Letters

Guidelines from the British Hypertension Society

See editorial by Campbell

Cholesterol values seem to diverge

EDITOR—The targets for cholesterol management seem to be ever decreasing, but I cannot get my head around the fact that in the new guidelines from the British Hypertension Society box 8 suggests we should consider treatment if the 10 year risk of cardiovascular disease is >20% and the total cholesterol level is >3.5 mmol/l but the target to be attained, which is printed beside box 8, is higher, 4 mmol/l.[1]

Can someone explain this anomaly to a simple general practitioner who will have to explain it to patients?

Gerry E Burns *general practitioner principal*
Duncairn Medical Practice, Belfast BT15 2GE
duncairn33@yahoo.ie

Competing interests: None declared.

1 Williams B, Poulter NR, Brown MJ, Davis M, McInnes GT, Potter JF, et al. British Hypertension Society guidelines for hypertension management 2004 (BHS-IV): summary. *BMJ* 2004;328:634-40. (13 March.)

Life in the real world may not allow recommendations to be implemented

EDITOR—Williams et al in their summary of the British Hypertension Society's guidelines say that people with "high normal" systolic blood pressure (130-139 mm Hg) or diastolic blood pressure (85-89 mm Hg) and people who have had high blood pressure readings at any time previously should have their blood pressure measured annually.[1] This implies that any patient who has ever had a systolic blood pressure greater than 130 mm Hg should from then on be kept under annual review.

A search of our general practice database of 6200 patients showed that 1700 fell into this category. A check of similar practices shows that this figure is reasonably representative in our area. Our practice population is below average in age and deprivation. Some simple mathematics suggests that as a practice we need to review 34 patients a week.

Can I ask the authors what consideration was given to the practical implications of their guidelines? Did they look at how this guideline might be implemented? Have they looked at the effect it might have on already overspent prescribing budgets? What effect will this have on practice workload?

The figures above suggest this guideline is unworkable in the real world of general practice.

Paul N Green *general practitioner*
Kemnay Medical Group, Kemnay, Aberdeenshire AB51 7JB
paul.green@kemnay.grampian.scot.nhs.uk

Competing interests: None declared.

1 Williams B, Poulter NR, Brown MJ, Davis M, McInnes GT, Potter JF, et al. British Hypertension Society guidelines for hypertension management 2004 (BHS-IV): summary. *BMJ* 2004;328:634-40. (13 March.)

BHS is set to bankrupt NHS

EDITOR—If the new British Hypertension Society (BHS) guidelines[1] are evidence based I'll eat my ALLHAT.[2] This and other evidence points to thiazide-type diuretics as the initial treatment of choice. New US guidelines reflect this,[3] but the BHS recommends a range of initial drug types for hypertension.

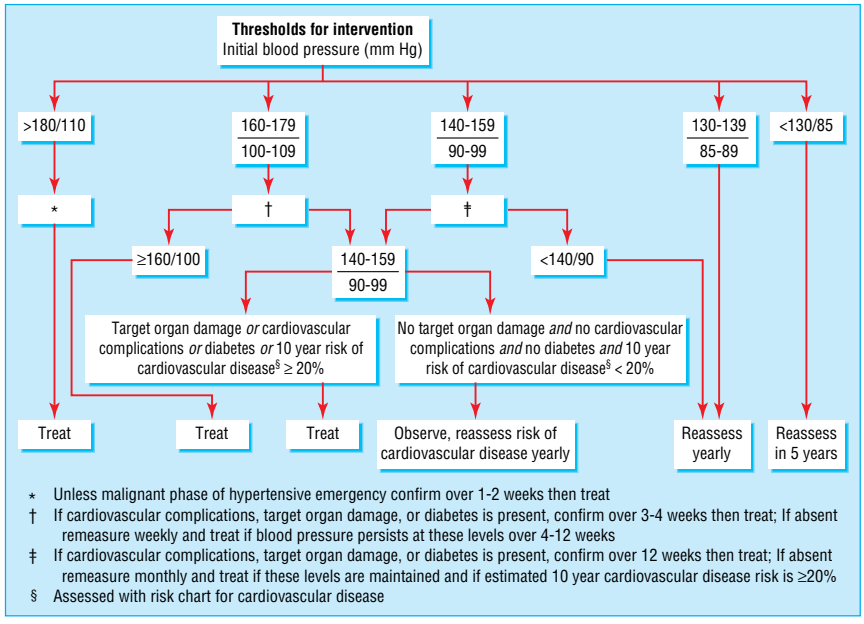
The BHS recommends primary prevention use of statins for those with sustained "starting" blood pressure >140 mm Hg systolic or >90 mm Hg diastolic, or both, and an estimated risk of cardiovascular disease >20% over the next 10 years. The set target is to lower total cholesterol by 25% or low density lipoprotein cholesterol by 30% or to reach <4.0 mmol/l or <2.0 mmol/l respectively, whichever is the greater.

Where is the evidence? The BHS cites Scandinavian cardiac outcomes trial-lipid lowering arm (ASCOT-LLA)[4] and the heart protection study.[5] In ASCOT-LLA subjects were chosen with high risk and higher blood pressure (>160/>100 mm Hg), or treated hypertension (>140/>90 mm Hg).[4] Most participants in the heart protection study had established vascular disease or diabetes.[5] The effect of the set statin dose achieved an average total cholesterol of 4.2 mmol/l in ASCOT-LLA[4]; around 50% had higher cholesterol. These studies did not chase a cholesterol target. Thus the BHS encourages unproved, aggressive treatment.

These proposals beggar belief and could beggar the NHS: 20% of the adult population could be given both blood pressure drugs and high dose statins. Society needs to decide whether it wishes to medicalise risks that largely relate to poor lifestyle choices. There is a need for political decisions based on affordability. The BHS compounds its dodgy interpretation of the evidence by dodging the wider implications of its recommendations.

Martin G Duerden *general practitioner*
Meddygfa Gyffin, Conwy, North Wales LL32 8LT
martin@theduerdens.co.uk

Competing interests: None declared.



Blood pressure thresholds for intervention

1 Williams B, Poulter NR, Brown MJ, Davis M, McInnes GT, Potter JF, et al. British Hypertension Society guidelines for hypertension management 2004 (BHS-IV): summary. *BMJ* 2004;328:634-40. (13 March.)
2 ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group. Major outcomes in high-risk hypertensive patients randomized to angiotensin-converting enzyme inhibitor or calcium-channel blocker vs diuretic: the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). *JAMA* 2002;288:2981-997.
3 Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. The seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VII). *JAMA* 2003;289:2560-72.
4 Sever PS, Dahlof B, Poulter NR, Wedel H, Beevers G, Caulfield M; ASCOT investigators. Prevention of coronary and stroke events with atorvastatin in hypertensive patients who have average or lower-than-average cholesterol concentrations, in the Anglo Scandinavian cardiac outcomes trial-lipid lowering arm (ASCOT-LLA): A multicentre randomised controlled trial. *Lancet* 2003;361:1149-58.
5 Heart Protection Study Group. MRC/BHF heart protection study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial. *Lancet* 2002;360:7-22.

Is hypertension really a disease?

EDITOR—In the guidelines from the British Hypertension Society Williams et al say that the prevalence of hypertension is 42% in people aged 35-64.[1] This must mean that in older patients the condition is present in well over half of the population.

With such a huge prevalence it is not surprising that control of this "disease" in the United Kingdom is so poor. Perhaps general practitioners would have been wise to calculate the time and effort (never mind the ethics) entailed in controlling the blood pressure of millions of elderly patients before accepting this aspect of the new contract for general medical services.

More importantly, has the disease model for diagnosis and treatment of hypertension been accepted by the population at large? Do people really want polypharmacy, with its attendant risks, so that they are marginally less likely to die of cardiovascular disease and so marginally more likely to die of something else? Or could it be that the dependence of the multibillion pound drug industry on antihypertensive agents is stifling the debate?

Paul A Sackin *general practitioner*
Alconbury, Huntingdon, Cambridgeshire PE28 4EQ
paulsackin@compuserve.com

Competing interests: PAS is a UK general practitioner. This means that from 1 April 2004 part of his income has been related to the control of his patients' hypertension.

1 Williams B, Poulter NR, Brown MJ, Davis M, McInnes GT, Potter JF, et al. British Hypertension Society guidelines for hypertension management 2004 (BHS-IV): summary. *BMJ* 2004;328:634-40. (13 March.)

Numbers are missing

EDITOR—The new guidelines from the British Hypertension Society exemplify the best and the worst features of current medical thought processes.[1 2] They exemplify the best in collating evidence from many trials and transforming it into a clear and useful form. They define the problem clearly and positively guide us as doctors, and patients, on future treatment of the defined problem.

Yet they miss some important wider issues. Maybe the omission is deliberate, or maybe the authors are not fully aware of these problems. From a secondary care perspective, seeing patients in admissions wards with strokes due to hypertension, to reduce blood pressure in everyone with hypertension seems to make sense. Yet when viewed from a primary care or public health viewpoint, such a view is far from proved.[3]

The hypertension guidelines give no information on numbers needed to treat to achieve a reduction in cardiovascular events. Yet the numbers who may need treatment are vast: 42% of those aged 35-64 (about 12 million people).[1] Williams et al also give no information on the figures that matter to patients—namely, their personal probability of benefit[4] from treatment and the number needed to treat to harm, either by pharmacological side effects or the psychological side effects from having a disease label.

Until these numbers are explicit, I as a primary care doctor cannot know whether in any individual case I am doing more harm or good to my patient in diagnosing hypertension. If I do not know this I cannot give my patient accurate information about treatment, and so I cannot obtain informed consent to, and concordance with, any treatment plan. This lack is a major omission before we decide whether to implement these guidelines and whether they can achieve successful reduction of individual levels of cardiovascular risk.

Peter Davies *general practitioner*
Mixenden Stones Surgery, Halifax HX2 8RQ
npgdavies@blueyonder.co.uk

Competing interests: None declared.

1 Laurent S. Guidelines from the British Hypertension Society. *BMJ* 2004;328:593-4. (13 March.)
2 Williams B, Poulter NR, Brown MJ, Davis M, McInnes GT, Potter JF, et al. British Hypertension Society guidelines for hypertension management 2004 (BHS-IV): summary. *BMJ* 2004;328:634-40. (13 March.)
3 Tate P. Hypertension: a tutorial for our time. *Educ Primary Care* 2002;13:541-3.
4 Misselbrook D, Armstrong, D. Thinking about risk: Can doctors and patients talk the same language? *Fam Pract* 2002;19:1-2

Authors' reply

EDITOR—The optimal lipid targets are a total cholesterol concentration of <4.0 mmol/l or a reduction of 25% from baseline. The percentage reduction approach is needed for patients starting statin treatment for secondary prevention or because of their high cardiovascular risk but whose total cholesterol value is already close to the target. For example, for such patients starting statin treatment with a total cholesterol of 4.1 mmol/l, lowering cholesterol to 3.9 mmol/l is clearly not sufficient and a 25% reduction is required.

Many people in the United Kingdom are indeed unaware that they have a raised blood pressure and are therefore at increased risk. Most will develop more serious hypertension over time. How will that be detected without a programme of monitoring? It may not be cost effective for Green to do it, but somebody should. The "real world of general practice" cannot meet the challenges of modern health care, so changes in service delivery are needed.

The ALLHAT study is just one of many reviewed by the BHS.[1] People 55 years of age or over were recruited. BHS-IV guidelines recommend diuretics as one of two evidence based options for initial treatment for people aged 55 years and above. Below this age other drugs have been proved to be more effective at lowering blood pressure[2]—the key objective of treatment. Hence the AB/CD algorithm provides a simple template for selecting the first and subsequent drugs to facilitate and encourage reaching blood pressure targets on the basis of age and ethnic group. We have suggested an audit standard of total cholesterol <5.0 mmol/l and an optimal target of 4 mmol/l. The former reflects established guidance, the latter increasing awareness, endorsed by clinical trials, that lower achieved cholesterol values further reduce cardiovascular risk.[3]

ASCOT-LLA was a primary prevention study that recruited patients with an average 10 year cardiovascular risk similar to the 20% risk threshold suggested by the guidelines for primary prevention.[4] In this study the addition of a statin for people with well controlled blood pressure (138/80 mm Hg) clearly showed an additional 36% reduction in fatal and non-fatal coronary events and a 27% reduction in stroke. This fully justifies considering statin treatment as a complementary means of further reducing cardiovascular risk in people with treated hypertension whose baseline 10 year cardiovascular disease risk is estimated to be $\geq 20\%$, irrespective of baseline cholesterol values.

Most older people have high blood pressure—75% of UK adults over the age of 65 years ($\geq 140/90$ mm Hg). However, BHS-IV is more conservative than other international guidelines. It does not recommend treatment for all people with stage 1 (mild) hypertension (blood pressure 140-159/90-99 mm Hg). Instead, for primary prevention, it recommends treating only patients at high risk of cardiovascular disease (10 year risk $\geq 20\%$). The cost effectiveness of treating hypertension was recently analysed by the National Institute for Clinical Excellence (NICE) as part of its guideline development process. Treating hypertension alone was shown to be one of the most cost effective medical interventions thus far evaluated—hence the incorporation of hypertension as one of the key targets in the new general medical services contract.

That a specific patient will benefit from a particular intervention is not certain, only that reducing blood pressure and cholesterol will on average reduce cardiovascular disease risk. The size of absolute benefit depends on the absolute risk and relative risk reduction. The former can be estimated using the risk tables in the guidelines and the latter is known. Extensive trial evidence is available to confirm that treatment benefits outweigh any harm across the treatment range recommended.

Many doctors have been reluctant to acknowledge the success of healthcare poli-

cies directed at reducing the risk of cardiovascular disease in the United Kingdom. Primary care has played a central part. Service redesign, coupled with effective implementation of current guidance, will continue to improve the nation's cardiovascular health.

Bryan Williams *guideline working party chairman*
Department of Cardiovascular Sciences, Clinical Sciences Building, Leicester Royal Infirmary, University of Leicester, Leicester
bw17@leicester.ac.uk

On behalf of the British Hypertension Society

Additional authors are: guideline working party members—Neil R Poulter, International Centre for Circulatory Health, Imperial College London and St Mary's Hospital, London; Morris J Brown, Clinical Pharmacology Unit, Addenbrooke's Hospital, University of Cambridge, Cambridge; Mark Davis, general practitioner, Moorfield House Surgery, Garforth, Leeds; Gordon T McInnes, Section of Clinical Pharmacology and Stroke Medicine, Division of Cardiovascular and Medical Sciences, Gardiner Institute, Western Infirmary, University of Glasgow, Glasgow; John F Potter, Ageing and Stroke Medicine Section, Department of Cardiovascular Sciences, Glenfield Hospital, University of Leicester, Leicester; Peter S Sever, International Centre for Circulatory Health, Imperial College London & St Mary's Hospital, London. British Hypertension Society member—Simon McG Thom, International Centre for Circulatory Health, Imperial College London and St Mary's Hospital, London.

Competing interests: All authors have received honorariums from a number of pharmaceutical companies for lectures and consultancy, and research grant support for clinical trials from the pharmaceutical industry.

1 The ALLHAT Officers and Coordinators for the ALLHAT Collaborative Research Group. Major outcomes in high-risk hypertensive patients randomized to angiotensin-converting enzyme inhibitor or calcium channel blocker vs diuretic: the antihypertensive and lipid lowering treatment to prevent heart attack trial (ALLHAT). *JAMA* 2002;288:2981-97.
2 Dickerson JE, Hingorani AD, Ashby MJ, Palmer CP, Brown MJ. Optimisation of antihypertensive treatment by crossover rotation of four major classes. *Lancet* 1999;353:2008-13.
3 Cannon CP, Braunwald E, McCabe CH, Rader DJ, Rouleau JL, Be R, et al. Intensive versus moderate lipid lowering with statins after acute coronary syndromes. *New Eng J Med* 2004;350:1495-504.
4 Sever PS, Dahlof B, Poulter NR, Wedel H, Beevers G, Caulfield M; ASCOT investigators. Prevention of coronary and stroke events with atorvastatin in hypertensive patients who have average or lower-than-average cholesterol concentrations, in the Anglo Scandinavian cardiac outcomes trial-lipid lowering arm (ASCOT-LLA): A multicentre randomised controlled trial. *Lancet* 2003;361:1149-58.

The full reply is available on bmj.com

NICE clinical guidelines

Maybe health economists should participate in guideline development

Editor—Wailoo et al highlight a fundamental challenge that the National Institute for Clinical Excellence (NICE) faces on a daily basis.[1] The government established NICE not only to advise the NHS on the quality of care that individual patients could expect (in terms of appropriateness and effectiveness) but also to address the other important dimensions of healthcare quality (equity, fairness, and efficiency) that society expects.

We agree that being required to address both in the guideline programme will lead

GERD PFEIFFER/SOA

If health economics is to contribute to the debate it must engage with the issues

to understandable tensions. But this is also true of the appraisal process. The appraisal committee's decisions have sometimes "favoured" the individual health perspective[2] and on other occasions public health has taken precedence.[3]

NICE guidelines and appraisals have differing roles in seeking to improve the quality of NHS care. While appraisals normally assess the role of a single intervention, a clinical guideline covers the whole range of the management of patients with specific diseases. Occasionally, both are undertaken in the same clinical area—for example, atypical antipsychotics and schizophrenia, β interferon and multiple sclerosis.

We also agree that health economic evidence is often sparse in established clinical areas and of variable quality. However, this is also common in the appraisal process. Final decisions will always depend on the exercise of judgment. This requires the presence of a variety of skills on NICE committees. For this reason, our guideline development groups have members drawn from the same range of stakeholders as the appraisal committees.

In establishing the current programme, NICE considers that integration rather than separation of the various key stakeholders is crucial to good guideline development. We acknowledge that special expertise is required to support areas where experience is scarce. We have certainly identified a need to improve the health economics input into guidelines, although health economists have not yet shown the same relish to become involved in guideline development as they have in appraisals.

Peter Littlejohns *clinical director*
peter.littlejohns@nice.nhs.uk
Gillian Leng *guidelines programme director*
National Institute for Clinical Excellence, London WC1V 6NA

Tony Culyer *chief scientist*
Institute for Work and Health, Toronto

Mike Drummond *director*
Centre for Health Economics, University of York

Competing interests: PL and GL are employed by NICE. MD is chairman of one of NICE's guideline review panels and was a member of the guidelines advisory committee, 1999-2003. TC was chairman of NICE (1999-2003).

1 Wailoo A, Roberts J, Brazier J, McCabe C. Efficiency, equity, and NICE clinical guidelines. *BMJ* 2004;328:536-7. (6 March.)
2 National Institute for Clinical Excellence. *Guidance on the use of riluzole (Rilutek) for the treatment of motor neurone disease.* London: NICE, 2001. (Technology appraisal No 20.)
3 National Institute for Clinical Excellence. *Beta interferon and glatiramer for the treatment of multiple sclerosis.* London: NICE, 2002. (Technology appraisal No 32.)

Account of guideline development was inadequate

Editor—Wailoo et al raise important issues but misunderstand aspects of the NICE programme.[1] They criticise the "confusion" between the views of society and those of patients. Guideline development groups are not confused; health economics are fully considered and not rated second best. Wailoo et al imply that the focus on efficacy arises because guideline development groups consist substantially of senior clinicians with special interests. This is inaccurate. Guideline development groups contain such clinicians but also a majority of general clinicians, general practitioners, and patients.

Wailoo et al imply that health economic data from randomised controlled trials are often the only data used. This is incorrect. Considerable use is made of data from other sources and economic models are developed. Guideline development groups also apply considerable judgment when developing recommendations from efficacy data; relevant factors include study populations, costs, and the application to the NHS, all of which influence recommendations.

The purpose of clinical guidelines is to encourage best practice by making available knowledge of efficacious, effective, and cost effective treatments, thereby reducing variation in the delivery of health interventions. This is best dealt with through a guideline development programme that fully integrates cost and efficacy data.

Their proposals for improving cost effectiveness are impractical. Guidelines are concerned with the treatment of a disease and not the application of a technology, and this is a more complex process than implied by the analogy with technology appraisals. Health economists need to be better informed about clinical guidelines, and health economic data need to improve, along with the methods for applying them to guideline development. We are convinced that this can be best achieved through development of the existing process, in which we expect health economics to have a crucial role.

Stephen Pilling *co-director*
National Collaborating Centre for Mental Health CORE, Department of Psychology, University College London, London WC1 7HB
s.pilling@ucl.ac.uk

Additional authors are Jacqueline Dutchak, director, National Collaborating Centre for Acute Care; Elizabeth McInnes, senior research and development fellow, National Collaborating Centre for Nursing and Supportive Care; Fergus Macbeth, director, National Collaborating Centre for Cancer; Mike Pearson, director, National Collaborating Centre for Chronic Conditions; Jane Thomas, director, National Collaborating

Centre for Women and Children; Nancy Turnbull, chief executive, National Collaborating Centre for Primary Care

Competing interests: All signatories have been in receipt of funding from the National Institute for Clinical Excellence for the development of clinical guidelines.

1 Wailoo A, Roberts J, Brazier J, McCabe C. Efficiency, equity, and NICE clinical guidelines. *BMJ* 2004;328:536-7. (6 March.)

Health economics must engage with complexity of issues

EDITOR—Wailoo et al are confused about the issues of incorporating economic considerations in clinical guidelines.[1] Several publications directly and usefully address the issues of incorporating economic perspectives into guidelines.[2–5]

The primary purpose of clinical guidelines is to inform clinicians' decisions with regard to patients, with a wider readership of interested parties, such as managers. Such guidance is not mandatory.

Wailoo et al argue that only health economists promote the social viewpoint within guideline development groups. We have shown that appropriately multidisciplinary groups of clinicians and consumers, supported by a health economist, are capable of adopting a social perspective on health care.[5] Although health economists may offer methods, they do not have an exclusive claim to the social perspective.

Wailoo et al propose removing health economic input into a separate process conducted away from the discussion of the meaning of the clinical evidence. They do not recognise two separate types of analysis. The incorporation of economic considerations into a guideline (the balancing of effectiveness, side effects, other harms, and financial cost in choosing strategies to lower blood pressure) must all be debated within the same forum. The cost impact of a guideline may be considered within or outside this forum. Both analyses will be plagued by inadequate data. The purpose of Wailoo et al in setting up a separate forum seems to be to produce a ranked cost utility list, presumably both within and across guidelines. This idea was recognised as unrealistic long before David Eddy articulated its impossibility in 1999.[4]

If health economics is to contribute to this debate it must engage with the complexity of the issues rather than propose one size fits all solutions.

Martin Eccles *professor of clinical effectiveness*
Centre for Health Services Research, University of Newcastle upon Tyne, Newcastle upon Tyne NE2 4AA
martin.eccles@newcastle.ac.uk

Competing interests: ME is a consultant on guideline methodology to and was chair of the Guideline Advisory Committee, 1999-2003, for the National Institute for Clinical Excellence.

1 Wailoo A, Roberts J, Brazier J, McCabe C. Efficiency, equity, and NICE clinical guidelines. *BMJ* 2004;328:536-7. (6 March.)
2 Eddy DM. *A manual for assessing health practices and designing practice policies: the explicit approach.* Philadelphia: American College of Physicians, 1992.
3 Williams A. How should information on cost effectiveness influence clinical practice? In: Delamothe T, ed. *Outcomes into clinical practice.* London: *BMJ* Publishing Group, 1995:99-107.
4 Eddy DM. *Doctors, economics and clinical practice guidelines: can they be brought together?* London: Office of Health Economics, 1999.
5 Eccles M, Mason J. How to develop cost-conscious guidelines. *Health Technol Assess* 2001;5(16).

Authors' reply

EDITOR—Clinical guidelines are different when they are produced by the National Institute for Clinical Excellence (NICE). NICE is an organisation charged with promoting the cost effective use of limited NHS resources. Our experience, and that of many of our colleagues who have been involved in the production of NICE clinical guidelines, is that the current processes do not facilitate the appropriate consideration of cost effectiveness issues.

We believe that the process of guideline development requires adjustment. Whether the blame for this lies with the health economics community or elsewhere, we share the hopes of Littlejohn et al and Pilling et al that our editorial will prompt a constructive debate about the appropriate methods for developing truly cost effective guidelines.

We do not claim that only health economists adopt a societal view, as Eccles says. Neither do we suggest that ranked cost utility lists should be produced. We do, however, acknowledge the scarcity of NHS resources and the need to compare options across NHS activities.

To date, guideline development groups have produced high quality guidelines, but these have been based predominantly on clinical effectiveness considerations. Technology appraisals may be imperfect, but they are an internationally reputed means for making health service policy decisions underpinned by cost effectiveness analysis. Clinical guidelines and appraisals may be different, but they also have common characteristics. The technology appraisal approach cannot be translated lock, stock, and barrel, but many of its core elements are equally relevant to guidelines.

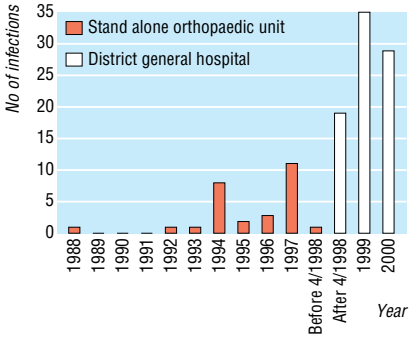
Allan Wailoo *lecturer in health economics*
a.j.wailoo@sheffield.ac.uk
Jennifer Roberts *senior lecturer in health economics*
John Brazier *professor of health economics*
Chris McCabe *senior lecturer in health economics*
Sheffield Health Economics Group, School of Health and Related Research (ScHARR), University of Sheffield, Sheffield S1 4DA

Competing interests: The School of Health and Related Research receives funding from NICE for work relating both to clinical guidelines and to technology appraisals.

Eradication of MRSA by "ring fencing" orthopaedic beds

Stand alone orthopaedic units may be way forward in reducing MRSA

EDITOR—Biant et al report on "ring fencing" elective orthopaedic beds to eradicate methicillin resistant *Staphylococcus aureus* (MRSA).[1] This quality improvement report should encourage many orthopaedic units to change their practice and act similarly.



Effect of change of location on number of infections

They do not, however, mention the number of cases that were treated each year to give the rate of infection. If the stand alone unit was dealing with a similar number of cases, then the infection rate underwent a true rise after April 1998. Before 1998 some 27 infections occurred in the preceding 10 (mean 2.7) years. Even when all the new precautions were taken from July 2000, 15 infections occurred in 12 months in the ring fenced district general hospital, more than five times the number of infections in the stand alone unit. Does this imply that stand alone orthopaedic units are the way forward in reducing postoperative infection?

Graham C Cheung *senior house officer in orthopaedics*
Ashutosh Acharya *specialist registrar in orthopaedics*
Royal Liverpool Children's NHS Trust, Alder Hey, Liverpool L12 2AP

Competing interests: None declared.

1 Biant LC, Teare EL, Williams WW, Tuite, JD. Eradication of methicillin resistant Staphylococcus aureus by "ring fencing" of elective orthopaedic beds. *BMJ* 2004;329:149-51. (17 July.)

Author's reply

EDITOR—The data presented before 1998 were for MRSA infections alone. In the same graph we showed a rise in the number of infections with methicillin resistant *Staphylococcus aureus* (MRSA) on wards where patients undergoing elective orthopaedic operations were nursed after the move to the district general hospital. At this point patients were mixed together with patients with trauma and patients from other specialties. This was the trigger for setting up the prospective trial.

The study showed that a ring fenced ward (or stand alone unit in a district general hospital), along with simple infection control measures, significantly reduced all infections and the MRSA infection rate after elective arthroplasty was zero.

Our study was not set up to comment on stand alone units, and the data collected cannot be extrapolated to do so.

Leela C Biant *specialist registrar in trauma and orthopaedic surgery*
Broomfield Hospital, Chelmsford
lcbiant@yahoo.com

Competing interests: None declared.

"Serious" and "severe" adverse drug reactions need defining

EDITOR—In her editorial on the new guidelines for preventing malaria in UK travellers Zuckerman claims that a recent double blinded study showed high tolerability to the four recommended drug regimens, with no serious adverse events.[1 2] Unfortunately, neither Zuckerman nor the cited study defines the term "serious."

Therefore readers can assume only that, in accordance with the definition of the Council for International Organisations of Medical Sciences, we are probably talking about adverse drug reactions that are fatal, life threatening, leading to or prolonging a stay in hospital, or resulting in severe disability.[3]

This restrictive definition unfortunately ignores less serious but nevertheless highly disturbing and often severe problems encountered by travellers taking prophylactic malaria drugs. Two large, double blinded studies have proved that mefloquine commonly causes moderate to severe (neuropsychiatric) adverse events in travellers.[2 4]

In addition to this, less common serious adverse reactions remain a concern, as Zuckerman points out. Since August 2003 the US version of mefloquine (Lariam) has been delivered with a guide warning of adverse neuropsychiatric events and rare reports of suicide.[5] No such guide is currently available to customers in other countries, leaving travellers no other choice than being informed by their doctors, pharmacists, or the international media. In view of the better tolerance of other (equally effective) drugs, the time has come for the Health Protection Agency advisory committee on malaria prevention for UK travellers to reconsider its use of mefloquine as a first line drug for the prevention of malaria.

Christian Frankenfeld *former side effect sufferer*
Hans-Schmitz-Straße 18, D-33378
Rheda-Wiedenbrück, Germany
cffeld@web.de

Competing interests: CF cooperates with the Coalition for Anti-malarial Drug Safety, a volunteer organisation that provides information and support to those who believe they have experienced side effects from anti-malarial drugs.

1 Zuckerman JN. Preventing malaria in UK travellers. *BMJ* 2004;329:305-6. (7 August.)
2 Schlagenhauf P, Tschopp A, Johnson R, Nothdurft HD, Beck B, Schwartz E, et al. Tolerability of malaria chemoprophylaxis in non-immune travellers to sub-Saharan Africa: multicentre, randomised, double blind, four arm study. *BMJ* 2003;327:1078.
3 Council for International Organisations of Medical Sciences. *International reporting of adverse drug reactions. CIOMS working group report.* Geneva: World Health Organisation, 1987.
4 Overbosch D, Schilthuis H, Bienzle U, Behrens RH, Kain KC, Clarke PD, et al. Atovaquone-proguanil versus mefloquine for malaria prophylaxis in nonimmune travelers: results from a randomized, double-blind study. *Clin Infect Dis* 2001;33:1015-21.
5 Lariam (mefloquine hydrochloride) medication guide. Nutley: Hoffmann La Roche USA, August 2003. www.fda.gov/medwatch/SAFETY/2003/LariamMedGuide.pdf . (accessed 21 Aug 2004).

Stigma of AIDS needs to be overcome

EDITOR—With reference to the editorial by Ruger, combating HIV-AIDS in industrialising countries requires improving the conditions under which people are free to choose safer life strategies and conditions for themselves and future generations.[1]

Sexually transmitted infections have always been imbued with stigma because of their association with behaviours considered deviant or immoral.[2] Drug use should be treated as a public health issue, not a criminal one. Despite a dearth of research on the topic, it is increasingly acknowledged that effective prevention and treatment strategies require an understanding of cultural frameworks, including stigmatisation.[3]

Many groups whose behaviour puts them at high risk for contracting HIV infection, such as men who have sex with men, commercial sex workers, and injecting drug users, are stigmatised and abused, and in some cases their behaviour is criminalised.[4]

Many countries with successful HIV policies and programmes do not implement effective HIV prevention policies and programmes for drug users because of a misperception that these are in conflict with supply control, endangering the lives of millions of drug users, their sex partners, and families.

Harm reduction programmes have been developed most thoroughly in Europe, Australia, and Canada. Such programmes seem to have had an impact in reducing the spread of AIDS and other diseases without raising levels of drug use in the general population.[5]

Effective prevention efforts will have to both acknowledge and challenge cultural mores, which often prevent frank discussion of issues surrounding sex and drug use, and will need to overcome the stigma that surrounds the disease and encourages its spread.

Ediriweera B R Desapriya *research associate*
Department of Paediatrics, University of British Columbia, Centre for Community Child Health Research, 4480 Oak Street, L 408, Vancouver, BC, Canada V6H 3V4
edesap@cw.bc.ca

Competing interests: None declared.

1 Ruger JP. Combating HIV/AIDS in developing countries. *BMJ* 2004;329-121-2. (17 July.)
2 De Bruyn T. HIV related stigma and decriminalization the epidemic continuous. *Can HIV AIDS Policy Law Rev* 2002;7:8-14.
3 Goldin CS. Stigmatization and AIDS: critical issues in public health. *Soc Sci Med* 1994;39;1359-66.
4 Heffernan J. Best practices for preventing AIDS. *J Ambulatory Care* 2004;27:190-1.
5 Fischer B, Haydon E, Rehm J, Krajden M, Reimer J. Injection drug use and the hepatitis C virus: consideration for a target treatment approach—the case study of Canada. *J Urban Health* 2004;81:428-47.

Shouldn't patients decide who should access their records?

EDITOR—Much misunderstanding exists in the NHS and other organisations about the Data Protection Act, but to deal with these concerns by granting clinical researchers freer access to confidential patient information, as suggested by Peto et al, would be excessive.[1 2] The Department of Health last year published a code of practice on patient confidentiality that should ensure that custodians of medical records are aware of their responsibilities and when they can share patient data with researchers.

The Patient Information Advisory Group was also concerned by the authors' apparent view that obtaining informed consent from patients is a bad thing. Clearly, how common law around confidentiality and consent has evolved in recent years has caused some confusion and inconvenience in the research community, but surely there should be no objection to researchers being required to obtain consent from patients to use their confidential information if it is practicable to do so.

The advisory group was established in 2001 to oversee arrangements introduced under section 60 of the Health and Social Care Act 2001. Its responsibility is to ensure that a wide range of essential NHS activities—including research—are allowed to continue when no practicable alternative exists to using patient identifiable information without consent. However, the organisations undertaking these activities should be required to show that they are delivering benefits to patients, have considered alternatives to using patient identifiers without consent, will use the information obtained appropriately and store it securely, and will reasonably try to devise a means of either obtaining consent or working with anonymised information in the future.

Although many patients and members of the public support clinical research, they would also like clinicians to discuss with them how their data can be used to support this important work. The NHS intends to give patients choice. Is it too much to ask that this concept should be extended to allow patients to decide who can access their records?

Joan Higgins *chair, Patient Information Advisory Group*
PIAG Secretariat, Department of Health, Leeds LS2 7UE
piag@doh.gsi.gov.uk

Competing interests: None declared.

1 Peto J, Fletcher O, Gilham C. Data protection, informed consent, and research. *BMJ* 2004;328:1029-30. (1 May.)
2 Correspondence. Data protection, informed consent, and research. *BMJ* 2004;328:1437. (12 June.)

Burns rehabilitation is more than skin deep

EDITOR—Edgar and Brereton discuss rehabilitation after burns injury in the ABC of burns.[1] Burns rehabilitation is often challenging and has several other dimensions, entailing much more than the sole aim of preventing scarring.

Psychological factors such as sexuality and changed body image require careful management. One model frequently used is the PLISSIT model,[2] which provides a framework for all health professionals to introduce sexuality and frank discussion into treatment comfortably and appropriately. Adaptation to long term disability should be integrated into the rehabilitation treatment plan as well as the assessment of post-traumatic stress disorder as the potential to develop this disorder exists owing to the often distressing nature of many of these injuries.[3] The input of psychological services is an invaluable aspect of burns rehabilitation.

Although Edgar and Brereton addressed physical considerations, they did not include nutritional aspects of wound healing and recovery. Adequate evidence supports the need for good nutrition after burns, for initial wound healing and long term scar reduction.

In addition, reintroduction to society and work may provide several challenges to a burns survivor. Issues related to a full return to the community, and their solutions such as behaviour therapy, occupational rehabilitation, and adaptive equipment may be outside the limits of a brief paper. However, follow up recommendations, including a more comprehensive checklist of potential areas of need, may be helpful.

Monique Berger *clinical nurse consultant*
mberger@stvincents.com.au
Sacred Heart Rehabilitation Service, St Vincent's Hospital, 170 Darlinghurst Road, Darlinghurst, NSW 2010, Australia

Stephen Wilson *senior lecturer (conjoint)*
Public Health and Community Medicine, University of New South Wales, Sydney, NSW 2052, Australia

Competing interests: None declared.

1 Edgar D, Brereton M. ABC of burns. Rehabilitation after burn injury. *BMJ* 20047;329:343-5. (7 August.)
2 Whitehead TL. Sexual health promotion of the patient with burns. *J Burn Care Rehabil* 1993;14(2 part 1): 221-6.
3 Lawrence J, Fauerbach J. Personality, coping, chronic stress, social support, and PTSD symptoms among adult burn survivors. *J Burn Care Rehabil* 2003;24(1): 63-72.

How protective is the working time directive?

Two doctors mull over personal horror stories

Editor—As junior doctors of many years' standing (and several more ahead of us), with experience of work and training in two different parts of the world, we empathise with Abbasi's experiences as the European Working Time Directive was conceived.[1 2]

The thrills of 56 hour continuous shifts are highly overrated. The heady mixture of sleep deprivation, adrenaline, and substance P plus or minus caffeine makes for a euphoric, addictive cocktail. But this can't be good for doctors, and less so for patients. An estimated 44 000-98 000 patients die in hospitals in the United States each year as a result of medical errors, numbers far in excess of deaths due to motor vehicle accidents (43 458), breast cancer (42 297), and AIDS (16 516).[3] Most preventable incidents result directly or indirectly from human error. How much of this is due to doctors' fatigue is difficult to measure, but there can be little doubt that it is a major factor in fatal and non-fatal medical errors.

One of us has experienced the horror of a colleague's suicide while on call and had to treat another for a generalised seizure, again while on call, brought on by sleep deprivation. Sentiments such as "No one dies of overwork" expressed on bmj.com are, therefore, ill advised and espouse unnecessary bravado.[4] This, however, does not detract from the commendable dedication of the many doctors who, of necessity, work beyond any working time directives in the developed and, particularly, the developing world.

Farheena N Mecci *clinical tutor*
Community Paediatrics, Dr Ambedkar Medical College, Bangalore-560045, India
f.n.mecci@doctor.com

Akheel A Syed *specialist registrar*
University of Newcastle, Newcastle upon Tyne NE2 4HH

Competing interests: None declared.

1 Abbasi K. Editor's choice. All doctors have a personal horror story. *BMJ* 2004;329:0-g. (7 August.)
2 MacDonald R. How protective is the working time directive? BMJ 2004;329:301-2. (7 August.)
3 Committee on Quality of Health Care in America, Institute of Medicine. *To err is human: building a safer health system.* Washington, DC: National Academy Press, 2000.
4 Goel A. No one dies of overwork. Electronic response to: All doctors have a personal horror story. bmj.com 2004. http://bmj.bmjjournals.com/cgi/eletters/329/7461/0-g (accessed 8 Aug 2004).

New Zealand is still dealing with the issues 20 years on…

Editor—The working time directive is a step in the right direction, but its implementation should not be underestimated, as MacDonald discusses.[1] In New Zealand the number of hours worked has been limited since 1985, but even today, almost 20 years later, the problems associated with implementing these restrictions have yet to be fully overcome.

Firstly, there was an initial shortage of doctors. As in the United Kingdom, more doctors were needed with the introduction of legal rosters. This led to the importation of many doctors from around the world and affected the quality of medical care delivered to patients. More recently, the education and training of overseas trained doctors has been scrutinised, but more home trained junior doctors are still needed.

Secondly, the attitudes of trainees (especially surgical trainees) are important. Most trainees want the best training they can get and the most clinical exposure while appeasing their consultants and the hospital management. They want to fit in and show they can "hack the pace."

Thirdly, attitudes of consultants matter. "We did it, therefore they need to." With the implementation of consultant led practice, what many consultants thought their job would be when they trained is different from what it is in reality today.

Fourthly, the dinosaurs, usually older consultants, who seem to think that the world should revolve around them and their attitudes, never change. Before they become extinct with a move to retirement they are often in a position to advise management and can make the introduction of change difficult.

Underlying these changes there must be a realisation that patients' safety and quality of care require that things change. How reasonable is it to expect a patient who needs an emergency operation for a potentially life threatening condition to have an operation from a resident who has worked 80 or more hours? It is no longer acceptable.

Frank A Frizelle *professor of colorectal surgery*
frank.frizelle@cdhb.govt.nz
Angus Watson *colorectal fellow*
University Department of Surgery, Christchurch Hospital, Riccarton Ave, Christchurch, New Zealand

Competing interests: Both authors work in excess of 80 hours a week most weeks.

1 MacDonald R. How protective is the working time directive? *BMJ* 2004;329:301-2. (7 August.)

…but Australia may have a way forward

Editor—The headache of working conditions continues, as MacDonald shows in her editorial on the European Working Time Directive.[1] I left the United Kingdom just before the banding pay scale was introduced. This came into effect after the junior doctors' section of the BMA had had the wind knocked out of its sails in trying to get a different outcome from its campaign at the time.

The United Kingdom will always have these problems so long as juniors are paid a salary that does not truly reflect the hours and conditions worked. In Australia doctors are paid an hourly rate that increases if 40 hours is exceeded and during unsociable hours, weekends, and public holidays. Every effort is made to keep the hours to around 40 a week.

Money talks. If the same rules applied in the United Kingdom it would put a much greater pressure on reducing the hours doctors worked and thus lead to compliance with the European Directive.

Cameron Burrows *medical officer*
Royal Flying Doctor Service, Western Operations, Derby, WA 6728, Australia
camerondownunder@yahoo.com

Competing interests: None declared.

1 MacDonald R. How protective is the working time directive? *BMJ* 2004;329:301-2. (7 August.)