BMA took legal action to keep bonus scheme

The BMA has taken legal action against the government over incentive payments for doctors, which it says are part of their contract and therefore should not be changed without negotiation. The action, which has now been put on hold, was part of ongoing negotiations on changes to the consultant contract in England.

BMA negotiators and the government have been discussing the possibility of reaching an agreement outside court that would allow consultants to retain their existing awards, the BMA said. The government argues the awards are non-contractual and so don't need to be retained in the new contract.

Clinical excellence awards—payments designed to reward outstanding work—have been awarded since 2003.

The BMA is also working with the government to develop a new system for performance related pay. Unlike the clinical excellence awards, the payments would be time limited and non-pensionable.

"Payments would also have a stronger link to the objectives of trusts and include protection for existing award holders," the Department of Health and Social Care said.

In a report submitted to the Review Body on Doctors' and Dentists' Remuneration, the department said that the legal claim had "complicated" the negotiation.

A BMA spokesperson said it was working with the government "to develop a successor awards scheme which continues to encourage and fairly reward excellence."

Abi Rimmer, *The BMJ*

Cite this as: *BMJ* 2018;360:k569

Doctors told to push safe vaping message to smokers

E-cigarettes pose only a small fraction of the risk of smoking, and encouraging smokers to switch completely to vaping would produce substantial health benefits, says a review of the evidence commissioned for Public Health England.

The review, written by an independent panel, says that under half of adults in Britain think e-cigarettes are less harmful than smoking. This falls to a third among smokers who have never tried them.

Health professionals should tell smokers clearly that "vaping is at least 95% less harmful than smoking" to communicate the large difference in relative risk unambiguously and to encourage more smokers to make the switch, the report says.

Compelling evidence shows that e-cigarettes should be made available to NHS patients, says PHE, and some should be regulated as medicines through the Medicines Healthcare Products Regulatory Agency, recommending a review of how to achieve this. It also calls on NHS trusts to ensure that e-cigarettes are available for sale in hospital shops alongside nicotine replacement therapies.

E-cigarette plateau

Over the past few years e-cigarette use has plateaued at just under 6% of the adult population in Britain, the report says, and around 40% of smokers have never tried to vape.

The most common reason for e-cigarette use continues to be to help stop smoking, and smokers who use them have a generally higher motivation to quit than other smokers. The report adds

THE REPORT adds that success rates in quitting have improved and that smoking rates are now as low as 15.5%

Vaginal mesh register must be mandatory

A mandatory register to record outcomes in all vaginal mesh treatments is essential to monitor any adverse effects, the Royal College of Obstetricians and Gynaecologists has said.

The college was responding to government plans for an audit of mesh problems, which aims to better understand complications related to implants used for incontinence and prolapse. It is expected to be completed by April.

Tim Hillard, the college's lead for patient safety, said that although he supported the audit, he would like to see more done. "Retrospective audits in general are incomplete and open to bias," he said. "What we would really like to see is a mandatory prospective registry of all of these procedures. We have been calling for that through the British Society of Urogynaecology and the college for many years."

Voluntary database

The society has had its own voluntary database for all urogynaecology procedures including mesh for more than 10 years. However, it is unlikely to record more than half of all procedures.

Hillard said it was hard to get a clear picture of how many women had sustained adverse reactions, but trials had found it could be as high as 10% after prolapse procedures, although lower when mesh is used for incontinence. "But, longer term problems seem to be emerging," he said. "Our priority is to ensure women are provided with the most effective and safest treatment for what are common and often distressing conditions. A prospective audit would allow us to collect the information and start to build a better picture."

Kath Sansom, founder of the Sling the Mesh campaign group, said a retrospective audit would give a better idea of the scale of the mesh problems, but she added, "A prospective register is 20 years too late."

Abi Rimmer, *The BMJ*

Cite this as: *BMJ* 2018;360:k586

that success rates in quitting have improved and that smoking rates are now as low as 15.5% in England.

E-cigarettes help 22 000 to 57 000 smokers successfully quit in England each year, the report estimates. The greatest success rate is among smokers who combine e-cigarettes with support from a local stop smoking service.

The report recommends that health professionals and stop smoking clinics should provide behavioural support to smokers who want to use an e-cigarette to help quit. A training course for healthcare professionals by the National Centre for Smoking Cessation and Training is available.

The Public Health England report notes widespread misconceptions about the relative risks from nicotine and tobacco, which it says must be corrected. For example, a survey found that only 8-9% of adults in Britain understand that most of the harms to health from smoking are not caused by nicotine.

Ann McNeill, lead author and professor of tobacco addiction at King's College London, said, "People smoke for the nicotine, but, contrary to what the vast majority believe, nicotine causes little if any of the harm. The toxic smoke is the culprit and is the overwhelming cause of all the tobacco related disease and death.

"Regular use of e-cigarettes among young people who have never smoked remains negligible"

Variety of alternatives

"There are now a greater variety of alternative ways of getting nicotine than ever before, including nicotine gum, nasal spray, lozenges, and e-cigarettes."

The review, an update of PHE's 2015 review, finds no evidence to support the concern that e-cigarettes are a route into smoking among young people. It says that e-cigarettes do not seem to be undermining the UK's long term decline in cigarette smoking among teenagers.

Linda Bauld, report author and professor of health policy at the University of Stirling, commented, "In the UK, research clearly shows that regular use of e-cigarettes among young people who have never smoked remains negligible, less than 1%, and youth smoking continues to decline at an encouraging rate.

"We need to keep closely monitoring these trends, but so far the data suggest that e-cigarettes are not acting as a route into regular smoking among young people."

Jacqui Wise, London

Cite this as: *BMJ* 2018;360:k575

Surgeon who faked keyhole experience is jailed for six years

A surgeon who lied about his work experience to land a job as consultant has been jailed for six years for fraud.

Sudip Sarker (right) was appointed a general and colorectal surgeon at Alexandra Hospital in Redditch, Worcestershire, in August 2011.

Suspended

But after another surgeon blew the whistle, a review by the Royal College of Surgeons in 2012 expressed serious concern. He was stopped from operating, on the royal college's advice, and then suspended on full pay in October 2012.

Worcester Acute Hospitals NHS Trust had advertised for a surgeon who was an expert in keyhole surgery, and Sarker, who had worked at London's Whittington and Royal Free hospitals, claimed to have carried out 51 keyhole operations.

Jacob Hallam QC, prosecuting, told the court that Sarker had left "a trail of devastation." The trust has paid damages totalling nearly £2m to patients whom Sarker had operated on, with one claim still outstanding.

The court heard that the RCS review had revealed that Sarker had a much higher mortality rate than other surgeons and a considerably higher rate of complications.

Restorative procedure changed

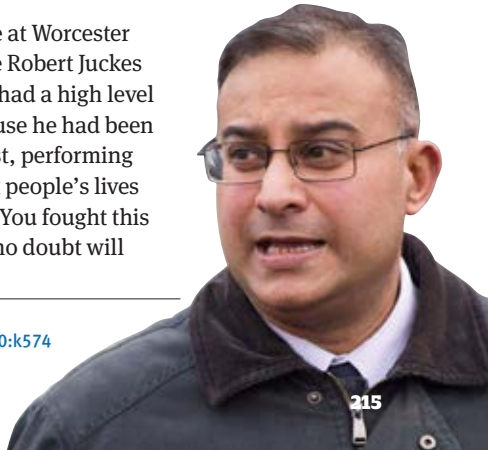
The RCS report stated, "Over half of the patients that were deemed to have a cancer that made them suitable for a restorative procedure had this changed, dramatically, to an operation that resulted in permanent colostomy. The review team has never in their collective experience seen anything similar.

"To have almost one patient in five with an operation for which they had not been counselled is, in the review team's opinion, unacceptable."

Sarker's defence counsel, Martin Hicks QC, said that experts had concluded that there was no evidence to support a case for manslaughter.

Passing sentence at Worcester Crown Court, Judge Robert Juckes told Sarker that he had a high level of culpability because he had been in a position of trust, performing operations that put people's lives at risk. He added, "You fought this at every stage and no doubt will continue to do so."

The trust has paid damages totalling nearly £2m to his patients, with one claim still outstanding



Clare Dyer, *The BMJ*

Cite this as: *BMJ* 2018;360:k574

of their responsibility to patients and have offered to cooperate with the regulatory authorities to weed out medically irrational FDCs."

Chicago based Abbott Laboratories was the top global maker selling unapproved combinations, with 18 formulations, including five of eight brands that combined two drug classes designated by WHO as "highest priority critically important antimicrobials."

Some of the formulations may be dangerous. For example, one Abbott product, Ertycin L, mixes levofloxacin and azithromycin (also sold by Indian companies under different brand names). Each drug has been independently linked to increased risks of cardiac arrhythmia and death. Data seen by *The BMJ* show it was launched in 2011 and was registering Indian sales in January 2016.

Lindsy Delco, Abbott's head of public affairs, told *The BMJ* it no longer sells Ertycin L in India: "The products listed in the study were medicines Abbott acquired in 2010, many of which are no longer sold in India. The medicines still available in India all have central government approval. Abbott follows all Indian laws and regulations."

Larger profit margins

Antibiotic combinations can be priced higher than single dose formulations, creating larger profits for manufacturers, wholesalers, pharmacies, and dispensing doctors.

Anita Kotwani of the University of Delhi, who is working on a government resistance action plan, said awareness of resistance in India "is really poor among all stakeholders."

Ramanan Laxminarayan, director of the Center for Disease Dynamics, Economics and Policy, a non-profit organisation with offices in Delhi and the US, said, "When you combine drugs in irrational combinations, you very efficiently are selecting for co-resistance. This is a direct threat to public health. It's probably worse than selling cigarettes."

India's drug controller's office and the Organisation of Pharmaceutical Producers of India did not respond to requests for comments.

Frederik Joelving, Copenhagen

Cite this as: *BMJ* 2018;360:k560

THE STUDY shows Indian sales of antibiotic combinations climbed by **38%** and accounted for a third of all antimicrobials sold—872m units—by 2011-12

failed to meet the criteria defined in the protocol, but in 2003 Restasis was approved on a surrogate marker, the Schirmer response, which measures tear production.

"Minimal benefit"

Applications to license the drug in Europe have failed. Allergan won a licence in Canada on the basis of a post-hoc analysis of the trial data. But the same data failed to convince Australian regulators, who found "minimal or no benefit over and above placebo at most time points."

Restasis costs around $400 a month. In 2016 NICE approved an alternative, Ikervis (also containing ciclosporin), which costs around £72.

Ikervis was licensed by the European Medicines Agency, but its underlying evidence is hardly more convincing than for Restasis. The pivotal trials failed to meet the prescribed endpoint, and secondary endpoints showed only modest improvements—but sufficient to be clinically meaningful, said the agency.

Nigel Hawkes, London

Cite this as: *BMJ* 2018;360:k492

FIVE MINUTES WITH . . .

Greg James

The GP trainee in Gwent talks to **Anne Gulland** about men's body image clinics

"For six months, fellow GP trainee Rhys Evans and I have been running the image and performance enhancing drug (IPED) clinic in Gwent. It's one of only a few such clinics in the country. Rhys is a competitive bodybuilder and I've done some weight lifting so it was an area of interest for us.

"I met Mike Mallett, who runs the needle exchange. Up to 60% of his work is with users injecting IPEDs. We then got together with Jo Hughes, a bloodborne virus nurse, who applied for funding.

"Public health evidence shows that bloodborne viruses, hepatitis B and C, and HIV, are increasing faster among IPED users than among traditional injecting drug users. The biggest population group we see are not bodybuilders, but people taking these drugs because they want to look better. They're mainly using anabolic steroids but also insulin, growth hormones, and a whole array of peptides. They're also using things like thyroid hormone to burn body fat, beta agonists to speed up the heart rate and burn fat, and water tablets. Some are also using antibiotics to cope with acne, a side effect of anabolic steroids.

"OUR PATIENTS USE ANABOLIC STEROIDS, INSULIN, GROWTH HORMONES, AND PEPTIDES"

"We offer a health screen: bloodborne virus, liver and kidney, thyroid, and heart. So far, nearly every patient we've seen has had some problem with their lipid panel. Some have shown early signs of kidney failure and some have deranged liver enzymes.

"The patients are great—very interested in their healthcare and how to minimise harm. One asked about the impact of anabolic steroids on the heart. He's now stopped using IPEDs.

"There's no physiological addiction but users get a psychological dependency. When they take anabolic steroids they feel well, their mood stabilises, they do well in the gym. Not only does it improve their physique but it also improves how they perceive it. When they stop taking them they get a rebound depression. It would be nice to offer counselling, to explore their body image beliefs.

"Most clinicians don't know anything about IPEDs or what they should do if someone tells them they've been using anabolic steroids. Prevention is better than cure and it would be good to talk to young people about these drugs."

Anne Gulland, London Cite this as: *BMJ* 2018;360:k558

RICHARD H SMITH

EDITORIAL

Bringing Vioxx back to market

Regulatory and transparency safeguards are essential to protect patients

In 1999, the US Food and Drug Administration (FDA) approved rofecoxib (Vioxx) for the treatment of acute pain and the pain associated with osteoarthritis. Its manufacturer, Merck, marketed the drug as an effective, safer alternative to non-steroidal anti-inflammatory drugs (NSAIDs) and obtained subsequent FDA approvals for the treatment of rheumatoid arthritis and migraine.

Additional studies were done to examine rofecoxib's efficacy in delaying the progression of Alzheimer's disease, preventing adenomatous polyps of the colon, and managing premenstrual acne. By 2003, millions of people were taking the drug and it had accrued more than $2.55bn (£1.8bn) in sales.[1] However, in September 2004, Merck withdrew rofecoxib from the market after concluding that it was associated with increased cardiovascular risk.[1]

Now, 14 years later, the small drug company Tremeau Pharmaceuticals has announced plans to bring the drug back to market for severe joint pain caused by haemophilia.[2]

Controversial history

Rofecoxib's previous turn on the US market provided some important lessons for those weighing the expected benefits and risks in both intended patient users and the broader population. The drug's history highlights how marketing and research can be used to influence the published evidence that informs patient care—problems that are not unique to rofecoxib.[3-7]

If relicensed, rofecoxib is likely to be used by a broader population of patients than those with haemophilia. We propose the following regulatory and transparency safeguards to ensure the integrity of evidence gathered in support of bringing the drug—and others like it—back to market.

First, as a condition of rofecoxib's market approval, safety outcome data should be routinely collected and independently arbitrated. This did not occur originally for the area of most concern, cardiovascular disease.[8] Trials examining its use in haemophilia related joint pain are likely to be short term, but cardiovascular safety should be assessed for their duration and participants should be followed up after use has stopped, since important events continued to accrue in previous trials of rofecoxib.[9]

Because any new evidence is likely to be underpowered to discriminate safety concerns, systematic postmarket safety evaluations must be required by regulators, including clinical trials and surveillance studies that exploit existing data sources.

Second, as already mandated by the FDA Amendments Act, all clinical trials should be registered on ClinicalTrials.gov before initiation and results should be reported within 12 months of completion. Though compliance with this requirement is improving,[10] timely registration and reporting remains suboptimal.[11 12]

Furthermore, all trial data should be made available after completion to independent investigators, both for reproducibility purposes and to facilitate additional research that may enhance our understanding of drug efficacy and safety for subpopulations of patients.[13] Broader access to the clinical trial data by independent scientists may have led to earlier identification of rofecoxib's cardiovascular risk.[14]

> Rofecoxib's history highlights how marketing and research can be used to influence the published evidence

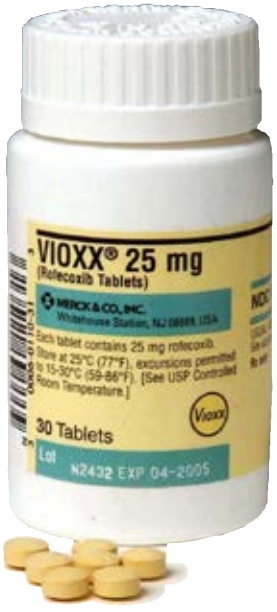
Third, while the intended population of patients with haemophilia is relatively small, the FDA should consider engaging in population surveillance to monitor off-label use of rofecoxib if it secures market approval. Many drugs have been approved for one use and used for another—for instance, more than 80% of gabapentin and amitriptyline use was characterised as off-label.[15]

If off-label use occurs, and passes a commonsense threshold (say, 20% of use), the FDA could require the manufacturer to conduct rigorously designed studies to evaluate its safety and efficacy for this off-label use and possibly secure a supplementary approval.

Formulary management

Finally, insurance payers, including the Centers for Medicare and Medicaid Services, should adopt formulary management strategies that restrict access to drugs with known safety risks like rofecoxib, including requiring prior authorisation or step therapy. Although not done routinely,[16 17] formulary management offers a unique opportunity to steer patients towards alternative therapies that may be equally effective and safer.

These regulatory and transparency safeguards should be considered for all marketed medical products to protect patients. But they would be particularly useful when considering bringing a drug with known safety risks back to market, particularly one likely to be used well beyond the intended population.



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EDITORIAL

Nucleic acid based therapies: new frontier for precision medicine

Affordability will be the key challenge

The genomic revolution, heralded by the completion of the human genome project, is providing unprecedented knowledge of the underlying genetic basis of disease.

In the UK, the 100 000 genomes project has begun to uncover the genetic basis of rare diseases, ending the diagnostic odyssey many families have had to face. Precision diagnosis, however, is only the first step in developing precision therapies. The molecular basis of disease needs to be understood to enable the creation of treatments targeted at individuals with specific mutations, to repair or overcome the molecular defect.

Understanding the molecular basis of cystic fibrosis has led to the development of small molecules, such as ivacaftor, that improve the functioning of the cystic fibrosis transmembrane conductance regulator (CFTR) in people with the G551D gene mutation—around 4% of those with cystic fibrosis.[1]

Identifying mutations also allows repurposing of medicines, such as the use of high dose riboflavin in childhood motor neurone disease, a condition caused by mutations in riboflavin transporters SLC52A and SLC52A.[2]

Gene therapy for haemophilia

Over the past year, some big advances have been made using nucleic acid based therapies. People with haemophilia A, an X linked disorder, currently require frequent infusions of factor VIII to prevent bleeding episodes. A recent small and preliminary dose ranging study using an adenovirus gene therapy vector showed that factor VIII concentrations returned to normal 52 weeks after a single infusion in six out of seven participants, with a reduction in bleeding episodes and rescue factor VIII infusions.[3] If the results were replicated in much larger studies this could be a remarkable advance.

Improved methods of packaging and delivering gene inserts could be transformational, not only for haemophilia A patients,[3] but also for those with sickle cell disease,[4] RPE65 mediated inherited retinal dystrophy and junctional epidermolysis bullosa.[5 6]

Antisense oligonucleotides provide another form of nucleic acid therapy. These single stranded oligonucleotides bind to their complementary mRNA, affecting splicing and restoring protein synthesis.[7] This is exemplified by the antisense oligonucleotide nusinersen, recently licensed for the treatment of spinal muscular atrophy, which works on the SMN2 gene, producing a full length protein.

A randomised controlled trial in 121 patients showed that treatment early in life significantly reduced mortality and improved motor function.[8] The cost is, however, enormous—$750 000 (£530 000) for the first year and $375 000 per year thereafter—which prompts questions about whether it is affordable.

Antisense therapy can also be used to prevent the formation of a mutated protein.[7] A lot of media excitement greeted the phase I trial finding that the drug Ionis-HTTRx, cut levels of the mutant huntingtin protein in 46 patients with early Huntington's disease in a dose dependent manner.[9] The trial has not been published, and it is too early to know if longer term therapy will improve symptoms and survival, but if shown to work clinically would be transformational.

Finally, genome editing holds great promise. We can now edit DNA to remove or correct a mutation, or alter the sequence of a gene at a precise location in the genome by using engineered nucleases such as the CRISPR-Cas9 system.[10]

Genome editing of embryos is already possible, as highlighted by a recent study in which a mutation in the MYBPC3 gene (which causes hypertrophic cardiomyopathy) was repaired.[11] Genome changes can be passed from one generation to another. This brings up ethical challenges, with (perhaps unfounded) fears that it could pave the way to "designer babies." Another concern relates to the specificity of the CRISPR-Cas9 system and whether it may produce unintended "off-target" mutations.[10]

> It is important not to overhype the promise of these therapies

Gene therapy for cancers

Somatic gene therapy is perhaps less of a concern ethically and is already finding application in malignancies. T cell therapies using chimeric antigen receptors (CAR) have been used successfully, for example in acute lymphoblastic leukaemia, leading to the first FDA approval. Tisagenlecleucel, a CAR-T cell therapy targeting the CD19 lymphocyte antigen, has a list price of $475 000 for a one time infusion.[12]

Advances in nucleic acid based therapies have been remarkable, providing treatments for diseases that have had few or even no satisfactory therapeutic options. But it is important not to overhype their promise. We need a realistic approach that allows proper assessment of efficacy and to develop monitoring to assess long term safety, especially as only small numbers of patients are likely to be treated, at least initially. A key challenge will be affordability, particularly as many may not be cost effective in conventional health economic models.

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CORRECTION

In last week's print journal we wrongly referred to Jack Adcock as "Jake," in both an Editorial (p 178) and the Editor's Choice covering the Bawa-Garba case and the death of the 6 year old boy in 2011. We apologise for this error.

PERSONAL VIEW Jacky Davis

The BMA should poll its members

A new survey of UK doctors found majority support for legal assisted dying. To reflect its membership the association should, at the very least, move to a neutral position

Last year, the consultant neurologist David Nicholl wrote in *The BMJ* about the change in his views on assisted dying. He argued that patients with a terminal illness should be allowed "a death with dignity on their own terms" and wondered why the views of the UK medical profession were reportedly so out of step with those of their patients, 82% of whom support legal reform.

The BMA has long been opposed, and its view is often quoted in parliamentary debate as representing that of doctors. BMA policy is made at its annual representatives meeting (ARM), where around 400 delegates vote after listening to debates. Nicholl, believing that doctors' views should be sought outside the ARM, asked doctors.net.uk to conduct an online poll.

The poll, which ran for 10 days last October, asked whether doctors agreed that assisted dying should be made legal in defined circumstances. In all, 733 people participated—more than double the 313 who voted on BMA policy at the 2016 ARM—and 55% agreed or strongly agreed with the proposition. Not implacable opposition, therefore, but a clear range of views with most respondents in favour of a change in the law. The sample was small, but the results chime with a 2015 medeConnect poll of 1000 GPs, which found that 56% thought that medical bodies such as the BMA and the Royal College of General Practitioners should adopt a position of neutrality on assisted dying.

> "The current disconnect between its policy and the views of doctors and patients undermines the BMA's credibility and excludes it from the public debate"

The current disconnect between BMA policy and the views of doctors and patients undermines its credibility, and its continuing opposition excludes it from the public debate. In a briefing to the House of Lords in 2014, the BMA said, "For reasons of inconsistency with BMA policy it would be inappropriate to engage with the detailed proposals in the Assisted Dying Bill." Its stance of outright opposition means that constructive engagement is impossible. Doctors who support legal reform, now in the majority according to the latest poll, are left without a voice.

Assisted dying does not represent a leap into a dangerous unknown. Other jurisdictions have proved that it is possible to change the law, and doctors have shown that such laws can work hand in hand with excellent palliative care. The spread of legislation for assisted dying means the subject will keep returning in the UK.

Recently, Noel Conway, a patient with terminal motor neurone disease, brought a judicial review challenging the law on assisted dying. He has now been granted permission to appeal an earlier decision by the High Court which rejected his case. The case for a change in policy is now stronger than ever. This latest poll throws down the gauntlet to the BMA: if it does not accept the result it must challenge it with its own ballot of the membership. If it accepts the result it cannot, in good conscience, continue to oppose assisted dying.

Ultimately legalisation for assisted dying will be a decision for UK society. The job of the BMA will be to contribute to the debate, not find itself sidelined because of its implacable opposition. Its members, and our patients, deserve better.

Jacky Davis, consultant radiologist, Whittington Hospital, London
drjcdavis@hotmail.com

Competing interests: I am a member of BMA council, a board member of Dignity in Dying, and chair of Healthcare Professionals for Assisted Dying

We invited the BMA to respond but it had not done so by the time *The BMJ* went to press

Cite this as: *BMJ* 2018;360:k301

FACUNDO ARRIZABALAGA/EPA/REX/SHUTTERSTOCK

Controversy tends to subside

Support for assisted dying among doctors and the public has tended to grow once it has become legal in North American jurisdictions, reports **Bob Roehr**

Brittany Maynard had terminal brain cancer and advocated for assisted dying in states where it is illegal. She moved from California to Oregon, which permitted assisted dying, and died in 2014 aged 29, surrounded by her family (above)

More than a quarter of Americans and Canadians now have the option of choosing a medically assisted death. California and Canada legalised the procedure in 2016, following five other US states and Washington, DC, in offering terminally ill patients access to drugs to induce death if they meet strict legal criteria.

Although plans to adopt assisted dying have caused much controversy, most places have found that once the political decision has been made this tends to subside. The pattern has been repeated many times, beginning 20 years ago in the state of Oregon.

Rhetoric from opponents of assisted dying creates the impression among the public that most doctors are opposed, but data suggest otherwise.

A 2016 survey of more than 7500 US physicians by the clinical news and training provider Medscape found 57% in support of assisted dying, up from 45% in 2010. Opposition fell from 41% to 29% over the same period. An online survey in September 2017 by another news and training site, MedPageToday, found 61% of 604 respondents, who were mostly healthcare professionals, in support and 22% opposed.

Physicians' attitudes mirror those of the general population—the majority support the option of assisted dying in every part of the US and among all demographics, including Roman Catholics, for whom church doctrine opposes the practice. Support has continued to grow as more jurisdictions have adopted it. The group Compassion and Choices, which advocates for assisted dying, has summarised the results from, and provides links to, many polls, including ones that found less support for assisted dying.

Despite polls suggesting majority public and professional support, many professional groups in the US either vehemently oppose assisted dying or are silent.

"That is a big mistake because doctors are going to be asked to do it," Stuart Youngner, a professor of bioethics and psychiatry at Case Western Reserve University School of Medicine, Cleveland, tells *The BMJ*. They need guidance, he argued in the *Annals of Internal Medicine*.

The American Medical Association (AMA), the largest association of US doctors and medical students, with nearly a quarter of a million members, opposes assisted dying.

Medical associations "tend to be dominated by

Rhetoric from opponents of assisted dying creates the impression among the public that most doctors are opposed, but data suggest otherwise

DEFINITIONS UNDER DISPUTE

Proponents and opponents of assisted dying do not all agree on the terminology used to describe the process.

Assisted dying
Proponents of the Assisted Dying Bill 2015 in England and Wales argue that this term best describes prescribing life ending drugs for terminally ill, mentally competent adults to administer themselves after meeting strict legal safeguards. Assisted dying, as defined like this, is legal and regulated in the US states of Oregon, Vermont, Washington, California, and Colorado. It is also legal in Washington, DC. In 2017, similar legislation was passed in Victoria, Australia.

Assisted suicide
This term is often intended to describe giving assistance to die to people with long term progressive conditions and other people who are not dying, in addition to patients with a terminal illness. The drugs are self administered. Some opponents of assisted dying do not accept that it is different from assisted suicide. Assisted suicide, as defined like this, is permitted in Switzerland.

Voluntary euthanasia
This term describes a doctor directly administering life ending drugs to a patient who has given consent. Voluntary euthanasia is permitted in the Netherlands, Belgium, and Luxembourg. In 2016, Canada legalised both voluntary euthanasia and assisted dying for people whose death is "reasonably foreseeable."

A BRIEF HISTORY OF ASSISTED DYING IN NORTH AMERICA

Oregon was the first US state to allow assisted dying in 1997. It established strict criteria to access the process, including mental competence, a terminal illness with a life expectancy of less than six months, and agreement of a second physician. Safeguards ensure good pain management and end-of-life care and that the patient does not feel undue pressure to choose the option. It has served as a model for other jurisdictions.

Washington state (2008), Montana (2009), and Vermont (2013) followed Oregon's lead. But the big expansion of coverage has occurred in the past two years as California, Colorado, and Washington, DC, have implemented assisted dying, raising to 18% the portion of the US population now offered the option. All of Canada also joined the fold, though implementation has been inconsistent at the provincial level.

A growing but still small total number of Oregonians (‹0.2%, 204 prescriptions written) and physicians (0.6%, 102 physicians wrote prescriptions) have participated in assisted death.

Barbara Coombs Lee (right), president of Compassion and Choices, was instrumental in the passing of Oregon's Death with Dignity Act in 1997

The Canadian Medical Association initially resisted assisted dying. But after the country's High Court ruled it to be a fundamental human right, the association embraced the decision and participated in writing the law

traditionalists," Youngner says. "The AMA should be out in front educating the public and doctors about this; how to do it responsibly, not keeping it like it is some kind of bad secret that you can't talk about."

The American College of Physicians, which represents more than 150 000 internal medicine specialists and students, recently reiterated its opposition to what it called "physician assisted suicide." The American Academy of Family Physicians, representing more than 110 000 family doctors and students, grappled with assisted dying at its annual meeting last September. Current policy opposes "physician assisted suicide," but members from California pushed to clarify that assisted dying is not considered to be suicide under the laws of their state and others that allow the procedure.

The Canadian Medical Association initially resisted assisted dying. But after that country's high court ruled it to be a fundamental human right, the association embraced the decision and participated in writing the law, provincial regulations, and training its members to implement that ruling.

Barbara Coombs Lee, president of the advocacy group Compassion and Choices, who has worked as a nurse, physician assistant, and lawyer, sees the medical establishment's stance as paternalism that conflicts with patient autonomy: "I, the patient, given good information, given the knowledge that a physician is willing to share, and given clarity about my own values and my own priorities, I am in the best position to decide what is in my best interest.

"The entire field [of medicine] is pretty much wedded to beneficence as the ethical imperative that trumps autonomy," she says.

Assisted dying cannot be paid for with federal tax dollars and so is not available under Medicare and Medicaid.

Kaiser Permanente, the largest integrated care provider in the US, with about 12 million members, has provided assisted dying for 20 years in Oregon, Washington state, California, Colorado, and Washington, DC. Coombs Lee praised Kaiser's efforts as "exemplary . . . they really have done a wonderful job in making their system accommodate medical aid in dying." But care providers seem not to like to talk about assisted dying. Kaiser declined *The BMJ*'s multiple requests to talk about what it has learnt over the years.

The Coalition to Transform Advanced Care (C-TAC), a group of 140 leading healthcare organisations, wants better care for patients with complex conditions, particularly at the end of life but says, "Physician assisted suicide and aid in dying [are] not within the scope of our work."

"It is very important that aid in dying is integrated into normal end-of-life care, because to segregate it implies that it is something marginal," says Coombs Lee.

"It absolutely should not become a medical specialty. It should be part and parcel of what good doctors are willing to do for their dying patients. It is not so complicated. It just involves skills that doctors should be applying all the time, which is accepting their patient's values, acceding to their patient's wishes."

Recently, a pair of Canadian physicians movingly shared trepidations about their first, and to date only, involvement in an assisted death in *JAMA Internal Medicine*. An assisted death was the right decision at the right time for this patient, they wrote.

"When many of our other patients died, the hardest part for the family was dealing with the uncertainties," they concluded. But with assisted dying "all of that uncertainty and agonized decision-making is removed. As a result, the family and the patient undergo much less stress."

In California, a request for

assisted dying triggers additional screening to assess whether a patient's needs are being met and that the request is not being made because of inadequately treated pain or unresolved family problems. That has had the unexpected benefit of encouraging conversations about end of life that often had not taken place previously.

"The silver lining is that patients who make the request, and go through the mechanism, are receiving just stellar end-of-life care," says Wenger.

Medical aid in dying, as it is called in Canada, allows terminally ill patients to self administer the lethal drugs or for a physician or nurse practitioner to do this. Most such deaths occur in the patient's home, with the family physician giving the drugs.

How and where death should occur is a matter of intense disagreement. No two jurisdictions operate identically. Some allow a physician to administer an injection, as happens most of the time in Canada, says Green; others require self administration.

The University Health Network in Toronto has implemented a programme that allows assisted dying only by intravenous administration at a hospital. UCLA Health, run by the University of California Los Angeles, prohibits assisted deaths at any of its facilities but will help patients to carry out the procedure at home. This is patient centred care because nearly all patients prefer to die at home, says Green.

Conscience clauses are another key debate. Individual physicians and some religiously affiliated health systems have said that they will not provide assisted dying.

Despite these ongoing debates, Green says she is gradually seeing increasing willingness among doctors to learn and participate in assisted dying when their patients express interest.

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COMMENTARY Bernard Ribiero

Assisting suicide is no role for doctors

Terminally ill patients sometimes talk to their doctors about wanting help to "end it all." Most have no serious wish to end their lives. They are signalling that they are desperate, seeking reassurance, and trying to establish where they stand and what lies ahead of them.

A good doctor will talk to the patient to find out what lies behind the request—is it the treatment regimen, does the patient have unreasonable fears or possible depression, is the pain uncontrollable and, if so, can palliative care help and have they tried it? Now consider the same scenario under a jurisdiction that permits assisted dying. The doctor may handle the request in the same way. But a doctor who interprets such a request as a wish to die and agrees to explore assisted suicide risks sending the message to the patient, however unintentionally, that in his or her circumstances a hastened death might well be, in the doctor's professional opinion, the best course of action—at least an option worth considering.

For strong willed patients who are clear that they want to die, this may make little difference to their view. But they are considerably outnumbered by other, more vulnerable patients who are even more reliant on the doctor-patient relationship. This is not to ignore the strong willed but to balance their wishes against the need to protect more vulnerable people. Assisting suicide, if it were ever to be made lawful here, is a matter for the courts, not for the consulting room.

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COMMENTARY Bobbie Farsides

Assisted dying is compatible with palliative care

Two decades ago, I argued that it was logically consistent to be a good palliative care doctor and to think that for some patients the best option would be a managed death. I have never campaigned for or against legal assisted dying. But I still challenge the belief that a wish to die at a particular time and in a particular way can be "cared away," however great the skill of the professionals and resources committed to end-of-life care.

An important debate is happening in wider society. Patients are more aware than ever of what is, and is not, possible for them as they approach the end of their lives, and practitioners need to be prepared and able to respond compassionately, especially when they cannot give patients what they most desire because the law precludes it.

There need be no contradiction between being a good palliative care doctor and respecting a patient's wish to die and their request for assistance. Rather than fighting it, I would urge this important group of professionals to think about how they would negotiate such a future in the best interests of patients.

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COMMENTARY Sarah Jessiman

I'm dying and I don't want to attempt suicide

I'm doing my best to live well with terminal cancer at 51 years of age. My reasons for wanting the choice of an assisted death are simple and shared by many patients in similar situations. I'm terrified of the sort of death I may have to face. I would draw huge comfort from knowing that I could say "enough" when I can no longer endure my illness, so I can die at home, supported by the people I love most. I don't want to go to Switzerland, and I don't want to attempt suicide. Why can't I die as I live—in an open and honest way?

Every day doctors support terminally ill people like me and do their best to keep us as free from pain as possible. However, they cannot yet offer the last and, to me, ultimate act of compassion—that is, to enable us to end our lives when a truly awful death is close.

I drag around the weight of this terminal illness, day and night. My load would be so much lighter if I knew assisted dying was a choice for me when the illness dictates.

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See bmj.com for the full versions, podcasts, and more about assisted dying

LEGAL

What Bawa-Garba means for your e-portfolio

Clare Dyer and **Deborah Cohen** examine if personal reflections can be used against doctors in criminal, civil, and fitness to practise cases

The case of trainee paediatrician Hadiza Bawa-Garba (right) —convicted of manslaughter and struck off last month—has rocked the medical profession. Doctors fear that their written reflections, an important tool for personal learning, could be used against them in court. There are widespread worries that doctors will be less than frank, threatening the learning culture that patient safety demands.

Did Bawa-Garba's reflections feature in her crown court trial?
The Medical Protection Society (MPS), which defended Bawa-Garba, says that documents from her e-portfolio "did not actually form part of the evidence before the court and jury" in her trial for gross negligence manslaughter in 2015. "Indeed, the court was clear that reflections were irrelevant to the facts to be determined and that no weight should be given to remarks documented after the event."

The MPS acknowledges, however, that it "may well have been the case" that the reflections, as *The BMJ* has stated, "fed into the trial."

Stephen O'Riordan, a consultant paediatric endocrinologist, met Bawa-Garba a few days after the death of six year old Jack Adcock from sepsis in 2011. O'Riordan recorded her reflections on a training encounter form. He gave evidence for the prosecution, and the form was appended to his witness statement.

But the MPS tells *The BMJ* that "the Crown did not adduce [cite as evidence] these reflections during the trial. Indeed, there is no statement from Dr Bawa-Garba in these hand-written reflections of admission of liability, civil or criminal, let alone being close to any suggestion of gross negligence manslaughter guilt."

It's very important to say 'I made a mistake', but also important not to say in any way 'I was negligent'
Mary O'Rourke, QC

Could reflections play a part in the decision to lay charges?
They are disclosable to courts, tribunals, and coroners, as legal advice obtained by the Royal College of Paediatrics and Child Health makes clear. The Crown Prosecution Service initially decided not to charge Bawa-Garba in 2012, but the decision was reviewed after the inquest into Jack's death. She was charged in 2014. A RCPCH spokesperson says it was the Bawa-Garba case that prompted it to seek clarity on disclosure.

Can the GMC obtain reflections for fitness to practise proceedings?
Yes. But it says that "the GMC does not ask a doctor to provide their reflective statements if it's investigating a concern about them." However, if a deanery reports a trainee, it may provide his or her reflective statements.

Doctors who are facing a GMC hearing may provide their reflective statements voluntarily as evidence of insight, as Bawa-Garba did—an important element of remediation.

Can reflections be part of civil cases?
In April 2016, Health Education England circulated a letter from postgraduate deans in London and the South East that read, "Recently, a trainee released a written reflection to a legal agency, when requested, which was subsequently used as evidence against the trainee in court. This has resulted in questions about whether trainees should still provide reflections about incidents in their portfolios." *The BMJ* understands that the case was a clinical negligence claim, and the MPS has pointed out that the trainee made the disclosure voluntarily.

Can I refuse to record written reflections?
As the deans' letter explained, "Doctors in training must continue to write reflections, especially when there are things that do not go well. This is an essential part of training and is needed to progress through a postgraduate training programme." A failure to record reflections honestly could give rise to a referral to the GMC.

How should reflections be recorded?
The Academy of Medical Royal Colleges advises doctors to avoid using patients' names or initials, birth dates, or "any unique condition or circumstance."

It tells doctors to "try not to be judgmental, both to yourself and others, particularly when reactions and feelings are still raw," providing instead evaluation and analysis: what was good and what could have been done better, what was learnt and what steps to take as a result.

"Take advice from an experienced colleague when writing reflections about cases that may be contentious or result in an investigation," the academy suggests.

Mary O'Rourke QC, who has represented many doctors in fitness to practise cases, agrees trainees should not produce a "mea culpa or beat their breasts" when something has gone wrong. "It's very important to say "I made a mistake, I got things wrong," but it's also important not to say in any way 'I was negligent.'"

She also advises trainees to include any external factors. "If there's anything that contributed to [an incident], make sure you put it in your e-portfolio," she advises.

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