Conflicts of interest and pandemic flu

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drugs prescribed will have prevented thousands of relapses, which the health economists might acknowledge. And as Professor Compston stresses, it leaves a platform for introducing new treatments and executing clinical research that is second to none in the world. Meanwhile, a treatment rate in the UK of around 10-15% of patients, compared with 55-70% in the United States and 40-50% in France and Germany, suggests that we may not have strayed excessively from a sound evidence base.

As for the financial reckoning, the expiry of patents beckons, and substantially cheaper interferon beta preparations are already available and being used (such as Extavia). To add a political point to this lively mix of medicine and economics, the workings of the market may ultimately achieve what central planners have not.

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## Conflicts of interest and pandemic flu

WHO must act now to restore its credibility, and Europe should legislate



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Fiona Godlee editor in chief, BMJ, London WC1H 9JP fgodlee@bmj.com Competing interests: The author has completed the Unified Competing Interest form at www.icmje.org/coi\_disclosure ndf (available on request from the corresponding author) and declares: (1) No financial support for the submitted work from anyone other than her employer: (2) No financial relationships with commercial entities that might have an interest in the submitted work; (3) No spouse, partner, or children with relationships with commercial entities that might have an interest in the submitted work: (4) FG has written articles on the challenges faced by WHO, and on the influence of the drugs industry. She is in favour of a more assertive approach to conflict of interest and supports efforts to control the influence of the drugs industry on medical research, medical education, and health policy.

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Cite this as: *BMJ* 2010;340:c2947 doi: 10.1136/bmj.c2947 The world should of course be thankful that the 2009 influenza A/H1N1 pandemic proved such a damp squib. With so many fewer lives lost than had been predicted, it almost seems ungrateful to carp about the cost. But carp we must because the cost has been huge. Some countries-notably Poland—declined to join the panic buying of vaccines and antivirals triggered when the World Health Organization declared the pandemic a year ago this week. However, countries like France and the United Kingdom who have stockpiled drugs and vaccines are now busy unpicking vaccine contracts, selling unused vaccine to other countries, and sitting on huge piles of unused oseltamivir. Meanwhile drug companies have banked vast profits-\$7bn (£4.8bn; €5.7bn) to \$10bn from vaccines alone according to investment bank JP Morgan. Given the scale of public cost and private profit, it would seem important to know that WHO's key decisions were free from commercial influence.

An investigation by the *BMJ* and the Bureau of Investigative Journalism, published this week, finds that this was far from the case.<sup>2</sup> As reported by Deborah Cohen and Philip Carter, some of the experts advising WHO on the pandemic had declarable financial ties with drug companies that were producing antivirals and influenza vaccines. As an example, WHO's guidance on the use of antivirals in a pandemic was authored by an influenza expert who at the same time was receiving payments from Roche, the manufacturer of oseltamivir (Tamiflu), for consultancy work and lecturing. Although most of the experts consulted by WHO made no secret of their industry ties in other settings, WHO itself has so far declined to explain to what extent it knew about these conflicts of interest or how it managed them.

This lack of transparency is compounded by the existence of a secret "emergency committee," which advised the director general Margaret Chan on when to declare the pandemic—a decision that triggered costly pre-established vaccine contracts around the world. Curiously, the names of the 16 committee members are known only to people within WHO.

Cohen and Carter's findings resonate with those of other

investigations, most notably an inquiry by the Council of Europe, which reports this week and is extremely critical of WHO. 

1 It concludes that decision making around the influenza A/H1N1 crisis has been lacking in transparency.

One of its chief protagonists is Paul Flynn, a UK member of parliament and a member of the council's Parliamentary Assembly. He and others raised concerns last year about the lack of evidence to justify the scale of the international response to H1N1 (as also covered in the *BMJ* in December<sup>3</sup>), and the lack of transparency around the decision making process for declaring the pandemic.<sup>1</sup>

WHO's response to these concerns has been disappointing. Although Margaret Chan has ordered an inquiry and WHO has stressed its commitment to transparency, her office has turned down requests to clear up concerns about potential conflicts of interest.<sup>2</sup> And at a hearing of the Council of Europe's Parliamentary Assembly in January, WHO denied any industry influence on the scientific advice it received.<sup>1</sup> Such a knee jerk defence before the facts were known may come to haunt the organisation.

This response is also disappointing given WHO's track record of standing up to industry. In the late 1970s WHO sparked two iconic clashes with multinational companies over the marketing of breast milk substitutes in the developing world and the setting up of the Essential Drugs Programme. Both issues set WHO at loggerheads with the United States where these industries had major holdings. Partly in response to WHO's position, America withdrew contributions to WHO's budget.

More recently, in 1999, when the forced disclosure of confidential tobacco industry documents alerted WHO to possible interference in its anti-tobacco activities, its then director general Gro Harlem Brundtland quickly set up an independent inquiry. She then published and press released its shocking findings—of an elaborate industry funded campaign to undermine WHO—without any attempt at interference or spin. <sup>5</sup> The report recommended that all staff, consultants, temporary advisers, and members of expert committees should be required to declare their conflicts of interest, with

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Response on bmj.com "Concerning the members of the Emergency Committee that advised WHO on the pandemic, including phase changes, the names will be released when the Committee finishes its work, as has always been intended."

Margaret Chan, directorgeneral, World Health Organization

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well enforced penalties for those who failed to do so.6

As Cohen and Carter report, WHO subsequently published in 2003 new rules on managing conflicts of interest. These recommended that people with a conflict of interest should not be involved in the part of the discussion or the piece of work affected by that interest or, in certain circumstances, that they should not participate in the relevant discussion or work at all. WHO seems not to have followed its own rules for the decision making around the pandemic.

WHO will not be the only body to come under scrutiny for its handling of the pandemic. The coming months will see a spate of reports, from the European Commission, the European Parliament, and from national bodies including the French Senate, and the UK's Cabinet Office. This soul searching takes place against a backdrop of hardening attitudes to conflicts of interest around the world. Last year's report from the Institute of Medicine<sup>8</sup> has been followed by new guidance from groups such as the World Association of Medical Editors<sup>9</sup> and the American College of Chest Physicians, <sup>10</sup> which stress that declaration alone is no longer enough. To quote the Institute of Medicine report, "Disclosure is the essential though limited first step in identifying and responding to conflicts of interest." The big question is what to do about the conflicts.

On the basis of our own investigation and those of others, the answer is now inescapable. As Barbara Mintzes says in Cohen and Carter's report, "No one should be on a committee developing guidelines if they have links to companies that either produce a product—vaccine or drug—or a medical device or test for a disease." The same, and more, must apply to committees making major decisions on public health. Where entirely independent experts are hard to find, experts who are involved with industry could be consulted but should be excluded from decision making. The United States has made important progress with its Sunshine Act and other legislation. European legislation on managing conflicts of interest is long overdue.

As for WHO, its credibility has been badly damaged.

Recovery will be fastest if it publishes its own report without delay or defensive comment; makes public the membership and conflicts of interest of its emergency committee; and develops, commits to, and monitors stricter rules of engagement with industry that keep commercial influence away from its decision making.

In a briefing at the end of last year, a spokesperson for WHO said, "Given the discrepancy between what was expected [from the pandemic] and what has happened, a search for ulterior motives on the part of WHO and its scientific advisors is understandable, though without justification." The implication is that, had there been a huge death toll, the process behind WHO's decision making would not have been subject to such scrutiny. This is almost certainly true. But it does not mean that we are wrong to ask hard questions. Neither does it make the answers we have found any less troubling. And nor does it remove from WHO the urgent need to restore its credibility and public trust before the next pandemic comes along.

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## Improving immunisation coverage in rural India

Incentives help, but not nearly enough



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Despite decades of rhetoric about improving health and two decades of economic growth, vaccination rates in India remain low. As in Ethiopia, Burkina Faso, and Afghanistan, measles vaccination rates in India are around 70%, and only 44% of children aged 1-2 years are fully immunised. Low vaccination rates have been alternately blamed on insufficient public funds, poor implementation of vaccination programmes, and a general apathy towards the health of the poor. Yet, we have remarkably little evidence to help us separate problems with implementation of vaccination programmes from design flaws that restrict take-up.

Banerjee and colleagues' linked cluster randomised trial brings together time tested methods from public health (randomised trials) with the latest thinking in economics on incentives and human behaviour to examine fundamental problems of design in the delivery of vaccinations.<sup>2</sup>

The authors compared two interventions in a region where vaccination rates are low. In the first intervention, vaccination camps were held in villages on a monthly basis. The second intervention also established camps, but the researchers provided households a small food incentive (lentils worth \$1; £0.66; €0.78) for every vaccination and a slightly larger incentive for children who completed the full package (plates, worth just under \$2). In the control villages with no interventions, 6% (95% confidence interval 3% to 9%) of children aged 1-3 years had received the basic package of vaccinations in the end point survey. This increased to 18% (11% to 23%) in villages that received the first intervention and to 39% (30% to 47%) in those that received the second intervention. The relative risk of being immunised was 3.09 (1.96 to 4.21) for the first intervention versus the control and 2.16 (1.54 to 2.78) for the second intervention versus the first intervention.

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