Personal paper

New drug treatment for Alzheimer's disease: lessons for healthcare policy

David Melzer

Department of Community Medicine, Institute of Public Health, University of Cambridge, Cambridge CB2 2SR

David Melzer, *clinical senior research associate*

dm214@medschl.cam.ac.uk

BMJ 1998;316:762–4

The launch of donepezil (Aricept), a specific treatment for patients with mild or moderate Alzheimer's disease, attracted intense interest. Clinicians and others were quoted in the media as being optimistic about the drug's effectiveness, but concerned that NHS funding would be withheld or uneven. However, reaching consensus on the clinical rather than statistical importance of this drug requires open debate, given the relatively small effect sizes and uncertainty over side effects in typical patients. Debate has been hampered because publication of the full results of the main clinical trials has been delayed. This episode highlights several issues of general policy importance that must be resolved if access to the information needed for clinical and other decision making is to be improved.

Summary points

- Licensing trials on highly selected patients may provide insufficient information on which to base clinical decisions, especially where effect sizes are small and comorbidity is common
- All trial evidence should be published before new drugs are marketed, and medical journals should not carry advertisements referring to unpublished data
- Communication of benefits and risks should emphasise clinical effect sizes rather than statistical significance
- Claims about effects on populations or services should be based on evidence
- Secrecy surrounding licensing should be ended and data from trials should be available for independent analysis
- Overvaluation of new technology could threaten funding for vital but more mundane care

The launch of donepezil—perceptions and reality

Alzheimer's disease is a common and devastating condition, and the launch of a specific treatment naturally attracted intense interest. The new drug, donepezil (Aricept), an anticholinesterase agent, was licensed in the United States in December 1996, with reports that it had produced "highly significant improvements in cognitive and clinical global assessments" in randomised trials lasting 30 weeks and had increased the proportion of "treatment successes" by 245%.[1]

The drug's launch three months later in the United Kingdom was greeted with optimism. The lay press quoted eminent clinicians as saying that donepezil "marks a sea change" in management of dementia,[2] that it should be seen as "a way to alleviate the burden of a terrible disease," and that it would "give hope to many people and their carers."[3] Several clinicians voiced fears about funding, including a comment that "we must make sure health authorities do not try to hold back."[2] One respected journalist even suggested that inability to fund treatments like donepezil could result in a mass move of all but the poor into private medical care, killing off the NHS.[4]

Closer to the NHS, the *Health Services Journal* quoted a professor as saying that using donepezil would reduce care costs, because it would halve the incidence of Alzheimer's disease.[5] The journal also reported that the NHS Confederation (representing trusts and health authorities) welcomed the drug and called for government funding to pay for it. A spokesperson argued that as the drug would mainly bring savings in social care, the estimated annual cost of £200 million could be switched from health to social services budgets. It was largely left to the Alzheimer's Disease Society to introduce a note of caution into many of the reports by complaining of the unhelpful leaks about donepezil before its launch and suggesting that the drug was likely to play a modest role.[6]

The little information available from the clinical trials suggests that the Alzheimer's Disease Society's caution may have been wise. According to the study's own clinicians, the additional treatment responses in the highly selected study group were predominantly of minimal clinical importance (see below). This mismatch between perceived benefits and the study data, together with the barriers to obtaining information, raises policy concerns of general importance in health care. These concerns fall into four main categories—

namely, the usefulness of the trials required for licensing, the publication of evidence, the communication of overall benefits to individuals, and the assessment of the impact on the population.

Policy concerns

Trials and the evidence of effect size

Clinical trials for drug licensing are designed to establish the efficacy and safety of new compounds. In the case of Alzheimer's disease, the United States Food and Drug Administration set specific requirements for trials, including the need for appropriate measures of outcome.[7 8] The agency, recognising that changes in psychometric test results alone might be trivial, proposed that clinically useful effects should also be determined by clinical assessment.

Clinical assessment

For people with Alzheimer's disease and their carers, benefits will depend on improvements in everyday functioning and quality of life.[9] Changes in the capacity to perform activities of daily living were not considered crucial by American standards, although European draft criteria do include these. As yet, no claims have been made that donepezil changes the outcome of any of these measures, although relevant data were collected. Therefore, the only available assessment of the drug's clinical benefits, other than the cognitive test scores, is the clinician's ratings.

> *"Lack of appropriate information from trials designed for drug licensing is … not unique to donepezil"*

The scale used for clinical assessment was the clinicians' interview based impression of change ("plus" version; CIBIC-plus), "a semi-structured instrument, examining general, cognitive and behavioural functioning and activities of daily living, rated by a study clinician based upon his/her observations at an interview with the patient, in combination with information supplied by a caregiver."[10] The seven point scale is ordinal, but the ratings are: marked, moderate, minimal or no change for improvement or deterioration, and it would be absurd to suggest that the notional rating of 3 for marked improvement implies a proportionate change from the 2 for moderate improvement. Despite this, so called statistically significant mean changes in this score (of 0.35 for a 5 mg dose compared with placebo at 24 weeks) have been widely quoted in promotional literature.

Benefits

The American prescribing information leaflet provides the only published breakdown of the CIBIC-plus results.[10] After 12 weeks of treatment (trial A301), the progressive decline in cognition in the placebo group was small and virtually the full effect of the drug (a mean gain of under 3.2 on the 70 point cognitive subscale of the Alzheimer's disease assessment scale) should have been evident as clinical improvement. Reading from the published histogram, for every hundred patients treated with the 5 mg dose of donepezil for this period, five additional patients showed non-minimal improvements and two avoided non-minimal decline. Results in the group taking the 10 mg dose were similar; here an additional 7.5 showed non-minimal changes. All other changes were rated by trial clinicians as of minimal clinical importance. Put in this way, the benefits of donepezil seem to be of a different order from those implied in the promotional literature, as letters to this journal have pointed out.[11 12]

Side effects

If the benefits seem smaller than claimed, what of the side effects? The American prescribing leaflet proves helpful again: the side effect events cited "reflect experience gained under closely monitored conditions of clinical trials in a highly selected patient population. In actual clinical practice or in other clinical trials, these frequency estimates may not apply."[10] Given the modest benefits, the frequency and seriousness of side effects in typical patients with mild or moderate Alzheimer's disease is clearly crucial to a doctor's assessment of the balance of risk and benefit in individual patients. Alas, few relevant trial data are available to help. This lack of appropriate information from trials designed for drug licensing is, of course, a widespread problem and not unique to donepezil.[13]

Presentation of the information

If a drug has modest effects and uncertain side effects in ordinary patients, the clinicians, patients, carers, and those providing funding will be required to make complex judgements on how the drug should be used. Unfortunately, nine months after launch the main clinical trials referred to in promotional leaflets still had not been published. It is worrying to note that in the United Kingdom the official summary of product characteristics offers no comment on benefits other than that the "tablets are indicated in the treatment of mild or moderate Alzheimer's disease." No information is available from the United Kingdom Medicines Control Agency, which currently works in secret (although limited information would have been released if European licensing procedures had been followed). The only systematic report of the outcome of the main trials is, as mentioned, in summary form in the American leaflet, which has not been distributed in the United Kingdom.

> *"People with dementia are directly affected by any switch in spending from supportive care to new drugs"*

Since the launch of donepezil, however, the two companies involved have offered doctors a journal article covering a preliminary trial; conference abstracts; promotional publications, including selected results from unpublished trials; and ball point pens marked with the drug's commercial name. In addition, advertisements have been published in respected journals, including the *BMJ*, citing unpublished "data on file." The promotional pack contained no information on exclusions from the trials and reported outcomes concentrated on "statistically significant" mean changes in cognitive scores and clinician ratings. Failure to detect changes on other measures was not mentioned.

Response to the marketing campaign

The lack of information with which to interpret trial results would not have been damaging if the press, statutory bodies, health professionals, and those marketing the drug had waited until this was available. Lack of published information proved no bar to welcoming donepezil. For example, an editorial in the *BMJ*,[9] while mentioning that effect sizes were modest, identified the main issues as ethical or relating to the need for equitable funding. In an impassioned debate on prescribing donepezil, the 1997 conference of the old age section of the Royal College of Psychiatrists was told that the time had come for psychogeriatricians to abandon their former approaches and become neuropsychiatrists, passing the caring roles to others. The motion in favour of prescribing the compound was carried by a large majority.

Population impact

Assessing the population impact of a new technology is complex, and far more information about the benefits and risks of this drug in ordinary patients is needed before responsible estimates can be made.[14] Claims of reduced rates of admission to institutions are highly speculative. Given that needs for institutional care are influenced by many factors, a randomised controlled trial in typical patients and circumstances would be the only way of determining whether the modest net effects reported for donepezil would result in savings in the costs of care.[15]

Policy implications

New technology and population aging are the two main determinants of rising healthcare costs, and the unwillingness of most governments to increase funding has resulted in restrictions in access to care. In the United Kingdom, access to support services in the community has reduced,[16] and the right to free nursing care in institutional settings, a core principle at the founding of the NHS, was withdrawn during the past decade.[17] Since over 80% of those in nursing homes have dementia, this group of patients is directly affected by any switch in spending from supportive care to new drugs.[18] Inflated optimism in assessing new drugs for elderly people could thus have negative practical consequences for the very people the drugs are designed to assist.

What can be done?

Among those formulating health care policy, consensus already exists that the evaluation of new healthcare technologies must be improved. However, much of the effort thus far has concentrated on including cost effectiveness studies in drug trials. This has met with little success, partly because of the technical problems involved.[19] The experience with donepezil suggests that more basic issues have not yet been resolved. Action within the current regulations is feasible and should include a requirement to conduct trials on patients who are representative of those for whom the drug will be licensed and marketed, a duty to publish full trial results before marketing drugs, and a duty to ensure adequate presentation of data so that prescribing doctors can judge the size of clinical benefits and risks. In addition, medical journals should not carry advertisements that refer to data outside the public domain. Given the need for meta-analysis and the existence of at least one example of serious misuse of study data by commercial interests, a further step might involve establishing a right of independent access, analysis, and publication of the raw data from trials of marketed drugs.[20] Dealing with more fundamental issues, such as the need for cost effectiveness information and the lack of a level playing field in research funding for non-patentable interventions, will require more radical moves.

Conclusions

Assessing the clinical importance rather than the statistical significance of interventions involves difficult judgments by clinicians, patients, carers, and those funding health care. Examination and debate of the relevant data are a prerequisite of adequate decision making, but the launch of donepezil has illustrated a number of shortcomings in current arrangements. Improving access to relevant data on the size of net benefits in patients representative of those for whom the drug is marketed should be the immediate priority in attempts to improve regulation of new technologies. In addition, clinicians, health care organisations, and learned journals should be cautious in their promotion of new technologies before open scientific examination of full study data has been carried out.

Funding: No additional funding.
Conflicts of interest: None.

1 Rogers SL, Doody R, Mohs R, Friedhoff L. E2020 produces both clinical global and cognitive test improvements in patients with mild to moderate Alzheimer's disease. *Neurology* 1996;46(suppl):A217.
2 Fletcher D, Irwin A. Alzheimer's drug too dear for NHS. *Daily Telegraph* 1997 April 5:9.
3 Ferriman A. Alzheimer's drug a success, but at what price? *Independent* 1997 March 28:13.
4 Toynbee P. Life or death? We must all decide. *Independent* 1997 February 12:13.
5 Eaton L. HAs call for extra funding to meet £200m cost of Alzheimer's drug. *Health Serv J* 1997;107:6.
6 Laurance J. First Alzheimer's drug could cost £1,200 per year. *Times* 1997 March 28:6.
7 Leber P. Guidelines for the clinical evaluation of anti-dementia drugs. 1st draft. Rockville, MD: US Drug and Food Administration, 1990.
8 Schneider LS. An overview of rating scales used in dementia research. *Alzheimer Insights* 1996;2:17.
9 Kelly CA, Harvey RJ, Cayton H. Drug treatments for Alzheimer's disease. *BMJ* 1997;314:693-4.
10 Eisai Corporation. *Aricept (donepezil hydrochloride tablets). Full prescribing information leaflet—USA.* Teaneck, NJ: Eisai Corporation, 1996.
11 Gray S. Advertisements for donepezil (Aricept) in the BMJ. *BMJ* 1997;314:1555.
12 Wagner N. Advertisements for donepezil (Aricept) in the BMJ. *BMJ* 1997;314:1555-6.
13 Rittenhouse B. *Uses of models in economic evaluation of medicines and other health technologies.* London: Office of Health Economics, 1996.
14 Tugwell P, Sitthi-Amorn C, O'Connor A, Hatcher-Roberts J, Bergevin Y, Wolfson M. Technology assessment: old, new and needs based. *Int J Technol Assess* 1995;11:650-62.
15 Rubenstein L, Nasr S. Health service use in physical illness. In: Ebrahim S, Kalache A, eds. *Epidemiology in old age.* London: BMJ Publishing Group, 1996:106-25.
16 Impallomini M, Starr J. The UK Community Care Act (1990) and the elderly. *Lancet* 1994;334:1230.
17 Bartlett H, Phillips D. Policy issues in the private health sector: examples from long term care in the UK. *Soc Sci Med* 1996;43:731-7.
18 Murphy E. A more ambitious vision for residential long-term care. *Int J Geriatric Psychiatry* 1992;7:851-2.
19 Abel-Smith B. The escalation of health care costs: how did we get here? In: *Health care reform. The will to change.* Paris: Organisation for Economic Cooperation and Development, 1996:17-30.
20 Wise J. Research suppressed for seven years by drug company. *BMJ* 1997;314:1145.

(Accepted 6 August 1997)

Should measles be eradicated?

F T Cutts, R Steinglass

Before measles vaccine was introduced, around 5.7 million people worldwide died each year of measles; by 1995 this total had fallen by 88%.[1] In Latin America, measles incidence and mortality fell by 99% after vaccination was introduced. As a result, an international meeting in July 1996 recommended a global programme of measles eradication by a target date between 2005 and 2010.[2] We discuss whether such a goal is feasible and appropriate.

Summary points

- Dramatic progress in reducing measles incidence and mortality in many parts of the world has recently led to calls for a global programme of eradication in the next 10 to 15 years
- Mass catch-up campaigns are being conducted—in some countries the aim is to interrupt measles transmission and in others to increase immunisation coverage rapidly
- Questions remain on the age range that should be included in catch-up campaigns, maintaining safe injection practices, and the feasibility and costs of achieving high enough coverage in poor countries
- Cost-benefit analyses of programmes to eradicate and to control measles are needed
- Effects on social development of diverting funds into programmes to eradicate measles must be assessed in poorer countries
- The international health and development community must address these issues and set priorities before declaring goals and time limits for global eradication of measles

Department of Infectious and Tropical Diseases, London School of Hygiene and Tropical Medicine, London WC1E 7HT
F T Cutts, *reader*
Basic Support for Institutionalising Child Survival, Arlington, VA 22209, USA
R Steinglass, *senior technical officer*
Correspondence to: Dr Cutts
fcutts@lshtm.ac.uk

BMJ 1998;316:765–7

Case for eradicating measles

Reducing mortality due to measles is a public health priority in developing countries. Measles eradication—defined as the interruption in the transmission of measles globally so that vaccination can be stopped—is possible theoretically because no animal reservoir is known to exist and measles vaccine is highly effective.[2 3] Eradication of the measles virus would obviate the need for the continuous monitoring of changes in measles epidemiology (and responses to this) induced by measles vaccination.[4 5] These epidemiological changes include a shift in the age distribution of measles towards older children and adults[6 7]; the occurrence of "post honeymoon" outbreaks, when numbers of susceptible people grow over years of moderate vaccination coverage until their total surpasses the epidemic threshold[5 6 8]; and the fact that babies born to mothers whose immunity is not natural but induced by vaccine have a shorter period of passive protection.[5 9]

Do we need to know more?

The World Health Organisation recommends that countries aiming to eliminate measles adopt the strategy used in Latin America of an initial catch-up campaign, with high coverage of routine infant vaccination, intensive surveillance, and periodic follow up campaigns.[2 10] However, questions remain on which age range to vaccinate in campaigns, maintaining safe injection practices, and the feasibility and cost of achieving high enough coverage in the poorest countries. Cost-benefit analyses need to compare programmes that aim to eradicate measles and those whose aim is control. Furthermore, the effects on social development in poor countries of diverting resources to a measles eradication programme must be assessed.

Age range

What age range should be included in catch-up campaigns? In Latin America, the age group 1-14 years was selected because catch-up campaigns were being carried out about 15 years after large scale vaccination programmes had begun, and disease surveillance showed few cases of measles in older people.[10] In many countries, measles surveillance is not good enough to inform decisions on which age group to vaccinate. In countries where vaccination coverage is low and the incidence of measles is high, school children are likely to have natural immunity, and targeting an age range narrower than 1-15 years might be as effective and less costly. Conversely, in sparsely populated areas such as the Sahel in west Africa, many adults may be susceptible, and vaccinating a wider age range may be appropriate.[11] Without adequate geographical data on trends in susceptibility to measles, predicting the cost effectiveness of simply adopting the age range used in Latin America is difficult.

Safe injection practices

Can safe injection practices be guaranteed if widespread campaigns are conducted now? In 1994, the WHO reported that up to a third of immunisation injections in four of its six regions were unsterile, carrying the risk of iatrogenic infections, including fatal septicaemia, and transmission of bloodborne pathogens.[12] Technological developments, such as autodestruct syringes, that make injections safer are costly, and proper collection and destruction of used needles is difficult.[13] Alternative methods of vaccine administration, including improved jet injectors and delivery via aerosol or intranasal routes, are under development and evaluation but do not offer a solution in the short term.[14 15]

Vaccination coverage in poor countries

What degree of coverage is feasible in the poorest countries? For the incidence of measles to fall towards zero, it is estimated that more than 90% (and possibly

TIM NUNN/PANOS PICTURES

Measles causes 800 000 deaths each year worldwide—500 000 of them are in Africa

more than 95%) of the population must be immune.[16] In Latin America, coverage greater than 90% was achieved in campaigns.[10] In the polio eradication programme, poor countries are achieving coverage of over 80% for oral polio vaccine on national immunisation days (Children's Vaccination Initiative, unpublished data, 1996). Measles campaigns are more challenging, however, because the target population is three or four times larger (polio campaigns target children less than 5 years of age since older children have natural immunity), and trained health workers are needed as the vaccine is given by injection.

In 1995, 32 countries reported measles vaccine coverage levels below 60% (WHO; unpublished data, 1996). A short but intensive effort to eradicate measles might be more feasible, therefore, than achieving and sustaining the high coverage needed for measles control. In Haiti, for example, reported coverage of routine infant immunisation is only 23%, but 94% of children aged 1-14 years were immunised in the 1994 campaign.[10] In countries where the coverage of routine vaccination is low, however, follow up campaigns might need to be repeated every year or two to prevent the resurgence of measles. Whether the poorest countries can achieve sufficiently high coverage in successive campaigns is unknown.

Cost-benefit analysis

What is the marginal cost-benefit of measles eradication compared with measles control? Measles control by immunisation has a high benefit-cost ratio in industrialised countries.[17] In developing countries, where measles case fatality ratios are up to 100-fold higher, mortality can be reduced to very low levels by control programmes that sustain high immunisation coverage of infants.[6 18] The measles case fatality ratio also falls as the socioeconomic status of a population increases.[19] Assessing the marginal benefits and costs of measles eradication compared with measles control in different settings is important.

The major additional benefits from measles eradication are predicted to be further savings on treatment of patients with measles and savings achieved by stopping measles surveillance and vaccination.[3] However, the appropriateness of stopping measles vaccination after eradication has been questioned. Aaby et al report that measles immunisation reduces overall child mortality through non-specific beneficial effects of the vaccine over and above the avoidance of measles or its complications. They suggest, therefore, that measles vaccination should be continued even if measles is eradicated.[20]

The marginal costs of eradication include the costs of public health campaigns, the additional vaccine and syringe costs, and any potential increase in health risks associated with the injection. The costs of the intensive surveillance, case investigation, and outbreak response components of eradication strategies will probably be high in countries with a poor health service infrastructure. The opportunity costs of investing in the extra activities required for measles eradication should also be reviewed in the context of competing health priorities such as introducing hepatitis B and other new vaccines.

Effects on social development

Would an eradication programme have effects on social development in poor countries? Official development assistance worldwide is at its lowest level in real terms for 25 years.[21] Knowing whether eradication programmes stimulate increased assistance for social development or compete for scarce resources is essential. An exciting eradication programme might attract new funds that would not otherwise be available. External donors supplied more than $25 million for Africa's national immunisation days in 1996, and a consortium of vaccine manufacturers will donate 100 million doses of polio vaccine plus $1 million to support polio surveillance in the region (Children's Vaccine Initiative, unpublished data, 1996). Systems must be established to show whether funds generated for eradication programmes are additional or are diverted from other programmes and to monitor the effect of specifically targeted expenditure on the overall development of health and social services.[22]

Reducing measles mortality in Africa—areas requiring simultaneous investment

- Infrastructure for routine health services in the poorest countries must be strengthened
- Research is needed to develop better ways of delivering vaccine and field laboratory assays to improve surveillance
- Basic research should be conducted to further our understanding of the long term effects of measles infection and vaccination in these countries

What should be done now?

Measles is currently estimated to cause almost 800 000 deaths a year, 500 000 of which occur in Africa.[1] Average reported coverage of measles vaccine in 1995 was only 53% in western Africa and 38% in central Africa.[23] Reducing measles mortality in these regions is a priority. Ideally, resources should be invested simultaneously in several areas of endeavour (box).

The feasibility and cost of developing safe methods of delivering measles vaccine in global campaigns—and a realistic schedule—need to be determined in consultation with the private sector. The coverage that can be

achieved safely and effectively in campaigns should be determined in the most difficult settings. The marginal costs and benefits of measles eradication should be estimated, and it also makes sense to include an analysis of a potential combined programme against measles, mumps, and rubella. Consensus should be sought from immunologists and virologists on the long term effects of measles vaccines and the implications of stopping vaccination should measles be eradicated. Lastly, coordinated processes of funding and accountability should be developed to monitor not only the investment in disease eradication programmes but also the effect of such programmes on social development in the poorest countries. We need answers to these questions before the declaration of an eradication goal sets severe time constraints on the search for informed solutions.

We thank Professor Paul Fine, London School of Hygiene and Tropical Medicine, and Dr Ron Waldman, BASICS, for helpful comments on earlier drafts of this paper.

1 Global Programme for Vaccines and Immunisation. *Progress of vaccine research and development and plan of activities—1996*. Geneva: WHO, 1996.
2 Expanded Programme on Immunisation. Meeting on advances in measles elimination: conclusions and recommendations. *Weekly Epidemiol Rec* 1996;71:305-12.
3 Hopkins DR, Hinman AR, Koplan JP, Lane JM. The case for global measles eradication. *Lancet* 1982;i:1396-8.
4 Cutts FT, Markowitz LE. Successes and failures in measles control. *J Infect Dis* 1994;170:S1-10.
5 McLean AR. After the honeymoon in measles control. *Lancet* 1995;345:272.
6 Cutts FT, Henderson RH, Clements CJ, Chen RT, Patriarca PA. Principles of measles control. *Bull WHO* 1991;69:1-7.
7 Gay NJ, Hesketh LM, Morgan-Capner P, Miller E. Interpretation of serological surveillance data for measles using mathematical models: implications for vaccine strategy. *Epidemiol Infect* 1995;115:139-56.
8 McLean AR, Anderson RM. Measles in developing countries. Part II. The predicted impact of mass vaccination. *Epidemiol Infect* 1987;100:419-41.
9 Mulholland K. Measles and pertussis in developing countries with good vaccine coverage. *Lancet* 1995;345:305-7.
10 De Quadros CA, Olivé JM, Hersh BS, Strassburg MA, Henderson DA, Brandling-Bennett D, et al. Measles elimination in the Americas. Evolving strategies. *JAMA* 1996;275:224-9.
11 Loutan L, Paillard S. Measles in a west African nomadic community. *Bull WHO* 1992;70:741-4.
12 World Health Organisation, UNICEF. *State of the world's vaccines and immunisation*. Geneva: WHO, 1996: 1-161.
13 Steinglass R, Boyd D, Grabowsky M, Laghari AG, Khan MA, Qavi A, et al. Safety, effectiveness and ease of use of a non-reusable syringe in a developing country immunisation programme. *Bull WHO* 1995;73:57-63.
14 Aylward B, Lloyd J, Zaffran M, McNair-Scott R, Evans P. Reducing the risk of unsafe injections in immunisation programmes: financial and operational implications of various injection technologies. *Bull WHO* 1995;73:531-40.
15 Cutts FT, Clements CJ, Bennett JV. Alternative routes of measles immunisation: a review. *Biologicals* 1997;25:323-38.
16 Fine PEM. Herd immunity: history, theory, practice. *Epidemiol Rev* 1993;15:265-302.
17 White CC, Koplan JP, Orenstein WA. Benefits, risks and costs of immunisation for measles, mumps and rubella. *Am J Public Health* 1985;75:739-44.
18 Cutts FT, Monteiro O, Tabard P, Cliff J. Measles control in Maputo, Mozambique, using a single dose of Schwarz vaccine at age 9 months. *Bull WHO* 1994;72:227-31.
19 Aaby P, Bukh J, Lisse IM, Smits AJ. Severe measles in Sunderland, 1885: a European-African comparison of causes of severe infection. *Int J Epidemiol* 1986;15:101-7.
20 Aaby P, Samb B, Simondon F, Seck AMC, Knudsen K, Whittle H. Non-specific beneficial effect of measles immunisation: analysis of mortality studies from developing countries. *BMJ* 1995;311:481-5.
21 Nelson EAS, Yu LM. Poverty focused assistance: new category of development aid. *Lancet* 1996;348:1642-3.
22 Taylor C, Cutts F, Taylor M. Ethical dilemmas in current planning for polio eradication. *Am J Public Health* 1997;87:922-5.
23 Expanded Programme on Immunisation. Measles control in the WHO African Region. *Weekly Epidemiol Rec* 1996;26:201-3.

(Accepted 9 September 1997)

The new genetics

Implications for clinical services in Britain and the United States

Ann Louise Kinmonth, John Reinhard, Martin Bobrow, Susan Pauker

Meeting the rising demand for genetic information and advice will require a major reorganisation of genetic services. In the United States, demand has led to the growth of private genetics services that are marketed directly to the public. In the United Kingdom, specialist genetic services are struggling to cope with increased workloads and it is acknowledged that some genetics services will have to be incorporated into mainstream clinical medicine, particularly at primary care level. A range of pilot schemes has been set up to establish how to do this, but few schemes have been fully evaluated. A broad educational effort is needed to increase awareness of the scope and potential of genetic information among health professionals and the public. This article reviews current developments and argues that contrasting approaches in Britain and the United States each offer special opportunities in innovation and evaluation.

Summary points

- Advances in genetics underpin the need to equip primary care teams with skills to assess genetic risk of disease, discuss the implications of gene testing, and control access to specialist services
- Involvement of primary care teams will vary with public awareness and uptake of tests, type and prevalence of disorder, precision of genetic tests, and therapeutic choices available
- Despite increasing availability of genetic tests, it is premature to offer population screening for genetic predisposition (such as to breast cancer), and even the case for screening carriers for cystic fibrosis through primary care is uncertain
- Different cultures of American and British health care may lead to faster innovation in United States but greater opportunity for development within a research framework in Britain

Current service configuration

The organisation of genetic services in the United Kingdom is currently based on regional centres. These mainly deal with relatively uncommon inherited and congenital disorders such as familial cancer and learning disorder syndromes. They provide information,

This is the third of four articles discussing the broader implications of advances in genetics

General Practice and Primary Care Research Unit, Institute of Public Health, University of Cambridge, Cambridge CB2 2SR

Ann Louise Kinmonth, *professor of general practice*

continued over

BMJ 1998;316:767–70

State University of New York at Buffalo, Buffalo, NY, USA
John Reinhard, *associate clinical professor of medicine*
University of Cambridge, Department of Medical Genetics, Addenbrooke's Hospital, Cambridge CB2 2QQ
Martin Bobrow, *professor of medical genetics*
Genetics Department, Harvard Pilgrim Health Care, Boston, MA 02116-3502, USA
Susan Pauker, *assistant professor*
Correspondence to: Dr Kinmonth alk25@medschl.cam.ac.uk

advice, genetic testing, and counselling about opportunities for disease prevention to individuals and their families. Their ethos (stemming from historical ethical concerns about forced eugenics) has traditionally been based on non-directiveness and non-paternalism.[1] Until recently clinical genetics was dominated by reproductive issues, but this may change rapidly as gene loci defining susceptibility to hereditary cancers (particularly breast cancer) and other common disorders are discovered.

In the United Kingdom the general practitioner's role in the diagnosis of genetic disorders has often involved indirect referral on clinical grounds. For example, cases of recurrent chest infection in infancy or recurrent miscarriage may be referred first to a local paediatrician or gynaecologist. Direct referral to geneticists arising from awareness of the implications of the family history are now increasing, and in the United States many patients refer themselves to geneticists.

Effects of rising awareness on workload of regional centres

In the United Kingdom there are currently only one or two consultant geneticists per million population. Increased interest and demand from patients and practitioners is already being felt, especially where regional centres are developing new services and raising awareness and expectations. Awareness is even greater in the United States, where websites and private genetics centres (box) promote genetic issues and testing opportunities.

Advances underpinning service developments

Scientific advances in genetics offer potential benefits to patients in three areas.

Public access to genetics services

In the United States genetic services are marketed directly to the public. Harvard Pilgrim Health Care, for example, provides a team of physicians and counsellors with expertise in genetics offering consultation, counselling, testing, support groups, education, and referrals. Through telephone access, the service is available 24 hours a day.

Guidelines for referral to consultation and counselling:
Concerned women considering pregnancy or already pregnant:
- Age ⩾35 years at delivery
- Considering early prenatal testing
- Have received an abnormal prenatal test result
- Have an affected child
- Had three or more miscarriages

Concerned couples having or already expecting a baby:
- Genetically related
- Known carriers of autosomal recessive disease
- Have a known genetic condition
- Family history of cancer; multiple cases, or multiple cancers
- Exposure to chemicals/radiation

Education and support:
- Updates in Medical Genetics on site at provider practices
- On line computer database on genetics literature
- "Difficult Decisions" monthly support group for patients

Educational materials and counselling

Referrals to other families in similar situations

Long term follow up and updating of risk assessment

Genetics services on the world wide web

- Genzyme Genetics (www.wwdir.com/genzyme.html)
- Oncor (www.clark.net/oncor/home.html)
- Genetics & IVF Institute (www.givf.com/givfhome.html)

Better tests for uncommon conditions—There are increasingly precise predictive tests for those referred to the clinic with suspicion of carrying gene mutations for a range of simple inherited disorders such as β thalassaemia and cystic fibrosis.

New tests for rare cases of common conditions—Identification of previously unrecognised highly penetrant genetic susceptibilities, within broad clinical groups of common disease, have excited media, public and professional interest alike.[2] The technical capacity to identify mutations at a particular gene locus allows, for the first time, the capacity to discriminate between the vast majority of people with small disease risks and small subsets at high risk which are otherwise clinically indistinguishable. Examples include breast cancer and early onset Alzheimer's disease.

New tests for common genetic contributions to common conditions—For common phenotypes with a contribution from low penetrance gene alleles, genetic advice can currently only be given in terms of empirical recurrence risks. In the next few years there is the possibility of tests developing that will identify specific risk predisposition or risk protection alleles for particular conditions and life styles and the search is on across the whole range of chronic diseases.[3]

If predispositional tests come to fulfil the classic criteria for screening,[4] they could be applied to large populations of asymptomatic people.[5] The rational introduction of any such tests for screening will critically depend on the availability of interventions of proved benefit among the population tested (or at least promising enough to justify further evaluation) and will for logistical reasons alone, be equally dependent on the involvement of primary care.[5–7]

These real and potential advances point to the need for primary care teams to develop the necessary skills to assess genetic risk, discuss the implications of gene testing, and hold the gate to specialist genetic services appropriately open or shut.

Integrating genetic risk assessment into medical general practice

Many general practitioners do not yet feel much need to prepare for the kind of practice in which predispositional genetic testing for susceptibility to common disorders may become as routine as assessing biological or behavioural risk factors is now. Models for service development have thus primarily been set up by genetics centres alone or in collaboration with academic departments of general or family practice, or with health maintenance organisations (HMOs) or individual enthusiastic family doctors. Most have focused on testing for well understood conditions such as cystic fibrosis.

Genetics centres in the United States now offer comprehensive genetic care plans for large HMOs,[8] or to other providers and their patients. Specialist clinics

have been set up primarily to facilitate further clinical and basic research. In the United Kingdom, over the past decade a range of regional and national genetic registers have been established.[9–12] Some, such as the familial adenomatous polyposi coli register in Newcastle, are linked to clinical care, with aims such as exclusion of people not at risk and reduction in early mortality among previously unrecognised gene carriers.[9] Genetic registers (box) allow long term direct contact with families for continuing support and allow risk status to be updated and treatment options changed as they arise. The cost of verifying and maintaining these registers and linking them to primary care should not, however, be underestimated.[10]

Setting up a genetic register

- Clear aims (research, clinical)
- Sufficient resources for set up and maintenance
- Defined access, ownership, and data confidentiality
- Ascertainment of probands
- Construction of pedigrees
- Identification of family members at risk
- Screening of members at risk

A complex process

Genetic risk assessment is complex for needs (and demand) will vary over time, according to public and professional awareness, uptake of tests, the type and prevalence of the disorder for which tests are available, the precision of the tests, and the therapeutic choices available.[6 13–16]

Cystic fibrosis is probably the most common autosomal recessive condition in the United Kingdom, and a range of pilot studies of genetic testing in general practice and commentaries on them have been published.[17–24] Despite this the case for screening for carriers through primary care is still not fully made. Acceptability of the test offered through general practice is variable and depends heavily on the setting. Understanding of the test result varies, as do the choices of patients with positive results. Cost effectiveness has not been established, and resource needs, especially for post-test counselling, may be underestimated.

Predispositional testing poses further difficulties. Families need information before and after testing and support in understanding their newly defined status and its implications for marital, reproductive, and other life choices, as well as the implications for surveillance and early diagnosis or treatment.[2 24 25] The time and genetic expertise required may be substantial and it is unclear how it can best be shared between primary and secondary care.

Developing expertise in primary care

Potential testing strategies for rare familial cases of common conditions depend crucially on classifying individuals accurately into low, medium, and high risk groups, using information from the family history.[6] The development of genetic expertise in primary care is likely to depend on establishing regional or locality based multiprofessional teams including genetic facilitators, counsellors, or nurse specialists who can provide accurate information and advice to local practices and their patients and liaise with voluntary groups and community leaders and genetic centres. Practice nurses will then be supported by nurse specialists or non-medically qualified counsellors linked with the multiprofessional team. Genetic assessment might be integrated into existing shared care schemes for diseases such as. haemoglobinopathies, diabetes, or asthma or into outreach services from clinical genetics centres directly.

IMAGES

Tests that identify specific alleles predisposing to or protecting from particular conditions are under development; these could be applied to large populations of asymptomatic people

Obtaining good family history data is an essential start in the assessment and management of genetic disorders, and the reliability of family histories obtained in primary care by direct questionnaire with or without computer or primary care practitioner support is being investigated by the NHS Research and Development and the Cancer Research Council's research programmes. Pedigree drawing programmes are available on the internet.[26]

The epidemiological basis of guidelines for risk stratification on the basis of degree and number of relations and age at onset of disease requires strengthening. However, primary care guidelines clarifying the current limitations of genetic tests, and when referral for specialist advice may have no advantage, are becoming available.[27] A study of intensive pretest counselling about BRCA1 gene testing among American women whose family history suggested they were at low to moderate risk showed that although the counselling increased their knowledge about the limitations of testing it had no effect on their desire to undergo testing.[28] If such results are replicated in Britain, primary care practitioners may find it hard to be effective gatekeepers, even if they are armed with time and appropriate expertise.

Promoting professional and public awareness

Educated patients consulting educated practitioners must be the aim, and public understanding is being addressed through awareness initiatives such as the Gene Shop at Manchester Airport,[29] consensus conferences, citizens' juries, and initiatives by organisations such as, in Britain, the Genetic Interest Group, which represents and supports charities, voluntary agencies, and support groups for those affected by or at risk of genetic disorders. Initiatives in undergraduate medical education are also under way.[30] General practitioners' knowledge and expertise can be increased through contacts with specialist centres, special interest groups, involvement in development and use of guidelines, and by collaboration in research projects as well as through the traditional forms of continuing education.

Establishing the cost effectiveness of different models and educational approaches will be difficult, for

the potential benefits and harms are numerous, hard to predict, and extend beyond patients to their families and future generations.[2 13] The costs of genetic screening thus relate as much or more to actions after testing than to the actual testing process.[25] Some costs may be offset by reduced surveillance of people at low risk or with negative test results. For example, predictive tests given to women with more than four first degree relatives with breast cancer might be paid for from savings made by limiting mammography among young women, in whom cost effectiveness has not been proved.

Incorporating change

In Britain, pilot developments led by enthusiasts provide a constructive way of introducing and testing out new service developments.[31] Pilot schemes in all sectors of health care are needed to define future service needs and professional roles. These schemes should incorporate risk management and appropriate referral and advice to the many relatives who have concerns but often have no additional genetic risk. Such an approach provides balance to the pressure to incorporate new technology into practice before it is fully evaluated. It also allows for the realities of the unpredictable development of knowledge and the need to gain experience of service applications while accumulating evidence of their cost effectiveness. Introducing services within a research and development framework allows for defining the general principles underpinning care, spanning the processes and clinical outcomes of different configurations of service delivery, and evaluating psychological and social impacts on individuals and families.[25 32] Comparison across tests and disorders is likely to provide valuable generic information.[33 34]

In the United States, most health care is provided through insurance and health maintenance organisations. Consumer demand and fear of litigation more readily drive healthcare activity than in Britain. Managed care maximises the ability to take advantage of unique local conditions and develop a flexible approach to programme development. Clinical and financial accountability, integrated healthcare systems, responsiveness to consumer concerns, and the ready availability of advanced computer systems to collect clinical and financial data are other advantages.

Conclusion

Clinical geneticists and innovative primary care teams on both sides of the Atlantic have a key role in planning, developing, implementing, managing, and evaluating services for the assessment and management of genetic risk. They also have a crucial part to play in devising training and support for clinical colleagues and ensuring that pilot programmes are evaluated rigorously. Genetic testing, wherever it is carried out, must be based on an accurate understanding of the clinical course of disease, the views of the patients (and their relatives), the performance of the tests, and the effectiveness of treatments or preventive strategies.

We thank the many colleagues in clinical and public health medicine who commented so constructively on earlier drafts, and Fawzia Khan and Fiona Walker for literature searching.

Funding: No additional funding.

Conflict of interest: None.

1 Geller G, Tambor ES, Chase GA, Hofman KJ, Faden RR, Holtzmann NA. Incorporation of genetics in primary care practice. Will physicians do the counselling and will they be directive? *Arch Fam Med* 1993;2:1119-25.
2 Davison C. Predictive genetics: the cultural implications of supplying probable futures. In: Marteau TM, Richards M, eds. *The troubled helix: social and sociological implications of the new human genetics.* Cambridge: Cambridge University Press 1996:317-30.
3 Bell J. The new genetics in clinical practice. *BMJ* 1998;316:618-20.
4 Sackett DL, Haynes B, Guyatt GH, Tugwell P. *Clinical epidemiology, a basic science for clinical medicine: how to decide when to seek an early diagnosis.* Boston: Little, Brown, 1991:167-70.
5 Harper PS. Genetic testing for common diseases and health service provision. *Lancet* 1995;346:1645-6.
6 American Society of Human Genetics. Statement on genetic testing for breast and ovarian cancer predisposition—summary of recommendations. *Am J Genet* 1994;55:i-iv.
7 Payne Y, Williams M, Cheadle J, Stott NC, Rowlands M, Stickle D, et al. Carrier screening for cystic fibrosis in primary care: evaluation of a project in South Wales. *Clin Genet* 1997;51:153-63.
8 Bachmann RP, Schoen EJ. Managed genetic care in a large HMO. *HMO Practice* 1996;10(2):54-8.
9 Burn J, Chapman P, Delhanty J, Wood C, Lalloo F, Cachon-Gonzalez MB, et al. The UK northern region genetic register for familial adenomatous polyposis coli. *J Med Genet* 1991;28:289-96.
10 Bulow S, Burn J, Neale K, Northover J, Vasen H. The establishment of a polyposis register. *Int J Colorectal Dis* 1993;8:34-8.
11 Davies F, Coles GA, Harper PS, Williams AJ, Evans C, Cochlin D. Polycystic kidney disease reevaluated: a population based study. *Q J Med* 1991;79:477-85.
12 Read AP, Kezin-Storrar L, Mountford RC, Elles RG, Harris R. A register based system for gene tracking in Duchenne muscular dystrophy. *J Med Genet* 1986;23:581-6.
13 Davison C, MacIntyre S, Davey-Smith G. The potential social impact of predictive genetic testing for susceptibility to common chronic diseases: a review and proposed research agenda. *Sociology of Health and Illness* 1994;16:340-71.
14 Parsons E, Atkinson P. Lay constructions of genetic risk. *Sociology of Health and Illness* 1992;14:437-55.
15 Faden RR, Tambor ES, Chase GA, Geller G, Hoffman KJ, Holtzman NA. Attitudes of physicians and genetics professionals towards cystic fibrosis carrier screening. *Am J Med Genet* 1994;50:1-11.
16 Boulton M, Cummings C, Williamson R. The views of general practitioners on community carrier screening for cystic fibrosis. *Br J Gen Pract* 1996;46:299-301.
17 Doherty RA, Palomaki GE, Kloza EM, Erickson JL, Haddow JE. Couple based prenatal screening for cystic fibrosis in primary care settings. *Prenat Diagn* 1996;16:397-404.
18 Watson EK, Mayall E, Chapple J, Dalziel M, Harrington K, Williams C, et al. Screening of carriers of cystic fibrosis through primary health care services. *BMJ* 1991;303:504-7.
19 Loader S, Caldwell P, Kozyra A, Levenkron JC, Boehm CD, Kazazian HH, et al. Cystic fibrosis carrier population screening in the primary care setting. *Am J Hum Genet* 1996;59:234-47.
20 Brock DJ. Carrier screening in the community. *J Inherit Metab Dis* 1995;18:525-32.
21 Bekker H, Modell M, Denniss G, Silver A, Mathew C, Bobrow M, et al. Uptake of cystic fibrosis testing in primary care: supply push or demand pull? *BMJ* 1993;306;1584-6.
22 Harris HJ, Scotcher D, Hartley N, Wallace A, Craufurd D, Harris R. Cystic fibrosis carrier testing in early pregnancy by general practitioners. *BMJ* 1993;306:1580-3.
23 Cuckle HS, Richardson GA, Sheldon TA, Quirke P. Cost effectiveness of antenatal screening for cystic fibrosis. *BMJ* 1995;311:1460-3.
24 Clarke A. Commentary: Cost effectiveness of antenatal screening for cystic fibrosis. *BMJ* 1995;311:1463-4.
25 Marteau TM,Croyle RT. Psychological responses to genetic testing. *BMJ* 1998;316:693-6.
26 Progeny at http:/tprogeny2000.com/body.shtml
27 Hoskins KF, Stopfor JE, Calzone KE, Merajver SD, Rebbeck TR, Garber JE, et al. Assessment and counselling for women with a family history of breast cancer. A guide for clinicians. *JAMA* 1995;273:577-85.
28 Lerman C, Biesecker B, Benkendorf JL, Kerner J, Gomez-Camineri A, Hughes C, et al. Controlled trial of pretest education approaches to enhance informed decision making for BRCA1 gene testing. *J Natl Cancer Inst* 1997;89:48-57.
29 Centre for Professional Ethics, University of Central Lancashire, Department Clinical Genetics. *Royal Manchester Childrens' Hospital: The Gene Shop.* Preston: The Centre [no date].
30 Teague KE, Brown JA, Meyer JM, Kahn MJ, Smith TJ, Keutzer KO, et al. Teaching efficacy of a medical education module on genetic testing for cancer. *J Cancer Educ* 1996;11:196-202.
31 Secretaries of State for Health, Scotland, and Wales. *Choice and opportunity. Primary care: the future.* London: Stationery Office, 1996. (Cm 3990.)
32 Mackay J, Pharoah P. A strategy for the management of individuals presenting with a family history of breast or ovarian cancer. Anglia and Oxford Health Authority, 1997.
33 Department of Health. *First report to the NHS Central Research and Development Committee on the new genetics.* Leeds: DoH, NHS Research and Development Directorate, 1995. (Chair: Martin Bobrow.)
34 Department of Health. *The genetics of common diseases: a second report to the NHS Central Research and Development Committee on the new genetics.* Leeds: DoH, NHS Research and Development Directorate, 1995.

Continuing medical education

Interprofessional working and continuing medical education

Linda A Headrick, Peter M Wilcock, Paul B Batalden

The increased focus on the results of professional practice (that is, the health outcomes of individuals and populations) creates two related tensions which will be considered in this paper. The first is the need for improved working and collaboration among different health professionals; the second is the demand for a broader vision of continuing medical education (CME).

Almost everyone who seeks medical care interacts with more than one health professional. The number of professionals involved and the importance of their ability to work collaboratively increases with the complexity of the patient's needs. New initiatives to improve management of diseases such as asthma, diabetes, or congestive heart failure invariably point out the need for interprofessional collaboration.[1] Increasingly, the "myth of the omnipotence of the independent practitioner" is being challenged as we discover the gains in quality and savings in cost when health professionals work together well.[2]

At the same time, traditional approaches to delivering CME for doctors are being questioned. A recent review of randomised controlled trials of CME concluded that it was undermined by difficulties with its delivery, that it seemed unable to respond to the urgent demands of healthcare reform, and that there was little evidence for its own effectiveness and efficacy.[3] The bulk of the studies focused on traditional approaches, although they identified a widening range of CME activities. Further, it was shown that even when there was change in doctors' behaviour there was "most often a small, less often a moderate, and rarely a large" effect on health outcomes.

In its working paper *Continuing Professional Development for Doctors and Dentists*, the Standing Committee on Postgraduate Medical and Dental Education (SCOPME) concluded that "conventional continuing medical education is no longer adequate to meet all the education and career development needs of doctors in modern health care."[4] It argued that CME needs to be set in the wider context of continuing professional development. While updates of clinical knowledge for individual doctors remain important, other learning is needed, including strategies for multidisciplinary and multiprofessional working. (Although the SCOPME report speaks of multiprofessional learning, the term "interprofessional" has since gained favour. For many, "interprofessional" better reflects the need for dynamic interaction among professionals to ensure that learning goes beyond merely having members of different professions sharing the same classroom together.)

Making interprofessional collaboration and teamwork a reality

Interprofessional working can be thought of as a spectrum, with more loosely coordinated efforts of collaboration at one end and more tightly organised work of teams at the other. Most doctors and other health professionals are required to work at multiple points on the spectrum (perhaps even within the same day), depending on the nature of the needs at hand. West described the characteristics of good interprofessional collaboration[5]; not surprisingly, they are similar to the requirements for good teamwork. This is shown in the box at top of p 772, which compares the attributes cited by West with the literature on successful teams, both in and out of health care.[6–12]

The table in the box lists a variety of elements that contribute to skilful and effective work across the "interprofessional working" spectrum. For example, without a clear objective, any group's efforts are less likely to succeed.[7] In health care, agreement regarding goals often emerges when the patient's needs become the explicit focus.

Health professionals tend to work autonomously even though they may speak of being in a team.[13] Common barriers to effective interprofessional work are well known and summarised in the box on p 773.[6 8 11 14] They range from fears of diluted professional identity to differences in schedules and professional routines. Physicians and other professionals face increasing accountability for the results of their work, but the health professionals caring for the same group of patients often are employed by different organisations and may be held to different standards. Since the introduction of general management the tensions between corporate working and individual clinical freedom have become a factor. Researchers discuss the importance of selecting a team with the right balance of skills and personalities,[7] but the reality of practice is often that the professionals with whom

Summary points

Greater focus on results of professional practice creates a need for improved collaboration by medical professionals and a broader vision of continuing medical education

Effective interprofessional working ranges from loosely coordinated collaboration to closely organised teamwork. Across this range, certain key elements increase the likelihood of success

Shared goals around patients' needs, and an approach focus in on processes that serve that need, can help transcend traditional barriers

Effective adult learning occurs when the topic is important to the learner and when learning combines reflection with concrete experience

Editorial by Toghill

This is the last in a series of seven articles looking at international trends and forces in doctors' continuing professional development

Department of Medicine, Metro Health Medical Center, Room 221, 2500 Metro Health Drive, Case Western Reserve University, Cleveland, OH 44109, USA

Linda A Headrick, *associate professor of medicine*

Bournemouth University Institute of Health and Community Studies, Bournemouth BH12 5BB

Peter M Wilcock, *specialist in healthcare improvement*

Health Care Improvement and Leadership Development, Dartmouth Medical School, Hanover, NH 03755, USA

Paul B Batalden, *professor of paediatrics*

Correspondence to: Dr Headrick lah5@po.cwru.edu

Series editors: Hans Asbjørn Holm and Tessa Richards

BMJ 1998;316:771–4

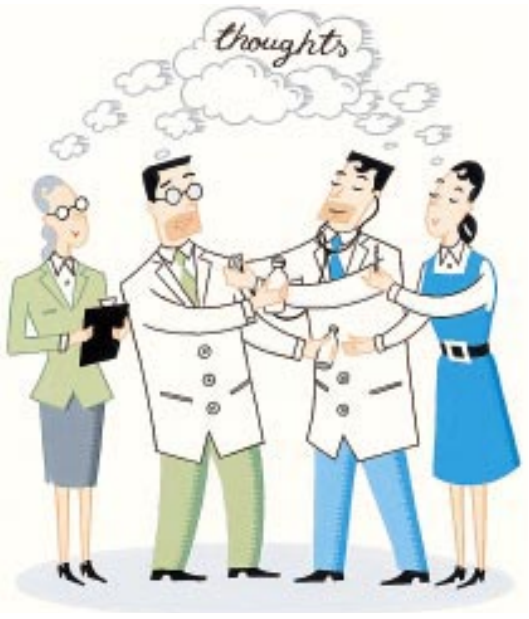
Characteristics of high quality interprofessional collaboration and teamwork

Collaboration[5]	Teamwork
Attainable, evolving shared vision	Direction is clear[9 11] Mission is engaging and motivating[7 9 11]
Clear, shared objectives	Goals and objectives are stated, restated, and reinforced[6 8]
Mutual support	Member roles and tasks are clear and known[6 9 11 12] Atmosphere is respectful[6] Responsibility for team success is shared among members[6 7 9 12]
Effective participation	Member participation is balanced appropriately to task at hand[11 12] Conflict is acknowledged and processed[6 11 12]
Task orientation	Goals fit organisational goals[7 9 12] Task is achievable[9 12]
Information and appropriate management structures	Clear specifications regarding authority and accountability[7] Decision making procedures are clear and known[6 12] Communication and information sharing is regular and routine[6 9 11 12]
Support for innovation	Enabling environment, including access to needed resources[7 9] Ongoing testing of assumptions[12] Mechanism to evaluate outcomes and adjust accordingly[6]

one must collaborate are the people who happen to be there. Given these challenges, how can we create professional development that will foster the interprofessional collaboration and teamwork needed for improved practice?

A place to start is the fact that most health professionals have at least one characteristic in common, a personal desire to learn, and that they have at least one shared value, to meet the needs of their patients or clients. Alongside this is the understanding that adults learn best when the topic at hand is geared closely to their interests.[15] Further, they learn best experientially, deriving for themselves abstract concepts from their own concrete experience and then testing these concepts in new situations.[16] Those who are no longer beginners are frustrated by theory based discussions of rules that have no context.[17]

Improved health outcomes usually lie outside the scope or control of any single practitioner. Real improvements are likely to occur if the range of professionals responsible for providing a particular service are brought together to share their different knowledge and experiences, agree what improvements they would like to see, test these in practice, and jointly learn from their results.[18 19] As they build their knowledge about how things currently work, such groups are likely to discover that their difficulties are more often derived from the processes they use than from each other. A recent study in Oxford showed that one consequence of establishing multiprofessional improvement teams in general practices was increased collaboration and focus on planning and strategy within the practices.[20] A powerful incentive for greater teamwork among professionals is created by directing attention to the areas where changes are likely to result in measurable improvements for the patients they serve together, rather than concentrating on what on the surface seem to be irreconcilable professional differences.



DAVID HITCH

A patient interviewed on the radio recently declared that the NHS needed "joined-up thinking"; perhaps it also needs joined-up education. One regional office is inviting bids from collaboratives of educators and service providers to establish practice focused, interprofessional, and academically accredited education which will have a defined impact on improving outcomes for specified groups of patients.[21]

The intent of interprofessional education is not to produce khaki-brown generic workers. Its goal is better described by the metaphor of a richly coloured tapestry within which many colours are interwoven to create a picture that no one colour can produce on its own.

The UK Centre for the Advancement of Interprofessional Education (CAIPE) generated a list of principles of effective interprofessional education to stimulate debate and assist its development, implementation, and evaluation (see box at bottom of next page).[21] Since by definition interprofessional education occurs outside usual professional boundaries, it must be supported by strong representatives of each of the professions involved.

Focus on improvement

The need to make care more efficient (doing things right) and effective (doing the right things)[23] has produced some of the best examples of continuing professional development in the context of interpro-

fessional collaboration. In addition to the Oxford study mentioned earlier, these include the Dorset Seedcorn Project in the United Kingdom and the Institute for Healthcare Improvement's Breakthrough Series in the United States.[24 25]

In the Dorset Seedcorn Project, sponsored by Dorset Health Authority, five primary care practices agreed to join a six month collaborative effort to improve something of concern within the practice. Educational and technical support was provided by the Institute of Health and Community Studies at Bournemouth University.[24] Project teams were formed from natural work groups within the primary care practices; each established its own ground rules before beginning. Grant funds made it possible for each team to take three half-days away from the practice over the six month period. At a meeting of project teams to share their results, all reported progress. Examples included: a redesigned system for incoming telephone inquiries with improved service for patients and less hassle for staff; a new health visitor surgery for young children with acute illness, with improved access and a decreased prescribing rate; better ways to meet the needs of patients who were frequent attenders at surgery; and a new system to improve the quality of medical records and accuracy of medications for elderly people at a local residential home. All five practice teams also reported improved interprofessional understanding and communication.

Similarly in the Breakthrough Series, healthcare organisations from across the United States send interprofessional teams to participate in cross organisational collaboratives focused around specific health issues. Examples are reducing caesarean birth rates, improving outcomes and reducing costs in adult cardiac surgery, providing more effective care for low back pain, and improving asthma care in children and adults.[25] While the focus is on the specific issue at hand, there is also explicit attention to learning about interprofessional teamwork and testing change. The cost is borne by each team's home organisation. Many have seen sufficient results to sponsor teams in several areas.

For example, the Breakthrough collaborative for improving asthma care brought together interprofessional teams from 12 medical centres. In 15 months, nine achieved satisfying results.[25] One team working to reduce emergency department visits and hospital admissions for patients with asthma increased the rate of steroid prescriptions for asthma patients seen in the emergency department (consistent with national guidelines) and improved communication between the emergency department and the primary care clinic. The rates of hospital admissions and emergency visits for asthma patients at high risk decreased by 50%; use of the emergency department by all primary care clinic patients with asthma decreased by 25%.

Effective interprofessional education[22]

- Works to improve the quality of care
- Focuses on the needs of service users and carers
- Involves service users and carers
- Promotes interprofessional collaboration
- Encourages professions to learn with, from, and about one another
- Enhances practice within professions
- Respects the integrity and contribution of each profession
- Increases professional satisfaction

Barriers to interprofessional collaboration and education

- Differences in history and culture
- Historical interprofessional and intraprofessional rivalries
- Differences in language and jargon
- Differences in schedules and professional routines
- Varying levels of preparation, qualifications, and status
- Differences in requirements, regulations, and norms of professional education
- Fears of diluted professional identity
- Differences in accountability, payment, and rewards
- Concerns regarding clinical responsibility

In both the Dorset Seedcorn Project and the Breakthrough Series, the focus for each interprofessional group was on a specific patient need, one that the participants felt was particularly important in their own work site. The learning involved both theory and practice. By studying the processes of their work, the participants discovered some of the reasons for current unwanted results, quite apart from the personal characteristics of the professionals who worked in those processes. They were given the resources (especially their own time) and the support (not the least of which was a feeling of safety) to make changes based on what they had discovered. They generated hypotheses about improvement, made a change, studied the results, and thought together about what should happen next. Their teachers worked as coaches, helping them discover new knowledge as the project demanded it and assisting them as they explored and tackled the group dynamics that arose along the way. One of the teacher-facilitators from the Dorset Seedcorn Project wrote: "The experience of learning and discovering together created excitement and great debate. This engendered mutual respect and an understanding of actual interrelationships and interdependencies which had not been explicit previously. Crucially, they (all the teams) achieved, and it was they, not us."

Implications for continuing medical education

The examples above suggest a path for continuing medical education which combines the professional development and interprofessional collaboration needed for improved practice. Interprofessional groups working within their own practice sites found a shared goal around patient need and discovered together how to improve results. Such an approach requires a different investment of resources: teachers who can coach rather than lecture; professional time away as a work group rather than as individuals; opportunities to study current processes, design and test changes, and analyse the results; and the support of interprofessional education from the senior leadership of each of the pro-

fessions involved, perhaps in exchange for time now spent in uniprofessional learning.

Schön wrote that what practitioners most need to learn is what professional education seems least able to teach.[26] He pointed out that much of professional education rests comfortably on the "high ground," where manageable problems lend themselves to solution through the application of research based theory and techniques. Unfortunately, the problems of greatest concern tend to lie in the "swampy lowland" of messy, confusing problems that defy technical solution. Broadening our vision of continuing medical education to include continuing professional development in the context of interprofessional collaboration and practice improvement may help doctors and their professional partners find answers to the swampy problems most important to the health of their patients and communities.

1 Headrick L, Crain E, Evans D, Jackson MN, Layman BH, Bogin RM, et al. National Asthma Education and Prevention Program Working Group Report on the quality of asthma care. *Am J Respir Crit Care Med* 1996;154:S96-118.
2 Ovretveit J, Mathias P, Thompson T. *Interprofessional working for health and social care*. Basingstoke: MacMillan, 1997.
3 Davis DA, Thomson MA, Oxman AD, Haynes B. Changing physician performance: a systematic review of the effect of continuing medical education strategies. *JAMA* 1995;274:700-5.
4 Standing Committee on Postgraduate Medical and Dental Education. *Continuing professional development for doctors and dentists*. London: SCOPME, 1994.
5 West M. Promoting interprofessional collaboration. *Newsletter of European Network for the Development of Multiprofessional Education in Health Sciences (EMPE)* 1997 February:12.
6 Baldwin DC. *The role of interdisciplinary education and teamwork in primary care and health care reform*. Rockville, MD: Bureau of Health Professions, Health Resources and Services Administration, 1994. (Order No 92-1009(P).)
7 Hackman JR, ed. *Groups that work (and those that don't): creating conditions for effective teamwork*. San Francisco: Jossey-Bass, 1990.
8 Headrick LA, Knapp M, Neuhauser D, Gelmon S, Norman L, Quinn D, et al. Working from upstream to improve health care: the IHI Interdisciplinary Professional Education Collaborative. *Jt Commission J on Qual Improvement* 1996;22:149-64.
9 Hill LA. *Managing your team*. Boston: Harvard Business Publishing, 1995. (Harvard Business School No 9-494-081.)
10 Katzenbach JR, Smith DK. *The wisdom of teams: creating the high performance organization*. Boston: Harvard Business School Press, 1993.
11 Bernard M, Connelly R, Kuder LC, Mellor J, Norman L, Tsukuda RA. Interdisciplinary education. In: Klein S, ed. *A national agenda for geriatric education: white papers*. Rockville, MD: Bureau of Health Professions, Health Resources and Services Administration, 1995:57-80.
12 Scholtes PR. *The team handbook*. Madison, WI: Joiner Associates, 1988.
13 Coles C. Educating the health care team. *Patient Education and Counseling* 1995;26:239-44.
14 Poulton BC, West MA. Primary health care team effectiveness: developing a constituency approach. *Health Social Care* 1993;2:77-84.
15 Brookfield SD. *Understanding and facilitating adult learning*. San Francisco: Jossey-Bass, 1986.
16 Kolb DA. *Experiential learning: experience as the source of learning and development*. Englewood Cliffs, NJ: Prentice-Hall, 1984.
17 Benner P. *From novice to expert*. Menlo Park, CA: Addison-Wesley, 1984.
18 Langley GJ, Nolan KM, Nolan TW, Provost L. *The improvement guide*. San Francisco: Jossey-Bass, 1996.
19 Nelson GC, Batalden PB, Ryer JC. *Clinical improvement action guide*. Oakbrook Terrace, IL: Joint Commission, 1998.
20 Lawrence M, Packwood T. Adapting total quality management for general practice: evaluation of a programme. *Qual Health Care* 1996;5:151-8.
21 NHS Executive, South and West Region, Interprofessional Education and Training Development Programme. 1997/2001 Invitation to bid for major and minor awards, 1997. Bristol: NHS Executive, 1997.
22 UK Centre for the Advancement of Interprofessional Education. Principles of interprofessional education. CAIPE Bulletin 1996;No 11:1.
23 Poulton BC, West MA. Effective multidisciplinary teamwork in primary health care. *J Advanced Nursing* 1993;18:918-25.
24 Campion-Smith C, Wilcock P. *Interim report, Dorset Seedcorn Project*. Bournemouth: Institute of Health and Community Studies, Bournemouth University, 1997. (Internal report.)
25 Weiss KB, Mendoza G, Schall MW, Berwick DB, Roessner J. *Breakthrough Series guide: improving asthma care in children and adults*. Boston: Institute for Health Care Improvement, 1997.
26 Schön DA. *Educating the reflective practitioner*. San Francisco: Jossey-Bass, 1987.

Lessons from children

Wiser beyond their years

Karl was suffering from advanced cystic fibrosis and aged just 12 when he told a school friend that he was going to die. A few days later Karl was admitted to hospital and his absence from school led his friend to think this was because he had died. This information got back to Karl's mother who, feeling too upset to handle it, asked me if I would talk with him.

Karl was still in hospital when I received this request, so, picking a time when the ward was quiet, I asked him if he would like a talk. He said he would. I then asked him if he would like it here in bed or in my room. He chose my room. Stalling for time, I then offered him a coffee. His immediate response was to accept, but said he would make it. Promptly fishing in his locker for his own supply, he went to the kitchen.

Waiting in my room for the coffee, I tried to think how best to cope with this interview. I would have preferred the bed because then I could have sat on it and been near enough to touch him. But this place was his choice and he had wanted us to drink his coffee, so it was very much his interview. Why then not let him sit in my chair and run the whole thing? This suggestion seemed to please him.

This was the first time that I had realised that my chair was higher than the comfortable one I normally gave to patients or parents, and so I found myself looking up at Karl and felt distinctly disadvantaged. Karl, on the other hand, seemed perfectly composed and asked several straightforward questions, clearly indicating that he knew how ill he was. When he eventually got round to asking when I thought he would die I told him honestly that I didn't know. I didn't. I explained how impossible this was to predict and reminded him of other patients we had both known who had lived well beyond everyone's expectations. Putting the ball back in his court I asked him when he thought he would die. Without a moment's hesitation, he answered "When I'm about 18."

That revealing statement showed that he had already given the matter careful thought and the way he said it suggested that he had already achieved a remarkable degree of acceptance. It also gave me a helpful understanding of his expectations. But the most unexpected and equally instructive outcome was the feedback I got from his mother: apparently, the only thing he told her about our whole conversation, and he said it with evident pride, was that he had sat in my chair and made me coffee.

This experience highlighted for me the need for all ill people, even quite young children, to keep some control over their lives. It also taught me to be aware in future of my seating arrangements.

(Karl died, aged 22, just two years after an unsuccessful heart and lung transplant.)

Olive M McKendrick, *retired paediatrician, Liverpool*

We welcome articles up to 600 words on topics such as *A memorable patient, A paper that changed my practice, My most unfortunate mistake,* or any other piece conveying instruction, pathos, or humour. If possible the article should be supplied on a disk. Permission is needed from a patient or a relative if an identifiable patient is referred to. We also welcome contributions for "Endpieces," consisting of quotations of up to 80 words (but most are considerably shorter) from any source, ancient or modern, which have appealed to the reader.