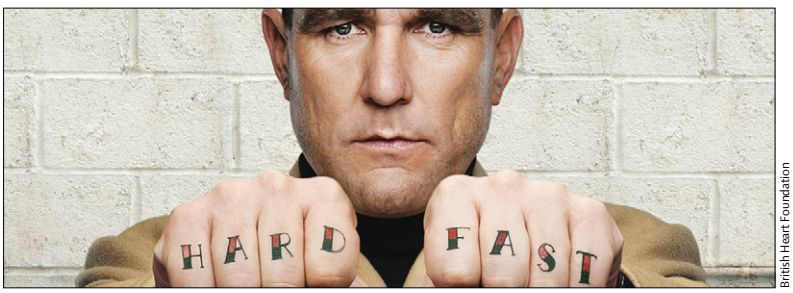
Ethics update The American College of Physicians has published an update to its ethics manual, recommending that physicians practise "parsimonious care". Although seen by many as a necessity, resource awareness is a controversial issue in the USA, where it can be synonymous with the withholding of care. The USA spends twice as much on health care as do other industrialised countries.

Vaccine expansion UNICEF is planning a major expansion of its global vaccination programme, increasing its reach to the most vulnerable. The organisation plans to triple its capacity over the next 5 years, updating and strengthening outdated public health systems to enable more effective administration of immunisations to the most marginalised people.

Food crisis in Sudan Reports from people fleeing the Sudanese states of Southern Kordofan and Blue Nile have indicated rising rates of malnutrition. UN humanitarian chief Valerie Amos outlined a plan promoting UN–Sudanese cooperation to halt the escalating food crisis, stressing the need for a solution to the "alarming" situation which has escalated since conflict erupted last May.

©Vanessa Davies/Getty Images

Double trouble In 2009, one in every 30 births in the US was a twin birth, compared with one in every 53 in 1980, the US National Center for Health Statistics reports. Between 1980 and 2009, twin birth rates nearly doubled for women aged between 35 and 39 years, and rose by more than 200% for women aged 40 years and older.



British Heart Foundation

Miss the kiss Call for help, and push the chest hard and fast to the beat of the track *Stayin' Alive*, is the message behind a hands-only cardiopulmonary resuscitation (CPR) campaign from the British Heart Foundation, delivered by footballer-turned-actor Vinnie Jones. The aim is to give people without training in CPR the confidence to act without worrying about the potentially off-putting "kiss of life".

Towards polio eradication Jan 13 was set to mark 1 year without confirmed cases of poliomyelitis in India—the longest period for the country. India, one of the four countries where polio remains endemic, is on the way to eradication after the introduction of the bivalent oral vaccine in 2010. New national immunisation days are planned for January and February.

On the pulse Pulse oximetry is essential in the assessment of neonates and aids early detection of critical congenital heart disease (CCHD), according to the American Academy of Pediatrics. The academy also stated that it supports a US Government recommendation to include CCHD in uniform screening for neonates. An article in *The Lancet* last year showed the accuracy of the test.

GSK fined GlaxoSmithKline (GSK) has been fined US$93 000 by Argentinian courts for irregularities in the recruitment of infants into a trial of its Synflorix pneumococcal vaccine. During 2007–08, the COMPAS trial recruited 24 000 infants in Latin America; Synflorix is now approved for use in more than 80 countries. GSK has denied the accusations and is currently appealing.

Pertussis increase Cases of pertussis more than doubled in Western Australia and in England and Wales in 2011, prompting the respective health authorities to encourage parents to ensure that their children's vaccinations are up to date. There were 3597 cases in Western Australia by Dec 23, 2011 (up from 1458 in 2010), and 1040 cases in England and Wales (up from 421 in 2010).

Lives of migrant workers A survey done on behalf of the Beijing Municipal Bureau of Civil Affairs found most migrant workers across three major industrial areas of China to be unhappy with their lives, with 70% describing their life as merely "acceptable". 403 workers were polled; low pay, little free time, and poor career prospects were the main factors undermining their happiness.

A breath of fresh Éire The hometown of James Joyce, Oscar Wilde, and Samuel Beckett is hosting a cultural festival for the first 2 weeks of 2012 that aims to reduce the stigma of mental illness. In partnership with the Irish anti-stigma organisation See Change, Dublin's *First Fortnight* event includes art exhibitions, plays, film screenings, and musical performances.

New FAO chief Brazilian José Graziano da Silva took up his position as the new Director-General of the UN Food and Agriculture Organization (FAO) on Jan 1 replacing Jacques Diouf, who had served in the role since 1994. Graziano da Silva has pledged to focus the FAO's work on sustainability, the eradication of hunger, and fairness in the world food system.

For the **American College of Physicians' ethics manual** see http://www.annals.org/content/156/1_Part_2/73.full.pdf#page=1&view=FitH

For **UNICEF's immunisation expansion plans** see http://www.unicef.org/immunization/index_61223.html

For more on the **twin birth rate in the USA** see http://www.cdc.gov/nchs/data/databriefs/db80.htm

For the **British Heart Foundation's hands-only cardiopulmonary resuscitation campaign** see http://www.bhf.org.uk/default.aspx?page=14087

For the **American College of Pediatrics's endorsement of pulse oximetry screening for critical congenital heart disease** see http://www.annals.org/content/156/1_Part_2/73.full.pdf#page=1&view=FitH

For ***The Lancet*'s paper on pulse oximetry screening for congenital heart defects in newborn infants** see **Articles** *Lancet* 2011; **378:** 785–94.

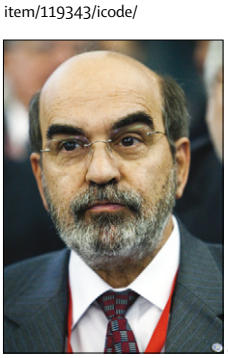
For more on **pertussis in Western Australia** see http://www.health.wa.gov.au/press/view_press.cfm?id=1105

For more on **pertussis in England and Wales** see http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1317132185149

For **See Change** see http://www.seechange.ie/

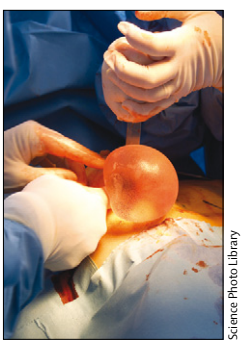
For the **First Fortnight festival** see http://firstfortnight.com/

For more on **José Graziano da Silva at the FAO** see http://www.fao.org/news/story/en/item/119343/icode/



Reuters

Silicone breast implants: lessons from the USA



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See Comment page 106

The scandal engulfing the use of silicone-gel breast implants in the UK and across Europe might seem an isolated example of regulatory failure for an uncommon device. But breast implants are widely used, the cosmetic industry is growing, and there are valuable lessons to learn from countries that have experienced their own regulatory crises. The USA is one such country. Last year alone, silicone-gel implants were used in almost 150 000 American women for breast augmentation and in 46 000 women for breast reconstruction.

That particular types of silicone breast implants are safe was twice re-emphasised by the US Food and Drug Administration (FDA) in 2010. On Aug 31, after 2 days of public testimony among silicone implant manufacturers, surgeons, and the FDA, the FDA's chief scientist concluded that American women can consent with confidence to procedures involving silicone implants, which are considered safe but with an acceptable risk of local complications (rupture, tissue hardening, pain, inflammation, and infection). In June, 2010, the FDA published a 63-page report assuring safety of silicone-gel breast implants after examining preliminary data gathered since their approval in 2006. This report also emphasised that implants are not intended to last a lifetime, and that women will most likely require additional surgery.

Why has the US been spared the silicone breast implant scandal that is currently taking place in the UK, France, and elsewhere? The history of silicone-gel breast implant regulation in the USA has not been without its own turbulence and controversy. Such implants have been available to American women since the early 1960s, but not until 1976 did they come under the regulatory umbrella of the FDA by law. The FDA's decision then was to leave implants on the market pending approval. The 1980s brought anecdotal reports of women with certain systemic conditions (connective-tissue disease and cancer) that were allegedly associated with silicone implants. In 1988, the FDA classified silicone breast implants as devices that needed their safety and efficacy to be proven in order to stay on the market. Device manufacturers were given 30 months to provide the necessary data. In late 1991 and early 1992, two FDA panel meetings concluded that what information was available was insufficient to fully assess the risks. In April, 1992, FDA Commissioner David Kessler imposed a federal moratorium on the availability of silicone breast implants. They were only to be used for reconstructive (medical), and not elective, purposes until their safety was proven. The next 14 years was an era of divisive and acrimonious litigation (including the biggest US class-action lawsuit in 1995 of US$4·3 billion)—as well as publications in peer-reviewed journals and a 400-page Institute of Medicine report in 1999—all failing to link systemic disease with silicone breast implants. The ban on implants was lifted in 2006 and since then just two manufacturers, Mentor and Allergan, have supplied the US market. Part of the FDA's decision depended on manufacturers conducting large post-approval studies following 40 000 women for 10 years after receiving breast implant surgery.

A crucial question for regulators is the meaning of safety. How safe is safe enough? Was the clinical experience in 1 million women over 30 years in the USA insufficient for these devices to be proven safe in 1992? Kessler put it this way: "the role of the FDA is not to prove a device to be unsafe before it can protect against its use, but rather the US law states that safety first is to be demonstrated by manufacturers". Since its 1992 moratorium, the FDA has implemented a much more conservative approach to regulatory approval, concentrating on safety. The FDA rightly sees itself as a protector of the American people. That said, the FDA needs to improve its record by ensuring that manufacturers complete post-marketing safety studies. The agency also needs to enforce a national registry of silicone-gel breast implant recipients.

Here are absolutely vital lessons to learn for governments, regulators, and the professions in Europe. It will be important for regulatory agencies to recall the setbacks and successes for silicone-gel breast implants in the USA. That debate continues for medical devices. Some critics argue that the FDA's approval process is too slow and bureaucratic. Unless it speeds up, the US will (these critics allege) lose the innovation race to overseas competitors. But at what cost to safety? Within this history one will discover solutions not only for the present scandal but also for the prevention of further crises in the future. Women should expect no less.

■ *The Lancet*

For the **FDA report** see http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/UCM260090.pdf

For the **Institute of Medicine report** see http://www.iom.edu/Reports/1999/Safety-of-Silicone-Breast-Implants.aspx

WHO and Margaret Chan: the next 5 years

Reuters

See Online/Correspondence
DOI:10.1016/S0140-6736(12)60040-3

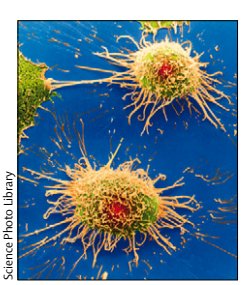
WHO is in the process of appointing a Director-General whose tenure will run from June, 2012, to June, 2017. Margaret Chan, the current incumbent, is the only candidate standing. WHO's Executive Board will consider her appointment when they meet later this month, and the World Health Assembly will ratify the Board's decision in May. It is certain that Dr Chan will win a second term.

Her renewed appointment comes at a perilous moment for WHO. As a letter we publish online this week from Oxfam reveals, WHO is in crisis. Rescue is needed. But is this predicament a fair reflection of the Director-General's performance? No, it is not. When Dr Chan was elected she made a promise—namely, that she wanted her term to be judged by progress on health for Africa and for women. WHO's leadership of Every Woman, Every Child, the UN Secretary-General's Global Strategy on Women's and Children's Health, has been her great success these past 5 years. Add to that the remarkable achievement in September, 2011, of a political declaration on non-communicable diseases, together with her refashioning of a failing health systems agenda around universal coverage, and you have a record that is a surprising success for an agency in the vortex of a financial emergency.

One cannot judge Dr Chan's legacy without recalling that her first priority 5 years ago was to deliver the initiatives begun by her predecessor, Dr Lee Jong-wook, who tragically died during his first term as Director-General. The most important project left unfinished was the Commission on Social Determinants of Health. Initially sceptical, Dr Chan not only saw this important report through to completion, but also became a significant champion of the social determinants agenda. Also recall that Dr Chan deftly led communications with the media and public during the 2009 influenza A H1N1 pandemic.

None of this is to say that there have not been disappointments. Her leadership team has not been a success. Only recently have the right people been selected for crucial portfolios. Several regional offices of WHO remain lacklustre backwaters. And sometimes one wishes for a sharper message, a stronger articulation of what WHO is for in the 21st century. These matters can be addressed during a second term. But that term will depend on proper financing of WHO by its donors. And here Dr Chan faces her greatest test of all. ■ *The Lancet*

The continuing fight against cancer



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For more on the **American Cancer Society** see http://www.cancer.org/

For ***Cancer Statistics, 2012*** see http://onlinelibrary.wiley.com/doi/10.3322/caac.20138/full

More than a million cancer deaths in the USA have been avoided in the past two decades, according to the American Cancer Society. In its annual report *Cancer Statistics, 2012*, it is estimated that, between 1990–1991 and 2008, overall cancer death rates in the USA decreased by about 23% in men and 15% in women. This reduction is largely an achievement of improved prevention programmes, detection, and advances in treatment.

Death rates for lung, colorectal, breast, and prostate cancer have continued to decline in the USA, although they remain the most common causes of cancer death. As the prevalence of smoking has decreased, so have the rates of lung and oropharyngeal cancer. Although the rates of oropharygeal cancer have decreased by around 1% in women, between 1999 to 2008 the incidence of HPV-related oropharyngeal cancers increased by 4·4% per year among white men and by 1·9% per year in white women.

Sadly, as highlighted in the report, obvious ethnic disparities prevail. Compared with whites, black Americans have poorer survival from cancer, with shorter 5-year relative survival for almost all types of cancer.

An estimated 1·6 million new cancer cases are predicted for 2012 in the USA. A large proportion of cancers are preventable—around 90% are influenced by environmental and lifestyle factors, including diet, sun exposure, and infections. Smoking accounts for 30% of all cancer deaths and 80% of lung cancer deaths.

With changes in disease prevalence, it is apparent that the landscape of cancer is changing. Clinical research and prevention strategies should anticipate the contribution of this change to disease burden. For example, whether vaccination against HPV is protective against HPV-associated cancers other than cervical and anal cancer is an important research priority.

Major successes have been made in combating the global challenge of cancer. Preventing disease, by targeting modifiable environmental and lifestyle factors, is an important public health opportunity. ■ *The Lancet*

Increasing requests for vitamin D measurement: costly, confusing, and without credibility

"Sunbathing boosts men's sex drives" proclaimed newspaper reports.[1,2] This headline was extrapolated from a cross-sectional study showing that serum 25-hydroxyvitamin D (25OHD) concentrations—a biochemical measure of vitamin D status—correlate to circulating testosterone concentrations in men referred for angiography, but neither sun exposure nor sex drive was directly assessed.[3] This anecdote epitomises what has become a bandwagon of vitamin-D-related epidemiological research fuelling easily accessible headlines in lay media. Such frequent and prominent headlines have cast vitamin D in the role of a putative miracle cure that can prevent and treat a burgeoning list of chronic disorders such as cardiovascular disease, diabetes, and cancer.

This media coverage has caused a massive rise in demand for measurement of blood concentrations of 25OHD from the public and physicians. Glasgow Royal Infirmary—the main provider of 25OHD tests in Scotland—has seen a rise in vitamin D test requests from 18 682 in 2008, to 37 830 in 2010, which has resulted in a longstanding backlog of 2000 tests. Similarly, a hospital in London, UK, had a sixfold increase in 25OHD test requests over 4 years, rising from 7537 tests in 2007, to nearly 46 000 in 2010 (personal communication). Similar trends have been noted in other countries—eg, Canada and the USA.[4,5] To match demand, manufacturers (eg, Abbott, Roche, and Siemens) are developing immunoassays (similar to liquid chromatography tandem mass spectrometry gold standard) for clinical use, and promoting them widely in North America, Europe, and elsewhere. A 25OHD test costs the UK National Health Service around £20. The economic burden of widespread routine vitamin D testing in the UK and elsewhere is therefore substantial.

But is this skyrocketing of 25OHD test requests and related costs justified? The prevalence of apparent vitamin D inadequacy is high in the UK.[6,7] For example, roughly 50% of 45-year-old UK adults (1958 British birth cohort) were vitamin D insufficient during winter months, with the greatest inadequacy recorded in Scotland (average concentration 35 nmol/L).[7] A patient in the UK attending a general practitioner in winter is therefore likely to be vitamin D insufficient (serum concentrations <50 nmol/L) or deficient (serum concentrations <25 nmol/L). But how should general practitioners interpret such test results? The key question is: does knowing the result usefully improve clinical practice and patient wellbeing?

To address this issue, whether vitamin D inadequacy has a predisposing relation with health consequences that could be avoided by intervention (eg, supplementation, diet, or sun exposure) needs to be established. Most evidence promoting a role for vitamin D in chronic disease has been extrapolated from epidemiological studies, but these results are often limited by factors such as potential reverse causality and residual confounding—particularly relevant limitations for vitamin D as a biomarker of health (table). Therefore, any conclusions about causality extrapolated from observational data are premature.[10]

The only reliable tests of causality are randomised trials. The effectiveness of vitamin D supplementation in rickets and osteomalacia has been proven.

	Why important for vitamin D?	Examples
Confounding and residual confounding	Many risk factors are related to both low 25OHD and poor health outcomes; statistical models might be incomplete if such factors are not measured, or measured imprecisely	Little physical activity (outdoor activity often related to sunlight exposure); low socioeconomic status; obesity; smoking; season
Reverse causality	Sunlight exposure is a major determinant of circulating-25OHD concentrations; pain or illness can limit sunlight exposure through inactivity, and thus disease could cause inadequacy rather than the reverse	Clinical diagnosis of many disorders (eg, multiple sclerosis) can be preceded by a period of preclinical disease when little time is spent outdoors; acute inflammation can drive down circulating 25OHD concentrations so that in acute illnesses or many hospitalised patients, low measurements are secondary to an acute-phase response
Publication and citation bias	Null or negative findings are less likely to be published, especially when overwhelming perception is of a positive association; thus, investigators are less likely to pursue publication or persist after manuscript rejection than if results were positive; null findings that are published are not frequently cited and result in little media interest, and therefore perception of the weight of evidence can be heavily skewed	Marniemi and colleagues' 2005 report[8] of no association of 25OHD with 130 cases of myocardial infarction in elderly people has been cited 33* times in Web of Science; by contrast, Wang and co-workers' 2008 article[9] reporting 25OHD inadequacy associated with 120 cases of cardiovascular disease in Framingham offspring has been cited 409* times

25OHD=serum 25-hydroxyvitamin D. *As of Nov 28, 2011.

Table: **Potential limitations in making causal inferences from observational epidemiology for vitamin D**

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