Research and development in the new NHS: another challenge for the profession

ABSTRACT—The continued implementation of the NHS research and development (R&D) strategy is necessarily a political response to the pressures on the NHS. Although the cumulative effect of the changes has yet to be thought through, what are the implications for the profession and where might further influence be beneficial?

Background

Research and development (R&D) and quality of care were seen to be vulnerable in an unmanaged NHS market. Both were threatened by the contracting process, short-termism and the emphasis on financial efficiency. Whilst the Clinical Standards Advisory Group, clinical audit and the clinical effectiveness agenda [1] were put in place to take care of quality, the NHS R&D strategy was supposed to protect and enhance R&D [2]. Many of the concerns about R&D are described in the Culyer report [3] and proposals to address some of these have been put forward [4]. The latest consultation document [5] indicates that many aspects are still to be clarified, implying that the consequences of the proposed changes have yet to be thought through. What are the implications for the profession and where might further influence be beneficial?

The ‘Culyer’ proposals

Although the Culyer report [3] discussed the widespread concerns about the support for R&D in the NHS, the current proposal [4] deals with one aspect of funding—the NHS contribution towards the costs of treatment and service which are increased while approved research studies are under way. These costs are only a subset of those concerned with academic practice from which R&D studies emanate. Even if the system works efficiently and according to plan (over which there must be much doubt), the problems below will remain over:

- start-up pre-protocol costs, especially in centres that do not gain facilities funding;
- the cumulative effect on the budgets of purchasers who have to support academic centres where additional clinical care has evolved from research studies.

- ensuring that patients are appropriately allocated to studies that cannot be completed from the patient flows associated with routine care;
- ensuring that the approvals and funding streams come together at the right time, particularly for multicentre studies [6].

The initial plan is to identify the costs associated with present R&D [4,7] and fund it from separate, identified budgets, but eventual redistribution of resources is envisaged and will, indeed, be necessary to engineer the grand plan [2]. There is as yet little information on how the quality and relevance of the NHS R&D will be assessed and related to the Higher Education Funding Council (HEFC) exercise. Previous experience suggests this will not be easy, nor possible without considerable help from academics in providing peer review [8]. Speculation on the effects of the redistribution has been limited [9,10].

Will the major academic centres (particularly the London postgraduate hospitals formerly under Special Health Authorities (SHAs)) lose out as more and more of the R&D levy is channelled into centres previously ineligible for a special increment for teaching and research (SIFTR) or direct support? Or will these major centres use their HEFC ratings, quality standards and experienced R&D managers to expand from the vantage point of their established base and facilities funding? Will health service researchers and those in primary and community care be given an easier ride to justify a share of the R&D levy, in order to foster the type of study said to be most desired by the National Health Service Executive (NHSE)? How will charities respond to the proposed partnership arrangements [5]? Will they too be prepared to give more priority to service research which meets the short-term needs of the NHS and less priority to the basic and often high-tech research most attractive to researchers? They will find much support for continued funding in a responsive manner [11] and, outside public health, as little professional support for the ‘rationing’ of R&D as for the rationing of clinical care. When those conducting scientifically valid, peer-reviewed research fail to attract levy funds to cover the service support costs, will they be expected to hand back their hard-fought funds or to challenge the decision? Or would they carry out their research regardless because the power to stop them is limited and the pressure on the patient care budget may not be their immediate concern? Academics are not above seeking judicial review [12]. Will the easier passage for those mounting approved studies be seen by the

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profession to compensate for the loss of other, less fashionable, R&D?

Much current R&D may be of low quality, in particular studies which take place without the scrutiny of peer review. Few academics would argue that such work should continue to receive explicit NHS R&D levy support if other more worthy work had to go without. But even in the best centres such studies are common. Pre-protocol and pilot work is a necessary prerequisite to formal studies and often a requirement for grant funding. Many trials fail to recruit as expected or are underminded in other ways. Most medical schools know how difficult it is to halt inappropriate or unproductive R&D, particularly when conducted by tenured staff with soft money. In the big centres, funding of the service costs of this sort of work is currently covered by SIFTR and in the near future may get lost in the block R&D levy grant: either a good or bad thing according to one’s perspective. The research assessment of the London SHAs [8] was the first exercise which led to loss of NHS funds from some previously privileged hospitals. This resulted in public threats of legal action and intense political lobbying by one centre which felt its R&D record had been undervalued. As R&D costs become more explicit and the redistribution starts, many other sacred cows may be threatened.

Now that the costing declarations have been received, comparisons with the identified R&D levy funds are taking place. Disparities between the levy funds and costs between regions have been identified, with North Thames having a disproportionate share of both. Any overall shortfall in identified excess costs is more likely to reflect ignorance about service support costs than an overgenerous levy. An excess of costs attributed to R&D might be expected to leave pre-protocol work exposed, since it was originally proposed that routine care, not R&D funds, would cover such work [3]. If the system does not drown in its own bureaucracy, the rules will be clearer by the next round and game-playing can start. For example, programmes with the highest ratings for quality and relevance may get more than their fair share of the costs of the academic component of diagnostic laboratories, allowing some pet projects of lower priority to slip through unnoticed. Similar mechanisms are used by Trusts in the NHS market; they load costs on to those parts of the service that have capacity and are not too price sensitive. With their light touch, the staff of the Regional Office may not be able to disentangle what happens within major R&D centres and they may not want to: their concern for the status of their R&D regional office in the national league may deter them from deflating their regional call on the national R&D levy.

We may have exchanged the current unsatisfactory SIFTR system for one which delivers the same result with more paperwork and higher costs. The greatest need now may be for some simulation exercises [13] to see how R&D service support might work in practice and how those with vested interests may act to protect the status quo.

Commerically supported studies

The proposals for commercially sponsored R&D in the NHS are not clear. Whereas R&D levy is not destined to cover such support costs [4], it is probable that in practice the NHS has been supporting much commercial work to date. Indeed some hospitals and their academic partners may have signed agreements with commercial partners, assuming that present arrangements will continue. When the ‘true’ costs (if they can be defined) are expected to be covered, will industry react by: a) putting more money in to buy the same amount of NHS studies; b) properly fund a more limited number of studies; c) conduct more R&D in cheaper centres overseas; or d) enter into more partnerships with charities and the MRC, or otherwise obscure the origin of their R&D to make studies more eligible for the R&D levy? This is another topic for simulation game-playing before the new arrangements are too advanced to be modified. At the least, some proper estimates of the cost to the NHS of supporting commercial work, and formal monitoring are required.

The consequences for the clinical academic

The difficulties for anyone attempting to undertake academic activity in the NHS have already been expounded at length [3,6,14,15]. Additional difficulties will be introduced by the new arrangements which are supposed to deal with them. Negotiating purchaser support introduces a new step for most academics, for which their training has not prepared them; few understand NHS costs in the new market. Failure to identify where services support costs are likely to arise will cause difficulties once the study starts. This additional hurdle on top of gaining peer reviewed funding and ethical approval, will not be welcome. Time spent in peer review will expand when R&D levy funds are allocated competitively and each research centre seeks a voice at the table and when funding bodies have to consider this wider dimension when allocating funds. The opportunity cost of the extra time spent on drawing up, refereeing and judging each application should be estimated.

Leading academic clinicians manage their diverse and demanding duties because they are backed by clinical and research teams. These may be curtailed by the shortened period of training for doctors [3,14] and the possible reluctance of industry to support research fellows when the inadvertent subsidy from the NHS is withdrawn. The longer time needed to initiate a formal study will be even less compatible with that available to a trainee; a slot in an established programme has its merits but the training in how to mount R&D studies will be lost. With more commercial funds going to the
NHS there will be less for researchers’ slush funds and travel to academic meetings. The clinical academics are squeezed from all sides [6]. They are pressed to achieve NHS ‘efficiency gains’ and replace the duties of junior staff, to produce research that attracts high HEFC ratings, and now face the extra burdens of initiating clinical research without the pump-priming from industry.

The way forward

So what is to be done? First, the long term game plan must be spelt out more explicitly and debated more widely. The more researchers and their funders understand and empathise with ‘NHS relevance’, the easier the changes will be. They must be reassured that relevance will not be a substitute for rigour. Public Health physicians must be seen as partners in this process, not as the ‘opposition’ advising purchasers.

Second, researchers and their sponsors must learn about the financial consequences to the NHS of conducting R&D so that they can estimate the need for additional service support and bid for it in time. Reliable measurement of these costs and easy ‘ready reckoners’ to enable the average researcher to estimate them would help.

Third, modelling, game playing and simulation may help to modify the ‘Culyer’ implementation plans before they have consequences that may not be thought through. The effects of shifting resources between regions, from secondary to primary care and from teaching hospital to DGH, must be considered and the political consequences broached. It is more than possible that the main losers will be London-based senior academics who are among the most powerful (and productive) figures in the profession.

Fourth, those who will allocate and handle the R&D levy must be provided with training and a career structure which will attract candidates with a suitable background in clinical and health services research.

Finally, the problems that will remain after the service support issue has been dealt with, must be addressed. Other anxieties about the interface between the NHS market and R&D were expressed to the Culyer committee [3], notably the uncertainty about the financial support which GP fundholders may give towards R&D.

Perhaps all these issues are already being debated at length in the Central Research and Development Committee and their view of the future arrangements for support of R&D are crystal clear. Until this vision is shared more widely, the medical profession should stimulate debate and help direct the process. Important aspects of the UK clinical academic tradition are at stake.

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