How to change clinical behaviour: no answers yet

CHANGING clinical practice to incorporate research findings remains the unanswered question in primary care. The question first arose as general practitioners started examining the quality of the care they provide, but so far we have no clear answer.

The first reaction was to assume that the problem was caused by too much information. Issuing guidelines that synthesise the evidence looked like a good idea. However despite the success of the British Thoracic Society guidelines on asthma,[1] first published in 1990 and updated several times since, we now know that isn't the answer either. Simply providing written material for practitioners is now acknowledged to have little effect on clinical practice.[2] The subsequent flood of guidelines pouring through the letterboxes of general practitioners, far from helping, merely led to the recipients feeling overwhelmed — when they were not feeling guilty at failing to attain set standards. Providing patients with information is insufficient to enable them to transform their behaviour; we should not be surprised if the same approach is similarly ineffective for clinicians.

Researchers have looked for other ways to help clinicians change clinical practice. This month's *BJGP* includes two papers exploring this territory. One reports a study addressing the quality of care for patients with angina or asthma.[3] The study groups received either guidelines alone (as the authors point out, this was counted as the control group since this is now regarded as having little or no effect), a reduced form of the guidelines giving more explicit instructions for clinicians which, in the third group, was augmented by audit data giving feedback on individual performance. The other paper reports on an education programme intended to improve clinicians' ability to provide nutritional advice in routine consultations.[4] The two studies offer a contrast: one using methods that could be deployed widely with limited additional resources, directed at two conditions already of major concern to practitioners, the other involving more intense input to engage practitioners in a vital area where the participants would be predicted to start from a point of relative ignorance and lower interest. Both studies produced disappointing results. In each case some benefits were reported, but overall there were no clear and consistent gains attributable to the interventions.

Even more disappointing, these are only the latest in a series of studies published in the past few years looking at different approaches to improving clinical care. One project failed to show major improvement in the care of patients following an educational intervention for general practitioners aimed at improving detection of depression.[5] This was one of many papers reviewed in a recent *Effectiveness Bulletin* on the recognition and management of depression in primary care.[6] Overall, this concluded that 'Successful guideline implementation and educational interventions were accompanied by complex organisational interventions, such as nurse care management, collaborative care or intensive quality improvement', and that 'these findings are in line with reviews of educational and organisational interventions aimed at changing professional practice. Research has shown that guidelines, by themselves, have little impact on clinical practice unless accompanied by a multifaceted strategy to implement them.' One study testing the effect of including a reminder card in the notes of patients with epilepsy did improve some recording, but this was possibly at the cost of encouraging less patient-centred care.[7] A study of educational outreach by pharmacists found a modest effect on practices overall, but most of the effect was felt in smaller practices, with larger practices showing very little change.[8]

Without being able to draw on systematic reviews, my reading of the literature is that simply disseminating guidelines is ineffective in bringing about change, and enhancing this with other interventions only slightly less so. It would be easy to adopt the nihilistic attitude that nothing ever changes in general practice. Yet this is incompatible with the experience of most general practitioners in the UK. Nor is it confirmed by the results of another paper in this month's *BJGP*, which reports striking improvements across a range of practices and encompassing different criteria, both disease-centred and patient-orientated.[9]

Even so, the perception of a conservative service persists. Faced with the apparent inability of the service to use the principles of clinical governance to improve practice, even in the comparatively well resourced setting of research studies, an administration impatient for change has recently published the details of the proposed contract for general practitioners in England containing a number of financial incentives to encourage improved care. Financial incentives are generally held to be effective drivers of change (although in passing it's worth noting that the Cochrane review on the subject reaches less clear conclusions[10]) and it has already been argued in the *BJGP* that the new contract will improve the quality of care in particular key areas.[11] However, the risks in this system are obvious: they are at least in principle inconsistent with patient-centred care; they are insensitive to local needs; the incentives will only ever address a small proportion of the overall work of primary care; and, in the long run, a workforce increasingly required to respond without questioning in mechanistic ways to financial incentives may not attract the kind of doctor any of us would want to consult when ill.

In their paper, Campbell and colleagues summarise the conditions required for bringing about quality improvement in the NHS: an amenable environment, effective leaders, and a culture that encourages everyone to benefit from clinical governance.[9] This helps to explain why some of the recent research has reported such disappointing results. As the anthropologists remind us, knowing the context is essential to understand the larger picture. The context of all recent studies in the UK is of a system already working at the limits of its capacity, where professionals have lost the sense of being in control of their own practice, and where additional

resources and time to facilitate change is difficult to find, even for research studies. While there is plenty of rhetoric about a culture of continuous quality improvement, it is not clear that it is understood enough, taken seriously enough, or given enough priority to enable the culture to develop. One of the comments in the *Effectiveness Bulletin* on depression was that many of the more effective interventions had been carried out in the United States. This conclusion may reflect a difference in the contextual factors at work in primary care.

All of this points to some tentative conclusions. First, and most important, we must all stop pretending that the writing of guidelines can of itself achieve anything. The evidence is consistent on this point, and the NHS is committed to respecting and acting on valid evidence. Second, research to identify effective methods for helping primary care teams improve the care provided must continue, and we hope to continue publishing the results. But the research should pay more attention to the contextual barriers to implementing change, and include a consideration of the barriers in the reports. Third, we need to ask whether the research methods being applied are appropriate. Since primary care is such a complex human process, a qualitative approach — getting practices to discuss the reasons for their successes and failures — might yield useful results, or shed light on the explanations behind the results in the quantitative studies. Or perhaps we know already, that it is practices with effective leadership, responding to local needs and doing the work themselves, willing and able to devote the necessary time and resources, that manage to achieve desired change. If so, it's going to be a difficult model to integrate into the very centralised structure and attitudes of the NHS.

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Efforts to ban direct-to-consumer advertising in New Zealand: a call to action

DIRECT-TO-CONSUMER advertising (DTCA) is big business in the United States, where it continues to grow almost exponentially, as well as in New Zealand where it is, however, now under attack. DTCA is banned in Europe and the rest of the industrialised world, where efforts by industry to allow it have been rebuffed. In this month's issue of the *BJGP*, Les Toop, Dee Richards, and a group of senior academics from all four academic Departments of General Practice in New Zealand,[1] summarise their important monograph,[2] prepared at the invitation of the Minister of Health. This excellent document cites chapter and verse, to make it clear that DTCA promotes neither education of the public nor any true public health benefits, and that in order to achieve its true goal — increasing profits for the pharmaceutical industry — it comes at great financial, social and, indeed, medical cost.

We will not recapitulate all the points made so well in this convincing document, which can easily be found at http://www.chmeds.ac.nz. We recommend that anyone interested in the topic of DTCA, or in the larger issue of the influence of the pharmaceutical industry on physician behaviour, or the even larger issue of how proprietary interests can impact and distort health care policy, should read it in its entirety. This is because the document is lucid and thorough and provides explicit support for each of its contentions, such that its ultimate conclusion — that DTCA should be banned, and replaced by an unbiased, publicly-funded source of healthcare information for our citizens — seems unarguable.

Not that this has prevented industry from arguing, or even resorting to personal attacks and intimidation in an attempt to discredit both the message and the messengers.[2-5] Readers can refer to the official University of Otago investigation by the ethicist Donald Evans,[6] in response to evidently baseless accusations brought against Toop *et al*, for the details of yet one more sorry example of efforts to suppress scholarship and/or advocacy when they threaten industry profits.

Many of the criticisms of DTCA expounded in the report to the Minister of Health speak for themselves, but there is one particular aspect of this issue that we would like to explore a bit further. It is commonly acknowledged that increased healthcare spending, such as is generated by DTCA, has adverse financial consequences; what is less obvious is how this translates into actual *medical* harm. Aside from the adverse effects generated by medicalisation of various aspects of normal life (promoted so strongly by DTCA) and by unnecessary use of medications, increased costs must lead to medical harm, particularly for the poorest among us, in a world where healthcare budgets are at their limits, because of what else we will be forced to give up.

Direct-to-consumer advertising does not promote inexpensive, therapeutically efficacious generic medications, or preventive health services; it far more typically pushes 'lifestyle' medicines, and new, expensive, 'me-too' drugs. The consequences of this for the public health can perhaps be better understood by looking at the companion topic of 'cost-effectiveness analysis', which is becoming increasingly popular in the medical literature. It has been pointed out that a great many such cost-effectiveness analyses consist mostly of data manipulation by marketing departments of proprietary companies, designed to prove that a terribly expensive new drug is 'really very cheap', because it only costs 'a little more', while it buys so much purported benefit.[7,8] Even ignoring the extremely questionable assumptions and interpretations upon which many of these 'studies' are based, Donaldson notes that few of them are really even about 'cost-effectiveness'.[9] Cost-effectiveness, from an economist's point of view, actually has to do with getting just as much benefit for less, or (in the tough cases), getting a little less benefit while saving substantial resources; it is not about spending more to get more. That is because whenever we spend even a 'little' more, for whatever purported benefit, we inevitably pay the opportunity cost for whatever else we are forced to sacrifice. We always have to give something up, because resources are not unlimited. The sacrifices may well be worth it in some cases, but it is impossible to know without at the very least considering what it is we will give up. The pharmaceutical industry is not interested in addressing the issue of limited resources — and why should it be, when it can create consumer demand by selling sickness to the public? In the US, money spent on DTCA has continued to increase dramatically, as has per capita spending on health care, without any demonstrable increase in health, and the industry enjoys continued lucrative profits despite a faltering economy.

The once touted, but now near-bankrupt, Oregon health care system has just announced drastic cuts that it plans to make with regard to critical medication benefits for the poor.[10] This cannot be understood outside of the context of a society where resources for health care (and education) are being decimated at the same time that US federal expenditures are dominated by the largest military budget in history. In the same vein, budget cuts in health care, and the public health consequences to which they will surely lead, are also inextricably linked to the skyrocketing cost of prescription medications, which is in turn owing in part to DTCA. If DTCA does not produce medical benefit (as Toop *et al* show it does not), then it is not simply medically neutral, because it will inevitably lead to the loss of critical services — typically those that are actually the most cost effective, such as childhood immunisations, or access to primary care, or the availability of inexpensive but tremendously effective medications, which are always vulnerable in the absence of powerful lobbies to champion them.

The European Union has recently rebuffed efforts to introduce DTCA, which is welcome news indeed. But the monograph by Toop *et al*, written in response to the New Zealand government's concerns about DTCA, represents the first real efforts to *reverse* a concession to industry that came at the expense of the public health. This is an even more critical step, as — if it is read seriously by that government, and actually leads to change — it can serve as a critical model in two ways.

First, the US Food and Drugs Administration (FDA), when it relaxed its rules regarding DTCA, promised to reconsider this after a fair period of evaluation. That period has passed, and it is high time for the FDA to stand up on behalf of the US public, follow the precedent being set in New Zealand, and roll back its ill-reasoned permissive policy on DTCA.

Secondly, bad decisions, once made, must not be inviolate. The pharmaceutical industry is an important contributor to modern health care, but when its hunger for ever-greater profits (already by far the highest of any industry) collide with the health needs of the population, the latter should always take precedence. Conditions and laws that propagate and nurture undue industry influence on individual physicians,[11] 'opinion leaders' in the profession, clinical research, universities, journals, and law-makers in government, should all, just like DTCA, be subject to critically important reform.

The case against DTCA is convincing, as any fair reading of the evidence, so well marshalled by Toop *et al*, makes abundantly clear. It is past the time for 'trial periods' and 'further study'. If all of us, including the pharmaceutical industry, *truly* value the public health more than we simply value unbridled profits, now is the time to act.

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Confidentiality: consent is not sufficient

IN their paper in this issue of the *BJGP*, 'Electronic summaries in general practice — considering the patient's contribution', Ward and Innes record that most patient concerns arose in respect of information being sent to outside agencies.[1] They also confirmed the findings of others that a substantial proportion of their medical records contained in-accuracies. Many of these inaccuracies would not be detected without input from the patient. Both observations are pertinent to work being undertaken by insurance companies and collaborating general practitioners (GPs) with the ultimate objective that Read-coded patient data will be routinely uploaded electronically from electronic GP records into company software that will perform the underwriting calculations.[2]

Guidance from the British Medical Association (BMA) and the Association of British Insurers (ABI) has been published recently with regard to the release of information copied from the patient's medical record[3] during the underwriting process. Crucial to the implementation of this report is a recommendation by the BMA, supported by the Royal College of General Practitioners, that insurance companies should offer applicants a non-prejudicial choice. *Either* a report should be provided from their medical records by their GP, *or* a doctor who is not involved in the care of the individual should take a medical history and examination. This latter option should be available for underwriting, to be based on medical information provided directly by patients on their own behalf. Having been rejected by the ABI, this discretion for patients should be imposed on insurers by the profession, with support from the Department of Health and the Information Commissioner.

The major public health problems can only be addressed at a personal level by the sharing of highly sensitive information; not least, for example, sexual behaviour and sexuality, alcohol and drug use, genetic profile, and testing for infectious disease. The environment, reassurance, and communications skills used by good GPs, genitourinary medicine consultants, psychiatrists, and counsellors in their clinical consultations to secure this information are unfairly abused when information collected for therapeutic purposes is used for an entirely different and conflicting purpose.

In common with other professionals, doctors — and indeed the entire health service — claim to provide a confidential service. The human right to privacy will be protected. GMC guidance asserts that 'without assurances about confidentiality, patients may be reluctant to give doctors the information they need in order to provide good care'.[4] The understanding is that other people will not be informed of the matters discussed by doctor and patient.

The discomforting corollary is that confidentiality facilitates deception by the patient. Confidentiality enables patients, should they so choose, to be economical with the truth. Doctors do not invite patients to deceive others. Nor would we necessarily endorse such deception; indeed, we may deplore it. However, if we respect patient autonomy, we are obliged to leave patients with the same choices over whether or not to divulge their own information to others as they had before they chose to consult us. Recognising this corollary, guidance on confidentiality has consistently determined that confidentiality is not absolute. Guidance defines the extraordinary overriding circumstances such that 'the public interest' requires the release of information without first obtaining the patient's consent. Such release is limited to situations that would otherwise place others at risk of death or serious injury. In other circumstances, standard guidance presumes, simply, that the consent of the patient is all that is required to justify the release of information. Such an analysis is over-simplistic.

Many agencies would like full medical information about prospective clients. Some of them, particularly underwriters, use a system of required consent. The provision of consent to the release of information by GPs is made a complete prerequisite for access to services provided by the agency. It is a fundamental principle of respecting patients' autonomy that consent should be free of any obligation, stated or implied. For example, when patients are asked to participate in research studies, they need to be reassured that declining to participate will not result in a withdrawal of routine care. By the process of 'required consent', the willing consent of healthy individuals effectively breaches the confidentiality of the reluctant, stigmatised minority. Taking out life insurance is commonly an economic obligation, particularly when linked to securing a home or employment. Placing an obligation on all clients to give consent to the release of their medical information results in consent not being genuinely voluntary. When consent is not freely given, the profession should only co-operate in circumstances that might otherwise justify information release without consent. Imprecise underwriting has never placed anyone at risk of death or serious injury. It should rarely be part of the doctor's role to police the integrity of patients in their dealings with others.

GP reports are an anachronism established in paternalistic times when it was deemed inappropriate to fully inform patients about their illnesses, treatment, and prognosis. Patients can now provide information on their own behalf. Patients have access to their own medical record should their memory be insufficient. The Data Protection Act explicitly

prevents any contract that requires that the records or a copy be handed over by the patient.[5] Since patients can withhold information in consultations,[6] and refuse consent for some consultants to release information to GPs,[7] required consent methods cannot even now provide a wholly reliable method of complete information gathering for the intrusive agency.

Medical information in the United Kingdom is uniquely vulnerable by virtue of our system of lifelong records held by an identifiable doctor, who provides near-monopoly access to medical care. Insurers in other countries are obliged to rely on information provided directly by the patient. Patients abroad can self-refer to other doctors, including specialists, and keep those consultations secret. In the brave new world of electronic backup, it will be much harder to conveniently 'lose' historical data.

The current system militates against the interests of patients with better doctors. Doctors who proactively seek to identify risks faced by their patients will disadvantage those patients in the underwriting process, even if, as a consequence of the doctor's intervention, those risks are diminished. By comparison, patients who carry the same, or higher, risks that have not been identified by their less rigorous doctors will be unhindered in their life insurance applications. For example, the diagnostic rate of 'depression' can vary substantially between GPs and is regarded as generally underdiagnosed.[8] When a proposer has been labelled with a diagnosis of depression, underwriters will load premiums.

The recent European Community-derived data protection and privacy laws require not only valid, freely given consent but, in addition, information release must be fair, relevant, not excessive, necessary, and compatible with the purpose for which the information was first obtained. These laws demand an evolutionary change in the advice of UK regulators. The control of patient information should be genuinely restored to the patient.

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