

Research governance—the NHS perspective

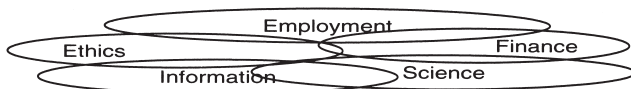
Marc Taylor

Head of NHS Research and Development Policy

When researchers crossed pigs with jelly fish to produce fluorescent coloured animals, they explained their work as contributing to xenotransplantation. But this sort of research plays to the popular notion that science is the province of boffins who are slightly mad.

Research governance, on the other hand, aims to ensure that science is carried out by people operating in supported structures that reflect the corporate responsibility of the organisations for which they work for. And there are usually several organisations involved.

In 2001 the government published a research governance framework, of which there will shortly be a second edition (*Research Governance Framework for Health and Social Care*). Research lies at the centre of several related domains of governance:



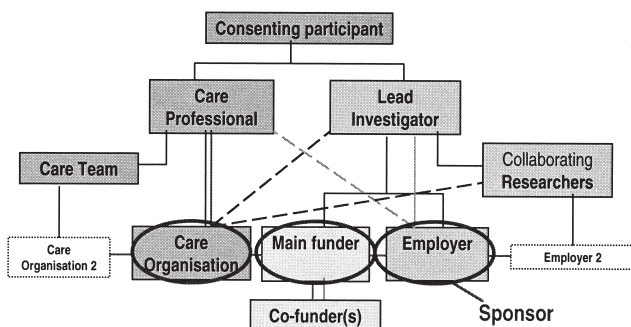
There should be systems of governance for all of these areas of activity, so that everyone knows what they are supposed to do, how they might support one another, and what might happen when the systems fail. These overlap in research governance.

In each of these areas are individuals with individual and corporate responsibilities that need to be clearly defined.

The need for a guarantor

The following schema describes the relationships between the NHS and research. On one side are the responsibilities of the NHS towards patients and on the other, the scientific chain of responsibility.

Roles in NHS research governance



Research and Development: Knowledge for Health and Social Care

This includes the implicit bargain between patients who agree to expose themselves to a certain amount of

risk when taking part in research and those who say that they will manage that risk. They need to do this in a way that is well understood and well controlled, providing a benefit proportionate to the amount of risk taken, and which comes with guarantees of how all that will be achieved.

Who should take a lead in all of this and act as a guarantor? Is it the funder, the employer, or the lead carer organisation?

Our view is that it should be the person who is most immediately involved in initiating and managing the study. It could be one of a number of bodies. But someone needs to take overall responsibility for the integrity of what can be a complicated set of relationships.

What we are aiming for is a clear understanding of who is doing what and an understanding of the way in which quality systems fit together, with the responses proportionate to risk.

This looks very complicated, and it highlights risks that some find unacceptable. Equally, some might feel that it's an attempt to stifle research with bureaucracy. This would be the case if everyone set up their own systems, which duplicated everyone else's, rather than taking the view that that this needs to be collaborative.

Putting checks and balances in place

Over the past couple of years the NHS has been working to an implementation plan, which runs to the end of April 2004, the eve of the European Union clinical trials legislation. This is the time table:

- 2001: checking systems for ethical approval and permission in NHS bodies
- 2002: establishing local implementation plans for research governance
- April 2003: setting up a network of research management primary care trusts
- April 2004: no research and development involving patients, their tissues, organs, or data may start or continue until a sponsor has confirmed acceptance of responsibility
- April 2004: research governance becomes a controls assurance standard so that it can sit within NHS risk management and is referenced into CHI and performance management at strategic health authority level.

We are trying to embed research governance into the systems the NHS has for checking corporate responsibility. Otherwise there is the risk that we might

not be able to comply with the European clinical trials legislation in May 2004.

Research fraud needs to be positioned within this system of supportive relationships.

The starting point is a quality research culture. This culture requires visible research leadership and expert management.

We need a common understanding between the NHS and the universities that the lead investigator will guarantee the outputs and that the employer has a clear code of practice, with clear lines of delegation and appropriate supervision.

Funding bodies need to check the research team's experience and expertise, while the sponsor is responsible for checking the overall integrity of the whole project, before it starts, and once it is up and running.

Publications have an important role in independent review of outputs linked to systematic reviews.

Corporate responsibilities

Fundamentally, the employer is responsible for ensuring there are systems for detecting and addressing fraud and scientific misconduct by employees. These should be analogous to those for responding to other kinds of corporate risks.

This includes systems to detect failures, such as routine and random monitoring, audit, reporting, and whistle blowing.

There are several responses to failures, including retraction of published outputs. The reasons for retracting relate to different aspects of quality control, only some of which are to do with fraud.

The NHS has created some robust processes and bodies relevant to quality control. For example, the National Patient Safety Agency is looking at adverse events and systems failures, while CHI/CHAI reviews and inspects institutions and the Medical and Healthcare

Products Regulatory Agency (MHRA) inspects quality systems for trials.

Behind these are professional regulatory bodies and the NHS counter fraud service. And there is always the possibility that if we identify evidence of criminal activity, the counter fraud services could run an investigation and prompt a criminal prosecution.

However, normally, this would be an over reaction to misconduct. We think that we should be looking for a mechanism that supports the actors in the other parts of the system. And we are very interested in proposals that support employers, particularly in organisations with little practice in handling or public exposure to, misconduct.

The EU directive, which will take effect in May 2004, only deals with trials involving medicines for human use. But it defines new legal duties for sponsors, investigators, and research ethics committees. And it makes falsifying information a criminal offence.

In summary, although we don't yet have complete systems in place, we have made significant progress. We have the processes in hand to create some robust systems. And we need to see misconduct and fraud in that context.

Cases of misconduct undoubtedly damage the trust that the public has in the NHS. But we also need to keep a sense of proportion. When things go wrong because of bad science in the nuclear industry or in veterinary science, the impact on public health is likely to be greater than when researchers falsify numbers in medical research.

Michael Farthing wondered whether the processes and structures in the NHS for dealing with employees might play in to some national repository. The General Medical Council was also extremely experienced in handling cases of research misconduct, but only covered registered medical practitioners and focused on the severe end of the spectrum. "Many of us feel there is a lot of noise out there in the system that is not being picked up by the GMC."