LETTERS

GUTHRIE CARDS IN REPUBLIC OF IRELAND

Irish public want Guthrie card archive kept rather than destroyed

The Republic of Ireland initiated the national neonatal blood card screening programme in 1966. In 2012 the Department of Health and Children (DOHC) announced its decision to destroy much of the archive from before 2010 (1 million cards), fearful of non-compliance with data protection legislation. After lobbying by interested parties, this destruction was deferred in March 2013. The DOHC sought justification for retaining the archive in relation to existing or potential clinical and research uses and asked for proposals for governance of the archive.

With research ethics committee approval, we recruited 145 parents attending our paediatric (103) and neonatal (42) services to complete an eight item questionnaire (table).

Most parents were unaware that their child’s card was stored and most felt adequately informed on the proposed archival destruction. Most accepted use in anonymised research and would accept sharing data with the police, in certain circumstances. Importantly most thought that, rather than destroy the archive, the DOHC should legislate to protect it and regulate its future use. The preference for an “opt-out” rather than “opt-in” approach is also notable, considering controversy about adoption of European Union legislation on donation.

This study could be rolled out to a wider population of parents and other adults. However, the message is clear: the Irish public feels ill informed and would prefer the government to legislate to protect this national resource rather than destroy most of it. The Irish government has recently enacted legislation on the much more contentious matter of abortion. We have shown that the public would prefer the government to do the same in relation to neonatal blood cards rather than destroy them.

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Competing interests: JO’BH is a member of the Royal College of Physicians of Ireland (RCP) working group on retention of newborn blood cards. EMD is a board member of the faculty of paediatrics in RCP. The views expressed here are their own and do not reflect RCP’s position on this matter. (JA and PM) have no conflicts of interest.


Results of our questionnaire on the proposed destruction of the national neonatal blood card screening archive (N=145)

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes (%)</th>
<th>No (%)</th>
<th>Other (%)</th>
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<tbody>
<tr>
<td>Were you aware that your child’s blood card was stored?</td>
<td>57 (40)</td>
<td>87 (60)</td>
<td></td>
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<tr>
<td>Do you feel the government has provided you with enough information about its decision to destroy your child’s blood card?</td>
<td>12 (8)</td>
<td>131 (92)</td>
<td></td>
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<tr>
<td>Would you consent to this card continuing to be stored into the future?</td>
<td>136 (94)</td>
<td>8 (6)</td>
<td></td>
</tr>
<tr>
<td>How long should your child’s blood card be stored for?</td>
<td>1 year 7 (5); 10 years 35 (25); 100 years 19 (14); indefinitely 79 (56)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Would you consent to this blood card being used anonymously for research purposes?</td>
<td>108 (75)</td>
<td>36 (25)</td>
<td></td>
</tr>
<tr>
<td>The stored samples are not covered by the data protection acts.</td>
<td>Destroy 20 (14); legislature 124 (86)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Would you prefer that the government destroyed your child’s blood card or amended current legislation so that all their data were adequately protected?</td>
<td>Opt in 57 (40); opt out 88 (60)</td>
<td></td>
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<td>If given the choice, would you favour an opt-in system (where you must specifically request that your child’s blood card is stored for future use) or an opt-out system (where your child’s blood card is stored unless you specifically request that it is destroyed)?</td>
<td>Yes 79 (55); yes (with a court order) 44 (31); no (never) 21 (15)</td>
<td></td>
<td></td>
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</tbody>
</table>

4 Levit M. The ethics and impact on behaviour of knowledge about one’s own genome. BMJ 1999;319:1283. (13 November.)
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UNIVERSAL HEALTH CHECKS

Universal health checks should be abandoned

Last autumn, a Cochrane review (also in the BMJ) on general health checks in adults found no benefit for morbidity and mortality from disease. 1 NHS Diabetes and Kidney Care and the Department of Health published an eBulletin, “Response to the Cochrane review,” on the NHS Health Check programme’s website. It looks like serious criticism of our work, but it is unfounded and misleading.

We sent a response to the eBulletin to the national director of NHS Diabetes and Kidney Care and asked for it to be published on the website, but this was declined. The NHS letter stated that government had already decided that “NHS Health Checks will be carried out as a national priority,” that the website is not a forum for debating the merits of such checks, and that “there are other more appropriate places to discuss government policy.” Why then did the programme publish its criticism on its website and not in a scientific journal?

It is interesting to contrast the reactions to our review in the UK and Denmark. In the UK, the programme was defended rigorously. In Denmark, the implementation of systematic health checks was high on our new government’s agenda. However, the Danish minister of health stated: “The analysis from the Nordic Cochrane Centre does not come as a surprise” and decided to put such checks “on ice.”

Screening programmes for healthy people are justifiable only when randomised trials clearly show that benefits outweigh harms. 4 For health checks, the trials seem to show the opposite. 5

An administration’s automatic defence of an existing screening programme can be viewed as a self interested response, given the investment of public funds and prestige, and it threatens the very idea of evidence based public healthcare, particularly when it means refusing open scientific debate.
Making dilemma of universal health checks clear to patients

Our practice is paid to provide health checks, which are both popular and appreciated.1 If the Cochrane review’s conclusions are correct,2 these checks do not benefit our patients. I see four options: (1) continue; (2) continue but report myself to the General Medical Council for promoting an intervention from which I profit irrespective of its validity; (3) stop; (4) for promoting an intervention from which I profit irrespective of its validity.

Our practice is paid to provide health checks, which are both popular and appreciated. Our practice is paid to provide health checks, which are both popular and appreciated.

Patients are being offered an NHS health check in the hope that it will help them live a longer and healthier life.

To many people it seems common sense that health checks lead to better outcomes, but the best evidence available (Cochrane systematic review) suggests that health checks don’t reduce illness or early death.

We know that some people have conditions detected at a health check that will not progress to illness or death if not treated, but we can’t tell who those people are. Once a condition is detected it is difficult not to treat it. Treatment may do more harm than no treatment.

People who choose a health check are often already interested in their health so the check tells them nothing new. Those who are less able to take the same interest, and who may be less healthy, are less likely to come for a check.

Some people might think it’s OK to continue risky behaviour like smoking once they learn that their cholesterol level, for example, is alright.

We feel it’s important that you know that a health check may not be good for you before you decide to have one.

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Full response at: www.bmj.com/content/347/bmj.f4788/rr/658021.


5 Minister: Vi har lagt helbredstjek på is. Ugeskrift For Læger 2012.


7 Minister: Vi har lagt helbredstjek på is. Ugeskrift For Læger 2012.

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UNIVERSAL HEPATITIS B VACCINATION

The aim is vaccine uptake

Including vaccines in the routine immunisation programmes of countries has become a kind of fetish with the World Health Organization—disconnected from its purpose of reducing disease. Who has recommended hepatitis B vaccination for all countries—at least three doses of the vaccine to be given to each person at birth, in infancy, or during adolescence. Vaccinating adolescents does not prevent the chronic hepatitis B infections in children that result from vertical transmission from mother to child or from horizontal transmission from child to child. WHO seems to be appeased so long as three doses of the vaccine are given to everyone.

The UK, 7700 new cases of chronic hepatitis B infection are detected each year. Only 300 of these infections are acquired in the UK, the remaining 7400 being identified in people entering the country from elsewhere.1 Vaccinating 700 000 newborn infants at a cost of £21 million each year will, at best, prevent 300 cases of chronic hepatitis.

The UK government has so far adopted a targeted approach in preventing these 300 cases. Testing mothers and vaccinating babies of carriers is particularly effective because, otherwise, infected newborn babies have a 90% chance of becoming chronic carriers. Vaccinating other high risk groups is less effective, but they also have a much lower chance of becoming chronic carriers after being infected.

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Unlike universal vaccination, this targeted approach will not help consume 2.1 million doses of the vaccine in the UK each year. This may be the problem: vaccine uptake rather than disease mitigation is the aim. It will be interesting to see how long the UK government’s evidence based, logical approach survives the demand to mindlessly conform with WHO guidelines.

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Competing interests: None declared.

A 24/7 service needs many more doctors

Written in the vacuum of the ethics dimension, this paper reminds me of the phrase, “it’s the economy stupid.” We used these arguments in the BMA negotiating committee, with Barbara Castle and David Owen.

In the 1970s I worked a one in two rota, all night on call. Doves of juniors were resident, however, as were experienced senior registrars. Patients stayed longer, and a wise junior could anticipate problems and have a call-free night. Now, fewer, less experienced juniors have many more patients and an eight day run of 13 hour night shifts, with the consultant at home. It is not hours, but intensity, that causes fatigue.

The second world war generation knew a lot about fatigue. Sir Archibald MacKintosh and others realised that senior house officers in the anaesthetics department were up all night, so they were given the next day off. Despite this, graduates of those departments had a good career progression.

In Sweden in the 1970s, overtime beyond 40 hours was heavily regulated, without compromising training. However, as with other European countries, more doctors were needed per head of the population.

The need to meet budgets means that fewer juniors are on call, resulting in fatigue and alleged unnecessary deaths in “failing trusts.” Politics and the media blame consultants and GPs who are apparently work shy and absent at nights and weekends. Despite evidence from many sources that consultants worked 55–60 hours a week, Milburn and successors forced through a 40 hour contract and additional pay for the extra eight hours allowed by the European Working Time Directive. The new
EWTD may contribute to fatigue

Sokol highlights the serious problems caused by exhaustion in doctors and indicates that one of the reasons why medical staff are overworked is non-compliance with the European Working Time Directive (EWTD).¹ The two issues are inextricably linked, but compliance with the EWTD may also contribute to fatigue.

Redesigning rotas to comply with the EWTD means fewer staff in hospital at any one time, which leads to remaining staff being overstretched. Furthermore, while the total hours in hospital for each doctor have been reduced, the amount of work that needs to be done remains the same, increasing working intensity. Shift rotas adopted to comply with the EWTD are more tiring than an on-call system.² Until action is taken to moderate the impact of the EWTD, the regulations will continue to compound the problem of fatigue.

Surgeons’ concerns about the reduction in operative training time as a result of the EWTD are well publicised.
³ Sokol’s article briefly lambasts the surgical community, implying that surgeons are out of touch with the rest of the medical workforce, senior surgeons in particular failing to understand the challenges presented by modern medicine. Precisely the opposite is true. Senior surgeons best see the disastrous impact of the EWTD on the quality of surgical training, and their concern for patients in the future causes them to “pull faces of disgust.”

British people have every right to be concerned about whether their surgeon is fatigued, but they should be equally concerned about whether their surgeon has had the best training possible. A balance must be struck between the two issues.

Christopher J A Cowie

Author's reply

Messian, his co-authors, and I agree on one thing: opinion is not science [see Response on facing page]. However, Messian and colleagues misled BMJ readers by suggesting that I used polls to prove whether a treatment is good or not. On the contrary, I cited the polls because the guideline sponsors need to explain why they failed to include even one sceptic on the guideline writing panel when it seems that most emergency doctors, including prominent and respected experts, do not believe the science supports the guidelines. Science is supposed to be a rigorous process that includes attempts to disprove the theory in question. For that reason, I cited a recent unpublished poll of 548 emergency doctors in which only 16% said they support the new guidelines; I included older published polls that show the new poll wasn’t a fluke. When there is this level of scientific debate, guideline panels should include sceptics.

Readers may like to know that Messian, Smith, and Gronseth served on the alteplase for acute stroke guideline panel and each has acknowledged ties to the manufacturers or distributors of alteplase during the guidelines writing process. The fourth signatory is an administrator for one of the sponsoring organisations, which has received generous funding from the manufacturers.

I have to wonder if Messian and colleagues actually read my article, because their letter evades the central point: too often, industry influence has led to the preferential selection of panelists who have published or expressed industry-friendly views. Messian and colleagues not only fail to respond to that crucial point, but they cite the endorsement of alteplase by multiple guideline panels—most comprising panelists with ties to the manufacturer—as proof that it must be safe and effective. Using this line of reasoning, those of us concerned about climate change should stop worrying, because among white papers put out by panels supported by the oil industry, there is agreement that global warming is a myth.

If Messian and colleagues want a real examination of the science behind alteplase for stroke, they should have included expert sceptics on the guideline panel instead of criticising and attempting to debate the science with the journalist who reported the problem. For readers who want to learn about analyses of alteplase for stroke that are completely independent of industry and its researchers, I refer them to the citations that follow.

Jeanne Lenzer


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American Academy of Neurology replies to Jeanne Lenzer

The recent *BMJ* article on viewing clinical guidelines with scepticism focused mainly on the recent American Academy of Neurology (AAN) and American College of Emergency Physicians (ACEP) guideline advocating use of tissue plasminogen activator (tPA; alteplase) in select patients within 4.5 hours of onset of ischaemic stroke.1

The author published a similar article in the *BMJ* in 2002 focusing on conflicts of interests among the investigators and potential methodological flaws in the original National Institutes of Neurologic Diseases and Stroke (NINDS) stroke study.2 This premise was subsequently debunked when an independent author panel reviewed the data and arrived at the same conclusions.3 Ensuing randomised trials have also supported the original findings. Since then, professional organisations including the American Heart Association/ American Stroke Association, the American Academy of Emergency Medicine, and the Society for Academic Emergency Medicine have published guidelines supporting alteplase in stroke. The Joint Commission for Accreditation of Hospital Organizations has made alteplase use a quality metric and has developed primary and comprehensive stroke center certification to encourage its use. These endeavours have probably contributed to the improving outcomes for stroke patients in the US.4

We would like to rectify the following errors or omissions in this most recent article by the author:

- The article incorrectly states that the International Stroke Treatment-3 (IST-3) study was not mentioned in the AAN/ACEP guideline. This study was published as the guideline was in the final stages of approval. After reviewing the new study and concluding that it did not affect the recommendations, it was decided to publish an addendum along with the guideline. The addendum noted that “IST-3 was designed to evaluate the effects of tPA on patients with ischemic stroke up to six hours from symptom onset in whom benefit was deemed to be uncertain (the vast majority of whom had contraindications to tPA defined by NINDS criteria in the 0- to 3-hour window or ECASS-3 criteria in the 3- to 4.5-hour window).” Thus, IST-3 looked at a different cohort of patients from those on which the policy recommends use.

- The article states that the results of the study were negative for the primary outcome in patients treated up to six hours after onset of symptoms but did not mention the significant benefit in those treated within three hours (adjusted odds ratio for excellent outcome 1.64, 95% confidence interval 1.03 to 2.62). Importantly, this benefit occurred despite the expansion of indications in IST-3 as above. The article states that only two of 12 randomised controlled trials found a benefit for thrombolysis in stroke. But many of these studies evaluated alternative thrombolytics to alteplase or different doses, and most used much longer time windows than currently recommended. Patient level meta-analyses of studies of standard dose alteplase show a significant increase in excellent neurological outcome in patients treated up to 4.5 hours, without evidence of heterogeneity in the data.6

- The article focuses on the fact that alteplase does not reduce mortality, but the guideline never claimed this. The evidence shows that functional outcome is improved when alteplase is given to eligible patients with acute ischaemic stroke. The Cochrane review cited in the article again included many studies of alternative thrombolytics, different doses of alteplase, or longer time windows for treatment. It found that thrombolysis given up to six hours after ischaemic stroke significantly reduced the proportion of patients who were dead or dependent (modified Rankin 3 to 6) at three to six months after stroke (odds ratio 0.81, 95% CI 0.73 to 0.90). It also found that use of a thrombolytic within three hours of stroke seemed more effective in reducing death or dependency (0.71, 0.52 to 0.96), with no significant adverse effect on death (1.13, 0.86 to 1.48).

A large part of the article also references outdated or unpublished polls and individual opinions by emergency medicine doctors who do not support the current guidelines, or do not believe in using alteplase for acute stroke. Doctors’ ideas about what they would prefer to do are not evidence for best practice. A disconnect between typical care and best practice is the strongest argument for development and dissemination of evidence based guidelines.

The AAN has strived to be at the forefront of clinical practice guideline development and the methodology for developing guidelines. This includes the process for managing conflicts of interest, which is always evolving and improving. The current process is discussed in detail in the AAN Guideline Process Manual (p 23-26). In conclusion, the clinical science that supports the many guidelines advocating the use of alteplase in selected patients with ischaemic stroke is strong. The authors should reconsider their recommendations for the use of intravenous alteplase for the management of acute ischemic stroke.

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Competing interests: SRM receives publishing royalties from Up-To-Date, formerly served on the speakers’ bureau for Boehringer Ingelheim (ended April 2011), and receives research support from WL Gore and the NIH. EES was on a scientific advisory board for Genentech in 2010; received speaker honorariums from the Canadian Conference on Dementia; is an assistant editor for Stroke; has served on speakers’ bureaus for QuantiaMD and BMJ Best Practice; is on the data and safety monitoring board for the MR Witness trial funded by the NIH/NINDS; and receives research support from NIH/NINDS, Canadian Institutes for Health Research, Canadian Stroke Network, the Alberta Heritage Fund for Medical Research, and the Heart and Stroke Foundation of Canada. TSDG has no conflicts to disclose. GSG is an editorial advisory board member of Neurology Now, serves on a speakers’ bureau for Boehringer Ingelheim, and receives honorariums from Boehringer Ingelheim and the American Academy of Neurology.

- 1 Lenzer J. Why we can’t trust clinical guidelines. BMJ 2013;346:f1380. (14 June.)

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