Research governance: panacea or problem?

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ABSTRACT – Clinical research must meet contemporary professional, legal and ethical standards. Research governance aims to improve quality whilst safeguarding the interests of the public. Research on humans is covered by several internationally recognised ethical codes designed to protect persons from the hazards of experimental treatment. However, to date there is no overarching statutory framework that regulates health and social care research, which is governed by common law principles. The recent European Union Clinical Trials Directive aims to harmonise regulation of clinical trials and protect the interest of study participants. Approval by the new Central Office for Research Ethics Committees (COREC) is now a mandatory requirement for research projects in the UK to ensure stringent ethical standards. Research that involves NHS patients, staff, resources or premises is subject to a framework for research governance that monitors performance and adverse incidents and delineates lines of responsibility and accountability. Researchers at all levels must be fully aware of these new initiatives and of their responsibilities. NHS organisations should acknowledge and commit to clinical research as an intrinsic component of high quality health service delivery.

KEY WORDS: Central Office for Research Ethics Committees (COREC), European Union Clinical Trials Directive, implications for NHS research, medical research, NHS research, research, research governance

It is essential for public confidence that medical research should be subject to quality assurance in order to meet contemporary professional, legal and ethical standards. The concept of research governance has evolved through the publication of a number of key documents that have emphasised the need to develop a high quality service for research,[1] and is underpinned by the Government's firm commitment to implement quality initiatives at all levels within the NHS under the aegis of clinical governance.[2]

The intrinsic value of medical research to society remains undisputed.[3] However, recent events have made it painfully plain that real distress can be caused to volunteers and families when research practice does not conform to expected standards. The Griffiths Report[4] of the enquiry into a controlled trial of neonatal ventilatory support raised fundamental concerns about how research is conducted, and emphasised the need for a framework of accountability in order to reassure the public and address concerns regarding safety and probity. In spite of being criticised,[5] the report has succeeded in raising yet another scandal to hit the NHS.[6] Further problems associated with research have arisen from unethical or fraudulent conduct,[7–9] sadly fuelled by the imperative to publish, which may lead to researchers taking 'short cuts'.[10] Poor project design, based on less than rigorous methodology, may result in misleading conclusions, waste resources, and can compromise the safety of participants. Consequently, there has been a demand for tighter control of research involving human subjects, and governance aims to improve quality whilst safeguarding the interests of the public. This paper examines the key issues surrounding research governance and the challenges faced by researchers in complying with these new requirements.

The legal and ethical framework

To date, there is no overarching statutory framework that regulates health and social care research on humans. The position, however, has recently changed for clinical research involving interventional trials conducted within the European Union, following the implementation of the European Union Clinical Trials Directive (2000/20/EC). The Directive is designed to harmonise the regulation of clinical trials across the European Union, to facilitate internal markets in medicinal products and to protect the interests of study participants. The Directive requires all studies to be subject to scrutiny and approval by an ethics committee. Volunteers must be given full information about the nature, significance, and risks of the trial. Consent should be obtained only after volunteers have been given time to consider all implications, and after understanding has been demonstrated. Participants must be advised of their right to withdraw at any time without detriment to themselves, or their future care. Good practice requires that participants are informed of the results of the study.

Several concerns were initially raised on the draft of the Directive.[11,12] The draft was fundamentally

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based on the model of commercial trials whereby an industrial company assumed the role of a sponsor in the development of a new and innovative product. In this model, a single identifiable sponsor would accept full responsibility and liability for adverse events. This paradigm did not fit easily with the collaborative approach of trials undertaken within the NHS in research partnerships. In particular, small non-commercial researchers who had neither the infrastructure to discharge such responsibilities nor the resources to meet potential liability, might have been disadvantaged and consequently marginalised due to high costs and the burgeoning bureaucracy involved in undertaking trials. Many interested parties believed that the increasingly rigid approach to the requirements of monitoring and pharmacovigilance, for new as well as established products, could seriously threaten academic and investigator research, and in response, the 'Save European Science Campaign' was launched to protect smaller investigators.[13] However, the arguments mounted by the UK and other Member States were taken on board. The amended Directive (brought into effect as the Medicines for Human Use (Clinical Trials) Regulations 2004) allows for the role of sponsor to be divided, which recognises the reality that, in the UK, publicly funded research is typically supported by a collaboration of interests. However, what is now required is a more explicit and formal distribution of the responsibilities of the sponsor.

Although the Medicines for Human Use (Clinical Trials) Regulations 2004 governs the design and conduct of clinical trials, research in general is governed by, *inter alia*, the common law principles of battery, consent and negligence. As far as consent is concerned, by law a person cannot consent to the infliction on himself of grievous bodily harm or his or her own death.[14] The level of risk involved in any research project must be ascertained prior to commencement. Guidance on this matter has been provided by interested parties. The Royal College of Physicians[15] has delineated different categories of risk for research and suggests that participants should only be enrolled where the benefit outweighs any potential detriment. Consent based upon adequate information with understanding is an essential prerequisite, whatever the level of risk involved. In the event of litigation, it would be a matter of evidence as to how much information had been provided to the participant. In determining whether the standard of care has been breached in an action framed in negligence, it is likely that a more objective stance will be taken rather than a deferential reliance on the traditional *Bolam* test.[16] Furthermore, recent case law has indicated that failure to warn about a risk (even one that is inherent and may materialise without fault or negligence) can lead to liability in law.[17] Whether these principles of clinical negligence might apply to injury or damage occurring as a result of participation in a research project remains to be tested in court.

The implementation of the Data Protection Act 1998 has also had an impact on research. Although the Act does not prohibit access to medical data for research by investigators, in practice data custodians are extremely circumspect about providing such information.[18] This reticence poses a potential threat to *bona fide* data collection, and a balance needs to be achieved between the need to safeguard patient confidentiality and the legitimate interest of public health research.[19] The use of routinely collected health data is regulated by Section 60 of the Health and Social Care Act 2001. Under this section, the prior permission of the Patient Information Advisory Group is required for medical researchers to access individual records without the informed consent of patients. The use of data for audit purposes, however, is not regulated by Section 60. This raises the concern as to whether specific types of research could slip through the regulatory safeguards under the guise of 'audit',[9] and anecdotal evidence suggests that this does happen. Research involving human tissue raises complex issues,[20] and researchers need to be aware that breach of the provisions of the Human Tissue Act 2004 (when brought into force) could lead to criminal liability.

Whilst statute has remained mainly silent on the matter of medical research involving humans, several internationally recognised ethical codes are in existence.[21] The first was the Nuremberg Code, which was created as a direct result of the war crime trials. The Code was consolidated into the Declaration of Helsinki drawn up by the World Medical Association in 1964, and revised in 2000. The Medical Research Council has published a comprehensive set of guidelines based on this Declaration. Doctors involved either in commercial or non-commercial research must also abide by GMC guidance in order to demonstrate responsible practice.[22] The ethical framework is designed to protect persons from the hazards of experimental treatment, although in certain situations, such as pandemics, an ethical issue that emerges is whether the magnitude of societal threat could be sufficient to justify relaxation of normal controls. Under such circumstances, could a refusal to participate based on personal autonomy be overridden by the 'greater good' for society? A further question that arises is whether information obtained from 'unethical' research should ever be used for the benefit of society. A typical example concerns data on paediatric hypothermia obtained from the victims of concentration camps during the Second World War. Ethical issues in medical research raise profound and disturbing questions that do not have easy answers.[23]

Ethics committees

The relative paucity of legal guidance, as well as the pointed nature of the ethical issues involved, have led to the belief that the vetting of projects by 'ethics committees' might offer a possible solution as to what constitutes quality research. Clinical ethics committees were introduced over three decades ago in the USA. To date, there has been no robust evaluation of their efficacy[24] and the added value to research has been questioned. It has been suggested that the bureaucracy attendant on obtaining ethical approval could adversely affect and even hinder medical research. Furthermore, it is possible that modifications to study design required by ethics committees could distort methodology to the extent that conclusions may be flawed.[25] There is also a tension between the need to comply with the protection of individuals' confidentiality while allowing sufficient access to medical information for epidemiological research.[26]

Since March 2004, the prior approval of the new Central Office for Research Ethics Committees (COREC) has become a mandatory requirement for research projects in the UK.[27] This has greatly increased the bureaucracy, time and effort required to submit an ethics application,[28] and ethics review has become complex and lengthy.[29] Any change to a protocol (however minimal) requires a further review, which may add to time and expense.[30] Certain categories of research study are likely to be more affected. For example, individual clinician research that involves the study of rare conditions falls uneasily between clinical investigation (which may not require ethical approval) and a research project that would need evaluation by an ethics committee.[31] Ethical standards are an essential requirement for all clinical research, but the idea that 'one size of ethics review fits all types of evaluation' is not tenable.[32] The level of detail and stringency required by an ethics committee should be proportionate to the type and nature of research for which approval is being sought. It must also be remembered that interdisciplinary research that crosses the boundaries of social and health care may present a unique set of issues that may not be covered by a traditional approach to clinical investigation.

Many of the dilemmas involved in ethical review of human research depend upon what would be acceptable to society, and can only be informed by intelligent public debate.[33] Ethics committees have done little to canvas public opinion on a wider scale. However, what has been achieved is harmonisation of the process of obtaining ethical approval through the introduction of a single review process and application form (although some might argue that this serves only to obfuscate and further complicate matters). Comprehensive advice needs to be taken when planning research, and when in doubt help should be sought.[33] It has been suggested that the concept of a 'local' ethics review is otiose, as the division between 'local' and 'central' ethical issues is arbitrary. Although local matters of contention could be addressed within the broader framework of research governance,[34] this would not have the advantage of an independent local lay voice, which in some instances could be invaluable.

Key Points

- **Medical research should be subject to quality assurance in order to meet contemporary professional, legal and ethical requirements**
- **The legal framework for research on humans is based on common law principles, and there is a paucity of statutory guidance**
- **The European Union Clinical Trials Directive aims to harmonise the regulation of clinical trials and to protect the interest of study participants**
- **A mandatory requirement for research projects in the UK is approval by the Central Office for Research Ethics Committees (COREC)**
- **The framework for research governance aims to improve quality whilst safeguarding the interests of the public**
- **Researchers need to be aware of their responsibilities under these new initiatives and NHS organisations need to make a serious commitment to facilitate a culture of high-quality research in the NHS**

The framework for research governance

Since April 2004, a framework has been introduced for all research that takes place on NHS premises or uses NHS patients, staff or resources.[35] The purpose is to ensure that systems are in place to safeguard those who participate in research, and to harmonise good practice. The aim is to promote a high-quality research culture, monitor performance and adverse incidents, and delineate lines of responsibility and accountability. The ambit of the framework is wide and includes research relating to public health, research by the Department of Health, social services, industry, charities, research councils and universities. Although the same standards are to apply across the board, there is a sensible caveat that for projects involving a lesser degree of risk, professional judgement and discretion would suffice.

Within the framework, the essential standards of a high-quality research culture include, *inter alia*, respect for participants' autonomy, safety, scientific integrity, accountability and management of research, staff training as well as explicit written procedures. Consent based upon information, vulnerable participants, and research involving tissues and organs have been stressed as being particularly pertinent matters to be taken into consideration. There is a need to comply with data protection and to maintain participant confidentiality. All health and social care research must be subject to independent expert peer review. Approval procedures must necessarily take into account the scientific quality of the project, as well as the capacity and experience of researchers to complete the project. Ethics approval prior to commencement is mandatory, and the responsibility for monitoring research lies with the sponsors but may be delegated to the trust that employs the researcher.

The framework is complex in its detail, and compliance has several implications. There is likely to be a substantial impact on resources in order to comply, including the need for training, appraisal, support and robust information systems. Other essential ingredients include monitoring, inspection, audit, risk management and continuous evaluation. Bodies charged with overarching responsibility to inspect and improve include the National Patient Safety Agency and the Healthcare Commission. Failure to comply may attract sanctions through local and professional regulatory bodies and there could be criminal sanctions for breaches relating to human tissue research.

Implications for researchers

It is expected that researchers in the health and social care services should conduct work that meets the highest ethical and quality standards. Investigators have always taken their role seriously and have reflected on the ethical dimensions of their work.[36] The legal requirements of the European Directive and National Standards of the Research Governance Framework can

seem bewildering. Researchers need to be assisted in navigating through the new legal and bureaucratic maze. The expansion in the volume of paperwork necessary to comply with the regulatory requirements makes it difficult for the average clinician to undertake research without adequate support.[37] There is a need to generate a climate that is sympathetic to research and allows protected time within job plans.

Good planning is essential if a researcher is to complete a project successfully. Those supervising research need to be aware of their responsibilities. Researchers, particularly students, should be informed at an early stage about research governance in the NHS. A number of initiatives might promote this.[38] Research governance should be included as part of an introductory module, and several universities already conduct courses that offer practical advice and training. Some universities and trusts are in the process of creating research governance implementation groups. A research governance lead might assist in coordinating the various responsibilities of those conducting research, in implementing appropriate standards, in monitoring the progress of research and managing complaints. Trusts must make a serious commitment to create a culture conducive to research of the highest ethical and scientific quality. Ring-fenced funds and dedicated training resources are required in order to equip investigators with the necessary competence for research in the modern NHS.

Conclusion

The scientific community has a responsibility to be accountable and transparent to the public, patients and healthy volunteers, who have all supported medical research with trust and goodwill over a number of years. Research governance sets the standards for high quality research that operates within such a framework of accountability. Governance ensures public confidence and augments benefits from research, and in our view represents one facet of a wider professional regulatory framework.[39] The Gordian knot of bureaucracy should not be allowed to stifle research. The challenge that lies ahead is to protect the safety of volunteers through governance and accountability while ensuring that research continues to inform medical advances with relevant and reliable data.

Research is an intrinsic component of our healthcare system, and not just an optional 'add-on'. Publicly funded clinical investigation undertaken by researchers within the NHS has always been an asset that should be continued and nurtured. The ability to conduct research is an integral part of providing high quality health services. If innovative treatments cannot be developed and evaluated rigorously, the quality of clinical care will inevitably decline relative to best practice.

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References

1 www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/
2 Halligan A, Donaldson L. Implementing clinical governance: turning vision into reality. *BMJ* 2001;**322**:1413–17.
3 Wingfield K, Ormond-Walshe S, Ray S. Risks in the advancement of medicine. *New Law J* 2002;**152**:325–6.
4 NHS Executive West Midlands Regional Office. *Report of a review of the research framework in North Staffordshire Hospitals NHS Trust* (Griffiths Report). Leeds: NHS Executive, 2000. www.doh.gov.uk/wmro/northstaffs.htm
5 Hey E, Chalmers I, Griffiths R, Stacey T, Struthers J. Investigating allegations of research misconduct: the vital need for due process. *BMJ* 2000;**321**:752.
6 Smith R. Babies and consent: yet another NHS scandal [editorial]. *BMJ* 2000;**320**:1285–6.
7 Ferriman A. Consultant suspended for research fraud. *BMJ* 2000; **321**:1429.
8 Dyer C. Consultant struck off over research fraud. *BMJ* 1997;**315**: 205–10.
9 Lock S, Wells F. *Fraud and misconduct in medical research.* London: BMJ Publishing, 1996.
10 Wells FO. Ethical issues in the pharmaceutical industry. *Br J Urology* 1995;**76**(Suppl 2):41–7.
11 Woods K. Implementing the European Clinical Trials Directive. *BMJ* 2004;**328**:240–41.
12 Mayor S. Squeezing academic research into a commercial straitjacket. *BMJ* 2004;**328**:1036.
13 Moulton B. Save European Research Campaign. *BMJ* 2004;**328**:286.
14 AG's Reference Case No 6 of 1980 [1981] 2 All ER 1057, R v Brown [1994] 2 All ER 75.
15 Royal College of Physicians. *Research involving patients.* Report of a Working Party. London: RCP, 1990.
16 Samanta A, Samanta J. Legal standard of care: a shift from the traditional *Bolam* test. *Clin Med* 2003;**3**:443–6.
17 Samanta J, Dunford R, Samanta A. Chester v Afshar: implications for clinical negligence. *Health Care Risk Report* 2005;**11**:22–3.
18 Peto J. Data protection, informed consent, and research. *BMJ* 2004; **328**:1029–30.
19 Wanless D. *Securing good health for the whole population.* Final report, 25 February 2004. www.hm-treasury.gov.uk/consultations_and_legislation/wanless
20 Samanta A, Samanta J, Price D. Who owns my body - thee or me? The human tissue story continues. *Clin Med* 2004;**4**:327–31.
21 Stauch M, Wheat K, Tingle J. *Sourcebook on medical law*, 2nd edn. London: Cavendish, 2002.
22 General Medical Council. *Research: the role and responsibilities of doctors.* February 2002. www.gmc-uk.org/standards/research.htm. Accessed 27/01/2005
23 Mason JK, McCall Smith RA, Laurie GT. *Law and medical ethics,* 6th edn. London: Butterworths, 2002.
24 Saunders J. Developing clinical ethics committees. *Clin Med* 2004; **4**:232–4.
25 Warlow C. Clinical research under the cosh again. *BMJ* 2004;**329**:241–2.
26 Ward HJT, Cousens SN, Smith-Bathgate B, Leitch M *et al.* Obstacles to conducting epidemiological research in the UK general population. *BMJ* 2004;**329**:277–9.
27 Central Office for Research Ethics Committees. *The ethical governance and regulation of student projects: a proposal.* London: COREC: January 2004. Accessed at www.corec.org.uk/applicants/index 16 December 2004.
28 Wald DS. Bureaucracy of ethics applications. *BMJ* 2004;**329**:282–4.
29 Jamrozick K. Research ethics paperwork: what is the plot we seem to have lost? *BMJ* 2004;**329**:286–7.
30 Jones A M, Bamford B. The other face of research governance. *BMJ* 2004;**329**:280–1.

31 Parker M, Ashcroft B, Wilkie AOM, Kent A. Ethical review of research into rare genetic disorders. *BMJ* 2004;**329**:288–9.
32 Glasziou P, Chalmers I. Ethics review roulette: what can we learn? *BMJ* 2004;**328**:121–2.
33 Pattison J, Stacey T. Seeking a balance: response from the Department of Health and COREC. *BMJ* 2004;**329**:622.
34 Wainwright P, Saunders J. What are local issues? The problem of the local review of research. *J Med Ethics* 2004;**30**:313–17.
35 Research Governance Framework for Health and Social Care. www.dh.gov.uk – Second draft published April 2003.
36 Ferguson PR. Legal and ethical aspects of clinical trials: the views of researchers. *Med Law Rev* 2003;**11**:48–66.
37 Meredith S. Commentary: better support for investigators is essential. *BMJ* 2004;329:285.
38 Soteriou P, Hek G. Research governance and students: what are NHS Trusts looking for? *Nurse Researcher* 2004;**11**:22–31.
39 Samanta A, Samanta J. Regulation of the medical profession: fantasy, reality and legality. *JRSM* 2004;**97**:211–18.