectives.	Measures current service without reference to a standard.	Measures against a standard.	Systematic, statistical methods to allow timely public health action.	Systematic, statistical methods may be used.
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.	May involve collecting personal data and samples with the intent to manage the incident.	Any choice of treatment is based on clinical best evidence or professional consensus.
Usually involves collecting data that are additional to those for routine care but may include data collected	Usually involves analysis of existing data but may include administration of interview or	Usually involves analysis of existing data but may include administration of simple interview or	May involve analysis of existing data or administration of interview or questionnaire to	May involve administration of interview or questionnaire to those exposed.

routinely. May involve treatments, samples or investigations additional to routine care.	questionnaire	questionnaire.	those exposed.	
Quantitative research – study design may involve allocating patients to intervention groups. Qualitative research – uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.	No allocation to intervention: the health professional and patient have chosen intervention before service evaluation.	No allocation to intervention: the health professional and patient have chosen intervention before audit.	Does not involve an intervention.	May involve allocation to control group to assess risk and identify source of incident but treatment unaffected.
May involve randomisation.	No randomisation.	No randomisation.	No randomisation.	May involve randomisation but not for treatment.
Normally requires REC review. Refer to	Does not require REC review.	Does not require REC review.	Does not require REC review.	Does not require REC review.

Figure 1. Development of ethical organisation in the UK[1,9-18]. (author's own)

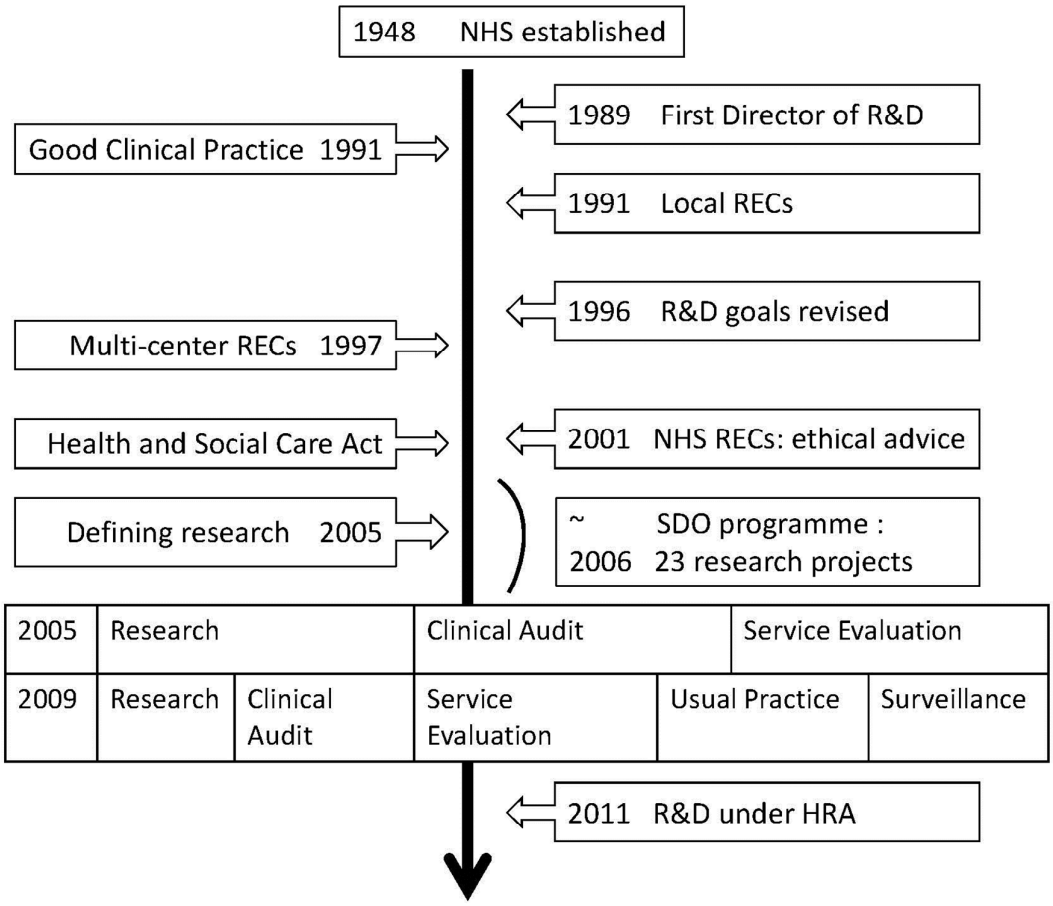
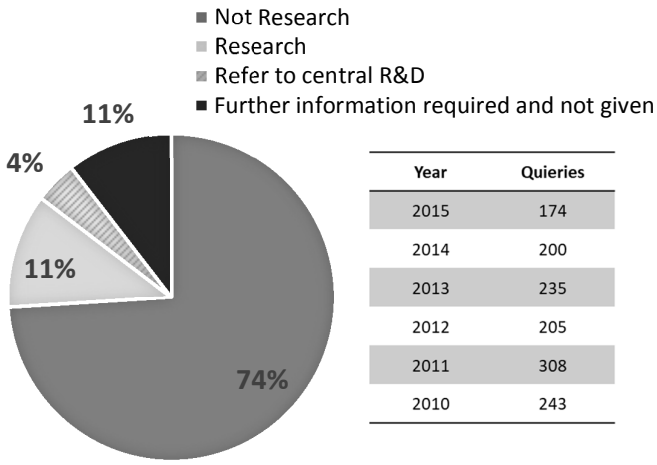


Table 2. Definition of research, service evaluation and clinical audit since 1990s[1,10,14,17,21].

	Research	Service evaluation	Clinical audit
1990			Quality assessment processes for clinical practice.
1997		Quality improvement study to judge the quality of care against existing standards.	
2001	The attempt to derive generalizable new knowledge by addressing clearly defined questions with systematic and rigorous methods.		
2006	The attempt to derive generalizable new knowledge by addressing clearly defined questions with systematic and rigorous methods.	Evaluation was seen as 'a set of procedures to judge a pilot's merit by providing a systematic assessment of its aims, objectives, activities, outputs, outcomes, and costs.	Quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery.
2009	the attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them. Specific questions generate a protocol driven project to derive new knowledge and understanding.	Designed and conducted solely to define or judge current care	Designed and conducted to produce information to inform delivery of best care, which serves to identify if desired standards of service delivery are being met

Figure 2. Advice given as to the nature of research activity in South East Scotland Research Ethics Service from 2010-2015[31].



Year	Quieries
2015	174
2014	200
2013	235
2012	205
2011	308
2010	243