

EDITORIALS

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

thebmj.com Read all our coverage of the UK general election at bmj.co/election

Prospects for the NHS in England in the next parliament

Investment and reform should be at the heart of the new government's programme



Chris Ham chief executive, King's Fund, London, UK
c.ham@kingsfund.org.uk

The newly elected Conservative government faces an immediate challenge in keeping the NHS solvent in 2015-16 and a more fundamental challenge of transforming care to better meet the needs of an ageing population. It must also continue to improve patient safety and the quality of care without accentuating financial pressures facing NHS providers.

These challenges have to be tackled in the context of an NHS already struggling to meet key targets for patient care let alone fulfil new commitments, such as seven day working. The additional funding made available in 2015-16 in the coalition government's autumn statement is undoubtedly welcome, yet NHS providers are forecasting a deficit of almost £2bn (€2.8bn; \$3bn) by the end of this year.^{1 2} Of equal concern is growing pressure on staff in a service where patient experience is strongly shaped by staff experience.³

Any government would face limits in finding new resources for the NHS when the public finances are constrained by the need to reduce the deficit. Failure to provide further funding beyond current plans either means accepting growing deficits within the NHS, or insisting that NHS organisations reduce their costs to live within available budgets. This may require unpalatable choices such as cutting back on staff or reducing activity—with effects on quality of care and waiting times.

The alternative is to redouble efforts to improve productivity to help the NHS realise the £22bn of efficiencies required under NHS England's plans for the NHS.⁴ Although there is undoubtedly scope to use the £11.6bn spent in the NHS more efficiently, it is improbable that productivity improvements on this scale can be delivered by the end of the parliament. To make progress, providers must do more to engage staff in improving productivity, and politicians must be realistic about the time needed to show results.

Finding solutions to these pressures depends on transforming how care is delivered. Fragmentation between providers is a major cause of treatment delays and waste. This requires the development of new models of care and the removal of barriers to their implementation.⁵



The biggest risk to safety and quality is that the new government uses its mandate to reinstate strict financial control in the NHS

The Conservative Party's support for the five year forward view, with its emphasis on integrated care, could help to make care closer to home a reality and reduce over-reliance on hospitals and residential care. Providing adequate funding for social care as well as the NHS is essential to support service transformation and to move towards the new health and social care settlement advocated by the Barker Commission.⁵ Social care is under even more pressure than the NHS, with an expected £4bn annual funding gap by the end of the new parliament on current plans.⁶ Unless these plans are revised, publicly funded social care risks becoming a threadbare safety net for the most needy members of society.

Quality and safety

The new government's third challenge is to continue work that has started in response to the failings of care at Mid Staffordshire NHS Foundation Trust to improve patient safety and the quality of care. This means strengthening leadership at all levels, including by

clinicians, developing cultures in which staff are motivated and supported to deliver compassionate care, and seeking and acting on patient feedback. Proportionate inspection by the Care Quality Commission has a role, but much more important is for every provider to take this work seriously alongside greater transparency in the outcomes they achieve.

The biggest risk to safety and quality is that the new government uses its mandate to reinstate strict financial control in the NHS, leaving providers no option but to cut back staff to live within their budgets. This will mean reversing recent staffing increases and may mean that providers are not able to satisfy the Care Quality Commission that they can deliver safe care within their available resources. Health ministers will then have to decide whether to make the case for the additional funds promised for the NHS to be injected sooner than planned to avoid this happening.

Underlying all these challenges is the much bigger question of how to ensure that public funding for the NHS is adequate to sustain a universal and comprehensive service that is largely free at the point of use. If current funding promises prove insufficient, tax rises may be necessary both to maintain current standards and pay for improvements like seven day working. The rub here is that the government's ability to raise more money through taxes has been constrained by commitments made during the election campaign not to increase income tax, national insurance contributions, and VAT.

A party seeking to govern for one nation, as the prime minister has stated, could show its intentions by confronting difficult choices about tax and spending, thereby securing the future of the NHS—the institution that is the most tangible expression of this aspiration. The alternative is to preside over its slow but steady demise by controlling spending too tightly and seeing standards of care fall. Spending on healthcare as a share of gross domestic product in the United Kingdom is not high by international standards, and a policy of increased investment linked to reform should be at the heart of the new government's programme.

Cite this as: *BMJ* 2015;350:h2541

thebmj.com

- Practice: Antenatal and postnatal mental health: summary of updated NICE guidance (*BMJ* 2014;349:g7394)
- Research: Maternal and fetal risk factors for stillbirth (*BMJ* 2013;346:f108)

Two linked papers use novel methods to reduce confounding, thus providing a valuable addition to the evidence base

Safety of psychotropic drugs in pregnancy

Reassuring findings on antidepressants and antipsychotics from the largest studies to date

Hind Khalifeh NIHR research fellow

Clare Dolman service user researcher

Louise M Howard NIHR research professor, Section of Women's Mental Health, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
louise.howard@kcl.ac.uk

Mental illness in pregnancy is common—around 10% of women experience a major depressive illness or anxiety disorder,¹ and an increasing number of women with psychotic disorders are able to conceive owing to the decreased use of antipsychotics with prolactin raising properties.² Evidence on the risks of psychotropic drugs from observational data is limited and contradictory, with important methodological limitations due to bias, confounding, and small sample sizes.⁵ In two linked papers in this issue, Furu and colleagues⁶ and Vigod and colleagues⁷ tackle some of these limitations by using novel methods to reduce confounding in large linked datasets, and thus provide a valuable addition to the evidence base on the safety of psychotropic drugs in pregnancy.

Furu and colleagues used national data from the five Nordic countries to examine the association between maternal use of selective serotonin reuptake inhibitors (SSRIs) or venlafaxine in the first trimester and birth defects among 2.3 million live singletons, including 36 772 (1.6%) exposed infants. To account for familial or unmeasured environmental confounding, the study included a cohort of around 2000 sibling pairs who were discordant for maternal antidepressant use and for congenital malformations.

In the whole cohort, and after taking into account key confounders, exposed infants had a small increased risk of any major birth defects and cardiac defects. In the sibling cohort, however, none of these outcomes was associated with exposure to SSRIs or venlafaxine. This suggests that the associations observed in the whole cohort may be due to confounding by familial or lifestyle factors, and points against a teratogenic risk from these drugs.

Vigod and colleagues used linked healthcare data in a matched cohort of 1021 women who were prescribed antipsychotics during pregnancy and 1021 women who were not. The matched cohort was derived using a statistical technique called high dimensional propensity score



Individual risk-benefit analyses needed

matching, which aims to minimise unmeasured confounding. Results were also reported for an unmatched cohort of around 1200 women who used antipsychotics and 40 000 women who did not. In the unmatched cohort, women who used the drugs had an increased risk of several adverse outcomes, with a high prevalence of preterm birth (15%), gestational diabetes (8%), hypertension (5%), and large for gestational age infants (4%). In the matched cohort, however, none of these outcomes was associated with antipsychotic use. This suggests that the associations observed in the unmatched cohort were not due to antipsychotic use in pregnancy but rather to confounding. Of note were the absolute rates of these adverse pregnancy outcomes (considerably higher than in the general population of pregnant women) and the high rates of pre-pregnancy diabetes and hypertension in the cohort that used antipsychotics.

Both studies have two key strengths; they are the largest comparative studies to date for their respective drugs, and they each contain a carefully chosen comparison group designed to deal with confounding. However, as the authors acknowledge, residual confounding, including confounding by indication, is likely. Moreover, the high rates of adverse outcomes in women using antipsychotics may be due to the presence

of other risk factors, which may be misclassified or not recorded in administrative data.⁸ Comprehensive assessment of physical and mental health and psychosocial risks in women with mental disorders is therefore vital. For women using antipsychotics, additional glucose monitoring including an oral glucose tolerance test is recommended.⁵

When deciding on whether to use a psychotropic in pregnancy, the potential risks to mother and unborn baby need to be balanced against the potential benefit of treatment, including reductions in the risk of postnatal mental illness. There is no randomised controlled trial evidence on the efficacy of antidepressants or antipsychotics in pregnancy (and only emerging such evidence of the benefit of antidepressants on postnatal depression),⁹ but observational studies suggest higher relapse rates among those who discontinue drugs,^{2 10} especially among women with recurrent or recent episodes, and those who stop drugs abruptly.^{2 11}

The two studies provide further reassuring safety data, but risks and benefits are still uncertain—especially for long term neurodevelopmental outcomes. For some mood stabilisers—particularly valproate, where there is clear evidence of a substantially increased risk of major congenital malformations (prevalence 11%) and developmental delay (prevalence 40%) in exposed infants¹²—the risks will outweigh the potential benefits, and alternative drugs such as antipsychotics will be preferable where effective. The threshold for drug interventions should generally be higher in the perinatal period, with priority given to psychological interventions where effective.

However, drugs will be necessary for some women, particularly those with severe mental illnesses who are at high risk of relapse.² Women and clinicians therefore need to be guided by individual risk-benefit analyses, which take into account the diagnosis, severity of illness, past response to treatment, medical comorbidities, likely risks to the mother and her unborn baby should she stop treatment, safety profiles of individual drugs, and personal preferences and choices.⁵

Cite this as: *BMJ* 2015;350:h2260

RESEARCH, pp 11, 12

thebmj.com

- ▶ Views & Reviews: Vaccinate boys as well as girls against HPV (*BMJ* 2014;349:g4834)
- ▶ Editorial: HPV vaccination (*BMJ* 2014;349:g4783)
- ▶ News: Australia launches national scheme to vaccinate boys against HPV (*BMJ* 2013;346:f924)

Of the 610 000 cancers annually attributable to HPV worldwide, 87% are cancers of the cervix

Who should be vaccinated against HPV?

The focus for lower income countries should remain on cervical cancer prevention

Karen Canfell director, Cancer Research Division, Cancer Council NSW, Woolloomooloo, NSW 2011, Australia
Karen.Canfell@nswcc.org.au

Vaccination of girls against the human papillomavirus (HPV) has been implemented in most developed countries, driven by prevention of cervical cancer as a public health priority. Bivalent (Cervarix, GSK) and quadrivalent (Gardasil, Merck) vaccines protect against subsequent infection with oncogenic HPV16/18, and quadrivalent vaccine protects against HPV6/11, which cause anogenital warts. Although HPV vaccination effectively protects against external genital lesions and anal intraepithelial neoplasia in males, only a few jurisdictions have so far recommended universal vaccination of boys. These include Australia, Austria, two Canadian provinces, and the United States. In other countries, a cautious approach has been due, in part, to uncertainties around the population level impact and cost effectiveness of vaccination of boys.

In a linked article, Bogaards and colleagues estimated the benefits to men of offering HPV vaccination to boys.¹ They used a dynamic simulation and a bayesian synthesis to integrate the evidence on HPV related cancers in men. The analysis takes account of indirect protection from female vaccination: heterosexual men will benefit from reduced HPV circulation in females, so if coverage in girls is high the incremental benefit of vaccinating boys is driven by prevention of the residual burden of anal cancer in men who have sex with men.

The findings reinforce those of prior analyses that found that adding boys to established vaccination programmes in girls becomes less cost effective as female coverage increases.² The cost effectiveness of vaccination of boys also depends on other local issues, especially vaccine type and vaccine and administration costs. A threshold total cost per vaccinated boy for cost effectiveness can be identified at any level of coverage in girls: such analyses can provide policy makers with the maximum rational vaccine price appropriate to the local environment. If vaccine coverage in girls is lower, however, the most effective use of resources is likely to involve increasing coverage in girls, if feasible.^{2,3}

In some countries, vaccination of boys might not be cost effective, even at lower vaccine prices,

due to higher administration costs.³ Recent developments towards reduced dose schedules could help. In 2013 the European Medical Agency recommended a two dose schedule for the bivalent vaccine in girls, in 2014 the United Kingdom switched to a two dose schedule, and the World Health Organization now recommends two doses for girls <15. Two dose schedules are the most cost effective option for girls provided protection lasts for ≥20 years⁴ and reduced dose schedules in boys are also likely to increase cost effectiveness if adequate efficacy is maintained.

Importance of preventing anal cancer in men

Bogaards and colleagues highlight the importance of vaccination for prevention of anal cancer in men who have sex with men. In part due to uncertainties in natural history, the effectiveness of anal cancer screening is not established.⁵ Primary prevention with targeted vaccination of men who have sex with men is an attractive option and is potentially more cost effective than universal vaccination of boys. The US Advisory Committee on Immunization Practices already recommends vaccination of men who have sex with men up to the age of 26 years.⁶ The UK's Joint Committee on Vaccination and Immunisation, as an interim position, recently stated that a programme to vaccinate men aged 16-40 who have sex with men with a quadrivalent vaccine should be considered, if cost effective.⁷ Lower coverage rates expected with targeted versus universal male vaccination are an important consideration, and

the two approaches are not mutually exclusive.

Several other developments should be factored in to future policy decisions. A recent study showed that the bivalent vaccine is effective in women aged ≥25 without a history of HPV disease.⁸ With a transition to primary HPV screening in several countries, an interesting possibility for evaluation is “screen and vaccinate” strategies in older women—that is, offering HPV screening, followed by vaccination for HPV negative women with extended (or perhaps no) recall for this group. Secondly, a nonavalent vaccine (Gardasil9, Merck), which protects against an extra five HPV types,⁹ has recently been recommended for use in the US.⁶ In women, this will increase protection against cervical cancer in those who are fully vaccinated (from about 70% to about 90%)¹⁰ but as most HPV cancers in men are attributed to types included in current vaccines,¹ tiered pricing structures for new generation vaccines based on differential incremental benefits (and thus differential cost effectiveness thresholds) in girls versus boys could be considered.

All these policy decisions must consider burden of disease, safety, effectiveness, acceptability, equity, and cost effectiveness. Although the focus in developed countries has now, appropriately, shifted to considering these issues for boys, men who have sex with men, and older women, broader efforts to prevent cervical cancer should remain the priority in low and middle income countries. Of the 610 000 cancers annually attributable to HPV worldwide, 87% are cancers of the cervix, and three quarters of these occur in countries with a low or medium human development index.¹¹ Even if a substantial majority of young girls in such countries were vaccinated, hundreds of millions of older women would remain at risk—vaccination alone will not prevent an expected increase in cervical cancers in the next few decades, driven by population ageing. Here, the priority focus should be the development of integrated programmes for vaccinating young girls and screening older women. Based on experience in developed countries, this will also provide benefits for men through indirect vaccine protection.

Cite this as: *BMJ* 2015;350:h2244

RESEARCH, p 13



A question of cost effectiveness

thebmj.com

► Views & Reviews: We are both doctors: an Israeli doctor writes to a Palestinian colleague (*BMJ* 2014;349:g5023)

► Analysis: Perils of criticising Israel (*BMJ* 2009;338:a2066)

There is the similarity between this complaint's attempt to stifle coverage of the conflict in Gaza and previous examples of campaigns provoked by articles critical of Israeli policies

Politics, medical journals, the medical profession and the Israel lobby

Criticism of the Israeli government does not necessarily equate with antisemitism

John S Yudkin emeritus professor of medicine, University College London, London, UK jjyudkin@clara.co.uk

Jennifer Leaning director, François-Xavier Bagnoud Center for Health and Human Rights, Harvard TH Chan School of Public Health, Boston, USA

In April, Reed Elsevier, publishers of the *Lancet*, received a complaint written by Professor Mark Pepys and signed by 396 physicians and scientists, including five Nobel Laureates.¹ They protested that the *Lancet* was being used for political purposes and for “publication of deliberately false material which deepens polarization between Israelis and Palestinians.”

The most recent example of what was termed this “political vendetta” was the July publication, during the latest Israeli assault on Gaza, of an “Open letter for the people in Gaza.”² They wrote that the letter “contains false assertions and unverifiable dishonest ‘facts,’ many of them libellous,” and that its authors had failed to declare conflicts of interest. The complaint insisted that the July letter be retracted (disagreeing with the *Lancet* ombudsman’s decision³) and that it contravened the code of the Committee on Publication Ethics. It asked for the support of all scientists and clinicians “on whom they [Reed Elsevier] depend for their business,” adding “none of us is under any obligation to submit and review material for publication in their journals or to serve on their editorial or advisory boards.”

An email chain soliciting support for this complaint was more explicit.⁵ In it Pepys accused the July letter of “viciously attacking Israel with blood libels echoing those used for a thousand years to create anti-Semitic pogroms” and being “written by dedicated Jew haters.” He suggested that “anybody who was not a committed anti-Semite would firstly not have published Manduca [lead author of the July letter] and secondly would have retracted instantly when her long track record of blatant anti-Semitism were [sic] exposed.” Two days before the complaint, the title of the email chain was modified to read “DO NOT CITE The Lancet in your work—Their content includes fraudulent data.”⁶

The July letter included a UN estimate of the number of Gazan children killed up to that date during the Israeli bombardment,⁷ which the Pepys email implied was exaggerated. The UN Office for the Coordination of Humanitarian Affairs (OCHA)



MOHAMMED TALATENE

Facts on the ground

has estimated the cumulative number of Palestinian children killed during the conflict as 551⁸; the estimate of Defence for Children International Palestine is 547, around two thirds of whom were aged 12 years or younger.⁹ A report cited by the *Telegraph* recorded that 137 children were killed during 15–22 July 2014, including 59 on 20 July, two days before the letter was published.¹⁰ Reports on the conflict from OCHA,⁷ Physicians for Human Rights—Israel,¹¹ B’Tselem,¹² and Amnesty International¹³ all concur that the July letter’s allegations of disproportionality in civilian deaths and injuries and of targeting residential areas, schools, power and water treatment plants, and medical facilities and staff were probably not overstated. None of these organisations imputes a motive regarding these findings. Certainly the outcomes raise issues of adherence to principles of international law and norms of humanity.

Medicine cannot avoid politics

These events raise two issues. The first is the appropriateness of medical journals discussing political issues that have bearing on health, including civilian mortality and morbidity. The Gaza letter in the *Lancet* provoked a statement from senior editors and presidents of diabetes and endocrinology associations saying that their “journals will refrain from publishing articles addressing political issues that are outside of either research funding or health care delivery.”¹⁴ In response, an editorial in the *European Journal of Public Health* referred to the upstream determinants of patterns of nutrition and physi-

cal activity that are driving the diabetes epidemic, quoting Virchow, who taught that “Medicine is a social science and politics is nothing else but medicine on a large scale.”¹⁵ The *Lancet*’s editor, Richard Horton, has transformed it into the leading journal in global health, with politics being intrinsic to many issues that the journal covers. If medical journals are fearful of entering the debate where medicine, politics, and ethics intersect, it is hardly surprising that professional associations are even more reluctant to do so.¹⁶ Yet to avoid such debate is to remain obdurately silent in the face of important trends and events that impact negatively on the wellbeing of individuals and groups. Inevitably, controversy will ensue, but this is a healthy aspect of public discourse on political matters.

The second issue is the similarity between this complaint’s attempt to stifle coverage of the conflict in Gaza and previous examples of campaigns provoked by articles in medical journals critical of Israeli policies, including allegations of hyperbole, accusations of antisemitism, and threats of boycott.^{17–18} Criticism of Israel, or more specifically of Israeli government policy, is not ipso facto antisemitic, and to label it as such is a tactic to stifle debate. It is possible to be a non-Jew or Jew (or in the case of one of the authors, *Jewish*¹⁹) and to oppose Israeli actions or policies without being antisemitic. One former editor subjected to such a campaign believes that “the best way to blunt the effectiveness of this type of bullying is to expose it to public scrutiny.”¹⁸ This is the purpose of this editorial.

The reports published by the UN and others point to the need for an independent investigation into the conflict by international teams to determine whether and by whom—from either side of the conflict—violations of international human rights and humanitarian law were committed. The effect of this war on civilian mental health, morale, and assets is magnified by the cumulative burden of still destroyed houses and livelihoods dating from previous conflicts. As a deputy editor of *The BMJ* has pointed out, “Future generations will judge the journal harshly if we avert our gaze from the medical consequences of what is happening to the occupants of the Palestinian territories and to the Israelis next door.”²⁰

Cite this as: *BMJ* 2015;350:h2377