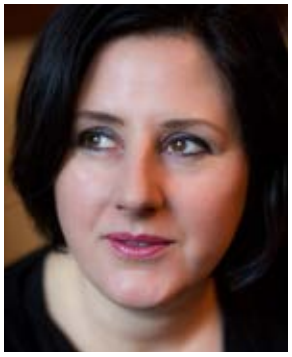
> Health screening advertisements should be independently vetted before publication or distribution, at cost to the advertiser

NO HOLDS BARRED Margaret McCartney

How private screening costs the NHS

It had to happen eventually: Bluecrest Health Screening has sent me my very own invitation for one of its private health assessments.



The invitation included a venue, a date, and a request that I call them to organise a time. The company takes out full page advertisements in national newspapers, claiming that you can "Help avoid a stroke with your New Year Health MOT" and asking, "Why leave your health to chance when you can be in control?"

The company offers "Five free tests when you accept in the next 28 days." Its tests include body fat percentage; "hydration levels"; height, weight, and body mass index percentages; and a QRISK2 assessment. Customers are also offered a "prostate cancer test" or "ovarian cancer test" and a "standard health screen," which includes blood pressure, liver function, full blood count, ferritin, renal function, glucose, lipids, and electrocardiography. If you're over 50 you may also be offered an "exclusive extra free offer" of a lung function test that can "detect COPD before any symptoms are apparent."

Over the years I've been contacted by many people who told me that they, or a family member, had taken up this offer because they thought that it was recommended by their doctor or would save the NHS money. In fact, Bluecrest encourages patients to "take your report to your GP to discuss any readings that cause you concern."

This is an outrage. Bluecrest offers non-evidence based screening, advertises using false and misleading information, and implies that the NHS doesn't offer screening at all. It implies that not having the screening misses an opportunity to control your health, overlooking the fact that all patients can already see their own NHS professional for cardiovascular risk screening. Bluecrest can then put the work associated with false positives and anxiety back onto the NHS while walking away with the profit.

The Advertising Standards Authority (ASA) has upheld each of three aspects of my complaint about this company.[1] Bluecrest will no longer be allowed to say that screening for peripheral arterial disease will reduce cardiovascular risk, and it can no longer advertise prostate specific antigen or CA-125 tests as "cancer tests."

This is a good result, but it's taken months, and I'd rather have spent that time doing other things. It's also not the first time a complaint about a Bluecrest advertisement has been found in breach by the ASA, and it doesn't deal with the longer term problems caused by screening of this sort.

Tackling these problems requires two actions. The first is that, given the risk to the public, health screening advertisements should be independently vetted before publication or distribution, at cost to the advertiser. The second is that companies that provide and promote health screening (and Bluecrest is just one of them) should be required to take out private insurance for follow-up of any non-UK National Screening Committee recommended tests—or be billed by the NHS for follow-up work.

Margaret McCartney, general practitioner, Glasgow
margaret@margaretmccartney.com
Twitter: @mgtmccartney

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ETHICS MAN Daniel Sokol

Knocking out written reflections

Self awareness improves performance, but committing it to paper is not the best way to do it

In a bid to lose my belly, which has expanded at such a rate that my trousers no longer fit, I have taken up boxing. In my second sparring session I fought "the Viking." Despite his bulk, he was so elusive that I was unable to hit him. He, on the other hand, punched me so hard and so often around the head that I suffered whiplash for three days.

In the following days I reflected on what happened. Why did I miss? Why was I such an easy target? What could I do differently? Identifying and avoiding mistakes were a priority for me because, frankly, being hit hurts.

Whether in boxing or medicine, meaningful reflection is crucial for improvement. Removed from the heat of the action, we can achieve greater clarity of mind and avoid repeating mistakes.

Meaningful reflection and self awareness undoubtedly benefit doctors. Yet, the recent case of Hadiza Bawa-Garba, in which a trainee paediatrician was struck off the register for her role in the death of a 6 year old from sepsis, has caused many doctors to question the wisdom of putting their reflections on paper. In Bawa-Garba's case, excerpts from a reflective document in her e-portfolio, completed a week after the incident, were referred to in her hearing at the medical practitioners tribunal.

Coaching sessions with someone who knows their way around the ring is the best way for doctors to reflect

The practical lesson here is that reflective pieces are not beyond the reach of lawyers. Written reflections are not protected by absolute confidentiality, so be careful what you write.

The case raises a broader question: are compulsory, written reflective exercises the best way to encourage meaningful reflection?

ACUTE PERSPECTIVE David Oliver

The Bawa-Garba case, doctors, and the GMC—what next?

Since the High Court ruled in January that the trainee paediatrician Hadiza Bawa-Garba must be struck off the UK medical register, much has happened that may change how NHS doctors work, how we're regulated, and how we raise concerns.

The General Medical Council (GMC) and the government have both announced reviews of how gross negligence manslaughter is applied to medical practice. Both reviews will make recommendations, but neither will have the power to make coroners' decision making fairer to doctors. Nor can these reviews alter the common law tests for gross negligence or the fact that such cases are tried by juries without medical experience or expertise.

Much has happened that may change how NHS doctors work, how we're regulated, and how we raise concerns

The GMC has put out a "frequently asked questions" document in response to concerns raised by doctors. When conditions feel unsafe, the document says, doctors should definitely not refuse to work but should ensure that they've reported concerns about staffing levels and workload up the line.

They should write a reflective entry about how unsafe it felt working in difficult conditions and, whatever they do, they shouldn't stop writing open reflections on their practice or stop being open and candid in discussing risks, inadvertent error, and harm.

After a summit with the BMA, the GMC also made a series of pledges. It would never ask doctors under investigation to provide their reflective statements; would collaborate with the Academy of Medical Royal Colleges and BMA in producing better guidance on reflection; would push for more standardised exception reporting throughout England; and would work with the BMA and wider medical profession to improve how doctors of all grades can raise safety concerns about working in an under-resourced environment.

The Medical Protection Society agrees that doctors must continue to be open and honest and to write written reflections. It says that Bawa-Garba's reflective diary did not form part of the evidence before the court and jury, but it acknowledges that her reflections may have "fed into the trial."

The GMC has also produced a "How do I raise concerns about

Role of coaching

The surgeon Atul Gawande, in a recent TED talk, spoke about the role of coaching in improving performance. He wondered why professional athletes have coaches, even those at the top of the world rankings, but doctors don't. Inspired by a conversation with the great violinist Itzhak Perlman, whose wife gave up her career as a concert violinist to be her husband's music coach, Gawande asked a retired professor of surgery to "coach him in the operating room."

Gawande said, "I didn't think there would be anything much he'd have to say when we were done. Instead, he had a whole page dense with notes. That one 20-minute discussion gave me more to consider and work on than I'd had in the past five years." As a result of this coaching, Gawande's complication rate dropped.

More effective and engaging than the written reflective piece would be to offer trainees "coaches" to discuss cases and performances, give insights, and prompt reflection, in one to one or seminar-style settings. Coaches may see what we cannot—like Gawande's coach, who noticed that the light had swung away from the wound and that Gawande was operating under reflected light. They usually have greater knowledge or experience. Face to face meetings with trusted coaches could also reduce the reluctance of trainees to make observations that might be used in subsequent legal proceedings.

All doctors fight in a metaphorical ring, seeking to beat a tough opponent, and will inevitably connect with a hard shot at some point, whether it's a relative's complaint, a patient's death, or a period of self doubt. When that happens, they should reflect on it, not by writing a text but through "coaching sessions": by talking to, and learning from, someone who knows their way around the ring.

Who is best placed to act as a coach is open to debate. What is plain is that the requirement to reflect should not be a formulaic tickbox exercise but a central aspect of the quest to improve and grow as practitioners of an art of infinite complexity.

Daniel Sokol, medical ethicist and barrister, London daniel.sokol@talk21.com

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inadequate staffing?" flowchart to guide doctors on what to do if they arrive at work and find that conditions are unsafe or putting them or their patients at risk. I realise that the flowchart was produced in good faith, but it's been widely lampooned as being out of touch with daily realities on the front line, where rota gaps and short staffing are the new normal.

Do doctors in already short staffed teams really need to spend time on all of this documentation rather than seeing patients and supporting colleagues? Why can't reporting be just a one or two click app? Besides, hospitals already know how overcrowded they are, where the rota gaps are, and whether IT systems or equipment are broken. Why should doctors waste clinical time reporting staffing and workload pressures, when it seemingly won't protect them from being held individually accountable in criminal law anyway?

It will be interesting to see how much this all helps the profession or patients. If it throws a bright spotlight on our current NHS staffing crisis and increasingly unmanageable workload, as well as some of the broken systems in and around acute care, I'd welcome it. In the court of opinion of the doctors it regulates, the GMC has been found wanting. We should perhaps appeal to the profession to give those doctors a chance to clear their name and move us forward constructively.

David Oliver, consultant in geriatrics and acute general medicine, Berkshire
davidoliver372@googlemail.com
Twitter: @mancunianmedic

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BMJ OPINION Nishma Manek

The real gatekeepers of general practice

New to a GP practice, I was recently asked to spend an afternoon with our practice receptionists. I wasn't sure what to expect, but that day gave me a new understanding of what they really do—and a realisation that it's one of the hardest jobs in primary care.

Fielding those who inevitably feel fobbed off in a system under pressure, day in day out, can't be easy. As GPs, we often consider ourselves to be "the frontline." But we're not really—receptionists are.

They might be the first people to hear the pain that illness stirs, the first to see the strain that it uncovers, and the first to be casually offered some specimen of bodily fluid as a greeting. Or even, as they told me, an envelope stuffed full of faeces from a patient who didn't quite follow the instructions.

The rewards felt few and far between. Like GPs, receptionists are exposed to the grit, the love, and the turmoil that exists in our community, witnessing the emotions that gather in the waiting room. But they can't do much to disperse them or step into the thick of it. Perhaps that's not what they go into the job for—but I wonder if that makes it harder. Because what's left felt like a pretty thankless task at times.

Receptionists offered their patience and kindness unreservedly

That afternoon showed me that there is a silent expectation of professionalism in the consulting room that isn't always evident at the door. And yet the receptionists offered their patience and kindness unreservedly, without much exposure to it themselves.

Like all of us, they may not always get it right. But they usually do. I've seen them placate a waiting room of fuming patients. And sometimes, without decades of medical training, act on instincts that change a patient's entire trajectory. They know our patients just as well as we do, and sometimes their astute observations make a bigger contribution to the patient's care than anything the GP might have done.

As GPs, we mourn the lack of time that we have for our patients thanks to rising demand, increasing complexity, and mounting reels of red tape. But our receptionists experience all of that too, while having to bear the heat of emotion it draws from patients.

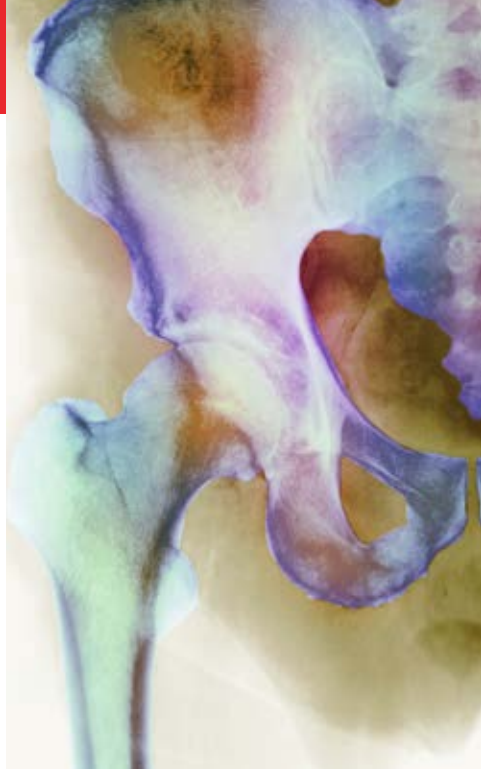
As we plough on through 2018, let's spare a moment to thank the people holding the whole thing together—our GP receptionists. Because, in truth, they're the real gatekeepers of general practice.

Nishma Manek, GP trainee, Cambridge

ANALYSIS

Metal-on-metal hip implants: is the new guidance on patient follow-up justified?

Recent recommendations for the surveillance of people with joint replacements are onerous, costly, and insufficiently evidence based, argue **Gulraj S Matharu and colleagues**



Metal-on-metal hips were commonly used in young active patients with arthritis, with about 1.5 million implanted worldwide.[1-3] However, the devices experienced high short term failure rates,[4 5] and many patients have had to have revision surgery because of abnormal reactions to materials generated by the implants (collectively termed adverse reactions to metal debris).[1-6] Metal-on-metal hip implants are now rarely used.[1 2]

Failure of conventional hip implants is associated with symptomatic bone damage and requires revision with a larger implant. However, adverse reactions to metal debris from metal-on-metal implants are associated with destruction of soft tissue (muscles, tendons, neurovasculature) as well as bone. The soft tissue destruction is often irreparable,[7 8] resulting in many patients doing poorly after revision procedures.[8] Furthermore, irreversible bone and soft tissue damage can occur without noticeable symptoms.[9] A few patients also develop systemic symptoms from exposure to high levels of metal ions, though these usually resolve after revision surgery (box). Reassuringly, large cohort studies have reported that patients with metal-on-metal hips are not at increased risk of cancer, heart failure, or death compared with patients with conventional hip replacements.[13-17]

Systemic effects of high metal ion exposure[10-12]

- Neurological
- Hearing impairment or loss
- Visual impairment or loss
- Peripheral neuropathy
- Cognitive impairment
- Cardiovascular
- Cardiomyopathy/ heart failure
- Breathlessness
- Endocrine
- Hypothyroidism
- Malaise
- Depression

KEY MESSAGES

- The MHRA's updated advice recommends more intensive follow-up for a larger proportion of people with metal-on-metal hip replacements
- This will affect over 60 000 patients in the UK, and many others in countries that follow MHRA advice
- The recommendations do not reflect the evidence showing that many asymptomatic patients with normal test results do not require annual follow-up
- Implementing the recommendations is likely to be associated with a substantial cost to health services

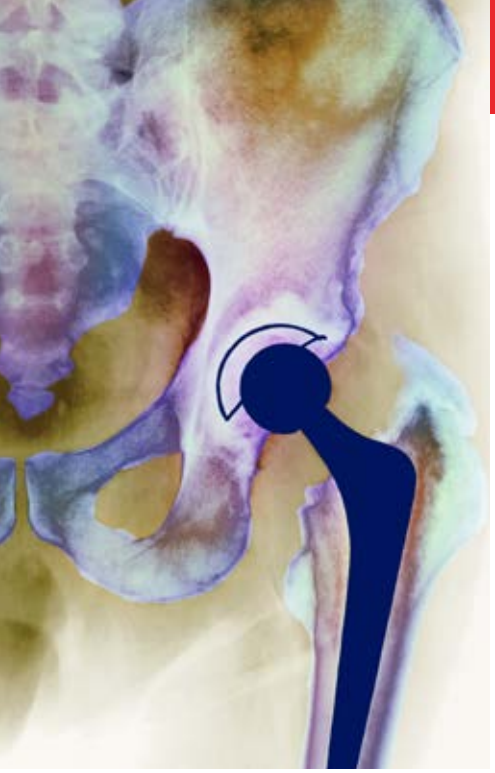
Regulatory authorities worldwide therefore recommend regular follow-up of patients with metal-on-metal implants in order to identify and treat adverse reactions early, and hopefully improve outcomes.[18-22] Surveillance can include clinical review, measurement of blood metal ion levels (surrogate marker of implant wear), hip radiography, and cross sectional imaging (ultrasonography or magnetic resonance imaging (MRI)). However, the follow-up recommendations vary between countries (UK, US, Europe, Australia, and Canada) and are not evidence based.[23]

In June 2017, the Medicines and Healthcare Products Regulatory Agency (MHRA) issued a planned update of its 2012 follow-up advice for patients with metal-on-metal implants.[18 24] These new recommendations, endorsed by professional orthopaedic bodies,[25] advise more intensive follow-up, with most patients now requiring annual investigations for the implant lifetime.[24] This will affect more than 60 000 patients in the UK,[2] as well as patients in many other countries that follow MHRA recommendations. Importantly, most patients have no symptoms and have well functioning implants.[26] We consider whether the latest MHRA recommendations are justified by the available evidence and assess the financial implications and potential impact on patients.

What has the MHRA changed?

The 2012 MHRA guidance recommended all patients with recalled metal-on-metal implants and patients with non-recalled implants who have hip symptoms were reviewed annually with metal ion measurement and cross sectional imaging (ultrasonography or MRI).[18] The 2017 guidance still recommends annual follow-up for all patients with symptoms but requires cross sectional imaging for low risk patients only (men with hip resurfacing femoral heads >48 mm and everyone with stemmed hip replacements with femoral heads <36 mm).

People without symptoms who have had metal-on-metal hip resurfacing (about 30 000 UK patients)[23 27] could previously be followed according to local protocol.[18] Many hospitals discharged such patients either immediately or if initial reviews were satisfactory.



SHFWIRE

However, the 2017 guidance has now added all women with hip resurfacings and men with small resurfacing implants (femoral head ≤48 mm) to the high risk group, which previously included only patients with withdrawn hip resurfacing implants and all stemmed hip replacements with femoral heads ≥ 36 mm. These high risk asymptomatic patients with hip resurfacings now require more intensive annual follow-up. The remaining asymptomatic low risk patients now require regular (annually to three yearly) radiography, metal ion tests, and Oxford Hip Score (OHS) assessment rather than follow-up as per local protocol.[28 29]

Some of the changes that the MHRA made to its recommendations are supported by the evidence. These include more comprehensive risk stratification for patients who have had hip resurfacing and more intensive surveillance for groups found to have more problems (such as women with hip resurfacings).[2 26] Men who have implants with an established track record, such as the Birmingham Hip Resurfacing (BHR),[2-30] now require less regular surveillance.

Recommendations to use the Oxford Hip Score to monitor pain and function[23] are also evidence based. It has been shown to detect suboptimally functioning implants, even in patients without symptoms.[31 32] However, some of the new MHRA recommendations seem inconsistent with the available evidence.

WHICH MHRA CHANGES ARE NOT SUPPORTED BY EVIDENCE?

Investigation of symptomatic patients

All worldwide authorities, including the 2012 MHRA guidance, recommend symptomatic patients have ion testing and cross sectional imaging.[23] This is because most patients with adverse reactions to metal debris have pain, with symptoms potentially signifying bone and soft tissue destruction that requires timely assessment and treatment.[8-33] The 2017 MHRA guidance still recommends ion testing and cross sectional imaging for symptomatic low risk patients. However, these recommendations have counterintuitively been downgraded for symptomatic high risk patients (such as women with recalled implants). High risk symptomatic patients now require imaging only if metal ion levels are abnormal. This change risks delayed diagnosis and treatment in high risk patients, poorer outcomes, and increased litigation.

Interpretation of metal ion measurements

The MHRA recommends that patients with metal ions of ≥7 parts per billion (ppb) require closer surveillance, based on early weak data.[34 35] Numerous studies show that metal ion levels are not useful for diagnosing adverse reactions,[36-40] so continuing to promote this ion threshold for identifying patients at risk of adverse reactions is not advisable. However, recent studies show that much lower ion levels (2-5.5 ppb) are effective at identifying patients at low risk of adverse reactions.[36-38] Therefore using these newer thresholds would help reassure many patients that they do not have adverse reactions.

Annual surveillance of patients with hip resurfacing implants

Longitudinal studies find little variation in metal ion levels in asymptomatic patients who have had hip resurfacing over the medium term (up to 10 years from surgery), even in those with high risk implants.[41-44] Similarly, patients who have normal results on cross sectional imaging two to eight years after surgery experience few changes when imaging is repeated within three years[45 46] with any problems developing only after 7-11 years.[47]

A longitudinal study of 152 asymptomatic patients who had had hip resurfacing showed that no patient with normal initial test results (metal ions <2 ppb and no abnormality on ultrasound scans) at a minimum of three years postoperatively developed adverse reactions when tests were repeated within five years,[31] suggesting that such patients do not need follow-up within five years. However, the new MHRA guidance recommends annual follow-up for many of these patients.

Registry data do not support guidance

The MHRA was concerned that UK National Joint Registry data (the world's largest arthroplasty registry) continued to show a risk of adverse reactions.[24 25] However, there will always be a risk of adverse reactions until all metal-on-metal implants are removed.[26] Importantly, we are unaware of any new registry evidence suggesting the problem is getting significantly worse, especially for patients with resurfacings.[24] For all hip resurfacings, the registry revision rates for the MHRA guidance in 2017 (12 years=13.6%)[2] and 2012 (8 years=9.1%) were consistent with an average 1.1% annual rate.[48] The Australian registry reports similar findings.[1] Furthermore, the annual number of revisions of metal-on-metal implants for all causes and for adverse reactions to metal debris has continued to decrease since 2012.[49 50] Therefore it is unclear how the registry data support the increased MHRA surveillance.

Conversely, registry data and other sources have shown clinical benefits since the 2012 MHRA guidance was implemented.[18] Increased awareness of potential problems and regular surveillance has led surgeons to revise implants earlier and for less severe abnormalities than before.[26] This has been associated with improved outcomes after revision surgery[50-52] compared with initial data.[8]

Given these observations and the limited evidence supporting the new MHRA proposal of increased surveillance, caution is warranted. A systematic review of 122 studies observed the prevalence of revision for adverse reactions was highly variable, even for similar implants, but was closely related to intensity of surveillance.[53] The variability in surveillance is probably related to the inconsistent way follow-up guidance has been interpreted by different hospitals and surgeons.[23] Increased surveillance can lead to overdiagnosis of problems that may never require revision and may put patients at unnecessary risks associated with revision procedures, especially given that abnormal reactions not requiring treatment occur in patients with well functioning conventional hip

replacements.[54 55] Universal prostate cancer screening has similarly caused overdiagnosis and treatment related complications.[56]

Costs of implementing the new MHRA guidance

Previous work reported that the 2012 MHRA guidance would cost £8.2m annually to implement in the UK.[23] Implementing the 2017 guidance is likely to cost much more than this. Although there will be savings from less regular surveillance of low risk patients, the more intensive follow-up for asymptomatic patients with hip resurfacings will result in higher costs overall.

In addition to initial reviews and investigations, there will be other costs to health services, such as organising extra clinics, the resources required to perform and interpret tests, and the further investigations needed if abnormalities are identified. To review 60 000 patients just once will take about 1000 staffed clinic days (two doctors per session). Concerned patients have been directed back to primary care,[25 57] sometimes without hospitals providing instructions on how to advise them. General practitioners often do not know which hip implant a patient has received, and they should not be asked to measure metal ions since the results require careful interpretation. The follow-up costs for hip replacements that were performed privately in the UK may also fall on the NHS.

Finally, the cost of revision surgery is substantial. The 500-1000 revisions of metal-on-metal implants performed annually in the UK equate to £5m-£10m a year.[50] The effect on hospital budgets of doing more revisions will be compounded by the NHS revision procedure tariff recently being reduced by nearly £3000.[58]

What do patients think about regular follow-up?

We spoke to five patients with metal-on-metal implants (box2). All felt reassured they were having annual or two yearly clinical reviews, radiography, metal ion tests, and in some cases cross sectional imaging.

Box 2 | Patients' views on regular clinical surveillance and tests

We spoke to three women and two men aged 50-76 who had had metal-on-metal hip replacements 6-10 years previously at one of two centres in the UK. All were asymptomatic and were having some type of hospital follow-up every one to two years. Between them they had six hip resurfacing implants and one stemmed total hip replacement (two patients had bilateral implants).

Perspective on regular reviews and tests

- All patients felt reassured that they were having regular clinical reviews, radiography, metal ion tests, and in some cases cross sectional imaging
- Patients felt these regular check-ups and tests provided them with security despite being pain-free and would allow any issues to be identified early
- No patient was concerned about the time needed to travel and attend these regular appointments
- One patient highlighted their data may benefit others in the future by contributing to research
- Patients did not feel they were being over investigated, though some recognised their views may have been different if the tests being performed were more invasive (eg, biopsies) or associated with more serious complications
- Two patients said they would prefer to have less regular reviews and tests in the future given there was now evidence that asymptomatic hip resurfacing patients with normal tests can be safely discharged for five years. These patients did consider the resource implications in their responses (ie, "Someone else can have my appointment if I do not actually need it.").

How follow-up could be improved

- All patients were happy with their implants, the follow-up received, and the information provided over the years by their surgeons and hospitals regarding issues with metal-on-metal implants
- They were also confident they could contact their clinicians between planned appointments if they developed any problems.
- One patient said that they would like a simple questionnaire to be developed that could help stratify patients for subsequent follow-up

Although none of the patients had any serious concerns about potentially being overinvestigated, some would prefer to have fewer regular reviews and tests in the future given there was now some evidence supporting this approach.

Protecting patients from poorly performing implants

The encouraging early results of the first hip resurfacing implant (BHR) were incorrectly extrapolated to apply to other metal-on-metal designs. These devices were subsequently widely marketed and implanted without robust evidence about their safety and effectiveness, which ultimately placed huge numbers of people at unnecessary risk.

To avoid repeating the failures associated with metal-on-metal implants, the introduction of new technologies must be rigorous and transparent. This should include usage by small expert groups, in randomised trials and independently controlled surveillance programmes. Any concerns must be reported to manufacturers and regulators early, and must be taken seriously to minimise any potential patient harm. The initial device experience should be interpreted in combination with registry and other data before any widespread introduction. Organisations such as Beyond Compliance and the Orthopaedic Data Evaluation Panel have been formed with the aim of safely introducing and monitoring the performance of new implants in clinical practice.[59 60]

Extra costs

The new 2017 MHRA commendations mean that many more patients with metal-on-metal hip implants will be subjected to annual reviews and testing for the implant lifetime, which means the burden of this problem for both patients and health systems will continue for many years. However, evidence increasingly supports less regular surveillance in many patients, which would allow better use of healthcare resources. Five yearly surveillance may help reduce anxieties and concerns in many asymptomatic patients with well functioning hip resurfacings, although patients should be consulted on the benefits and harms of different follow-up approaches.

It is unlikely that the substantial increase in follow-up costs will be offset by detecting the small proportion of asymptomatic patients with adverse reactions from hip resurfacing who would otherwise have been missed. Given the known pressures within health services there are serious concerns about how financially sustainable the new MHRA recommendations are. It remains to be seen whether implant manufacturers will contribute to some, or all, of the extra costs.[61]

Gulraj S Matharu, orthopaedic registrar
gsm@doctors.org.uk
Andrew Judge, professor of translational statistics
Hemant G Pandit, professor of orthopaedic surgery
David W Murray, professor of orthopaedic surgery, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford

References are in the version on bmj.com
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OBITUARY

Mathilde Krim

Doyenne of AIDS research funding in the US

Mathilde (Galland) Krim (b 1926; PhD biology, University of Geneva, Switzerland, 1953), died from unreported causes on 15 January 2018

Mathilde Krim's early life was the stuff of a Hollywood screenplay. Born Mathilde Galland in Como, Italy, to Swiss and Austrian parents in 1926, she grew up primarily in Geneva, isolated from the worst of the second world war. But she saw Jewish refugees and heard the distain for their requests for asylum, and later she was shocked by newsreel footage of the liberation of extermination camps.

She converted to Judaism while a student at the University of Geneva, where she gained a PhD in biology at a time when few women did. She started smuggling guns to the Irgun, a Jewish paramilitary group fighting to create an independent Israel. Galland married David Danon in 1948, and the couple moved to Israel in 1953, but they divorced not long after.

US move and AIDS research

As a researcher at the Weizmann Institute of Science, she was introduced to a visiting American, Arthur Krim, a movie executive and power within the Democratic Party. They married in 1958 and settled into a busy life in New York City, where Mathilde juggled roles as wife, socialite, and virology researcher, first at Cornell Medical College, then at Memorial Sloan Kettering Cancer Center. She pursued research on cancer caused by virus and became known as the "Interferon queen" for championing research into the anticancer properties of the protein.

In 1981 Greenwich Village physician Joseph Sonnabend started to notice an outbreak of Kaposi's sarcoma in what seemed to be otherwise healthy young gay men, and he referred many of them to his friend Mathilde. The rare skin cancer had previously been seen only in very old men or cancer patients whose treatment left them immunocompromised.

"I knew nothing about the gay community in 1981," Krim would later tell *POZ Magazine*. But patients quickly educated her, and Mathilde's sense of social justice kicked in. She said she was "disgusted by the way society accused gay men of having created something terrible," when in fact it was society that had created the stigma and persecution within which the infection flourished.

Unconventional funding

Traditional sources, such as the National Institutes of Health, were slow to fund research into the emerging AIDS epidemic, and so, in June 1983, Krim became a cofounder of the AIDS Medical Foundation (later amfAR), along with others such as Nobel laureate David Baltimore, philanthropist Mary Lasker, and patient activist Michael Callen.

Arthur Krim donated an initial $100 000 (£70 000), and within three months Mathilde had raised an additional $550 000 to fund research, prevention, and clinical care. Because of the fear and stigma surrounding the disease, the group was prohibited from listing its full name in the lobby of its Park Avenue office building, instead it had to go by the name AM Foundation.

Hollywood icon Elizabeth Taylor had been enlisted in parallel activity in Los Angeles, established with $250 000 from the estate of her friend, the late actor Rock Hudson, whose death from AIDS sparked much of the first mainstream media coverage of the disease. In 1985 she and Krim combined efforts to form amfAR.

AmfAR often took chances in providing initial resources for research, such as its current efforts towards finding a cure for HIV, when other larger organisations were slower to move. Historically, it supported needle exchange programmes and safer sex activities, and, before many others were willing to do so, spoke out against stigma associated with the disease and with homosexuality. It has raised $517 million to date.

ANNIE LEIBOVITZ

Krim became known as the the "Interferon queen"

Krim testified before Congress against the use of double blinded placebo controlled trials for evaluating the antiretroviral drug AZT (azidothymidine) in patients with advanced AIDS. Thanks to pressure from her and the activist community, HIV research soon came to use standard of care rather than placebo as the comparator arm for most clinical trials.

Krim's high profile association with AIDS didn't sit well with the leaders of Sloan Kettering; she left the organisation, and essentially her own laboratory research, in 1985.

She stepped down as founding chairman of amfAR in 2004, succeeded by designer Kenneth Cole.

"Dr Krim was a close friend and mentor," said musician Elton John in a statement released by his foundation. "We would not be where we are today without her, and we must continue to work tirelessly to further understand and prevent the disease."

Mathilde Krim's awards included 16 honorary doctorates, and the US's highest civilian award, the Presidential Medal of Freedom, in 2000. She leaves a daughter, and two grandchildren.

Bob Roehr, Washington, DC
bobroehr@aol.com

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BURNING ISSUES FOR 2018

Increasing costs and training non-doctors

My burning issues (Editor's Choice, 6 January) were emphasised by your article about the £700 000 once only injection for inherited retinal disease (Seven Days).

My first two issues are the increasing cost of healthcare and the startling difference between medical resources in the developed and developing world. The $1m treatment doesn't even fully restore the vision of one patient. That money could fund 20 000 or more cataract extractions with over 90% permanent restoration of vision.

My third issue is more nuanced. The biggest reason for cataract blindness is the dearth of ophthalmologists. Orthopaedic surgeons in Leicester faced with a backlog of carpal tunnel surgery decided to train intensively one theatre nurse. As a result, our carpal tunnel surgery service is probably the best and most cost effective in the country. Having a person who is not a "fully qualified doctor and surgeon" operating on cataracts could be the best solution.

John Sandford-Smith, retired ophthalmologist, Leicester

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Long term funding of the NHS

I have experienced many attempts to "improve" the system. The value of these has been, at best, questionable. The burning issue today is unchanged (Editor's Choice, 6 January): the long term funding of the NHS. Healthcare is constantly becoming more effective, and as we "save lives" (or defer deaths) we incur future costs to the state.

We must find out what people want from the NHS and what they are prepared to pay for. A gap will exist between the two, and we should be honest about the certainty that some favoured drugs or procedures cannot be provided. Even though interest groups will bring pressure to bear, rationing is inevitable.

We must tackle the healthcare system as a whole, and, above all, we must decide whether to fund long term care and for whom. The service needs long term funding to enable effective planning, especially of workforce needs.

David Tweedie, retired anaesthetist, Warwick

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LETTER OF THE WEEK

We need a review of all sepsis deaths

NHS England estimates that approximately 37 000 deaths a year are caused by sepsis. So between 2011 and 2017, around 259 000 people died from sepsis in England. But only one of these deaths, that of Jack Adcock in Leicester in 2011, has resulted in the conviction of health professionals for manslaughter (Hadiza Bawa-Garba and Isabel Amaro) (Editorial, 3 February).

Sepsis can be difficult to diagnose, and delays and omissions in its diagnosis and treatment contribute to the high death rate. Even the former chair of the General Medical Council, Graham Catto, has admitted that he failed to diagnose sepsis in a timely manner, an error that contributed to a patient's death.

Why were Bawa-Garba and Amaro convicted of gross negligence manslaughter? Was their management of Jack Adcock so different from the management of other cases of sepsis that resulted in death that they were justly convicted? Or were they involved in just one of many cases where suboptimal management of sepsis contributed to death? Guidance has only recently set out the expectations of best practice in sepsis care—several years after Bawa-Garba and Amaro were charged.

We need an objective review of sepsis deaths to identify the contribution of suboptimal management to the death, not the prosecution of health professionals, if we are to improve clinical outcomes for patients with sepsis.

Azeem Majeed, professor of primary care, London
Paul Morgan, consultant intensivist and sepsis lead, Cardiff

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CHILD ASTHMA ATTACKS

Metered dose inhalers and spacers are underused

Bush and Griffiths discuss suboptimal management of asthma exacerbations in children (Editorial, 6 January). They also remind us that metered dose inhalers with spacers are equivalent or superior to nebulisers in all but the most severe exacerbations.

This simple technology remains underused. Every person with asthma should have a metered dose inhaler and a spacer, and they (or their caregivers) should know how to use them to increase temporarily the dosage of β agonists and inhaled corticosteroids when symptoms worsen. This should be the case even for older children and adults who receive their regular treatment using other types of inhaler.

All health professionals should know the importance of careful clinical assessment of exacerbations, and the need for oral corticosteroids, pulse oximetry, and oxygen for severe episodes.

Continued availability of metered dose inhalers is essential while solutions are found to concerns over the environmental impact of the propellants they contain.

Duncan Keeley, GP, Thame

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DATA CONTROL IN EHRs

Patients find it easy to select data

New and colleagues argue that patients must be informed about how their data in electronic health records are to be used and for what purpose (Analysis, 6 January).

We saw that patients found it simple to say which data they would not want to be shared when they were given copies of their records. We produced algorithms and a patient portal that allowed patients to select data in their records that had been categorised into chapter headings: infectious diseases, growths, endocrine, blood disorders, mental health, neurological, cardiovascular, respiratory, genitourinary (includes breast and gynaecology), pregnancy, skin, musculoskeletal, neonatal, accident, and injury.

Generally, patients selected pregnancy and mental health, including drug and alcohol problems, and chose data relating to employment, genetics, and social stigma. I think that patients in the future will see the data at source and state which data they do not want shared.

Richard Fitton, retired GP, Crowden

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FETAL MONITORING DEBATE

Randomised trials are not the only evidence

Neither electronic fetal monitoring nor intermittent auscultation has ever saved a baby or harmed a mother directly (Head to Head, 9 December). What saves (or

harms) is intrauterine resuscitation or delivery.

The trials of monitoring versus intermittent auscultation are difficult to interpret because none of them specified how clinicians should respond to heart rate patterns. The rules are disputed; we have to decide on the basis of non-randomised evidence. The patterns that predict hypoxia, death, or brain damage are confused by the interventions mandated in response—the so called treatment paradox.

One review of the non-randomised evidence showed fewer intrapartum deaths with monitoring. Rates of cerebral palsy have begun to fall in the past 10 years, as formal training in interpretation has become widespread. Correlation does not prove causation, and observational studies may be biased, but given what we know about physiology, the evidence, at least for intrapartum death, is supportive.

Jim Thornton, professor of obstetrics and gynaecology, Nottingham

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Cardiotocography and pattern recognition

The INFANT trial did not test cardiotocography versus intermittent or no auscultation, but rather whether decision support software could aid interpretation of cardiotocographs (Head to Head, 9 December).

The counterargument for the flaw of "learning in the control group" in this trial was that some people have "intrinsic pattern recognition inability" that is not improved by training. But this inability cannot apply to most clinicians. Cardiotocography detected abnormal fetal heart rate patterns but did not trigger appropriate intervention. Clinicians regularly see cardiotocography saving lives and preventing neonatal morbidity.

In 2007, NICE adopted the fundamentally flawed concept that most fetal heart rate decelerations were caused by cord compression and should be called "variable." Scientists have now concluded this was unscientific. A generation of birth attendants might have learnt the wrong pattern recognition and, therefore, are unable to acquire the "art" of cardiotocograph interpretation.

Shashikant L Sholapurkar, obstetrician and gynaecologist, Bath

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New approaches for fetal hypoxia

We commend *The BMJ* for this timely debate (Head to Head, 9 December). Cochrane, the International Federation of Gynecology and Obstetrics, and NICE have all said that no evidence shows that human or computerised interpretation of cardiotocographs reduces the rates of intrapartum stillbirth and cerebral palsy.

We propose two new approaches to the care of fetal and neonatal hypoxia. Firstly, we should assess mobile resuscitation devices for newborn resuscitation at the bedside with an intact cord. Timely management of complications is the cornerstone for recovery. Secondly, carbon monoxide breath analysers are a simple, cheap, fast, and non-invasive way to identify the most frequent conditions responsible for hypoxia and metabolic acidaemia: carboxyhaemoglobin due to smoking or underestimated environmental causes (such as heating systems and motor vehicles).

Our longstanding reliance on cardiotocography might be related to vested interests from equipment manufacturers, plaintiff lawyers, and experts with lucrative medicolegal practices.

Susan Bewley, professor of women's health, London
Alain Braillon, senior consultant, Amiens

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BAWA-GARBA CASE

Second letter to the GMC chair

Dear Professor Stephenson,

My letter to you of 9 November 2017 about Hadiza Bawa-Garba was followed by a stream of similar comments in the medical and national press and on social media. In striking a physician off the medical register for making mistakes, you may have called into question the future of the GMC.

Your principal defence has been that to allow Bawa-Garba to continue to practise would "unpick the criminal court conviction." That is not so. Only the courts of appeal can do that, and I hope they will.

You opted to go further than the criminal courts, and it was not an automatic process imposed by statute.

Like Bawa-Garba, you erred. In your case no one died, but a doctor lost dignity, respectability, and a career, buried for good measure in an outpouring of hostility and racial bigotry. Although no one else was seriously harmed, you inflicted further damage on a profession's already battered sense of self worth (This Week, 3 February). How should we, the public, respond?

I am a layman, much more closely aligned with patients and generally scornful of professional self interests, but your behaviour has shaken my confidence in the medical profession. You cannot expect doctors to be candid about errors, to complain about systemic failures, and to stay in the profession in sufficient numbers, if you set lawyers on them and throw them to the wolves when they make rare clinical mistakes.

You have created a head of steam, and we must not let it dissipate. I propose that if by 1 March 2019 the GMC has not produced a clear statement that puts patient safety first, medical candour second, adversarial procedures last, and retribution nowhere, all doctors should give notice that they will refuse to comply with the GMC, prompting the government to put in place a new organisation fit for purpose.

That may sound an empty threat. But, as you know, the government is considering your future anyway, along with that of the other eight bodies that regulate UK healthcare. I am not convinced that, on careful consideration, patient groups, politicians, and the public will be so dismissive of starting with a clean slate. They realise that to err is human. They understand that medical error is an ever present danger. They have seen how the commercial air industry has put safety ahead of blame and that the government has wisely brought in the air accident investigator Keith Conradi to advise the NHS. We must all try to avoid acting disproportionately; but boycotting the GMC will not be disproportionate if it cannot admit its error and then quickly and substantially reform.

Please can you and the council clarify whether you are proud of the decision you took on Bawa-Garba and would take it again or that, with hindsight, it was a mistake you will not repeat.

Yours sincerely.

Nick Ross, broadcaster and journalist, London

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RESPONSE

GMC responds to concerns raised by Bawa-Garba's erasure

If you think your working conditions are unsafe for you or your patients, document the situation, but don't walk away says **Charlie Massey**

MATT SAYWELL

No one can be left in any doubt that the case of Hadiza Bawa-Garba has raised genuine concerns in the medical profession. I know too that this case has set the General Medical Council back in our desire to support doctors as the best way to protect patients.

There are some things the GMC will never be able to do, but there are things we can and will do to support you. We speak up about the pressure that doctors are under, and we challenge employers when we have evidence that training environments compromise patients' safety—and the training itself—by not meeting our standards. But as the independent regulator we can act only on evidence and data, whether that is local data from one site or national trends and concerns.

If you think your working conditions are unsafe, document the issue and escalate it at the earliest opportunity, but don't walk away. One of the commitments we have made with the BMA is to confirm that if doctors follow this guidance it will very much weigh in their favour if the GMC subsequently receives complaints.

There are deep and complex questions about the application of manslaughter legislation in medicine

Our joint work with the BMA includes a reaffirmation that we do not ask for doctors' reflective statements when we investigate concerns. It is important that doctors are aware that Bawa-Garba's reflective notes from her portfolio were not used in evidence in her criminal trial and were used only at the medical practitioners tribunal when she chose to submit them.

Many have asked us about the disproportionate representation of black and minority ethnic doctors in fitness to practise investigations. We have been concerned about the over-representation of BME doctors in complaints, and that is one of the reasons the GMC now has more staff on the ground to support local responsible officers in handling complaints. We are also dramatically scaling up our free induction sessions for doctors new to UK practice. And we'll continue to ensure that our own processes are regularly and independently audited, to assure doctors that our rules and processes operate consistently and in a non-discriminatory way. But we recognise that there is more to do here.

Much of the comment on the Bawa-Garba case has focused on whether the original conviction of gross negligence manslaughter was appropriate, given the wider systemic issues. We recognise that there are deep and complex questions about the application of manslaughter legislation in medicine.

That is why we are committed to bringing together a wide range of voices, from across the UK, to examine this issue and ensure that the way criminal law operates can support the open and honest culture we all want. That work will include looking at the pathway leading from reporting to investigation and prosecution; distinguishing between errors and exceptionally bad failings; the role of expert witnesses; and the need for reliable data to support a genuine understanding of incidence and trends.

I promise that we will keep listening and working to change those things that we can influence, to support you in providing safe care for patients.

Charlie Massey is chief executive and registrar, General Medical Council, London
chiefexecutive@gmc-uk.org

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