# this week

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BURGER PHANIE/SPL

## Surge in exceptional funding requests

The number of exceptional funding requests that doctors in England are making on behalf of their patients for treatments such as cataract removal, hip and knee replacements, and mental health interventions has increased markedly, an investigation by *The BMJ* has found.

Richard Vautrey, deputy chair of the BMA's General Practitioners Committee, said that the figures were a sign that clinical commissioning groups were under increasing financial constraint. "There is undoubtedly more pressure on CCG budgets and attempts to reduce referrals and costs, and the greater use of individual funding requests (IFRs) may be one way some are trying to do this," he told *The BMJ*.

Doctors made 73 900 IFRs to CCGs last year, a 47% rise from 2013-14, when they made 50 200, data collected by *The BMJ* under a freedom of information request show. In just the past year the number of requests rose by more than 20%, from 60 400. Just over half (52%) the requests made in 2016-17 were approved, but even patients who are granted access to treatment may have waited months for it.

IFRs, which first emerged in England in the 2000s, are made by GPs or consultants for treatments that are not routinely funded in their area. Local panels decide which to approve. Most are for cosmetic procedures or fertility treatment. But GPs in some areas are now being told to apply for exceptional funding for a wider range of treatments.

Chiltern and Aylesbury Vale CCGs in Buckinghamshire recently told doctors that all referrals for hip and knee surgery must go through an IFR process.

Stephen Cannon, vice president of the Royal College of Surgeons, said the move was a misguided attempt to save money. "These CCGs are unfairly and unnecessarily prolonging the time patients will spend in pain, possibly immobile and unable to carry out daily tasks or to work," he said.

Vautrey urged NHS England to set clear guidelines on which treatments should require an IFR ."It's clearly unfair for patients to be subjected to this postcode rationing, and it also adds further to GPs' workload," he told *The BMJ*.

Julie Wood, chief executive of NHS Clinical Commissioners, said that CCGs had to make "difficult decisions" on funding services. "Unfortunately the NHS does not have unlimited resources," she said.

Gareth Iacobucci, *The BMJ*

Cite this as: *BMJ* 2017;358:j3188

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**Treatments such as cataract surgery are becoming increasingly difficult to obtain in parts of England**

### LATEST ONLINE

- Women in Northern Ireland to get free abortion on NHS in England
- Practice that suspended GP who later died by suicide criticised by coroner
- NHS bosses soften cost cutting plans after concerns

# MHRA issues new guidance on metal-on-metal hips


**_The BMJ_ questioned the safety of metal-on-metal hips back in 2012**

All patients with metal-on-metal hip implants are advised to have blood tests and either plain radiographs or scans, under new guidance by the Medicines and Healthcare Products Regulatory Agency (MHRA).

Concerns have been repeatedly raised about these devices, and the regulator previously recommended in 2012 that symptomatic patients or those with particular types of implants should undergo tests.

Over 50 000 UK patients have had metal-on-metal hip replacements fitted. The MHRA said that the majority currently have well functioning hips but that some patients will develop progressive soft tissue reactions to the wear debris generated by the hips, and not all will be symptomatic.

So far only DePuy, the manufacturer of one type of implant, is paying the costs of follow-up investigations and revision procedures in patients who have one of its ASR implants.

As tens of thousands more patients need follow-up with potential early revision procedures, the cost to the NHS is likely to be substantial. *The BMJ* has learnt that the tariff for a revision procedure has been cut by almost £3000, which is likely to place extra financial pressure on trusts, and some providers that carry them out for the NHS are questioning whether they should continue to do them. The Department of Health and NHS England were contacted for comment but had not responded by the time of publication.

### Safety fears

Back in 2012 *The BMJ* questioned the safety of metal-on-metal hips and specifically warned that total hip replacements with a large diameter head and hip resurfacing in women and in smaller men carried higher risks of failure.

This latest guidance builds on those concerns by advising that all patients who have had a metal-on-metal hip replacement should be reviewed. However, the frequency of the blood tests and the type of imaging required will depend on patients' sex, whether they have symptoms, and the type of hip replacement used.

Neil McGuire, MHRA clinical director of medical devices, said, "The clinical advice we have received indicates that patients will likely have the best outcomes if these problems are detected early, monitored, and treated if necessary."

The MHRA also told *The BMJ* that it is reviewing available information about long term systemic effects of the ions released from metal-on-metal hips. The agency said that it was "aware that there has been some limited research carried out looking for an association with cardiac failure and [that] the scientific literature contains a small number of case studies of some patients with very raised metal ions who have developed systemic symptoms, in relation to a rapidly wearing hip."

Deborah Cohen, *The BMJ*

Cite this as: *BMJ* 2017;358:j3246

# Senior trainees will be balloted on new consultant contract, says BMA

Senior trainees, as well as all consultants, will be balloted on proposals for a new consultant contract, the BMA has said.

Delegates at the BMA's annual representative meeting (ARM) in Bournemouth on 29 June voted in favour of a motion which said that "all consultants, [BMA] members on the specialist register, and junior doctors of year 3 specialty training and above should be balloted on the new consultant contract proposals."

The motion was passed by 116 votes to 89 (57% for the motion, 43% against).

Earlier this year, consultants voted against automatically holding a collective ballot of consultants and senior trainees on a new contract. At the BMA's consultants' conference in February, delegates voted against a motion calling on the association's Consultants Committee neither to approve nor accept any new contract "without balloting appropriate branches of the BMA membership."

**BMA members agreed that senior trainees should have a say on the contract**

### Voice for members

Proposing the motion at the ARM, Latifa Patel, a year 4 specialty trainee in paediatrics, said, "Our greatest asset in negotiations with the government remains our membership."

"As such, we owe it to ourselves, the membership, to ensure that each and every voice is [heard]. As we reach a consultants' contract which our committee are proud of, why wouldn't we mobilise our members? Why wouldn't we give a voice to our members?" Patel added.

Tom Martin, an ear, nose, and throat consultant, also spoke in favour. "Those who are not yet consultants may well be those who have to work under these conditions for the longest time," he said. "I think that they must be given a voice."

David Rouse, chair of the BMA's North Thames Junior Doctors' Committee, spoke against. He said that there was a need to be "practical and pragmatic" about the issue. "We need to think about where this leads," he said. "If you vote for a ballot, and the ballot fails, then what? Are you willing to push for strike action?"

Vishal Sharma, one of the BMA's consultant contract negotiators, also spoke against the motion, saying there had not yet been any decision to forgo a ballot. He said that the possibility of providing individual consultants with the option of choosing whether or not to move onto the new contract was currently under consideration.

Tom Moberly, *The BMJ*

for England and Scotland: Sally Davies and Catherine Calderwood. In 2015 and 2016 there was a triumvirate of female CMOs before Ruth Hussey retired as CMO for Wales. The president elect of the Royal College of Psychiatrists, Wendy Burns, was also unable to attend.

Though this picture celebrates female empowerment, bastions of male dominance persist. Neither the BMA nor the GMC has had a female chief executive or chair; the *Lancet* has not had a female editor in chief; and the Academy of Medical Sciences has never had a woman as president.

The ascent of female leaders reflects demographic change in the profession. The latest GMC figures show that the male-female split on the medical register as a whole is 54.5% to 45.5%.[1] But in the GMC's latest survey of trainees those figures are reversed: 55.9% of respondents were women and 44.1% men.[2]

In other areas of medicine women are yet to achieve equal status. A report by the Exeter Business School said that just 25% of medical directors are women,[3] and the latest data from the Medical Schools Council show that just 18% of professors are women.[4] Godlee said, "Having so many women in senior leadership positions in medicine is something to be celebrated and will benefit female and male doctors as well as patients. However, we must not be complacent: gender equality is something we must continue to strive for."

Anne Gulland, London

Cite this as: *BMJ* 2017;358:j3250

RICHARD H SMITH

FEATURE

# Law, ethics, and emotion: the Charlie Gard case

The fight over a terminally ill baby's treatment has been unprecedented, legally and in the social media coverage. After the European Court of Human Rights ruled he should now be allowed to die, **Clare Dyer** considers where it leaves doctors' presumptions about a child's best interests


A 10 month old baby lies in the intensive care unit at London's Great Ormond Street Children's Hospital, kept alive by a mechanical ventilator and fed by a tube. Unable to breathe unaided or move his arms and legs, he has epileptic seizures which, because he is unable to move, can be detected only by electroencephalography. His brain has severe damage.

Doctors at the hospital believe they can do no more for Charlie Gard, a baby with an exceptionally rare inherited disease, infantile onset encephalomyopathic mitochondrial DNA depletion syndrome (MDDS). Caused by mutations in a gene called RRM2B inherited from both his parents, the condition leads to severe depletion of mitochondrial DNA in his tissues. The clinicians treating him think that he is in the final stage of the disease and that they are no longer serving his best interests by keeping him alive.

But Charlie's parents, Chris Gard and Connie Yates (right), refuse to give up. They found a professor of neurology at a mainstream medical centre in the United States who was willing to give him nucleoside therapy, an experimental treatment that has never been given to a patient with the RRM2B form of MDDS. And they raised more than £1.3m through crowdfunding to take him there. Some 18 people around the world with a TK2 mutation, a less severe type of MDDS, have had some benefit from nucleoside therapy, but the condition had not affected their brains.

### Nucleoside treatment

Back in January, the doctors treating Charlie had considered trying nucleoside treatment themselves and had drafted an ethics committee application. But after Charlie had several seizures, his parents were told that he had severe epileptic encephalopathy and that the treatment would be futile. Cue the start of a legal battle.

**Charlie's doctors continue, as they must, keeping him alive, providing treatment that they believe is futile**

All the treating clinicians and the experts who gave evidence in the High Court agreed that the treatment, which cannot reverse existing brain damage, would not benefit Charlie. Even the US professor of neurology who gave evidence by telephone link conceded during the court hearing that Charlie was unlikely to benefit from the therapy, given his severe encephalopathy. But he added, "I would just like to offer what we can. It is unlikely to work, but the alternative is that he will pass away."


Daily Mail
Our desperate legal fight to stop hospital turning off our baby's life support


DAVID MIZOEFF/PA

Battles between parents and hospitals over children's treatment are nothing new and hit the headlines regularly. But the fight over Charlie's treatment is unprecedented, both legally and in its coverage on social media. It has involved seven judges in three courts in the UK and seven more at the European Court of Human Rights in Strasbourg, which agreed that undergoing experimental treatment would "continue to cause Charlie significant harm."

### Keeping Charlie alive

On 11 April the High Court in London ruled that it would be in Charlie's best interests to come off the ventilator, to have only palliative care, and not to have nucleoside treatment. But the declarations were put on hold through unsuccessful forays to the Court of Appeal, UK Supreme Court, and Strasbourg.


DAVID MIZOEFF/PA

**PARENTS *v* DOCTORS: HOW DO THE COURTS DECIDE?**

The courts cannot order a doctor to carry out a particular treatment but can declare whether a treatment is lawful and in the child's best interests if a dispute arises and one party takes the case to court.

The starting point in deciding where the child's best interests lie is that there is a strong presumption in favour of preserving life. As the Court of Appeal put it in the case of Wyatt *v* Portsmouth NHS Trust in 2005: "In our judgment, the intellectual milestones for the judge in a case such as the present are … simple, although the ultimate decision will frequently be extremely difficult. The judge must decide what is in the child's best interests.

"In making that decision, the welfare of the child is paramount, and the judge must look at the question from the assumed point of view of the child. There is a strong presumption in favour of a course of action which will prolong life, but that presumption is not irrebuttable. The term 'best interests' encompasses medical, emotional, and all other welfare issues."

The court considers whether a treatment causes or will cause the child pain or suffering and whether the likely benefits outweigh the burdens of having the treatment. In Charlie Gard's case, the treating doctors believe he is experiencing pain and suffering, which would continue while having nucleoside therapy. When, as in his case, the consensus of all the doctors who have examined him is that the treatment would be futile, there are no benefits to put on the scale.

The law says that doctors cannot be required to provide treatment that they consider to be against a patient's best interests. Yet the successive stays have obliged doctors to continue keeping Charlie alive for months on artificial ventilation, against what they believe to be his best interests.

On 19 June, to enable the Strasbourg court to consider the case urgently, the UK Supreme Court extended the stay again "with considerable hesitation" until midnight on 10 July. "We three members of this court find ourselves in a situation which, so far as we can recall, we have never previously experienced," said the court's deputy president, Lady Hale. "By granting a stay, even of short duration, we would in some sense be complicit in directing a course of action which is contrary to Charlie's best interests."

She added, "Every day since 11 April 2017 the stays have obliged the hospital to take a course which, as is now clear beyond doubt or challenge, is not in the best interests of Charlie. The hospital finds itself in an acutely difficult ethical dilemma."

**Rights to private and family life**

The case has challenged the established view that a judge, in weighing up parents' and doctors' conflicting views on treatment, must simply decide what is in the child's best interests. That was the traditional path the case followed in the High Court. But when it went to the Court of Appeal, the parents' new legal team, led by leading human rights lawyer Richard Gordon QC, mounted a new argument.

He contended that where the parents are proposing a viable treatment elsewhere, the state cannot interfere unless this puts the child at risk of significant harm. Withholding treatment when the parents have a legitimate contrary view favouring an alternative treatment would involve interference by the state with the parents' right to private and family life "on a massive scale," he argued. The courts rejected the argument.

During this legal process, Charlie's doctors continue, as they must, keeping him alive, providing treatment that they believe is futile and causing him suffering. During a discussion last month at Serjeants' Inn Chambers in London, led by several of the barristers in the case, David Hicks, interim medical director at the hospital, asked: "Where does this leave the doctors at Great Ormond Street? My colleagues feel in a completely invidious situation. They are now required to provide treatment to a certain date which they do not agree with, while at the same time being told that they can't be directed to give treatment, according to the law.

**Where does this leave the doctors at Great Ormond Street?**— David Hicks interim medical director

"They feel that they are at risk of being reported to their regulator, the General Medical Council, for changing treatment, sustaining treatment, or avoiding treatment… They've experienced delay after delay in being able to do what they feel is the right thing in Charlie's best interests."

Clare Dyer, legal correspondent, *The BMJ*
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**Cite this as:** *BMJ* 2017;358:j3152

ESSAY

# When "patient centred" is not enough: the challenges of collaborative health

Sweeping technological, economic, and social changes are taking some of the power out of doctors' hands and they will have to alter their behaviour to retain public trust, writes **Michael L Millenson**

A quarter of a century ago, researchers proposed "patient centred care" as a conceptual framework that "consciously adopts the patient's perspective" about what's important in interactions with providers and institutions.[1]

Today, technological, economic, and social changes are moving healthcare in directions unanticipated by the patient centredness pioneers. It's not that patient centredness no longer pertains; rather, it's being subsumed under these larger forces reshaping 21st century medicine. I suggest "collaborative health" as an umbrella term framing how clinicians should respond.

The Victorian parliamentarian and novelist Edward Bulwer-Lytton declared, "A reform is a correction of abuses; a revolution is a transfer of power." Patient centred care began as a correction of abuses, a response to patients being treated like "imbeciles and inventory."[2] Decades later, what's claimed to be patient centred still too often reflects a paternalistic attitude, ironically expressed by comedian Stephen Colbert in a different context on the *Late Show* in 2015: "See what we can accomplish when we work together by you doing what I say? It's called a partnership."

In contrast, collaborative health describes a shifting constellation of collaborations for sickness care and for maintaining wellbeing that is shaped by people based on their life circumstances. The result is not reform, but a transfer of power in which the traditional system loses some control. That system will often be part of wellbeing and care relationships—providing patient centred, person-centric, or collaborative care—but other times (and not by choice) it will be excluded.

> Though the role of the doctor is in flux, there remains great value in professional expertise rooted in ethical and legal traditions


**BIOGRAPHY**

Michael L Millenson is a writer, consultant, researcher, and activist for patient centred healthcare.

As a healthcare reporter for the *Chicago Tribune* he was nominated three times for a Pulitzer prize.


### Dissolving old boundaries

The digital health domain provides some of the most visible evidence of this shift. Increasingly, people can find, create, control, and act on an unprecedented breadth and depth of information. For example, according to its website the for-profit patient network and research platform PatientsLikeMe has amassed more than 520 000 patient profiles for more than 2700 conditions, filtering data reported by patients through analytical tools in an independent online collaboration.[3]

Although most PatientsLikeMe users are American, participation in this and similar platforms will grow as the digital divide continues to diminish. In 2015, more than half of adults in 21 emerging and developing countries reported using the internet or owning a smartphone (rising to 87% in 11 advanced economies).[4] In 2017, an estimated 8.4 billion objects were part of the "internet of things" (sensors and web connectivity in everyday objects).[5] People can increasingly "integrate data from diverse aspects of life—financial, medical, home automation—and control what to share with whom," the web's creator, Tim Berners-Lee, has said. And they can decide whether that sharing necessitates real world partners, such as their doctor.

Much attention has been paid to the emergence of "e-patients."[6] As significant, however, are efforts by private and government organisations bearing financial risk for medical costs. These efforts can be relatively rudimentary: the NHS, for example, provides an online repository of vetted diagnostic and health management apps. But organisations can also play an important part in proactively engaging vulnerable populations, who otherwise risk being left out of patient driven initiatives.

Consider a vendor placing biometric sensors in the home of an older person wishing to "age in place." The sensors transmit information to a computer centre, where algorithms flag potential problems—for example, a change in toilet habits could mean a possible urinary tract infection. When an alert is triggered, a clinician from the company (not the family doctor) contacts the person. This collaboration may involve just the family and vendor. But it could also involve another party with an interest in the person's wellbeing—for example, a US retirement community[7] or an Italian municipal government.[8]

### Beyond technology's glitter

Finally, the collaborative health umbrella covers activities that may have little or no consumer e-health element. Chronic disease is implicated in 60% of all deaths globally,[9] prompting more intense attention to the socioeconomic factors that affect health. The result has been an upsurge in interventions by organisations that bear financial risk for medical costs. Their purview has expanded both to areas once thought to be reserved for clinicians, such as drug adherence, and to the work of social service organisations.

In the US, for example, some health plans have been helping members with food, shelter, and even finding a job. The motivation may be less Matthew 25:36 ("I was naked and you clothed me, I was sick and you looked after me") than mammon (lower medical costs). Yet whatever moral message this may send, sick people are being looked after (particularly if they're at risk of getting expensively sicker) in collaborations outside the traditional clinical and public health infrastructure.

## THREE CORE PRINCIPLES

**Shared information**

Opening the complete electronic health record for patients to read, comment on, and share improves their ability to manage their health.[20] Moreover, by making sharing the default, the profession sweeps away a critical information asymmetry and has a moral standing to demand that corporations and governments practise similar transparency with the "big data" they collect. That's imperative at a time when half of consumers are willing to share health data with Apple, Samsung, Microsoft, or Google.[21] At the same time, the profession will have to be much better at communicating information.

**Shared engagement**

Collaborative health is multidirectional and multidimensional. For example, a paediatrician related how parents of a baby with a rare condition referred him to a Facebook group where families exchanged stories. What he learnt there shaped the eventual clinical decision.[22]

Collaboration also means accommodating varying engagement preferences. Elsewhere,[23] I've suggested that clinicians adopt an approach which encourages active exchange of ideas and the explicit negotiation of differences.[24] This flexibility fits those who may want or need the doctor to guide prevention or care, those in the do-it-yourself health movement, those who prefer shared decision making, and those whose preferences may shift because of illness or a new life situation. It's also a model that sometimes allows one partner to say, "I want you to decide."

**Shared accountability**

This may pose the greatest challenge. Hierarchies have clear lines; shared power is more complex, particularly among diverse individuals and organisations. For example, a device company offers consumers a diabetes management app developed with an artificial intelligence company.[25] Who is accountable for that individual's health, and what role does the doctor play?

Important questions related to ethical and legal responsibilities for care continuity, communication, privacy, and security remain. However, adopting an explicit collaborative health framework that acknowledges the presence and power of traditional and non-traditional actors—not just "providers" and "patients"—allows and encourages the raising of these kinds of questions.

### Cops and docs

Analogous trends in crime prevention reflect the influence of the same larger societal forces driving collaborative health. In the US, UK, and elsewhere, data driven analytics and decision making are being used to prevent crime in much the same way those strategies are being used to prevent acute illness. Interventions with a healthcare counterpart include "hot spotting" (timely identification of extreme patterns in data), home visits, and focusing on frequent users.[10] Some crime prevention and healthcare strategies even engage the same groups, such as churches, and, for both, their collaborations may at times exclude the professionals who have historically served as the public face—that is, the police officer or family doctor.

To be clear: prevention has limits. We'll always need cops to catch bad guys and medical professionals to minister to those coping with what Susan Sontag famously called the "night side of life" in the "kingdom of the sick." All of us are vulnerable, and the core values of competence and compassion for people in need remain unchanged.

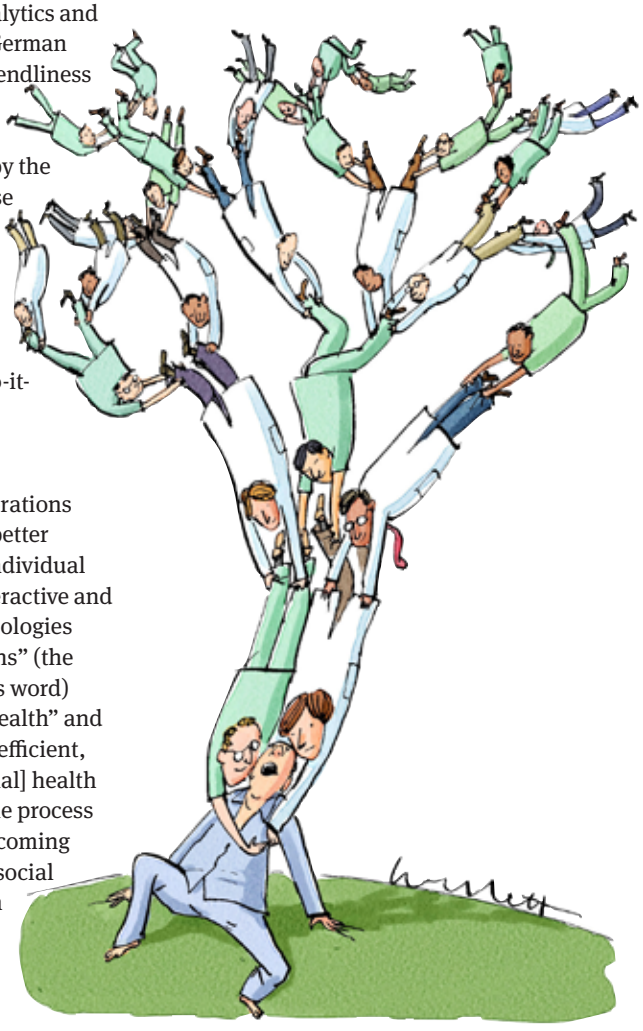
What the collaborative health concept provides, however, is a framework for understanding how the traditional and non-traditional will coexist and interact in a healthcare ecosystem with new players and relationships. Pieces are already in place: the Australian Coles supermarket chain collecting health and fitness data; a US wellness firm combining genomic, clinical, lifestyle, and behavioural data with predictive analytics and health coaching[11]; the German Agency for Self Help Friendliness aiding hospitals in collaborating with patient groups formed by the chronically ill.[12] All these take place alongside doctors treating heart attacks, trauma, and children with earaches, and "digital natives" dabbling at home in "do-it-yourself" health.[13]

### Control issues

These emerging collaborations promise better health, better healthcare, and more individual autonomy. Already, interactive and personalised web technologies are empowering "citizens" (the European Commission's word) "to manage their own health" and "contribute to modern, efficient, and sustainable [national] health systems."[14] Although the process of biomedical actors becoming more active in tackling social problems[15] is often seen as medicalisation, that characterisation only partially fits here. Not only are many of these non-traditional actors not biomedical, the unifying principle underlying collaborative health is a fervent desire by both individuals and organisations to have fewer medical interventions. Rather than creating illness for professional privilege[16] or profit, collaborative health could as easily be termed demedicalisation.[17]

The real potential of collaborative health, however, is accompanied by equally real dangers. Control of patient data has been dubbed "the new money,"[18] and global corporations are in hot pursuit. Today's incentives may become tomorrow's coercion. Digital datasets may be used to "manipulate, coerce, surveil, target, and manage people," as well as perpetuate "existing social injustices and disadvantages."[19]

In other words, while collaborative health provides an important framework for understanding and responding to



disruptive changes under way, how we as a society shape those changes remains crucial. Particularly critical is the professional response. Three core principles of explicitly and voluntarily sharing power—in the forms of information, engagement, and accountability—should guide medical practice in this new environment (box).

**Greener pastures, not higher fences**

An aphorism popular in some sections of the US system goes this way: "Greener pastures, not higher fences." It suggests doctors should embrace, not resist, the changes needed to make their practices more attractive to patients and to maintain their trust.

Are physicians willing to create a "greener pasture" of true collaboration in diverse wellness and sickness relationships? Will they accept sometimes being cut out entirely until we call upon them? If so, nine out of 10 of us want our doctor as a partner.[27] Or will doctors seek to maintain the high fences of professional privilege, resisting revolution and holding ever tighter to incrementalism?

In the information age, "the magic, mystery, and power of the profession may be somewhat diminished," one informatics pioneer observed, but the opportunity to "bolster the cognitive and moral pillars" of professional identity will grow.[28] Mutual trust is the foundation upon which those pillars must rest. Taking concrete actions to implement shared information, engagement, and accountability are critical to building that foundation. The Quill and Brody model, as well as the collaborative deliberation model suggested by Elwyn and colleagues,[29] are good places to start.

Though the role of the doctor is in flux, there remains great value in professional expertise rooted in ethical and legal traditions.[30] As economic, technological, and social changes give rise to new networks of collaborations, we the citizenry (your sometime patients) need you at our side, both for our sake and to counteract others' economic or political agendas. Accepting a less central role may feel at first as if collaborative health is shrinking the profession's importance. In reality, accepting true partnership will profoundly expand the profession's influence in the days to come.

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Find the full version with references on bmj.com.

Cite this as: *BMJ* 2017;358:j3048

**COMMENTARY** Iona Heath

# Information without wisdom

This is the dystopian future: health related data are to be harvested from a huge variety of digital sources, including biometric sensors attached to individual bodies. This information is then fed back to the supposedly autonomous person and can be used to trigger algorithms and offer possibilities for remedial interventions.[1]

Technology is remarkably seductive and may delude us into thinking that the human condition is changing faster than it really is. Big data, biometric sensors, and the vaunted promise of e-health have undoubted contributions to make to contemporary healthcare but fall far short of delivering the moral core of medicine that has always been the relief of suffering. Despite all its cleverness, big data and biometric sensors cannot access the lonely subjective experience of the fearful and distressed individual in the face of the threat of disease and death.

The whole process is profoundly normative, always looking for deviations from the mean to define abnormality and a need for action. The biologically normal is a broad and accommodating phenomenon, but big data will be interpreted within arbitrarily set limits. From experience, these limits will likely be narrowed in the financial interests of companies eager to maintain their place in the healthcare market. The likelihood of false positives is enormous and further medicalisation inevitable.[2] T S Eliot was prescient: "Where is the knowledge we have lost in information?"[3] Let alone the wisdom?

Medicine cannot afford to leave wisdom to be considered only by humanist scholars and writers. In his profoundly wise book *Mortality, Immortality and Other Life Strategies*, the late Zygmunt Bauman describes 'the primacy of individual mortality among the constituents of the human predicament'[4] and posits the whole of human culture as a gigantic ongoing effort to give meaning to human life in the face of intolerable and unavoidable finitude of death. For Bauman the current obsession with monitoring fitness and health is a futile attempt "to redefine the unmanageable problem of death . . . as a series of utterly manageable problems."[5] We deny death but also the dying, whose care is an essential part of medicine within which big data and e-health have nothing to offer. This is no coincidence because the proponents of e-health also seem to draw only a minimal distinction between the currently well and the currently sick and yet these categories demarcate fundamentally different needs and experiences of healthcare systems.

**Despite all its cleverness, big data and biometric sensors cannot access the lonely subjective experience of the fearful and distressed individual in the face of the threat of disease and death**

Any healthcare professional who has been seriously ill knows that information rarely reduces the fear that is intrinsic to all illness, beyond the self limiting and trivial, and that it can often aggravate fear by suggesting a range of possibilities that might not have come to mind without the information. Too much contemporary healthcare exacerbates fear systematically in the interests of profit and reputation[6] but there may be much worse to come. Recent history suggests that the latest wave of technological innovation will work more in the interests of the medical-industrial complex than in those of the distressed and suffering individual.

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Find the full version with references on bmj.com.

Cite this as: *BMJ* 2017;358:j3203

EDITORIAL

# Judging the benefits and harms of medicines

Only trustworthy evidence will earn the public's trust

How should society judge the safety and efficacy of drugs? This was the question posed by England's chief medical officer, Sally Davies, in February 2015. Citing controversies about oseltamivir (Tamiflu) and statins, as well as growing disquiet about overmedication by doctors and conflicts of interest among researchers, she feared an erosion of public trust and asked the Academy of Medical Sciences to undertake a review.[1] In June that same year, editorialists in *The BMJ* called on the academy to recommend "simple practical improvements that would address legitimate concerns."[2] The academy has now published its report.[3] Does it deliver?

The academy confirms that there is a problem. Its survey found that only one in three members of the public trusts the results of research. In response to this finding, which the chair of the report, John Tooke, called "startling,"[4] the academy has produced a wide ranging report that says many of the right things. But the overall result is disappointing. The academy report includes welcome calls for researchers to involve patients and be more transparent (see box of recommendations on bmj.com), but its main focus is better communication with patients and the public. It offers few new or concrete suggestions to tackle what the UK's Science and Technology Committee identifies as a crisis in reproducibility of research and an upward trend in misconduct and mistakes.[6]

## Missed opportunities

*The BMJ* has been closely involved in issues that triggered the report and continues to campaign on them. What does the report say about these issues, and what could it have said? A "detailed account" of the statins saga sticks to the version presented in various places by the Cholesterol Treatment Trialists collaboration.[7] The report says that future controversies could be prevented through better communication and, among other things, better access to data. But the debate about statins in people at low risk has not gone away,[8-11] and the anonymised trial data remain inaccessible. The academy could have put its weight behind calls for an independent review of the evidence,[12] similar to the review on breast cancer screening commissioned by the UK's cancer tsar in 2012.[13]

**The academy's priorities seem to be to reassure patients so that they will take their pills, and to collaborate closely with industry to develop more**

The report makes far less of the controversy around oseltamivir, despite this being perhaps the best illustration of why the public and professionals cannot trust the published evidence. The academy could have used its position to hold Roche accountable for withholding data, undermining public trust, and wasting public money. It could also have made concrete proposals for better independent research during future pandemics.

## Optimism bias

As for overmedication, this has many causes. Most relevant to judging the benefits and harms of medicines is the optimism bias afflicting the medical literature. Poor science, research misconduct, and publication bias all contribute to the systematic exaggeration of benefit and understatement of harm.[16] Communicating this overoptimistic view more effectively will only compound the problem. But the academy's priorities seem to be to reassure patients and the public so that they will take their pills, and to collaborate closely with industry to develop more. It would have been good to see the academy acknowledge the avoidable harm and cost caused by overmedication, and to propose possible solutions and avenues for further research into the problem.

The report looks to funders and the next research excellence framework to incentivise better research and publication practices. But the academy could also lead by example. Its nearly 1200 fellows comprise a sizeable swathe of the UK's medical science leadership. They could be required to declare their competing interests on the academy website. They could also publicly commit to involving patients in their research, making their data shareable, sharing their data on reasonable request, running their own research teams in ways that promote reliability and transparency, and publishing their research in full, in a timely manner, and in open access journals.

## Status Quo

The academy had an opportunity to show leadership and independence. But its report says little to unsettle the status quo, suggesting it was not the right group to take on this task. By contrast, the Evidence Manifesto initiative (evidencelive.org/manifesto/) leaves no room for doubt that there is a crisis in our evidence base and sets out an agenda for radical change.[19] We hope that the UK science and technology committee will pick up its inquiry into research integrity,[6] which was postponed for the general election. As Carl Heneghan, director of the Centre for Evidence Based Medicine in Oxford, said at the recent Evidence Live conference, there is a problem with the E in EBM. If we want the public to trust the evidence, we must make the evidence trustworthy.

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Cite this as: *BMJ* 2017;357:j3129

Find the full version with references at http://dx.doi.org/10.1136/bmj.j3129

EDITORIAL

# Is psychiatry becoming more coercive?

The rising trend is damaging for patients, unsupported by evidence, and must be reversed

More and more people are being subjected to coercive psychiatric interventions, even within well resourced mental health systems. The term coercion has a broad definition in mental healthcare,[1] but here we focus on the use of force or compulsion. In England, the rate of involuntary psychiatric hospital admission has increased by more than a third in the past six years.[1] In Scotland, the number of detentions has increased by 19% in the past five years.[2] More than half of admissions to psychiatric hospitals in England are now involuntary, the highest rate recorded since the 1983 Mental Health Act.[1]

The use of coercion in mental healthcare is a global phenomenon. As well as involuntary admission, coercive measures include forced administration of medication, involuntary confinement in isolation or seclusion, and manual or mechanical restraint.[3]

## Expansion of institutions

The increasingly coercive culture in mental healthcare is also evident from a renewed trend towards institutionalisation of mentally ill people.[4] The marked expansion of "protected" housing (secure housing, with restricted freedoms) for people with mental illness in the community and increase in the number of forensic psychiatric beds in many European countries are indicative of this trend.[5] New types of secure mental health facilities are also emerging, replicating some of the functions of old style asylums. In Italy, for example, a new law in 2012 required the development of secure residential facilities for people with mental disorders considered "socially dangerous." Legislation such as this, disguised as innovation, represents a backwards step.[6]

Our prisons are also increasingly used to manage and contain mentally ill people. There are now over three times more mentally ill people in jails and prisons in the US than in hospitals, and 16% of them have serious mental illness.[7] In the UK, 15%-25% of the prison population reportedly has a psychotic illness.[8]

More generally, psychiatric practice, even in seemingly unrestrictive settings, is undergoing a cultural shift towards greater coercion. This is shown by the advent of compulsory treatment in outpatient settings and in the community. Community treatment orders are now "a feature of most developed mental health services,"[9] although there is little evidence that they offer any benefit.[10] The use of such orders in England has increased every year since their introduction in 2008.[11]

Risk management has become a central tenet in the care of mentally ill people. Clinical practice seems no longer driven by the needs of the individual but by risk assessments, often of dubious validity.[13]

Psychiatric facilities are increasingly relied upon, instead of prisons, for long term detention of people who have committed sexual or other violent crimes. For example, use in England of the controversial diagnosis "dangerous and severe personality disorder" to detain people in psychiatric hospitals because of their perceived risks to others is an ill conceived attempt to hide preventive detention behind the veneer of respectability provided by a mental health context.[14]

**Further social exclusion of people with mental illnesses is inevitable if we continue to conflate the concept of dangerousness with poor mental health**

In the US, so called sexual predator laws[15] allow serious sexual offenders to be detained indefinitely in mental health treatment facilities after they complete prison terms. Although society has the right to be protected, using healthcare facilities to detain people for punishment rather than treatment, is inconsistent with basic medical ethics.

## Counterproductive

This cultural shift in psychiatry, which prioritises risk management over individual health and social needs is likely to be counterproductive. The stigma associated with mental illness will increase as care becomes more coercive. Further social exclusion of people with mental illnesses is inevitable if we continue to conflate the concept of dangerousness with poor mental health. Those who might benefit from psychiatric care are likely to delay or avoid contact with health services for fear of losing their liberty and compromising their basic rights.

Collaborative and person centred care leading to recovery is an aspiration of most modern mental health services. This aspiration is entirely inconsistent with the increase in compulsion and involuntary care across much of psychiatry. As three commentators recently concluded, "It would be more humane, just and effective to implement alternatives that serve to reduce experienced and actual coercion, promote the wider involvement of people in their care, and potentially improve outcome."[16]

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Cite this as: *BMJ* 2017;357:j2904

Find the full version with references at http://dx.doi.org/10.1136/bmj.j2904