EDITORIALS

Editorials are usually commissioned. We are, however, happy to consider and peer review unsolicited editorials

See http://resources.bmj.com/bmj/authors/types-of-article/editorials for more details

Drug policy debate is needed

To deal with the public health consequences of the criminalisation of drug use

ITGilmore honorary professor of medicine, University of Liverpool, Liverpool L69 3BX, UK igilmore@liverpool.ac.uk

This year marks the 100th anniversary of the signing of the International Opium Convention, the first legal instrument on international drug control. In recent weeks the 55th session of the Commission on Narcotic Drugs-the policy setting body of the United Nations on drug control matters that is composed of 53 member states was held in Vienna.¹ It adopted 12 resolutions, including ones on the treatment, rehabilitation, and social reintegration of drug dependent prisoners, treatment as an alternative to imprisonment, and the prevention of death from overdose. Yury Fedotov, executive director of the UN Office on Drugs and Crime, emphasised the prioritisation of the health agenda, stating: "At present, the balance between our work on the supply and demand sides stays firmly in favour of the supply side. We must restore the balance. Prevention, treatment, rehabilitation, reintegration, and health have to be recognised as key elements in our strategy."2

This recent emphasis on health is welcome, because discussions on drug policy are too often dominated by criminal justice arguments and polarised opinions on how to solve the so called war on drugs. Indeed, it is hard to maintain a neutral position on this topic, and any argument in favour of reviewing current policy in the light of existing evidence is in danger of being portrayed in the media as championing the legalising of all drugs, inciting headlines of the "top doc drug shock" variety. This also makes it difficult for national governments to advocate a shift in policy. It is worthy of note that the supporters of drug reform listed on the Transform Drug Policy Foundation website include the current UK prime minister and his deputy, who offered their support while in opposition, although their appetite for reform may have since diminished.3

The proportion of adults aged 16-59 in England and Wales who report recent use of illicit drugs fell from 11.1% in 1996 to 8.6% in 2009. This reduction is mainly the result of a drop in cannabis use, and the proportion of problem drug users, including those who inject, has risen slightly in the past four years to 2% of 25-34 year-olds. In addition, cocaine use continues to



The aim is to prioritise health considerations

increase. But it is the global picture of multibillion dollar organised crime and the subjugation and virtual destruction of whole countries in Central America and South America that makes evidence based international action urgent. It is possible that the harm caused by drug policy might exceed that from the drugs themselves. The presidents of Costa Rica, Guatemala, El Salvador, Colombia, and Mexico have said in recent weeks that they wish to open up discussions on legalising drugs, forcing a reluctant US Vice President Biden to meet them.

What would drug reform look like? Most serious commentators call for decriminalisation—that is, downgrading of the status of personal drug use—so that using drugs is not a crime or is a lesser one. The aim is to prioritise health considerations over criminal ones in personal users, but with the secondary goals of reducing criminal behaviour and improving the health of the population. This is not the same as legalising drugs.

However, it is difficult for countries to act alone to decriminalise drug use while the 1961 UN Single Convention on narcotic drugs remains in force: the Beckley Foundation in England has set up a global initiative for drug policy reform to draft a fresh UN convention that would allow signatory countries more freedom in deciding their own national drug policies (www.beckleyfoundation.org).

What problem might decriminalisation solve and what is our legitimate interest as clinicians? It is important to distinguish the damage that drug use causes to individuals from its wider societal harms, but both have an impact on public health. The problems we see in our acute hospitals arise more from infected needles, contaminated drug supplies, and the consequences of social exclusion than from the drugs themselves. Prison health is dominated by drug misuse. A survey of 1500 prisoners in 2005-6 found that nearly 80% had a history of illicit drug use at some time in their life. A national survey in 1997 found that a quarter of heroin users started using the drug in prison. The criminalisation of drugs damages families and communities in a way that is not confined to the impact of crime, and it has far reaching health consequences.

What can we learn from other countries? Those on both sides of the argument will marshal statistics from countries such as Portugal and the Netherlands. However, a UK trial of a non-punitive and supportive approach to recidivist heroin injectors has shown that the supply of clean drugs and equipment under supervision can improve individual health, wellbeing, and social integration.

Why should we look again at UK policy now? The present government has taken a brave policy approach to alcohol and tobacco in the interests of the nation's health, and a review of drug policy is timely from several perspectives alongside the Commission on Narcotic Drugs meeting in Vienna. The Liberal Democrat Party voted overwhelmingly at its conference last autumn to set up a panel to consider decriminalising all drugs, which makes it official party policy, and there is support for decriminalisation from the all party parliamentary group on drug reform. The home affairs select committee is also currently considering drug policy.8 As well as their responsibility to individual patients, doctors have a collective responsibility to encourage a rational debate on how best to minimise harm to the health of the population through advocating evidence based policies, and this evidence in the field of illicit drugs has recently been clearly laid out by Strang and colleagues.9 Government may not welcome this debate, but the potential health gain is great and doctors should support it.

 ${\color{red}\textbf{Competing interests}}. \ {\color{red}\textbf{None declared}}.$

Provenance and peer review: Commissioned; not externally

References are in the version on bmj.com.

Cite this as: *BMJ* 2012;344:e2381

BMJ | 21 APRIL 2012 | VOLUME 344

bmj.com

- Effect of training traditional birth attendants on neonatal mortality (Lufwanyama Neonatal Survival Project): randomised controlled study (*BMJ* 2011;342:d346)
- Effect of timing of first postnatal care home visit on neonatal mortality in Bangladesh: a observational cohort study (*BMJ* 2009;339:b2826)

Reducing neonatal mortality in resource poor settings

What works is now clearer but implementation is a challenge

Kim Eva Dickson senior adviser (maternal and newborn health) kdickson@unicef.org

Mickey Chopra associate director, chief of health, Health Section, Unicef. NY 10017, USA

Since the announcement in 2000 of the millennium development goals (MDGs), progress towards achieving these goals has resulted in considerable reductions in deaths from communicable diseases such as HIV, tuberculosis, and malaria (MDG 6); maternal mortality (MDG 5); and child deaths (MDG 4). Child deaths for instance have declined from more than 12 million in 1990 to 7.6 million in 2010.¹ However, progress in reducing neonatal deaths—deaths within the first month of life—has lagged behind. Neonatal deaths now account for a greater proportion of global child deaths than ever before—nearly 41% of all deaths in children under 5 years occur during the neonatal period.²

In this context, the results of the linked trial by Bhandari and colleagues are of particular interest and importance.3 It is the first study to evaluate India's large and complex Integrated Management of Neonatal and Childhood Illness (IMNCI) programme, which is an approach to neonatal and child care that is being implemented across the country. Bhandari and colleagues evaluated the Indian IMNCI programme and found that it significantly reduced infant and child mortality. Worldwide, 99% of neonatal deaths occur in low and middle income countries, and 50% of these deaths occur at home.4 In 1990, more than half of these deaths occurred in just five countries-India, Nigeria, Pakistan, China, and the Democratic Republic of Congo²—and India had the largest number of neonatal deaths in the period 1990-2009.

India's adapted IMNCI programme is different from the generic programme in that it places an emphasis on the use of community based providers (auxiliary nurse-midwives or Anganwadi workers) and training of these groups for home visits for postnatal care of the newborn baby. This strategy has already proved to be effective. The current study reports a significant reduction in the infant mortality rate (hazard ratio 0.85, 95% confidence interval 0.77 to 0.94) and a reduction in neonatal mortality for babies born at home (0.80, 0.68 to 0.93) for the adapted programme. Overall, the findings of the linked study indicate that the adapted IMNCI programme can be implemented



Community based midwife

on a large scale and can reduce infant mortality and neonatal mortality in settings where a large proportion of babies are born at home. However, they also raise several questions that need to be investigated further.

Firstly, although Bhandari and colleagues showed a significant reduction in neonatal mortality for babies born at home, mortality was not reduced for babies born at the health facility. This might be the result of a statistical artefact, such as regression to the mean; because of the greater fidelity to the intervention by the community workers; or because of unmeasured bias between the groups. It would be premature to conclude that this intervention should be restricted to nonfacility based births, and further evaluation of the reasons for this difference is needed.

Secondly, it is not clear which part of the comprehensive intervention was most effective. Several different components were implemented, including women's groups, home visits, and improved clinical care training, and fidelity to the protocol was variable for each. For example, although the study managed to achieve a relatively high number of home visits (73.5%) within the first 10 days of childbirth, only 42.6% of mothers and infants had the recommended three visits and only 56.6% were visited in the first two days. As the intervention is scaled up within the country, it would be useful to know which parts of the complex package of interventions should be most actively promoted.

Lastly, the lack of impact on neonatal mortality rates in the first 24 hours, regardless of the place of birth, is of concern. This finding may be partly explained by the relatively low level of home visits within the first 48 hours. It is crucially important

to strengthen interventions that are targeted at reducing early neonatal mortality, because three quarters of the estimated four million neonatal deaths each year occur in the first week, with the highest risk being on the first day of life.⁴

The MDG for child survival cannot be met without substantial reductions in neonatal mortality. A lack of policies is no longer the main problem. Since the publication of the *Lancet* series on neonatal survival in 2005, many countries now have adequate policies in place to tackle child mortality. Gaps remain in implementation and action. We need to find ways to identify and reach the most vulnerable—and to adopt an equity focused approach to the implementation of policies—with more global and political commitment to invest in community based approaches.

Bhandari and colleagues' trial adds to the growing body of evidence that cost effective community based interventions can substantially reduce neonatal mortality even when resources are scarce. We know what to do, but how to ensure that we reach the most vulnerable when they are at their most vulnerable remains a challenge that requires political commitment, focused programmes, research, and funding to be overcome.

Competing interests: None declared.

Provenance and peer review: Commissioned; not externally peer reviewed.

- Unicef, WHO, World Bank, and UN Population Division. Levels and trends in child mortality. Report 2011. www. childinfo.org/files/Child_Mortality_Report_2011.pdf.
- Oestergaard MZ, Inoue M, Yoshida S, Mahanani WR, Gore FM, Cousens S, et al. Neonatal mortality levels for 193 countries in 2009 with trends since 1990: a systematic analysis of progress, projections, and priorities. PLoS Med 2011;8(8):e1001080.
- 3 Bhandari N, Mazumder S, Taneja S, Sommerfelt H, Strand TA. Effect of implementation of Integrated Management of Neonatal and Childhood Illness (IMNC) programme on neonatal and infant mortality: cluster randomised controlled trial. BMJ 2012;344:e1634.
- 4 Lawn JE, Cousens S, Zupan J. 4 million neonatal deaths: When? Where? Why? *Lancet* 2005;365:891-900.
- 5 Bang AT, Bang RA, Baitule SB, Reddy H, Deshmukh MD. Effect of home-based neonatal care and management of sepsis on neonatal mortality: field trial in rural India. *Lancet* 1999;354:1955-61.
- 6 Lawn JE, Cousens S, Darmstadt GL, Bhutta ZA, Martines J, Paul V, et al. 1 year after the Lancet neonatal survival series—was the call for action heard? *Lancet* 2006;367:1541-7.
- 7 Darmstadt GL, Bhutta ZA, Cousens S, Adam T, Walker N, de Bernis L. Evidence-based, cost-effective interventions: how many newborn babies can we save? *Lancet* 2005;365:977-88.

Cite this as: *BMJ* 2012;344:e2197

© RESEARCH, p 17

Although improved regionalisation would increase the patient volumes in some English NICUs... smaller high risk obstetric services and NICUs should be consolidated with geographically proximate services to create a smaller number of larger tertiary centres

Managed clinical networks in neonatal care

Reduces morbidity after preterm births but regionalisation of obstetric care is key

Ciaran S Phibbs health economist, Health Economics Resource Center (152), VA Palo Alto Health Care System, Palo Alto, CA 94025, USA cphibbs@stanford.edu

A large body of evidence supports the concept of regionalising neonatal intensive care. Both mortality and serious morbidity are significantly reduced for high risk infants who are born in hospitals that have a high volume of cases, tertiary level obstetric services, and neonatal intensive care units (NICUs). ¹ Although these benefits are most pronounced for the highest risk infants, such as those with extreme prematurity or major congenital anomalies, evidence suggests that benefits extend to all at risk deliveries and possibly to low risk ones as well. ³ It is also much better to move women with high risk deliveries to these high volume tertiary centres than to move critically ill neonates after delivery. ⁴ ⁵

In a linked paper, Gale and colleagues study the effects of the reorganisation of neonatal services in England that occurred as a result of this evidence.6 In 2003, neonatal services in England were formed into managed clinical networks. The changes improved access to NICUs and put specific emphasis on transferring women at high risk of preterm labour to a specialist centre before delivery, so reducing the number of babies who needed acute postnatal transfer. Gale and colleagues use data from before and after the reorganisation to examine the effects of the changes in care on infants with a gestational age of 27-28 weeks. They report an increase in the proportion of 27-28 week deliveries that occurred in designated tertiary hospitals after 2003-from 18% to 49%—but note that there is still a long way to go to achieve full regionalisation of care for high risk newborns.

One factor that may have contributed to the limited success of this reorganisation is that it affected only NICUs. Because successful regionalisation requires that all high risk deliveries are moved to the designated tertiary hospitals, full participation of obstetric providers is also essential. High risk cases need to be identified early enough for mothers to be safely moved to the designated tertiary hospitals for delivery so the reorganisation needs to be expanded to include obstetric services.

It is possible to achieve much higher levels of regionalisation of obstetric services; studies of services in Portugal, Finland, and the Cincinnati



Newborn receiving intravenous treatment

metropolitan area have reported that 90-95% of very preterm (<32 weeks) or very low birthweight (<1500 g) infants are delivered in designated tertiary hospitals.⁷⁻⁹ The Portuguese experience shows the potential of improved regionalisation. In 1990 the Portuguese health service closed all small delivery services and small NICUs and put in place an effective system of regionalisation, which resulted in more than 90% of all deliveries of very low birthweight infants taking place in designated tertiary hospitals.8 Neonatal mortality in Portugal decreased from one of the worst in Europe to well above the median. England is a geographically compact country without serious barriers to travel. There is therefore no reason why England cannot match the 90% plus levels of regionalisation that have been achieved in other regions.

In addition to the challenge of putting systems in place to shift all high risk deliveries to designated tertiary hospitals, England faces a second challenge that will require political support. Even if almost all high risk deliveries were shifted appropriately, England probably has too many NICUs. Gale and colleagues also examined data on NICU size and found that almost none of the NICUs studied reached the patient volumes that have been associated with the best outcomes. The most recent data show clear gains in reduced mortality up to a volume of at least 100 deliveries of very low birthweight infants a year. 10 Although improved regionalisation would increase the patient volumes in some English NICUs, many would still be below 100 deliveries of very low birthweight infants. The policy implication is clear—smaller high risk obstetric services and NICUs should be consolidated with geographically proximate services to create a smaller number of larger tertiary centres.

Such changes will be difficult to implement politically. Capital investments will probably be needed to expand some existing units, successful merging of staff from different units will be a challenge, and the closure of hospital services may meet resistance. Political opposition recently forced Germany, which is even more deregionalised than England, to abandon a policy to force the closure of small NICUs. Full regionalisation of neonatal care is the correct thing to do, however. Portugal faced similar political opposition to the closure of NICUs and delivery services in 1990, but policy makers stood firm and the country has reaped the benefits.

England has made a good start on improving the regionalisation of neonatal care, but it has a long way to go before neonatal care can deliver the best possible outcomes for all high risk deliveries. Competing interests: None declared.

Provenance and peer review: Commissioned; not externally peer reviewed.

- 1 Lasswell SM, Barfield WD, Rochat RW, Blackmon L. Perinatal regionalization for very low-birth-weight and very preterm infants: a meta-analysis. JAMA 2010;304:992-1000.
- 2 Phibbs CS, Baker LC, Caughey AB, Danielsen B, Schmitt SK, Phibbs RH. Level and volume of neonatal intensive care and mortality in very-low-birth-weight infants. N Engl J Med 2007;356:2165-75.
- 3 Heller G, Richardson DK, Schnell R, Misselwitz B, Kunzel W, Schmidt S. Are we regionalized enough? Early-neonatal deaths in low-risk births by the size of delivery units in Hesse, Germany 1990-1999. Int J Epidemiol 2002;31:1061-8.
- 4 Bowman E, Doyle LW, Murton LJ, Roy RN, Kitchen WH. Increased mortality of preterm infants transferred between tertiary perinatal centres. BMI 1988:297:1098-100.
- 5 Lee SK, Zupancic JA, Pendray M, Thiessen P, Schmidt B, Whyte R, et al. Transport risk index of physiologic stability: a practical system for assessing infant transport care. J Pediatr 2001:139:220-6.
- 6 Gale C, Santhakumaran S, Nagarajan S, Statnikov Y, Modi N. Impact of managed clinical networks on NHS specialist neonatal services in England: population based study. *BMJ* 2012;344:e2423.
- 7 Binder S, Hill K, Meinzen-Derr J, Greenberg JM, Narendran V. Increasing VLBW deliveries at subspecialty perinatal centers via perinatal outreach. *Pediatrics* 2011;127:487-93.
- 8 Neto MT. Perinatal care in Portugal: effects of 15 years of a regionalized system. Acta Paediatr 2006;95:1349-52.
- 9 Rautava L, Lehtonen L, Peltola M, Korvenranta E, Korvenranta H, Linna M, et al. The effect of birth in secondary- or tertiarylevel hospitals in Finland on mortality in very preterm infants: a birth-register study. *Pediatrics* 2007;119:e257-63.
- 10 Chung JH, Phibbs CS, Boscardin WJ, Kominski GF, Ortega AN, Gregory KD, et al. Examining the effect of hospital-level factors on mortality of very low birth weight infants using multilevel modeling. J Perinatal 2011;31:770-5.

Cite this as: BMJ 2012;344:e2423

© RESEARCH, p 18

bmi.com

US doctors are unwilling to pay more to abolish industry funded education (BMJ 2011;342:d2948)

The Institute of Medicine

of all commercial funding

from CME with continued

attendance at the same

activities would roughly

double the amount that

doctors spend each year

number and types of

on CME

estimated that elimination

Funding CME: Time for optimism (BMJ 2011;342:d3351)

Commercial funding of accredited continuing medical education

Is decreasing but more needs to happen

Jeffrey A Tabas professor of emergency medicine, University of California, San Francisco (UCSF), San Francisco, CA 94110, USA jeff.tabas@emergency.ucsf.edu
Robert B Baron associate dean for graduate and continuing medical education, UCSF, San Francisco, CA 94143, USA

Funding from the drug industry and manufacturers of medical devices supports a large proportion of costs for accredited continuing medical education (CME) in the United States. However, newly released data from the Accreditation Council for Continuing Medical Education (ACCME) show that funding for CME from drug companies and medical device makers (including advertising and exhibit income) fell in 2010 to \$1.1bn (£0.7bn; €0.84bn), the third consecutive annual decline from a high of \$1.5bn in 2007, and the lowest figure since 2002.¹ The proportion of total CME funding from commercial support, advertising, and exhibit income has steadily decreased from a high of 62% in 2004 to the current rate of 49%.

In recent years, there has been increasing debate among the public and medical profession about the role of industry funding in medical education. Several prominent organisations—including the Association of American Medical Colleges, the Institute of Medicine, and the Josiah Macy Jr Foundation—have called for

limits to the amounts and scope of commercial support for medical education.²⁻⁴ These recommendations have ranged from calls to manage commercial support with stricter "firewalls," by receipt and coordination of funding through a central CME office, to calls to eliminate commercial funding entirely from the content and processes of CME.2 4 This year, the American Medical Association House of Delegates approved a report by the Council on Ethical and Judicial Affairs that called for "CME that is independent of funding or in-kind support from sources that have financial interests in physicians' recommendations," while acknowledging some circumstances in which support from such entities or individuals may be needed.5 The report stopped short of recommending that commercial support be entirely eliminated from CME, as had previously been suggested.

The Physician Payments Sunshine provision of the Patient Protection and Affordable Care Act, signed into law in March 2010 by Barack Obama, brought these concerns about the relations between doctors and industry into law. This federal legislation requires companies to report on compensation to doctors, including speaking and consulting fees, meals, and gifts from any organisation that manufactures or purchases drugs, devices, or medical supplies. A freely accessible database detailing this compensation will be established by 2013.

Many factors may be driving the decrease in commercial funding of accredited CME. Some of the decrease may reflect elimination of certain funding practices after updated standards of commercial support were implemented by the ACCME in 2004. For example, a person or organisation with a commercial interest in an

educational activity is not allowed to have control of funds or content as an educational partner. The largest drop in commercial funding (from about \$635m in 2004 to \$286m in 2010) occurred within the category of providers described as publishing or education companies. This category included some companies that delivered education primarily as a

marketing strategy in return for funding. Such companies have probably moved to non-accredited forms of medical education after implementation of the updated standards, or disappeared entirely. Other factors may include release of the drug industry's own updated guidelines and standards in 2009, greater legislative scrutiny, and depression of the global economy.

As commercial funding has reduced, a larger proportion of the costs of medical education have been offset from other sources, such as participant registration fees. Increasing costs to learners makes the question of whether all commercial support and exhibits should be eliminated from accredited CME a complex one. The Institute of Medicine estimated that elimination of all commercial funding from CME with continued attendance at the same number and types of activities

would roughly double the amount that doctors spend each year on CME, which averaged about \$1400 in 2007.³ A recent survey of CME participants showed that although only 8% of doctors preferred to attend a commercially supported CME course, 62% believed that CME providers should accept commercial support if doing so reduced the cost to the attendee.⁸

The current trend in funding of accredited CME is encouraging because it reflects a reduction in commercial influence. However, a substantial proportion (half) of accredited CME continues to be funded with support from the drug industry and medical device industry. Availability of funding may be one factor that affects quality and dissemination of educational materials. Alternative funding sources or mechanisms will be needed if the dependence of accredited CME on industry sponsorship is to be further limited, or eliminated. As we move towards more individualised assessments of doctors' performance and patient outcomes, some of the costs for CME will increase. Doctors should play a central role in making decisions about funding, regardless of whether the solutions are internally driven or externally mandated.

 ${\color{red}\textbf{Competing interests}}. \textbf{None declared}.$

Provenance and peer review: Commissioned; not externally peer reviewed.

- 1 Accreditation Council for Continuing Medical Education 2010 annual report data. 2011. www.accme.org/sites/ default/files/null/604_2010_Annual_report_20111012.
- Association of American Medical Colleges. Industry funding of medical education: report of an AAMC task force. 2008. https://www.aamc.org/initiatives/coi/.
- 3 Institute of Medicine. Redesigning continuing education in the health professions. National Academies Press, 2010.
- Fletcher SW. Chairman's summary of the conference. Continuing education in the health professions: improving healthcare through lifelong learning. J Contin Educ Nurs 2008;39:112-8.
- 5 American Medical Association Council on Ethical and Judicial Affairs: Financial relationships with industry in continuing medical education. 2011. www.ama-assn.org/ resources/doc/ethics/ceja-1a11.pdf.
- 6 Peterson ED, Overstreet KM, Parochka JN, Lemon MR. Medical education and communication companies in CME: an updated profile. J Contin Educ Health Prof 2008;24:205-19.
- 7 Pharmaceutical Research and Manufacturers of America. Code on interactions with healthcare professionals 2009. www.phrma.org/sites/default/files/108/phrma_ marketing_code_2008.pdf.
- 8 Tabas JA, Boscardin C, Jacobsen DM, Steinman MA, Volberding PA, Baron RB. Clinician attitudes about commercial support of continuing medical education: results of a detailed survey. *Arch Intern Med* 2011:171:840-6

Cite this as: BMJ 2012;344:e810

Each subsequent second generation drug has been marketed as an important advance over previous ones. The findings of [a] recent meta-analysis suggest a limited or non-existent incremental benefit of each new antidepressant

Choosing a second generation antidepressant for treatment of MDD

Drugs for major depressive disorder have similar efficacy but side effect profiles differ

Helen Lester professor of primary care, University of Birmingham, Birmingham B15 2TT, UK h.e.lester@bham.ac.uk

Simon Gilbody professor of psychological medicine and health services research, University of York and HYMS, York, UK

Depression is a major cause of disability worldwide, with costs and consequences at the level of the individual, the family, and society.² Effective treatments—both drug based and psychological—are much needed. A variety of antidepressants have been shown to be effective in clinical trials, and primary care and secondary care clinicians seem to have almost too much choice. However, recent meta-analyses of the comparative efficacy and safety of second generation antidepressants have reached conflicting conclusions, muddying the therapeutic waters. The most recent meta-analysis found little difference in efficacy among second generation antidepressants,3 whereas an earlier one found that escitalopram and sertraline had the best efficacy to acceptability ratio.4 National Institute for Health and Clinical Excellence guidance in England and Wales suggests that the first choice antidepressant should be a generic selective serotonin reuptake inhibitor (SSRI).5

The most recent meta-analysis reviewed 234 studies (including 118 head to head drug trials) published between 1980 and August 2011 and focused on the benefits and harms of 13 pharmacologically different second generation antidepressants for treating major depressive disorder.3 Their method included inviting key stakeholders to help the study team refine their review questions and they sought unpublished research in this area, which is bedevilled by publication bias and conflicts of interest. Just under two thirds of the patients responded to treatment by 12 weeks and just under half achieved full remission. This provides evidence that antidepressants are an effective treatment for depression and counters recent claims of low effect sizes or no effect for people with anything less than very severe depression.6

The study highlighted important limitations in the primary research. Most of the trials recruited highly selected populations and the analysis did not include studies conducted in patients older than 65, which limited the transferability of research to older adults. In addition, no studies directly compared the efficacy, effectiveness, and harms between subgroups and the general population.

The meta-analysis found no clinically important differences between drugs in efficacy or effectiveness in acute, continuation, and maintenance phases of major depressive disorder, although small differences were noted in how quickly different drugs started to work and their side effect profiles. For example, nearly two thirds of patients had at least one adverse event, but effects varied between drugs. A low incidence of sexual dysfunction was seen for bupropion but the incidence was high for paroxetine; mirtazapine was more likely to lead to weight gain but had a faster onset of action than citalogram, fluoxetine, paroxetine, and sertraline; trazadone had a greater sedative effect and sertraline had a higher incidence of diarrhoea than comparator drugs; and venlafaxine (a serotonin noradrenaline (norepinephrine) reuptake inhibitor) had a higher incidence of nausea and vomiting than SSRIs as a class. In short, the drugs were "the same but different," in that each seemed to work, with minimal differences in efficacy, and no drug was without problems, although side effects differed.

What are the lessons for clinicians? The authors of this high quality meta-analysis focused on clinical rather than statistical significance. Although similarly effective, the newer antidepressants offer different therapeutic options in practice. In the absence of an obvious best treatment, the clinical consultation needs to focus discussing side effects with patients so that they can make an informed choice.

Clinicians might take a moment to reflect on advances in, and limitations of, drug treatments for depression. It is now 25 years since the first SSRI, fluoxetine (Prozac), was licensed. Second generation antidepressants were hailed as a major advance over first generation ones. Systematic reviews have since shown that the benefits of second generation drugs over first generation ones are smaller than originally envisaged. Each subsequent second generation drug has been marketed as an important advance over previous ones. The findings of the recent meta-analysis suggest a limited or non-existent incremental benefit of each new antidepressant. Newer drugs are unlikely to be of sufficient additional benefit

to make them cost effective compared with older second generation drugs. Many second generation agents are now off patent, and cost conscious prescribing should give primacy to generic preparations where possible.

Evidence from randomised trials and observational studies indicates that overall rates of discontinuation of antidepressants are high and adherence rates



are poor, which reduces the effectiveness of these drugs. Collaborative care tackles these problems by integrating shared decision making with medication management, where case managers check patients' understanding and worries about drugs and liaise closely with general practitioners if problems arise. This approach increases the use of antidepressants and improves patient outcomes, according to a large body of evidence from more than 36 randomised trials. ⁸ In the long term, better services may have more effect on improving care than choice of antidepressant.

Nearly 40 years ago, when reviewing which form of psychotherapy was the most effective, researchers arrived at the so called dodo verdict: "Everybody has won and all must have prizes" (from Lewis Carroll's *Alice's Adventures in Wonderland*). The same verdict seems appropriate for second generation antidepressants. The immediate challenge is not to try to work out which drug is best but to make the most of what is available through cost conscious prescribing and shared decision making.

Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure. pdf (available on request from the corresponding author) and declare: they had financial support from the UK National Institute of Health Research to support research on the management of depression in primary care; no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Provenance and peer review: Commissioned; not externally peer reviewed.

References are in the version on bmj.com.

Cite this as: BMJ 2012;344:e1014

Response on bmj.com

• "Within hours of the *BMJ* publishing this peer reviewed editorial, I was being sent gloating emails by anti-wind farm activists, jubilant that a prestigious journal had published the editorial. In this instance, the *BMJ* needs to look at the adequacy of its peer review process" Simon Chapman, professor of public health, Sydney

Wind turbine noise

Seems to affect health adversely and an independent review of evidence is needed

Christopher D Hanning honorary consultant in sleep medicine, Sleep Disorders Service, University Hospitals of Leicester, Leicester General Hospital, Leicester LE5 4PW, UK chrisdhanning@rockuk.net

Alun Evans professor emeritus, Centre for Public Health, Queen's University of Belfast, Institute of Clinical Science B, Belfast, UK

The evidence for adequate sleep as a prerequisite for human health, particularly child health, is overwhelming. Governments have recently paid much attention to the effects of environmental noise on sleep duration and quality, and to how to reduce such noise. However, governments have also imposed noise from industrial wind turbines on large swathes of peaceful countryside.

The impact of road, rail, and aircraft noise on sleep and daytime functioning (sleepiness and cognitive function) is well established. Shortly after wind turbines began to be erected close to housing, complaints emerged of adverse effects on health. Sleep disturbance was the main complaint. Such reports have been dismissed as being subjective and anecdotal, but experts contend that the quantity, consistency, and ubiquity of the complaints constitute epidemiological evidence of a strong link between wind turbine noise, ill health, and disruption of sleep.

The noise emitted by a typical onshore 2.5 MW wind turbine has two main components. A dynamo mounted on an 80 m tower is driven through a gear train by blades as long as 45 m, and this generates both gear train noise and aerodynamic noise as the blades pass through the air, causing vortices to be shed from the edges. Wind constantly changes its velocity and direction, which means that the inflowing airstream is rarely stable. In addition, wind velocity increases with height (wind shear), especially at night, and there may be inflow turbulence from nearby structures—in particular, other turbines. This results in an impulsive noise, which is variously described as "swishing" and "thumping," and which is much more annoying than other sources of environmental noise and is poorly masked by ambient noise.4 5

Permitted external noise levels and setback distances vary between countries. UK guidance, ETSU-R-97, published in 1997 and not reviewed since, permits a night time noise level of 42 dBA, or 5 dBA above ambient noise level, whichever

is the greater. This means that turbines must be set back by a minimum distance of 350-500 m, depending on the terrain and the turbines, from human habitation.

The aerodynamic noise generated by wind turbines has a large low frequency and infrasound component that is attenuated less with distance than higher frequency noise. Current noise measurement techniques and metrics tend to obscure the contribution of impulsive low frequency noise and infrasound.⁶ A laboratory study has shown that low frequency noise is considerably more annoying than higher frequency noise and is harmful to health-it can cause nausea, headaches, disturbed sleep, and cognitive and psychological impairment. A cochlear mechanism has been proposed that outlines how infrasound, previously disregarded because it is below the auditory threshold, could affect humans and contribute to adverse effects.8

Sixteen per cent of surveyed respondents who lived where calculated outdoor turbine noise exposures exceeded 35 dB LAeq (LAeq, the constant sound level that, in a given time period, would convey the same sound energy as the actual time varying sound level, weighted to approximate the response of the human ear) reported disturbed sleep. ⁴ A questionnaire survey concluded that turbine noise was more annoying at night,



Wind turbines near housing in Austria

and that interrupted sleep and difficulty in returning to sleep increased with calculated noise level. Even at the lowest noise levels, 20% of respondents reported disturbed sleep at least one night a month. In a meta-analysis of three European datasets (n=1764), sleep disturbance clearly increased with higher calculated noise levels in two of the three studies.

In a survey of people residing in the vicinity of two US wind farms, those living within 375-1400 m reported worse sleep and more daytime sleepiness, in addition to having lower summary scores on the mental component of the short form 36 health survey than those who lived 3-6.6 km from a turbine. Modelled dose-response curves of both sleep and health scores against distance from nearest turbine were significantly related after controlling for sex, age, and household clustering, with a sharp increase in effects between 1 km and 2 km. ¹¹ A New Zealand survey showed lower health related quality of life, especially sleep disturbance, in people who lived less than 2 km from turbines. ¹²

A large body of evidence now exists to suggest that wind turbines disturb sleep and impair health at distances and external noise levels that are permitted in most jurisdictions, including the United Kingdom. Sleep disturbance may be a particular problem in children, ¹ and it may have important implications for public health. When seeking to generate renewable energy through wind, governments must ensure that the public will not suffer harm from additional ambient noise. Robust independent research into the health effects of existing wind farms is long overdue, as is an independent review of existing evidence and guidance on acceptable noise levels.

Competing interests: Both authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure. pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; CDH has given expert evidence on the effects of wind turbine noise on sleep and health at wind farm planning inquiries in the UK and Canada but has derived no personal benefit; he is a member of the board of the Society for Wind Vigilance; AE has written letters of objection on health grounds to wind farm planning applications in Ireland.

Provenance and peer review: Not commissioned; externally peer reviewed.

References are in the version on bmj.com.

Cite this as: BMJ 2012;344:e1527