

SECTION FOURTEEN

RESEARCH GOVERNANCE AND RESEARCH IMPLEMENTATION

This section considers:

- the research governance framework within the PCT
- supporting and to monitoring the uptake of research in practice across all professional groups
- monitoring and reporting on the uptake of Nice guidance and the implementation of NSFs.

The requirements of research governance

The recent *Research Governance Framework for Health and Social Care* defines the steps that PCTs (and other NHS bodies) must take to ensure that any primary research activity in which their own staff or those of their constituent practices are involved is conducted in accordance with the highest standards of ethical and scientific probity. In commissioning care from other providers PCTs must also have explicit evidence that any research activity which involves their own patient population will equally conform to these standards.

'Research Governance

- Sets standards
- Defines mechanisms to deliver standards
- Describes monitoring and assessment arrangements
- Improves research quality and safeguards the public by:
 - enhancing ethical and scientific quality
 - promoting good practice
 - reducing adverse incidents and ensuring lessons are learned
 - preventing poor performance and misconduct
- Is for all those who:
 - participate in research
 - host research in their organisation
 - fund research proposals or infrastructure
 - manage research
 - undertake research.'

Department of Health, 2001

The care provided by the PCT and its constituent practices must be based upon reliable and robust evidence. To this end, the Board and PEC must assure themselves that appropriate steps have been taken to disseminate the outcomes of NICE guidance, and of key research findings, to clinical staff. They must also use evidence routinely as a basis for their professional judgement.

Additionally, a recently announced ministerial review will increase the focus upon the research and the learning capacity and agenda in primary care.

'Prominent among the issues that led to the announcement of the review was how, within the new NHS structure, PCTs could be supported to deliver on learning and research, while providing improved local patient care.

The review, which will be conducted during the course of 2003, will be linked to the activity of the National Primary and Care Trust Development Programme (NatPaCT).'

CEO Bulletin 145 Dec 2002.

Key learning from the pilot programme

Research governance had not, at the time of the pilot programme, received the systematic attention from many PCTs that it demands.

Equally, although all PCTs recognise the importance of ensuring that practice is based upon the best available research, even those that have systems in place to maximise access to clinical research have few mechanisms to effectively monitor its systematic impact upon, and implementation in, practice

The majority of the PCTs in the pilot programme found the issue of Research Governance and Research Implementation challenging. After Clinical Audit it was the most problematic of the 'technical components' of clinical governance, scoring 4.3 on the progress scale (range 2 to 6.2). The lowest overall score for any individual PCT response to a whole section was the 2.0 recorded for Research which reflected the difficulties faced by a new PCT that serves a deprived community and has inherited so daunting an agenda of crises and competing priorities that the Board and PEC have scarcely been able to register their duties and obligations in relation to research governance.

Generally the newer PCTs had struggled to come to terms with these issues scoring only 3.9 for this section compared with the 4.6 scored by more mature PCTs.

While most PCTs understood the overall duty to govern the primary research activities of their own or their contracted staff, few had undertaken a 'baseline measure' of existing activity or had appropriate systems in place to monitor and track compliance in relation to new research. Very few had recognised that their overall duty of care to their patient population required them to seek assurances from those from whom they commissioned care that appropriate research governance structures were in place to secure the probity of the treatment of their patients whilst in the care of this other organisation.

With a small number of exceptions, PCTs themselves had not yet become active in identifying research questions arising out of their public health or provider functions or in commissioning new research activities, although a far larger number supported the individual research interests of their own clinical staff.

No PCTs had developed explicit strategies and actions to promote Knowledge Management – a key issue given the overwhelming volume of national and international research that has relevance for one or other of the multifarious facets of primary care, although the overall function is likely to be more effectively and leanly managed via an emergent national strategy that is supported by a targeted dissemination programme.

While all PCTs recognised the importance of the research underpinnings of clinical practice, very few had systems and processes in place to monitor the extent to which current research evidence did inform and underpin practice, even where they had made significant efforts to secure access to research resources for their community staff. This reflects the generally low levels of direct accountability of clinical practice in primary care (see Section 11) and contributes to the difficulty that PCTs experience in generating robust evidence of the clinical effectiveness of practice (see Section 15).

Given the importance that the new Commission for Health Audit and Inspection attaches to the 'intelligent information' that should underpin judgement these issues merit the sustained attention of all PCTs.

The governance of new or existing research activity

Any investment of time or other resource in new research and development initiatives needs to reflect the clinical governance and organisational priorities of the PCT as well as the clinical and professional interests of individual staff.

In the light of the new requirements of Research Governance, the PCT Board and PEC needs to ensure that a systematic baseline measure is undertaken of existing and ongoing commitments to research projects (including those undertaken by GPs on behalf of drug companies or by staff as integral parts of education and training programmes) which involve:

- any of their own staff
- the commissioned time of GPs
- the commissioned time of staff employed by their constituent GP practices
- the commissioned time of community dentists, pharmacists or optometrists
- the PCTs patient population.

'All health and social care providers must have systems in place to ensure that they are aware of, and have given permission for, all research being conducted in or through their organisation, whether or not it is externally funded.'

Department of Health, 2001

REFLECTION

What evidence is there that the Board/PEC have considered the requirements of research governance? Has any action been taken?

This 'baseline measure' should enable the Board/PEC to assure itself that all such activity conforms to the standards established in the Research Governance Framework (RGF).

'Organisations providing care are responsible for ensuring that any research involving their patients, users and carers or staff meet the standards set out in this framework.'

Department of Health, 2001

Any decision to invest time and resource in new primary research activity needs to:

- ensure that the investment can be justified by reference to the PCT/local health economy's clinical governance priorities
- ensure compliance with RGF ethical and scientific standards
- ensure multi-professional involvement where this is appropriate
- confirm corporate ownership of the research process
- ensure corporate monitoring of progress and research products
- ensure that corporate action is taken (where appropriate) on findings.

'Proper governance of research is therefore essential to ensure that the public can have confidence in, and benefit from, quality research in health and social care. The public has a right to expect high scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements.'

Department of Health, 2001

Assuring the implementation of research in practice

In the last decades the NHS has invested heavily in primary research activities. It has also struggled to find ways to ensure that the findings of research are systematically and routinely used to inform clinical practice. CHI reviewers have expressed significant concern about the failure of a number of Trusts to disseminate national guidance promptly and effectively so that it can improve standards of practice.

This is neither a new nor a unique phenomenon. Despite some evidence that lemon juice could prevent scurvy, it was not widely 'prescribed' for nearly 200 years. In addition to ensuring sufficient vitamin C particularly in the naval diet, this treatment resulted in the sobriquet 'Limey' being applied to English sailors.

'In 1601 James Lancaster showed that lemon juice was effective, but it was not until 1747 that James Lind repeated the experiment, and the British navy did not fully adopt this innovation until 1795 (not until 1865 in the case of the merchant marine).'

Haines and Jones, 1994

A proliferation of new knowledge has resulted from the globalisation of health and the ease of disseminating information via new technology. As a result, professional staff – particularly those in primary care who have generalist responsibilities which cover the entire spectrum of health and illness topics – are faced with an even more daunting challenge if their practice is to remain up-to-date and evidence-based.

Dr David Sackett has calculated that, in order to keep abreast of the emerging body of new research findings, clinicians would have to spend every hour of every week reading and digesting the literature; this would leave them no time to engage in their core care tasks.

Systematic approaches to implementing the results of research can include:

- developing and implementing care pathways
- implementing national guidance and clinical guidelines through developing and implementing local clinical guidelines
- developing and implementing clinical protocols.

Staff at all levels must understand the need for any development and implementation to be robust and legally sound.

PCTs and other health providers must put in place processes and mechanisms that help to ensure that the results of robust and significant research studies are identified, flagged and made accessible to front line professional staff. These should be clearly differentiated from actions that have been shown to have little or no value.

'The challenge is to promote the uptake of innovations that have been shown to be effective, and to prevent the uptake of ineffective innovations.'

Haines and Jones, 1994

Efforts to ensure routine application in practice of outcomes from NICE, the Cochrane Studies and other key research sources demand the development of pro-active strategies which are themselves based on evidence of efficacy in terms of 'impact on practice'. The implementation of key research findings by all relevant clinical (and, where appropriate, management) staff must be kept under active review and must itself generate reliable and robust evidence that will stand the test of external scrutiny by CHI and the new CHAI.

As well as scrutinising the care provided by the PCT from this perspective, Boards and PECs need to ensure – through their commissioning arrangements – that the care provided on their behalf by another body is itself appropriately research-based.

REFLECTION

What evidence does the PCT have of the routine use of research in practice?

Targeted implementation of research in practice

The task confronting PCTs in generating robust evidence of research implementation in practice, within any defined time period, can be considerably eased if a number of Clinical Governance Priorities have been identified and explicitly owned within and across the PCT, with the SHA and, where possible, across the local health economy. Efforts to map, evaluate and implement new research findings can then be targeted and their impact evaluated and measured (see Section 8).

Research and research implementation must be considered by the Board and PEC in the context of, and as a key contribution to, the overall clinical governance agenda and not as a discrete and unrelated set of technical activities. It must also be adequately incorporated into the commissioning agenda.

'Purchasers of health care could promote the uptake of research findings during contract negotiations.'

Haines and Jones, 1994

Implementation of robust research evidence makes a major contribution to clinical effectiveness and to the overall and assured quality of care that a PCT provides or commissions.

Priorities for action

Now that you have finished reading through this section, please identify three priorities for the PCT in relation to research and research implementation.

- 1
- 2
- 3

References

CEO Bulletin 2002. Issue 145 December. www.doh.gov.uk

Department of Health 2001. *Research Governance Framework for Health and Social Care*. London: DH

Haines, A. and Jones, R. 1994. Implementing findings of research. *British Medical Journal*, 308, 1488-92

Resources

Bandolier

www.jr2.ox.ac.uk/Bandolier/index.html

EPIC – developing National Evidence-based Guidelines for Preventing Healthcare Associated Infections in England

www.epic.tvu.ac.uk/index.html

National Electronic Library for Health – rapid access to reliable evidence

www.nelh.nhs.uk

National Electronic Library of Protocols and Care Pathways (NeLPCP) – a guide to relevant literature and on-line resources of good practice

www.nelh.nhs.uk/carepathways.asp

PCT Research and Learning Review – full text of the ministerial statement on the PCT Research and Learning Review:

[www.info.doh.gov.uk/doh/point.nsf/66b6fo4bdca6defc0025693bo05ladao/956ac3do4ef5662780256c7fo0362644/\\$FILE/minstat.PDF](http://www.info.doh.gov.uk/doh/point.nsf/66b6fo4bdca6defc0025693bo05ladao/956ac3do4ef5662780256c7fo0362644/$FILE/minstat.PDF)

Protocol based care information pack – from the Modernisation Agency and NICE at:

www.modern.nhs.uk/protocolbasedcare

Rating the PCT's current stage of development

Please rate the PCT's current stage of development in relation to the following questions.

Remember to use the Response Sheet provided for your answers.

14.1 To what extent do the Board and PEC understand their Research Governance duties and responsibilities?

14.2 To what extent are systems and protocols in place that ensure that these duties and responsibilities are implemented in practice?

14.3 To what extent is there a strategy to monitor the implementation of research into practice across the PCT community?

14.4 To what extent do the Board and PEC monitor the implementation of NICE guidance?
