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NEWS

Government tries to end confusion over swine flu advice to pregnant women, as cases mount

Adrian O'Dowd LONDON

The UK government has issued new guidance to try to end confusion over advice to pregnant women on how to avoid the A/H1N1 virus.

The guidance comes after a weekend of conflicting messages from different sources.

The National Childbirth Trust issued advice suggesting that women should consider delaying conception, saying that the guidance was taken from the health department's website.

A joint statement from the Royal College of Obstetricians and Gynaecologists and the Royal College of Midwives said that current advice was for pregnant women to avoid crowded places whenever possible in times of flu outbreaks.

The health department subsequently posted a new document on its website reiterating previous advice but emphasised that it was no longer telling women to delay conception or to stay away from busy workplaces or transport.

A statement from England's chief medical officer, Liam Donaldson, said that the health department was not advising pregnant women to avoid going to work or busy public places. But it advised that they should observe good hand hygiene, avoid contact wherever possible with someone who is known or suspected to have swine flu, and to contact their GP if they had flu-like symptoms.

Professor Donaldson added, however, that some pregnant women might "exercise their choice now, on a highly precautionary basis," to avoid large, densely populated gatherings.

AP/PHOTO/PAT/ROQUE

Children are screened in the Philippines, where there have been three deaths and 2688 cases of A/H1N1

Pregnant healthcare workers should avoid seeing patients with flu-like symptoms if this is possible, the Royal College of GPs says.

So far the UK has had 29 deaths among people infected with the virus, including four children and two mothers who died shortly after giving birth.

The latest figures (20 July) from the European Centre for Disease Prevention and Control show that Europe had 16 969 confirmed cases; and globally there were 139 566 confirmed and reported cases and 781 deaths.

In Australia, where the winter is thought to be helping the spread of the disease, 1130 new cases were reported in just 24 hours from Sunday 19 to Monday 20 July, bringing the total there to 13 178 cases, including 32 deaths.

A national pandemic flu service is being launched this week in England to help take some pressure off "overwhelmed" GPs, who are being swamped with calls from worried patients (*BMJ* 2009;339:b2932, 20 July).

Cite this as: *BMJ* 2009;339:b2984

Leading academic recommends shake-up in NICE procedures

Lynn Eaton LONDON

The UK National Institute for Health and Clinical Excellence (NICE) has been attacked for the lack of transparency in the way it makes its decisions and how it informs the drug industry of the process.

Ian Kennedy, a leading medicolegal lawyer and former chairman of the Healthcare Commission, has outlined the need for a major shake-up in the way NICE carries out—and communicates—its role. His 52 page report was due to go to NICE's council meeting on Wednesday 22 July.

He gives 25 recommendations to try to increase understanding of the organisation's role, improve the way it handles innovations (from drugs and devices to psychological therapies), and how best to build confidence in its processes among the public and the drug industry.

Central to the debate, Professor Kennedy says, is the way the drug industry sees the role of NICE: "The impression is one of undeclared hostilities, if not war. Pharma sees NICE as a barrier to its ambitions to bring products to patients. NICE sees itself as the guardian of the public purse and of all patients.

"It is not clear how, in fixing a price for the UK market, the costs of R&D and marketing incurred globally are distributed among the various markets."

The report is at www.nice.org.uk.

Cite this as: *BMJ* 2009;339:b2993

Ultraorthodox Jews riot in Israel after mother is arrested for Munchausen by proxy

Judy Siegel-Itzkovich JERUSALEM

Hundreds of Jerusalem residents of the ultraorthodox Mea Shearim quarter took to the streets and demonstrated after a mother was arrested. She is accused of starving and abusing her three and a half year old boy for two years as a result of fabricated or induced illness, the psychiatric disorder Munchausen's syndrome by proxy. A few dozen people were arrested. The parents are members of a concentrated extremist Hasidic sect.

Some residents burned dustbins, threw rocks at policemen and passersby, and smashed equipment in a welfare office. The violence surged after a court "gag order" was cancelled, allowing the press to publish the story (but not of the family name so the children would not be identified). In reaction to the violence, Jerusalem's mayor, Nir Barkat, ordered the temporary closure of the neighbourhood's welfare offices.

Doctors at Jerusalem's Hadassah University Medical Center are trying to nurse the boy back to health. The 30 year old mother, who has four other children and is in her fifth month of pregnancy, was arrested after hospital staff filed a complaint with the social welfare authorities. The hospital had conducted intensive tests, consultations, and assessments over a period of months during which the mother periodically brought the boy in for treatment.

When doctors were convinced that his "failure to thrive" was not the result of medical illness, and the woman was reportedly observed several times adding unknown substances to his feeding tube or disconnecting them in the paediatric ward, she was detained by police while leaving a Jerusalem welfare office.

Social workers said that the other children in the family were not abused, noting that people with Munchausen by proxy usually attack only one specific child. During the first 10 days after his mother was separated from him, the boy's weight has risen from 7 kg (the weight of a 5 month old baby) on admission to 8.7 kg. He has been able only to lie in bed, but he talks and seems to know how to walk.

Yair Birnbaum, deputy director general of the Hadassah Medical Organisation, said that physically the boy is on the right track.

Cite this as: *BMJ* 2009;339:b2909

Subsidise artemisinin to treat

TONY KARUMBA/AFP/GETTY IMAGES

Expensive combination therapy for malaria would need to be subsidised before it leaves the drug company

Bob Roehr WASHINGTON, DC

A mixture of subsidy and market forces is being touted as a way to promote the use of combination therapy for treating malaria, which the World Health Organization has recommended since 2001.

The long term goal is to reduce and delay the emergence of resistance to the artemisinin family of compounds and extend their lives as effective drugs.

"If we used artemisins in the same way we used chloroquines, which was as a monotherapy, the chance that we would lose it within about 10 years is extremely high,"

JAMA told to change its policy on investigating competing interests

Janice Hopkins Tanne NEW YORK

The American Medical Association has recommended that the editors of its journal (*JAMA*) change its procedures for dealing with complaints over undisclosed conflicts of interest by journal authors. The journal laid out its procedures, which attracted much criticism, in an editorial in March (*BMJ* 2009;338:b1352).

The journal's editorial said that people complaining about such conflicts of interest should remain silent while their complaints were investigated.

The editorial has now disappeared from *JAMA*'s website, and a new, milder editorial appears in the 8 July issue of the journal (*JAMA* 2009:302:198-9).

The new editorial does not give the names of the two doctors whose questions about an undisclosed conflict prompted the March editorial. They were Jonathan Leo, professor of neuroanatomy at Lincoln Memorial University in Tennessee, and his colleague, Jeffrey Lacasse, of Arizona State University.

The new editorial notes that "conflicts of interest have taken an increasingly prominent role in politics, business, and medicine . . . *JAMA* editors take issues of undisclosed conflicts of interest very seriously and investigate such allegations rigorously."

The American Medical Association's statement said that its board of trustees had reviewed and acted on recommendations put forth by its journal oversight committee, which had been "charged with examining concerns raised over how *Journal of the American Medical Association* senior editors responded to a report that a study author had failed to comply with the journal's editorial policies regarding conflicts of interest."

Rebecca Patchin, chairwoman of the association's board, said, "We anticipate *JAMA*'s procedures for resolving undisclosed conflicts of interest by journal authors will be improved."

The issue arose when Dr Leo raised the question of non-disclosure of conflicts of interest about an article published in *JAMA* about the use of escitalopram, problem solving therapy, or placebo in patients who had had a stroke (*JAMA* 2008;299:2391-400).

Dr Leo and Dr Lacasse wrote to *JAMA* and the *New York Times* saying that the study's lead author, Robert Robinson of the University of Iowa, had not disclosed support from the drug's manufacturer, Forest Laboratories. Dr Robinson and his coauthor later acknowledged industry support (*JAMA* 2009;301:1023-4).

Dr Leo told the *BMJ* that he had received a response to his message saying that *JAMA* "would look at it." After five months and no further response he posted his letter on the *BMJ*'s website (http://bmj.com/cgi/eletters/338/feb05_1/b463#208503,9Feb2009).

After the letter was published, *JAMA* editors contacted Dr Leo and his dean and subsequently published the online editorial which called for whistleblowers to remain silent while the journal investigated their concerns.

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malaria in order to delay resistance, say experts

said Ramanan Laxminarayan, a policy analyst with the charity Resources for the Future. He was speaking at a forum in Washington, DC, on 14 July, where a paper he coauthored in *Health Affairs* was released (2009;28:949-61).

The challenge is to get patients to take artemisinin drugs, which are more expensive than chloroquines, when they would not benefit directly. The advantages would not become apparent on a population basis for a decade or more.

A centralised medical model has proved successful to identify and treat HIV and tuberculosis, where initiation of treatment is often long after infection.

By contrast, malaria progresses rapidly from the onset of symptoms, with an almost immediate need for effective treatment. More than half of all drugs used to treat it are purchased from local shops in the private sector, without the patient seeing a medical provider.

Any solution has to be compatible with this existing network of distributing antimalarial drugs, says the paper.

A 2004 report by the US Institute of Medicine put forward the idea of heavy subsidy of the more expensive combination therapy products before they leave the drug company. This would allow the drugs to move through distribution channels to local shops, with standard mark-ups, and be competitively priced on the store shelf.

After years of discussion the Affordable Medicines Facility-malaria (AMFm) was created, under the administration of the Global Fund to Fight AIDS, Tuberculosis, and Malaria. The UK Department for International Development played a key role with a £40m (€47m; $66m) pledge last October. It will begin operations in about six months.

Dr Laxminarayan calls the Affordable Medicines Facility-malaria "a financing and delivery mechanism to deal with the reality of delivery standards in poor countries." It is a way to work around healthcare delivery systems, which are often lacking in these settings, he said.

See the recent Analysis piece on access to antimalarial therapy (*BMJ* 2009;339:b2606).

Cite this as: *BMJ* 2009;339:b2908

HIV clinics in South Africa are halting enrolment of new patients as funding stalls, MSF warns

Bob Roehr WASHINGTON, DC

The international charity Médecins Sans Frontières (MSF) is calling for better and cheaper first line and second line treatments for HIV in the developing world, in a new report released on 20 July at the opening of the International AIDS Society meeting in Cape Town.

MSF says that a first line treatment regimen should be based on tenofovir rather than stavudine, an older, less potent drug that is more susceptible to the emergence of viral resistance and carries potential side effects of lipodystrophy and peripheral neuropathy. The World Health Organization has recommended use of tenofovir since 2006.

A generic tenofovir based regimen costs two to three times more than one based on stavudine, but the price should fall as the volume of purchases rises. Also, the more potent regimen would delay development of viral resistance, thus deferring a switch to an even more expensive second line therapy, and would avoid costs associated with stavudine's side effects.

MSF found that in Khayelitsha, South Africa, which has one of the charity's longest running HIV treatment programmes, 16% of patients failed a first line treatment within five years. A quarter of those who were switched to a second line regimen failed to suppress their virus at the end of two years, leaving them with no further treatment options.

ANNA ZIEMINSKI/AFP/GETTY IMAGES

A quarter of patients on second line therapy in one programme in South Africa fail within two years

MSF's report calls for a simple, rapid, inexpensive diagnostic test to be developed that measures the HIV viral load to identify when a regimen is failing, thus cueing the switch to alternative treatment.

Patients who experience undiagnosed treatment failure stay on the failing regimen longer, resulting in greater and possibly irreversible damage to their immune system. The virus also has greater opportunity to develop resistance to other drugs in the regimen that might otherwise be preserved as part of an ongoing combination therapy.

MSF also urges drug companies to deposit their patents into a "patent pool" that manufacturers of generic versions might use under set licensing terms, with the freedom to create pills that combine several drugs as they see fit.

The report notes that "financing for HIV/AIDS is stagnating." The financial crisis has led to a cut in the South African government's budget for health, and finding alternative funding is proving difficult in the short term.

Eric Goemaere, MSF's head of mission in South Africa, said, "All around us, clinics stop enrolling patients because there are just not enough ARV [antiretroviral] supplies. The waiting lists are growing on a daily basis, with the risk that patients die before they start ARVs."

Cite this as: *BMJ* 2009;339:b2966

IN BRIEF

German drug misusers to get diamorphine on prescription: On 10 July the Bundesrat, Germany's upper house of parliament, approved a controversial law that was barely passed in May by the lower house, the Bundestag, allowing severely addicted drug users to receive synthetic heroin diamorphine on a prescription basis, paid for by public health insurers.

Recycled television screens have potential use in medicine: Researchers from the University of York have found they can recover a chemical used in television sets with liquid crystal display technology and transform it to use in tissue scaffolds that help parts of the body regenerate. The recycled material can also be used in pills and dressings that are designed to deliver drugs to particular parts of the body, they say in the journal *Green Chemistry* (doi:10.1039/b906607a).

Smoking ban is relaxed in Bavaria: Bavaria's parliament voted on 15 July to relax a ban on cigarette smoking in pubs and nightclubs that was approved just 18 months ago. From 1 August smoking will be allowed in one-room pubs less then 75 m^2 in area and in separate rooms of larger pubs.

German medics should be called "doctor" without need to do PhD: The European Research Council and the German Science Council have called for the abolition of rules that require German medical students to do a doctoral degree in order to be called "doctor." The councils say that 90% of medical students do a minor piece of work which does not meet PhD standards. The term "medical doctor" should be the name of the profession, they say.

Kit is launched to help displaced children: Unicef has launched a new early childhood development kit to help children who have been displaced or affected by war and natural disasters. The kit, with 37 different items, aims to help children regain a sense of normality and assist their cognitive development. Unicef says that early childhood is the most critical period for brain development, making young children vulnerable to the stresses of war and natural disasters.

Cite this as: *BMJ* 2009;339:b2916

Commissioners publish highly critical reports on mental health services

Lynn Eaton LONDON

The poor standards of care and supervision of people with severe mental health problems in NHS hospitals in England have come under the spotlight in two damning reports issued by the Care Quality Commission, which recently took over the work of the Mental Health Act Commission.

Coercion and Consent, the 13th (and final) report of the now defunct Mental Health Act Commission, looked at services throughout England and Wales between 2007 and 2009. It also looked at the causes of the 1392 deaths of detained patients between 2005 and 2008.

Of these deaths, 1123 were ascribed to natural causes, 205 to suicide, 30 to accidental causes, two to incorrect medication, and four to the intervention of a doctor (iatrogenic). The causes of death were unknown in 28 cases.

The report highlights the apparent failure to monitor patients who were meant to be under continuous observation. One patient found hanging in 2007 was showing signs of rigor mortis, although checks were meant to be made every 15 minutes. It also draws attention to the use of restraint and the importance of staff being properly trained in appropriate techniques.

Barbara Young, chairwoman of the Care Quality Commission, said she was "deeply concerned" about the safety and quality of care provided to some people who are detained. She said, "These are some of the most vulnerable people for which the NHS is responsible. We have got to ensure that services meet their needs more effectively."

Paul Farmer, chief executive of the mental health charity Mind, said that the report highlighted some "astounding" failings in delivering the most basic level of care. "When a ward fails to provide a safe and secure place where people can receive good quality therapeutic treatment, the whole purpose of the ward is thrown into question. They can become a place of neglect rather than recovery."

The second report looked at services at the West London Mental Health Trust, which includes in its remit Broadmoor, one of England's three high security hospitals for mentally ill criminals.

Scientific testing on animals grew by 14% in 2008, figures show

Helen Mooney LONDON

The number of licensed animal testing procedures in the United Kingdom was just over 3.7 million in 2008, a rise of 14% on 2007 and the seventh consecutive yearly rise. The number has risen from 2.6 million procedures since 1997.

The Home Office, which regulates animal testing, said that the increase in procedures was mainly the result of more breeding of genetically altered animals, accounting for nearly two fifths of all tests. Applied studies for human medicine or dentistry accounted for about a fifth of all procedures.

In 2006 the number of procedures rose by 4% to exceed three million for the first time since 1991, again largely as a result of genetically modified animal experimentation.

The data on scientific tests on live animals in 2008 also showed a rise in the number of experiments on "old world" primates such as monkeys, up by 33% since 2007, with 1000 tests carried out last year.

STUART CLARKE/REX FEATURES

The Home Office says tests on animals remain vital

The use of turkeys in testing rose by 135%, while there were also big increases in numbers of tests on fish, which increased by 85%, and on pigs, up by 114%.

Mice, rats, and other rodents together accounted for more than three quarters (77%) of procedures. Fish were used in 17% of procedures and birds in 3%.

The report can be seen at http://rds.homeoffice.gov.uk/rds/scientific1.html.

Cite this as: *BMJ* 2009;339:b2989

ROBIN ANDERSON/REX

Opened in 1863, Broadmoor was deemed unfit for purpose in 2003 and still is today, says the report

The trust's chief executive, Simon Crawford, resigned the week before the report was published. Mr Crawford was previously finance director at Broadmoor. He has accepted a position at NHS London.

The report criticises the trust for failing to act quickly enough in addressing some of the concerns that have been highlighted over the years. These include 31 suicides across the whole trust between 2005 and 2007 and five attempted suicides. Of the suicides, 17 took place while the patient was in the community and 14 involved inpatients, of whom five were at Broadmoor.

High numbers of staff vacancies were a major problem: one ward at Broadmoor had a 23% vacancy rate, she said.

Coercion and Consent: Monitoring the Mental Health Act 2007-2009 **and** ***Investigation into West London Mental Health Trust*** **are available at www.cqc.org.uk.**

Cite this as: *BMJ* 2009;339:b2978

Ara Darzi resigns as minister but remains an adviser

Nigel Hawkes LONDON

Ara Darzi, appointed a health minister in Gordon Brown's "government of all the talents" in 2007, announced his resignation on 15 July.

The resignation represents a serious blow to the government, as Lord Darzi had made some progress towards convincing doctors that their role in improving NHS care was being taken seriously. His "next steps" report, published in June 2008, emphasised quality of care as the driving force for NHS reform, something with which doctors could sympathise (*BMJ* 2008;337:a642, doi:10.1136/bmj.a642).

Lord Darzi's resignation letter implies that he was finding the burden of being a minister too onerous. "During my time as a minister, I have maintained my clinical practice and research," he wrote. "The time has now come for me to return to care for my patients, lead my academic department, and continue my research full time."

He defended the parliamentary bill to create the Care Quality Commission from three existing regulators, although he had no hand in planning this change and little enthusiasm for it.

Niall Dickson, chief executive of the King's Fund, said "There is no doubt that the number one priority for the NHS from now on will be improving quality of care, while delivering greater value for money. Lord Darzi's personal commitment has been crucial in driving this forward."

See Is Lord Darzi's resignation proof that politics and medicine don't mix? on doc2doc.bmj.com at http://ow.ly/hkx7

See OBSERVATIONS, p 201

Cite this as: *BMJ* 2009;339:b2898

Academics criticise plan to allow new drugs to bypass NICE

Deborah Cohen BMJ

Plans drawn up by the government to boost the life sciences industry have been criticised by some academics for eroding the cost effectiveness model of the National Institute for Health and Clinical Excellence (NICE) and for undermining academic independence.

In their life sciences blueprint, innovative drugs will be approved for NHS use for a set period without having first gone through NICE's appraisal process to allow data to build up to show cost effectiveness. After a predetermined period they will then go through the usual NICE appraisal process.

The so called innovation pass will be piloted in 2010-11, with a budget of £25m (€29m; $41m), and then evaluated. Although what constitutes a successful pilot has yet to be decided, NICE will play a key role in developing and applying eligibility criteria for the pass and is set to enter discussions with industry and the NHS.

Mike Rawlins, chairman of NICE, told the *BMJ* that the pass would be for products whose cost effectiveness is difficult to acertain. "What we'll almost certainly do is set up an expert advisory committee to decide whether something is sufficiently innovative to warrant going down this pathway."

NICE is understood to have agreed with the new arrangements provided that the money does not come directly from the health service, because the project was devised in pursuit of England's industrial policy, not health policy.

Iain Chalmers, coordinator of the James Lind Initiative, said that there is much to be applauded in the blueprint, such as the promotion of clinical research as an integral element of the NHS and the accreditation of bioscience degrees. But he is concerned about how the blueprint's commitment to cost effectiveness will play out. "Unless it has been established that a treatment has at least some beneficial effects there is no basis for attempting to estimate its cost effectiveness," he said.

"It seems that boosting the economy is the most important influence [of this blueprint]. And it would be perverse to object to this. But it's completely unacceptable if patients are to be expected to pay the price of inadequately evaluated innovations."

The blueprint is at www.info4local.gov.uk/

See *BMJ* 2009;339:b2887, and **OBSERVATIONS, p 201**

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