Letters

NICE and its value judgments

Option of safe "understudy" treatments should be available

Editor—The National Institute for Clinical Excellence (NICE) aims for the highest attainable standards of care.[1] The bedrock of its advice is published evidence of benefits from treatment (mainly pharmaceuticals).

In the report accepted in May consideration of safety issues focused on invasive surgical and diagnostic procedures, and the "judgment" on risk assumed that such risks are small and calculable.[2] In economic terms, to distinguish between real risk (calculable and potentially manageable) and uncertainty, where judgment of costs is purely subjective, is important.

In July the new health service director of research and development announced a forthcoming national programme of research on drug treatment in children. Given the serious and quite common adverse consequences of paediatric treatment reported,[3] a fundamental reassessment of child health interventions is warranted. Adverse drug reactions or interactions between new and existing drug treatments are uncertain in caring for children aged 0-16 years. NICE has hitherto sought to judge the best treatment (singular), but in an uncertain interaction between doctor and child simultaneous identification of "good enough" second line treatments that can understudy for the "best" treatment when the safety of an individual child may preclude using the most cost effective drug may make good economic sense. This "good enough for some children" standard is not currently in the expertise of the licensing authorities, but it could become a feature of NICE expertise.

In the absence of safe treatment alternatives, the long term costs to some children and families (and the health service) of adverse drug reactions could be heavy. For adult health care the burden of adverse drug reactions is 6.5% of hospital admissions.[4] For childhood drug treatment, what will be our options?

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Competing interests: WC is being maintained on at least five drugs concurrently.

1 Rawlins MD, Culyer AJ. National Institute for Clinical Excellence and its value judgments. *BMJ* 2004;329:224-7. (24 July.)
2 National Institute for Clinical Excellence. *Scientific and social value judgements.* London: NICE, 2004.
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Utilitarian values are inadequate

Editor—The values of the National Institute for Clinical Excellence (NICE) turn out to be utilitarian and economic.[1] Predictably, NICE's attempt to use them to generate advice to professionals for achieving the highest attainable standard of care often founders on the narrowness of perspective. High quality care demands an understanding of human suffering that transcends the urge to fix biological machine faults.

Take obesity. In 2001 NICE approved the prescription of orlistat and sibutramine to obese patients, a tiresome diversion in the face of a developed world pandemic of obesity. Obesity is about consumption, and consumption is woven into the fabric of society. No amount of medical technology or guidelines stands any meaningful chance of changing this. The problem is cultural, and the solutions are political and educational.

We might be spared these distractions if NICE added two new questions to their appraisals.

Firstly, is the problem for which the technology is intended best dealt with by a medical approach delivered in the NHS?

Secondly, would receiving the technology be likely to benefit the health (broadly defined) of the individual patient?

These questions demand values that clarify the purpose of the NHS and the nature of health. They must recognise that illness occurs in a network of relationships: with ourselves, society, and nature. The difficulty here reflects what MacIntyre calls the grave disorder in the language of morality.[2] But we must try, or accept that medicine will choke on its own trivial non-solutions for enormous problems.

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1 Rawlins MD, Culyer AJ, National Institute for Clinical Excellence and its value judgments, *BMJ* 2004;329:224-7. (24 July.)
2 MacIntyre A. *After virtue.* London, Duckworth, 1985:2.

Favourable appraisal amounts to compulsory purchase order

Editor—The role of the National Institute for Clinical Excellence (NICE) in reducing the postcode lottery is limited by the denial of its legitimate role in healthcare rationing.[1 2] The focus on new and expensive drugs, and the requirement by the government that NHS bodies implement NICE guidance within three months, seriously skew local priorities.

The use of sales data to monitor the uptake of a NICE approved drug militates against an orderly and considered uptake of new technologies. A favourable NICE appraisal amounts to a compulsory purchase order. The agenda is therefore set not by NICE but by those who apply to NICE for their products to be appraised.

The reason why NICE has not appraised yoga or transcendental meditation for stress and hypertension, or a lifestyle intervention involving 3-4 kg weight loss and 150 minutes of moderately vigorous physical activity a week as a "technology" that cuts the risk of overt diabetes by 50% is obvious. It would have been interesting to see how the implementation of such technologies would have been enforced.

The excessive focus on drug treatments also ignores the real postcode lottery of life—a lottery that applies far more to the determinants of health (housing, education, job opportunities, healthy food) than to health care. The mandatory requirement to implement expensive and marginally effective NICE appraised treatments means that we in the NHS have less time and no resource to devote to other public health interventions that may well yield a far bigger health dividend for a larger number of people.

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1 Rawlins MD, Culyer AJ. National Institute for Clinical Excellence and its value judgments. *BMJ* 2004;329:224-7. (24 July.)
2 Maynard A, Bloor K, Freemantle NK. Challenges for the National Institute for Clinical Excellence. *BMJ* 2004;329:227-9. (24 July.)

Authors' reply

Editor—Caan may be right about second line treatments, but the point applies to more than just paediatric prescribing. Fortunately, there is nothing in NICE's current appraisal methods to exclude these considerations,[1] and we have already done so on several occasions.

House and Peters are wrong to call NICE's values utilitarian, but they are certainly consequentialist. By this we mean that NICE evaluates the likely consequences of using the technologies; this is certainly economic in trying to quantify consequences, being explicit about the value judgments involved, and taking account of the NHS resources that will be used. Whether health is better promoted by means beyond the NHS is pertinent, although it not a question NICE has been charged with answering.

We have much sympathy with what elsewhere is called the population health approach. From next April, guidance on public health will form part of NICE's portfolio. Rao also supports this approach but does not approve of the selection of technologies we review. Topics are selected by ministers after widespread consultation, and they are certainly not set by manufacturers.

We think it inevitable that any attempt to create fairness in access to medicines in England and Wales is bound to compromise some "local priorities." But it was, of course, differing "local priorities" that created the postcode prescribing in the first place, and the public will not tolerate its re-emergence. We readily concede that NICE's recommendations entail difficult choices about resource allocation, but we emphasise that no local decisions about allocation of resources are subjected to anything approaching the rigour of NICE's approach to cost effectiveness. Neither is there any distant analogy between our procedures and wartime "rationing," which both of us vividly remember.

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1 National Institute for Clinical Excellence. *Guide to the methods of technology appraisal.* London: NICE, 2004.

The evidence base for shaken baby syndrome

Meaning of signature must be made explicit

Editor—Reece et al's response to the editorial of Geddes and Plunkett claims to be a response of "106 doctors."[1 2] What, precisely, do the 106 signatures attached to this letter signify? That all had reviewed the letter and were in full agreement with the entire content? That they agreed in general with the thrust of the letter? Or was this more a show of solidarity on the part of doctors who care deeply about the risks of shaking on children?

This needs clarification if the signatures are to carry any weight whatsoever. Science—even medical science—is not a popularity contest. The meaning of a signature must be made explicit for it to add weight to a document.

Each signature carries with it responsibilities of authorship. Reece's letter declared no competing interests, but all signatories would need to comply for this to be true.

Six of the signatories (Levin, Chadwick, Alexander, Barr, Jenny, and Reece) are medical practitioners on the International Advisory Board of the National Center on Shaken Baby Syndrome (www.dontshake.com). They participate in this group's conferences and are presumably compensated or reimbursed for this work—information requiring disclosure under *BMJ* guidelines.

The letter of Reece exemplifies a problem identified in my own paper[3]—that the literature on shaken baby syndrome is polarised and based more on strong beliefs and opinions than strong data. Ten thousand signatures cannot change this.[4]

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Competing interests: None declared.

1 Reece RM. The evidence base for shaken baby syndrome. *BMJ* 2004;328:1316-7. (29 May.)
2 Geddes JF, Plunkett J. The evidence base for shaken baby syndrome. *BMJ* 2004;328:719-20. (27 March.)
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Competing interest declaration of the 106 authors and an editorial explanation

Editor—The *BMJ* asked my co-authors and me to complete a competing interests form only after our letter was published.[1 2]

Competing interest declaration: Many of the letter's authors practise, teach, lecture, consult, and do research on matters involving child abuse, including shaken baby syndrome. Some lecturers receive honorariums for their lectures, many of which are given to the lecturer's institution.

Some receive research funding for a variety of projects. Many have testified in civil and criminal courts, having been called in the main, though not exclusively, by departments of social services, families, prosecution, and defence. They are generally paid for their time.

Some serve on non-profit boards of organisations with concerns about child maltreatment, including shaken baby syndrome, and are not compensated for this service.

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❊It is our policy to obtain a competing interest declaration before publication. In this case our oversight occurred because Professor Reece's letter did not come in the usual way via bmj.com and our checking mechanisms failed—Editor

1 Reece RM. The evidence base for shaken baby syndrome. *BMJ* 2004;328:1316-7. (29 May.)
2 BMJ declaration of competing interests. Available at: http://bmj.bmjjournals.com/cgi/content/full/317/7154/291/DC1 (accessed 17 Sep 2004).

Response to Reece et al from 41 physicians and scientists

Editor—Reece et al have implied that child abuse is a particularly difficult area in which to conduct research.[1] This difficulty does not justify circular reasoning, selection bias, imprecise case definition, unsystematic review publications, or conclusions that overstep the data.[2-5 w1-w3]

Geddes and Plunkett described the use of evidence based medicine in evaluating the causes of head injury in infants and children.[w4 w5] Evidence based medicine is the conscientious, explicit, and judicious use of scientific evidence in making medical decisions and cautions against unsystematic, untested reasoning and intuition based clinical applications. It integrates scientific principles and clinical experience with valid, current research.[w6]

While much of clinical medicine still relies on observation, it is critical that these observations are verified and validated. Often, the clinician must be more deliberate than the experimentalist who uses a planned systematic approach. The clinical researcher may have to await the natural sequence of events—deducing relationships that lie below observed phenomenon, being more logical and less dogmatic, and avoiding the fallacy of mistaking correlation with causation.[w7] If the principles of science and evidence based medicine are not critically applied to observational studies, a set of formulated beliefs among like-minded people may be reinforced, leading to misconceptions and misinterpretations. When this occurs, the primary principle of medicine—first, do no harm—may be violated.

Child abuse in any form is always unacceptable. However, if errors in diagnosis, false accusations, and wrongful convictions result from untested and unverified beliefs, then we have done harm.

Critically evaluating one's own understanding is far more constructive than

criticism of those who differ. If we can approach differences objectively and resolve them with rational analysis, then we have moved decisively towards answering difficult questions.

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This letter is signed by another 40 physicians and scientists (see bmj.com for details).

Competing interests: See bmj.com

1 Reece RM. The evidence base for shaken baby syndrome. *BMJ* 2004;328:1316-7. (29 May.)
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P+ *Details of the other 40 signatories and all competing interests are available on bmj.com, as are references w1-7.*

Post-immigrant refugee medicine

Population mobility must be considered

Editor—Adams et al highlight the importance of pre-departure and migration history in post-immigration refugee medicine,[1] but health professionals must also consider the ongoing reality of mobility in this population.[2]

For example, a newcomer, in whom diabetes has been diagnosed during screening, happens to mention the recent death of her mother. This leads to the discovery of plans to travel back home to the Sudan and a timely provision of health advice, malaria prophylaxis, and a summary of drug treatment.

Population mobility in the context of refugees refers to the forced movement of people beginning before departure and continuing for years, sometimes a lifetime, as people search for a place to call home. Historically, refugee programmes have focused only on early integration: screening and disease treatment. Refugees will often continue to move as they seek community support and employment, and they will often return to home (or near to home) countries to visit friends and relatives.

These movements unveil global health disparities related to diseases and access to health care—for example, immigrants are at increased risk of travel related illness.[3] Immigrants are often unaware of the importance of travel advice and disease prevention strategies. Acknowledging the reality of this mobility can allow for a systematic delivery of advice on travelling home, health promotion for cancers and cardiovascular diseases,[4] and low cost mechanisms to communicate and transfer medical histories.

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1 Adams KS, Gardiner DL, Assefi N. Healthcare challenges from the developing world: post-immigration refugee medicine. *BMJ* 2004;328:1548-52. (26 June.)
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Children's needs should not be seen in isolation

Editor—Adams et al discussed the challenges of post-immigrant refugee medicine.[1] The physical and mental health needs of refugee children are unique. Children comprise nearly half of the refugee population in many countries and may arrive malnourished without any screening or immunisation. They need culturally sensitive dietary advice and information about sexual habits and avoiding drugs.

Despite increasing focus on the mental health of refugee children, research data are lacking.[2] Some researchers have found an increased risk of post-traumatic stress disorder, depression, and anxiety.[3] Others found no differences between the incidence of psychiatric disorders in refugee children and the local population.[4] Whether this reflects better assimilation of these children into the society or unknown variables remains to be explored.

Children are worried not just about health but about loss of family members, loneliness, feeling cold, being depressed, lack of money, being bullied, language barriers, and being used as interpreters for their parents.[5] They may not seek care for legal reasons or fear of persecution.

Doctors need training in interviewing skills that explore these unique issues and awareness of locally available resources to act as advocates on their behalf. Collaboration between doctors and mental health, social, and education services is required. Children's needs should not be seen in isolation but in the context of their families. The best way to help them is to help their families. A timely understanding of these needs will be critical in safeguarding our future.

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1 Adams KS, Gardiner DL, Assefi N. Healthcare challenges from the developing world: post-immigration refugee medicine. *BMJ* 2004;328:1548-52. (26 June.)
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Millennium development goals: whose goals and for whom?

Editor—Millennium development goals are the most recent statement of commitment towards narrowing gaps between the developed and developing regions of the world.[1] But how realistic are these goals?

Although goals help in making assessments of progress, they should not be blind to existing potentials for progress, which is conditioned by the existing status as well as the motivation of nations and states towards realising them. Unfortunately, millennium development goals are considered to be a tool for assessing accountability and highlight a need for urgency that could violate the autonomy of nations and states. This raises the question of whose goals they are.

Often such initiatives are seen as global priorities, overriding local concerns. The best example is the vaccination initiative, which has consistently reflected failures by countries without the required infrastructure. In other circumstances, such externally aided initiatives are never integrated into the local health system to make the most of such intervention. In terms of measuring the extent of achievement of such goals, caution is advised in assessing progress conditioned by local realities that may not always be conducive to making the expected progress.

Finally, who benefits from the achievement of such goals needs to be made clear. Would there be any space to account for inequities resulting in achievement of such goals? If yes, the assessment of progress in achieving these goals needs to make adjustments for this to have a realistic evaluation of progress.

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1 Haines A, Cassels A. Can the millennium development goals be attained? *BMJ* 2004;329:394-7. (14 August.)

Women in medicine

Doctors of both sexes are seeking balance between life and work

Editor—The Medical Women's Federation supports Heath's statement in her editorial that all occupations should seek to mirror the demography of society.[1] Child care support at levels found in Scandinavian countries would greatly support women in medicine to achieve their potential. How-

ever, access to flexible training at specialist registrar level, which is highly variable by region and speciality, needs to be improved.[2]

Many female doctors (and their male partners, many of whom are also doctors) have or wish to have families, and hours of work and working conditions are a key factor in the career choices made by young doctors.[3] Career paths for men and women doctors must allow for flexibility in the early years for a less than 24 hour commitment to medicine. Young children grow up rapidly, and in a working life of 40 years women doctors can easily achieve and function effectively in top posts and professional activities, provided that they are supported during this critical time. We cannot afford to squander the passion, commitment, and intelligence of young doctors by not providing this flexibility at critical times for both parents. Doctors of both sexes are looking for a better balance between work and life.[4]

We have moved beyond the world where women could have a career in medicine only by sacrificing family and children on the altar of ambition. Women doctors want successful medical careers and a family life, and a social climate where childcare is shared with the father, and they are showing it can be done.

Above all we want expert medical practitioners, exercising their professional talents for the enhancement of society's health at all levels. We need to address the real issues in medicine, those of equity in a modern Britain.

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Competing interests: SFG is the president of MWF, a charity which aims to advance the personal and professional development of women in medicine.

1 Heath I. Women in medicine: continuing unequal status of women may reduce the influence of the profession. *BMJ* 2004;329:412-3. (21 August.)
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Women do not have to choose

Editor—Heath's editorial on the increasing number of women in medicine and the resulting loss in status and influence of the profession was disappointing.[1] She says that the hourly earnings of male and female doctors are very different. This is not surprising, given the higher percentage of men currently in senior positions. Are the hourly earnings of male and female senior house officers, registrars, and new consultants different? The answer is obviously no. The number of female consultants has risen by more than 50% in the past 10 years and is set to continue to do so.

What is the logic in saying that a feminised profession loses status and influence? We cannot compare ourselves with totalitarian societies such as the Soviet Union. Women do not have to choose between personal commitments and professional power. In a working life of 40 years, it is not a matter of great importance for a woman to spend a few years working less than full time for family reasons. Women are able to reach the top of the profession, given the right structures and the removal of discriminatory practices and sexist attitudes.

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1 Heath I. Women in medicine: continuing unequal status of women may reduce the influence of the profession. *BMJ* 2004;329:412-3. (21 August.)

Sexism is not only reason for women's "unequal status" in the workplace

Editor—Heath expresses many misconceptions about women in the workplace.[1] Women are compelled to look after their children, work part time, earn less money, and do different jobs from men. Better state support for childrearing, she implies, would produce equality in the workplace.

Many legitimate factors cause sex differences in earnings and occupations. Women earn less because they work fewer hours, have less experience, work in less-risky jobs, have more career interruptions, and attach less weight to salary. Different interests lead men and women to select different jobs.[2]

Heath complains that men abandon occupations when women enter them. However, changes in occupations themselves may be responsible. In the United States, pharmacy has become increasingly female, not because women make the profession less attractive to men but because the profession consists decreasingly of owners of small businesses and increasingly of employees of chain stores.[3] Men tend to favour the autonomy and entrepreneurship of business ownership, whereas women like the lower risk and flexibility of employment.

Many mothers do not want to work when their children are young, and many women prefer to work part time.[4] Like women, men must choose between personal commitments and professional power, but men are more inclined to choose professional power.

Family policies will not necessarily have the desired effect. Policies facilitating childbearing often increase fertility,[5] which may attenuate women's workplace attachment. Increasing the proportion of the population employed in childcare would likely increase occupational segregation, as in Sweden, because women fill most childcare jobs.

Heath's goal—parity of wages and occupations to afford genuine choice—contradicts itself. For both biological and social reasons, men and women have different preferences. When they act on their preferences, they choose differently. Only by constraining preferences—the antithesis of affording "genuine choice"—can workplace outcomes be rendered identical.

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1 Heath I. Women in medicine: continuing unequal status of women may reduce the influence of the profession. *BMJ* 2004;329:412-3. (21 August.)
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Status cannot be the driver

Editor—With reference to Heath's editorial on women in medicine,[1] what does "status" mean and how relevant is it to those of us deemed to be in "low" status work, such as family practice?

Simply to express status in terms that are measurable, such as pay, job position, and head counts, does not address the real themes, which are personal and professional contentment. The eroding social status of doctors should be viewed positively for professional vanity has divided the profession and alienated patients. The influx of people from lower social classes and of women has done much to break the old hierarchy and the destructive "status culture" over the past 30 years. Status is an individual perspective and should never be confused with mere "position." Childcare, also, is not a panacea to reach professional equality, and many doctors positively choose to parent their own children. The impact of these commitments long outlasts the grey flaking portraits that hang in the royal colleges.

To reach true equality lies paradoxically by challenging the largely unresearched gender role of men in society. Are men cardboard cut out figures: inarticulate, cold, aggressive, uncaring, incapable of loving or caring for their children? Is it time men be allowed and encouraged to emulate women's dual role? For this to happen, however, society and the profession need to tackle the "stereotype" of maleness and ditch some of the outdated assumptions that gender is a one way street.

Finally, women have helped "humanise" the medical profession. We should strive to have a profession dominated by doctors who care and not encourage more self obsessed and status driven applicants.

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Competing interests: None declared.

1 Heath I. Women in medicine: continuing unequal status of women may reduce the influence of the profession. *BMJ* 2004;329:412-3. (21 August.)