The instability of the political stage compares badly with the selflessness and dedication of NHS staff and emergency services.

To the best of humankind, thank you

Berra is a tiny outer island of Scotland, a slight comma falling off the end of the landscape of the Outer Hebrides. Its runway is a white stretch of beach, embraced by the sea. The body of 14 year old Eilidh MacLeod was flown onto it, back to her home, after she was murdered in the recent terrorist attack in Manchester. With great dignity and to a pipers’ lament, her friends and family received her body and took her to be buried. It is entirely, utterly, heartbreaking.

And then, Grenfell Tower. Dozens of people killed in a fire in an accident waiting to happen, as residents predicted. I write this as a minority government holds together a ragbag non-coalition, in chaos. It’s hard to know how to respond to the hubris except to note that it’s a repetition. I’ve been looking back through political biographies. So many profoundly important decisions have so often rested on chance, coincidence, bargaining, and unexpected changes in a political environment.

Twenty five years ago I felt anxious driving through Northern Ireland on my way to Dublin, through the searchlights on the border. It was routine to be stopped by soldiers with guns. Now, I’m used to a border that’s hardly obvious unless you know where to look. Brexit looms: what next?

The UK has, on average, been the second biggest arms dealer in the world over the past decade, selling arms to Saudi Arabia despite its multiple human rights violations. This should be incompatible with British values. Post-Brexit, who knows what trade deals we’ll be made to swallow? I wonder where our underlying moral compass will point. It feels dangerously uncertain.

But some things feel less so. Public services and the NHS may be under profound pressure, but there is much to admire. The community groups surrounding Grenfell Tower offered the survivors immediate help, and firefighters risked their own lives. The police and healthcare staff who have responded so admirably deserve our humble thanks. There is our strong and stable leadership, in spades. The professionalism, immediate sense of duty, and loyalty to the needs of people exemplify humankind’s absolute best.

I’m unlikely to come across the acute aftermath of terrorism, but the collegiate nature of the NHS means that we all feel concern for those who do this work.

The instability of the political stage compares badly with the selflessness and dedication of the NHS staff and emergency services. Kirsty Boden, an Australian nurse, ran towards people in need of her help at London Bridge, towards her own death. This desperate tragedy makes the whole NHS family mourn. So often the systems we’re organised into rub against each other: I doubt that we cherish each other enough.

I got out the poems of one of my early loves, John Donne. You’ll know these words, but they’re worth drinking in again: “No man is an island entire of itself; every man is a piece of the continent, a part of the main; if a clod be washed away by the sea, Europe is the less, as well as if a promontory were, as well as any manner of thy friends or of thine own were; any man’s death diminishes me, because I am involved in mankind. And therefore never send to know for whom the bell tolls; it tolls for thee.”

May Eilidh, and everyone killed in these tragedies, rest in peace. May the staff who work beyond their written contracts to their own moral ones know, at least, our appreciation.

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OBSERVATIONS Gerd Gigerenzer

Is your smartphone able to predict pancreatic cancer?

Gerd Gigerenzer discusses how search engines use big data analytics to “diagnose” your state of health

Imagine this warning popping up on your search engine page: “Attention! There are signs that you might have pancreatic cancer. Please visit your doctor immediately.” Just as search engines use big data analytics to detect your book and music preferences, they may also be able to “diagnose” your state of health.

Microsoft researchers have claimed that web search queries could predict pancreatic adenocarcinoma. A retrospective study of 6.4 million users of Microsoft’s search engine Bing identified first-person searches suggestive of a recent diagnosis, such as “I was told I have pancreatic cancer, what to expect.”

Then the researchers went back months before these queries were made and looked for earlier ones indicating symptoms or risk factors, such as blood clots and unexplained weight loss. They concluded that their statistical classifiers “can identify 5% to 15% of cases, while preserving extremely low false positive rates (0.00001 to 0.0001),” and that “this screening capability could increase five year survival.”

The New York Times reported that the study “suggests that early screening can increase the five year survival rate of patients with pancreatic cancer to 5 to 7%, from just 3%.”

Thus it appears that the researchers have found a low cost, high coverage surveillance system that produces almost no false alarms and saves lives—an improvement over previous diagnostic attempts using biomarkers or imaging.

In this column, I do not deal with the typical problems of big data, such as intransparent algorithms and the danger of overfitting noise, or with the ethics of not soliciting users’ consent to having their personal data (albeit anonymously) analysed. Rather, I take the results as given and focus on how the presentation of these results invites several potential misunderstandings.

Survival rates

Firstly, consider the prospect of increased survival rates, which suggests that surveillance saves lives. In fact, in the context of screening, the correlation between increases in survival rates and decreases in

ACUTE PERSPECTIVE David Oliver

Time for a truly independent NHS statistics authority

In the current febrile environment around health policy, I propose that we need a statutory Independent Office for Health and Care Statistics.

I have no problem when politicians, government department public relations teams, media commentators, lobbyists with vested interests, or privately funded, partisan political think tanks with ideological agendas take positions; whether on the funding of health and care systems, current and future workforce, or historical or international comparisons of performance.

But I do have a problem with them partially selecting or willfully misrepresenting data—until the soundbites and assertions, cobbled together from factoids, enter the public consciousness as received gospel.

People on all sides pump out inaccurate or partial information to justify their cause. For instance, the government said last October that the NHS would receive an additional £10bn by 2020, but the King’s Fund showed that the additional funding is only around £4.5bn. Jeremy Hunt, the health secretary, also erroneously claimed that the NHS had received the sixth biggest funding increase in its history. Similar examples abound.

In 2010, the UK established the Office for Budget Responsibility: a statutory body, independent of political interference, to provide rigorous, neutral, expert economic forecasts and information. More recently, the Labour Party called for a similar body for health finances (though not for other types of data).

The Office for National Statistics provides a range of highly respected national data relevant to many areas of public policy, including healthcare. The National Audit Office, which also has a statutory politically independent role, produces hard hitting and well evidenced reports on key aspects of health and social care service
mortality rates is approximately zero for the 20 most common solid tumours over the past 50 years. One reason for this is called “lead time bias.” Early detection implies that diagnosis occurs at an earlier stage of a disease, which leads to higher five year survival rates from the time of diagnosis—even if the patients ultimately do not live any longer in terms of absolute age. Reporting survival instead of mortality rates misleads the reader about the benefits of cancer screening.

Secondly, consider the extremely low false positive rates. Does that mean that Bing users who get the news that they are positive are seldom falsely alarmed?

To answer that, let us go through a simple example. Assume 1 000 000 users, 10 of whom have undetected pancreatic cancer. Given a sensitivity of 10% (the average of 5% and 15%), we expect that one user correctly tests positive and the other nine are missed. Given a false positive rate of 1 in 10 000 (or 0.0001), we expect that about 5% and 15%), we expect that one user correctly tests positive and the other nine are missed. Given a false positive rate of 1 in 10 000 (or 0.0001), we expect that about 10 users test positive even though they do not have cancer. Thus, we expect a total of 11 users to test positive, of whom 10 do not have pancreatic cancer. The general point is that, even with low false positive rates, the proportion of false alarms among all users who test positive can be high if the disease is rare.

Systematic misunderstandings
The authors note that surveillance by Bing does not replace a physician. Yet their presentation of the statistical results easily invites systematic misunderstandings by patients and doctors.

In the New York Times, one of the authors of the research, Eric Horvitz, mentions his hope that the study will stimulate quite a bit of interesting conversation. My response is that, in order to demonstrate the clinical usefulness of big data analytics, the first step should be towards more transparency and fewer misleading statistics. Not doing so recalls the rise and fall of Google Flu Trends, which in 2009 was trumpeted as being able to predict influenza but disappeared from sight after years of failing to meet its own projected rates of predictive accuracy.

Big data are known for fanfare and hype. In this case, all has been quiet since the buzz last summer.

Gerd Gigerenzer, director, Max Planck Institute for Human Development and Harding Center for Risk Literacy, Berlin gigerenzer@mpib-berlin.mpg.de

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Black box thinking in maternity care

Florence Wilcock

The recent publication of the Each Baby Counts report from the Royal College of Obstetricians and Gynaecologists is a stark reminder to all of us in maternity care of just how much work there is to be done.

The report details what happened to 11 366 babies in the UK: 126 intrapartum stillbirths, 156 early neonatal deaths, and 854 severe brain injuries.

To err is human. Where there is life there is death, and death is inevitable in every medical specialty. The inadequate nature of the investigations detailed in the report, however, is both avoidable and unacceptable. People often choose a caring profession, such as midwifery or medicine, because of a desire to help others—so how can it be that these same people are also responsible for this poor standard of investigation when things go wrong?

When facing a family who have been bereaved, saying sorry is one of the hardest tasks we face.

I recently read Black Box Thinking by Matthew Syed, which describes this incongruity both in healthcare and other areas. The idea of cognitive dissonance—where a system clings to its beliefs despite increasing contradictory evidence—really struck home with me. I guarantee that, if you walk into a maternity ward and ask a member of staff about their processes, they will tell you that safe systems are in place—there is risk reporting, risk teaching, a risk team, and investigations of incidents. It is unlikely that there is anyone investigating an incident who thinks they are doing a bad job or that we are not learning from their work. It is only when these investigations are collectively scrutinised that the depth of our ignorance becomes apparent.

In some ways it is understandable. Facing a family who have been bereaved, explaining that mistakes have been made, and saying sorry is one of the hardest tasks we face. It is not surprising that, unwittingly, we sometimes fall into the trap of non-disclosure. It is troubling, however, that we don’t recognise that this is what we are doing.

Each Baby Counts contains recommendations to counteract this behaviour. These include more recognition of the value of parental input into reviews and of the presence of external panel members on every local investigation. Meanwhile, hospital executives must try to preserve quality in an ever more challenging financial context, the pressure to succeed is unprecedented, and the competitive culture of the internal market discourages organisations to invite external scrutiny of mistakes.

Florence Wilcock is a consultant obstetrician at Kingston Hospital, London.
Are drug regulators really too slow?

Approval processes are often accused of delaying the arrival of new drugs onto the market. Using FDA data, Tom Marcinialiak and Victor Serebruany determine whether this view is justified.

Empirical analyses have shown the US Food and Drug Administration gets drugs to market faster than other major regulators. Still the agency finds itself the perpetual target of criticisms that it is too slow. Indeed, the 21st Century Cures Act that passed last year was promoted by those who perceive the agency as a bureaucratic behemoth that is hindering innovation. Could the agency speed up approvals without affecting patient safety? We have taken a closer look at the facts, analysing the time from completion of clinical trials to eventual drug approval in the FDA’s cardiorenal division, allegedly one of the agency’s “least efficient” (slowest).

**Empirical analyses have shown the US Food and Drug Administration gets drugs to market faster than other major regulators.**

**Potential for delay**
Critics portray the “new drug application” process as wholly in a regulator’s hands. But this crude depiction ignores industry’s contribution to the clock after clinical trials are completed but before the FDA receives the formal application. It also depicts the FDA as a monolith, whereas licensing has two distinct elements: FDA scientific review and the subsequent decision making by FDA management.

We assessed the time attributable to drug companies, FDA scientists, and FDA management for all novel drugs approved by the FDA’s cardiorenal division during 2011 to 2015. Using date information from documents posted on Drugs@FDA and trial publications, we assigned drug company time as the period between last patient visit in the final pivotal trial to submission of an approval application; FDA scientific review time as application submission to completion of the primary clinical reviews; and FDA management time as the remaining time to approval (or non-approval) action letters.

**Drug companies: eight months**
Drug companies took a median eight months (mean 12 months) after the completion of clinical trials to submit an application to the FDA (table 1). Although analysing data and writing a trial report may be time consuming, cardiovascular trials are typically several years long, and the detailed analysis plan should have been drafted well in advance of completion. Reducing the time that companies take to submit their applications—for example, to the four months achieved for apixaban and rivaroxaban (table 1)—seems a feasible and worthy goal.

Time to submission was highly variable (standard deviation 12 months), with four of 15 drugs taking more than a year and one taking 51 months. The companies did not publicise the reasons for these long delays, but likely reasons include inexperience of smaller companies in submitting applications, focus on other drugs in a company’s pipeline, and deliberation over how to interpret or present the results when trials are conflicting.

What our statistics do not show are other sponsor related delays. For example, an application was submitted for cangrelor six months after the end of the last pivotal trial, but its approval was delayed by much longer because the first two pivotal trials had negative results. The submission was delayed by four years while a third trial was completed.

The first two trials failed because of misclassification of endpoint events.

**KEY MESSAGES**

- FDA primary review times for cardiorenal drugs appear reasonable
- Modest improvements in approval time may be achievable by improving FDA management decision making
- Improving drug sponsor presubmission processes offers better opportunities for accelerating drug approval
- Requiring resubmission, while adding time to approval, often facilitates approval without forcing longer delays for additional studies
based on changes in creatine kinase MB alone, despite creatine kinase MB’s clinical use as a surrogate marker for more than 40 years. An outcome of major cardiac adverse events (myocardial infarction, stroke, and death) in a large, initial trial would probably have resulted in approval earlier with a trial size equal to or less than the sum of the three trial sizes—and have provided better data on patient outcomes. It is underappreciated that use of surrogate markers may not be more advantageous than the use of clinical outcome measures, and the case serves as a warning against increased use of such markers in approval trials.

**Scientists: eight months**

FDA scientists took a median of eight months to complete their review (table 1). This seems a reasonable time to produce a 200 page report analysing and summarising not only one or more major cardiovascular outcome trials but also an entire drug development programme. In fact, the typical FDA review involves analysing raw patient data (case report forms and datasets) rather than merely reading the drug sponsor’s clinical study reports. Pivotal cardiovascular trials often have more than 10000 participants and take longer to analyse than smaller trials used in fields such as cancer drugs, where a trial typically has 420 participants. There was little variation between the drug applications (SD=2), suggesting limited opportunity for shortening primary review times.

The review times are largely consistent with the performance goals agreed between the FDA and industry under the Prescription Drug User Fee Act (PDUFA). The act requires drug companies to fund the FDA in return for the FDA promising to meet negotiated performance standards—making a decision on 90% of submissions within eight months for priority reviews (treatments that are a threatening condition) or within 12 months for standard reviews. There was little variation (SD=0.5-1). This may suggest an excessive time for a decision, particularly considering that FDA management becomes aware of any major concerns with an application during a “mid-cycle” meeting with FDA scientists.

Despite this, the data show that submissions with perceived problems often take longer to deal with. Consider the cases of ivabradine and vorapaxar, which had the longest management decision times among drugs approved on the initial submission. For ivabradine, the primary issues to be resolved were discrepancies between the one successful trial and two failed trials and subgroup variations that might affect labelling. The primary and secondary reviewers recommended more restrictive labelling than the drug company proposed; FDA management ultimately sided with the company. For vorapaxar, FDA clinical pharmacologists were concerned about use in patients with low body weight. The FDA clinical reviewers were less concerned and consistently recommended approval with minor labelling variations from those proposed by the sponsor, so the reasons for extra time are not clear.

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**Table 1 | Time to FDA decision for approved cardioenal drugs, 2011-15**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Year approved</th>
<th>Last pivotal trial</th>
<th>No of participants</th>
<th>Trial end to NDA</th>
<th>NDA to FDA review</th>
<th>Review to FDA decision</th>
<th>Total</th>
<th>No of pages in review</th>
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<tr>
<td>Selecapip</td>
<td>2015</td>
<td>GRIPOHON</td>
<td>1156</td>
<td>8</td>
<td>8</td>
<td>4</td>
<td>20</td>
<td>139</td>
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<tr>
<td>Patience</td>
<td>2015</td>
<td>OPAL-HK</td>
<td>263</td>
<td>15</td>
<td>8</td>
<td>4</td>
<td>27</td>
<td>89</td>
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<tr>
<td>Sacubitil/valsartan</td>
<td>2015</td>
<td>PARADIGM-HF</td>
<td>8442</td>
<td>7</td>
<td>5</td>
<td>2</td>
<td>14</td>
<td>170</td>
</tr>
<tr>
<td>Cangrelor</td>
<td>2015</td>
<td>PHOENIX</td>
<td>11145</td>
<td>6*</td>
<td>9</td>
<td>4*</td>
<td>19</td>
<td>178</td>
</tr>
<tr>
<td>Rivabradine</td>
<td>2015</td>
<td>SHIFT</td>
<td>6558</td>
<td>51</td>
<td>5</td>
<td>5</td>
<td>61</td>
<td>231</td>
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<tr>
<td>Lidoxyban</td>
<td>2015</td>
<td>ENGAGE</td>
<td>21105</td>
<td>8</td>
<td>9</td>
<td>3</td>
<td>20</td>
<td>278</td>
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<tr>
<td>Vorapaxor</td>
<td>2014</td>
<td>TRA2P</td>
<td>26449</td>
<td>17</td>
<td>7</td>
<td>5</td>
<td>29</td>
<td>195</td>
</tr>
<tr>
<td>Drozidas</td>
<td>2013</td>
<td>301</td>
<td>162</td>
<td>14</td>
<td>4</td>
<td>2*</td>
<td>20</td>
<td>62</td>
</tr>
<tr>
<td>Macintosh</td>
<td>2013</td>
<td>SERAPHIN</td>
<td>742</td>
<td>7</td>
<td>8</td>
<td>4</td>
<td>19</td>
<td>153</td>
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<tr>
<td>Rociganti</td>
<td>2013</td>
<td>CHEST-1</td>
<td>262</td>
<td>8</td>
<td>5</td>
<td>3</td>
<td>16</td>
<td>198</td>
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<tr>
<td>Apxidaban</td>
<td>2012</td>
<td>ARISTOTE</td>
<td>18201</td>
<td>4</td>
<td>8</td>
<td>1*</td>
<td>13</td>
<td>260</td>
</tr>
<tr>
<td>Trigelbre</td>
<td>2011</td>
<td>PLATO</td>
<td>18624</td>
<td>9</td>
<td>7</td>
<td>6*</td>
<td>22</td>
<td>266</td>
</tr>
<tr>
<td>Rivaroxaban</td>
<td>2011</td>
<td>ROCKET AF</td>
<td>14264</td>
<td>4</td>
<td>7</td>
<td>3</td>
<td>14</td>
<td>303</td>
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<tr>
<td>Azilsartan</td>
<td>2011</td>
<td>491-019</td>
<td>1291</td>
<td>8</td>
<td>8</td>
<td>2</td>
<td>20</td>
<td>325</td>
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<tr>
<td>Mean (SD)</td>
<td>12 (12)</td>
<td>7 (2)</td>
<td>3 (1)</td>
<td>22 (11)</td>
<td>203 (78)</td>
<td></td>
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<td>Median</td>
<td>8</td>
<td>8</td>
<td>3</td>
<td>20</td>
<td>197</td>
<td></td>
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</tbody>
</table>

NDA=New drug application to FDA
*Resubmission requested.
†49 months from end of two earlier failed pivotal trials to NDA.

**FDA reviews are complex and cover critical topics such as data quality and safety details**

The review times are largely consistent with the performance goals agreed between the FDA and industry under the Prescription Drug User Fee Act (PDUFA). The act requires drug companies to fund the FDA in return for the FDA promising to meet negotiated performance standards—making a decision on 90% of submissions within eight months for priority reviews (treatments that are a threatening condition) or within 12 months for standard reviews. Overall, the FDA is meeting these goals. The most recent (2014) data show median approval times of 7.9 months (priority review) and 10 months (standard review). Speeding approvals by demanding faster reviews from FDA scientists may be not only difficult but harmful. Analyses have found increased rates of safety problems for drugs approved near the PDUFA deadline.

**Management: three months**

Often overlooked in analyses of the approval process is the time it takes FDA management to make a decision after the scientific review is completed. For cardioenal drugs, the FDA took a median of three months for both initial submissions and resubmissions (tables 1 and 2), with low variability (SD=0.5-1). This may seem an excessive time for a decision, particularly considering that FDA management becomes aware of any major concerns with an application during a “mid-cycle” meeting with FDA scientists.

Despite this, the data show that submissions with perceived problems often take longer to deal with. Consider the cases of ivabradine and vorapaxor, which had the longest management decision times among drugs approved on the initial submission. For ivabradine, the primary issues to be resolved were discrepancies between the one successful trial and two failed trials and subgroup variations that might affect labelling. The primary and secondary reviewers recommended more restrictive labelling than the drug company proposed; FDA management ultimately sided with the company. For vorapaxor, FDA clinical pharmacologists were concerned about use in patients with low body weight. The FDA clinical reviewers were less concerned and consistently recommended approval with minor labelling variations from those proposed by the sponsor, so the reasons for extra time are not clear.
The management review time for these two submissions was two months longer than the median management review time (three months), suggesting that faster review would not reduce approval times by more than a few months.

Resubmissions

The one FDA action that substantially lengthens time to approval is requiring resubmission, which the FDA demands when the FDA judges that the submission has a deficiency not readily correctable. A resubmission request increases the time from initial submission to approval by 50–100% (table 2, see bmj.com), particularly if a new trial is mandated. For the five years we examined, the FDA required resubmission with a new trial for only one approved drug: droxidopa.

Droxidopa’s initial submission contained one small successful trial that used symptoms as an endpoint (but with highly positive and unusually homogenous results at a single site) along with two negative studies. The confirmatory study in the resubmission was a continuation of an existing study in which the primary endpoint was changed after an unblinded interim analysis and then changed again. This confirmatory study showed benefit on the twice changed endpoint but with a small effect size and many dropouts. The primary reviewer continued to recommend against approval, but FDA management approved the drug after an advisory committee meeting that included many patient testimonials.

In three cases, the FDA required resubmission but without additional trials. The official FDA reasons for requiring resubmission are documented in its “complete response” but these do not always reflect all of the problems identified by the reviewers (box). None of the resubmission requests looks unjustified.

FDA reviews are complex and cover critical topics such as data quality and safety details not covered in journal publications. Devoting some months to scrutinising these details seems justifiable. Responsibility for delays due to resubmissions is debatable. On the one hand, the drug sponsor should have identified the trial problems before submission and acted on them. On the other hand, closer collaboration between the sponsor and the FDA during the initial submission might have facilitated first round approval. Whichever party is at fault, the extended review times for the resubmissions were probably in the best interests of the drug companies because the extra discussion mostly resulted in the FDA being able to approve the drug without further study. Counterintuitively, therefore, longer timelines often actually “save” drugs that may otherwise have been rejected.

Accelerating drug approvals?

Our analysis suggests limited opportunity to speed approval of cardioenal drugs by reducing the time taken for FDA review or decision making. Delays by drug companies in submitting applications had the greatest variation and may therefore represent the best opportunity to speed up approval.15 16 The reasons for delays in time to submission are various and not amenable to legislative correction.

Importantly, we did not consider whether the approvals were appropriate, and our results may not apply to other FDA divisions. They do, however, show the complexity of regulatory decision making around approvals, especially when evidence is conflicting. In addition, approval committees have to consider other aspects such as what should be communicated to practitioners and patients in the drug labelling.

It may be possible to accelerate drug approvals in other ways, such as by changing processes earlier in the development programme, before the end of the pivotal trials. For cardioenal drugs, we believe that traditional double blind, randomised clinical trials that do not use surrogate outcome measures for novel indications are needed. Trying to accelerate FDA drug approvals by lowering standards, as parts of the 21st Century Cures Act direct, may prove costly for patients and healthcare budgets.17 18
LETTERS

Selected from rapid responses on bmj.com.

See www.bmj.com/rapid-responses

OCCUPATIONAL HEALTH

NHS integration will not improve access to services

Integrating occupational health services with the NHS (Editorial, 3 June) won’t remedy lack of access. An effective solution requires consultation with stakeholders; a systematic approach to problem solving; and benchmarking against other models. European countries that achieve the highest rates of access do so largely through private services.

Expecting uniform delivery of services against longstanding criticisms of postcode delivery of NHS care is naïve. The deep funding crisis in the NHS and services being dependent on local commissioning mean that provision of occupational health services should not be assumed to be deliverable where more urgent healthcare priorities exist.

Service delivery has not kept up with changes in business. Together with workforce shortages, and in the absence of radical measures, this could worsen access. We should start an inclusive and independent process to propose considered, definitive, sustainable, and effective solutions.

Paul J Nicholson, occupational physician, London

Cite this as: BMJ 2017;357:j3086

Challenges of training in occupational medicine

Occupational medicine training faces several challenges. It is expensive and occurs in Defence Medical Services, commercial organisations, and the NHS. Developing a curriculum and confirming that trainees’ skills are core roles of the Faculty of Occupational Medicine.

The GMC process for establishing a training position is complex, so the faculty has produced guidance for employers. The faculty’s role, along with the

BMA, the Society of Occupational Medicine, and the National School of Occupational Health, is to deliver robust arguments for more training positions.

Integrating occupational medicine in the NHS would ensure that it was included in workforce planning and would require more trained occupational health specialists. A meaningful debate about how to increase training posts would be valuable but would have to include representatives from all parties involved in training.

Ian Aston, consultant occupational physician, Nottingham

Cite this as: BMJ 2017;357:j3088

LETTER OF THE WEEK

Putting social care on the map

McCartney’s call for reflection on the status of social care and its integration with the health system will resonate with many (No Holds Barred, 3 June). We have been investigating the concept of a “community of clinical practice” for analysing the provision of care. We mapped care providers nominated by each patient on to a diagram of concentric circles with the patient at the centre. Carers’ distance from the centre indicated the patient’s view of their importance.

Patients have validated the maps as meaningful representations. Participants can quickly identify other carers and, to some extent, infer the nature of their involvement. The patient’s perspective includes relatives, friends, neighbours, and community groups making valuable contributions to care. Their absence implies social isolation.

Developing and maintaining the maps requires conversations with the patient, incurring a cost. Their benefit is that doctors, nurses, social workers, and care agencies can be aware of who else is involved and can share “soft knowledge” that is usually lost to the system, as McCartney points out.

We imagine such maps as a visual display in the electronic clinical record. Click on each participant for their role, contact details, and other information. That may be a pipe dream, but a map of a patient’s community of clinical practice is only a conversation away. Who will have that conversation?

Tony G Egan, honorary senior lecturer, New Zealand; Chrys Jaye, associate professor, New Zealand; Jessica Young, assistant research fellow, New Zealand; Martyn Williamson, senior lecturer, New Zealand

Cite this as: BMJ 2017;357:j3085

AMI AND PAINKILLERS

Risk of NSAIDs may be overestimated

Bally et al’s study of the risk of myocardial infarction in people taking NSAIDs confirms other studies, including randomised trials (Research, 9 May). But the reporting of this study and its interpretation may be flawed.

The immediate onset of increased risk is compatible with inadequate adjustment for confounding or reverse causation. Some people taking NSAIDs may have prodromal effects of myocardial infarction, causing pain that requires painkillers. The data are based on date of prescription or dispensing and not on date of taking, so an early rise in risk may not be due to pharmacology of the drug.

Nearly all reported odds ratios overlap, and no comment is made on absolute risks—when headlines emphasise relative risks we should beware. NSAIDs are associated with risks of myocardial infarction, but this study may have overestimated the effects, especially for short duration of use.

Stephen J Evans, professor of pharmacoepidemiology, London

Cite this as: BMJ 2017;358:j3176

Authors’ reply

We do not agree that immediate onset of increased risk is explained by failure to adequately adjust for confounding or by reverse causation.

Confounding by indication is unlikely because we excluded studies published after rofecoxib was withdrawn, when the choice of NSAID was unrelated to risk of myocardial infarction.

We think that doctors correctly identified prodromal symptoms and that patients subsequently given a diagnosis of myocardial infarction did not self medicate with NSAIDs. Thus, reverse causality does not explain the early increase in risk.

We don’t agree that risks are systematically overestimated by prescribing or dispensing because the resulting misclassifications of exposure would affect cases and controls differently. Not using an NSAID on index date does not inform on indication or presence of pain on that date.

We estimate the absolute risk of myocardial infarction associated with use of NSAIDs to be about 0.5%–1% a year.

Michèle Bally, epidemiologist, Montreal; James M Brophy, professor of medicine and epidemiology, Montreal

Cite this as: BMJ 2017;358:j3185
OBITUARIES

Daphne Marsh Baston
General practitioner
Whiteparish, Hampshire (b 1927; q Birmingham 1950; MRCPG), died from motor neurone disease on 1 June 2017
Daphne Marsh Baston (née Hampton) did house jobs in ear, nose, and throat medicine and eye medicine at Queen Elizabeth Hospital in Birmingham. She also worked in accident and emergency medicine before going into practice with her husband, John, in Whiteparish. For more than 20 years they worked together in a rural dispensing practice, and she greatly enjoyed being a general practitioner. A past president of Salisbury BMA and of Salisbury Medical Society, Daphne had a prominent role in founding the local hospice with a friend and senior physician. For the past eight years, Salisbury Cathedral played an important part in her life—she was a floor guide, a server, and a subdeacon. She leaves John, three children, five grandchildren, and a great granddaughter.

John Baston
Cite this as: BMJ 2017;357:j2887

David Burns Moffat
Professor emeritus
in anatomy Cardiff University (b 1921; q 1943; MD Lond, FRCS Eng), d 21 May 2017
David Burns Moffat was thrust into the second world war as a surgeon lieutenant. He enjoyed various postings to naval air stations, but he also survived multiple Atlantic convoys. After the war he remained in the Royal Naval Volunteer Reserve and achieved the rank of surgeon captain aboard the minesweeper St David. An academic career then beckoned. He became an anatomy demonstrator in Cardiff in 1947 and a senior lecturer in 1962 before assuming a personal chair in 1970. He nominally retired in 1987 and was then appointed professor emeritus. His early research (published from 1952 onwards) on the structure, function, and development of blood vessels encompassed several organ systems. He was also a prolific author. Predeceased by his wife, Joan, in 2008, he leaves three children, seven grandsons, and five great grandchildren.

Bill Moffat
Cite this as: BMJ 2017;357:j2895

Christopher William Burke
Consultant endocrinologist Radcliffe Infirmary and John Radcliffe Hospital, Oxford (b 1934; q Oxford 1960; DM, FRCP), died from oesophageal cancer on 23 December 2016
Christopher William Burke read chemistry at Oxford before switching to medicine. Having gained experience of general and endocrine medicine in three London hospitals, as well as some months in general practice, he was appointed consultant physician with a special interest in endocrine and metabolic disease to the Oxford hospitals in 1973. He was highly regarded for his clear and practical teaching of his younger colleagues, and he published on a wide range of topics. In 1990 he attended Don Berwick’s course on quality improvement and designing care in Boston, Massachusetts, and on his return to Oxford he set up a district quality and audit group. He retired to Devon in 1994. He leaves his wife, Jilly; two children from his first marriage; and five grandchildren.

Derek Hockaday
Cite this as: BMJ 2017;357:j2822

Timothy Hugh Moss
Consultant neuropathologist Frenchay Hospital, Bristol (b 1954; q Bristol 1977; PhD FRCPath), died from colorectal cancer on 6 July 2016
Although Timothy Hugh Moss (“Tim”) was inclined towards music, he was persuaded to study medicine at Bristol University. After completing house jobs, he started a PhD, soon realising that academia was even more precarious than clinical medicine. He chose pathology and specialised in neuropathology. He trained in Bristol under Betty Brownall, whom he succeeded as consultant in 1986. He published academic books and was a committee member of the British Society of Neuropathology. When the loss of postmortem material reduced the workload in neuropathology, Tim enhanced his expertise to support colleagues in breast and skin pathology. He retired at 55, enjoying six years of a full and active life. He leaves his wife, Stasia, and two brothers.

Stasia Moss, David Mumford
Cite this as: BMJ 2017;357;j2826

Bryan Furnass
Consultant physician and foundation director of the Australian National University Medical School (b 1927; Oxford 1949), died after a fall on 4 March 2017
Stanley Bryan Furnass (“Bryan”) received a scholarship to attend Oxford University Medical School and completed postgraduate physician training at the Middlesex Hospital. This was followed by two years in Sierra Leone on compulsory national service with the Royal Army Medical Corps; he specialised in tropical medicine. However, most of Bryan’s adult and professional life was spent in Australia, where he and his wife, Anne, and their young family arrived in early 1960. He was the foundation director of the Australian National University Medical School in Canberra, and remained there for 25 years until he retired in 1991. Bryan rightly saw humanity’s changes to our environment and our climate as threatening our wellbeing on many fronts. Bryan leaves Anne and five children.

Sue Wareham
Cite this as: BMJ 2017;357:j2899

John Richard Newton
Consultant of obstetrics and gynaecology University of Birmingham (b 1938; q Barts 1962; MD, MRCS Eng, FRCOG, DOBST RCOG, LLM), d 11 March 2017
John Richard Newton was awarded the Lawson Tait chair of obstetrics and gynaecology at the University of Birmingham in January 1979 and held it until he retired on 1 August 2000. John was also interested in fertility problems, helped to bring modern fertility treatment to the West Midlands, and was at the forefront of minimal access gynaecological surgery. His contribution to family planning and contraception is substantial, and his publications ran into the hundreds. He was active in professional societies, sat on committees, and served on task forces with the World Health Organization. In retirement John became a trustee of the Ironbridge Gorge Museum and an active member of social committees in the Sandbanks Association. He leaves his wife, Tricia; two daughters; and grandchildren.

K K Chan
Cite this as: BMJ 2017;357:j2758
Brian Webb

Paediatrician who transformed Somerset’s perinatal care

Brian (“Bertie”) Wykeham Webb (b 1921; q Middlesex Hospital, London 1945, MD, FRCP, FRCPCH) died 21 May 2017

In 1957 paediatrician Brian Webb arrived with his suitcases in Taunton at the start of the biggest challenge of his career. Used to the facilities of large teaching hospitals, he was now thrown on his own resources.

The newly appointed consultant was the only paediatrician in Somerset and had no junior staff to help him and was responsible for all of Somerset’s 60 000 or so children. As his friend and colleague Peter Dunn, now emeritus professor of perinatal medicine and child health, remarked, “Brian Webb had his work cut out.”

Malacca to the Middlesex Hospital

Webb was born in Malacca, Malaya, where his father, Oliver, a civil engineer, was working. He returned to England with his parents at the age of six in 1927. He was educated at Monkton Combe School in Bath before coming to London to train at the Middlesex Hospital.

He later told his colleague David Milligan that it was around this time that he found he couldn’t change gear when he was driving. His left foot wouldn’t press down on the clutch properly. In this way he discovered he had polio, but fortunately went on to make a full recovery.

After qualifying, Webb moved to Edinburgh for two years’ national service, working as a surgeon lieutenant in the Royal Naval Volunteer Reserve at Port Edgar Naval Hospital.

He returned to London in 1947 and spent much of the next decade training in general medicine and paediatrics at the Middlesex Hospital, Great Ormond Street Hospital for Children, and King’s College Hospital.

It was during this time that he came under the influence of two of the most distinguished paediatricians of the day—Alan Moncrieff and Wilfrid Sheldon. He also spent six months in Canada at the Hospital for Sick Children in Toronto, from which colleagues say he acquired a great respect for evidence based medicine—long before the term was coined.

West Country career

On coming back to the UK, Webb was appointed consultant paediatrician to Somerset. His predecessor, John Coates, died in 1958, and Webb began a friendship with his widow, Eve. In time they became close and married in 1961.

Based at Musgrove Park Hospital in Taunton, Webb devoted himself to “putting Somerset on the map,” according to paediatrician Tim David, who was a junior doctor at the hospital at the time. As well as being a shrewd diagnostician, Webb was a skilled communicator. David said that his appreciation of the skills of others, particularly the nursing staff, helped him build a first class team.

Long before computerised searches and portfolio learning, Webb was an enthusiastic user of medical literature and kept a book in which he wrote about cases and reflected on what he had learnt.

Webb developed the special care baby unit and in the 1960s organised a rotating paediatric registrarship with Kenneth Cross of the Medical Research Council and with the Royal London Hospital. It was a way to attract some of the best young doctors to the region. Registrars would spend a year in Taunton, a year at the London Hospital, and a year doing neonatal research.

To further aid networking and research, Webb persuaded the pharmaceutical company Beechams to provide funds for a postgraduate centre in the grounds of Musgrove Park Hospital. There he organised annual conferences for family doctors, which were called “Fresh Looks.” He took great pains over the invitations to speakers, such as that it was impossible to refuse him. It was Webb’s boast that no one ever declined his invitations to speak.

From 1981 until 1983 Webb chaired a survey of the south west region’s perinatal service. His team of five visited 48 maternity units and made 160 recommendations. The effect was astonishing—perinatal mortality in the region went from being the worst in England to being the best.

Webb’s influence, however, was not confined to Somerset. He also made time to contribute to the British Paediatric Association’s academic board and to serve as president of the South West Regional Paediatric Committee. He also spent a year in Sudan as visiting professor of paediatrics at the University of Khartoum.

After retiring in 1986, Webb had more time for the pastimes he loved: the English countryside, his garden in West Monkton, and playing golf with his friend Peter Dunn.

In 2005 his wife died suddenly, and a year later he himself had the first of a series of strokes. He later moved to a home in Bishops Lydeard, where he died at the age of 95. Despite his debility, he remained upbeat, responding to queries about his health with “Cheerfulness keeps breaking out!”

Bertie Webb enriched many people’s lives and he will be much missed by his friends. He didn’t have any children.

Penny Warren, London

Cite this as: BMJ 2017;357:j2829
**DIGITAL HIGHLIGHTS**

**Is sorry the hardest word?**

In a recent issue of *The BMJ* (BMJ 2017;357:j2874), we reported that the Medical Defence Union had issued advice on Scotland’s Apologies Act 2016, which now makes it clear that an apology outside legal proceedings is not an admission of liability. This news story got doctors talking on Twitter about when they say sorry to patients:

- **Trisha Elliott @trisha_the_doc**
  I’ve been offering apologies all my life as a doctor (if something has gone wrong)

- **Mike Henley @trentconsultant**
  I’ve taken the same approach. Often as a doctor you end up as a general apologiser: for medical care, catering, car parking, and health policy

- **Emma Vaux @VauxEmma**
  Car parking apologiser is my area of expertise

- **Medical mummy @Medical_mummy**
  That’s a truly in demand specialty. I am a “sorry for your wait”-ologist

- **Andrew Murray @Andrew_AMD**
  Too often, I hear doctors say they did nothing wrong and have nothing to apologise for when perceived as rude: “But I don’t think I was…”

**BMJ Podcast: Childhood IQ and cause of death**

Findings from a range of prospective cohort studies around the world indicate that higher intelligence in childhood is related to a lower risk of all cause mortality in adulthood. A new study in *The BMJ* tried to dig into that association further with a whole population cohort.

- You can listen to one of the authors of that study, Ian J Deary, discuss what they found at bmj.co/child_iq_mortality

**FROM THE ARCHIVE**

**Patriotism as a public health risk**

On this day in 1776 the first public reading of the US Declaration of Independence took place, although it is the adoption of the declaration by the Continental Congress four days earlier that is celebrated each year in America. *The BMJ* cast a rather disapproving eye over such festivities in 1899:

“Americans are demonstrative in their patriotism, and their feelings of loyalty to their flag are apt to find vent in manifestions of which the leading motive is noise. For the proper celebration of the fourth of July…able bodied citizens deem it their duty to make the welkin ring with every instrument of acoustic torture, and to shout themselves hoarse and each other deaf with barbaric yells. The day is made still more hideous by the firing of guns and pistols.”

The journal went on to report (Br Med J 1899;2:357) how that year’s commemoration was “followed by something like an epidemic of tetanus. Of 144 deaths which occurred throughout the States as the direct consequence of the celebration of the Declaration of Independence, 83 were due to tetanus. Of these, 26 occurred in New York or its immediate neighbourhood. In almost every instance the tetanus was the result of a pistol shot wound of the hand received on the fourth of July. The toy pistol, it is said, is responsible for these fatalities, the wad of the blank cartridge penetrating deep into the tissues of the hand, which we hope it is no offence against the majesty of the American people to assume was in most cases not ideally clean. A considerable proportion of the cases were treated with antitoxin, in most instances by means of intracerebral injections. The percentage of recoveries is not accurately known, but it is certain that a large proportion of the patients died. Nearly all these victims of national sentiment were young lads. Their country could doubtless have better spared an equal number of Fourth of July orators, and poetic justice would have been satisfied if those voluble persons had been overtaken by lockjaw.”

**MOST READ ONLINE**

- **I am your trans patient**
  *BMJ* 2017;357:j2963

- **Are millennial GPs shunning full time working?**
  *BMJ* 2017;357:j3059

- **Physical activity, cognitive decline, and risk of dementia**
  *BMJ* 2017;357:j2709

- **Childhood intelligence in relation to major causes of death in 68 year follow-up**
  *BMJ* 2017;357:j2708

- **Five things I wish I’d known at the start of my career as a GP**
  *BMJ* 2017;357:j3042