# comment

"The ASA upheld complaints about Babylon's misleading adverts" **DAVID OLIVER**
"My average time per consultation is about 16 minutes" **HELEN SALISBURY**
**PLUS** Role of physician associates; specialty recruitment crisis

**CUT TO THE CHASE** Gabriel Weston

## Looking out for others

It's the annual camping trip. Every summer half term we congregate in a field with a big group of other families, pitch tents, roast a pig, and try to let go for a couple of days. Over the 10 years we've been doing this, the first aid pack I bring with me has grown as the medley of minor ailments and injuries I've had to attend to—often in the dark, with a torch—has become more elaborate. This year, however, I've realised that my most important piece of kit won't go in the bag.

Last month the *European Heart Journal* published a paper with some alarming findings. Researchers from the Netherlands, looking at nearly 6000 people, have discovered that women who have a cardiac arrest outside hospital are significantly more likely to die than men in the same situation. The main reason is that women receive lifesaving defibrillation much less often, and an important factor seems to be that bystanders often don't recognise when women who collapse are having a cardiac arrest.

The authors also observed gendered differences in the way patients are subsequently treated in hospital. Women have myocardial infarction diagnosed less frequently and are less likely to receive either coronary angiography or percutaneous coronary intervention. What this amounts to is the scary statistic that, all other things being equal, the chance of a woman surviving to be discharged from hospital after having a cardiac arrest in the community is about half that of a man (12.5% *v* 20%).

Hanno Tan, study author and cardiologist, and his colleagues are now calling for a range of measures to tackle this problem. Top of the list is launching a public awareness campaign to teach people that women having a heart attack may experience symptoms that are less easy to call: fatigue, fainting, and neck or jaw pain, as opposed to the more classic chest pain often reported by men.

As I check in at the campsite and note the defibrillator, in prime position above the fresh eggs and apple juice, I find that I'm less reassured by the sight of it than usual. I can see now that, whether it's the defibrillator in reception or the first aid kit squashed into my holdall alongside our other essential medical supplies (the kids' variety pack and my bottle of gin), being equipped to help someone in extremis is only partly about the equipment.

What really saves lives is a certain kind of readiness: being prepared to look outwards from one's own situation, register a problem when it arises, and then actually jump in and do something. Let's make sure that it isn't just the men getting this crucial attention.

Gabriel Weston is an ENT surgeon, Surrey
gabriel.weston@nhs.net
Cite this as: *BMJ* 2019;365:l2388

A woman's chance of surviving to be discharged from hospital after having a cardiac arrest in the community is about half that of a man's

**PERSONAL VIEW** Natalie King

# Physician associates: we need to challenge the traditional hierarchy

Not allowing physician associates to become senior decision makers is a waste of their expertise, says **Natalie King**

Having supported the physician associate (PA) role for many years, I was eager to hear the debate at the recent BMA Junior Doctors conference on the role of medical associate professionals (MAPs). At the debate on 18 May, junior doctors voted to "actively oppose" MAPs being treated equally to them when it comes to medical staffing.

The BMA has previously stated that three quarters of medical specialties face doctor shortages, and although the debate was positive about new roles to support doctors the motions proposed centred on placing restrictions on MAPs.

Many of the points raised in the debate had validity, but a broad brush approach that treats MAPs as a single group fails to recognise the important differences and merits of the four professions. PAs practise across the breadth of medicine and—importantly—in general practice. They are a flexible workforce and the only MAP that can move across specialties as the need arises without significant retraining. The three remaining MAPs—physician assistants, surgical care practitioners, and advanced critical care practitioners—have been developed from within their specialties following years of clinical practice as well as specific training.

Each group therefore needs individual evaluation when considering the debated motions. Take, for example, medical rotas. PAs are able to competently take a history, examine, formulate a differential diagnosis, and instigate a management plan—which is useful for front door specialties and general practice. PAs are not doctors, however, and require consultant or GP supervision to ensure that they are not working outside their competency or adding to trainees' workloads. Trying to directly replace a doctor on a rota with a PA is unlikely to work. The contribution to rotas for other MAPs, however, may be different.

### Social media is no help

Employers are eager to recruit PAs but are unsure how to embed, supervise, and govern them. Where PAs are used as "quick fixes" to staff shortages they enter a medical workforce unprepared for them. This has no doubt made trainees anxious about the effect of PAs on their training and about what role they have in supervising them. Social media has added fuel to the fire, and the relationship between doctors and PAs has suffered as a result.

**BMJ OPINION** Anna Schumann

# Inflexibility is at the heart of the NHS specialty recruitment crisis

Only 37% of foundation doctors went straight into specialty training during the last recruitment round; this is a dramatic decrease from 71% in 2011. There is no doubt that the worsening state of the NHS has greatly impacted on junior doctors' wellbeing and enthusiasm for the profession. Instead of continuing straight into a training programme, many want to pursue other interests or work in other countries, while a significant number feel they would risk burnout were they to carry on.

A clear majority of doctors in training are positive about interrupting their clinical training. Despite that, throughout medical school and foundation training, proposing any deviation from the norm and investing in a portfolio career is almost always met with discouragement and words of caution by programme directors. But taking an "F3"—the widely used term for a year out before specialty training—has become the norm even if the stigma of taking time out is not shifting.

Quitting a training post and trying to re-enter later is still regarded as career suicide

Recently, we have made some progress, with increasing opportunities for taking time out of the training programme, if one can cope with the mountain of paperwork that goes with it. General practice, which is experiencing some of the most severe recruitment difficulties, is the only specialty currently considering deferred entry into training. Why are we waiting until crisis point before we make training more attractive to doctors? Allowances are made to interrupt training for exceptional circumstances, but why must I carry on unless I get sick or

The first year after qualification sees a steep learning curve during which PAs need support to consolidate their knowledge. Consultants and GPs worry that they will not have time to supervise another role in addition to their trainees. In reality, PA supervision is rather different and evolves with regular contact and development of the supervisor-PA relationship. With time, less support is needed.

A PA I know well has worked in the same specialty for six years with the same supervisor and is vital to his team; he is a generalist working in a medical specialty and as such has acquired significant clinical knowledge. He teaches on registrar simulation sessions, is able to competently perform and teach pleural procedures, and is trusted and valued for his opinion. While he will not and should not hold the title of consultant at any point as a dependent practitioner, he is very able to make what might be considered a "senior decision." The motion carried that PAs should not become senior decision makers when they have attained a level of experience and competence seems to me a waste of their expertise.

As doctors we need to be prepared to challenge the traditional hierarchy to ensure we keep the patient at the centre of what we do. There are simply not enough doctors, nor will there be any time soon. MAPs can widen access to healthcare and are entitled to be involved in determining their future development. We need to create mutually beneficial and supportive working arrangements matching demand by skill mix and not by title. Only by collaborative working will this be achieved. The last thing needed is further division.

Natalie King is a clinical lead for acute medicine, Surrey and Sussex Healthcare NHS Trust, UK natalie.king4@nhs.net

Cite this as: *BMJ* 2019;365:l2394

pregnant? The truth is, I do not think that NHS specialty recruitment can afford to make such rigid demands for much longer, as they will lose more and more doctors to other countries, alternative careers, or locum agencies.

Quitting a training post and trying to re-enter at a later point is still regarded as career suicide in the NHS, despite many specialties asking for a seven year commitment to training.

Our workforce will continue to decline in numbers and morale unless we realise that taking time out to pursue our passions, care for our families, or prioritise our own mental health really is investing in our career, not detracting from it.

Anna Schumann is a foundation year 2 in anaesthetics at Darent Valley Hospital, UK

**ACUTE PERSPECTIVE** David Oliver

# Lessons from the Babylon saga

The long awaited evaluation of Babylon's GP at Hand service has been published. Patients had fewer health problems than conventional users, were younger, and yet were higher users of NHS 111 and urgent care.

It noted that GP at Hand didn't provide the full range of conventional services and that expansion would affect IT, infrastructure, and the GP workforce. But it could "not fully assess whether GP at Hand is affordable or sustainable."

The saga of Babylon's entry to the NHS market raises several concerns.

First, independent evaluation matters. Babylon's medical director, Mobasher Butt, said that randomised controlled trials and peer review aren't so suitable for such quickly evolving technology. But other pragmatic evaluation is available. NICE has recently published guidance for evaluating new health tech. Let's adopt these standards when it comes to spending on new technology in a safety critical service.

Second, we need legislation to ensure that private companies contracting with the NHS are open to scrutiny and subject to the same disclosure requirements as NHS organisations. Doctors outside Babylon have raised concerns that advice given in response to symptoms they entered into the checker was misleading and potentially dangerous.

Third, ministerial codes should ensure that no health secretary promotes individual companies with the enthusiasm Matt Hancock has shown. This has drawn formal complaint from Labour about ministerial conduct.

Fourth, consider the impact and opportunity cost of any similar innovation on other service users. The Babylon evaluation exemplified the inverse care law, whereby youngish, educated urban professionals with low health needs consumed a disproportionately high amount of NHS resources.

Fifth, infrastructure is vital, in terms of financial payment mechanisms, affordability, and workforce.

Sixth—and most importantly—we must clamp down on aggressive marketing. The Advertising Standards Authority upheld complaints about Babylon's misleading adverts. Babylon also claimed that its symptom checker could outperform humans in the MRCGP exam, although researchers dispute this.

GP at Hand is being rolled out to Birmingham amid claims about the problems it will solve in urgent care.

But it's just one of many disruptive technology innovators wanting to enter the NHS market. We need a far tighter code of practice so that objective evidence is clearly distinguished from promotional and marketing claims made by commercial organisations seeking to profit.

David Oliver is a consultant in geriatrics and acute general medicine, Berkshire davidoliver372@googlemail.com

Cite this as: *BMJ* 2019;365:l2387

The Babylon evaluation exemplified the inverse care law

**PRIMARY COLOUR** Helen Salisbury

# The 10 minute appointment

GP appointments in the UK last on average 9.2 minutes, a considerably shorter time than in other rich nations, and there's no evidence that this is because our patients are healthier or have fewer questions. A recent report by the Royal College of General Practitioners suggested that all appointments should be at least 15 minutes long.

Very few GPs feel as though they can comfortably do a good job and provide holistic care in a 10 minute appointment. For some of my patients it takes more than a minute to walk the few yards from the waiting room and another minute to find the list of things they want to ask me. By the time we've negotiated the priorities for today and the patient has taken two more minutes to undress enough for me to listen to her chest, I'm pushing up against the allotted time. That's before I've tackled any of the agenda from the Quality and Outcomes Framework nag-box in the corner of my screen: checking blood pressure and organising tests, reviewing medication, or referring to diabetes prevention services.

I technically run 10 minute appointments, which work out at a bit over 13 minutes if you include my catch-up slots; in reality, my average time per consultation is about 16 minutes, which means that I usually run late. What's counted is the time the notes are open on my screen, so this includes a quick catch-up on the last consultation or hospital letter before I see the patient and then documenting the consultation at the end. Referrals have to wait until later.

It's probably time to quit the pretence that we can do a good job in a very short time, especially considering that the average number of problems discussed in each GP consultation is 2.5. If we timetable 10 minute appointments we can fit lots of them in, at least on the screen, but it means that patients are kept waiting, and stressed doctors work through their lunch break.

If we are realistic and recognise that good consultations usually take at least 15 minutes we will reduce our number of appointment slots by a third. Many surgeries have done this. The price paid is patients waiting longer for an appointment, and problems that might previously have waited a few days can transform into urgent demands for the duty doctor in the face of a three week delay.

In a brave new world of multidisciplinary teams some patients will consult nurses and physician associates instead, but in our experience these staff are even harder to find than GPs. Rearranging appointment lengths may reduce on-the-day delays and pressure on GPs—but it clearly won't solve the understaffing crisis in general practice.

Helen Salisbury is a GP in Oxford
helen.salisbury@phc.ox.ac.uk
Cite this as: *BMJ* 2019;365:l2389

It's probably time to quit the pretence that we can do a good job in a very short time

## LATEST PODCAST

### Who funds patient groups?

A recent analysis article in *The BMJ* found that from 2012 to 2016 the drug industry donated over £57m to UK patient organisations. In a new podcast, author Piotr Ozieranski explains the implications:

"We found that, overall, drug companies were far more interested in funding patient group activities related to policy engagement, lobbying, and also research . . . We are not saying that there is anything improper about receiving money from the industry. If patient organisations want to carry out their activities, drug company funding is something that they need to consider, so we need to be realistic about that. The concern that one might have is, given the scarcity of public funding, to what extent are patient groups able to maintain their independence and do the things that they would do naturally. It is very tricky and we do sympathise. The industry has got a lot more resources so we want to put the focus of attention a bit more on their side."

### The NHS and tech: A tale of two cultures

The NHS provides care for people free at the point of delivery, while tech has been defined by the maxim of Facebook founder Mark Zuckerberg, "move fast and break things." The health service is increasingly looking to harness the potential of digital tech, but can those two cultures be reconciled? In this podcast we hear from people working at that interface, including Neil Sebire, chief research information officer at Great Ormond Street Hospital, who says:

"There is a vast difference in the quality and amount of data that's required to show something from an academic clinical perspective, versus a tech company selling it or exposing it for venture capital. We have various tech companies saying, 'This is amazing, it's more than 95% effective at doing X,' and you say, 'Wow, you must have a study with thousands of patients there,' and they've got 22 patients."

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Edited by Kelly Brendel, deputy digital content editor, *The BMJ*

ANALYSIS

# Modernising vaccine surveillance to improve detection of rare adverse events

Amid measles outbreaks and public concerns over the safety of vaccines, **Rebecca Chandler** argues that we need to modernise vaccine pharmacovigilance to restore public trust

Even in countries with high vaccination rates, public concerns over the safety of vaccines are not uncommon.[1 2] This year, citing measles outbreaks, the World Health Organization declared "vaccine hesitancy" one of 10 threats to global health, and public health officials worldwide are leading efforts to increase vaccine coverage.[3] Current vaccine safety infrastructure needs to be reviewed to ensure its adequacy to address public concerns and to consider how improvements in the science of vaccine pharmacovigilance could help.

**When a new vaccine comes to market there is some uncertainty about its safety profile**

### Needles and haystacks

Before vaccines are licensed their efficacy has to be shown in clinical trials. The trials, however, are generally not powered to evaluate safety. Even phase III trials collect only limited safety data, mostly on common adverse events that occur shortly after vaccination, such as local and systemic reactions related to the immunogenicity of the vaccine.[4] As a result, when a new vaccine comes to market there is some uncertainty about its safety profile, specifically about rare events or those occurring a longer time after vaccination. Such effects cannot be detected until the vaccine is administered within large populations. That is the work of vaccine pharmacovigilance.

WHO defines vaccine pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and communication of adverse events following immunisation and other vaccine or immunisation related issues, and to the prevention of untoward effects of the vaccine or immunisation."[5] Pharmacovigilance is essentially a hypothesis generating activity whereby suspicions of harm spontaneously reported by manufacturers, healthcare providers, and patients in reporting systems give rise to questions of causality between medicines or vaccines and adverse events. Adverse event reports are collected and pooled into large databases in order to identify rare safety concerns in a timely fashion (box).

The response to several recent vaccine safety concerns shows the robustness of the current system. Examples include intussusception with the rotavirus vaccine RotaShield and narcolepsy with the 2009 H1N1 pandemic influenza vaccine Pandemrix. In each case, these signals were first detected from adverse event reports and were subsequently evaluated in epidemiological studies. These studies showed an increased risk of these events in vaccinated people, suggesting that the vaccines caused these events. However, the process can be slow. Cases of narcolepsy were first reported in Finland and Sweden in the spring of 2010, and although multiple studies reported an increased risk in association with Pandemrix,[8-12] the scientific community still disagrees on whether the relationship is causal.[13 14]

Below I use the example of HPV vaccines and postural orthostatic tachycardia syndrome (POTS) to highlight the difficult challenges faced by pharmacovigilance.

### HPV vaccines and POTS

The introduction of HPV vaccines into childhood vaccination programmes has resulted in lower infection rates and fewer cases of genital warts and cervical dysplasia,[15-18] but there have also been reports of suspected harm. The first of these emerged in 2013 with spontaneous reports of complex regional pain syndrome (CRPS) in Japan,[19] POTS in Denmark,[20] and long lasting fatigue in the Netherlands.[21]

POTS is a complex disorder of the autonomic nervous system, with an average time to diagnosis of 5 years and 11 months.[22] Patients with POTS typically experience multiple symptoms affecting multiple organ systems; primary symptoms include headache, dizziness, fatigue, abdominal pain. About 25% of patients with POTS are so disabled that they are unable to attend school or work.[23] Evidence is growing that POTS is an autoimmune disease—autoantibodies to numerous receptors within the autonomic nervous system have been identified,[24] although establishing their causal role is challenging.

In 2015, the European Medicines Agency undertook a review of the safety concerns of HPV vaccines in relation to POTS and CRPS. In its final report, EMA acknowledged the inherent difficulty in a review of these signals but concluded that the available evidence did not support a causal association between HPV vaccines and POTS or CRPS. No further regulatory actions were considered necessary.[25] As of early 2019, no formal epidemiological study has yet investigated the causality hypothesis generated from the hundreds of

### KEY MESSAGES

- The difficulty in assessing alleged serious harms from HPV vaccines shows weaknesses in current vaccine pharmacovigilance
- New data analysis approaches such as machine learning and systems immunology may allow us to improve monitoring of vaccine safety
- Such approaches will also advance knowledge of individual variation in immune responses
- Improving vaccine pharmacovigilance is essential to improving the public trust in vaccine policy

reports of POTS that continue to come into VigiBase, the global database of suspected adverse drug reactions, from physicians and patients worldwide.

**Hard to diagnose illnesses are invisible**

Signal detection for vaccines on the market is done in large databases of spontaneous reports of adverse events such as VAERS (Vaccine Adverse Event Reporting System) in the US and EudraVigilance in the EU. Routine surveillance of statistical signals is based on a pair-wise analysis that detects disproportionality between the number of observed versus expected reports of a single vaccine and a single adverse event (eg, pneumococcal vaccine and febrile seizure). The numbers of expected reports used in these analyses are statistical predictions using all reported vaccines and adverse events within the database, assuming there is no association between any single vaccine and event.

The non-specific symptoms of POTS made it hard for this system to detect. Early spontaneous reports of suspected harm after HPV vaccination included multiple events describing non-specific symptoms and signs such as headache, dizziness, and tachycardia. Furthermore, although the case reports often described multiple physician visits and debilitating symptoms, many did not meet official criteria for "serious" adverse events—a specific category meant to highlight potential harms in need of increased scrutiny. Nor did the majority of reports include a diagnosis or other "adverse events of special interest," which would also trigger further evaluation.

Because the system analyses single adverse events, it could not differentiate reports potentially describing POTS from those reporting the generalised systemic effects expected after vaccination. As a result, no further clinical review of these cases was considered necessary. Only after a few physicians diagnosed these cases as POTS and included this term on the adverse event reporting forms did the signal become visible in 2013.

**Lack of consensus on diagnosis**

Unfortunately, visibility of the signal is not enough. To validate and assess the detected signal, another type of analysis is performed, this time comparing the number of the reported adverse events with the number of cases of the event "naturally" expected to occur in that population (using estimates of disease incidence). This requires standardised case definitions such as those developed by the Brighton Collaboration.[26]

Since the pathophysiology of POTS has not yet been fully elucidated and its symptoms overlap with multiple other clinical syndromes, it could have been labelled inconsistently. Similar clusters of symptoms have been labelled on reporting forms as POTS in Denmark and CRPS in Japan. Others have proposed that the signal could be better described as chronic fatigue syndrome[27] or fibromyalgia.[28] Another suggestion is that the signal is best described by the underlying pathology, such as small fibre neuropathy[29] or autoantibodies to specific g protein coupled receptors, which are common to POTS, CRPS, and chronic fatigue syndrome.[30-32] Without clinical consensus on what the signal is, standardised case definitions cannot be applied.

**Rare events are important to individuals**

Signal evaluation requires testing of the causality hypothesis. This is done through epidemiological studies, typically using prespecified diagnostic coding from health insurance claims or electronic health records. Given that events as rare as 1 in 10 000 to 1 in 100 000 people may be important in a healthy, vaccinated population, large linked databases have been created in the US (VSD: Vaccine Safety Datalink) and the EU (ADVANCE: Accelerated Development of Vaccine Benefit-Risk Collaboration in Europe) to facilitate studies of sufficient power to detect small risks. Nonetheless, safety concerns in at-risk subpopulations may escape current epidemiological detection. One classic example is Guillain-Barré syndrome and tetanus vaccination: despite multiple observational studies showing no increased risk of the syndrome with tetanus toxoid containing vaccines at the population level,[33-35] there is a famous case report of a 42 year old man who received tetanus toxoid on three occasions over 13 years and developed a self limited episode of Guillain-Barré after each vaccination,[36] explained as "unusual susceptibility to Guillain-Barré syndrome."[35]

A literature review of reports of POTS after the HPV vaccine speculated: "if POTS does develop after receiving the HPV vaccine, it would appear to do so in a small subset of individuals."[37] There is some evidence of a potential common pathophysiology: autoantibodies to β2-adrenergic and muscarinic-2 receptors have been isolated from one person in the US[38]

**THE LANGUAGE OF PHARMACOVIGILANCE[6 7]**

Post-marketing pharmacovigilance comprises several steps:

*Signal detection* is the identification of a potential causal relationship. Signals can be detected from different types of data sources but most commonly from large databases of adverse event reports that are routinely screened by statistical methods

*Signal validation* is the process by which the data supporting the signal are evaluated to determine whether further analysis for a new causal relationship between the drug/vaccine and adverse event is justified

*Signal assessment* is the review in which all available evidence is considered in the development of a causality hypothesis. Signal assessment in pharmacovigilance relies on the Bradford Hill causality criteria

*Signal evaluation* is the testing of causality hypotheses, typically using observational databases to estimate the risk of occurrence

and in a large proportion of a sample of patients in Denmark (J Mehlsen, personal communication). Schofield and Hendrickson proposed the existence of a subgroup vulnerable to autoimmune dysautonomia after HPV vaccination and called for research to define the phenotype or genotype of those who are at risk.[39]

**Adverse events have been shown to be under-reported in journal publications**

### Barrier of reporting bias

Systematic reviews of randomised trials can be used to investigate rare harms reported after the vaccine is marketed provided that the trials are large enough and have adequate follow-up time. However, adverse events have been shown to be under-reported in journal publications, the main source for most systematic reviews.[40]

Jørgensen and colleagues tried to conduct a systematic review of the association between HPV vaccines and POTS using clinical study reports instead of journal publications. They began by creating an index of HPV vaccine clinical studies, from which they found that only half (38/79, 48%) of the manufacturers' randomised clinical trials and follow-ups of Cervarix and Gardasil were included in the EMA review of POTS and CRPS.[41] Three years after requests to regulators and manufacturers, the independent investigators obtained only half of potentially eligible reports for their systematic review, and even they were incomplete and contained redactions.[42]

### Responding to challenges

New challenges in vaccine safety surveillance are on the horizon and must be met with methodological innovation. Vaccines with novel adjuvants may lead to more complex types of adverse events that are difficult to detect. Direct introduction of new vaccines into resource limited countries is another challenge, as such countries may lack diagnostic capacities or local epidemiological data, complicating the use of standardised case definitions. Also, several recent vaccine related safety concerns that have received substantial public attention (Pandemrix and narcolepsy, Dengvaxia and severe dengue, Stamaril and yellow fever vaccine associated viscerotropic disease) have suggested there are individual level risk factors for these adverse outcomes; it is our duty to openly acknowledge these events and commit ourselves to understanding what happened in these cases to ensure public trust.

Different approaches to data analysis and the application of machine learning may allow us to more readily identify unexpected, complex clinical syndromes. After we were asked to put reports of POTS from Denmark in a global context, my group at the Uppsala Monitoring Centre applied a non-traditional method of signal detection. We used a data driven approach to identify clusters of HPV vaccine reports with similar patterns of adverse events, rather than relying on signal identification from single specific diagnostic terms. Most reports in our cluster of concern described the same clinical scenario (long lasting, debilitating symptoms of headache, dizziness, and fatigue) but did not include a diagnosis of POTS; furthermore, other cases in our cluster reported similar diagnoses such as chronic fatigue syndrome, postviral fatigue, and even fibromyalgia.[43] Further methodological development is needed to apply this approach more broadly.

The emerging field of systems immunology aims to describe the complexity of the immune system by measuring its multiple individual components and predicting their interactions with each other using computational mathematical methods. Knowledge from systems immunology can further our understanding of the way vaccines work, and the tools have been used to explore biomarkers of vaccine safety. Initiatives such as BIOVACSAFE are under way systematically to identify biomarkers of relatively common inflammatory events induced by adjuvanted vaccines on the market.[44] Application of such technologies has shown variation in the molecular signature between those who did and did not experience adverse events after receiving adjuvanted H1N1 vaccine.[45] Further exploration into biomarkers may allow us to identify people at risk of rare adverse events such as atopy and autoimmunity.[46] Danish researchers have recently published plans to use systems vaccinology to investigate biomarkers for people at risk of developing adverse events after HPV vaccination.[47]

The current system of vaccine pharmacovigilance is designed to detect common, well characterised harms and to estimate risk at the population level. It is also designed for regulators and policy makers rather than those seeking to advance scientific knowledge about how vaccines cause adverse reactions. Advances in machine learning and systems immunology will enable us to understand the heterogeneity of responses and to optimise vaccines and their use in public health programmes. Improved communication to the public is also required. As we move away from "one size fits all" approaches, more nuanced messages will be needed to reflect the scientific advances that allow us better to appreciate individual variation in immune responses to vaccination.

Rebecca E Chandler. research physician, Uppsala Monitoring Centre, Uppsala, Sweden
rebecca.chandler@who-umc.org
Cite this as: *BMJ* 2019;365:l2268

# LETTERS Selected from rapid responses on bmj.com


LETTER OF THE WEEK

## Climate change: public health responsibilities

Stott et al's editorial is as timely as the Extinction Rebellion protests and Greta Thunberg's blunt warnings (Editorial, 4 May). Climate change together with ecosystem damage and biodiversity loss are by far the greatest public health threats of the century.

Public health professionals have a responsibility to recognise, warn about, and help society to deal with threats to public health, and climate change is no exception. All but the most wilful deniers now recognise the existence, if not the scale, of the problem. We must warn of the consequences. The GMC should make it clear that non-violent protest warning of substantial risks to health, even if it leads to criminal charges, is consistent with, rather than contravening, the duties of a doctor. Directors of public health and chief medical officers should warn that, unless politicians take urgent action, the health of the populations for whom they are responsible will suffer.

Environmental sustainability should be a key consideration in all planning, commissioning, and procurement of health and social care services and should be made a statutory responsibility of NHS authorities and local government. NHS organisations should have carbon budgets, reducing over time, that are rigorously performance managed, and NICE should tailor its guidance to help them meet the resulting constraints.

Public health professionals must continue, through our contribution to emergency planning, to help society respond to the environmental and other catastrophes that are inevitable as the climate warms and will become even more frequent if we do not take immediate action.

**Jeremy Wight, chair of sustainable development special interest group, Faculty of Public Health**
**John Middleton, president, Faculty of Public Health**

Cite this as: *BMJ* 2019;365:l2371

**Public health doctors have duty to warn**

LESSON FROM SCHOOL PUPILS

## Overpopulation is the elephant in the room

There is very little to argue against in the editorial by Stott et al (Editorial, 4 May), but I have noticed that human population growth is rarely mentioned by the "green" environmental movement.

We can all make more environmentally conscious life choices and "vote only for representatives who prioritise climate change," but this is not enough. Even if every single person in the world reduced their carbon footprint, humanity would still have a massive collective carbon footprint, with our global population of about 7.7 billion in early May 2019.

Global overpopulation is the elephant in the room, which many environmentalists don't see, won't see, or prefer not to talk about.

Unless we moderate population growth, we will remain on a dangerous climactic thermal trajectory, despite the best efforts of Extinction Rebellion and others. We must take every possible step to counter this climate emergency that threatens our existence.

**Gee Yen Shin, consultant virologist, London**

Cite this as: *BMJ* 2019;365:l2373

MORAL INJURY

## Physician burnout: moral injury is a questionable term

Use of the term "moral injury" in medicine (Sixty Seconds, 4 May) is highly inappropriate. Suggesting equivalence between the experience of warriors and the (very real) stresses of medicine is naive and is demeaning to those who defend their countries.

Proponents of moral injury usually assert other dubious corollaries. The term "burnout" doesn't blame physicians or absolve healthcare systems of responsibilities. The discussion of individual approaches to enhancing resilience often has a condescending tone, including the mistaken belief that resilience cannot be taught or developed. Multiple examples of effective resilience training exist—in the military, the police, and firefighting.

Introducing questionable terminology obfuscates the need to develop strategies to prevent and mitigate physician distress. I am not arguing unequivocal support for the term burnout, as there are legitimate questions about its nature. But the term moral injury in medicine should be gone in 60 seconds.

**Michael J Asken, director, Provider Wellbeing, UPMC Pinnacle Health Hospitals**

Cite this as: *BMJ* 2019;365:l2375

INACTIVITY AND HEALTH

## Public health informed by evidence

Kivimäki et al show that physical activity probably has no effect on dementia risk (Research, 4 May). This is bad news for population health, but it could be good news for evidence based public health.

Using an interesting data analysis approach, the authors could limit the risk of reverse causation and move from a prediction exercise to a true causal inference study. Observational epidemiology aiming to address causal relations has suffered major drawbacks, notably in nutrition and environmental science; if confirmed, the null finding in the study by Kivimäki et al could uncover a new drawback of observational studies.

Such failures are dangerous for public health. To better inform evidence for public health, we must move towards a postmodern epidemiology, clearly distinguishing description, prediction, and causal inference in observational studies and taking advantage of new methods in causal analyses.

**Arnaud Chiolero, public health physician and epidemiologist, Bern**

Cite this as: *BMJ* 2019;365:l2379

SCREENING FOR ATRIAL FIBRILLATION

## Waiting for randomised trial data

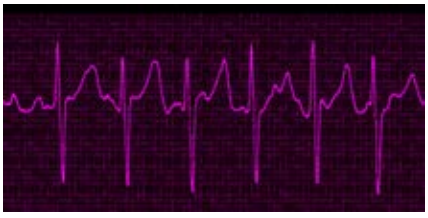
We agree with Berge that Wilson and Jungner would not approve of screening for atrial fibrillation (Letters, 6 April). The key problems are that we do not know whether screen detected atrial fibrillation carries the same risk of stroke as disease that is clinically detected and that the treatment, anticoagulation, has adverse effects.

Screening programmes should "do more good than harm at reasonable cost", unless we have robust evidence that finding and treating atrial fibrillation in an asymptomatic population reduces stroke rates or mortality without relying on lead time and volunteer bias—and can do so without conferring significant morbidity from anticoagulation—we can't recommend the introduction of a national screening programme.

Such evidence can only be obtained in randomised trials, where randomisation takes place at the point of invitation to screening. Studies are under way and will be given full attention by the UK National Screening Committee when they report.

**Robert Steele, independent chair**
**John Marshall, evidence lead**
**Anne Mackie director of screening, UK National Screening Committee**

Cite this as: *BMJ* 2019;365:l2383



LEARNING DISABILITY

## Managing challenging behaviour —a parent's perspective

"She is quite obviously not behaving normally." I don't remember much more of the first consultation we had with our GP when my daughter was 15 months old. We had some concerns about her delayed development and behaviour, but this was not the comment we were expecting.

Absoud et al provide a thorough and clear summary of the issues and proposed clinical pathway for managing challenging behaviour in children with possible learning disabilities (Practice Pointer, 4 May). But they don't mention the importance of kindness. That first consultation may be the first time the parents have faced the possibility that their child will not develop "normally"—the first time that their hopes for the future must be readjusted. It is difficult to describe the emotions that follow this news. The words of that GP resonate in my head 10 years later; sadly, I know we are not alone.

**"Not behaving normally"—the words of that GP resonate in my head 10 years later**

**Sarah A Logan, consultant in general internal medicine and infectious diseases, London**

Cite this as: *BMJ* 2019;365:l2395

EFFECT OF PATIENT CHOICE

## Commercialisation of healthcare is fatally flawed

Hawkes reports that introducing competition into the NHS to increase quality has had the opposite effect for some elective procedures (This Week, 20-27 April).

When correctly delivered, healthcare is not and never can be a commercial undertaking. Clinical choices should be guided by the most reliable evidence available—which should include the risks inherent in profit driven provision, especially the potential conflicts of interest and incentives.

The concept of a market in healthcare is fatally flawed because the "rational agent" on whom it is founded does not exist. The rational agent is assumed to take account of available information, probabilities of events, and potential costs and benefits and to act consistently in choosing the best path of action. Such patients are rare.

The notion of choice is further impaired by the circumstances in which choices have to be made, when illness, injury, suffering, or the apprehension of death cloud judgment.

**Steven Ford, retired general practitioner, Haydon Bridge**

Cite this as: *BMJ* 2019;365:l2324

ARE GPs DOING TOO MUCH?

## Clinical work has become boring

Surely Mathew is wrong in arguing that GPs are doing too much (Rammya Mathew, 4 May). We have reduced our range of clinical work so much it has become less stimulating and even boring. I used to do on-call work, obstetrics, minor surgery, musculoskeletal medicine—and, yes, electrocardiograms (ECGs). It was satisfying and interesting.

What I did not have was the Quality and Outcomes Framework, the Care Quality Commission, lots of guidelines, and demand from anxious patients stimulated by awareness campaigns. Medicine has also taken on the role of priest, which, frankly, we are rubbish at.

Now we have "first contact physio," so we are deskilled in musculoskeletal medicine, we have no role in obstetrics, we can't do minor surgery, and we are deskilled in acute care.

It's not ECGs we must cut down on, but all the rubbish that we have had forced on us in recent years.

**Edmund A Willis, GP locum, Brigg**

Cite this as: *BMJ* 2019;365:l2396

## Rediscover the joy of general practice

If anything, GPs are not doing enough. The appeal of being a GP is the broad range of activities.

In the past few weeks I have attended a patient with stroke thrombolysis and a major trauma call. I have GP colleagues who work on the consultant physician rota in a rural hospital, provide secondary care dermatology services, run diabetes clinics, respond to pre-hospital emergencies, and run a hyperbaric chamber treating decompression sickness. Not to mention those who provide the full range of medical services 24/7 to remote island communities of several hundred people with no other medical cover available.

I encourage Mathew (or anyone else who feels overwhelmed) to rediscover the joy of general practice. Many flexible opportunities are available.

**N J Shepherd, rural hospital practitioner and locum GP, Wick**

Cite this as: *BMJ* 2019;365:l2397

## OBITUARIES

### Manubhai Dahyabhai Tailor

**General practitioner Worcester and Great Witley, Worcestershire (b 1937; q Birmingham 1962), died from progressive Alzheimer's disease on 18 March 2019**

Manubhai Dahyabhai Tailor ("Manu") moved to the UK from his native Kenya in 1955. After completing his houseman's year in Birmingham, he returned to Kenya to pursue a career in general practice. In 1983 he returned to the UK and eventually joined a rural practice in Great Witley, Worcestershire, where he became involved in setting up an integrated health centre. He worked at the practice until he retired in 2007. Manu enjoyed travelling, particularly going on cruises, and he visited many places around the world. Unfortunately, his active retired life was cut short by the onset of dementia in 2013. Predeceased by his wife in 1996, he leaves a daughter.

**Satish Mehta**

Cite this as: *BMJ* 2019;365:l2243

### Thomas Burnett Hogarth

**Consultant paediatric and adult ear, nose, and throat surgeon Nottingham (b 1923, q Leeds 1948; FRCS Ed), died from old age on 9 May 2019**

Thomas Burnett Hogarth ("Tom") joined the Royal Army Medical Corps (1942-48) and was attached as a regimental surgeon to the 1st/10th Gurkha Rifles in Malaysia. He first came to Nottingham as a house surgeon in the 1950s. In 1958 he changed his career to ear, nose, and throat surgery and was appointed consultant in Scarborough in 1960. In 1964 he was invited to apply for the consultant post in Nottingham after the sudden death of one of the surgeons. Tom retired in 1988. His interests included sailing, fishing, and "light" conversation. He lived in Thurgarton, Nottingham, until advancing age and illness restricted his mobility and he moved to a care home in Formby to be near his family. He leaves two children and grandchildren.

**Patrick J Bradley**

Cite this as: *BMJ* 2019;365:l2300

### Jan Kuzemko

**Paediatrician (b 1933; q National University of Ireland, Cork, 1958; DRCOG, DCH, MD, FRCP Ed, FRCP Lond), died after a stroke on 31 January 2019**

Jan Kuzemko was born in Krakow, Poland, and was smuggled out to the UK through Germany in a Red Cross truck at the age of 12. He was a junior doctor in Rochdale, Oxford, and Liverpool. As consultant general paediatrician at Peterborough District Hospital for 28 years, he specialised in asthma, allergy, cystic fibrosis, and neonates; he retired in 1996. His publications included 57 academic papers and six books. He spoke at over 50 national and international conferences and was president of the paediatric section of the Royal Society of Medicine. Jan's interests included his family, music, opera, the *Times* crossword, and sports. He died peacefully with his family around him. He leaves Janet, his wife of 58 years; three sons; and five grandchildren.

**Elaine Carter , Janet Kuzemko**

Cite this as: *BMJ* 2019;365:l2302

### Dennis Thornton Price

**General practitioner Handforth, Cheshire (b 1930; q Manchester 1961; MRCGP), died from a small bowel obstruction 6 December 2018**

Dennis Thornton Price graduated in chemistry in 1953 before studying medicine at Manchester University. He started practising as a general practitioner in Hyde, before joining a local practice in Handforth, Cheshire, in 1964, where he became senior partner in 1972. His research secured agreement and funding for the first purpose built health centre in the area. Completed in 1976, the centre offered a range of community health and pharmacy services. When mandatory vocational training was introduced in the late 1970s, he became one of the first local GPs to become a trainer. After retiring in 1996 Dennis dedicated his time to caring for his wife, Heather, until her death in 2005. He leaves three children and five grandchildren.

**Gill Price**

Cite this as: *BMJ* 2019;365:l2297

### Martin Cooper

**Medical director Royal Devon and Exeter NHS Foundation Trust (b 1947; q Royal Free Hospital Medical School 1971; MS, FRCS), d 24 November 2018**

Martin Cooper was appointed to the Royal Devon and Exeter Hospital as a consultant general surgeon with an interest in upper gastrointestinal and breast disease in 1988. He became clinical director of surgery in 1992, and in 1995 he led the successful process of cancer centre registration. He was clinical director of cancer services until 2009 and went on to become medical director of the Peninsula cancer network, clinical director of cancer services in Exeter, and eventually the hospital's medical director. He retired in March 2015. From 2014 he was a patron of the Exeter based cancer charity FORCE (Friends of the Oncology and Radiotherapy Centre Exeter). Martin leaves his wife, Joan; a daughter; and two grandchildren.

**Trina Lake**

Cite this as: *BMJ* 2019;365:l2230

### Frank Ivor Tovey

**Consultant surgeon Basingstoke and District General Hospital (b 1921; q Bristol 1944; OBE, ChM, FRCS), died from bronchopneumonia on 29 April 2019**

Frank Ivor Tovey was accepted by the Methodist Missionary Society (MMS) for service overseas in 1945. In 1948, as a qualified surgeon, he and his new wife, Winnie, travelled to south west China to work in a 40 bed hospital. They left before the final Communist takeover. Frank's next posting with the MMS was in 1951 to Holdsworth Memorial Hospital in Mysore, south India. In 1966 Frank was awarded an OBE for his surgical work in India. In 1967 the family moved back to the UK and from 1968 to 1986 Frank was consultant surgeon to Basingstoke and District General Hospital. Predeceased by his wife, he leaves four children, seven grandchildren, and nine great grandchildren.

**Rosemary Dove**

Cite this as: *BMJ* 2019;365:l2305

# Richard Lacey

Microbiologist who came under fire for claiming a link between mad cow disease and variant CJD in humans

**Microbiologist who came under fire for claiming a link between mad cow disease and variant CJD in humans**

Richard Lacey was the dissident University of Leeds medical microbiologist who was ridiculed in 1990 for suggesting a possible link between the cattle disease bovine spongiform encephalopathy (BSE) and its human variant, Creutzfeldt-Jakob disease (CJD).

Vindicated in 1996, Lacey stands out as one of the most controversial figures in British medicine over the past 50 years. He was acclaimed as brave, fearless, and totally principled and as one of the few academics who did not weigh his career prospects against his beliefs. He was also denounced as a panic monger with a penchant for worst case scenarios based more on guesswork than solid science.

### "Unfit for human consumption"

Lacey hit back at his critics in the early 1990s with the polemics *Unfit for Human Consumption, Hard to Swallow*, and *Mad Cow Disease*. Unusually, if not uniquely, for an academic, he also appeared in a BBC thriller on BSE called *Natural Lies*. (He was not a shy man.)

It is easy to see why this balding, portly, ruddy faced figure was so contentious. A walking definition of the awkward squad, he spoke his mind, irrespective of the consequences, recognising that officialdom often reacts more quickly to controversial media reports than to the quiet voice of reason.

The *Times* denounced him as a terrorist and a Tory MP as a "bogus professor." Angry correspondents in the farming press even described him as an agent of the former Soviet Union. In turn he alleged that MI5 had tapped his phone and exposed him "to some real nastiness, a lot of it of a very personal nature."

In one of his most outspoken media interviews, for the *Sunday Times*, he called for the slaughter of all BSE infected herds. The article was accompanied by the headline, "Leading food scientist calls for slaughter of six million cows." This led to reassuring press releases from the Ministry of Agriculture, Fisheries, and Food (MAFF) and the pantomime of the then secretary of state, John Gummer, feeding his daughter Cordelia a hamburger before a bank of TV cameras. Gummer insisted that British beef was safe.

Lacey was roasted by a parliamentary select committee for a "tendency to extrapolate sensational conclusions from incomplete evidence," for promoting a "mixture of science and science fiction," and for being out of touch with the real world. But the then health secretary, Stephen Dorrell, later conceded that there might be a link between BSE and CJD.

Reassurances that the ban on brain, spinal, and other high risk beef offal being used in human food meant that the risk of eating beef was minimal did not allay public fear—especially in the face of Lacey's description of vCJD as "the time bomb of the 20th century, equivalent to bubonic plague."

The government decided that a cull of 4.4 million cattle was the only way to restore public confidence, despite the vast cost to farmers and the taxpayers. By 2017, 178 definite or probable cases of vCJD had been officially identified in the UK.

### Lone voice

Lacey often seemed to be a lone voice, although one of his former colleagues said that MAFF scientists agreed with his conclusions, but were "scared stiff" to say anything. At the time, he added, MAFF was closing down research stations to save money, and people feared for their jobs.

Lacey's rebellious nature emerged at Felsted School in Essex, where his housemaster admonished him for his "bad attitude." Hating games and cold baths, he hid in the biology laboratories. But he shone academically, reading medicine at Cambridge. He was later appointed as reader in clinical microbiology at the University of Bristol. After a spell as a consultant in King's Lynn he became professor of medical microbiology in Leeds in 1983.

He joined the MAFF veterinary products committee in the mid-1980s, but resigned in 1989, alleging that "the pharmaceutical industry, MAFF, and the vets were manipulating the drugs for commercial gain." True to form, he did not go quietly but complained to the media that the committee lacked independence. This followed his robust defence of health minister Edwina Currie's highly controversial claim that British eggs contained salmonella—a claim that destroyed her political career. In 1994 a health service manager made a surprise visit to Lacey's department in Leeds—which was 60% funded by the NHS—and announced that all his staff were to be transferred to another authority. This meant that although Lacey would continue to be paid, he could do no work.

He took early retirement at the age of 58 to potter in his garden, paint, and make a small fortune from his antique collection. He published his autobiography, *Poison on a Plate*, in 1998. In 1972 he married Fionna Stone. They had two daughters.


A walking definition of the awkward squad, Lacey spoke his mind, irrespective of the consequences

EYEVINE

John Illman, London, UK john@jicmedia.org

Cite this as: *BMJ* 2019;364:l1078