Use mesh as last resort, says NICE

Surgical mesh or tape should be used to treat stress urinary incontinence or pelvic organ prolapse only after all non-surgical options have been reviewed, NICE has said in draft guidance.

When mesh or tape is used, procedures and any related complications should be recorded in a national database to help with future decisions about its use, it said.

The safety of mesh implants has been brought into question by thousands of women around the world, many of whom are taking legal action against manufacturers, including in the UK.

In July the use of surgical mesh for stress urinary incontinence was suspended in England by the life peer Julia Cumberlege, just days after she began taking evidence from women affected by mesh as part of an independent review.

But NICE’s advice this week is not new. The agency made the same call for a register of mesh procedures in 2003 and also recommended it as a treatment of last resort that should be carried out only by specialist surgeons, a BMJ investigation shows (p 53). The investigation also reports scant evidence for mesh despite its rapid uptake and widespread conflicts of interests among surgeons and royal colleges (p 56).

NICE said that the suspension of the use of mesh in England should remain in place until the national database for registering operations and complications is up and running and when all operations can be performed by specialist surgeons based at specialist treatment centres.

All women who have surgery for urinary incontinence or prolapse that uses mesh or tape should be fully informed of the possible risks and be offered a follow-up appointment within six months, says NICE.

Owen Smith, chair of a parliamentary group on mesh, said, “This is a welcome U turn from NICE, who in their 2016 guidelines for mesh did not recommend any other treatment options for [incontinence] and in fact stated that complications from mesh were ‘infrequent.’”

Kath Sansom, from the campaigning group Sling the Mesh, said that mesh should be offered only after medical and other surgeries failed, as is planned for Scotland. “That way it is a belt and braces approach so mesh truly is the last resort,” she said. “Our ideal scenario is to see pelvic mesh stopped. The risks are too great.”

Owen Smith MP (centre) welcomed the guidelines, though Kath Sansom (centre left) said that they could have gone further.
Subclinical hypothyroidism more than 90% of persons with treatment recommendations, are at first sight cautious with “Although current guidelines of Bern in Switzerland, said, by Martin Feller of the University JAMA a review of 21 trials reported in thyroid related symptoms or associated with improvements Thyroid hormone therapy is not Treatment does not help Research news role promoting public health.”

Brexit Drug agency consults on effects of no deal The Medicines and Healthcare Products Regulatory Agency opened a consultation on how its legislation and regulatory processes would have to change in a “no deal” Brexit. Ian Hudson, the agency’s chief executive, said that it wanted to retain a close working partnership with the EU based on three principles: “That patients should not be disadvantaged, that innovators should be able to get products to the UK market as quickly and simply as possible, and that the UK continues to play a leading role promoting public health.”

Research news Treatment does not help subclinical hypothyroidism Thyroid hormone therapy is not associated with improvements in thyroid related symptoms or general quality of life in adults with subclinical hypothyroidism, a review of 21 trials reported in JAMA found. The researchers, led by Martin Feller of the University of Bern in Switzerland, said, “Although current guidelines are at first sight cautious with treatment recommendations, more than 90% of persons with subclinical hypothyroidism and a thyrotropin level of less than 10 mIU/L would actually qualify for treatment. Results of this meta-analysis are not consistent with these guideline recommendations.”

Cancer May announces new strategy to boost survival The prime minister, Theresa May, said that the government will lower the age of bowel cancer screening from 60 to 50 and invest in new equipment as part of a new cancer strategy for the NHS. By 2028 this will mean 55 000 more people than today being alive five years after their diagnosis because of earlier detection, she told the Conservative Party’s annual conference in Birmingham. The strategy will form “a central part” of the government’s long term plan for the NHS, she said.

Waiting time Symptoms worsen while waiting to see GP A third of people trying to access GP services for mental health thought that their condition deteriorated while waiting for an appointment, in a large survey of over 8000 people by the charities Mind and Picker. A third of respondents had to wait six days or more for their most recent appointment, usually because it was the first available. Almost half (44%) of those said that they had waited longer than expected and that their mental health had worsened in the meantime.

Awards BMJ paper wins RCGP research paper of the year A paper published in The BMJ on type 2 diabetes screening and prevention won the Research Paper of the Year award at the RCGP’s annual conference. It found that HbA\(_1c\) was neither sensitive nor specific in detecting pre-diabetes and that fasting glucose was specific but not sensitive. Because screening is inaccurate, many people found to have pre-diabetes have it incorrectly diagnosed and are referred for interventions, while others are falsely reassured. The authors concluded that “screen and treat” policies are unlikely to have a substantial impact on the worsening epidemic of type 2 diabetes.

NHS payout Teenager with brain injury gets £20m The NHS will make compensation payments that could total nearly £20m to an 18 year old woman who was left severely brain damaged when deprived of oxygen during treatment at age 5 months. A judge decided that doctors at the University Hospital of Wales in Cardiff had failed to ventilate the patient adequately before and after respiratory arrest. She stopped breathing after an operation to correct a malformed oesophagus.

Overseas India’s top medical regulatory body is dissolved India’s government discontinued the Medical Council of India, the country’s top regulatory body for medical education, with immediate effect. It issued the order after an oversight committee said that the council had misinterpreted court orders and had challenged the committee’s authority.
**MEDICINE**

**GP recruitment**

**NHS widens net for international staff**

In a bid to boost GP numbers, the NHS aims to target doctors working in Australia. In August 2017 NHS England said that it intended to recruit at least 2000 foreign doctors to general practice over the next three years, but just 85 new GPs were working in practices by April this year. It said that doctors who left the UK and GPs who trained in Australia will be offered enhanced relocation packages and have a shorter application procedure of three months rather than the current 12.

**Regulation**

**Doctor who changed consent form is struck off**

A specialist registrar in neurosurgery who changed a patient’s surgical consent form to cover up a mistake and failed to disclose his disciplinary problems when seeking a hospital post was struck off the UK medical register for persistent dishonesty. Ibrahim Hafez told a tribunal panel that he had not thought it necessary to consult the patient about changing the form after marking up the patient’s wrong side, as the patient knew that the operation was on the left side. But the tribunal found that Hafez falsely assured the surgeon that the patient had seen the corrected form before signing. The tribunal also did not believe Hafez’s claim that omissions in his job application and interview were inadvertent.

**GP is erased for sexually motivated behaviour**

A medical practitioners tribunal ordered a locum GP to be struck off the UK medical register after finding that he had displayed sexually motivated behaviour towards one woman while under a General Medical Council investigation for an “inappropriate sexualised conversation” with another. Mohammad Qasim Ihsan was struck off after the tribunal chair said that only erasure could reflect the seriousness of the misconduct. Ihsan’s counsel told the tribunal that it had “got the facts wrong” and that his client may appeal.

**MEANING HEALTH**

**Ambulance callouts to children with mental health problems rose 32% between 2013 and 2017, from 15444 to 20322**

**APPLICATION**

**3 MONTH PROCEDURE**

Doctors from Australia are being offered enhanced relocation packages to work in the UK

**SIXTY SECONDS ON…**

**EMMA’S DIARY**

**SOUNDS RACY!**

Sadly, Pepys this is not. Emma’s Diary is a commercial company that provides pregnancy advice (and advertising) to women through its website, app, and magazine. It also provides health advice and until recently was affiliated with the RCGP.

**OH BABY, WHAT HAPPENED?**

In August the Information Commissioner’s Office fined Lifecycle Marketing (Mother and Baby) Ltd—the company also known as Emma’s Diary—£140 000 for illegally collecting and selling personal information belonging to more than a million people to the Labour Party for use in its 2017 general election campaign.

**DID THEY MIX UP THEIR LABOURS?**

Emma’s Diary says the fine related to data it provided to the consumer credit reporting agency Experian, some of which was used by the Labour Party “for a one-off mailing in connection with Sure Start Children’s Centres.” It said it had never previously provided data to a political party and would never do so again.

**SO THE RCGP CUT THE CORD?**

Yes, in September the college announced its decision to terminate (their word, not mine) the relationship.

**DID GPs EVEN KNOW ABOUT THE LINK?**

They may not have done, although GP and pregnant woman Heather Ryan has been very verbal on social media about her disapproval of Emma’s Diary and its connection to the college. And it’s not just the selling of data she has a problem with.

**THERE’S MORE?**

Ryan says the fictionalised diary of a woman called Emma is unhelpful and patronising.

**ANY SPECIFICS?**

She said the attitudes towards working during pregnancy, body image, and risk factors were very unhelpful. “There was quite a lot of stuff about how Emma was struggling to work because she was so forgetful and useless, and I was doing 12 hour days as a GP partner and reading this,” Ryan says.

Abi Rimmer, The BMJ

Cite this as: BMJ 2018;363:k4237

Cite this as: BMJ 2018;363:k4234
Vitamin D supplements do not protect bone health

Vitamin D supplementation does not prevent fractures or falls or have any clinically meaningful effects on bone mineral density, a large meta-analysis has found. The authors said there “is little justification to use vitamin D supplements to maintain or improve musculoskeletal health,” as is currently advised by Public Health England.

In July 2016, PHE issued guidance that the general population should consider taking a daily supplement containing 10 mg of vitamin D in autumn and winter as people may not get enough of the vitamin through sunlight on the skin and through diet. This recommendation coincided with the publication of a report by the Scientific Advisory Committee on Nutrition that concluded that everyone over the age of one year should consume 10 mg of vitamin D daily.

The findings of the new meta-analysis, published in *Lancet Diabetes and Endocrinology*, now question the benefits of taking vitamin D supplements. The authors reviewed 81 randomised controlled trials (53 537 participants) that assessed the effects on health.

GSK will resume paying doctors to promote drugs after policy U turn

GSK has announced it will once again pay doctors to speak on its behalf about its drugs and associated diseases.

The UK based company announced at the end of 2013 that it would stop paying key opinion leaders and rely more on its own clinical experts.

That move came amid a major bribery probe in China, which resulted in a record fine, and was an attempt to improve the company’s reputation.

GSK had hoped that other companies would follow suit, but this did not happen, placing it at a competitive disadvantage.

“Certainly there’s been that our educational programs have not been as widely available, or seen as compelling to health care professionals, compared to other company programs,” a statement from GSK said. “We believe this has led to a reduced understanding of our products and is, ultimately, restricting patients’ access to truly innovative medicines and vaccines.”

The updated policy says that the company will make fair market value payments to expert practitioners who speak about the new science behind GSK products, their associated diseases, and clinical practice in promotional settings.

It will also pay reasonable travel costs, except in the US, for a healthcare professional to attend a GSK organised meeting, as well as registration fees for remote congress webinars and webcasts. However, it will still not sponsor doctors to attend conferences.

Fiona Godlee, editor in chief of *The BMJ*—who had praised GSK’s move in 2013—said, “Sadly, this shows again that we can’t rely on industry to do the right thing. We need a Sunshine Act to ensure that payments from industry are publicly declared. We also need action from the royal colleges.

“We don’t let judges or journalists take money from the people they are judging or reporting on: we shouldn’t let doctors do this either. Paid opinion leaders are a blot on medicine’s integrity, and we should make them a thing of the past.”

Jacqui Wise, London

Cite this as: *BMJ* 2018;363:k4157

**FIVE MINUTES WITH...**

**Terry Kemple**
The former RCGP president on a toolkit to help make general practices more environmentally friendly

“*W*e all know we need to look after the planet better and be more sustainable. But what can GPs actually do? The answer: ‘think global but act local.’

*With the Green Impact for Health toolkit we wanted to keep it simple. The first level starts with simple things like double sided printing, using fairtrade products, using paper that’s sourced from properly managed forests, or making sure that you’re not wasting energy by turning things off when they aren’t needed.

“We’re hoping that you’ll look at the toolkit and think, ‘Oh, actually this suggestion is interesting, we could do that.’ If you really get into it, you can get points for what you’ve done. At the end of the annual toolkit cycle, which is basically the academic year, we get local university students to audit the work that practices have done and they’re awarded points, which correspond with bronze, silver, and gold levels. There’s also an overall winner, which is the practice at the gold level with the most points.

“A practice from Frome in Somerset was the overall winner of last year’s award. The idea of using the toolkit was raised by one of the salaried GPs, and he managed to persuade the practice manager to take on the leadership role and get the rest of the team involved.

“We appreciate that GPs can’t do everything. But all organisations need to think about how they can be more environmentally friendly. These changes will save you money because they mean that your practice is being more efficient.

“As GPs we are role models; we are highly visible. If someone sees their GP cycling through the town rather than driving an SUV, that has an impact on people. If they see their GP going on a parkrun and encouraging others to join in, that has an effect on people. If we’re being environmentally friendly, we’re going to influence our patients.”

For more information visit www.greenimpact.org.uk/giforhealth

Abi Rimmer, *The BMJ*

Cite this as: *BMJ* 2018;363:k4215
VITAMIN D supplements made no clinically relevant difference to bone mineral density at any site (range −0.16% to 0.76%)

Congo gynaecologist shares Nobel peace prize for work with rape victims

An “extraordinary and courageous” Congolese gynaecologist who has spent decades helping women raped as a weapon of war has been awarded the 2018 Nobel peace prize.

Denis Mukwege, 63, shares the prize with the Iraqi Yazidi human rights activist Nadia Murad, who was tortured and raped by Islamic State militants and later became the face of a campaign to free the Yazidi people.

Mukwege was operating at Panzi hospital in Bukavu, in the Democratic Republic of Congo, when he heard the news, which was announced in Oslo on 5 October. He is now medical director of the hospital that he founded in 1999, where he lives under the permanent protection of UN peacekeepers.

He dedicated his award to all women affected by sexual violence. “This Nobel prize is a recognition of the suffering and the failure to adequately compensate women who are victims of rape and sexual violence in all countries around the world,” he said.

Mukwege and his colleagues are said to have treated about 30 000 women after rape, developing great expertise in the treatment of serious injuries sustained during sexual assaults that were carried out as a weapon of war.

The advocacy group Physicians for Human Rights said Mukwege has been tireless in his efforts to increase protection for women and to advocate that those responsible for sexual violence be brought to justice, including the Congolese government.

His work has put him in great personal danger. In October 2012 Mukwege was attacked and his family held at gunpoint at his home in an assassination attempt. But both he and Murad have continued to campaign on behalf of people affected by sexual violence.

The Nobel Peace Prize Committee described Mukwege as “the foremost, most unifying symbol, both nationally and internationally, of the struggle to end sexual violence in war and armed conflicts.”

It continued, “The importance of Dr Mukwege’s enduring, dedicated, and selfless efforts in this field cannot be overstated. He has repeatedly condemned impunity for mass rape and criticised the Congolese government and other countries for not doing enough to stop the use of sexual violence against women as a strategy and weapon of war.”

Physicians for Human Rights said that when dozens of girls were raped in the village of Kavumu from 2013 to 2016, Mukwege and colleagues collected evidence that was critical to the imprisonment of a powerful regional lawmaker and 10 members of his militia.

Mukwege has developed great expertise in the treatment of serious injuries sustained during sexual assaults that were carried out as a weapon of war

Commenting on the findings, Adrian Martineau, clinical professor of respiratory infection and immunity at Queen Mary University of London, said PHE’s recommendations “are designed specifically to elevate vitamin D levels out of the deficient range” of <25 nmol/L. “Achieving this target in the whole UK population would save lives by preventing the most extreme manifestations of vitamin D deficiency (seizures and heart failure in infants), which occur every year in the UK,” he said.

“The findings of the new paper do not provide any reason to revisit or reconsider this sound advice.”

Ingrid Torjesen, London

Cite this as: BMJ 2018;363:k4223

Jacqui Thornton, London

Cite this as: BMJ 2018;363:k4240

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of vitamin D supplementation published before 26 February 2018. Pooled analyses showed that vitamin D supplementation had no effect on total fractures, hip fractures, or falls. Supplementation made no clinically relevant difference to bone mineral density at any site (range −0.16% to 0.76% over 1 to 5 years).

Results were similar in trials of high dose versus low dose vitamin D and in subgroup analyses of randomised controlled trials that used doses greater than 800 IU a day.

The authors concluded, “Vitamin D supplementation did not have meaningful effects on fracture, falls, or bone mineral density, and future trials are unlikely to alter these conclusions.” Guidelines should change to reflect these findings.

The authors considered the only exception to be vitamin D supplementation for the prevention or treatment of rickets and osteomalacia, which can occur after a prolonged lack of exposure to sunshine that leads to 25-(OH)D concentrations lower than 25 nmol/L.
GPs and technology: the good, the bad . . . and the ugly babies

Technology was the buzz topic at this year’s conference of the RCGP. The college’s chair, Helen Stokes-Lampard, made it the centrepiece of her speech, in which, amid the ongoing debate over the pros and cons of online consulting and apps, she fiercely rejected the notion that GPs were “technophobic dinosaurs.”

Far from being afraid of innovation, GPs were, Stokes-Lampard argued, “bright, intelligent people who gladly embrace good, safe technology.” But she said that the NHS shouldn’t be sucked into adopting new technology and cited the “lovely baby” idea of Mary Dixon-Woods, professor of health services research at the University of Cambridge. Her theory has it that everyone believes their own child to be beautiful but that it sometimes takes an objective outsider to say, “Hey, that really is an ugly baby.” So while tech companies are fiercely protective, they must face independent, evidence based appraisal before their products are deployed in the NHS.

**Cause of outrage**
Speaking to *The BMJ* after her speech, Stokes-Lampard said that technology had been one of the major topics of “outrage” brought to her attention by college members over the past year. “The outrage has been over perceived inequity, perceived cherry picking, perceived bad behaviour,” she said. “The opportunities out there [from technology] are sometimes breath taking, but it’s how we manage it. We’ve got good and bad technology: what we need to do is weed it out.”

His ears burning all the way from Whitehall, the technophile health secretary for England, Matt Hancock, appeared (by video link, naturally) to assure GPs that they were the bedrock of the NHS and that, despite his ringing endorsement of the GP at Hand digital app, he did not favour one digital provider over any other. The video link worked smoothly, avoiding what the mischievous RCGP vice chair Martin Marshall described as a potentially dangerous irony.

Elsewhere at the conference Ben Goldacre, recently appointed to chair the government’s new health technology advisory board, showcased the fruits of his Open Prescribing project, an online tool enabling anyone to access and interrogate open data on GPs’ and CCGs’ prescribing. The aim, he said, was to make it easier to monitor trends and ultimately to make prescribing safer and more cost effective. The GPs in the room were enthused, with not a technophobic dinosaur in sight.

Stokes-Lampard told *The BMJ* that

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**GMC should hold register of conflicts**

All UK doctors should be required to submit their declarations of interest to a public register held by the General Medical Council, the GP and former columnist for *The BMJ* Margaret McCartney argued at the conference.

In a session focusing on doctors’ links to industry, McCartney said that while the medical regulator encouraged doctors to be transparent, it hadn’t yet given them the tools to do this properly.

**Inconsistent policies**
McCartney said she had emphasised the need for the GMC to hold such a register in her response to its 2016 consultation about a proposed update to the register. The GMC acknowledged the view in its response but has no plans to change its policy. McCartney said the current system—where each practice, organisation, or CCG holds its own register of interests—was inconsistent and often impossible for patients to find and make sense of. She said, “You could potentially have four or five different jobs as a GP with four or five different registers. Patients will not know where to look.

“We need a central register which is updated annually and can be updated over the year. It means that it’s searchable and transparent, and it means that any patient, commissioner, or organisation can access it and know that is where the data is.”

McCartney also raised the matter of how British doctors are viewed from abroad. “The rest of the world is looking at us, and it doesn’t look good,” she said.

**Fit notes** could become part of GP training

Modules on understanding “fit notes” may be incorporated into GPs’ training, England’s deputy chief medical officer said. The fit note, which replaced the “sick note” in 2010, enables GPs to include advice on how a person “may be fit” to work with reasonable workplace adjustments.

Gina Radford said, “We are looking to build more training, knowledge, and awareness of fit notes into GP postgraduate and undergraduate training so that people are aware of its purpose, the opportunities it gives, and what is needed to make it do what we had hoped it would do.”

Radford reiterated the government’s plan, announced last year, to allow healthcare professionals other than doctors to sign sick notes. “We’re working to legislate for an extension for fit note certification for other healthcare professionals,” she said.

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No deal Brexit a “disaster” for Northern Ireland

Doctors and patients in Northern Ireland are being failed by politicians in the Brexit negotiations, the conference heard.

In a lively Question Time-style debate, John O’Kelly, a GP in Derry and former chair of RCGP Northern Ireland, told how his practice had staff and patients who lived either side of the Irish border who could be badly affected if the UK government failed to reach an agreement with the EU on the terms of the exit.

Some cross border patients who currently have the right to use NHS services if they work and pay taxes in Northern Ireland could potentially lose this right. “I view a potential no deal Brexit as a potential disaster for us. Why does politics seem to be failing us at the moment?” asked O’Kelly.

Final say

Panellist Stephen Dorrell, chair of the NHS Confederation and also chair of the European Movement, a pressure group working to keep the UK in the EU, acknowledged O’Kelly’s concerns and said it was essential that citizens were given the final say on the Brexit deal.

He said, “There is no prospect of the government having a deal that can pass through the House of Commons. With the European Movement, we have been campaigning for a people’s vote, because it’s absolutely clear that what was promised in the referendum is not going to be delivered.

“The only people who can commit us to this path are the people themselves,” he said. Dorrell urged GPs who agreed with him to march for a people’s vote in London on 20 October.

The writer and Guardian columnist Owen Jones, said that stories like O’Kelly’s showed what was at stake. “It’s outrageous, it’s disgraceful. We need to hear voices like this more because the public need to know the consequences of a calamitous no deal Brexit,” he said.

CQC-style inspections don’t raise standards or improve safety

Inspections such as those carried out by the Care Quality Commission are not effective in raising standards or ensuring patient safety, conference delegates argued.

The conference hosted a debate on the merits of inspection, in which Rebecca Payne, a GP and clinical adviser to the CQC, spoke in favour of the current regulatory model and Miles Mack, a Scottish GP, argued against.

After a passionate debate delegates rejected a motion from Payne that “This house believes that CQC-type inspection is an essential lever in raising standards and ensuring patient safety.” Payne had argued that the CQC’s inspection regime provided the means to expose poor practice and to provide “the right diagnosis” to help practices improve. “Where there is a CQC report, people take action and practices are supported,” she said.

Demoralising
She also argued that issues that the regulator picks up, such as out-of-date drugs and fridges at incorrect temperatures, “really matter.” But Mack said he did not believe that the CQC’s style of approach accurately depicted the quality of GP services. “This can be a deeply demoralising practice . . . particularly at times when clinicians are working in extremely difficult circumstances,” he said. “It is wrong to believe the CQC approach is the only way forward.”

Mary McCarthy, a Shropshire GP, criticised the “tick box mentality: that somehow you can judge competence and kindness and caring and compassion by ticking whether you have a bucket the right way up.” She added, “This is nonsense.”

Gareth Iacobucci, The BMJ
Cite this as: BMJ 2018;363:k4220

the death this year of Julian Tudor Hart, an “inspiration” to her, highlighted why the NHS should debate the purposes of technology rather than just rushing ahead to adopt it. “Technology should be used to reduce inequalities but is actually widening them in the short term,” she warned. “That doesn’t mean we shouldn’t use technology, but it does mean we should be cognisant of it.”

Victor Adebowale, chief executive of the charity Turning Point, picked up on this idea in a speech in which he argued that reversing the inverse care law should be the NHS’s primary mission. He argued that in terms of adopting new technology the NHS should be setting out the problems that need solving and then inviting providers for solutions. “If technology companies are deciding the question and the answer, then we really are stuffed,” he warned.

Gareth Iacobucci, The BMJ
Cite this as: BMJ 2018;363:k4227
Last year’s Grenfell Tower fire in London is a recent and shocking reminder of what can happen if building safety is compromised and of society’s obligation to provide safe social housing for the world’s growing urban populations.

A new exhibition at the Wellcome Collection in London, Living with Buildings, explores the positive and negative effects that architecture, town planning, and design have on people’s health and wellbeing. It looks at the overcrowded conditions and poor sanitation of 19th century slums and the efforts of town planners and architects to provide better housing by way of garden cities, new suburbs, and “utopian villages” such as Bournville, created by the owners of Cadbury for its staff. These ideal villages offered safe housing, schools, healthcare, and leisure facilities.

The exhibition features the postwar development of social housing and high rise buildings. Andreas Gursky’s photo Paris, Montparnasse, 1993 (main picture) shows the Mouchotte building, the city’s largest single residential block. An aim of high rise housing was to free up green spaces and providing modern and “hygienic” living conditions, but the reality was often very different. The decline of high rises is shown in a film by Rab Harling that documents what residents thought about living in Balfron Tower in Poplar, east London—and their subsequent reaction to being evicted and relocated elsewhere. A series of photographs by Rachel Whiteread depicts the demolition of high rise tower blocks in east London.

But buildings can also have healing power, from the sanatoriums of the past to modern day Maggie’s centres, designed to promote health and wellbeing and to aid patients’ recovery from illness through an attention to light, a mix of communal and private spaces, and access to gardens.

In the first floor gallery is the “Global Clinic” (bottom right), an innovative mobile health clinic designed by architects, engineers, and the charity Doctors of the World. Its intended use is in providing emergency humanitarian aid to groups such as refugees and survivors of natural disasters. After the exhibition it will be deployed by a Doctors of the World team.


Juliet Dobson, The BMJ

Cite this as: BMJ 2018;363:k4235
EDITORIAL

Vaginal mesh

Surgical mesh and patient safety

A mandatory device registry is long overdue

The use of surgical mesh for vaginal prolapse and stress urinary incontinence increased rapidly for 20 years and then fell from grace, mainly because of a failure to take patient safety seriously. The BMJ investigation by Jonathan Gornall itemises the many failings that made this rise and fall inevitable: the lack of postmarketing studies; the failure to establish device registries; the influence of financial conflicts of interest; and, in the UK, the ineffectual role of NICE. Between them, these factors distorted the research evidence and adversely affected the care that women received, causing many of them unnecessary and irreparable harm. “Nobody involved with the mesh revolution emerges covered in glory,” says Gornall.

The first duty of healthcare systems should be to avoid unintended or unexpected harm during the provision of healthcare. The mesh story shows how global healthcare systems have failed in this duty. Systemic problems exist with how medical devices are approved, and, once they are on the market, how they are assessed as safe and effective.

Regulatory approval is not a marker of either effectiveness or safety, and this is unlikely to change with the updated EU medical device directives. The problem is, as Gornall explains, that it is not feasible to study absolute long term safety and performance of any implant before market launch. This can be achieved only after approval, through the diligent collection and independent monitoring of data on outcomes. In 2003, NICE recommended that data on mesh should be collected “over a period of 10 years or more,” but this didn’t happen. Other UK regulatory bodies, including the MHRA, discussed the need for a national registry, but none was forthcoming.

Globally, more than 100 000 women are suing manufacturers—over 1000 in the UK alone. A 2016 Cochrane review of transvaginal mesh for vaginal prolapse reported 10% of women required reoperation in the mesh group.

In December 2017, too late to prevent substantial harm, NICE issued guidance, effectively banning mesh for use in pelvic organ prolapse because the evidence of long term effectiveness was “inadequate in quality and quantity.”

In July 2018, it ordered a full suspension of the use of vaginal mesh in England to avoid further risk of “life-changing injuries” to women. NICE’s latest draft guidance (out this week) states non-surgical options for stress urinary incontinence or pelvic organ prolapse must be offered before any operation, the procedures should be done only by specialist surgeons, and “surgeons must also record any intervention using surgical mesh/tape in a national database.”

National registries can improve outcomes and patient safety. In Sweden, government registries are complemented by over 100 Swedish healthcare quality registries designed to improve care. The Swedish national cataract registry has data on 96% of all cataract removals since 1992 and is used to drive down postoperative complications. In South Korea, national health insurance data contain information on treatments, procedures, and diagnoses for almost 50 million beneficiaries and inform the ongoing monitoring and prevention of adverse events.

Registries must be adequately funded: Sweden spent $47m in 2016 on its registries. Legislation is needed to mandate what is measured and in whom, since voluntary entry of data has been shown to fail, and to ensure reporting requirements are adhered to and completeness of information is maintained. Finally, registries should collect data on the whole chain of care from start to finish, not just on isolated incidents.

The postmarketing assessment of vaginal mesh has been a shameful episode in the history of implantable devices. Surgeons, manufacturers, regulators, and governments have all played their part in this failing.
A simple pyramid shaped graph derived from Hospital Episode Statistics for England over the past two decades tells the story—or at least part of the story—of how mesh became a four letter word.

Introduced in 1998 as a novel surgical treatment for stress urinary incontinence, the polypropylene mesh sling was hailed as a quick and easy remedy for women and eagerly adopted by surgeons. Twenty years later, amidst claims that it has left many thousands of women around the world irreversibly harmed, mesh is at the centre of a storm of protest that has launched tens of thousands of compensation claims, divided the medical profession, exposed major flaws in regulatory procedures, and raised serious questions about the financial relations between clinicians and researchers and the manufacturers of devices that outraged campaigners say are not fit for purpose.

The story is hair raising, offering lessons for the entire medical community, manufacturers, and regulators.

In 1998-99 just 214 women in England had treatment for stress urinary incontinence, a common condition typically triggered by childbirth or the menopause, with an innovative and minimally invasive technique known as the tension-free vaginal tape (TVT) procedure. But the following year there was an explosion in the use of the procedure and a closely related variant using transobturator tape (TOT).

By 2001 the TVT procedure had already become the most performed operation for stress incontinence in the UK, and by 2009 the annual number of operations using polypropylene mesh tape had climbed to an all time high of 11 365 in England. Over the same period, use of the previous standard treatment for the condition, colposuspension, all but ceased.

Meanwhile, the overall number of surgical procedures for stress incontinence more than doubled to 13 201 in 2008-09. By 2014, 29 different products had appeared on the market, and between 2005 and 2013 over 170 000 devices were sold in the UK, and more than 3.6 million worldwide.

Mesh's subsequent fall from grace was almost as precipitous as its rise. From the peak of 11 365 operations in 2008-09, by 2016-17 the number of TVT and TOT procedures had fallen to just 6227.

Mesh sheets were also adopted to treat pelvic organ prolapse in women, though never carried out on the same scale. However, as would become clear, the complication rates for the prolapse procedures were much higher.

Unmet need
Stress urinary incontinence is caused by a weakening of the ligaments (hypermobility) or muscles (sphincter deficiency) of the urethra and affects up to a third of women over the age of 40. Until 1998 the standard surgical treatment was colposuspension, a major abdominal procedure in which vaginal tissue around the urethra is raised and held in an elevated position by sutures attached to ligaments at the back of the pubic bone. At that time colposuspension involved an average of seven days in hospital. As would become clear, the complication rates for the prolapse procedures were much higher.

Between 2005 and 2013 over 170 000 devices were sold in the UK, and more than 3.6 million worldwide. to take the risk of having more major surgery.”

By contrast, the arrival of mesh procedures, apparently just as successful as colposuspension but done under local anaesthetic in under 30 minutes, seemed like a cost effective godsend.

In 2003, each TVT kit cost £425 plus VAT, and the economic advantages seemed obvious. In 2000-01, just before use of TVT exploded, colposuspensions carried out in England and Wales cost the NHS a total of 26 174 bed days. By 2008-09, when the number of day case mesh procedures was at its height, colposuspensions carried out accounted for only 1200 bed days.

Then, as reports of serious complications began to emerge and medical negligence lawyers started to circle, the mesh bubble burst.

What went wrong?
Exactly what happened depends on who you ask. Anti-mesh campaigners insist that all mesh devices are not fit for purpose. They want them scrapped and compare the mesh “scandal” to the thalidomide disaster. Many surgeons continue to insist that mid-urethral slings remain the...
In 2003 NICE approved TVT for stress urinary incontinence but did so with a raft of caveats. If all of them had been heeded, today’s mesh crisis might have been largely averted.

Best treatment available for most women with stress urinary incontinence and that it still has an invaluable role in carefully selected women with prolapse.

Either way, nobody involved with the mesh revolution emerges covered in glory: not the companies who aggressively hustled the products into widespread use; not the regulators who aided and abetted them on the flimsiest of evidence; and not the medical profession, which failed to ensure surgeons were properly trained or that patients were carefully selected and properly informed of the risks and, perhaps most importantly, failed to set up comprehensive registries for the new procedures that might have identified unforeseen complications far sooner.

The story also exposes the extent to which individual surgeons, researchers, and professional bodies are reliant on device manufacturers for financial support, creating a potential for bias and even a public perception of corruption that undermines the medical profession’s ability to argue the evidential case for mesh convincingly. In the process, it reveals the weakness of the NHS’s recently launched register of interests.

As it is not feasible to study absolute long term safety and performance of any implant in patient groups of sufficient size and diversity before market launch, postmarketing surveillance is vital, but in the case of mesh this role was largely neglected.

Rapid approval

The rapid adoption of the technology is alarming. TVT was invented by Ulf Ulmsten, a Swedish obstetrician and gynaecologist. He sold the rights to global healthcare giant Johnson and Johnson in 1997, on the back of just two studies that he and his colleagues had carried out, and the procedure was in use in the US by 1998.

TVT gained rapid approval in the US thanks to the principle of “substantial equivalence,” under which a device can be fast tracked if its makers can show it works in a similar way to a product that has already been approved. The first modern mesh product was Boston Scientific’s ProteGen sling, approved for use by the FDA in 1996. It was recalled in January 1999 after it was found to cause high rates of erosion, infection, and pain. But Johnson and Johnson’s Ethicon subsidiary was still able to piggyback Ulmsten’s TVT to market on the strength of ProteGen’s original approval.

The story of how TVT then came to be approved in England—even as a largescale Ethicon funded study comparing the new procedure with colposuspension was still enrolling patients—is disturbing.

A 2002 paper in The BMJ reported the results of the first randomised controlled trial of the new procedure. It concluded that, “in the short term,” TVT was as effective as colposuspension at curing stress incontinence. Perioperative complications were more common, but “colposuspension was associated with more postoperative complications and longer recovery.”

But in an extraordinarily candid exchange between the trial’s investigators, published in a book the same year by the Royal College of Obstetricians and Gynaecologists (RCOG), concern was expressed that approval for TVT had already been granted in the UK in the absence of any evidence of its safety and efficacy.

The discussion, at an RCOG study group convened in 2001, focused on the decision made by the Safety and Efficacy Register of New Interventional Procedures (SERNIP), a forerunner of NICE, to give TVT an A rating.

Paul Hilton, consultant gynaecologist and urologist at the Royal Victoria Infirmary, Newcastle upon Tyne, and lead investigator of the UK and Ireland TVT Trial Group, whose investigation was still ongoing, said it was “highly regrettable” that TVT had been A rated “on the basis of no evidence at all,” other than “documentation submitted by the manufacturers of the device.”

Another trial investigator, Paul Abrams from Bristol’s Southmead Hospital, said he too had been “upset and worried” by TVT “leaping” from SERNIP category C (“Safety and efficacy not proven) to A (“Safety and efficacy established”).

Hilton, now retired, told The BMJ that Ethicon had begun marketing TVT in the UK early in 1998, even before the trial it was sponsoring had started recruiting patients. As a result, Hilton asked the company to fund “a register of TVT procedures, so that outcomes, and especially adverse outcomes, could be identified and quantified” but “they declined to support such a development.” A spokesperson for Johnson and Johnson said it was “not familiar” with the request to establish a registry in 1998, but insisted Ethicon had “a long history of supporting pelvic mesh tape registries and the data provided by these registries is an important part of our postmarket surveillance programme.”

Even as other surgeons around the country were eagerly adopting the new, untested procedure, says Hilton, “I did not carry out TVT in my own unit, other than in the trial context, until randomisation was completed and outcomes reported.”

Wael Agur, a urogynaecologist who was part of the NHS England working group on transvaginal mesh and of the Scottish independent mesh review panel, believes the aggressive fast tracking of TVT shunted a promising evolution of standard surgical treatment, colposuspension, into a siding.

“Surgery for stress incontinence was at a crossroads,” he says. “The next natural progression was to perform colposuspension by keyhole. Several researchers were making fantastic progress, when Johnson and Johnson went in and flooded the market with TVT.”

Unheeded recommendations

In 2003 NICE approved TVT for stress urinary incontinence but did so with a raft of caveats. If all of them had been heeded, today’s mesh crisis might have been largely averted.

NICE stated clearly that it was recommending the procedure as only “one of a range of surgical options for women with uncomplicated urodynamic stress incontinence in whom conservative management has failed.” Furthermore, properly selected patients should be “fully informed of the advantages and drawbacks” and the procedure should be done “only by surgeons who have received appropriate training in the
The Glacial Progress to Monitor the Safety of Mesh

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<th>2003 &gt;&gt;</th>
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<td>NICE recommends a national mesh registry to audit the safety and efficacy of mesh</td>
<td>British Society of Urology gynaecology register set up but on voluntary basis. By 2010 only around 30% surgeons are using it.</td>
<td>NHS England orders “cost-benefit” analysis into a mesh registry</td>
<td>NHS England sets up subgroup to consider mesh registry</td>
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NICE (National Institute for Health and Care Excellence)

A systematic review for the NHS by Aberdeen University recommends a surveillance system to track long-term complications of mesh technique, and who regularly carry out surgery for stress incontinence in women.” This advice reads like a checklist of the complaints made by women who have subsequently come forward to say they were harmed by mesh—that they weren’t offered alternative surgical or non-invasive interventions, that they weren’t warned of the dangers of TVT, and that their surgery was carried out by an inexperienced surgeon.

Crucially, NICE also recommended that observational data should be collected over at least 10 years. Preferably, “this should be nationally co-ordinated in the form of a registry of audit data.”

Had that advice been adopted, by 2013 a decade of data would have been available, offering crucial insights into long-term complications.

Later in 2003 more warning shots were fired, in a systematic review carried out by University of Aberdeen’s Health Services Research Unit as part of the NHS health technology assessment programme.

“At face value,” the review concluded, TVT was almost as effective as colposuspension, no riskier in the short term, and likely to be cost effective. But these conclusions, the authors stressed, should be treated with caution, because there was “very limited information currently available about the long-term performance of TVT.”

There was, in other words, no shortage of prophetic warnings in 2003, but the mesh genie was already out of the bottle. By 2002-03 over 4000 TVT and TOT operations a year were being carried out in England and no registry of procedures was in sight.

Tim Hillard, a consultant obstetrician and gynaecologist at Poole Hospital NHS Foundation Trust and clinical lead for patient safety for the RCOG, says things were moving fast. “The British Society of Urologygynaecology [BSUG], which was very much in its infancy, was saying, ‘Let’s keep a register of these things,’ but meanwhile the mesh explosion had been followed by a prolapse mesh explosion.”

Registry delays

At BSUG, work on setting up a registry “started in the mid-2000s but really got going in about 2007,” he says. This was nine years after the first TVT procedure had been carried out in England and four years after NICE’s call for an audit.

Even after the BSUG registry was set up, getting surgeons to use it was another matter. “It was voluntary,” says Hillard. “Over the past 10 years the number of people using the database has increased dramatically, but if you go back to 2010 probably only about 30% were using it.”

Things began to improve, he says, after NICE issued guidance on the management of urinary incontinence in women in 2013 and once again emphasised that surgeons “should maintain careful audit data and submit their outcomes to national registries.” But this was merely an echo of the call for action NICE had made a decade earlier. Progress towards a national database for mesh procedures can be described only as glacial.

In its interim report in December 2015, the NHS England mesh working group noted that “it is very difficult to ascertain the true rate of adverse incidents for [mesh] procedures [and] ideally the group would like to see the establishment of a registry.” But its only recommendation—17 years after TVT had first been approved—was for yet more delay. “A cost-benefit analysis should be undertaken,” it suggested, “on whether such a registry would be viable.”

When the final report of the mesh group was delivered 19 months later, it reported only that a registries subgroup should continue to meet to consider the best way to capture accurate data and would make recommendations by November 2017. But it didn’t. It wasn’t until 21 February 2018 that Jeremy Hunt, then health secretary, announced that his department would be investing £1.1m “to develop a comprehensive database for vaginal mesh to improve clinical practice and identify issues.”

At the same time the government announced a retrospective audit of vaginal mesh implants. The RCOG said that, while it supported the audit, which would amount to nothing more than an analysis of Hospital Episode Statistics, it would be of “limited value in understanding the nature of the problems women experienced.”

What was really needed, it said—with no apparent sense of irony, given the profession’s 20 year failure to pick up and run with this particular ball—was “a mandatory prospective registry of all of these procedures.”

It fell to Kath Sansom, a Cambridgeshire journalist who founded the campaign group Sling the Mesh after treatment for stress incontinence in 2015 left her in agony, to point out that “a prospective register is 20 years too late.” Campaigners, she said, “would like every single woman who has ever received a mesh implant to be contacted individually so that she may give a clear idea of her outcome on a national recall basis.”

As predicted, when the promised audit was delivered, it proved to be nothing more than a summary of what was already publicly known through Hospital Episode Statistics and shed no light on claims that mesh was a public health disaster.

In July 2018 the use of mesh implants to treat stress urinary incontinence was suspended in the NHS in line with an interim recommendation of the Independent Medicines and Medical Devices Safety Review being led by Julia Cumberlege. The BSUG condemned the temporary ban as “unnecessary” and “not based on any scientific logic or thinking.”

Jonathan Gornall, investigative journalist, jgornall@mac.com

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The mesh of relations between doctors and industry

Despite government guidance, it remains difficult to unpick industry funding of clinicians—and specialists in vaginal mesh treatment are no exception. Jonathan Gornall reports

The associations of individual surgeons and professional bodies with device manufacturers have done little to assuage the concerns of anti-mesh campaigners that sections of the medical profession are biased towards the technology. They argue that conflict of interest played a part in the rapid adoption of mesh for the treatment of incontinence and prolapse.

The very first trial of the tension free vaginal tape (TVT) procedure was funded by device manufacturer Ethicon. Published in The BMJ in July 2002, the authors concluded that vaginal tape “shows promise” and that the trial “was planned in 1997-98 and was undertaken to the highest standards of research governance at the time.” In the ‘90s, he said, “funding for surgical research from medical research councils was virtually non-existent. Had we not had commercial funding the trial almost certainly would not have been undertaken at all.

“Readers of our papers, and the subsequent reviews that have included its outcomes, must of course be aware of the trial funding and declared interests; the credibility of the work, however, lies in the quality and transparency of the protocol and trial reports. But, would I seek commercial funding for medical research myself, two decades on? Never.”

But the medical profession’s financial involvement with mesh manufacturers cannot be dismissed as historical. Harder to explain to aggrieved patients is why some researchers and professional bodies accept financial support from industry while others do not.

Guideline authors

In September 2017 a joint meeting of the European Urology Association and the European Urogynaecological Association published a consensus statement on the use of implanted materials to treat pelvic organ prolapse and stress urinary incontinence. Of the 24 coauthors of the paper, 17 declared financial relations of some sort—as consultants, speakers, researchers, etc—with a total of 34 companies. All three UK coauthors declared links with industry: two with five companies and the other with six.

Discovering the precise nature of these involvements, and their financial value, is difficult for the public, despite NHS guidelines on conflicts of interest that came into force in 2017. The guidelines require all trusts to publish a public annual register of interests on their websites. The guidance applies to all “decision making staff,” clinical or administrative, and a spokesperson for NHS England told The BMJ that this specifically included clinical staff who had the power to enter into contracts on behalf of their organisation or who are involved in making decisions about the commissioning of medicines and medical devices.

Some trusts, however, are interpreting this definition narrowly to include only non-clinical, board level executives, while others have so far failed to make registers publicly available online.

Linda Cardozo is a professor of urogynaecology and a consultant gynaecologist at King’s College Hospital, London who, in addition to being a coauthor of the 2017 consensus paper, is a
Of the 24 coauthors of the paper, 17 declared financial relations of some sort—as consultants, speakers, researchers, etc—with a total of 34 companies.

In April a spokesperson said the trust was “updating its conflict of interest policy and the register of interests.” A full register would be in place within weeks. It was not. On 5 October a spokesperson told The BMJ that the policy had not been ratified by the board until July. Guidance and information about it would “shortly be circulated to staff ... and a register of interests subsequently published on the trust’s website.”

Cardozo declined to disclose how much money she had received from industry over the past 10 years, from which companies, and for what purposes. However, she told The BMJ that it was “standard practice” for companies developing new drugs or devices “to approach the leaders in the field for their advice and guidance” and, for doctors, “engaging in such a process is part of one’s duty.” It was not, she said, “in itself a conflict of interest but a reflection of that person’s standing within the scientific and medical community.” It was “only right that doctors are compensated for the time they spend advising companies and that their travel and accommodation costs are covered as well as any out-of-pocket expenses.”

It was, she added, “important that doctors decide what treatment is appropriate for each patient based on the most up-to-date guidelines and evidence published in peer reviewed literature, and not on any relationship they may have developed with a pharmaceutical company or device manufacturer.”

She had, she said, “often gone to companies to ask for support for trainees to present their research at meetings” and “requested sponsorship to put on educational meetings and run courses and to sponsor such activities at the RCOG and the Royal Society of Medicine. Thus the majority of the money that I obtain from industry is not for personal gain but for the greater good of others.”

The failure of some trusts to comply with NHS guidelines on the management of conflicts of interest contributes to a lack of clarity that benefits neither doctors nor patients.

The UK organiser of the 2017 consensus paper was Chris Chapple, a consultant urological surgeon at Sheffield Teaching Hospitals NHS Foundation Trust. Chapple has published and lectured extensively on the problems caused by the use of mesh and is working with scientists at Sheffield University to develop a polyurethane-based alternative material. On the consensus paper he declared five industry associations including with known mesh manufacturers Boston Scientific and Medtronic. The value of only one of these associations—the £10 162 he received as a speaker, consultant, and researcher from Astellas in 2016—is publicly available, again through ABPI transparency data. Medtronic and Boston Scientific are both manufacturers of mesh products, but Chapple says his involvement with Medtronic was as a member of its advisory board on sacral neuromodulation and he was “not aware they marketed a vaginal mesh product.” He has never spoken on mesh on their behalf, nor for Boston Scientific. “I have never spoken on Boston Scientific’s behalf on the marketing of mesh,” he said.

But none of this is apparent on the Sheffield trust’s website, which does not maintain a register on its website of the interests of decision making clinical members of staff, though the trust told The BMJ in April that that was about to change. It still hasn’t.

The third UK coauthor of the consensus statement was Mohamed Abdel-Fattah, a consultant urogynaecologist at Aberdeen Maternity Hospital, who declared five industry associations: “past speaker for Bard, Coloplast, AMS, Pfizer, and Astellas; research grant from Coloplast; previous chairman of the Scottish Pelvic [Floor] Network, sponsored by various industrial companies.”

None of these payments are declared by the trust.

UK trails in transparency stakes
The UK trails far behind the US, where since 2013 companies have had to publicly record all financial relations with physicians.1

Jonathan Gornall, investigative journalist jgornall@mac.com
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EDITORIAL

Gender neutral vaccination against HPV

A cause for celebration

Human papillomavirus (HPV) is a common sexually transmitted virus and the cause of nearly all cervical cancers. In 2008, the UK governments implemented a school based HPV vaccination programme for 12-13 year old girls. This has already substantially decreased HPV prevalence in target populations.1 Uptake in the UK has remained consistently high (over 80%).2

Over the past decade, however, awareness of the burden of HPV attributable cancers in men has increased. In the UK, between 2002 and 2011, incidence of oropharyngeal cancers increased by 101%, with three quarters of cases occurring in men, and more than half being caused by HPV.3 In England in 2016, there were 8.9 oropharyngeal cancers per 100000 men, compared with 9.4 cervical cancers per 100000 women.4 In Wales, as in the United States, oropharyngeal cancers in men are now more common than cervical cancers in women.5,6 Incidence of anal cancers has also increased, with more than 80% attributable to HPV,7 although these cancers are still more common in women than men (3.1 v 1.7 per 100000).8

Policy change

The Joint Committee on Vaccination and Immunisation (JCVI) is the expert group that advises the UK governments on vaccination policy. Since 2013, the JCVI has reviewed evidence supporting vaccination of males and in November 2015, the committee advised that the vaccine should be available to gay men.9 Then, in July 2018, the JCVI recommendation was revised to support gender neutral vaccination.10,11 This reflected increasing incidence of HPV associated cancers in men, coupled with technical changes to the cost effectiveness model’s assumptions, to recognise that the benefits of vaccination will accrue over an extended period. Additionally, the change from the original three dose schedule to a two dose regimen has reduced costs, while the switch to a vaccine formulation conferring protection against HPV types that cause genital warts, as well as those that cause cancer, has increased benefits.

The most recent analysis suggested that vaccinating boys would prevent cases of HPV attributable cancers in women—for example, cervical, vulval, vaginal, and anal cancers; and in men—including oropharyngeal and anal cancers. On this basis the JCVI concluded that vaccinating boys confers clear health benefits.

Equality of treatment for all sexes and sexual orientations has been a strong argument for gender neutral vaccination. Vaccinating only girls does not offer a comparable level of protection to boys. Vaccinating only girls may also reinforce the impression that sexual health is primarily a female responsibility. The JCVI is not tasked to consider ethics and equality issues; it did observe, however, that if an equitable programme would be highly cost effective.

Health ministers in Wales, Scotland, and England quickly announced that boys would be included in the vaccination programme. Internationally, the UK now joins around 20 countries that already recommend gender neutral HPV vaccination, including Australia, Austria, Brazil, Canada, Germany, Israel, Italy, New Zealand, Norway, and the US.

To ensure high uptake of HPV vaccination in adolescent boys as well as girls, a clear public health message must accompany roll-out of gender neutral vaccination. It is important to stress that HPV is a common infection, and most sexually active adults, both men and women, will be exposed to it. The HPV vaccine is highly effective, as shown by both a recent Cochrane review and a supplementary analysis of that review,12,13 and to ensure maximum efficacy, vaccination must occur before sexual debut. The same review found no evidence of an increased risk of serious adverse effects associated with HPV vaccines.

An important victory

This policy change represents the culmination of a long journey, beginning with recognition that cervical cancer had an infectious cause, through identification of HPV as the agent responsible, to development of subunit vaccines through recombinant DNA technology, followed by accumulating evidence for multiple malignancies caused by HPV, and finally to implementation of gender neutral national vaccination. This story is an important victory in the struggle against infectious disease and cancer, and it should be celebrated.