

clarifying, agreeing, and safety-netting are the ones I most often use, but when I'm conscious of a consultation going wrong, the problem usually lies deeper. You only have to ask: 'Do I give patients who irritate me a worse deal?' to appreciate the importance of attitudes in human communication. But do attitudes determine skills, or can attitudes be forged by attention to skills? It's an ancient debate, neatly articulated by Skelton.

Innes completes the triad of communication papers with an application of chaos theory to complex consultations. It's a deep and thoughtful approach, which brings us neatly in where we started:

*'For too long, the medical process has been presented as one based on predictability and certainty, a presentation supported by the myth of physician supremacy and the power of modern medicine ... The "necessary fallibility" that arises from the complexity of individuals and health has been largely ignored'.<sup>12</sup>*

Innes believes that by viewing the consultation as a complex adaptive

system, 'it increases our understanding of uncertainty and unpredictability'.

The challenge is how to communicate this understanding. GPs are already very adept at 'hedging'. Many consultations can be reduced to the sentence, 'I'm not entirely sure what the diagnosis is, but I'm fairly certain it's nothing too serious', but as nurse practitioners filter out more straightforward problems, GP consultations are becoming increasingly difficult. In addition, we have to assimilate the twin political pressures of a very computer-driven, disease-based style of practice with offering patients myriad choices that they may not want. If communication research and teaching are going to be useful and relevant, we must move on from simplistic skills and get real about the complex politicised chaos facing frontline GPs and patients.

#### PHIL HAMMOND

GP Returner  
St Augustine's Practice, Keynsham

#### REFERENCES

1. O'Neill O. *A question of trust: The BBC Reith Lectures 2002*. Cambridge: Cambridge University Press, 2002.
2. Mendel D. *Proper doctoring*. Berlin and New York:

Springer Verlag, 1984.

3. Balint M. *The doctor, the patient and the illness*. London: Pitman Medical, 1957.
4. Blau JN. Clinician and placebo. *Lancet* 1985 **i**: 344.
5. Salford Royal Hospitals Trust. Trust Policy on Informed Consent 2002. In: Tallis R. *Hippocratic oaths: medicine and its discontents*. London: Atlantic, 2004.
6. Holloway R. *Godless morality: keeping religion out of ethics*. Edinburgh: Canongate, 1999.
7. Tallis R. *Hippocratic oaths: medicine and its discontents*. London: Atlantic, 2004.
8. Department of Health. *Building on the best: choice, responsiveness and equity in the NHS*. London: HMSO, 2003.
9. Edwards A, Elwyn G, Wood F, *et al*. Shared decision making and risk communication in practice: a qualitative study of GPs' experiences. *Br J Gen Pract* 2005; **55**: 6–13.
10. Skelton JR. Everything you wanted to know about communication skills. *Br J Gen Pract* 2005; **55**: 40–46.
11. Silverman J, Kurtz S, Draper J. *Skills for communicating with patients*. Abingdon: Radcliffe, 1998.
12. Innes A. Complex consultations and the 'edge of chaos'. *Br J Gen Pract* 2005; **55**: 47–52.

#### ADDRESS FOR CORRESPONDENCE

##### Phil Hammond

St Augustine's Surgery, 4 Station Rd,  
Keynsham, Bristol BS31 2BN  
E-mail: phammond@doctors.org.uk

## Ensuring that research governance supports rather than stifles research

A research governance framework was introduced in 2001 and updated in 2003 to ensure 'high scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements for research taking place within the NHS'.<sup>1,2</sup> The overall aim is to improve the quality of research and protect the public while minimising bureaucratic processes.<sup>3</sup> However, the haphazard application of the laudable aims of the framework risks having the opposite effect and bringing multicentre research to its knees.

Anyone intending to conduct research in primary care must obtain permission from

the primary care trusts (PCTs) in which the research will take place. PCTs have a responsibility to maintain records of all research being conducted in their area and to ensure that it meets the defined standards. In particular, all research must have ethical approval, be peer reviewed and have a defined sponsor who takes ultimate responsibility for its quality.

Ensuring the quality of research is clearly vital. But a well-intentioned policy has been implemented in PCTs with little experience of hosting research, by staff who are inadequately prepared and may have other priorities, against a backdrop of complex legislation, with often chaotic results. Although researchers have

repeatedly complained about the difficulties of obtaining ethical approval,<sup>4</sup> our recent experience suggests that this is now relatively straightforward compared with obtaining research management and governance (RM&G) approval.

In order to conduct a national postal survey of GPs, for example, it is necessary to seek approval individually from every PCT in England. RM&G contacts are often difficult to identify and there is a lack of consistency between PCTs regarding the documentation they require. The volume of paperwork, from the researchers' point of view, is almost overwhelming. For one recent project we needed to send 44 different documents to

be considered by each PCT. Some PCTs require hepatitis B status checks, occupational health reports, or criminal record bureau checks for researchers without any apparent risk assessment having taken place, even (absurdly) for office-based staff who have no contact with patients and who never visit the area covered by the trust. Other PCTs wish to comment on protocols or patient information sheets that have already been subject to peer review and ethical committee consideration.

These problems have led to excessive delays. For example, in one recent study taking place in 120 PCTs, 42 sent approval within 2 months, but 39 took 6 months or more. Repeated telephone calls and reminders are often required. Common issues are confusion about data protection and a requirement that research staff apply for separate honorary NHS contracts in each individual PCT (despite official advice that this is not usually necessary).<sup>5</sup>

The consequences of this are serious for primary care research. It is now almost impossible to conduct national studies in primary care unless researchers have sufficient funding to employ an administrator for 6 months before the research begins. This adds considerably to costs for research funders, and the duplication of effort in PCTs across the country multiplies this waste of resources.

More importantly, the delays mean that some important research questions cannot be addressed. The evaluation of new models of care is obstructed because health service developments cannot be delayed for months waiting for research governance approval. Minimising the burden of research governance, for example, by choosing to recruit from PCTs with efficient approval systems, has become an important consideration in research design even though generalisability may suffer.

Fortunately, the NHS R&D Forum Primary Care Working Group is trying to address some of these problems and has developed an excellent website and guide for PCTs.<sup>6</sup> The recently released database of research governance contacts for all primary and secondary care trusts<sup>7</sup> will be an essential resource for researchers, although contact details are still missing

for more than a quarter of the trusts listed. The forum is also seeking to develop a national standard application form for research governance approval.

These developments are extremely welcome. However, from our perspective as researchers, further improvements are needed. Applications for research governance approval should be subject to the same 60-day time limit that applies to applications for ethical approval, and the two should run in parallel. Researchers should only need an honorary contract with one NHS organisation, unless there are clearly specified reasons for local variation. Requirements for criminal record or hepatitis B status checks should be standardised and dependent on risk, for example, direct patient contact. Data protection protocols for each study should be considered by one organisation on behalf of the NHS (perhaps via the multicentre ethics committee that approves the research). Individual PCTs hosting research would then only need to receive letters confirming that research sponsorship, ethical approval, data protection approval, and honorary contracts were all in place. They would also need a copy of the protocol and details of resource implications, to ensure patient care locally is not compromised. The administrative burden for PCTs and the delays for researchers would then be greatly reduced.

It is also important that possible grounds for refusal of permission to conduct research are clearly specified, with an appeal mechanism. Otherwise, there is concern that the emphasis on managerial approval may make it difficult to conduct research that asks awkward questions about fashionable ideas; this ability to question orthodoxy is one of the most important roles of researchers.

Finally, we would like to appeal for a sense of proportion in considering the risks and benefits of primary care research. A postal questionnaire survey of GPs does not carry the same risks as a randomised controlled trial of a new form of surgery, and GPs do not, in our experience, find it difficult to consign to the bin studies they do not wish to support.

The different groups involved in research — researchers, participants,

ethics committees, and PCTs through the research governance framework — may sometimes feel they are not pulling in the same direction. But they all share a common long-term interest in high quality research that brings benefits to patients. It is, therefore, very important to ensure that the research governance process supports rather than stifles research in primary care.

### CHRIS SALISBURY

*Professor of Primary Health Care  
Academic Unit of Primary Health Care,  
University of Bristol*

### BRENDA LEESE

*Reader in Primary Care Research  
Centre for Research in Primary Care,  
University of Leeds*

### RICHARD J McMANUS

*Clinical Senior Lecturer and Clinical Director of  
Midlands Research Practice Consortium  
Department of Primary Care and General  
Practice, University of Birmingham*

### REFERENCES

1. Department of Health. *Research governance framework for health and social care*. London: Department of Health, 2001.
2. Department of Health. *Research governance framework for health and social care*. [http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/ResearchGovernanceArticle/fs/en?CONTENT\\_ID=4002112&chk=PJlaGg](http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/ResearchGovernanceArticle/fs/en?CONTENT_ID=4002112&chk=PJlaGg) (accessed 1 Dec 2004).
3. Research and Development Directorate. *NHS permission for R&D involving NHS patients*. DH Gateway reference 2567. London: Department of Health, 2004.
4. Warlow C. Clinical research under the cosh again. *BMJ* 2004; **329**: 241–242.
5. Department of Health. *Guidance note on research governance and honorary contracts*. [http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/ResearchGovernanceArticle/fs/en?CONTENT\\_ID=4002301&chk=6paXea](http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/ResearchGovernanceArticle/fs/en?CONTENT_ID=4002301&chk=6paXea) (accessed 17 Nov 2004).
6. NHS R&D Forum. *Research governance documentation and information guide for primary care trusts*. <http://www.rdforum.nhs.uk/workgroups/primary/pcifoguide/introduction.htm> (accessed 17 Nov 2004).
7. NHS R&D Forum. Local R&D Links. <http://www.rdforum.nhs.uk/links/locallinks.htm> (accessed 17 Nov 2004).

### ADDRESS FOR CORRESPONDENCE

#### Chris Salisbury

*Academic Unit of Primary Health Care,  
University of Bristol, Cotham House,  
Cotham Hill, Bristol BS6 6JL.  
E-mail: C.Salisbury@bristol.ac.uk*