

# **Patient perspectives on the regulation and governance of medical research**

**An independent report by**

**The Association of Medical Research Charities (AMRC)**

**and**

**INVOLVE**

## **1. Background**

In March 2010 the Academy of Medical Sciences (AMS) was asked by the Department of Health to conduct an independent review of the regulation and governance of medical research <http://www.acmedsci.ac.uk/p47prid80.html>. The review is chaired by Sir Michael Rawlins and is likely to report early in 2011. In the course of its inquiry the panel invited AMRC and INVOLVE to hold a workshop which would provide an insight into patient perspectives on the conduct of research and associated regulatory issues. It was agreed that the conclusions of the workshop would be fed into the review and that AMRC and INVOLVE would separately produce an independent report of the event.

The half-day workshop was attended by thirty participants with a background of public involvement in research either as patients or in a more formal capacity. Further details on the programme and format for the workshop can be found in the appendix. In the report that follows, direct quotes from patients have been italicised. The results of a workshop exercise to prioritise actions in each issue area are contained in box-inserts.

## **2. Key headlines**

- Patients should be able to expect a National Health Service (NHS) in which research is seen as integral to the delivery of quality care
- Generating a national ambition and appetite for research should be seen as a whole system responsibility of the NHS, those who work in it and patients
- Patients should be placed at the centre of research and given a pivotal role in the shaping, conduct and scrutiny of health research activity and its regulation and governance
- Creating trust is key in engaging with patients and making them feel confident to participate in research

- Good communications and professional attitudes are fundamental to creating the right culture for research including issues around consent
- Regulation and governance should support and remove barriers to – not hinder - patient participation and involvement in health research
- Public involvement in the regulation and governance of research must be robust, well-informed and properly resourced
- Any move towards a single regulator must not be at the loss of expertise and experience that has been built-up within the existing regulatory system.

### 3. Key principles for the regulation and governance of medical research

Participants were asked to react to four draft principles for regulation then under consideration by the review:

**Principle One:** Safeguard the wellbeing of research participants

**Principle Two:** Enable high-quality medical research in the public interest

**Principle Three:** Be proportionate, efficient, co-ordinated and streamlined

**Principle Four:** Maintain and build confidence in the conduct and value of medical research through transparency, accountability and consistency

Those present broadly supported the principles. However, it was felt that they could be strengthened by the addition of a statement that presaged them with a clear explanation of the purpose and underpinning philosophy behind regulation:

*'Is it about doing the right thing, or doing it right, or both? It's like digging the moat inside the castle walls, or outside the castle walls. Digging a moat is the right thing to do but putting it inside the castle is totally ineffective – are we in danger of this? We don't want researchers to be regulating themselves.'*

A range of comments were made – and clarification sought - about the meaning of individual words or phrases in the principles and the order of the principles. These underlined the importance of each principle being explained in more detail if they were to avoid the charge of being *'motherhood and apple pie'* statements. For example, some participants expressed concerns that Principle Three could be interpreted in different ways and could be used to either undermine patient rights in the regulatory process or to support them, and Principle 4 was seen to be the most ambiguous, particularly the use of the word 'value'.

Surprise was expressed that none of the principles articulated why it was important to do research or the benefits of research to patients and quality care: *'we need to say: It's really good to do research – not just to find cures but to improve treatments.'* It was also felt that this was an important tenet on which to build public trust and confidence. A more aspirational and positive tone to the principles was therefore seen as vital to setting expectations around the culture necessary to improve the environment for health research.

The workshop expressed a strong preference in favour of the use of the term ‘health’ as opposed to ‘medical’ research: not only did it better describe the full range of research activity of relevance to patients, but it was felt that it was a term that would resonate more strongly with the public.

Attendees questioned the absence of a principle on ‘consent’ issues given its importance to patients and in recent public debate. Some felt that ‘transparency’ was deserving of a principle in its own right – *‘If you make mistakes, tell us – rather than protecting us from something we know nothing about.’*

‘Encourage,’ ‘facilitate’ and ‘protect’ were seen as the most important watchwords for any regulatory body or bodies charged with overseeing research.

The following issues were discussed in smaller groups:

#### **4. Creating the right culture for research to happen**

**An environment in which patients:**

- Can access a national health and research service
- Are seen as partners and treated with respect
- Will benefit from clinical practice where research is seen as integral

*‘It should be called the National Health and Research Service – not just health.’*

Unsurprisingly given the background and involvement in research of those taking part, there was unabashed support among those present for the need to champion research within the NHS, to communicate its value to patients now and in the future. This was seen as an important foundation on which to base an effective regulatory and governance framework. Indeed, there was frustration that the NHS has not been bolder or more upfront with patients about their important role in research which could ultimately lead to better care:

*‘Research needs to be a core part of the NHS and a routine part of any first appointment letter – the NHS approach should be anticipatory that patients will want to take part in research.’*

There was a strong desire for patients to be placed at the heart of the research endeavour:

*‘They should take the researcher away from the centre and put the patient at the heart of research.’*

## **The role of professional groups in shaping attitudes**

Discussion also focused on the role of different professional groups in influencing the attitudes of patients and the public towards research. It was commonly agreed that researchers often found it difficult, or are reluctant to, communicate with patients and those fulfilling a 'lay' role in the current system. Many were able to cite examples of this from personal experience:

*'As the lay chair of an ethics committee I needed to discuss an application with a researcher. I was told by his PA that he had said 'I don't talk to lay people – they don't understand research. When his application remained in the pending tray because he hadn't given me the information I needed he soon changed his mind.'*

Stronger opinions emerged in conversations about the role of healthcare professionals in general with many regarding them as not only poor communicators but also as being not 'particularly clued-up' on research that could be relevant to their patients. It was generally held that some doctors and health care managers saw research as a burden and not as a routine part of healthcare;

*'We do research because that's how you get better treatment. I'd like to see that carved in stone above every hospital door.'*

## **Patients as partners**

People were acutely aware of the dangers of shifting the balance too far towards a scenario in which researchers felt that they were being watched over by a 'patient police force.' But it was felt by many that paternalistic attitudes towards patients persisted within the medical community and particularly when it came to research.

A common thread running through group discussions was to reach a position in which patients were seen as partners:

*'We need common sense. Patients are partners in care and want to work with medical professionals to get the best from healthcare. We need to shift away from the paternalistic approach of the old days – patients know a lot more now.'*

Some groups went so far as to explore possible models in which this partnership could grow including 'multi-stakeholder groups' being initiated that would not only help to set research priorities but also help to ensure translation and break down professional boundaries and cultural barriers at key points.

## **Communication**

Communications was seen as critical to helping forge partnership with workshop participants identifying three possible foci for such work:

- Encouraging new participants in research through success stories, accurate reporting and clear information
- Celebrating examples of the partnership where and when it occurred

- Ensuring that patients who took part in clinical studies received feedback and information about the study and what it had found after its conclusion.

However, participants did not see this communication role as the function of regulatory agencies alone but as a ‘whole system’ responsibility.

*‘NHS Choices should be telling stories of NHS research. It should be their role to help the cause of research.’*

## 5. Use of patient data and tissue for research purposes

### **An environment in which regulation:**

- Supports and removes barriers to patient recruitment to, and participation in, clinical research
- Supports the work of its partners in providing opportunities for patients to proactively come forward and take part in research.

It was generally agreed that patients should have the right to be informed about research opportunities but that they should be able to opt-out of the research arena if they wish to do so.

Discussion about the degree of knowledge required by a patient to make such a decision was inconclusive. Nonetheless the opportunity to make a ‘choice’ either way was seen to be fundamental and in the interests of both research and patients:

*‘Don’t assume that I’ll be too stressed out post-op to be asked about donating my tissue.’*

Many participants were able to give examples of websites and registers where patients can actively pursue research opportunities and it was agreed that charities, patient groups and ‘honest brokers’ might be helpful routes to keeping patients informed about research. However, until there was a change in NHS culture and associated professional attitudes the onus would continue to be on patients to find their own way.

On the specific issue of use of patient data for research purposes – and given that many of those at the workshop had been involved in one or more consultations on the subject – there was a sense of ennui that policy and practice remained unclear and that patients continued to be in the dark about either the benefits, the process for collecting and using such data, or particular provisions governing consent.

The group readily recognised that a massive amount of data is already used in research but emphasised that the key consideration for patients would continue to be whether their data is anonymised or identifiable. Views about the use of identifiable data varied but consent was seen as a given, supported by simple guidelines and clear information about how data is accessed, by whom, how it is managed, and how it is kept secure.

*'It would be damaging if people thought that there was a cavalier attitude to the use of tissue or data, you know, 'give it here and off we go.' Good communications and a professional attitude to consent are vital.'*

## 6. Public involvement in the regulation of medical research

### **A regulatory system in which public involvement is:**

- Robust, substantial and informed
- Founded on clarity of purpose
- Properly resourced and funded

The general consensus of the workshop was that public involvement should be a key feature of how regulation is 'shaped' and how it is put into practice – 'scrutiny,' that it should permeate all aspects of the regulatory system. This put the onus on regulators to be clear about both its purpose and what it was expected to deliver. For participants the contribution of public involvement was articulated in terms of accountability, transparency, sharing and influence, insight and experience.

As regards high-level governance structures including the Board and sub-committees, proposals for the proportion of lay members ranged from 30-50%. People were cognisant of the need for such members to be able to demonstrate leadership, passion, experience and, above all, to be able to take an informed and broad view of matters:

*'We need to be taken seriously so we need to be careful to ensure that we're not recruiting lone guns with an axe to grind.'*

There was some - but not overwhelming support - for the suggestion that these members should be democratically elected and accountable. Charities and patient groups were seen as good routes by which to recruit suitable candidates although people felt it was important to look beyond obvious sources.

All agreed that *'getting the right people to do the right things on the board'* was a *'massive challenge'* and that lay members would need to be well-supported and given the right tools to do the job properly. Workshop participants hoped that some benchmarking of public involvement in other regulatory agencies would be conducted to identify the right approach for research regulation.

## **A single research regulator**

People were cautious about proposals for a single research regulator. While able to see the rationale for such a move, people expressed concern about the risks of losing the expertise and experience that had been built-up by existing regulatory agencies. It was felt that it would be important to map generic areas of regulation and those that required a more specialised approach with the structure designed around this.

## **7. Concluding statement**

AMRC and INVOLVE welcome this opportunity to build on their previous submissions to the Academy of Medical Sciences' review with this workshop. We believe it provides a useful insight into how health research and its regulation is viewed by patients and the public. Nonetheless there is no doubt that the evidence base in this area needs to be strengthened. We hope that this will be achieved experientially through a strong commitment to public involvement in the regulatory system as it unfolds, but also by proactive engagement with the public on the benefits of research by all those who have a part to play in its advancement.

*AMRC and INVOLVE would like to gratefully acknowledge the Academy of Medical Sciences' financial contribution to this project.*

## **Appendix One – About AMRC and INVOLVE**

**The Association of Medical Research Charities (AMRC)** is a membership organisation of the leading medical and health research charities in the UK. Working with our member charities and partners, we aim to support the sector's effectiveness and advance medical research by developing best practice, providing information and guidance, improving public dialogue about research and science, and influencing government. [www.amrc.org.uk](http://www.amrc.org.uk)

**INVOLVE** is a national advisory group which supports greater public involvement in NHS, public health and social care research. INVOLVE is funded by the National Institute for Health Research (NIHR). [www.invo.org.uk](http://www.invo.org.uk)

## **Appendix Two – Workshop Programme and Questions**

### **AMRC and INVOLVE Research regulation workshop**

**@ NCVO, Regent's Wharf, 8 All Saints Street, London N1 9RL**

#### **Programme and additional Information**

**Tuesday 2<sup>nd</sup> November 10.00am – 1.45pm**

#### Programme

##### ***Introduction***

- 10.00am: Arrival and coffee
- 10.15am: Chair's Welcome  
*Simon Denegri, CEO, AMRC*
- 10.20am: Introduction: The Academy of Medical Sciences review of medical research and emerging themes  
*Rachel Quinn, AMS review Secretariat*

##### ***Discussion***

- 10.40am: Principles for a regulation and governance framework
- 11.00am: Breakout group discussion of Topic 1
- 11.40am: Refreshment break
- 11.50am: Breakout group discussion of Topic 2
- 12.30am: Breakout group discussion of Topic 3

##### ***Conclusions and summary***

- 1.10pm: Conclusion and next steps over lunch  
*Sarah Buckland, Director, INVOLVE*  
*Genevra Richardson, AMS review Working Group*
- 1.45pm: Close

## **Background information and points for consideration**

### **Introduction**

A regulation and governance framework for medical research is necessary to protect the public against the risk of untested medicines and other technologies, to provide oversight of researchers conduct in academia, universities and the public sector, and to protect participants in research, society, and the researchers themselves.

The type and number of regulatory and governance checks and assessments required to initiate a study depend on the nature of the study being undertaken. Any study that is defined as research under the Department of Health Research Governance Framework must obtain ethics approval and NHS Trust R&D permission. Additional authorisation, approvals or licenses may be required for certain types of studies, for example, clinical trials of investigational medicinal products require clinical trial authorisation.

Please see Annex for a diagram depicting the current regulatory and governance framework.

The Academy of Medical Sciences was asked by the Department of Health in March 2010 to review the regulation and governance of medical research in the UK and identify opportunities to enhance and streamline the current pathway, while ensuring the protection of the safety of research participants.

Multiple advisory and regulatory bodies have a role in the regulation and governance of medical research, many of which were included in the Department of Health's review of Arm's-Length Bodies in July 2010. The Department of Health proposed that the research approval functions of bodies included the National Research Ethics Service; Human Tissue Authority; Human Fertilisation and Embryology Authority be brought into a new single research regulator. In response the Academy of Medical Sciences has collected evidence on the proposal for a single research regulator as part of the review.

The review is being undertaken by a Working Group chaired by Sir Michael Rawlins FMedSci and is intended that the findings will be published at the turn of the year.

Further information on the review and emerging recommendations will be presented at the meeting. Throughout the evidence submitted to the Academy, many organisations and individuals outlined the importance of patient and public involvement. The topics that have been chosen for discussion at this meeting represent those issues that came through as priorities in the evidence.

## **Discussion**

### **Principles for a regulation and governance framework**

As part of the review the Working Group is developing a set of principles that they feel should underpin the regulation and governance of medical research. We have included a draft version of these principles below:

#### **The regulation and governance of medical research should:**

**Principle One:** Safeguard the wellbeing of research participants

**Principle Two:** Enable high-quality medical research in the public interest

**Principle Three:** Be proportionate, efficient, coordinated and streamlined

**Principle Four:** Maintain and build confidence in the conduct and value of medical research through transparency, accountability and consistency

#### **Questions for consideration:**

- How do you interpret these principles –e.g. what does ‘wellbeing’ mean to you?
- Do the principles reflect what you feel should be the priorities underpinning how we regulate medical research?
- Do you have any comments on or examples of where the current regulatory and governance framework meets/or does not meet these objectives?
- Are there any principles that should inform and be applied to the regulation and governance of medical research that you feel are lacking?

#### ***Topics for breakout sessions***

During the breakout sessions we will be asking participants to consider Topics 1-3. We will provide further information on the day relating to the evidence the review has received to inform the discussion.

The topics are listed below together with some questions for consideration.

#### **Topic 1: Culture of research**

The review has received evidence highlighting the importance of embedding a culture of research in the NHS.

- How important do you think medical research is and why?
- What is your experience of the attitude and approach of patients, healthcare professionals (GPs, consultants, nurses etc), approving bodies (e.g. ethics committees), pharmaceutical companies and researchers towards research?

- How, when and by whom do you think information on research is best communicated to patients and the public? Is this the same for different types of research e.g. clinical trial vs population study and different clinical conditions e.g. cancer vs diabetes?
- Research is dependent on the involvement of the public, patients, research funders, clinicians, industry, government and regulators. What do you feel are the different roles and responsibilities of these groups in enabling an appropriate culture and attitude towards research?

### **Topic 2: Use of patient data and tissue for research purposes**

The review has received evidence that indicates there are regulatory and governance complexities to accessing patient data for use in medical research, whether in population studies or to identify eligible participants for clinical trials.

- There is a commitment in the NHS Constitution that all patients should have the right to be informed about research opportunities. Do you think that this is an important patient right – and if so how should it be enabled?
- What do you feel are the key issues for patients when considering the use of patient data or tissue in medical research (e.g. consent)? How could they be addressed within the regulatory and governance framework?

### **Topic 3: Patient and public involvement in the regulation of medical research**

The review received evidence that outlined the importance of patient and public involvement in the regulation and governance of medical research. It will be important to consider this role in respect to the proposal for creating a single regulator of research.

- What role should patients/public have in decisions relating to the regulation and governance (please refer to Annex) of research? For example, should the role be in shaping the regulation and governance pathway or in scrutinising? At what stage is that role most crucial?
- Are there any areas of research that you feel require more public confidence in their regulation and governance? How might this be achieved.

