Funding research in primary care: is Culyer the remedy?

Research has been called good business, a necessity, a gamble, a game. It is none of these — it's a state of mind. Martin H Fischer

INVESTMENT in research and development (R&D) should be informed by the white paper *Primary care: delivering the future*, which identified the need to address three areas: funding arrangements, infrastructure, and ensuring that research findings are relevant and taken up by professionals in their everyday work.[1] It also emphasized that an evidence-based health service requires some understanding of R&D on the part of all primary care professionals. A range of suggestions have been proposed for the development of research in primary care, including the promotion of multi-disciplinary and multi-professional working.

There is an urgent need to expand upon the research capacity in primary care from its present low base, where research is poorly funded yet fundamental to the operation of the National Health Service (NHS). This month we can expect the publication of two long-awaited reports with major implications for the development of research in primary care: the affectionately named Mant Report[2] and the Medical Research Council's Topic Review on Primary Health Care.[3] Both reports have benefited from the input of respected senior academics from our research community; the long gestation period of the documents reflects the complex nature of the issues for research in primary care and the political consequences of their recommendations.

More than a year ago, the R&D Board agreed to convene a national working group to undertake a strategic review of R&D in primary care, chaired by Professor David Mant. The remit of the group included the collection of evidence on current investment and research activity, the identification of strategic priorities for the NHS, and the recommendation of actions necessary to achieve these strategic priorities. The group has approved mechanisms to support R&D in all primary care settings, including nursing, midwifery, health visiting, pharmacy, dentistry, optometry, and professions allied to medicine. This has included strategic objectives to increase the amount of high quality R&D of importance to NHS primary care; the recruitment, development, and retention of R&D leaders in primary care; the number of clinicians with R&D expertise; the involvement of non-clinical disciplines; and the achievement of an evidence-based culture in primary care.

Over recent months, expectations have been raised that the implementation of the new R&D support for NHS providers would facilitate the provision of a greater research infrastructure in primary care.[4] This followed the publication of the Culyer Report in 1994, which recommended that the diversity of funding arrangements through which the NHS had supported research should be replaced by a single NHS budget.[5] Professor Culyer perceived that much research in the NHS, especially that done outside teaching hospitals, was unrecognized and that the costs were subsumed in clinical prices. The identification and declaration by NHS providers (acute and community trusts only) of their research activity in the year up to 31 May 1996 was the first time that an attempt was made to document and cost research activity in this way.

The total budget for NHS R&D was calculated to be £425 million, derived from a 1.3% levy on NHS expenditure. At present, only 7% of the levy is used on R&D related to primary care, but a small shift in R&D funding would have a major impact in primary care research. The levy should support R&D activity that provides new knowledge, is generalizable, and whose findings are disseminated widely. It is divided into Budget 1 (previously labelled Culyer and providing support for NHS R&D undertaken by providers) and Budget 2 (amounting to £75 million and providing support for the NHS R&D Programme, mainly research project grants). Full operation of the new arrangements will take place in April 1998. Funding from Budget 1 will then be 'redistributed' on a competitive basis that will include bids from primary care providers. Both budgets are expected to continue for the foreseeable future, but Budget 2 may be sacrificed as Budget 1 increases. Currently, regions also provide financial support for research training fellowships and studentships from Budget 2.

Over the first quarter of 1997, regional R&D offices were busy supplying details and guidance for the application for Budget 1 funding. In each region a contact person was identified for personal discussion about outline bids, and it was obviously important to discuss potential approaches with regional directors of R&D. Bids for these contracts were based on a robust local strategy, and required alliances between the research community and universities on the one hand and a single NHS provider, such as an individual general practice or a consortium of providers (as in a research network), on the other. The timetable was very short: in England and Wales, expressions of interest and outline bids were required by April and final bids were submitted by the end of June (one month later for Scotland and a year later for Northern Ireland).

Providers with large-scale, rolling R&D programmes were eligible to bid for inclusive four-year portfolio funding (three years in the first round). Other providers were encouraged to bid for task-limited funding to support particular lines of research (one to four years). It was expected that task-linked funding would particularly enable providers who had not been players previously to enter the research arena. Those who did not express an interest in task-linked funding this year may apply next year.

Criteria for assessing bids included the demonstration of a track record in research and the ability to manage research programmes and their financial resources effectively. In other words, support will be given to the 'doers and leaders' of research — those who can deliver. All bids were assessed initially at a regional level according to 10 dimensions and their associated indicators. Funding recommendations have been passed centrally, and confirmation of the aggregate funding for task-linked bids for each region is eagerly awaited. Regional officers will then have the daunting task of deciding how to allocate the funds. Portfolio bids are being further assessed nationally, with final decisions being made by ministers. The results of all this year's applications will be known in November. A one-day national meeting will be held at the Royal College of General Practitioners on 28 November to share experiences of the process and to draw lessons for primary care.

More than 500 expressions of interest for funding were received in England alone (the ratio of task-linked to portfolio bids being approximately 4:1). Of the 403 task-linked expressions, 131 were general practitioner led and 358 were from trusts. The sum of the expressions of interest amounted to over 25% of this financial year's declared total, with many trusts submitting increased bids and primary care bidding for the first time. It is likely that up to 75% of the task-linked expressions did not proceed to a full bid. Most funding will clearly be allocated to the large portfolio bids with a secondary care lead (but not exclusively so).

The opportunity costs in preparing bids has been very high, with no financial support given to allow protected time for first-time bidders in primary care. As the deadline for final bids approached, confusion arose over the balance between the training needed to do

research and the research itself. Moreover, training to 'do' research was acceptable whereas training to 'understand' research was not.

As the research community pauses to catch its breath, important questions remain to be answered. Were alliances negotiated in time, given the short timetable for this year? How will the new funding arrangements help research in general practice and primary care? What was the role of academic departments of general practice and primary care in the preparation and ongoing support (e.g. subcontracting to provide coordination, training, project design, and statistical advice) for bids submitted? What will be the likely size and nature of the final demand? Were we ready for multiprofessional/multidisciplinary research networks or will the successful bids in primary care be mainly uniprofessional? How will the model of research general practices be developed?[6] Can the barriers and disincentives to working together be overcome? How should we evaluate the success of primary care research networks? How will research facilities in primary care requiring capital investment be created in the future?

The implementation of Culyer and *Delivering the future* both promised new opportunities for primary care practitioners in R&D. The previous government clearly indicated that it wanted to promote primary care research and made a commitment to increase NHS R&D expenditure in primary care from £25 million to £50 million over the next five years. It is not clear, however, where the new money will come from. At present, it is safest to assume that, as with the service increment for teaching (SIFT), there will be no new money in the system and the danger of destabilizing trusts will continue as money is moved around the system. It is hoped that staff at the regional R&D offices will not be 'tasked' with simply managing disappointment at the end of such a hectic year.

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Genetic advances: great promise tempered with concern

THE aim of the Human Genome Project, which began in 1990, is to determine the sequence of the human genome in an attempt to identify all the genes that make up a human being. This is an immense project: the DNA sequence is composed of over three billion based pairs containing enough information to code from between 100 000 and 300 000 genes. The human genome is estimated to contain between 50 000 and 100 000 genes.[1] After five years, which is one third of the expected lifespan of the project, around 12 million bases of human DNA (0.4% of the total) had been sequenced. However, progress in this subject is expected to be exponential, and the Medical Research Council, in its evidence to the House of Commons Science and Technology Committee's report on human genetics, stated: 'The task of completing the Human Genome Project is estimated to take 10 to 15 years. However, the development or improvement of technologies may reduce this figure substantially.'[2]

There is no doubt that the application of advances in our knowledge of genetics will transform the practice of medicine. Identification of the genes associated with a single gene disorder will afford an opportunity for earlier diagnosis. Many diseases of multifactorial aetiology, such as diabetes, asthma, hypertension and cardiovascular disease, will be shown to have a genetic linkage. Information from genome research is broadening our ability to identify carriers for various genetic disorders preconceptually and to make fetal genetic diagnosis in utero.

We may be able to design a new classification of diseases based on the biochemical and physiological mechanisms involved, not on the symptoms the patient presents, thus allowing patients at risk to be identified early when asymptomatic. Genetic knowledge will allow individuals who are at risk to be targeted, and treatment could be designed to take account of genetic factors that may influence its success or failure. It is likely that some common psychiatric and neurological illnesses will be found to have a genetic component, and identifying this will enable a clearer analysis to be made of the environmental factors that trigger such conditions, because genetic and environmental influences contribute to the development of the disease in a mutual and interconnected fashion. In general, advances in genetic knowledge will produce a clearer understanding of the biochemical and physiological mechanisms of disease processes, enabling more rational targeting — not only of drugs for controlling symptoms, but also of interventions.

We are therefore on the brink of a revolution in our ability to detect, prevent, and treat disease. What are the ethical implications of this revolution? In the face of such impressive scientific advances it might appear churlish to sound a cautionary note and advise a pause for reflection, but it is important to realize that the possession of genetic information has significant ethical implications, and will present individuals and society as a whole with difficult decisions. Discussion of these implications throughout society, and not simply within the medical and scientific community, is essential.

We are already able to screen for some genetically linked or genetically determined diseases. The gene for cystic fibrosis has been identified, and screening is possible both to enable adults to make informed reproductive decisions, and (if a carrier couple is identified) to provide prenatal diagnosis, with the offer of a termination if the baby is affected.[2] Two genes for breast cancer, BRCA1 and BRCA2, have been identified: these relate only to familial breast cancer (5% of the total), and so are a poor predictor at population level.[4] It is estimated that 80% of women carrying one of these genes will develop breast cancer at some stage in their lives. Predictive genetic testing soon will be possible in female fetuses with a strong family history of breast cancer.

Is a fetus identified as carrying the breast cancer gene to be considered normal or abnormal? Is termination of such a pregnancy to be offered? Many questions arise when a young girl has been identified as carrying one of the breast cancer genes.[5] At what stage of her life is she to be informed of this risk? Should she be offered early bilateral mastectomy? Should she go on lifelong Tamoxifen? Should she be regularly screened for the early detection of the tumour? Is there a risk that the availability of prenatal diagnosis for a large number of diseases will produce a changed attitude to parenthood, with parents demanding the right to a perfect baby? This could be called the commodification of babies — the concept of babies as commodities, with only the perfect product being acceptable. Designer babies would become the norm, with parents being encouraged to consider the consequences of reproductive choice. In such a scenario, bringing a less-than-perfect child into the world could be considered irresponsible.

We may have fundamentally to redefine what we understand by normality. Disability is a social construct, and society will have to define how far it is prepared to tolerate deviations from such a socially determined norm. In this societal redefinition of normality there will emerge a new social identity: neither 'well' nor 'ill', but 'at genetic risk'. It is highly likely that that there will be psychological consequences for someone who is identified as a carrier, or who is found to be at risk of serious disease. What will be the effect of this self-knowledge? At what age should such a person be informed that the gene is present? Will such knowledge entail a redefinition of identity, of relationships, of future plans?

In their discussion of the public understanding of the new genetics, Durant, Hansen and Bauer describe the discourse of great promise and the discourse of concern.[6] The discourse of great promise outlines the medical and social benefits of the Human Genome Project. The discourse of concern raises a number of potentially difficult ethical and social issues; these include the geneticization of society, with a danger that emphasizing genetic determinism will promote a reductionist view of the human condition and an underestimation of the role of environmental factors. For example, an increased prevalence of a postulated aggression gene within a prison population, or of an alcoholism gene within an inner-city vagrant population, might be coupled with a decreased emphasis on the lifestyle and environmental influences that contribute to these disorders, thereby reducing efforts at environmental modification.

The possibility is therefore raised of genetic discrimination and stigmatization of the symptomless ill. There is already evidence of public misunderstanding of carrier status: the House of Commons Science and Technology Committee states in its report on human genetics that 'a US scheme to identify asymptomatic carriers (sickle cell trait) backfired because of racial overtones, poor public education, inadequate counselling, and genetic stigmatization, with large numbers of carriers being denied health insurance or employment.'[2]

There are ethical dilemmas concerning access to an individual's genetic information, and building societies, insurance firms, and employers are all potentially interested players. Only recently the Association of British Insurers (ABI) has stated that individuals who have undertaken genetic testing will have to report the results to a company from which they seek insurance cover. The ABI said that the companies would ignore the results of any genetic tests if they were part of an application to buy a house worth £100 000 or less — with a clear implication that they would consider such information if higher cover were required. It has been reported that many American companies already require applicants for insurance to undergo genetic testing, which could become an integral part of an insurance company's assessment of most prospective policy holder's risk profiles. There will emerge an insurance underclass of people who, because of genetic testing results, either cannot obtain insurance or can obtain it only with heavily loaded premiums.

Issues also arise over the confidentiality of genetic information, which has important implications for family members. What right does one family member have to the genetic results of another family member? What obligations are there on people who, from their own test result, discover that other family members are at risk of having affected children? The Nuffield Council on Bioethics is of the view that, in exceptional circumstances — when an individual cannot be persuaded to inform family members who have a legitimate right to know his or her results — confidentiality may be overridden.[7] The House of Commons Select Committee's report on human genetics disagrees: 'If counselling cannot persuade someone to consent to sharing information with their relatives, the individual's decision to withhold information should be paramount.'[2] Which view is to prevail?

I suggest that there are enormous potential concerns for patients resulting from advances in our knowledge of medical genetics, and that the first port of call for patients (both those with a real risk of genetic disease and the 'symptomless ill' or 'worried well') is likely to be their general practitioner. I see a major educational need at undergraduate level, in vocational training for general practice, and in postgraduate medical education. The North West Faculty of the Royal College of General Practitioners has set up a genetics group, which hopes to provide an information pack for general practitioners. General practice needs to forge closer links with departments of medical genetics to enable us to translate the often complicated statistics of genetics into an accessible, informed, and comprehensible consultation in our surgeries.

In summary, the discourse of great promise points to a future in which advances in genetic science will transform medicine, with presymptomatic diagnosis, targeting of at-risk individuals, and more rational interventions, including somatic cell gene therapy. The discourse of concern, on the other hand, suggests (not for the first time in the history of medicine) that diagnostic techniques have outstripped therapeutic possibilities, and that we now face a more profound problem in which the human intellect has outgrown our current moral sensibilities and outlook. The ethical implications of advances in medical genetics must be debated as widely as possible to allow the construction of a framework through which to solve the resulting dilemmas.

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