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## How a minimum unit price for alcohol was scuppered

Remember Disraeli: “the first consideration of a minister should be the health of the people”

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Taking advice on health policy from those with direct commercial interests has not been successful in the past, most notably in the case of tobacco. We should not be surprised, therefore, to read that evidence based alcohol policy in the United Kingdom has been systematically subverted by those who supply or sell the product. Of particular importance is the sudden decision not to pursue a minimum unit price for alcohol in England, despite personal commitments from the prime minister. But even weathered public health campaigners will be dismayed to read about the politics behind that change.<sup>1</sup>

After consulting on the strategy, the Home Office minister Jeremy Browne announced to parliament that he lacked “concrete evidence” that responsible drinkers on low incomes would not be greatly disadvantaged by minimum unit pricing. However, as Jonathan Gornall reveals, the government commissioned and received that evidence, but it was embargoed until after the announcement. Also, a review of how that consultation was conducted raises important questions about its integrity.<sup>2</sup> This, and evidence presented by Gornall, provides a strong case for the health select committee, which recommended minimum unit pricing in 2010,<sup>3</sup> to review the government processes that led to the policy being deferred, if not dropped completely.

Minimum unit price is just one, albeit particularly important, plank of an evidence based strategy. The top 10 recommendations for a model strategy were recently published by the University of Stirling and the Alcohol Health Alliance in *Health First*.<sup>4</sup>

The problem for the NHS, as hospitals face the tide of alcohol induced illnesses, is that none of the other nine recommendations features highly in the government strategy either. Instead, the strategy relies on largely discredited voluntary partnerships with industry, such as the “responsibility deal.” Those public health organisations

that had not already left this scheme did so after the decision not to proceed with minimum unit pricing. The whole saga must be an embarrassment to the prime minister, particularly given his adviser Lynton Crosby’s links to the drinks and tobacco industries.

Not all *Health First* recommendations are easy for governments to implement, although a ban on alcohol companies sponsoring sports and music events already exists in France and is planned in Ireland. However, it is hard to see why lifesaving recommendations, such as lowering the drink driving limit from 80 to 50 mg alcohol per 100 mL, have not been adopted. The UK stands alone with Malta within Europe in retaining this limit, in spite of the North report.<sup>5</sup> And would any reasonable person support the current situation of cinema advertisements for alcoholic products being shown at films rated as suitable for unaccompanied 12 year olds?

A recent study showed that 10-15 year olds saw more alcohol advertising on television than adults.<sup>6</sup> Children are heavily exposed to alcohol promotion through advertising, sponsorship, and social media. Marketing documents show that the alcohol industry targets young people, including through the development and promotion of sugary, alcoholic confections.<sup>7</sup> Whatever the public’s stance on personal choice and freedom, it

would not support any government that can be manipulated to condone such practices.

### Industry access and spin

Although the UK lags behind some other countries, it is not alone in failing to protect the young and vulnerable from a powerful industry. Gornall highlights some of the reasons: the remarkable access of the industry to policy makers; the industry’s ability to spin the problem as being the fault of a few users rather than an inherently risky psychoactive substance with a propensity to induce dependence; its promotion of voluntary alternatives to regulation; and its use of non-peer reviewed “junk science” to counter the evidence.

The Home Office minister Jeremy Browne also signalled a particular mindset when he told parliament “we do not yet have concrete evidence”—in

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other words, the onus is on those in public health to prove their case beyond reasonable doubt. But the policy passes even that harshest test—recent evidence from a Canadian province (scientific research available to ministers at the time of the policy shift) showed that minimum pricing led to a rapid and highly significant reduction in harm.<sup>8</sup>

There are clear parallels with tobacco companies, which still resist public health action through lobbying, public relations, commissioned reports, voluntary agreements, and extreme demands for proof of impact for new measures such as standardised packaging. That is hardly surprising, given the close links between the two industries.<sup>9 10</sup>

The pace of action on alcohol in Britain and globally has lagged behind that on tobacco. An alcohol equivalent to the UN Framework Convention for Tobacco Control would be an important step in encouraging governments to implement evidence based measures for alcohol.

The government has, to its credit, done a double U-turn on tobacco standardised packaging—first backing it, then conceding to industry pressures, but now likely to implement it. It is testament to the influence of the alcohol lobby that it achieved a U-turn from the prime minister, who had personally backed the policy. A double U-turn would be welcome recognition that public health and safety must outweigh the interests of such a powerful industry.

Public health organisations must hope that the *BMJ*’s further exposure of the alcohol industry’s lobbying and public relations activities will encourage politicians to take the evidence based action that can bring so much benefit to the community. “After all,” as the prime minister’s predecessor Benjamin Disraeli famously said, “the first consideration of a minister should be the health of the people.”

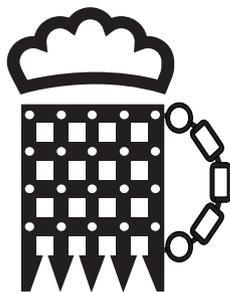
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FEATURE, p 18



**If each company defines its own terms and conditions for access to its data, the metaphor for the end state of “data transparency” could easily be a maze**

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- ▶ Views & Reviews: Evidence based medicine is broken (*BMJ* 2014;348:g22)
- ▶ News: MPs call for full results of all past clinical trials to be made public (*BMJ* 2014;348:g13)
- ▶ News: EU nations approve law to overhaul clinical trials (*BMJ* 2013;347:f7682)

## Clinical trial data: get them while you can

The window into the European Medicines Agency’s archives may not be open for long

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Third party access to clinical trial data seems an obvious and uncontroversial core requirement for the production and dissemination of trustworthy medical evidence. For the past four years, the *BMJ* has actively campaigned to compel greater transparency of clinical trial data. Anybody following this matter will know that movement is occurring at many levels and involves a large number of actors including industry, politicians, regulators, academia, and medical journals. The debate encompasses which data should be shared and with whom, when, and under what conditions. However, even the keenest observers will probably be uncertain about just what has happened, is happening, and where things will eventually land.

One development to watch out for in 2014 will be the progress of the European Union’s proposals on clinical trial regulation.<sup>1 2</sup> Other developments include the European Medicines Agency’s (EMA) future policy on publication and access to the clinical trial data that underpin marketing authorisation decisions,<sup>3</sup> and the US Institute of Medicine’s (IOM) consensus study on responsible sharing of clinical trial data.

The IOM is expected to release an interim report in January 2014, followed by public consultation and a final report in about a year’s time.<sup>4</sup> If the committee endorses onerous restrictions on access to clinical trial data, this could have a chilling effect on transparency efforts worldwide. One concern is the project’s funding: several large drug companies are listed among its financial supporters, including AbbVie, one of the major orchestrators of industry resistance to data transparency.

The EU’s proposals for clinical trials regulation were agreed on by representatives from every member state last month and await ratification. If enacted, the regulation will mandate prospective registration of all trials carried out in the EU. It will also compel trial sponsors to post

summary results on the EU Clinical Trials Register within one year of the trial’s completion, thus bringing Europe into line with US transparency legislation.<sup>5</sup> The regulation will go a step further, however, by putting companies’ full clinical study reports in the public domain. (Clinical study reports are documents produced by study sponsors primarily for drug regulators. They run to many hundreds or thousands of pages, comprising substantially more information about a trial than journal articles and providing relatively unbiased material for evidence synthesis.<sup>6</sup>)

In 2013, much attention focused on the initiatives of big drug companies, most notably GlaxoSmithKline’s new policy on access to anonymised patient level data from some of its trials. In GlaxoSmithKline’s footsteps, Roche and Pfizer have set out similar policies. GlaxoSmithKline, Roche, Boehringer Ingelheim, Sanofi, and ViiV Healthcare will mediate access to data through a web portal ([www.ClinicalStudyDataRequest.com](http://www.ClinicalStudyDataRequest.com)).

Although these announcements may be steps in the right direction, the processes are new and largely untested, and how they will work remains to be seen. Of concern is that each company’s policy includes conditions that seem contrary to the spirit of openness.

For example, GlaxoSmithKline, Roche, and Pfizer all largely exclude trials that tested off-label use of their drugs. With about a fifth of prescription drug use being off-label in the United

States,<sup>7</sup> what legitimate reason is there to treat these data as secret?

Furthermore, can initiatives by individual drug companies represent anything more than incremental progress? We must remember that drug companies have always entertained individual requests for data in their holdings. What is new is simply the heightened public attention and procedures to streamline access to those data. However, initiatives by individual companies will only ever cover trials sponsored by that particular company. If each company defines its own terms and conditions for access to its data, the metaphor for the end state of “data

transparency” could easily be a maze. Current industry-wide proposals are not comprehensive (they exclude all previous trials and future trials of off-label prescribing) and, lacking compliance mechanisms, are essentially aspirational.<sup>8</sup>

### It could all be so much better

Only medicines regulators hold vast archives of trial data across manufacturers. Therefore, positive transformation of the rules that govern third party access to data in regulators’ holding could create a sweeping change in the landscape of open data. When the EMA launched its policy on access to documents on request in November 2010, it opened a window into the regulatory decision making process that had never been opened before. Since then, the EMA has provided third parties, including industry—with no terms or conditions and free of charge—around two million pages of clinical trial data and other administrative documents.<sup>9</sup>

Then, in mid-2013, as a result of two well known legal cases, semi-paralysis set in at the EMA, after an EU judge prevented the EMA from releasing clinical trial data requested for drugs marketed by AbbVie and InterMune. As a result, the EMA soon began denying requests for types of trial data it had previously released.<sup>9</sup>

Now the access to data window is possibly wide open again—or at least as open as it could be—after the superior EU Court of Justice struck down the lower court’s injunction late last November.<sup>10 11</sup>

So get your data while you can. The AbbVie and InterMune lawsuits against EMA remain active, and if they are not withdrawn before the final decision, a victory in favour of the companies may effectively terminate the EMA’s current and planned future policy on access to clinical trial data. We hope that this window will stay open, but if it closes, this may be the last chance to take advantage of a truly unencumbered process for public access to data.

Requests for data may be submitted via the EMA’s website.<sup>12</sup>

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● LETTERS, p 25



Opportunity knocks

## Hospitals that are good at reducing readmissions for one diagnosis are good at reducing readmissions for all diagnoses

# Readmission rates

Edging slowly towards a deeper understanding and ultimately better care for patients

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The US Centers for Medicare and Medicaid Services initiated public reporting of 30 day readmission rates for patients with acute myocardial infarction, pneumonia, and heart failure in 2009,<sup>1</sup> and financial penalties began to be imposed on underperforming hospitals in 2012. Since then hospitals and health services researchers have been searching for ways to reduce hospital readmissions while trying to understand the causes and importance of readmissions. The ultimate objective is to improve care, but the path to that goal is not clear. Two linked studies help point us in the right direction.<sup>2 3</sup>

The literature on readmission rates has three general themes. The first consists of challenges to the suitability of readmission rates as quality measures,<sup>4</sup> including their potential to decrease access to care,<sup>5</sup> and a vexing concern regarding a possible inverse correlation between 30 day readmission for heart failure and mortality rates.<sup>6 7</sup> The second includes studies of various interventions to reduce readmission rates,<sup>8</sup> such as risk prediction tools.<sup>9</sup> Studies of these efforts report mixed results, and comprehensive programmes seem to be more effective than focused interventions.<sup>8 10</sup> The two linked studies contribute to the third theme—investigations into the drivers of readmissions.

Dharmarajan and colleagues analysed the inpatient claims of all US beneficiaries of Medicare readmitted within 30 days of an index hospital admission for heart failure, myocardial infarction, or pneumonia during 2007 to 2009. They found that high performing hospitals (those with lowest readmission rates) had fewer readmissions across all three diagnoses.

Donzé and colleagues analysed data from 10 731 patients discharged from a single US hospital during 2009 to 2010, 2398 of whom were readmitted within 30 days to one of four hospitals within the same network. They determined that five of the most common primary readmission diagnoses were related to one of seven comorbidities. Furthermore, in patients readmitted with a diagnosis related to a comorbidity, most had a different primary diagnosis at the time of their index admission. In other words,

the patient's comorbidities are as likely to be the cause of readmission as the principal diagnosis at the time of the first admission.

What lessons can we learn from the observations in these two studies? The first confirms the findings of others: patients are readmitted and not diagnoses.<sup>11</sup> Interventions to reduce readmissions that focus solely on the principal diagnosis at the time of the index admission are unlikely to achieve optimal results.

The second lesson is similar and is equally intuitive: hospitals that are good at reducing readmissions for one diagnosis are good at reducing readmissions for all diagnoses. There is apparently something in the way these institutions provide care that is not disease specific and that results in favourable outcomes across conditions. This finding is reminiscent of a qualitative study by Curry and colleagues,<sup>12</sup> which found that hospitals with low 30 day mortality rates after myocardial infarction were differentiated from poorly performing hospitals by an organisational culture that supported efforts to improve care across the hospital and not by specific interventions. It is therefore possible that excellent performance on 30 day readmission rates could also be driven by organisational characteristics.

### What do high performing hospitals do?

Through these efforts a clearer picture is beginning to emerge of underlying causes of high readmission rates and the approaches to improving not only this metric but also measures such as mortality and quality of life that give a more holistic view of care. Nevertheless, further research is needed in several other areas. Firstly, we need an in-depth understanding of the specific interventions that high performing hospitals use to reduce readmissions and insights into organisational characteristics that may be the true drivers of success. Secondly, the causes of readmission—including the contributions of inadequate treatment, poor systems for handling over care between incoming and outgoing staff, socioeconomic factors, and progression of disease—need to be understood more fully.



Until we meet again

Thirdly, we also need a better understanding of the impact that various “actors”—including hospital physicians, outpatient providers, hospitals, payers, and the patients themselves—exert on readmissions. In addition, studies should determine the true value of the various risk prediction tools for reducing readmissions in a broad array of hospitals. What are the crucial elements in these tools, and how can we implement them more effectively?

Finally, the use of readmission rates as accountability measures

for large numbers of hospitals raises further questions that deserve prompt attention. Are hospitals gaming the system by artificial manoeuvres, such as placing patients in “observation status” to make the numbers look better? And the most fundamental question of all: what is the balance of benefits and harms associated with using readmission rates in incentive programmes for providers? The proposed benefits of transparency may have unintended consequences, such as distracting providers from other quality improvement efforts and decreasing access to care for the sickest patients. The possible inverse relation between 30 day readmission and mortality rates for patients with heart failure has yet to be tested in the setting of the strong financial incentives now placed on all US hospitals.

Despite intense interest among health services researchers, our understanding of the causes of readmissions, effective interventions to avoid them, and the full impact of using readmission rates as measures in a hospital incentive programme remains rudimentary. We need additional insights of the type provided by Dharmarajan and colleagues and Donzé and colleagues to provide the right answers for our patients.

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RESEARCH, pp 11, 12



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## New and unproved medical devices

Choices supported by limited data have clinical, ethical, and legal implications

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There is a well established nomenclature for describing the uptake of new technologies.<sup>1</sup> “Innovators” adopt a novel approach the fastest; they are often mavericks and have personalities that feature a high tolerance for risk. “Early adopters” are the next to take up the new technology. Their behaviour, which is only slightly more circumspect, has been described as self conscious experimentation.<sup>2</sup> Together, these professionals are one standard deviation greater than average in terms of speed of adoption than their peers and make up about 16% of the relevant population.<sup>2</sup>

In a linked paper, Kynaston-Pearson and colleagues show that innovation research would have accurately predicted the proportion of orthopaedic surgeons in England and Wales at the vanguard of using new technology.<sup>3</sup> The authors examined the National Joint Registry of England and Wales to identify the range of prostheses used in total hip arthroplasty in 2011, and they found that about half of the 261 brands in the database had been on the market for fewer than three years. After conducting a systematic review of the literature, they found that about half of these recently introduced brands had no published evidence of clinical effectiveness. These 57 brands accounted for nearly 8% of all hip implants put in place during that time in England and Wales.

### Flying blind

Not all studies of new medical products are published, but the real problem is that there is little chance in this case that the evaluations have been done. The characteristics of medical device regulation encourage surgeons to use unproved and inherently risky new technology in total hip arthroplasty. The United Kingdom and other European nations do not require promising new medical devices to show benefits in controlled testing before routine use. Instead, new devices are studied in small numbers of patients to see whether they appear to be safe and perform as expected. The difference is crucial. A left atrial appendage exclusion device, for example, can be approved in

the European Union after showing that it can be deployed in the heart as intended. By contrast, in the United States, the Food and Drug Administration has the authority to ensure that new high risk devices are first tested for effectiveness and safety.<sup>4</sup> As a result, the left atrial appendage device might be approved only if it reduces risk of stroke—the main reason for its use in the first place.

However, the FDA's authority to demand rigorous evidence before new medical devices can be used in American patients applies only to the small fraction of products classified as conferring high risk. Moderate risk devices, such as prostheses used in hip reconstruction, can be cleared through the 510(k) programme, in which manufacturers show that the new product has “substantial equivalence” to a device already on the market. Formal effectiveness trials are rarely done. Manufacturers in the US have used the 510(k) pathway to make strings of iterative changes to existing devices, with each new product deemed “substantially equivalent” to a predecessor, such that hip implants available in 2012 were approved through linkage back to implants produced nearly three decades before.<sup>5</sup>

Even if only a small fraction of physicians choose to use the most recently approved medical devices, the public health implications can be great if these devices confer incremental risk without clear incremental benefit. Kynaston-Pearson and colleagues found that the earliest adopting orthopaedic surgeons carried out more than 10 000 hip implantations in 2011. These results undermine claims that patients outside the US are denied early access to such devices because centralised funders cover only well studied interventions.<sup>6</sup> Lack of centralised oversight of reimbursement for new medical devices in the US can lead even more physicians to adopt new products with an insufficient evidence base. For example, nearly two thirds of implantable cardioverter defibrillators used in the US are the most current model made by the manufacturer.<sup>7</sup> Although being an early adopter can be positive when the product is transformative and evidence based, many of these models have not been studied in clinical trials.<sup>8</sup>

The fact that some physicians are drawn to use untested new technologies instead of better studied existing products, even in the absence of

convincing evidence of clinical advantage, raises important ethical questions relevant for reform of medical device regulation, currently under way on both sides of the Atlantic. Legislators in the EU and US continue to give regulators greater leeway to approve new treatments on the basis of limited data. For example, the European Parliament has supported draft regulations to strengthen oversight of Notified Bodies, the private entities that certify medical devices, but not replace them with a centralised Europe-wide regulatory agency or require rigorous evidence of effectiveness for new high risk devices. As Kynaston-Pearson and colleagues suggest, new products could be phased in, starting with centres with the capacity to engage in ongoing clinical trials of the products. In the US, the government can approve “coverage with evidence development” for new products with the requirement that their safety and effectiveness be studied once they are in use.<sup>9</sup>

The ability of manufacturers to promote devices or drugs that are authorised by regulators for widespread use but that do not have rigorous preapproval data should also be restricted. The medical products industry often targets early adopting physicians with substantial promotional resources,<sup>10</sup> and some physicians receive royalties in relation to devices that they implant or have shares in the companies involved.<sup>11</sup> In a recent case in Oregon, the US Department of Justice successfully sued two interventional cardiologists who had not informed patients that they received “training” payments from the manufacturer for each device they implanted. These payment were alleged to lead the cardiologists to select the manufacturer's device over other alternatives.<sup>12</sup> In place of widespread industry led promotion, physicians who adopt new technologies that have little or no evidence of superiority over existing products need to be educated about the implications of their choices. They should also ensure that their patients know about the benefits and risks of the new—but often unproved—medical devices that they are receiving.

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