MRC/Wellcome Trust workshop:

Regulation and biomedical research

13 – 14 May 2008

SUMMARY

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The human side of regulation

Regulation of medical research is necessary. It is important to protect the public against the risks of untested medicines and other technologies, to provide appropriate checks on commercial motives and scientists' interests, and to protect participants in research and the researchers themselves.

But regulation is also complex. There are difficult balances between public benefit and participants, patient and consumer risk, and many stakeholders making competing demands on regulators. There is potential for confusion, conflict and hindrance of the very processes that the regulations aim to assist.

Developing regulations for medical research has tended to be piecemeal, with overlapping and muddled remits. There is often an inappropriate approach to the risks involved, resulting in frustration among researchers and others, and inefficiency in the system. Scientists experience delays that hold up their research, and ultimately the development of therapies and other benefits for human health. They can feel negative emotions, such as irritation and demoralisation.

These feelings emerged in a workshop, sponsored by the Medical Research Council and the Wellcome Trust, in May 2008. The workshop participants – which included representatives from academia (including biomedical researchers and lawyers), industry, Government, UK and overseas regulators – spoke about their views of regulation, the problems associated with it and how they may be resolved.

At heart of the problem lie human personalities, emotions and uncertainty. Lack of communication between the various players, and the perception that rules are over-complicated and unreasonable, damage trust and confidence in the value of the regulations. It is this trust that needs to be restored.

Although it would be unrealistic, at least in the short-term, to change existing regulation in a fundamental way, regulators should aim to keep the regulatory burden to a minimum. What is needed is a clarification and – if appropriate – simplification of regulations, as well as a drive to improve communication and engagement with all concerned to justify the reasons for the rules' existence.

Clear and simple

Regulations are complex for several reasons. There is the complexity of the issues themselves, complexity of the language, and complexity in the way the regulations are designed and the process of implementing them.

Complexity of the issues cannot be avoided. Therefore the other complexities must be tackled. For a start, much legislation is drafted in a way that non-lawyers cannot readily understand.

Also, some regulation is not well-designed or well-implemented, a view that is held by the UK Government. The Better Regulation Executive (BRE), part of the Department for Business, Enterprise and Regulatory Reform (BERR), suggests that good regulation should be accountable, consistent, transparent, targeted and proportionate, and notes that some regulations do not meet all of these criteria.

The 'Better Regulation Task Force (BRTF)' – an independent body set up in 1997 to advise the Government on regulation – recommended that whenever a regulation is added, another should be removed. This principle is not being followed.

In many cases, there is a lack of understanding of risks associated with medical research. For example, the current regulatory regime does not currently take account of the substantial difference between research that involves an intervention on an individual, which has obvious risks for that person, and that which requires access to information from his or her tissue samples or records.

This absence of precision causes problems in the implementation of regulation. For example, under the Data Protection and the Health and Social Care Acts, there are serious hurdles for researchers in accessing patient records without their consent.

Poor design and implementation cause confusion and unrest. Researchers report feeling annoyed by what they see as 'constant trivia' brought up by regulators, and say they are exhausted by the effort required to deal with regulation. They also recount emotions of anger and disappointment at what they view as over-regulation, which forces researchers either to conduct substandard research with misleading results, or to give up research altogether. Scientists often believe that problems in regulation are insuperable.

We can learn positively about the design of regulation from other sectors. The Food Standards Agency, for instance, is a success because it has a clearly-defined remit, its processes are transparent and inclusive and it approaches regulation in an integrated way. For the regulation of the railways, there is a single regulator, which results in a process that is simple and direct.

Communication is key

Keeping researchers informed and helping them understand regulations will go some way in establishing trust and reducing anxiety. This we already do to some extent; the UK Clinical Research Collaboration (UKCRC), for example, makes existing regulations easier to navigate. The National Research Ethics Service (NRES) Integrated Research Application System (IRAS) is a single online facility that allows an applicant to enter information about a project once instead of duplicating information on separate applications forms.

Communication is vital because it is a way of addressing the interests of researchers, to prevent the inhibiting of research that may improve human health. It also helps researchers understand that they should not set their ideals too high and that medical research is often a small part a larger issue; for example, in the Mental Capacity Act or the Human Fertilisation and Embryology Bill (now Act).

Transparency is also of value to industry, which continues to work in the UK because of the strength of the life sciences but also wants and expects regulation to be consistent, proportionate and predictable.

Regulation tends to be more effective when it complements public opinion and support. It is therefore important to consult the public, whom regulation often exists to protect, and who have the weakest voice but may not readily complain. One approach may be to work with the media to encourage them to include more issues on regulation. There is currently a lack of evidence about how regulation affects trust and confidence among the public.

Communication between regulators and those who are regulated is essential, preferably in the early stages of the process of establishing legislation. For example, in the development of European regulation, UK Government and those regulated should become involved in the process as early as possible. Europe-wide bodies should aim to organise themselves rapidly at a relevant level to provide a unified position to influence the regulation.

A different attitude

At the root of regulation there must be trust. Trust stems from transparency, communication and the perception that the rules are realistic and related to the magnitude of risk.

With more trust, there is more compliance. Potentially, reviewing compliance can be very expensive for the regulator. If there is a higher level of trust between stakeholders, intensive reviews would not be necessary. Regulators could instead attempt random spot checks, tailoring their inspections to particular circumstances and in accordance to risk.

Finland has an effective regulatory process of medical research. It is simple and straightforward, and has one Act to cover all medical research. In the Nordic countries, there tends to be greater trust in authority and participation in research – so regulation can be less strict, but this may work in those countries because of their size.

Legislation should provide the incentive for the right kind of activities and not inhibit unnecessarily what it is designed to regulate. Once this is achieved, implementation should be effective, economical and efficient, inspiring even more confidence in the process. The optimal outcome is harmony between stakeholders and the protection in various forms that the regulators initially set out to accomplish, ensuring that health benefits become available to the public as quickly as possible.

10 February, 2009.