

A/H1N1 FLU PANDEMIC

Neuraminidase inhibitors in pandemic A/H1N1 flu

Jefferson and colleagues describe the effectiveness of neuraminidase inhibitors in otherwise healthy adults infected with seasonal flu virus,¹ but it is mainly the A/H1N1 flu virus that is currently in circulation.

Given the limited availability of vaccine against 2009 pandemic A/H1N1 flu, antiviral drugs have assumed a prominent role in reducing severe flu related morbidity and mortality during the pandemic. Summarised data show benefit from neuraminidase inhibitor treatment in reducing complications, including admission to intensive care and death, among hospitalised patients with A/H1N1 infection.² These data were collected during the current pandemic in the United States and Mexico without industry funding.^{3,4} Data from seasonal flu investigations such as that by Lee et al also show a reduced risk of death among hospitalised patients with laboratory confirmed flu who received a neuraminidase inhibitor, even more than 48 hours after the onset of symptoms.⁵

The risks associated with the use of neuraminidase inhibitors during the pandemic are being monitored. In the United Kingdom, for example, information has been collected on around a million treatment courses. Adverse effects have not changed, and no new safety concerns have been identified. No evidence has been found of oseltamivir being directly responsible for any death.⁶

In the context of 2009 pandemic A/H1N1 flu, the benefits of treatment with neuraminidase inhibitors outweigh the risk of adverse events among people who present with severe disease or who have risk factors for developing severe disease. With vaccination, antiviral treatment remains effective and essential in reducing severe illness and death among patients with 2009 pandemic A/H1N1 flu.

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Data access is matter of trust

The UK Faculty of Public Health strongly supports the *BMJ*'s call for mandatory disclosure of raw data of all trials cited in drug licensing applications and marketing claims.¹

We see this as a first step towards a position in which only external independent trials published in peer reviewed journals, with full access to raw data, should be allowable when seeking a licence or marketing a product. This would require international agreement by health technology regulators.

Interpreting the evidence base for healthcare planning and commissioning is a key public health function. Full disclosure and openness to scrutiny of evidence on efficacy and safety are crucial if the pharmaceutical industry is to maintain the full trust and confidence of patients, practitioners, policy makers, and

the wider public.

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- 1 Godlee F. We want raw data, now. *BMJ* 2009;339:b5405. (10 December.)

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Zanamivir should be inhaled, not nebulised

Jefferson and colleagues say that nebulisation is the route of administration for zanamivir.¹ However, prescribers should be aware that the approved use of zanamivir in the United States and European Union is by inhalation, not nebulisation.^{2,3}

The Food and Drug Administration recently issued a warning against using the inhalation formulation in a solubilised form for nebulised delivery,⁴ and letters have been sent to prescribers in the US proscribing the use of zanamivir by the nebulised route because of a reported death after administration this way.⁵

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Life threatening infections labelled swine flu

Algorithms for remote diagnosis and issue of antiviral drugs are indispensable during a pandemic.¹ Their application through the National Pandemic Flu Service to both high and low prevalence areas is, however, controversial, and the lack of specificity in



the use of the algorithm has been highlighted by Payne et al and at November's meeting of the Federation of Infection Societies in Birmingham.²

Over six weeks (1 July 2009 to 15 August 2009) we reviewed cases of potentially life threatening conditions admitted to the Newcastle infection services in which diagnosis and management were delayed because of an initial, incorrect diagnosis of swine flu. During this time, rates of novel H1N1 swab positivity (22/336) suggested a local prevalence of 6.5% of patients presenting to hospital with a flu-like illness compared with 11.8% throughout England.³

A label of swine flu resulted in an average diagnostic delay of three days in six adults and two children who were admitted with potentially life threatening infection requiring timely antimicrobials. They had instead meningococcal meningitis; severe (11% parasitaemia) and mild (0.2%) *Plasmodium falciparum* malaria complicated by renal failure; acute myeloblastic leukaemia presenting with febrile pancytopenia; *Campylobacter* gastroenteritis with renal failure; *Haemophilus influenzae* respiratory tract infection (bone marrow transplant recipient); complicated soft tissue infection; and a fatal *Staphylococcus aureus* bacteraemia with multiorgan failure.

Our results show that a concise history must cover travel, immunosuppression, and drug exposure comprehensively and that current local epidemiological data should influence the interpretation and application of algorithms. Algorithms do not replace comprehensive history taking, clinical acumen, laboratory support, and, above all, common sense.

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DRUG FIRM CONFLICTING INTERESTS

Radical change, not tweaking, is needed

Lawton makes the case against major reform of the way the pharmaceutical and medical device industry currently does business against Goldacre's call for the conduct of clinical trials by disinterested third parties to offset the inherent biases of industry sponsored clinical trials.^{1,2} He dismisses Goldacre's argument that the commercial interests of the industry produce biased evidence that misleads doctors and thereby increases patient morbidity and mortality. Instead, Lawton urges tweaking of the current system to improve its functioning, putting forth several threadbare arguments about the productivity of industry research and efficacy of government regulation and quality control oversight.

Fisher provides a revealing view of what goes on in the offices of doctors who receive funding from industry to conduct research on their patients and its biasing effects.³

The political momentum in the United States seems to be building for broader reforms in view of the extent of conflicts of interest reported by the US Health and Human Services Office of the Attorney General among grant recipients of the National Institutes of Health and the staff themselves.^{4,5}

If society is really serious about improving the public health through the production of valid and reliable science for use by doctors on behalf of their patients, Lawton's recommendation for tweaking the current system to achieve marginal improvements should be rejected. The weight of evidence points to the need for radical change, not tweaking.

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- 1 Lawton V. Is the conflict of interest unacceptable when drug companies conduct trials on their own drugs? No. *BMJ* 2009;339:b4953. (27 November.)
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The limits of impartiality

I cannot imagine why anyone would think that a system of self assessment by vendors could work.¹ Human beings simply are not equipped to undertake impartial assessments of their own income earning products. They never have been, and they are becoming less able to do so as moral standards slip.

Wake up and look around you. We simply cannot be trusted to run a system impartially or even fairly any more. My local NHS trust has been found guilty of falsifying statistics. So has my local MP. And my bank. And my local climatologist. And so on.

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- 1 Lawton V. Is the conflict of interest unacceptable when drug companies conduct trials on their own drugs? No. *BMJ* 2009;339:b4953. (27 November.)

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If only industry funded trials were as well done as the WHI

Lawton shoots himself in the foot when he uses the women's health initiative study as an example of a non-industry funded study that deviates from good standards.¹ Unlike many industry funded studies this enormous and extremely complex trial had impeccable standards. The



protocol was published in great detail, including details of the data safety monitoring procedures, and the trial was stopped because the design-specified weighted log rank test statistic for breast cancer ($z=-3.19$) crossed the designated boundary ($z=-2.32$). There was no post hoc change in the significance level as claimed, and breast cancer was one of the end points of the study from the

start, as can be seen in the protocol published in 1998, the trial being stopped in 2002. Such transparency in study design is unfortunately rare for industry funded studies, in which changes in outcomes or analyses or simply a decision not to publish are not rare.

Obviously not all non-industry funded trials are so well designed and performed, but the empirical evidence shows that the biases introduced into the literature by industry funded trials are substantial, biases which can adversely affect our health.

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- 1 Lawton V. Is the conflict of interest unacceptable when drug companies conduct trials on their own drugs? No. *BMJ* 2009;339:b4953. (27 November.)

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THE PRICE OF SILENCE

Liverpool chairman responds

I am concerned about the way in which the article by Gornall, originally researched in July 2009, was eventually published in October, and also the disgraceful editorial comment that accompanied it.^{1,2}

Despite earlier contact during July, the trust was not afforded the courtesy of being informed that you intended to publish after a lapse of some three months. Had you chosen to inform us that you were going to print we could have perhaps corrected some of the factual inaccuracies in the piece. An example of this is the assertion that all of the compromise agreements entered into by the trust were with doctors in order to “gag” them. Accurately reported, the article could have referred to the fact that agreements were with a range of staff who left the trust for various reasons, only two of whom were doctors. It would also have been accurate and balanced to have reported that there is a specific clause in such agreements which states that “nothing . . . prevents the employee making disclosures to the National Patient Safety Agency or any NHS regulatory body.”

Apart from being guilty of taking the same biased approach as the main article, the editorial is also written in the most insulting, inflammatory, and unprofessional terms about an organisation that has a long track record of success and an excellent reputation locally, nationally, and internationally.

The slapdash and biased treatment of what is undoubtedly a serious issue does little to further a mature debate and in the process brings the standing of the *BMJ* into disrepute. Fortunately your discerning readers will recognise that this was an error of judgment on the editorial department’s part.

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- 1 Gornall J. The price of silence. *BMJ* 2009;339:b3202. (27 October.)
- 2 Delamothe T. Gagging for it. *BMJ* 2009;339:b4444. (29 October.)

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Two doctors?

The management of Liverpool Women’s NHS Foundation Trust now make the claim that they have gagged only two doctors.¹ I am shocked and surprised by this new claim. Two years ago I made a freedom of information request for all the compromise agreements containing gag clauses which “the trust had entered into with doctors.” At the Information Commissioner’s instigation the trust provided the agreements, with names

and dates black pencilled. There were 12. The decision notice issued by the commissioner in November 2009 confirmed that my request related solely to agreements with doctors.² If management wish to persist in this new claim, perhaps it would be wise for them to provide all 12 agreements, with job titles, for independent inspection by the Department of Health or an appropriate member of parliament.

I also note that management are attempting to fire off a few angry flares at the *BMJ* rather than deal with the serious issues arising from Gornall’s piece.³ The trust used a local law firm, Mace and Jones, where one of the trust’s non-executive directors sits as chairman, to draft at least some of these compromise agreements—certain of which included “super gag clauses” preventing doctors from making any communication about any NHS matter with any member of the media. That law firm is now under investigation by the Solicitors Regulation Authority for a possible conflict of interest.

The same law firm threatened my father with an injunction if he spoke about his concerns to local members of parliament. Questions surrounding the trust’s behaviour need answers, since management are behaving like Roman centurions, with the aid of lawyers, in the rabid persecution of any critical comment.

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Competing interests: AB is editorial lawyer for News International, Mirror Group Newspapers, and Independent News and Media. He reported Mace and Jones to the Solicitors Regulation Authority.

- 1 Morris K. Liverpool chairman responds. *BMJ* 2010;340:c144.
- 2 Decision Notice, Freedom of Information Act 2000 (Section 50). Reference FS50202562, 17 November 2009.
- 3 Gornall J. The price of silence. *BMJ* 2009;339:b3202. (27 October.)

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Gagging and duties

Jane Cassidy’s article raises several pressing questions.¹ The examples given are shocking, but many of us will be aware of others. There seems to be a trend for NHS trust administrations to abuse power—with law, regulations, guidelines, agreements reached, and promises made ignored or bypassed as convenient.

Why? Firstly, because this is a way for administrators to assert their power and impose decisions. Administrators also have an impossible task—they are expected to extract

more from less, with guidelines and objectives altered unpredictably. Secondly, because there is no immediate counter to this abuse. NHS reforms brought in a sea change in philosophy, a revolution in the way things are done, a plethora of regulation, and inadequate or absent checks and balances. Any political mechanism lacking the latter (also transparency and accountability) inevitably evolves towards dictatorial abuse.

Abuse can be countered in three ways. Firstly, a united approach by doctors in a trust. Doctors, however, are notoriously difficult to persuade to

act in this manner. Secondly, legal action. But public disclosure of incompetence and dishonesty would be damaging to organisations and individuals. Thirdly, a framework within the NHS to examine and adjudicate in matters of administrative abuse would help defuse the situation. Many NHS employees, not just doctors, are demoralised and fearful of vindictive and abusive actions. Patients have an ombudsman; employees need the same. This request

needs to be stated forcefully, loudly, and persistently to have a chance of succeeding.

For this we need the leadership and initiative of the BMA, which could also help assert the overarching obligations of doctors. All practising doctors are primarily regulated by the ethics of the profession, even if this contradicts local regulations, contracts, or administration decisions.

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Competing interests: None declared.

- 1 Cassidy J. Falling foul of gagging clauses. *BMJ* 2009;339:b4203. (27 October.)

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VARENICLINE AND SUICIDE

Safety data from New Zealand

The recent letters on varenicline and suicide raise interesting issues about different approaches to identify and quantify risk in pharmacovigilance.^{1,2} In New Zealand the Intensive Medicines Monitoring Programme (IMMP)³ is currently performing an observational cohort study of varenicline. Our cohort is established directly from pharmacy dispensing data, which more accurately estimates varenicline exposure than prescription records used in database studies.⁴ The IMMP identifies adverse events from follow-up questionnaires sent to patients’ doctors, spontaneous reports

Causes of death in IMMP first year cohort*

Case	Age	Treatment duration (days)	On medicine at time of death?	Time to death after last dose (days)†	Cause of death
1	24	Not known	Yes	Not known	Suicide
2	65	78	No	7	Subarachnoid haemorrhage; cerebrovascular accident
3	61	55	No	25	Femoral thrombosis; respiratory failure; lung carcinoma
4	61	47	No	42	Carcinoma disseminated
5	64	127	No	53	Metastatic carcinoma bronchus
6	49	46	No	56	Respiratory failure
7	80	14	No	58	Myocardial infarction
8	44	14	No	66	Respiratory failure
9	67	43	No	68	Respiratory failure
10	67	43	No	90	Ovarian cancer; cerebrovascular accident; myocardial infarction

*First year IMMP cohort included all New Zealand patients dispensed a varenicline prescription from 1 April 2007 to 31 March 2008.
†Deaths occurring more than 100 days after stopping varenicline were excluded from this analysis.

to the NZ Pharmacovigilance Centre, and record linkage to national mortality datasets to identify patients who have died.³

Early results from the IMMP study may help quantify the risks of varenicline in postmarketing use. Of 3415 patients dispensed varenicline during the first year of monitoring, 10 died, including one from suicide (table). Deaths were equally distributed between men and women.

Using intensive follow-up methods we believe we are unlikely to have missed other deaths and thus estimate the risk of completed suicide is 1 in 3415 patients or 3/10 000 (95% confidence interval 0.07 to 16/10 000). This estimate may change as the IMMP study continues and the cohort increases in size.

Identifying and quantifying risk is important for doctors prescribing medicines and patients taking them. It is unlikely that one study or methodological approach will provide all the answers we need. In monitoring the post-marketing safety of medicines, we sometimes refer to the “pharmacovigilance tool box” and recognise that different tools are suitable for different purposes. We must work collaboratively and share our data whenever possible in the interests of public health.

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OSTEOPOROSIS AND ANTIANDROGENS

An under-recognised risk

Osteoporosis is another important but under-recognised risk of androgen deprivation therapy.¹ Few guidelines exist to help detect and manage bone loss in these men.

As survival from prostate cancer increases, osteoporosis and its complications will probably become more common. A retrospective study of over 50 000 men with prostate cancer found a significant association between number of doses of gonadotrophin releasing hormone agonist and fracture risk.² Importantly, fractures in these patients are an independent adverse predictor of survival.³

Patients and general practitioners should be given clear information and lifestyle advice to reduce the risk of osteoporosis, emphasising the need for exercise, reducing smoking, limiting alcohol consumption, and a diet that includes calcium and vitamin D. Exercise and diet are particularly important because the effects of androgen deprivation include muscle loss and increased body fat.

In the absence of guidelines, teams managing prostate cancer need to formulate and implement coherent strategies to minimise morbidity from this treatment. Dual energy x ray absorptiometry (DXA) scans are cheap, easy to perform, and underused in these patients in the UK. We recommend that a DXA scan be considered for all men starting long term androgen deprivation therapy.

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THE MYSTERIOUS DR FOSTER

Coders need guidance

Nigel Hawkes shows how Dr Foster's hospital standardised mortality rate can be influenced by the presence of comorbidities.¹ It is hard to believe that hospital mortality figures now depend more on how the hospital's coders perform than on the skills of its doctors and nurses. Some coders believe that they can use information on comorbidities only from the current episode for coding purposes whereas others use information from previous episodes. Such variations are widespread, and the responsible bodies such as NHS classifications service need to produce clear guidelines to standardise coding across the country and make Dr Foster's analysis more equitable.

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- 1 Hawkes N. The mysterious Dr Foster. *BMJ* 2009;339:b5242. (2 December.)

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BABY P HOSPITAL

Putting the matter straight

We've said that we wish to resolve issues with Dr Holt swiftly and amicably, and this is best done through dialogue. However, your news report by Clare Dyer is inaccurate.¹ Great Ormond Street Hospital did employ the doctors in the Haringey community service, but we did not run the service or set funding levels. Great Ormond Street ran the service only from April 2008.

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- 1 Dyer C. Doctors had warned of understaffing at Baby P hospital, inquiry finds. *BMJ* 2009;339:b5404. (9 December.)

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