Warnings on two birth control pills are too weak, FDA panel rules

Jeanne Lenzer, New York

Labels on the popular birth control pills Yasmin and Yaz should be strengthened to include more information about the risk of blood clots, an advisory committee to the Food and Drug Administration said on Thursday 8 December.

The panel voted 21 to five to change the labels but stopped short of recommending that the labels should warn that the drugs, whose main ingredient is drospirenone, are more likely than other contraceptive pills to cause blood clots. Instead it suggested that the labels say that evidence about blood clots conflicts. But the panel was not shown documents cited in a report by David Kessler, a former FDA commissioner, who claims that Bayer, which markets both drugs, withheld safety data from the agency.

Dr Kessler said that Bayer scientists concluded in a 2004 draft analysis that Yasmin has a “several-fold increase” in reporting rates for thromboembolic events when compared with three other oral contraceptives and that Yasmin’s rate of all serious adverse events was “10 fold higher than that with the other products.”

Despite the draft analysis, Bayer did not report the increased rate of thromboembolism in the 2004 “white paper” it submitted to the FDA. Dr Kessler’s charges are in a 196 page report that came to light two days before the hearing on 6 December. Dr Kessler is an expert witness for the plaintiffs in the suit.

Dr Kessler’s report says that Bayer failed to report safety data, engaged in off-label promotion of the pills, and paid $450 000 (£290 000; €350 000) to a high profile gynaecologist to sponsor her book tour in which she promoted off-label uses of the pills.

Dr Kessler states in his report that Bayer knew that three studies in the BMJ showed that drospirenone posed a greater risk of thromboembolic events than other birth control pills yet failed to report the data to the FDA until long after it learnt of the findings (BMJ 2009;339:b2890; 2011;342:d2139; 2011;340:d2151).

In response to Dr Kessler’s claims Bayer told the BMJ, “We have nothing further to add as these are matters of litigation.”


Cite this as: BMJ 2011;343:d8104

Screening for diabetes: the audit is a wake-up call for the need for better care, said Bob Young

Susan Mayor, London

About 24 000 people in England with diabetes are dying each year from complications that could be avoided with better management, the first national audit of diabetes mortality says.

The mortality audit linked information on 1.42 million people with diabetes included in the 2007-8 national diabetes audit with death certificate data.

From its inception the audit team at the NHS Information Centre had planned to include mortality in its outcomes, but this is the first time it has been able to do so. Tracking death certificate data showed that 69 282 of the people in the 2007-8 audit died in the period from 1 November 2008 to 31 October 2009.

The audit included 68% of the 2.1 million people in England estimated on the basis of national Quality and Outcomes Framework data to have diabetes, so the audit group estimated that a total of 70 000 to 75 000 people with diabetes die each year.

The figures showed that the risk of premature death for patients with type 1 diabetes was 2.6 times that in the general population and that the risk for people with type 2 diabetes was 1.6 times the general rate.

Just over 16 000 more people died among those included in the audit than would have been expected if their risk of death were the same as the general population. Extrapolating this to include patients not in the audit gave a total of about 24 000 excess deaths each year in England in people with diagnosed diabetes.

Bob Young, a consultant diabetologist in Salford who was the audit’s lead clinician and is also clinical lead for the NHS Information Centre’s national diabetes information service, said, “For the first time we have a reliable measure of the huge impact of diabetes on early deaths. Many of these early deaths could be prevented.”

The audit showed that excess mortality was much greater in young and middle aged adults with diabetes. In young women aged 15-34 with type 1 diabetes, mortality was around nine times that in people without diabetes; in men in this age group it was four times that in people without diabetes. For type 2 diabetes, death rates were approximately six and 3.6 times as high, respectively. In people over 85 years all these ratios had dropped to less than two.

Dr Young said, “It’s quite striking that the relative impact on mortality is so much greater in people of working age and younger as opposed to older people.” He said that this may relate to previous findings from the diabetes audit showing that young people with diabetes are more likely than older people to receive all components of recommended diabetes care. The audit results are at www.ic.nhs.uk/nda.

Cite this as: BMJ 2011;343:d8081
 Directors of Calcutta hospital are arrested after fire kills 90

Zosia Gkmtowicz LONDON

Six directors of the Amri Hospital in Calcutta have been arrested and charged with culpable homicide after at least 90 people are thought to have died in a fire that broke out at the facility on 9 December. They have been denied bail.

Reports suggest that the 190 bed private hospital had been warned about inadequate safety standards. Most of those who died were patients, although four member of staff are believed to have lost their lives. It has been reported that most staff abandoned the hospital when the fire started and did not try to help patients to safety.

The fire is thought to have started in the basement of the hospital, where inflammable materials were stored, and that it was a few hours before the alarm was raised.

The US writer and surgeon Atul Gawande, who pioneered the World Health Organization’s checklist for safer surgery, sent several tweets at the weekend saying that the fire showed that even the richest Indian hospitals had not learnt patient safety.

Dr Gawande, who is of Indian origin, said that it was a sad coincidence that the fire came almost exactly 50 years since a fire in a hospital in Hartford, Connecticut, killed 16 people. The lesson of the Hartford fire was that people needed to share data more than blame, he said.

Mamata Banerjee, chief minister of West Bengal, told the Associated Press that authorities had warned the hospital in September of inadequate safety standards in the hospital’s basement but that no action was taken. The hospital denies the charges.

English health secretary unveils 60 performance indicators

Anne Gulland LONDON

England’s health secretary, Andrew Lansley, has unveiled 60 NHS performance indicators that will be used to hold the NHS Commissioning Board to account.

The indicators are part of the NHS Outcomes Framework 2012-13 for England, which, alongside the forthcoming public health and adult social care outcomes frameworks, will encourage collaboration and the “provision of integrated services for patients.”

The Department of Health says that the outcomes framework will be part of the “broader mandate” used to hold the commissioning board to account. “The mandate will set out the objectives that the board should seek to achieve, including the outcomes they will be expected to improve.”

The 60 indicators fall into five domains: preventing people from dying prematurely; enhancing quality of life of people with long term conditions; helping people to recover from episodes of ill health or an injury; ensuring that people have a positive experience of care; and treating and caring for people in a safe environment and protecting them from avoidable harm.

For the first time the government is measuring “potential years of life lost” to take into account the “extent of prematurity of death under 75.”

Individual indicators include reducing premature mortality (under 75 years) from the four major causes of death: cardiovascular disease, respiratory disease, liver disease, and cancer. They also include increasing one and five year survival rates after treatment for breast, lung, and colorectal cancers.

Reducing infant mortality, neonatal mortality, and stillbirths is also included in the framework, as well as reducing the number of premature deaths in people with learning disabilities and people with serious mental illness. The NHS will also measure whether young people and children’s experience of care has improved.

Launching the framework at Guy’s Hospital in London, Mr Lansley said that it set “the direction for the whole NHS. Orienting the NHS back towards the people who really matter: its patients.”

Norman Williams, president of the Royal College of Surgeons, said that the college supported the focus on improving clinical outcomes.

“It will help the NHS Commissioning Board, clinical commissioning groups, NHS trusts, and all clinicians and managers to focus on our most important challenge: to work together to bring the quality and standard of care for all patients, of all ages, up to that currently being experienced by those treated in the highest performing hospitals. At the moment, patient death rates and standards of care vary significantly between hospitals and specialties; and, as we have consistently recommended in our national guidance, this must be improved.”

The Royal College of Physicians’ president, Richard Thompson, said, “The RCP’s own audits on stroke, falls, continence, inflammatory bowel disease, chronic obstructive pulmonary disease, and multiple sclerosis have shown that regularly measuring and publishing outcomes leads to better patient care.”

Mike Farrar, chief executive of the NHS Confederation, said, “This initiative will require significant investment in collecting data to allow useful comparisons between providers on a consistent basis. It is imperative these measurements are focused on what is really important to good quality care and based on information that is practical for organisations, including general practice, to collect.”

The health department also published a new map of local health services, which patients will be able to access through the “any qualified provider” policy starting from April 2012, and a new map of general practices on NHS Choices.


Cite this as: BMJ 2011;343:d8031

Cite this as: BMJ 2011;343:d8105
UK private healthcare faces investigation

Nigel Hawkes LONDON

The Office of Fair Trading (OFT) is minded to refer the private healthcare market in the United Kingdom to the Competition Commission.

A final decision will be made after an eight week consultation to give interested parties a chance to make representations if they disagree with the referral. One private provider, Nuffield Health, has already backed the OFT, saying that it fully supports its decision and that it is in the interests of the patients who use private healthcare and the industry itself.

The OFT began its investigation in March this year. In a report it says that it found a number of concerns about the way the private healthcare market works. These restrict or distort competition and merit further investigation.

A primary concern is a lack of information on quality and costs. Patients seeking care cannot easily compare one provider with another, which means that competition is not as keen as it might be. Full costs of treatment are not always made plain.

The OFT is also concerned about the small number of competing organisations, which can mean that in some local areas one provider may command an effective monopoly. This may give a degree of market power to the providers, as insurance companies will rely on them if they are to provide a nationwide coverage. For example, existing providers can retaliate in various ways against an insurance company that plans to make use of a new entrant to the market.

The finding, from a review carried out by the National Collaborating Centre for Mental Health at the Royal College of Psychiatrists, should put an end to research investigating the psychological effects of abortion, said Tim Kendall, director of the centre and a member of the review’s steering group. “A more fruitful line of inquiry is to look at the mental health needs of [women] with an unwanted pregnancy—not the resolution of that pregnancy,” he told a press briefing.

The review, funded by the Department of Health for England, was set up to provide an answer to women who seek an abortion and ask about the risks to their mental health. Many studies and reviews have examined the question, but the quality of the results and interpretation of the findings are variable and conflicting.

In the latest review, the researchers identified 44 studies, involving many hundreds of thousands of women, which met their inclusion criteria. All of these studies measured mental health outcomes in women more than 90 days after they had had an abortion or had given birth.

The review concluded that it makes no difference to a woman’s mental health whether she chooses to have an abortion or to continue with an unwanted pregnancy. However, it also found that about a third of women who have an unwanted pregnancy have mental health problems, whether it results in an abortion or a birth. This is three times higher than the rate of 11-12% of people with mental health problems among the general population.

**Induced Abortion and Mental Health**, together with comments and responses, is at www.nccmh.org.uk.

More “responsible” science reporting is needed, Leveson inquiry hears

Helen Mooney LONDON

The media must ensure that they report science and scientific studies much more carefully and understand their “huge responsibility” to do so, the Science Media Centre has said in its evidence to the Leveson inquiry into the ethics of the press.

The centre, an independent press office for science, has warned that “the public are ill served by a media that emphasises the most alarming figures when the scientists are saying that these are the least likely scenario.”

It said that the public still got most of its information about science from the mass media, including daily newspapers, and that “the potential of the media to influence and inform the public on science” came with a “huge responsibility.”

“When the media gets it wrong,” it added, “the impact is devastating and causes real harm to individuals and society. The furor over the measles, mumps, and rubella (MMR) vaccine, which started in 1998 after a rogue doctor claimed a link between the vaccine and autism, is the best known example of how poor media reporting can cause harm.”

The centre’s evidence to Lord Justice Brian Leveson’s inquiry, which was set up by the prime minister, David Cameron, to investigate the ethics of the press, states that MMR vaccination rates dropped from 92% to 80% after the scare.

Cite this as: BMJ 2011;343:d8051

**Review finds abortion does not increase mental health problems in women**

Zosia Kmielowicz LONDON

Having an abortion makes no difference to a woman’s mental health, shows a major review of the evidence to date.

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Cite this as: BMJ 2011;343:d8045
IN BRIEF

Israeli doctors end protests: Three months of walkouts and mass resignations by trainee doctors in Israel dissatisfied with a nine year labour deal brokered by the Israel Medical Association in August ended on 8 December after external mediators intervened. Trainees won bonuses, higher pay, a commitment to only six late night and weekend shifts a month, and a contract review in 2015. In turn they agreed that hospital doctors would clock in and out to show they were not moonlighting during regular hours.

Asking about organ donation should be routine in end of life care: Organ donation should be considered as a usual part of care planning at the end of life, with every hospital having a policy and protocol for identifying potential organ donors and managing the consent process, says NICE in new guidance. Around 10 000 people in the UK are on waiting lists for a transplant, and about 1000 die each year waiting for an organ.

MHRA warns over super-strength menopause remedy: The UK Medicines and Healthcare Products Regulatory Agency is warning consumers that “natural” does not always mean safe after it asked the manufacturer of FSC Black Cohosh 1000 mg capsules to remove it from the market because it did not have the appropriate authorisation and contains 50 times the approved dose for menopausal complaints. Since 1998 the agency has received 50 reports of suspected adverse reactions associated with various unlicensed black cohosh products, including jaundice, liver problems, and hepatitis.

Attacks on hospitals during conflict are war crimes: Attacks on medical workers, patients, and health facilities during conflicts are war crimes that contravene the Geneva conventions, says the International Health Protection Initiative (www.ihpi.org), which has a website to register such incidents in confidence.

Atlas highlights variations in care: Rates of prescribing of antimetabola drugs vary 25-fold across England, shows the NHS Atlas of Variation (www.rightcare.nhs.uk/index.php/atlas-of-variation-2011), which the Department of Health has published to highlight the amount that each primary care trust spends on clinical services and how this relates to patients’ health outcomes. The atlas’s 71 maps will help commissioners learn from one another, says the department.

Research into neglected diseases falls for first time since 2007

Nigel Hawkes LONDON

Global funding for research into neglected diseases fell in 2010, as the effects of the recession were felt. The UK was one of only a handful of countries whose contributions increased, according to the annual G-Finder survey (Global Funding of Innovation for Neglected Diseases).

This was the first year since the survey began in 2007 to show an overall fall. It would have been much greater but for an increase in spending by large drug companies that offset falls in government and philanthropic funding.

Total reported spending for the diseases covered in the survey was $3.1bn (£2bn; €2.3bn) in 2010, a fall of $109m (3.5%) on the 2009 figure. Though this might seem small in view of the depth of the economic downturn, Javier Guzman, director of research at Policy Cures, an independent research group that compiled the data, warned that it could mark a turning point.

“The situation is critical,” he said. “It has taken the world a decade to reach this point, and it is vital that funding continue if we are not to lose the gains made.”

Joris Vandeputte of the TB Vaccine Initiative said that there was a goldmine of knowledge out there that now needed to be exploited. “Ten years ago nobody would have believed that in 2011 we would have 40 TB [tuberculosis] vaccines in clinical trials,” he said. “Now we need money to bring them to market.”

The United States is still by far the biggest contributor to research efforts, through the National Institutes of Health and the Gates Foundation. In third place is the worldwide drug industry, followed by the UK Department for International Development, which contributed $97m in 2010. The Wellcome Trust and the Medical Research Council also appear in the list of the top 12 funders, with $80.5m and $60.1m, respectively. This was the first year in which the Medical Research Council had been in the top 12.

Although government funding fell almost universally among developed countries, the UK was one of the very few exceptions, providing $21m more in 2010 than in 2009. Other countries to increase their contributions included Switzerland, Australia, and India. “The UK figures are a highlight,” Mr Guzman said, “showing a $21m increase in very difficult times.” By comparison, US funding was down by $75m and the European Commission by $26m.

HIV and AIDS was the best supported of the disease classes, attracting just over a third of total research funds, followed by tuberculosis, malaria, dengue fever, and diarrhoeal diseases. Neglected Disease Research and Development: Is Innovation under Threat? is at www.policycures.org/

Cite this as: BMJ 2011;343:d8036

High cost of essential drugs forces millions into poverty

Peter Moszynski LONDON

Two billion people are unable to access essential drugs, and the high cost of drugs pushes 150 million people below the poverty line each year, say the organisers of the third international conference on improving use of medicines (ICIUM).

The conference’s rapporteur, Hans Hogerzeil, professor of global health at the University of Groningen, Netherlands, told the BMJ that “appropriately used medicines are key to the health and wellbeing of individuals and to the efficient use of scarce resources in health systems.”

Last week the former director for essential medicines and pharmaceutical policies at the World Health Organization gave a briefing on the conference’s conclusions at the Science Media Centre. The conference, which is held every seven years, took place last month in Antalya, Turkey, and included more than 600 participants from 80 countries.

The event had originally been scheduled to be held in Alexandria, Egypt, last February but had to be rescheduled because of the “Arab spring” revolution. However, some 250 Egyptians participated in the discussions through a live webcast.

The conference recommended that there needed to be more use of generic drugs, more transparency over pricing and availability of drugs, and better regulation of prescribing.

Professor Hogerzeil said that rational drug use only really works where there is centralised funding of health systems, because such schemes can function properly only where the government regulates prescriptions, and that “any health insurance scheme without an essential drug list will soon go bankrupt.”
Childhood obesity can be prevented, says Cochrane

Melissa Sweet  SYDNEY

Strategies to promote healthy eating and physical activity in schools and other settings are effective in preventing childhood obesity, says an updated Cochrane Collaboration review released this week.

The publication is an update of a 2001 review that reached more equivocal conclusions when last updated in 2005. It includes 55 studies of interventions targeting children up to age 18 years, with most involving children aged 6 to 12 years.

The review’s lead author, Elizabeth Waters, the Jack Brockhoff chair of child public health at the University of Melbourne, told the *BMJ* that the most effective interventions sought to change social and physical environments and norms, rather than just individual behaviour.

These included policies for healthy eating and physical activity in schools and early childcare settings, support for teachers and other staff to do health promotion, and support from parents and at home for children to eat better, move more, and spend less time looking at screens.

The review found that the best estimate of effect on body mass index (BMI) (kg/m^2^) was a reduction of 0.15, or a 0.4-1.6% reduction in individual weight, which would correspond to a “small but clinically important shift in population BMI if sustained over several years.”

Professor Waters said: “The implication of this is quite remarkable—were these programmes able to be implemented across the population, we can be confident that this would translate into a reduction in body weight that would have substantial effects on the consequent child health concerns, such as the rising rates of diabetes.”

She said that policy makers with responsibility for schools and other settings where children spent time had a responsibility to act.

“By not putting in place these strategies, which we know work, the health of children will be affected as obesity rates are predicted to continue to rise,” she said.

The review’s authors said there was now so much evidence about the impact of interventions in children aged 6 to 12 that further such trials in this age group seemed unnecessary.

“Childhood obesity prevention research must now move towards identifying how effective intervention components can be embedded within health, education and care systems and achieve long term sustainable impacts,” they wrote.

However, the review found “substantial unexplained heterogeneity” in the size of intervention effects, and the authors suggested this could reflect “small study bias.”

Boyd Swinburn, director of the World Health Organization’s Collaborating Centre for Obesity Prevention at Deakin University in Melbourne, said that policy makers must now respond to the challenge of rolling out the interventions widely.

But he cautioned that the review findings did not absolve governments from taking broader action at a population level to tackle junk food marketing and to ensure better regulation of food labelling.


Cite this as: BMJ 2011;343:d8014

German health system makes record surplus in 2011

Ned Stafford  HAMBURG

Germany’s public health insurance system, made up of independent insurers regulated by the government and covering nearly 90% of the population, has recorded a surplus of €3.9bn (£3.3bn; $5.2bn) in the first nine months of 2011, says the German health ministry. The surplus in the same period in 2010 was €277m.

In a statement issued on 6 December on public health insurance “financial developments,” the ministry said that insurers spent €133.8bn in the first nine months of 2011 and collected €137.7bn in premiums. Mandatory monthly premiums for workers now stand at 15.5% of gross wages, often referred to as a payroll tax in Germany, with the cost split between employees and employers.

The system was able to post a surplus despite spending 2.5% more for each insured person than at the same time last year, including a 4.2% rise per insured person for hospital treatments. But several major public insurers have said that the surplus will allow them to cancel a controversial monthly “additional premium” of €8 a month levied in early 2010 when the system was facing a large deficit (*BMJ* 2010;340:c615).

The €3.9bn surplus will probably not hold to the end of the year, the ministry said, because spending by insurers in the final quarter of a calendar year is normally as much as €1.5bn higher than in the other quarters.

One of two main reasons for the surplus, the ministry said, is a larger inflow of premiums. The other main reason was a 5.7% decrease in spending on drugs by public insurers in the first nine months, compared with a year ago.

Cite this as: BMJ 2011;343:d8047
Deal to cut emissions is a “modest but significant step forward”

John Vidal DURBAN

The United States and major developing countries such as China, Brazil, and India will for the first time be legally committed to reducing climate changing emissions from 2020, after a historic deal struck in Durban, South Africa.

The package of measures agreed between 194 countries was struck in the early hours of 11 December and came after six days and three nights of ministerial wrangling.

The talks resulted in a decision to adopt the second commitment period of the Kyoto Protocol next year in return for a “road map” to a global legal agreement covering all parties for the first time. Negotiations will begin on the agreement in the New Year.

However, the day after the agreement Canada announced that it was invoking its legal right to withdraw from the Kyoto Protocol, saying that the accord would not work.

Canada’s environment minister, Peter Kent, said that because two of the world’s largest two emitters of greenhouse gases, the US and China, were not bound by Kyoto the agreement would not work. Canada also faced fines of $13.6bn (£8.7bn; €10.3bn) for failing to meet its targets.

It was also agreed that countries will be able to offset their emissions by creating forests, and a new global climate fund was set up to handle the $100bn pledged by rich countries to help poor countries adapt to extreme weather events.

But the outcome in the South African coastal city brought the world only marginally closer to holding global temperature rises under 2°C in the 21st century. Analysis of the pledges so far made by countries indicate that if nothing more is done temperatures can be expected to rise by at least 3.5°C over the preindustrial average by the end of the century, enough to make large areas of the earth uninhabitable.

There was also widespread concern in Durban that the new legal agreement will not come into force until 2020 and that many rich countries will be allowed to exploit loopholes in the text to avoid cutting emissions for many years.

Cite this as: BMJ 2011;343:d8080

“Strategic vacuum” after end of NHS London threatens patient care

Zosia Kmietowicz LONDON

The government needs to spell out who will be responsible for coordinating health services across London when the capital’s strategic health authority is abolished in April 2012, says the healthcare think tank the King’s Fund.

A fund report warns that the situation raises “a real risk of declining financial performance and a failure to tackle unacceptable variations in the quality of care in the reformed NHS.”

The Health and Social Care Bill, which is currently before parliament, does not deal with what the fund refers to as “a strategic vacuum” in the coordination of London’s health services.

Clinical commissioning groups, which will take on responsibility for commissioning most NHS services under the bill, are unlikely to be able to provide the leadership needed. Instead they “will need to work with the NHS Commissioning Board, local authorities and providers to bring about further improvements in care,” says the report.

It adds, “The time it takes to bring about complex service changes adds urgency to the work that needs to be done. The government must explain who will take the lead in improving health and health care in London and how the many different organisations that have an interest in doing so will work together.”

Although some services in the capital have improved—notably stroke and trauma services—a number of challenges remain including concentrating emergency care in fewer hospitals, tackling high rates of dissatisfaction with GPs, and large health inequalities. Eighteen acute trusts in London are forecast to have a net deficit totalising around £170m (£200m; $265m) by 2014, and London’s NHS also faces costs from private finance initiatives of £19bn to be paid by 2048.


Cite this as: BMJ 2011;343:d8130

Half of acute trusts in London are not viable, say MPs

Nigel Hawkes LONDON

The financial and clinical viability of many NHS hospitals has deteriorated, making it “extremely difficult” for them all to become foundation trusts by April 2014, the House of Commons Public Accounts Committee has concluded.

London presents especially acute problems. “We are particularly alarmed that the healthcare system in London has been allowed to deteriorate despite its problems having been known about for many years,” the committee’s report says. “At least half of the acute trusts in London are not viable in their current form.”

To become foundation trusts, hospitals need to have strong governance, long term financial viability, and a framework to deliver high quality services. Between 2004 and September 2011 139 acute care trusts in England satisfied these demands and became foundation trusts, and the government intends the remaining 113 to join them by April 2014. “It is already clear that this will be extremely difficult to achieve,” the report says.

Achievement of Foundation Trust Status by NHS Hospital Trusts is available at www.parliament.uk/business/committees/committees-a-z/commons-select/.

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