

Clinical research by GPs in their own practices

We enjoyed reading Julian Tudor Hart's typically iconoclastic contribution to the March Back Pages.

We do share with him some of his concerns about Research Governance and the delays that ethical review can cause to the initiation of research studies. The variability in the outcomes of ethical review is well known and to a certain extent this is to be expected since two committees may come to different conclusions about a study, although both are acting ethically in accordance with the priority they place on the different ethical principles.¹ However, the Department of Health has made considerable strides in recent years in harmonising the process of ethical review although it does remain a complex, laborious, and tedious process well known for delaying the start of individual research studies. There have been moves in recent months by the National Research Ethics Service to streamline the process further, and these have been supported by the RCGP.

However, we think that just as healthcare teams have got larger and cross-practice collaborations have become more important, the impact of single practitioner research studies are limited: they are mainly of value to the researcher rather than making a substantial contribution to the expansion of the evidence base for our care. Such research has considerable benefits for the practitioner, the practice, and the patients but rarely results in a major contribution to the sum of our clinical knowledge — indeed one wag has described clinical research done by individual GPs in their own practices as 'occupational therapy for doctors'!

We believe that the days of the 'gentleman amateur' working to produce research in a general practice 'cottage industry' are now over and it is essential for our discipline that we conduct clinical research in our practices which makes the best possible contribution to the knowledge base of our discipline. The individual GP doing research in his or her own practice should be encouraged to ask for support from their local academic department.

It is difficult to do clinical research without being a member of a network of research practices that provide the necessary infrastructure to undertake good research — the UK primary care research networks and the MRC network of practices for example, both provide this. That such GP networks can produce world class clinical research in the form of multicentre trials is not in doubt as demonstrated by the recent outstanding Research Assessment Exercise (2008) results for primary care. The development of successful networks of teaching practices in recent years provides a model for engagement of GPs in research and is a good example of how practices can improve the quality of their clinical and academic work through mutual support and development.

The College has played an important role in the process of moving from individual researcher to network participation for many years by providing 'pump priming' money to support individual GPs with a good research idea to undertake research through the RCGP Scientific Foundation Board (SFB). Encouragement is given to successful applicants to work closely with their local academic department since the difficulties of conducting high quality clinical research in individual general practices are well recognised. In addition, the RCGP 'Research Ready' scheme has provided a quality standard by which practices can check whether they have the necessary competences and infrastructure to get started in research (www.rcgp.org.uk/researchready).

It is also inaccurate to say that research by primary care and within primary care has no 'systematic funding'. The creation of the National Institute for Health Research (NIHR) and specifically the National School for Primary Care in 2006 has provided the opportunity to develop systematic programmes of practice-based research led by general practice, within general practice, and for general practice. In addition, for those studies adopted as part of the NHS research portfolio under for example, the

NIHR Research for Patient Benefit Programme, support costs are available to individual practices to enable GPs and/or practice nurses to search records and identify patients who might be suitable for inclusion in a particular study. A fee is also payable for each patient recruited — all of which can contribute to greater harmony within a practice when one of the partners engages in research activities.

Many opportunities for research training for GPs have been created in recent years, such as the 'In Practice Research Training Fellowships' and the Walport Academic Training Fellowships, that, for the first time provide a career pathway for academic GPs and support research within general practices. Of course more could be done but within this context it is our view that it would be neither useful nor a sensible use of limited resources for the College to approach the DoH on behalf of its members to 'reinvent the wheel' and ask for the provision of 'systematic funding' for GP research. 'Special case' pleading does not usually go down well with the DoH and it is very important in building our academic discipline that we can demonstrate the high quality of our research to our colleagues by competing on an equal basis despite the particular obstacles to conducting research in general practice. We believe that a more appropriate role for the RCGP than that suggested by Tudor Hart is to contribute to the setting of national research funding priorities and continue to support research through the SFB and Research Ready schemes.

It is certainly true that in general, patients trust their GPs and GP involvement in research studies increases participation but with the development of new IT systems within general practice, new issues have arisen which need to be addressed if both the volume and quality of the research undertaken by GPs within their practices is to increase — in particular, the use of GP patient data for research and the issue of patient consent to participation in studies. The Wellcome Trust in conjunction with the College have recently produced a

Sense about mammography

consensus statement which addresses these urgent issues which cause considerable problems for researchers.² In our view Tudor Hart would be better expending his considerable experience and knowledge of research to addressing these types of problem rather than 'tilting at the windmills' outlined in his article!

Finally, there is the issue of the College's research committee which Tudor Hart describes as 'an occasional meeting between the three or four minor research empires scattered about the UK to divide whatever cake was available'. He will be interested to hear that the RCGP research committee ceased to exist in 2006 having done an excellent job over a number of years contributing to and influencing the strategic changes to research funding and infrastructure outlined in the earlier part of this article. It has been replaced by the RCGP Clinical Innovation and Research Centre (CIRC) whose remit includes 'developing clinical excellence through clinical audit and effectiveness, service development and research projects'. Contained under its umbrella is the RCGP Birmingham Research Unit which is one of the 'jewels in the research crown' of the College with a world class reputation for original research. In addition, we celebrate the prestigious RCGP Research Paper of the year award (now in its 14th year) and in 2009 we will be awarding the RCGP Discovery Prize for original research in general practice, of which Tudor Hart is a previous winner.

Any suggestion therefore that the College does not lead or play an important role in the conduct of research in general practice is incorrect. The RCGP is an academic organisation which exists to promote the highest standards of general practice. Research has always been and always will be an important part of our remit for improving the care of our patients.

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Since reading some 15 years ago an authoritative study which demonstrated that breast self examination was 'more effective at generating anxiety than detecting tumours', I have been trying to pass on this message to female patients who express concerns about breast cancer.¹ I have found that, rather than producing a sigh of relief or a gasp of liberation, this information is more likely to cause irritation, even indignation.

No doubt these responses are partly a result of exasperation at the experience of receiving contrary advice from different sources. A more important factor seems to be anger at being cheated of the alluring prospect offered by such screening tests — that early detection will confer a better chance of avoiding a premature death from breast cancer. I am often left with the feeling that I am the target of resentment, as though I had blurted out the truth about Santa Claus.

The recent controversy surrounding claims that 'women are still not given enough, or correct, information about the harms of screening' is likely to cause many more similar consultations in our surgeries.² Peter Gøtzsche and colleagues at the Nordic Cochrane Centre argue that the current promotion of mammography exaggerates the benefits and downplays the harms resulting from screening. On the basis of their earlier systematic review, the authors claim that if 2000 women are screened regularly for 10 years, one will benefit while 10 healthy women will become cancer patients and undergo unnecessary treatment.³ Furthermore, about 200 women will experience the psychological stress of a false alarm.

Here I should declare an interest. I was a signatory to the letter to *The Times*, published in the same week as Gøtzsche's article in the *BMJ*, which drew attention to the problems of overdiagnosis and overtreatment resulting from screening and pointed out that none of the official invitations for mammography 'comes close to telling the truth'.⁴ The immediate withdrawal of the leaflet used by the NHS breast screening programme marked a triumph for the campaign led by the breast surgeon Michael Baum and the patient advocate Hazel Thornton, as well as others over the past decade.

The popularity of screening tests for

breast cancer, from self examination to mammography, reflects the powerful commonsensical appeal of the notion that early diagnosis confers a better prognosis. But, according to Gøtzsche, 'it has not been proved that screening saves lives'. It may do, but it is clear that the benefit of mammography is relatively small, certainly much smaller than the public — influenced by a combination of wishful thinking and public health propaganda — believes. If the current controversy leads to a less paternalistic and manipulative presentation of health information then this will have much wider benefits.

Broadcaster Michael Blastland has shown how the statistics of breast cancer screening can be presented in such a way as to enable women to make an informed choice about mammography.⁵ He follows the approach recommended by Professor Gerd Gigerenzer of the Max Planck Institute, who favours presenting absolute rather than relative risks, 'natural frequencies instead of conditional probabilities'.⁶ In an inspirational summary of his approach, Gigerenzer and colleagues insist that 'statistical literacy' is 'a necessary precondition for an educated citizenship in a technical democracy'. Their conclusion emphasises the wider political and social significance of the accurate presentation of information about health:

'Understanding risks and asking critical questions can also shape the emotional climate in a society, so that hopes and anxieties are no longer as easily manipulated from outside and citizens can develop a better-informed and more relaxed attitude toward their health'.⁶

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