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A/H1N1 FLU

Time for case-control studies of NSAIDs and oseltamivir

Hama highlights our ignorance about the harmful effects of oseltamivir (Tamiflu) and the non-steroidal anti-inflammatory drugs (NSAIDs) commonly used in flu.¹ Shimazu suggests that aspirin enhanced virulence in the 1918 epidemic,² and, as Hama notes, the effects of NSAIDs should be studied in Mexico now.³

We need these data to decide in what circumstances these drugs are worth using. Without such data decisions will be guided mainly by panic and hope—a recipe for huge and potentially dangerous waste of resources.

The UK and the US could mount the required large case-control studies, perhaps using only cohorts of people exposed to the virus. Such studies should if possible also include other countries and be encouraged by the World Health Organization. We hope that the authorities that should be concerned will promptly tell the world what they intend to do.

We also believe that the uncertainty about the benefits and harms of oseltamivir should be admitted and then tackled through a placebo controlled randomised trial. Any future widespread use of the drug should be evaluated in this way, and now is the right time for such a trial to be planned and prepared.⁴

We agree with English and colleagues that at this stage of the pandemic people should be warned not to use oseltamivir because most will be at such small risk from the disease that any harm from neuropsychiatric reactions would far outweigh any benefit, and widespread use will hasten the development of resistance.⁵

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Competing interests: MC is director of the UK Cochrane Centre, RE is director of the WHO-Uppsala Monitoring Centre, AH and YL are co-convenors of the Cochrane Adverse Effects Methods Group, TJ is coordinator of the Cochrane Vaccines Field and first author of a Cochrane review on antivirals for influenza in healthy adults.

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- 4 Walley T. Call for flu research under way. *BMJ* 2009;339:b2731. (8 July.)
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Cite this as: *BMJ* 2009;339:b3048

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Cite this as: *BMJ* 2009;339:b3050

NICE ON BACK PAIN

NICE outraged by ousting of pain society president

The British Pain Society has voted to force its president, Professor Paul Watson, out of office because some members disagreed with a recommendation in the recent guideline on low back pain from the National Institute for Health and Clinical Excellence (NICE) that he helped to develop.¹ The society's sustained campaign against a highly respected pain management and rehabilitation expert is shameful and professional victimisation of the worst kind.

All NICE guidelines are developed by independent clinical and patient experts who give up their time and expertise over two years to produce robust, evidence based guidance. It is totally unacceptable for guideline developers to be singled out and have their professional integrity called into question simply because some groups don't like a robust, evidence based recommendation that has been developed by a group of independent experts.

The guideline developers' only aim is to help to improve the care and treatment of people with specific conditions by highlighting gold standard approaches based on the available evidence. The British Pain Society shows that it does not accept evidence based medicine. Moreover, its actions fly in the face of a recent High Court judgment.² A judicial review of NICE's guidelines on chronic fatigue syndrome dismissed all claims, the judge highlighting that health experts must be able to express their opinions without fear of retribution.

The British Pain Society has made its president a scapegoat because some of its members refuse to accept that there is not the scientific evidence to support their interventions. It is a sad day for the freedom of experts to express views, evidence based medicine, and the ideals of the medical profession.

HPA advice on antipyretics contradicts NICE guideline

Julius Wagner-Jauregg won the Nobel prize in 1927 for developing an effective treatment for syphilis which entailed deliberately infecting patients with malaria. This research suggests that fever may be a beneficial response to infection. The 2007 guideline from the National Institute for Health and Clinical Excellence (NICE) on feverish illness in children under 5

reviewed the sparse evidence on using antipyretic medicines, which seems to indicate that artificially lowering a fever may reduce the immune response and prolong illness. NICE therefore recommended, "Do not routinely give antipyretic drugs to a child with fever with the sole aim of reducing body temperature."¹

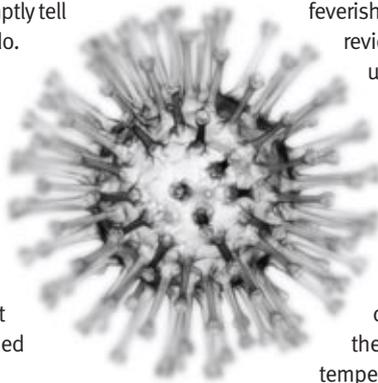
A small trial on the use of antipyretics in an intensive care unit was stopped because mortality was 16% in the treated group and 1% in the untreated group.²

The existing evidence suggests that antipyretics should be avoided in patients with pandemic flu,³ yet the Health Protection Agency (HPA) continues to recommend their routine use.⁴ We urgently need more research into the potential harmful effects of antipyretic medicines. When will the large scale randomised controlled trials be done?

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Competing interests: None declared.

- 1 National Institute for Health and Clinical Excellence (NICE). Feverish illness in children. Assessment and initial management in children younger than 5 years. NICE guideline 47, 2007. www.nice.org.uk/nicemedia/pdf/CG47QuickRefGuide.pdf



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Competing interests: None declared.

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Cite this as: *BMJ* 2009;339:b3028

ABDOMINAL AORTIC ANEURYSM

Is screening cost effective?

The cost effectiveness of an intervention (especially in those aged 65 and over who are subject to the multiple effects of ageing on survival) should be determined by its effect on the overall survival of the intervention group compared with that of the control group and not on the difference in survival of those with the condition under study.

Some statistical sleight of hand that is said to correct for other comorbidities seems to have gone on in the Multicentre Aneurysm Screening Study (MASS),¹ but is incomprehensible to the non-statistician. However, I find it inconceivable that an intervention should be declared cost effective when the deaths from all causes were 10 274 (average age at death 75.4 years) in the intervention group and 10 481 (average age at death 75.0 years) in the control group. Presumably the groups were well matched for age and comorbidity but no mention is made of this in the paper.

Unless this discrepancy can be satisfactorily explained to the non-statistician, one is forced to conclude that the intervention merely changes the cause of death without affecting survival and therefore screening for aortic aneurysm is a waste of time and money.

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Competing interests: None declared.

- 1 Thompson SG, Ashton HA, Gao L, Scott RAP, on behalf of the Multicentre Aneurysm Screening Study Group. Screening men for abdominal aortic aneurysm: 10 year mortality and cost effectiveness results from the randomised Multicentre Aneurysm Screening Study. *BMJ* 2009;338:b2307. (24 June.)

Cite this as: *BMJ* 2009;339:b3040

Deciding on whether to screen

Godlee ably manages a difficult editorial balancing act by recognising that occasionally less is more.¹ Medicalisation can be bad for your health, as “screening for abdominal aortic aneurysm seems to be effective” hints. I agree with Heath’s informed decision to say no to breast screening.² Should I have screening for abdominal aortic aneurysm?

Buxton’s pertinent editorial discusses cost effective modelling.³ “A 42% relative risk reduction in mortality related to abdominal aortic aneurysm (absolute risk reduction from 0.33% to 0.19%)” sounds impressive. But how many were harmed, died, or were falsely reassured? “There may be a small increase in net deaths in the short term” is worrying.

Editors should require the statement of benefits and harms in absolute terms. Thompson and colleagues state: “We used unadjusted Cox regression to compare deaths related to abdominal aortic aneurysm (censoring other causes of death) and all cause mortality.”⁴ The crucial data in table 1 are as McLaren states (previous letter),⁵ and, furthermore, the hazard ratios are 1 in the control group and 0.97 in the invited group.

So now I can decide whether to chance a high risk operation with an immediate risk of killing me for a small long term benefit, or to choose to remain in ignorance.

Yours blissfully.

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Competing interests: None declared.

- 1 Godlee F. Less medicine is more. *BMJ* 2009;338:b2561. (30 June.)
- 2 Heath I. It is not wrong to say no. *BMJ* 2009;339:b2529. (23 June.)
- 3 Buxton MJ. Screening for abdominal aortic aneurysm. *BMJ* 2009;338:b2185. (24 June.)
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Cite this as: *BMJ* 2009;339:b3041

Authors’ reply

Being a very large study, the randomised groups in the Multicentre Aneurysm Screening Study (MASS) were very well matched at baseline.¹ As shown in table 1 of our paper,² there were 155 aneurysm related deaths in the group invited to screening and 296 in the control group, a halving of the aneurysm related death rate. There were almost equal numbers of deaths from other causes, 10 119 in the invited group and 10 185 in controls, indicating no advantage or disadvantage of screening for other causes of death. The cost effectiveness was estimated assuming no difference between randomised groups in these other causes of death. The average age of all the deaths which occurred in the invited group was the same as that in the control group (74.7 years). There is no “discrepancy” to be explained here, as claimed by McLaren.

Lewis is rightly concerned about the potential harms as well as the benefits of aneurysm screening. The postoperative deaths after elective aneurysm surgery, shown in table 1, are already included in the count of aneurysm related deaths. Other long term medical problems as a result of

elective open aneurysm repair are uncommon.³ There is no convincing evidence of any effects on quality of life, after either positive or negative screening results, or of any long term effects after surgery.^{1,4,5} Of course, anyone invited to aneurysm screening is at liberty to decline, as may those offered aneurysm surgery, but in our view it would be to their disadvantage to do so.

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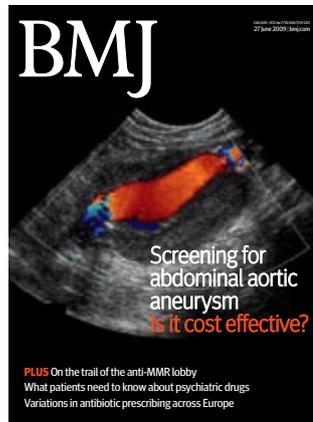
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Cite this as: *BMJ* 2009;339:b3043

Comparing studies for cost effectiveness of screening

Ehlers and colleagues conclude from their long term modelling study that screening men aged 65 for abdominal aortic aneurysm is not cost effective.¹ This conclusion conflicts with that of the 10 year follow-up of the randomised Multicentre Aneurysm Screening Study (MASS),² our detailed long term modelling based on individual patient data in MASS,^{3,4} and other recent modelling studies.

To try to understand the reasons for the difference, we substituted the unit costs and parameter estimates provided by Ehlers into our model based on MASS. Although the cost per quality adjusted life year (QALY) increased from



our original estimate of £3000 to around £6000, it does not begin to approach their figure of £43 000. So there must be other explanations, such as the structure or assumptions of their model, which cannot be investigated without further information from the authors.⁵

Their cost effectiveness estimate is implausible. From observed data in MASS, we showed that cost effectiveness after 10 years was £9400 per QALY.² Cost effectiveness will improve when considered over the longer term, since costs are generally up front while benefit accrues over time. But Ehlers and colleagues' estimate of lifetime cost effectiveness is worse than that which we have already observed after 10 years.

Moreover, they present the modelled number of deaths related to abdominal aortic aneurysm that accrue as a screening programme is launched, and claim that a net reduction is not reached until after nine years. Rerunning this analysis based on the data observed in MASS shows that benefit is seen after two years.

Ehlers and colleagues' hypothetical modelling does not agree with the data observed in the MASS trial, which provides most of the worldwide randomised evidence. If one had to choose the basis on which to make policy decisions, real data are surely preferred.

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Competing interests: None declared.

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Cite this as: *BMJ* 2009;339:b3044

STATISTICS FOR HEALTH

Let's communicate risk clearly

Health understates one important issue in her observations on breast screening¹: the systemic illiteracy of doctors, epidemiologists, and other health professionals in communicating statistical results.

Gigerenzer pointed out just how badly professionals misinterpret risk when given the

data as conditional probabilities.² He contrasted this with the (much improved) results when the facts are communicated as natural frequencies. Despite this we continue to use the format that doesn't work.

I have used the statistics around screening for HIV, prostate cancer, and breast cancer to show decision makers why the way you communicate the facts affects people's ability to make sense of them. Surprisingly, public health people in the NHS are often shocked at the implications of the statistics on breast cancer screening once they understand them (they often seem to start with a belief that mass screening programmes are an effective public health intervention).

We need to stop assuming that the problem is people's inability to comprehend statistics and recognise that the problem is statisticians' (and other experts') inability to communicate. Let's change the way we communicate risk so people don't keep making the same errors.

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Competing interests: None declared.

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Cite this as: *BMJ* 2009;339:b3034

Let's start with reporting

Clinical epidemiology is now well established. Therefore no article should be published without mentioning the number needed to treat. This is especially important when dealing with issues around medical prevention, such as statins.¹

Gigerenzer et al recommend using frequency statements instead of single event probabilities, absolute risks instead of relative risks, death rates instead of survival rates, and natural frequencies instead of conditional probabilities.²

They also say: "reporting relative risk reductions without clearly specifying the base rates is bad practice because it leads readers to overestimate the magnitude of the benefit. Consider one medication that lowers risk of disease from 20% to 10% and another that lowers it from 0.0002% to 0.0001%. Both yield a 50% relative risk reduction, yet they differ dramatically in clinical importance."

The communication of risks or therapeutic effects is a critical and responsible task. So why is a meta-analysis published without the number needed to treat?

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Competing interests: None declared.

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Cite this as: *BMJ* 2009;339:b3035

PATIENT SAFETY

Importance of near misses

The sixth report of the government committee on patient safety emphasises serious events such as the case of Wayne Jowett, who received a fatal injection of an anticancer drug at the wrong site.¹ However, less than 30% of adverse events result in death or severe injury.² Common and minor events should be taken seriously—the iceberg analogy may be appropriate for the burden of morbidity lying below the surface.

The root causes of all adverse events, including near misses, show the same underlying patterns of failure. High reliability industries such as the aviation industry treat near misses and minor adverse events as rigorously as those that result in death or permanent disability. By addressing near misses and minor adverse events, the underlying causes can be corrected before they lead to a disastrous incident.³



The report states that samples of patients' case notes should be systematically and periodically reviewed to record data on adverse events. However, more intensive investigation, including discussion with healthcare professionals, gives a higher yield of information.⁴

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Competing interests: None declared.

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Cite this as: *BMJ* 2009;339:b3032

INTRAVENOUS FLUIDS IN SURGERY

Authors of guideline respond

In their criticism of the British consensus guidelines on intravenous fluid therapy for adult surgical patients Liu and Finfer assert that high quality research is needed before guidelines can be useful and that “guidelines should be avoided completely, and clinicians would be better off making clinical decisions on the basis of primary data.”^{1,2} They evidently disapprove of guidelines in principle, especially those, like ours, derived from a diverse range of sources.

We disagree. Perioperative fluid therapy is highly complex and poorly practised and badly taught.^{3,4} To expect most clinicians to be aware of each of the primary sources of evidence and assess these themselves is unrealistic. Furthermore, the uncertainties in this area cannot be resolved until some degree of uniformity of practice is achieved.

Liu and Finfer accuse us of shying away from “a systematic evidence based approach because high quality evidence is lacking.” We used what evidence exists and graded it according to internationally recognised criteria. We included and referenced many systematic reviews; indeed Liu and Finfer were selective in their choice of evidence in criticising the use of dexamethasone, which was supported by both meta-analysis and systematic review.⁵ Systematic reviews and meta-analyses have a crucial role in assessing evidence but must be focused on specific, defined questions. Our consensus guidelines collate such pieces of evidence into a broader, multidisciplinary clinical approach to the patient’s journey through perioperative care.

We have, with the advice of expert colleagues, taken many months to achieve rigour in this assessment process. So the guidelines represent a commonly agreed base for the teaching of what we know now. The guidelines will be revised as new evidence emerges, but meanwhile we call for a more constructive debate on how to further develop this consensus.

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Monty G Mythen Smiths medical professor of anaesthesia and critical care, University College London, London

Competing interests: The authors have reviewed the literature and have written the British consensus guidelines on intravenous fluid therapy.

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Cite this as: *BMJ* 2009;339:b3030

LEARNING FROM JOHN LEWIS

Mystery shoppers for medics?

I remember the bonuses I received during my part-time employment as a sales adviser and then customer services manager at John Lewis while I was at medical school. I felt valued and motivated as a core team member, and the extra cash served as a useful buffer against spiralling student debt.

However, democratic principles are not the only concept that John Lewis can offer the health profession.¹ Successful retail companies such as John Lewis ensure customer loyalty through providing excellent customer service. In an increasingly consumer focused health service, staff would do well to spend time in the retail industry, learning and practising the ABCs (acknowledging, building, and closing) of good customer service² and having their performance assessed in the workplace by “mystery shoppers.”

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Competing interests: None declared.



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Cite this as: *BMJ* 2009;339:b3027

PROSTHETIC JOINT INFECTION

Treatment without long courses of systemic antibiotics

We manage prosthetic joint infection without systemic antibiotics or prolonged hospital admission (or intravenous antibiotics via outpatient intravenous services).¹ We target antibiotic treatment to organisms isolated from either a diagnostic aspirate or joint washout (in the case of early infection). At the first stage revision, after thorough debridement of all infected material, we then use cement beads loaded with an appropriate antibiotic based on the aspirate results.^{2,3}

Systemic antibiotics are generally not required beyond surgical prophylaxis because high eluted concentrations of antibiotic from the cement beads provide effective local antimicrobial activity with minimal or no systemic absorption. Outcome data using this approach are comparable to those described by Matthews and colleagues.⁴

Matthews and colleagues state that managing prosthetic joint infection with antibiotic loaded spacers is expensive and time consuming and results in tissue damage. We think that infected prosthetic material requires surgical debridement along with dead tissue and bone, which does indeed take time. However, treating patients at home with antibiotic loaded cement in situ is more cost effective than treating them in hospital with intravenous antibiotics or in an outpatient intravenous service. It also has the benefit of reduced *Clostridium difficile* infection, line associated bacteraemias, and side effects from long term antibiotics.

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Competing interests: None declared.

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Cite this as: *BMJ* 2009;339:b3052