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Vaccines rarely cause adverse events, concludes US review

Bob Roehr WASHINGTON, DC

Vaccines are safe to use and only rarely result in adverse events, a committee of the US Institute of Medicine has concluded after an extensive review.

The study was commissioned for use by the National Vaccine Injury Compensation Program, a no fault compensation scheme created in 1988 to maintain a forum for people injured by vaccines.

"We reviewed in detail more than 1000 peer reviewed articles from the scientific literature," explained the committee's chairwoman, Ellen Wright Clayton, director of the Center for Biomedical Ethics and Society at Vanderbilt University, Nashville, Tennessee.

The review looked in particular at epidemiological studies and studies of biological mechanisms of action of possible adverse events. The purpose was to differentiate between coincidence and plausible causality in considering compensation.

The committee's conclusions fell into four categories according to the strength of evidence. The first category is where there is convincing evidence supporting a causal relationship. Examples include the measles, mumps, and rubella (MMR) vaccine; the varicella vaccine against chickenpox; and the influenza, hepatitis B, meningococcal disease, and tetanus vaccines. All these can trigger anaphylaxis shortly after vaccination in some people. Another is the live polio vaccine, which can cause paralytic polio in some people.

The second category is where the evidence favours acceptance of a causal relationship: the evidence is strong, though not convincing or established. "We can say that the MMR vaccine probably can cause temporary aches and pains in the joints in some cases," said Dr Clayton.

The third is where the evidence favours rejection of a causal relationship. "The MMR vaccine does not cause autism," Dr Clayton said. "The diphtheria, tetanus, acellular pertussis (DTaP) vaccine does not cause type 1 diabetes, and the killed flu vaccine does not cause Bell's palsy or trigger episodes of asthma."

Finally, there are areas where the evidence is not strong enough to reach a causal relationship.

Adverse Effects of Vaccines: Evidence and Causality **is at http://bit.ly/o2FjEB.**

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FRANCOIS MORI/AP/PA

Hospitals became strategic targets as pro-Gaddafi forces battled rebels for control of Libyan cities

Gaddafi's forces repeatedly attacked hospitals and staff

Sophie Arie LONDON

Forces of Muammar Gaddafi's regime repeatedly attacked hospitals, ambulances, patients, and doctors in Libya over the past six months, says a report from Physicians for Human Rights.

The report details widespread violations of international conventions on war and human rights—including failure to respect medical neutrality and the right to medical care—during the two month siege by Libyan forces of the port city of Misrata.

It identifies a pattern in which hospitals became strategic targets as pro-Gaddafi forces battled rebels for control of different cities. They bombed medical facilities and then placed snipers on their roofs; civilians were denied treatment; patients and doctors were abducted; other doctors were forced to work round the clock to treat only soldiers loyal to Gaddafi; and ambulances were attacked and medical equipment and drugs removed.

One volunteer ambulance driver from the eastern city of Ajdabiya described being dragged from his vehicle by pro-Gaddafi troops after delivering an injured civilian to a hospital there. His hands were bound, and he was then forced to the floor and severely beaten with rifle butts and a metal bar, which was also rammed into the back of his mouth.

"The core issue, across the region, is that medical workers, supplies, transport, and facilities are being targeted," said Richard Sollom, deputy director of Physicians for Human Rights, who compiled the report from 54 interviews carried out in Misrata in June. "Governments are using hospitals almost as a dragnet to find people who are wounded and disappear them. It's almost like these are crimes against humanity because they are systematic," he said.

Since Tripoli fell to rebels, more details have emerged of crimes committed inside the capital's hospitals. Up to 200 people were found dead in the city's Abu Salim Hospital last week after staff fled the hospital amid heavy fighting there. It is not yet clear how they died.

Physicians for Human Rights is calling for greater awareness of attacks on medical targets and more legislation against them. "There has never been an international court [after a conflict] that actually addressed these questions of medical neutrality," said Dr Sollom.

The chairman of the Libyan National Transitional Council, Mustafa Abdul Jalil, announced last week that enough medical supplies to supply the whole country for a year had been found at the Gadaffi family compound in Tripoli. Meanwhile hospitals in several cities across Libya are still struggling to cope with hundreds of injured people.

Witness to War Crimes **is available at http://physiciansforhumanrights.org.**

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One in 10 suicides occurs in people with a physical illness

Anne Gulland LONDON

A report on the link between suicide and physical ill health has found that one in 10 people who take their own life is chronically or terminally ill.

The report, by think tank Demos, is one of the first such comprehensive studies to look at the links between suicide and physical ill health. It says that the figure, which came from coroners and primary care trusts (PCTs), is likely to be a substantial underestimate because coroners do not always include the relevant health information with their inquest reports.

Demos believes that the findings provide strong evidence that people with chronic and terminal illnesses should be regarded as a high risk group for suicide and should be given better "medical, practical, and psychological support."

Researchers sent freedom of information requests to all PCTs in England on the relationship between physical ill health and suicide and conducted interviews with coroners. PCTs are meant to carry out suicide audits but 10 trusts told Demos that they did not conduct such an audit. Demos recommends that because suicide is such a serious public health matter the audits "should not be optional" and PCTs—and the forthcoming health and wellbeing boards—should be required to compile annual reports that detail the characteristics of people who die by suicide.

Demos also found that coroners' policies on collecting and sharing information on suicides vary widely. The report stated, "This is an issue of national importance and it should not be left to individual coroners to decide."

The government launched a consultation on suicide in July which identified five high risk groups for suicide: people in the care of mental health services (1200 suicides a year); people in the criminal justice system (80 suicides in prison a year); adult men aged under 50 (2000 suicides a year); people with a history of self harm (950 suicides a year), and occupational groups such as doctors, nurses, and farmers. There were 4390 suicides in England in 2009, which, using Demos's calculation, would mean that more than 400 of these were among people with a chronic or terminal illness. Demos believes that this group should be identified as high risk.

The report calls on GPs and others in the primary care team to ensure that appropriate local services are available to respond to the emotional and practical needs of people who are coping with painful or limiting illness. Louise Bazalgette, author of the report, said it was important that doctors treating people with a chronic or terminal illness were aware of the issue.

"Doctors should be thinking about the possibility that a person with chronic health problems may be depressed and struggling. They should ask them if they ever feel suicidal," she said.

The report includes extracts from suicide notes. "It's impossible to tell whether these people were receiving good healthcare or not from their doctors. It may be that some people aren't able to discuss these issues with their doctors," she said.

She added, "PCTs tend to focus on high risk groups identified nationally. It's important that the national strategy is comprehensive and ambitious and that it provides support to local agencies such as PCTs and health and wellbeing boards," she said.

Simon Gillespie, chief executive of the Multiple Sclerosis Society, said: "There is a big difference between someone wanting to end their life having explored and received every care option, and someone giving up hope because they feel they have nothing available to them. The right care and support can make a huge difference to an individual's life."

The Truth About Suicide **is at www.demos.co.uk.**

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JOHN THYS/REPORTERS/SPL

Services should ensure emotional and practical support for people with chronic or terminal illnesses

Give naloxone to families of drug users to save lives, says study

Richard Hurley BMJ

A pilot scheme has shown that providing family and friends with training and the drug naloxone seems to reduce deaths from overdose among heroin users and other opioids misusers, says the English National Treatment Agency for Substance Misuse.

During the pilot scheme 20 users overdosed, and carers gave naloxone to 18. All the users survived. Family members, partners, or other drug users are often first to find a user who has overdosed.

"If they can be trained in how to manage such an emergency and keep the victim alive while waiting for the ambulance, potentially hundreds of lives could be saved in the UK every year," said Paul Hayes, chief executive of the treatment agency.

Commenting on the findings John Strang, head of the addictions department at King's College London, said, "We are approaching a time when a clinician might be considered negligent if he or she did not tell the family of a user how to manage an overdose, particularly if the user later overdosed and was initially found alive, but then died because the family didn't know what to do.

"The numbers in this pilot are small but they allow you to conclude that the families of users are hungry for this information."

Some people may think that providing families with naloxone gives out a mixed message, said Professor Strang, but he added, "It is surely better for family and friends to know how to deal with an overdose emergency, even though you do everything possible to avoid it happening."

He believes the reason the NHS has been so slow to roll out naloxone is that the novelty makes people nervous. "Empowering families feels alien; it's similar to when Epipens [adrenaline autoinjectors] became

CHRIS HOWELLS

A report suggests that hospitals funded by private finance initiatives cost more in the long term

Private finance initiatives to build hospitals do not give value for money

Matthew Billingsley BMJ

Private finance initiatives (PFI) used to fund the building of hospitals and other major infrastructure projects do not provide value for money and the long term contracts impose inflexible conditions, says a report from English MPs.

PFIs seemed attractive to government departments because the capital upfront costs are covered by the private sector and do not have to be included in departmental budgets.

But MPs on the Treasury Select Committee, a group that looks at public spending, are concerned that this incentive has caused departments to make poor investment decisions. The committee found that the debt to the taxpayer on a £1.7bn (€1.9bn; $2.8bn) publically funded project was similar to that of a £1bn PFI investment over the same period.

Andrew Tyrie MP, chairman of the committee, said, "PFIs should be brought on balance sheet and we must also impose much more robust criteria on projects that can be eligible for PFI by ensuring that as much as possible of the risk associated with PFI projects is transferred to the private sector."

The report found that 101 of the 135 new NHS hospitals built between 1997 and 2009 were funded through PFI. The committee analysed projected costs for the Royal Liverpool and Broadgreen University Hospital NHS Trust's PFI project currently in the procurement phase, and found that the government could have spent £175m less if it had borrowed directly from capital markets rather than through a PFI intermediary.

Neil Bentley, deputy director general of the Confederation of British Industry, defended the involvement of private finance: "With the state of the public finances, it is absolutely essential we attract the billions of pounds of private finance needed to upgrade our national infrastructure."

But MPs on the select committee claimed that PFI payments, which are often structured over a 30 year period, are short sighted because they "build up big commitments against future years' current budgets not yet allocated or agreed."

In light of the £20bn efficiency savings the NHS is being asked to make by 2014-15, Jo Webber from the NHS Confederation told the committee, "There will be a big affordability challenge over a long period."

The report notes that long term PFI contracts should incentivise providers to maintain buildings to a high quality, so reducing costs in later life. However, the committee found no clear evidence that PFI projects had performed better in this compared with publicly funded projects.

The report is at www.publications.parliament.uk.

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Medtronic submits spinal protein data to independent scrutiny

Deborah Cohen BMJ

The company at the centre of an investigation by a US Senate committee into an alleged failure to mention the side effects of a spinal treatment it makes has agreed to fund an independent review into the safety and effectiveness of the product. It is the first time that a medical technology company has agreed to this type of detailed scrutiny.

Medtronic announced in early August that it will give Yale University $2.5m (£1.5m; €1.7m) to review all published and unpublished data on the safety and effectiveness of Infuse Bone Graft, a recombinant bone morphogenetic protein 2 (rhBMP-2) that is used to stimulate bone growth in spine fusion surgery. Academics will be granted access to full patient data possessed by Medtronic.

In June, *Spine Journal* highlighted the "remarkable absence" of side effects or complications in the original industry sponsored trials and the subsequent emergence of adverse reactions associated with rhBMP-2 in independent studies.

Harlan Krumholz, professor of medicine and public health at Yale University, approached Medtronic to take part in a transparency programme for industry that he had already set up, after Infuse received widespread negative coverage in the media.

He was motivated to set up the programme because, as he told the *BMJ*, he was tired of the "lack of community spirit around access to data when there are questions about a drug's safety and effectiveness."

Omar Ishrak, chief executive officer of Medtronic, has reiterated his firm belief in the integrity of the rhBMP-2 data.

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available for people with allergies. But we must get over this: we can hardly allow deaths to occur once we establish that they could be avoided," said Professor Strang.

He added, "What we need is a big randomised trial, which is in hand." The N-ALIVE (NALoxone InVEstigation) study will randomise more than 50 000 prisoners with a history of heroin use to being given naloxone on release or not.

The pilot study ran from July 2009 to February 2010 at 16 drug treatment centres in England. In all, 495 carers received training in basic life support techniques, including the recovery position and cardiopulmonary resuscitation. At 15 of the centres carers were also trained to give, and provided with, naloxone.

Even though naloxone is a prescription only drug in England it is legal for it to be used by anyone for the purpose of saving a life in an emergency (see *BMJ* 2006;333:614). Mostly, the carers in the pilot scheme gave naloxone to somebody other than the person named on the prescription.

Rick Lines, executive director of Harm Reduction International, said, "Risk of fatal and non-fatal overdose is a major concern for people who inject drugs around the world. It is also a risk that can be reduced through targeted overdose prevention programmes, including provision of naloxone. The encouraging results of the UK trial are consistent with the growing body of international evidence demonstrating that such targeted overdose prevention programmes are effective and save lives."

The report is at www.nta.nhs.uk.

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FAYE NORMAN/SPL

Knowing how to deal with an overdose can save lives

IN BRIEF

Diabetes prescriptions make up 8% of NHS drugs bill: Prescriptions in England for antidiabetes drugs cost £725m (€820m; $1.2bn) in 2010-11, accounting for 8.4% of the entire NHS net bill for primary care drugs in England, show new figures from the NHS Information Centre. This compares with 6.6% in 2005-6. Between 2005-6 and 2010-11 the number of prescribed items for the disease rose by 41% to reach 38.3 million—equivalent to one in every 25 prescribed items written. *Prescribing for Diabetes: England, 2005/6-2010/11* is at www.ic.nhs.uk/pubs/prescribingfordiabetes05-11.

Malaria cases are reported in Greece: Since June 2011 six cases of malaria have been reported in the south and east of Greece, says the UK Health Protection Agency. All six cases were among people with no history of travel to a country where malaria is common. This is the third consecutive year that small numbers of cases have been reported in Greece as a result of local transmission. The agency adds that there is no need for visitors to Greece to take antimalarial drugs.

Canada announces strategy for patient centred research: Canada's government has announced a strategy for patient oriented research to speed up the delivery of innovative treatments to patients. The strategy, which has been developed by the Canadian Institutes of Health Research in collaboration with health charities, academic healthcare organisations, and industry, will identify the most urgent research priorities and drive up recruitment and funding for clinical trials.

Proportion of Dutch smokers falls: A "spectacular" annual fall in the proportion of Dutch smokers from 26.5% to 24.3% has sparked calls for the government to reverse its decision to save money by removing smoking cessation treatment from the basic health insurance package. The Dutch tobacco control group Stivoro, which compiled the figures, believes that the insurance cover, introduced on 1 January, has encourage smokers to quit (www.stivoro.nl).

France plans new "soda tax": The French government has announced a new tax on sugary soft drinks in a bid to help cut the budget deficit and tackle the country's growing obesity problem. The new tax, which is due to come into force in January 2012, is projected to raise €120m (£106m; $170m) for the social security budget. Taxes on tobacco and alcohol are also set to be raised.

Cite this as: *BMJ* 2011;343:d5494

Cigarette firms sue regulators over graphic pack warnings

Jeanne Lenzer NEW YORK

Five tobacco companies have filed a lawsuit in the US federal court against the Food and Drug Administration over the requirement to include graphic depictions of the risks of smoking on all cigarette packs by September 2012.

The 2009 Family Smoking Prevention and Tobacco Control Act requires manufacturers to place colour pictures depicting the risks of smoking on the top half of the front and back panels of cigarette packs and in the prime 20% of print advertisements.

The FDA says that the graphics are useful as part of a "broader strategy to help tobacco users quit and prevent young people from starting."

The cigarette manufacturers say in their lawsuit that the required pictures are "disturbing and emotionally charged" and that being forced to put them on cigarette packs violates their "free speech rights" and forces them to serve as a "mini-billboard for the government's antismoking campaign" (http://legaltimes.typepad.com/files/motion-for-summary-judgment.pdf).

The images to be used, posted on the FDA's website, include pictures of dead bodies and diseased lungs and a picture of a person with lip cancer and rotting teeth (http://1.usa.gov/pyQ1dw). Thirty countries already require such graphics.

The 2009 act was supported by the American Cancer Society and the American Heart Association. Howard Leventhal, professor of health psychology at Rutgers University's Institute for Health, Health Care Policy and Aging Research, told the *BMJ* that the required graphics "might have important effects not just for individuals but also for society, by making smoking less acceptable and turning smokers into 'outliers.'"

But some antismoking activists say that the act is likely to have little or no effect on smoking rates. Joel Nitzkin, former chairman of the Tobacco Control Task Force of the American Association of Public Health Physicians, told the *BMJ* that studies showed that graphic warning labels on cigarette packs in the United Kingdom had had no effect there.

Dr Nitzkin said, "I sympathise with the impulse behind this campaign, but the only way it can work is if it is combined with other initiatives, such as tax hikes and help for current smokers to quit."

Unfortunately, he said, the 2009 act "gives the appearance of effective regulation but not the substance," which is the result of a political decision by some antismoking organisations to promote only legislation that was acceptable to tobacco companies. Two of the most prominent groups that lobbied Congress on behalf of the bill were the Campaign for Tobacco-Free Kids, an antismoking group in Washington, DC, and Philip Morris.

bmj.com **News: Tobacco companies launch legal action against plain packaging (*BMJ* 2011;343:d4270)**

Cite this as: *BMJ* 2011;343:d5492

Canadian regulators dismiss complaint about campaign publicising low testosterone

Barbara Kermode-Scott VANCOUVER

Canada's regulator of drug advertising and its national health department have dismissed a complaint from a group of doctors, pharmacists, and researchers about a consumer advertising campaign about testosterone deficiency.

The complaint was about advertisements that appeared in Canada's national newspaper the *Globe and Mail* between 6 June and 2 July. The group said these were "disease mongering."

Health Canada's response to the formal complaint said, "It is the department's view that this particular campaign is not promotional material in disguise." The drug regulator said the message did not fit the definition of an "advertisement" given in Canada's Food and Drugs Act.

Abbott Laboratories ran a "help seeking message directed to consumers" asking, "Has he lost that loving feeling?" Abbott, the manufacturer of the testosterone gel AndroGel, also sent an email to doctors informing them of the consumer campaign.

An Abbott representative, Eileen Murphy, said, "This campaign is designed to raise awareness of low testosterone, or low T, among men who may be at risk or have the condition so they can have the appropriate dialogue with their healthcare practitioners and then determine if treatment may be right for them."

Cite this as: *BMJ* 2011;343:d5501

BILL AND MELINDA GATES FOUNDATION

Pakistani children queue to receive polio vaccine at the Torkham border crossing

Japan lends cash to help curb rising incidence of polio in Pakistan

Sophie Arie LONDON

Japan has provided a $65m (£40m; €45m) loan to help efforts to eradicate polio in Pakistan amid concern that rising numbers of cases there could undermine global progress on wiping out the disease.

The number of recorded cases of polio in Pakistan is 69 so far this year, compared with 37 in the same period last year, show the latest figures from the World Health Organization. By the end of 2010, 144 new cases had been recorded, compared with 32 in 2007.

Although the incidence of polio has been reduced by 99% over the past 20 years, the rising number of cases in Pakistan has led the Global Polio Eradication Initiative to warn that it "risks becoming the last global outpost of this vicious disease, jeopardising the global effort" (*BMJ* 2011;343:d4685).

Nigeria, India, and Afghanistan are the only other countries where polio has persisted, but efforts to defeat the disease in those countries have been far more successful.

Despite an emergency programme launched by the Pakistan government in January, "there are still too many children being missed," said Oliver Rosenbauer, a spokesman for the eradication initiative, a partnership between WHO, Unicef, the Centers for Disease Control and Prevention, and Rotary International.

Pakistan's situation is unique. The disease is rooted in three areas—Balochistan Province, Karachi, and the Federally Administered Tribal Areas (FATA) that border Afghanistan. In the tribal areas, where Taliban affiliated groups and bandits control much of the territory, it is so dangerous that health workers struggle to gain access. In Balochistan, the tribal system of governance is difficult to negotiate and health workers are not trusted. In Karachi "leadership is not fully engaged," said Mr Rosenbauer.

Karachi is failing to vaccinate about 25% of under 5s, and in FATA as many as half are being missed. Even southern Afghanistan, which has similar security problems, has managed to reduce the proportion of under 5s it is failing to reach from 30% to 10%.

Floods last year created conditions that helped the disease to spread, and mass migration then took it to new parts of the country. Infections have been recorded in eight new districts this year.

Japan's loan will provide the Pakistan government with funds to buy the oral polio vaccine, pay immunisation workers, and organise vaccination programmes. The loan is underpinned by an innovative financing approach referred to as a "loan conversion" mechanism under which the Bill and Melinda Gates Foundation will repay the credit to Japan on behalf of the Pakistani government if it meets target numbers of children vaccinated.

Even with the new Japanese loan, the Global Polio Eradication Initiative is still $35m short of the estimated $196.5m needed for Pakistani programmes between now and 2013.

Since 2007, polio has also reappeared in Angola, the Democratic Republic of Congo, and Chad, where over 100 new cases have been recorded this year. The initiative still believes the disease could be wiped out worldwide if it could raise the last $590m of its total global target.

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Rise in assisted reproduction tourism in Asia threatens local medical services

Nayanah Siva LONDON

Local health services in low income countries and women of reproductive age are the unacknowledged victims of increasing demand for cheap assisted reproduction from people in rich countries, says a review in the journal *Reproductive Health Matters* (2011;19:107-16).

Andrea Whittaker, associate professor at the School of Population Health at the University of Queensland, Australia, and author of the study, says she is particularly concerned about the lack of regulatory systems to prevent and reduce exploitation of medical resources and women for surrogacy in poorer countries.

Asia, India, and Thailand are major hubs for assisted reproduction treatments. Thailand has 30 IVF clinics, and in 2004 the Thai government made a conscious move to encourage travel to Thailand for medical treatment by promoting the country's well trained medical staff, and substantial savings in cost compared with developed countries, she says.

A full cycle of IVF in the Thailand costs about $2000 to $4000 in 2002 compared with $10 000 in the US. With about 400 000 foreigners travelling to Thailand each year for IVF treatment the trade has been predicted to bring in about $4.3bn in 2012.

Marge Berer, editor of *Reproductive Health Matters*, said the rise in assisted reproduction treatments is taking medical resources away from local communities. "Services are more likely to be set up by private health providers and to attract health professionals away from the public sector."

Dr Whittaker is calling for greater regulation across national borders.

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PAVLOS CHRISTOFOROU/ALAMY

Assisted reproduction tourism depletes local care