Surgical patients are not getting the care they should

Zosia Kmietowicz | LONDON
The care of patients in the UK before and after surgery needs to be radically overhauled to identify those at high risk of complications and death, to ensure they get the appropriate care, say the authors of a nationwide audit.

The latest National Confidential Enquiry into Patient Outcome and Death (NCEPOD) shows that only half of high risk surgical patients received care that the advisers said they would accept from themselves or their own institutions.

The inquiry describes a damaging list of essential services that are absent in many UK hospitals, putting patients at greater risk of death after surgery. It collected data on 19,097 patients who underwent surgery during one week in March 2010 in 301 hospitals and retrospectively reviewed data on 829 high risk patients.

It found that 16% of hospitals had no preadmission anaesthetic assessment clinic and 17% had no surgical assessment clinic. Five hospitals had neither. Overall, 21% of high risk elective patients were not seen in preassessment clinics, and 30 day mortality among those who weren’t seen was almost seven times that among those who were (4.8% versus 0.7%).

Arrangements for recovery were also poor. Four hospitals had no post-anaesthetic recovery area at all, and more than 60% of those that did could provide ventilatory support only in an emergency or for a maximum of six hours.

A third of hospitals had no critical care outreach team, and only 22% of high risk patients went to critical care. The 30 day mortality rate among patients who were returned to wards was four times higher than among those who went to critical care (5% versus 1.4%). In 74 cases, high risk patients who were returned to wards died there without being taken to critical care.

The inquiry also reported that one in eight hospitals (12%) had no policy for identifying acutely ill patients; a third had no policy for identifying perioperative hypothermia; and only a small proportion of high risk patients had arterial lines (9%), central lines (14%), or cardiac output monitoring (27%), despite evidence that haemodynamic monitoring works.

The report concludes that “there is a long way to go in this country before we can suggest that we have reached an acceptable position.”

Post-surgical mortality among UK patients who have a predicted risk of death of up to 5% is eight times that in the United States.

Alex Goodwin, a coauthor of the report and a consultant in anaesthesia and intensive care, said care should include case planning and identification of the facilities needed to achieve the best outcomes.

Knowing the Risk is at www.ncepod.org.uk.

Cite this as: BMJ 2011;343:d7983

Mid Staffordshire inquiry will advise on dangers of reform and how to avoid them

Clare Dyer | BMJ
A “tide of public anger” over what happened at Stafford Hospital will be assuaged only if the right measures to guarantee the safety of patients and the quality of care are identified and put in place, Robert Francis QC said in his closing remarks as chairman of the public inquiry into failings at Mid Staffordshire NHS Foundation Trust.

In the 13 months that the inquiry had been sitting, serious concerns had surfaced elsewhere in the NHS in various reports, many of them “with disturbing echoes of what happened here,” said Mr Francis. “To the extent that it was ever thought to be the case, I do not think anyone now maintains that at least some of the appalling experiences of which I have heard are unique to Stafford.”

The challenge he faced was “to draw out the lessons to be learnt for the system as it now is and indeed as it may well change into under the proposed reforms.”

He would not say when his report will be delivered, but as he begins to write it a major shake up of the NHS is taking shape. He said that the report might help those planning the “ever shifting components” of the system if he indicated in advance some areas in which he was likely to make recommendations.

These included the nature of standards for the safety and quality of care (and which organisations should set and enforce them); and training, support, and regulation of NHS managers.

His remarks came after a day long submission by Tom Kark QC, senior counsel to the inquiry.

Mr Kark accused David Nicholson, chief executive of the NHS in England, of having a “dangerous attitude” when he argued that no other hospital had “failed so profoundly and persistently” as Stafford, which served to emphasise “the singular rather than the systemic nature of the case.”

That was “a naive assumption,” the QC said.

Cite this as: BMJ 2011;343:d7920
Clinical grade stem cells are created by scientists at King’s College London

Nigel Hawkes LONDON

What is thought to be the world’s first clinical grade stem cells free of animal derived products have been created by scientists at King’s College London and submitted to the UK Stem Cell Bank.

The success marks an important step in the development of human embryonic stem cells for medical use, said Peter Braude, emeritus professor of obstetrics and gynaecology at King’s College. But he cautioned that the research had already taken almost 10 years and that more work lay ahead before clinical trials could begin.

The news will provide a fillip to stem cell researchers, still shocked by the withdrawal last month of the US company Geron from stem cell research. Geron had launched one of the first clinical trials of stem cell treatment, aiming to repair severe spinal cord injury. Four patients had been treated, with no evidence of benefit but no safety problems, when Geron pulled out, arguing that it could get a better return on investment in other clinical areas.

Geron used a line of stem cells developed for research purposes and cleared for clinical use in this specific case “as a matter of expediency,” Professor Braude said. In the long run, according to Dusko Ilic, leader of the King’s College team, it would be safer and ultimately cheaper to use stem cells grown in a way that ensured that they were uncontaminated by any animal products, so called “xeno-free” stem cells.

Two new xeno-free cell lines have emerged from the research at King’s and have been submitted to the Stem Cell Bank. A team at the University of Manchester is due to submit another cell line shortly. Both teams have been backed by the Medical Research Council over the past decade to reach this point. Other UK universities, including Edinburgh and Sheffield, are believed to be not far behind.

The cell lines were derived from embryos created in the course of in vitro fertilisation and not required by the couples for whom they were made. The couples had the choice of donating the embryos to somebody else, having them destroyed, or allowing them to be used as a source of embryonic stem cells.

The creation of the new lines is described in a paper in Cytotherapy by a 13 strong team led by Dr Ilic (doi:10.3109/14653249.2011.623692). That the cells were not cultured from animal products such as serum, enzymes, and “feeder cells” used in earlier experiments means that the tests needed to ensure their

New body aims to streamline regulation of research in NHS

Geoff Watts LONDON

The Department of Health has announced the creation of the Health Research Authority. The new body, formally established on 1 December and welcomed by the prime minister in a speech on Monday 5 December, will streamline the conduct of research in universities and the NHS while ensuring that the interests of patients are not neglected.

John Tooke, president of the Academy of Medical Sciences, also welcomed the new authority. But he went on to warn against any assumption that a new system will be safer and ultimately cheaper to use stem cells grown in a way that ensured that they were uncontaminated by any animal products, so called “xeno-free” stem cells.

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Clinic threatens bloggers with legal action over criticisms of treatments

Margaret McCartney GLASGOW

A US clinic has issued legal threats to health bloggers in the United Kingdom over their criticisms of its treatments.

The Burzynski Clinic in Houston uses anti-neoplaston treatments, which it says on its website “are based on the natural biochemical defense system of our body, capable of combating cancer without harming the healthy cells.”

The clinic was the subject of an article in the Observer newspaper on 20 November, written by Luke Bainbridge, a founding editor of Observer Music Monthly, which described a fundraising campaign by Mr Bainbridge to send his 4 year old niece, who has a glioma, to the clinic for treatment. Mr Bainbridge said that fundraising efforts were required for a “pioneering treatment at the Burzynski Clinic in Texas . . . The estimated cost is £200 000 [€235 000; $315 000]. It is not available in this country, it is new and there are no guarantees . . . But it might save her life. So you have got to try.”

Several UK bloggers then looked at the evidence for the treatments offered at the clinic. Andy Lewis, creator of Quackometer.net, said, “There are many warning signs given out by the clinic that are typical of cancer quackery, and so great caution is required.”

He went on to outline the costs that patients needed to pay to enrol in the clinic’s trials and stated that there was “no good independent peer reviewed RCT [randomised controlled trial] evidence suggesting it [antineoplaston therapy] is effective.”

Rhys Morgan, a schoolboy from Wales with Crohn’s disease, disputed on his blog the effectiveness of the treatment.

A man called Marc Stephens then contacted Andy Lewis and Rhys Morgan, through their respective websites, saying that he represented the Burzynski clinic. He wrote, “You published libelous and defamatory information.” Mr Morgan was also sent emails with Google map screenshots of his house attached.

On 29 November the Burzynski Clinic published a press release stating that Marc Stephens no longer worked for the clinic but that the “bloggers will be contacted by attorneys representing the Clinic.”

Cite this as: BMJ 2011;343:d7865
Safety will be simpler and less time consuming, he said. But this does not mean that the cells are ready for use.

Glyn Stacey, director of the Stem Cell Bank, said that the cells would need a series of further tests. “The process of testing will be rigorous, and not all cell lines will make the grade. We will need significantly more cell lines submitted to fulfill our plan to make available a panel of characterised and tested clinical grade lines within the next three years,” he said.

Professor Braude said, “We have succeeded where many substantial commercial companies have not. Many more xeno-free lines should follow, which demonstrates the validity and foresight of this and previous governments in this important endeavour.” The cell lines would be made available for anybody to use on an open access basis, because they had been the product of publicly funded research, he said.

He refused to be drawn on how soon clinical trials might start, but Mr Stacey said he hoped that the necessary tests could be completed in the course of next year.

Daniel Brison, codirector of the Manchester group, said he hoped that the cells developed there could be used for the regeneration of cartilage within “a few years.” The team had shown that its stem cell line could be turned into cartilage cells in a process taking 12 days, and such cells might be used to treat sports injuries such as damage to the knee.

**Further pay restrictions are a “bitter blow” to NHS staff, says BMA**

**Helen Mooney** LONDON

The government has added to its already acrimonious dispute with public sector employees over pensions by announcing a cap of 1% on pay rises for the next two years.

On the back of the current pay freeze public sector workers can expect no more than an annual increase of 1% in their pay packets from 2013 to 2015. Announcing the new measures, the chancellor of the exchequer, George Osborne, also suggested that there could be an end to national bargaining in future.

Responding to the plans for a pay rise cap, Hamish Meldrum, chairman of the BMA, said: “The chancellor’s decision to bypass the normal pay review process for a further two years and announce another sub-inflationary pay award will come as a bitter blow to all those who work in the NHS.”

Cite this as: BMJ 2011;343:d7858
Environmental risks of breast cancer remain uncertain, says IoM

Bob Roehr WASHINGTON, DC

Women may be able to reduce their risk of breast cancer by minimising exposure to environmental risk factors, but incomplete data and interactions with genetic susceptibility make it difficult to quantify the effect for individual women, says a new report from the US Institute of Medicine.

The 364 page review of the evidence was commissioned by the breast cancer charity Susan G Komen for the Cure and released on 7 December at the San Antonio Breast Cancer Symposium. The strongest evidence for reducing environmental risks is for women to:

- Avoid inappropriate exposure to medical radiation
- Avoid combination menopausal hormone therapy unless it is medically appropriate
- End active smoking and exposure to secondhand smoke
- Limit or eliminate alcohol consumption
- Maintain or increase physical activity
- Maintain healthy weight or reduce overweight and obesity

- Limit or eliminate exposure to chemicals that are plausible contributors to breast cancer, and
- Consider use of chemoprevention if their risk of breast cancer is high.

The Institute of Medicine’s committee concluded, on the basis of animal or mechanistic data, that bisphenol A, found in some plastics, and some other chemicals were “plausible” hazards. The committee found no strong evidence that non-ionising radiation and personal use of hair dyes were associated with an increased risk of breast cancer.

The committee cautioned that there is little quantitative evidence to indicate what difference avoiding the known hazards will make.

“The breast undergoes substantial changes from the time it begins developing in the fetus through old age, especially in response to hormonal changes during puberty, pregnancy, lactation, and menopause,” the committee wrote.

“The timing of a variety of environmental exposures may be important in directly increasing or

A third of UK cancers are “potentially preventable”

Jacqui Wise LONDON

A third (more than 100 000 cases) of all cancers in the United Kingdom are caused by just four risk factors and are potentially preventable, concludes a comprehensive review of the evidence.

The researchers estimated that 106 845 cancers in the UK in 2010 were associated with smoking, poor diet, alcohol, and excess weight. And when all 14 lifestyle and environmental risk factors were included, this figure rose to 134 000 or (43% of the total).

The review, published as a supplement in the British Journal of Cancer (http://bit.ly/uoHuLZ), found that 45% of all cancers in men and 40% in women could be prevented. The review looked at all the available evidence together with the latest (2010) estimates of cancer incidence.

The study’s lead author, Max Parkin, a Cancer Research UK epidemiologist who is based at Queen Mary college, University of London, said, “Leading a healthy lifestyle won’t guarantee you won’t get cancer, but doing so can greatly stack up the odds in your favour.” He added: “Nine out of 10 lung cancer cases can be prevented. Half of all colorectal cancers are due to the main four risk factors.”

The most important lifestyle risk factor for men and for women is smoking—causing 23% of cancers in men and 15.6% in women. Harpal Kumar, chief executive of the Cancer Research Campaign, said, “Smoking is still the biggest priority to tackle in terms of cancer prevention. The rates did come down substantially but have now plateaued, so we need to do much more. We need to get the message across that smoking is not just a risk factor for lung cancer but other cancers too.”

For women, being overweight was shown to have a greater effect than drinking alcohol. The percentage of cancers in women linked to overweight and obesity was 6.9%, double the 3.3% for alcohol. “Being overweight is a clear risk factor for breast cancer, and because breast cancer is so common, that makes it higher in the ranking,” said Professor Parkin. Infections such as human papillomavirus were linked to 3.7% of cancers in women, excessive sun exposure and sunbeds to 3.6%, and lack of fruit and vegetables to 3.4%.

For men, the next biggest risk factor, after smoking, was a lack of fruit and vegetables, at 6.1%. Occupational risks, such as exposure to asbestos, was linked to 4.9% of cancers in men. Alcohol was linked to 4.6% of cancers and being overweight or obese to 4.1%.
Reducing breast cancer risks or in acting indirectly by influencing the developmental events. There may be critical windows of susceptibility (eg, periods of rapid cell proliferation or maturation) when specific mechanisms that increase the likelihood of a breast cancer developing may be more likely to come into play.

Among its recommendations for future research are calls for integrated and transdisciplinary studies across the life course; a better understanding of the mechanisms of action of environmental risk factors; a focus on high risk individuals; and comparative effectiveness research on imaging procedures and diagnostics that takes the potential negative effects of those tools into account.

The American Cancer Society estimates that breast cancer will be diagnosed in 230 480 women and 2140 men in the US in 2011, while 39 520 women and 450 men are projected to die from the disease. The incidence of the cancer peaked in the US in 1999 and has fallen over the past decade.


Cite this as: BMJ 2011;343:d7929

Brokering a deal to replace Kyoto will take years, European ministers say

John Vidal DURBAN

Hopes of a breakthrough to unblock the stuttering United Nations talks on climate change remained slim this week as ministers from 190 countries flew to Durban, South Africa.

With Canada, Russia, and Japan refusing to sign up to a second period of the Kyoto protocol, and the United States stating it would not be legally bound to any treaty unless poor countries were too, it was left to the European Union to try to broker a compromise. The Kyoto protocol, which legally binds all rich countries except the US to cuts, runs out in 2012.

The EU’s Durban “roadmap” initiative seems to square the circle by keeping Kyoto alive and bowing to most US demands, and it appealed immediately to the coalition of 42 small island states (Aosis) and the 48 least developed countries. But persuading China, India, Brazil, and Indonesia, with a combined population of nearly three billion people, to start negotiating a new, possibly weaker, and economically damaging treaty without concluding the first, proved tough from the start. Privately, European negotiators admitted this week that it would take years to negotiate and would depend on governments showing political will.

But while attention focused on a possible treaty on 6 December, ministers reported that agreement was close on key areas such as finance for developing countries, forest protection, and technology.

The UK Climate and Health Council partnered with the international coalition Health Care without Harm and the US think tank the Aspen Institute to run a climate and health summit covering the effects of temperature rises on health, particularly reproductive health, and development.

South Africa’s health minister, Aaron Motsoaledi, warned that climate change could undermine all health efforts put in place in the past few decades. African countries, he said, were expected to be the most adversely affected, with widespread poverty hindering their ability to adapt to extreme weather events.

Cite this as: BMJ 2011;343:d7963

German internet clinic based in London angers German doctors

Annette Tuffs HEIDELBERG

A London based German online medical practice that treats patients by email has been heavily criticised by the German Medical Association.

In a press statement on 30 November the association said that the professional code of conduct for German doctors does not allow treatment and medical counselling without any personal contact. “Diagnosis and treatment solely via the internet cannot be in the interest of the patient,” it says.

The German online Dr Ed service (www.dred.com) is based in London because it is legal to operate it in England, said its spokesman, Jens Apermann. Medical consultation websites like Dr Ed are quite common in England, he says. Furthermore, the doctors employed by the company are based in London.

The website is run by the private investment company Health Bridge Limited and is registered with the UK General Medical Council and the Care Quality Commission.

Cite this as: BMJ 2011;343:d7933
Australians must have their children immunised to receive benefit

Melissa Sweet SYDNEY

Parents who do not have their children fully immunised by the age of 5 years stand to lose $A2100 (£1375; €1600; $2150) in benefits under reforms announced by the Australian government.

Under current arrangements, families who meet immunisation requirements when their child turns 2 and 5 receive a maternity immunisation allowance of $A129 per instalment.

From next July, this allowance will no longer be paid, and families instead must have their children fully immunised to receive an existing tax benefit supplement, which is not paid to the highest income earners.

The payment, worth $A726 per child each year, will be paid once a child is fully immunised at 1, 2, and 5 years of age. Meningococcal C, pneumococcal, and varicella will be added to the immunisations needed to qualify for the payment.

Although parents can register as “conscientious objectors,” the number who do so is thought to be small—about 1.7%. They can still get the payment if they have a form signed by a health professional.

Julie Leask, a senior lecturer in the Sydney School of Public Health at the University of Sydney, said it is better that these families can access payments because it means children who already miss out by not being immunised are not further disadvantaged through economic disparities, and because the interaction with a health professional ensures parents are fully aware of the risks of not immunising.

The government also announced that, from July 2013, the combination vaccine Priorix-Tetra will be added to the immunisation schedule, replacing individual doses of the MMR and varicella vaccines.

The government says this will make it easier for parents to immunise their children and will bring forward immunisation for measles, mumps, and rubella to 18 months instead of the current 4 years of age.


Cite this as: BMJ 2011;343:d7877.

Authors of list of “skimpy” services under US health reforms have links to insurance industry, say doctors

Jeanne Lenzer NEW YORK

A national doctors’ organisation says that most of the authors of a federally sponsored report on recommended health insurance coverage have financial ties to insurers and drug companies and that the insurance scheme will leave many US citizens without access to healthcare.

The Institute of Medicine, which was contracted by the federal government to write the report, brought in security guards at the institute’s annual meeting to prevent doctors from distributing leaflets outlining the financial conflicts of interest of the report’s authors. The doctors, former institute fellows and members of Physicians for a National Healthcare Plan, were registered at the meeting and tried to give the leaflets to colleagues attending it.

Danny McCormick, assistant professor at Harvard Medical School and a former fellow of the institute, distributed leaflets at the meeting. He has signed a protest letter sent to the US secretary of health and human services, Kathleen Sebelius, along with more than 2400 doctors, nurses, and health advocates, stating that the recommendations for “essential benefits” to be provided under the Affordable Care Act will provide “skimpy” care that would endanger the health of many citizens.

Although the report outlines 10 categories of benefits that insurers must cover, such as costs of hospitalisation, preventative care, and ambulance transport, it does not prohibit insurers from shifting costs to patients through premiums, copayments, deductibles, and cost sharing. In the event of a catastrophic illness or injury, patients could be hundreds of thousands of dollars in debt.

Dr McCormick said that a serious pitfall of the recommended essential benefits is that they would give patients the illusion that they have “real insurance.” He said, “Most patients, no matter how well informed, have no idea what their insurance policy covers. It’s only when some catastrophic event occurs that they find out that they are not fully covered.”

Nor would the insurance scheme necessarily cut overtesting and overtreatment—which Dr McCormick says should be cut. Although the report panel recommends establishing an independent “national health benefits council” to review scientific evidence regarding new technologies, the plan does not task the council with assessing current testing and treatment strategies that might be unnecessary or dangerous.

Howard Brody, a member of the Institute of Medicine and Physicians for a National Healthcare Plan, told the BMJ that the Affordable Care Act “is truly a game changer” that will extend coverage to more people. Nevertheless, he added, “It’s not enough.”

Dr Brody called the act a “sop to the insurance industry” and a “political decision, not a scientific decision,” since a single payer system is considered unacceptable in the United States. He said that the institute was assigned a narrow task of defining only “what absolutely must be covered.” Unfortunately, he said, nothing in the recommendations would prevent insurers from providing “shoddy” coverage.

Dr Brody said that the institute’s actions to prevent doctors from leafleting about the panellists’ conflicts of interest were “indefensible.”

The institute said that it complied with its policy on conflicts of interest by promptly disclosing committee members with a conflict of interest but whose expertise was needed.


Cite this as: BMJ 2011;343:d7932.