

## Calcium channel blockers

*The jury is still out on whether they cause heart attacks and suicide*

Calcium antagonists are used extensively for treating high blood pressure and angina. Since 1995 they have been accused of causing myocardial infarcts, cerebrovascular events, cancer, bleeding, depression, and suicide by mechanisms that include pro-ischaemic, pro-arrhythmic, negative inotropic, hypotensive, and reflex sympathetic effects (cardiovascular events); inhibition of apoptosis (cancer); inhibition of platelet aggregation and the normal vasoconstrictive response to bleeding (bleeding); excess hypotension or interference with neurones and receptors involved in mood regulation (depression). A recent review of the evidence recommended no change to current guidelines and clinical practice,<sup>1</sup> but since then a report of raised suicide rates among patients taking calcium antagonists has been published,<sup>2</sup> together with three randomised controlled trials suggesting that myocardial infarcts might be increased in diabetics on calcium antagonists.<sup>3-5</sup>

Much of the evidence concerning risk of cardiovascular events, cancer, and bleeding, both published and unpublished, was reviewed in 1996-7 by an ad hoc subcommittee of the Liaison Committee of the World Health Organisation and the International Society of Hypertension.<sup>1</sup> The principal conclusions were that the available evidence did not prove the existence of either beneficial or harmful effects of calcium antagonists on the risks of major coronary heart disease events and that there was no good evidence for adverse effects of calcium antagonists on either cancer or bleeding risks. The committee commented that the bulk of the evidence for adverse effects was derived from observational studies or small randomised clinical trials and pointed to a "clear failure of pharmaceutical companies, regulatory authorities, and clinical researchers to ensure the timely conduct of studies, involving both large numbers of cases and random assignment of treatments." Many such large randomised clinical trials are now in progress, but reliable detection of any modest adverse or beneficial effect of calcium antagonists is not expected until early in the next century. Do these recent published studies alter the picture enough to suggest clinicians should change their practice?

Prompted by several studies suggesting a link between calcium channel blockers and depression, Lindberg et al investigated the associations between use of cardiovascular drugs and suicide in Sweden.<sup>2</sup> In a cross sectional ecological study they found a significant correlation between the rates of use of calcium channel blockers and age adjusted suicide

rates in 152 of Sweden's 284 municipalities ( $r=0.29$ ;  $P<0.001$ ). Furthermore, in a population based cohort study in one municipality they reported that the relative risk of suicide, adjusted for differences in age and sex, among users of calcium channel blockers was 5.4 (95% confidence interval 1.4 to 20.5) compared with users of other antihypertensive agents. It is noteworthy that there were only 9 suicides in the cohort study (5 users of calcium antagonists and 4 non-users). The authors concluded that use of calcium channel blockers may increase the risk of suicide.

These two studies were observational: treatment was provided to individual municipalities (ecological study) and individual patients (cohort study) on the basis of clinical indication, rather than random assignment. In these circumstances the potential for systematic errors, principally due to confounding by indication, is great. Calcium channel blockers have been reported to be used more commonly in sicker patients,<sup>6</sup> so the differences in suicide rate could have been due simply to differences between the types of patients given each type of drug.

The Multicenter Isradipine Diuretic Atherosclerosis Study (MIDAS) was a multicentre, randomised, double blind, controlled trial in 883 hypertensive patients, comparing the effect of isradipine and hydrochlorothiazide on the progression of early atherosclerosis in carotid arteries.<sup>3,7</sup> After three years' follow up there was no difference in the primary endpoint between the two treatments. There was, however, a trend for an increased incidence of major vascular events (myocardial infarction, stroke, congestive heart failure, angina, and sudden death) in patients taking isradipine compared with those taking hydrochlorothiazide (25/442 v 14/441;  $P=0.07$ ). In a recent reanalysis of the trial the increase in major vascular events associated with the use of isradipine appeared to be largely confined to patients with impaired glucose metabolism.<sup>3</sup> Patients with a glycosylated haemoglobin greater than 6.6% and randomised to isradipine had more than double the risk of an event than those randomised to diuretic (15/199 v 6/216;  $P=0.04$ ).

In the Fosinopril Amlodipine Cardiovascular Events Trial (FACET) the relative benefits of fosinopril and amlodipine were compared in 380 hypertensives with non-insulin dependent diabetes.<sup>4</sup> The patients receiving fosinopril had a significantly lower risk of major cardiovascular events (fatal or non-fatal acute myocardial infarction, fatal or non-fatal stroke,

hospitalised angina) than those receiving amlodipine (14/189 v 27/191;  $P=0.03$ ).

The Appropriate Blood Pressure Control in Diabetes (ABCD) trial is a prospective, randomised, blinded trial comparing the effects of moderate control of blood pressure with those of intensive control on the incidence and progression of diabetic nephropathy, neuropathy, retinopathy, and cardiovascular events. The study also compared nisoldipine with enalapril as first line antihypertensive agents in terms of the prevention and progression of complications of diabetes. The primary end point was the change in 24 hour creatinine clearance. Secondary end points included cardiovascular events, retinopathy, clinical neuropathy, urinary albumin excretion, and left ventricular hypertrophy. The recent report in the *New England Journal of Medicine* concerns only data on a secondary end point (myocardial infarction) in the subgroup of patients who had hypertension ( $n = 470$ ).<sup>5</sup> After five years' follow up the data safety and monitoring board recommended that nisoldipine treatment should be terminated in the hypertensive patients, as in this subgroup it was associated with a higher incidence of fatal and non-fatal myocardial infarction than enalapril (25/235 v 5/235;  $P < 0.001$ ).

Commenting in the *Lancet* on the results of the above three trials, Pahor et al recommended that angiotensin converting enzyme inhibitors and low dose diuretics, rather than calcium antagonists, should be the preferred first line agents for hypertensive patients with impaired glucose metabolism or diabetes.<sup>8</sup> However, these trials are some distance from definitively proving deleterious effects of calcium antagonists in diabetes. The trials were relatively small—in aggregate a total of 92 cardiovascular events occurred in 1265 patients—and hence prone to random errors. More than half of the original cohort of the ABCD trial discontinued their assigned study medication before completion of the study, raising the possibility of systematic bias. In both the MIDAS and ABCD studies cardiovascular events were secondary end points, and the apparent adverse effects were identified only by subgroup analyses. The authors of the ABCD trial themselves commented that their results should be interpreted cautiously and would require confirmation. In both the ABCD and FACET studies long acting calcium channel blockers were compared with angiotensin converting enzyme inhibitors; without a placebo group it is impossible to say whether these studies show harmful effects of calcium antagonism or beneficial effects of angiotensin converting enzyme inhibition. Interestingly, in the ABCD trial the rate of myocardial infarction among patients with non-insulin dependent diabetes who were randomly assigned to treatment with nisoldipine was similar to that seen in historical controls.

Some researchers and clinicians clearly consider that the evidence against calcium antagonists is sufficient to advise the use of alternative types of drug where possible. In considering this evidence, however, we should remember the "cholesterol controversy" of the early 1990s. At that stage evidence from observational studies suggested an association between low cholesterol concentration and increased non-cardiovascular morbidity and mortality.<sup>9</sup> Several meta-analyses of randomised clinical trials reported negative

effects of lipid lowering interventions on non-coronary heart disease mortality.<sup>10</sup> Lipid lowering strategies could have been abandoned on the basis of these studies. The benefits associated with effective lipid lowering by statins, in terms of reductions of both coronary events and all cause mortality, seen in the large, adequately powered, randomised lipid lowering trials—4S, WOSCOPS, and CARE<sup>11-13</sup>—illustrate clearly that this would have been a mistake.

When used in hypertension or angina, calcium channel blockers probably either have no effect on risk or cause modest harm or modest benefit. Reliable detection of a 20% increase or decrease in risk requires studies in which at least 1000 patients develop the relevant event during follow up. Two trials are currently under way of sufficient size and duration to definitively confirm or rule out modest effects on cardiovascular risk and all cause mortality. The Antihypertensive and Lipid Lowering treatment to prevent Heart Attack Trial (ALLHAT) is a comparison of first line therapy with amlodipine, lisinopril, doxazosin, or chlorthalidone; the Anglo-Scandinavian Coronary Outcomes Trial (ASCOT) is a comparison of the effect of two therapeutic regimens,  $\beta$  blockers with or without diuretics versus calcium antagonists with or without angiotensin converting enzyme inhibitors, on non-fatal myocardial infarction and fatal coronary heart disease in hypertensive patients at high risk of cardiovascular events. Hence, I would advocate no change in current clinical practice on the basis of non-randomised observational studies, or subgroup analyses of small clinical trials not specifically designed to assess morbidity and mortality. The conclusions of the 1997 WHO and International Society of Hypertension committee remain valid<sup>1</sup> until we have the results of large randomised trials.

Alice V Stanton *Senior lecturer*

Department of Clinical Pharmacology and Epidemiology, National Heart and Lung Institute, Imperial College of Science, Technology, and Medicine, St Mary's Hospital, London W2 1NY

I have been and will be involved in trials of all classes of antihypertensive agents, including the ASCOT trial.

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## Toys and games: poorly recognised hearing hazards?

*European case ascertainment will help to confirm the association*

In 1995 the World Health Organisation estimated that 120 million people worldwide had a disabling hearing impairment.<sup>1</sup> Many causes of hearing impairment are recognised, but noise exposure in childhood has been largely ignored.

There is evidence to suggest that children's hearing is particularly vulnerable to noise. Animal experiments have shown a period of particular sensitivity shortly after birth.<sup>2</sup> Moreover, the heads, ears, and external auditory canals of children are shaped differently from those of adults, allowing greater amplification of high frequency sounds,<sup>3</sup> which are relatively more harmful to hearing than low frequency sounds. Over the past decade the incidence of high frequency loss in school-children has not decreased in Scandinavia,<sup>4</sup> although it has in protected industrial workers.<sup>1, 2</sup>

Several studies have reported permanent sensorineural hearing loss in children related to noisy toys, games,<sup>5</sup> fire crackers,<sup>6</sup> and gunfire exposure.<sup>7</sup> Squeaky, brightly coloured toys for babies and toy motor vehicles may emit sounds of 78-108 dB(A) measured at 10 cm distance,<sup>8</sup> while at arm's length model aeroplanes may emit high pitched sounds of 112 dB(A). At the child's ear sound levels of up to 122 dB(A) for toy mobile telephones and 150-160 dB(C) (which exceeds the noise at work peak action level<sup>9</sup>) for toy weapons have been reported and may cause severe auditory damage. Certain toys may be "safe" if used properly, but if used improperly the noise level may greatly exceed the sound levels carrying risk for hearing damage—for example, if a firecracker is thrown and explodes next to the ear, or a toy gun is fired next to the head, as portrayed in videos and films.

Importantly, young children up to the age of 6 years cannot describe hearing loss, and older ones, who can complain of hearing loss or tinnitus after a loud bang, may be reassured by adults who do not understand the risk of damage. Single cases tend not to be reported in medical journals, any individual clinician is unlikely to see many cases, and few doctors have relevant experience and interest.

Reporting the relation between noisy toys and hearing loss is also problematic, as a causal association can be confirmed only when hearing loss or tinnitus is reported immediately after exposure and audiometry results from before and after the incident are available. No such cases have been published. A highly probable relation can be assumed if a normal audiogram was obtained one to three years before the alleged incident. A probable relation is established if the peak sound level of an offending toy exceeds 140 dB(C) and exposure is followed by audiometrically confirmed immediate hearing loss. A probable relation may also be identified by population studies if a worse high

frequency hearing loss, with a characteristic 4 kHz audiometric notch, is identified among children who have used noisy toys than in non-users. However, pure tone audiometry is relatively insensitive for monitoring minor damage, and only children at the more sensitive end of the distribution of noise susceptibility may be affected, so such findings would depend on accurate reports of the amount of use of all types of noisy toy. Newer sensitive tests of cochlear function, such as otoacoustic emission measurements, may help in detecting minor, but definite, auditory deficits.

Toy manufacturers suggest that toy related noise induced hearing loss is rare, and they may be correct. However, the vulnerability of children's hearing to intense sound is unknown, and the lack of reports may reflect only a failure to report such incidents. Precisely because such cases are thought to be rare the approach of case ascertainment is appropriate, as well as the more usual approach of comparing retrospectively exposed and non-exposed groups. Experimental studies in children are unethical, but population studies of young people show about 10% of cases with hearing loss that might be attributable to noise.<sup>8</sup>

The European Concerted Action on Protection Against Noise has established a centre in Gothenburg that will evaluate any possibly hazardous toy and compile a European directory of clinical cases. From this central directory clearer conclusions may emerge about the prevalence of dangerously noisy toys and the consequences of such exposure in childhood. If conclusive evidence does emerge to link noisy toys and hearing damage legislation could ensure that no toy is capable of producing hazardous levels of noise.

Linda M Luxon *Professor of audiological medicine*

Institute of Laryngology and Otology, University College London, London WC1X 8EE (linda.luxon@ucl.ac.uk)

on behalf of Protection against Noise Leisure Noise Research Group, c/o Per-Anders Hellstrom, Sahlgren's Hospital, Hearing Research Laboratory, PO Box 8417, 40275 Göteborg, Sweden

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## Screening for *Chlamydia trachomatis*

*The case for screening is made, but much detail remains to be worked out*

This month the chief medical officer of England published the report of an expert advisory group on *Chlamydia trachomatis*, which highlighted the need for immediate action to reduce the prevalence of chlamydia infection and the morbidity associated with it.<sup>1</sup> Chlamydia is the most prevalent, treatable sexually transmitted infection in the United Kingdom and has serious sequelae, including pelvic inflammatory disease, infertility, ectopic pregnancy, and neonatal infections. All these conditions, except for infertility, have been shown to be preventable if chlamydia trachomatis is treated in its asymptomatic phase. The expert group is proposing an education campaign to increase awareness of chlamydia infection coupled with opportunistic screening of asymptomatic sexually active young women.

The advisory group's main recommendations are to offer testing to all men and women with symptoms of infection, all attenders at genitourinary medicine clinics, and women seeking terminations of pregnancy and to screen opportunistically sexually active women aged under 25 and those over 25 with new sexual partners in the previous 12 months. The group considers that screening for chlamydia meets the Wilson and Junger criteria for a workable screening programme: *C trachomatis* infection is an important problem, asymptomatic infection can be accurately diagnosed, and effective treatment exists. However, having established the case for screening, the group recommends research to design and implement an appropriate screening programme and outlines a research programme amounting to £3.2m. This would address the cost benefit of different approaches, the need for public and professional education, the acceptability of screening, which tests, specimens, and treatments to use, and the most effective way of tracing partners. The government has responded by announcing two pilot projects to start this year as part of a general feasibility study.

The recommendations to target all sexually active women aged under 25, those undergoing terminations of pregnancy, and others at high risk (such as women with a new sexual partner in the previous 12 months) are based on data collected by several centres, but none are sufficient to give a true national picture. In the United States, in family planning settings, screening the under-25s missed 20% of cases of chlamydia infection while screening the under-30s missed only 7%.<sup>2</sup> Data collected from genitourinary medicine clinics in England in 1996 show that 25% of uncomplicated cases of chlamydial infection in women occur in those aged 25-34.

The advisory group has concluded that general practitioners and family planning clinics are best placed to carry out opportunistic screening as, between them, they will see over 95% of their registered patients over a three year period. The group suggests that screening should be offered by general practitioners during routine consultations and that this would be "unlikely to significantly increase the costs associated with treatment." When community midwives offered HIV testing

to all at booking clinics, however, it added an average of 7 minutes per consultation (range 2-15).<sup>3</sup> General practitioners and family planning clinics will need additional time and resources to carry out this programme, and the pilot projects need to address this issue.

Another issue that is likely to emerge is that of reporting by general practitioners of sexually transmitted disease on health reports for insurance purposes. Prior consultation with the Association of British Insurers could prevent recurrence of the types of problems encountered in HIV testing.<sup>4</sup>

For patients with positive results (and the best specimen to take and test to perform have yet to be determined) the advisory group advises referral to genitourinary medicine clinics for a full screen for sexually transmitted diseases and contact tracing. The group recognises, however, that some patients may not want to attend such a clinic. Contact tracing for chlamydia, which currently does not receive high priority in genitourinary medicine clinics and is ineffective elsewhere,<sup>5</sup> needs much improvement before a screening programme will be successful.

The role of chlamydia in infertility is well documented: the disease may be implicated in as much as 50% of cases. Many cases of infertility occur in the absence of clinical pelvic inflammatory disease, and when this disease process occurs is unknown. A reduction of the incidence of chlamydia infection in the community may therefore produce a corresponding fall in the related incidence of infertility.

The role of health education needs to be emphasised to ensure the efficacy of any screening programme. As schools can provide education about sexually transmitted disease only with parental consent, the burden of providing such education would presumably fall to general practitioners and family planning clinics. The research projects could usefully address whether the severe consequences of untreated chlamydia infection warrant an active government role in providing sexual health education. Indeed, final judgment on the value of the proposed screening programme—and whether Britain can achieve the reductions in morbidity that have been seen in, for example, Sweden<sup>6</sup>—must await the promised pilots.

Fiona Boag *Consultant physician in genitourinary medicine*

Frank Kelly *Authors' editor*

Chelsea and Westminster Hospital, London SW10 9NH  
(madames@crusaid-star.co.uk)

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# Chronic obstructive pulmonary disease

*No longer any justification for therapeutic nihilism*

In an environment where clinicians are increasingly conscious of the conflicting pressures of patients' expectations and evidence obsessed purchasers, there is a temptation to regard guidelines as a potential straightjacket (and protocols and clinical pathways even more so)—or just irrelevant. But the recently published British Thoracic Society guidelines for managing chronic obstructive pulmonary disease should be welcomed.<sup>1</sup>

Together with their international counterparts,<sup>2-4</sup> they signal a sea change in attitudes towards the management of this common disease, historically summed up at best as "treat it as if it were asthma" and at worst as neglectful nihilism. In addition, they set out a pragmatic definition of chronic obstructive pulmonary disease—a chronic slowly progressive disorder characterised by airways obstruction which does not change markedly over several months—which ought to see the end of the paralysing effect of trying to define similarities and differences between chronic obstructive pulmonary disease and asthma (are you a lump or a splitter?). This should also liberate perceptions about the scope for management of the disease and lead to improvements in standards of care.

The British guidelines offer an important advance over previous ones. They move clearly in the direction of an evidence based rather than merely consensus based approach to drawing up guidelines, although arguably not far enough. These guidelines often make the distinction between a treatment for which evidence indicates that it will have no benefit from one for which evidence on efficacy is simply lacking. The approach is less rigorous than in a recent set of guidelines for the management of asthma in which categories of evidence and the strength of recommendations were clearly set out,<sup>5</sup> but it is nevertheless a step towards more rational and effective management of a disease for which expensive drugs often achieve so little. Clinicians need to know (or be told?) when time honoured practice has been shown not to work.

This approach has also permitted a more balanced emphasis on the merits of non-pharmacological treatments. In particular, the role of smoking cessation rightly receives pride of place, and pulmonary rehabilitation is introduced. But here the American Thoracic Society standards<sup>2</sup> offer much more—notably a specific protocol for smoking cessation and a clearer outline and evaluation of what constitutes a pulmonary rehabilitation programme. If these approaches are to be encouraged rather than paid just lip service, then something more of the evidence in their favour as well as the "how to" is required in the guidelines, particularly for the non-specialist.

Given that inhaled drug treatment will remain an important issue for most clinicians treating chronic obstructive pulmonary disease, the guidelines could have helpfully given a more definitive approach to the vexed question of reversibility testing and its relevance to the effectiveness of long term treatment (as opposed to prognosis) using either inhaled bronchodilators or

corticosteroids. This is particularly important given the justifiable emphasis which the guidelines place on obtaining spirometric values for diagnosing chronic obstructive pulmonary disease and assessing its severity. Here, an earnest attempt to present balanced evidence on a subject beset with contradictions and caveats has complicated the attempt to give clear directions. For bronchodilators, the problem is summed up: "a negative FEV<sub>1</sub> response does not preclude benefit." This concurs with the position of the American Thoracic Society: "the absence of a response never justifies withholding bronchodilator therapy."<sup>2</sup> This emphasis on acute reversibility tests as a guide to the potential benefits of long term treatment is the residue of an era when asthma and chronic obstructive pulmonary disease were lumped and not split. Perhaps such acute-chronic response relations ought to be studiously ignored. For inhaled steroids, the Australian and New Zealand guidelines advocate just such an approach.<sup>3</sup> Given that the effectiveness or otherwise of inhaled corticosteroids and of long acting bronchodilators is the subject of current research—and that the guidelines cannot yet draw on definitive evidence about the role of these agents—then perhaps a revision should already be planned.

In the meantime, the value of these British guidelines should be emphasised and not diminished. They are well presented and brief and for general practitioners place appropriate emphasis on community based aspects of management. They represent an educational resource which is concise and excellently referenced: they should be required reading for trainees in general practice and medicine. Tucked away in the summary, we learn that the guidelines are intended to offer "a benchmark for current best practice." But a statement of this goal is unfortunately missing from the foreword. Indeed, the aims and the intended applications for these guidelines, as well as a description of the methodological approach, ought to have been presented much more prominently, as was done to some extent by the European group.<sup>4</sup> The guidelines deserve to be promoted as a credo and not just offered as an option.

D Robin Taylor *Senior lecturer in respiratory medicine*

Department of Medicine, University of Otago Medical School, Dunedin, New Zealand

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# Breaking down language barriers

*The NHS needs to provide accessible interpreting services for all*

The movement of human populations over vast distances in the search for a better or safer life is not new,<sup>1</sup> but the 20th century has been distinguished by migration on an unprecedented scale: 90 million people may now live outside their country of birth, over 13 million of them refugees.<sup>2</sup> Their countless individual journeys have transformed the demographic characteristics of large Western cities, which are now home to many different minority ethnic communities.

The NHS was established before the period of greatest immigration into the United Kingdom, and doctors could once have expected to share the same culture and language as their patients. This expectation has changed—minority ethnic groups comprise 6% of the UK population<sup>3</sup>—but it is far from clear that the NHS as a whole has changed rapidly enough, especially in the inner cities, to meet the challenge posed by patients whose English may not be good enough to communicate adequately with health professionals.

Health authorities lack knowledge about the languages spoken in their districts and of the extent of the need for interpreter services, which are generally not available outside traditional working hours.<sup>4</sup> Inadequate resources devoted to communication and information services underlie a much impaired service for patients from minority ethnic groups.<sup>5</sup> Doctors and other healthcare workers struggle to provide adequate care but are thwarted by an institutional orientation towards a standard service no longer appropriate for a heterogeneous population.

Most initial healthcare contacts take place in general practice. General practitioners in inner cities can often obtain a professional interpreter for “important” consultations, but what of consultations that are not planned in advance? Only practices with a majority of patients from a single language community can expect to have an interpreter available throughout surgery hours. The much more typical inner city practice, with small numbers of non-English speaking patients from several language communities, is likely to have very limited access to professional interpreting.

Healthcare professionals then must choose between several imperfect alternatives. Phelan and Parkman have drawn attention to the disadvantage of using friends and relatives for interpreting medical consultations and, in particular, the importance of not using children.<sup>6</sup> Children lack the emotional and cognitive maturity to assume the responsibility of interpreting conversations between parents and professionals. In many families details of bodily function and dysfunction are private and an unsuitable subject for discussion with children. Despite official acceptance that children are not appropriate interpreters for their parents, young children are often used as interpreters. The lack of interpreting services for non-English speaking patients presenting acutely is a source of real danger for the patient and adds significantly to the stress experienced by the clinician and the informal interpreter. If we are

really committed to a multicultural society and equal access then we must close this gap.

Provision of physically present interpreters for all possible languages, 24 hours a day, in all health settings is unrealistic. But great improvements can be made with some additional resources. Pointon has highlighted the advantages of telephone, or remote, interpreting.<sup>7</sup> Appropriate equipment and training are essential: ideally a hands off conference telephone should sit between doctor and patient to allow the consultation to be consecutively interpreted. Telephone interpreting carries the obvious disadvantage of not allowing the interpreter to see a patient's non-verbal communication and is demanding for both doctor and patient. However, patient confidence in the confidentiality of the consultation may be higher when the interpreter is not present, especially if physically present interpreters would otherwise be recruited from the patient's local community.

In the United Kingdom commercial telephone translation services are available but are expensive and employ interpreters who may not have experience in medical interpreting; some districts run local telephone interpreting services, but provision is patchy. Little is known about the effects of different translation provision on the quality or costs of health care, but evidence from the United States, where interest in telephone translation is growing,<sup>8</sup> suggests that it can allow high quality consultations and is valued by patients.<sup>9</sup> Clearly more research is needed into the effects of remote interpreting, and we need to explore how various combinations of remote and physically present interpreter services might best meet needs at an affordable cost. One day, a rapid access, all day, comprehensive telephone interpreting service in the NHS might help to make equality of access to health care more of a reality for some ethnic minority groups.

David Jones *Lecturer*

Department of Primary Care and Population Sciences, Royal Free and University College Medical Schools, Whittington Hospital, London N19 5NF

Paramjit Gill *Senior lecturer*

Department of General Practice, Medical School, Birmingham B15 2TT

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