

## (NOT) WARTS AND ALL

### Government fully considered HPV vaccine

It was unfortunate that Hammond wrote his piece without asking us the government's reasons for choosing the human papillomavirus (HPV) vaccine.<sup>1</sup> We fully considered all of the issues he raised and much more that was scientific, logistic, and economic.

We used the cost effectiveness analysis of Jit et al to allocate points for the quality of scientific information on protection against cervical cancer, protection against warts, and stability out of the cold chain,<sup>2</sup> and only after the scoring was completed were the prices revealed. With the same analysis,<sup>2</sup> the prices were scored for cost effectiveness in balance with the other factors. The scoring system had been shared in advance with the manufacturers. In central contracts the price offered by manufacturers can differ considerably between products and against the list price.

We took full account of the burden of genital warts and the benefits that might come from vaccinating males. Perhaps Hammond might have asked himself how much he was prepared to pay to prevent genital warts; I assume that even he must have a figure in mind beyond which it would not be cost effective to use a quadrivalent vaccine.

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**Competing interests:** None declared.

- 1 Hammond P. (Not) warts and all. *BMJ* 2008;337:a2186. (23 October.)
- 2 Jit M, Choi HY, Edmunds WJ. Economic evaluation of human papillomavirus vaccination in the United Kingdom. *BMJ* 2008;337:a769. (17 July.)

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### “Annoyance” of genital warts

As Hammond said,<sup>1</sup> and my website shows in the wart section ([www.chestersexualhealth.co.uk](http://www.chestersexualhealth.co.uk)), genital warts are not just an annoying nuisance.



Both human papillomavirus (HPV) vaccines are so far equally effective for HPV 16 and 18, but it will be many years before we know whether one has longer efficacy than the other. The Department of Health estimated the cost of wart treatment at an all time low of £134 per patient. The cost is around £423 per patient in my clinic, where even first visit payment by results is £153 and follow-up £90; most warts need a few visits.

Despite GSK's assertion of winning eligible contracts, I am not aware of any country that has chosen Cervarix as the national vaccine. Also, why won't the Food and Drug Administration approve it? Has it concerns that the British don't know about? Now that top-up payments are in the clear in the UK, can parents top up and buy Gardasil? The NHS price of both vaccines is £80 a shot, with three shots needed.

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### All data on both vaccines must be considered

The government chose the human papillomavirus (HPV) vaccine of GlaxoSmithKline (GSK), Cervarix, after considering protection against cancer causing HPV 16 and 18, HPV 6 and 11 (which cause genital warts), and HPV strains not included in the vaccine formulation; price; and supply.<sup>1</sup>

Its decision was based on a comprehensive review of published and unpublished clinical efficacy and safety data. New data from GSK included the demonstration of high protection against HPV 16 and 18 for over 6.4 years, the longest protection reported for any cervical cancer vaccine to date. The study is being extended for up to 9.5 years in a subset of women.

The UK has awarded a national licence, but in many other European countries licences are awarded regionally. Only once licensed in a country can a vaccine compete in tender applications. Gardasil was licensed in the European Union a year before Cervarix, and was, until recently, the only product available for this indication. Since it was licensed, Cervarix has been awarded around two thirds (27/42) of the

competitive tenders submitted in the EU.

GSK's application with the Food and Drug Administration (FDA) is progressing. GSK has submitted its response to questions raised by the FDA in the complete response letter, received in December 2007, and discussions continue to be positive and productive. Each regulatory agency operates independently. To date, Cervarix has been approved in 67 countries around the world, including the 27 member countries of the EU, Mexico, Australia, Singapore, and the Philippines.

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- 1 Hammond P. (Not) warts and all. *BMJ* 2008;337:a2186. (23 October.)

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## PRESERVATION OF FERTILITY

### Uncertainties in preserving fertility in cancer treatment

Infertility is one of the more devastating long term effects of cancer treatment in young patients,<sup>1</sup> but predicting who is at high risk of infertility is difficult. Patients often did not receive adequate information, but a recent prospective analysis of UK paediatric oncologists showed that risk to fertility was discussed with most children and adolescents at all ages, and with 76% and 86% of postpubertal boys and girls.<sup>2</sup> Consequently 83% of postpubertal boys (the only group for whom an established method of fertility preservation is available) were referred to a fertility unit.

The constant development of chemotherapy regimens limits the ability of doctors to counsel patients accurately on the impact of a proposed treatment on fertility. This is important when fertility preservation requires significant intervention—for example, ovarian stimulation with oocyte/embryo cryopreservation, and laparoscopy to retrieve ovarian tissue. Our criteria for cryopreservation of ovarian cortical tissue include age <30 years and a high risk of treatment induced immediate ovarian failure in a patient with a realistic chance of long term survival.<sup>3</sup> We have performed ovarian tissue cryopreservation in 36 women and girls with up to 13 years of follow-up.<sup>4</sup> Seven have since had spontaneous pregnancies with five live births, and only two patients have ovarian failure.

The uncertainty of preserving fertility must be conveyed to women considering an invasive procedure of unknown efficacy (only five babies have been born from this technique worldwide) at a time of high emotional vulnerability and acute, life threatening illness. The issues over consent for children to undergo this are even more complex.<sup>5</sup>

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## SURGICAL SITE INFECTION

### Guidelines or misguidance?

The drive to minimise surgical wound infection should be an instinct instilled early into surgical trainees on the basis of surgical pride and the need to minimise harm to their patients. The more the process is devolved into sets of guidelines<sup>1</sup> the less effective the outcomes will be, and the less personal responsibility will be taken by clinicians at all levels.

What is astonishing is that the guidelines by Leaper et al and the accompanying commentary do not mention any of the most important factors in wound infection—namely, the skill and training of the surgeon, and, most importantly, judgment, planning, and the avoidance of tissue damage and haematoma.<sup>1,2</sup>

I predict a continuing fruitless struggle to deal with wound infection that no amount of well-meaning guidelines will solve while:

- Trainees' hours are systematically reduced for fear of the European Working Time Directive
- There is no continuity, because of shift systems, to allow trainees to follow up and deal with the clinical consequences of their actions
- Consultants are inhibited from forceful condemnation of poor practice by fears of accusations over bullying or harassment
- There is increasing micro-specialisation, making it impossible for trainees to maintain a holistic view of treatment of patient rather than condition

- Problems and responsibilities for postoperative infection are devolved to less educated wound care specialists whose activity is rarely, if ever, audited
- Every aspect of medical and surgical care is subject to guidelines and rules instead of allowing clinicians to think for themselves and take the fullest responsibility for their own actions.

Leaper et al simply cannot be allowed to get away with their suggestion that money should be thrown at the implementation of their document by "training adequate healthcare professionals."<sup>1</sup> Unless of course they mean reverting to decent surgical education by apprenticeship.

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## DOES THIS WORK FOR YOU?

### Individuals, averages, and evidence based medicine

In asking "Does this work for you?"<sup>1</sup> Christakis finds the heart of evidence based medicine—"the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients."<sup>2</sup> The individual approach can also reconcile clinical trial results with the demands of clinical practice: "managers and trialists may be happy for treatments to work on average; patients expect their doctors to do better than that."<sup>3</sup>

That not all patients achieve great benefit and need an individualised approach has been shown in treating depression<sup>4</sup> and is particularly true for pain.

In acute pain, patients either have very good or very poor pain relief with non-steroidal anti-inflammatory drugs. In neuropathic pain fewer than half of patients commonly achieve adequate pain relief with any treatment. In migraine the proportion of patients achieving rapid and prolonged pain relief (adjusted for the placebo response) is only about 25%. With TNF-antagonists in rheumatoid arthritis the proportion achieving a beneficial outcome after 12 months is 60% for ACR20, 40% for ACR50, and 20% for ACR70. In osteoarthritis the 80-20 rule applies, 80% of patients getting 20% pain relief, and 20% getting 80% pain relief; about half get half pain relief, a very good outcome.

Various solutions would make clinical trials

more useful—for example, better reporting of conventional trial designs and use of enriched enrolment randomised withdrawal designs, especially when the proportion of patients experiencing benefit is low.<sup>5</sup> Clinical effectiveness trials comparing different treatments and reporting a level of response that makes sound clinical sense would have immediate clinical impact, would underpin clinical decision making and guideline development, and may offer more relevant approaches to health economic assessment.

The individual patient approach is even more important in clinical practice, especially when few if any interventions produce high rates of good response. In difficult conditions such as neuropathic pain many interventions are needed to be able to achieve a good result for the patient we are treating. Restrictive formularies don't help.

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## POPADAD TRIAL

### Don't stop taking aspirin

The POPADAD trial shows no benefit from daily prophylactic aspirin (hazard ratio 0.98; P=0.87) in people who have diabetes and early peripheral arterial disease. However, no firm conclusions should be drawn from a single trial, but the result be incorporated in a meta-analysis of all available evidence from relevant trials.<sup>1</sup>

The absence of evidence of benefit is not surprising as the trial was seriously underpowered. The annual cardiovascular event rate observed was only 2.9%, while the event rate expected was 8%. The 95% confidence limits for the effect of aspirin (0.76 to 1.26) include a possible 24% reduction in vascular events. This is consistent with the effect of aspirin in other trials of primary prevention. It

is also consistent with the CLIPS trial in people with peripheral arterial disease, 76% of whom also had diabetes, in which low dose aspirin prophylaxis was associated with a significant reduction in vascular events ( $P=0.01$ ).<sup>2</sup>

Belch and colleagues suggest that statins may have led to the low vascular event rate during the trial, giving little opportunity for the detection of additional benefit from the aspirin. This important hypothesis requires testing, the authors giving no data on a possible interaction between aspirin and statins.

The life threatening consequences of diabetes—mainly heart disease and stroke—are at least twice as frequent in people with diabetes as in those without. Guidelines issued by expert bodies in the United Kingdom and in the United States therefore recommend low dose aspirin prophylaxis in people with diabetes.<sup>3,4</sup> Against this background, and in view of the evidence of benefit in other trials it would be most unfortunate if the results of POPADAD were to lead diabetic patients discontinuing aspirin prophylaxis. At the very least, the results of yet another large trial in diabetic subjects, ASCEND, should be awaited.

In due course appropriate overviews may ensure that recommendations about aspirin prophylaxis in diabetic patients will be consistent.<sup>5</sup> In the meantime older diabetic patients should keep taking daily low dose aspirin.

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- 1 Belch J, MacCuish A, Campbell I, Cobbe S, Taylor R, Prescott R, et al. Prevention of Progression of Arterial Disease and Diabetes Study Group, Diabetes Registry Group, and Royal College of Physicians Edinburgh. The prevention of progression of arterial disease and diabetes (POPADAD) trial: factorial randomised placebo controlled trial of aspirin and antioxidants in patients with diabetes and asymptomatic peripheral arterial disease. *BMJ* 2008;337:a1840. (16 October.)
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## Author's reply

We support Elwood's suggestion to include our study in a meta-analysis of all aspirin primary prevention studies. We believe this may already be in draft form, but such an analysis, albeit without POPADAD, yielded negative results.<sup>1</sup>

We agree that the event rate in the study was low—a testament to the efforts of the consultants to modify lipids and blood pressure optimally. We plan a subgroup analysis looking at the interactions with statins, as was predefined in our protocol.

Nevertheless, there may be a good reason for aspirin being ineffective in primary prevention in this population. With an atherothrombotic event, clot is formed and ruptured plaque is a huge stimulus for platelet aggregation. However, in primary prevention, where there has been no event, thrombus is not routinely formed. Statins and antihypertensive drugs are effective prophylaxis in primary prevention.<sup>2,3</sup> Targeting vessel wall rather than thrombus, they might be expected to be more efficacious than an antiplatelet agent.

In contrast in secondary prevention, such as in CLIPS, aspirin has a role in preventing secondary events. This remains speculative, however, but there are a number of other trials in which aspirin as primary prevention, has been ineffective.<sup>1,4</sup> We too await the results from ASCEND.

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## Time for a proper study of aspirin after a vascular event?

Belch et al add to the documentation that long term aspirin has little or no benefit in patients who have or are at risk of atherosclerotic cardiovascular disease.<sup>1,2</sup>

Few long term trials of aspirin have shown a reduction in mortality or major morbidity. However, editors of journals persist in publishing papers on aspirin with conclusions designed to mislead health professionals and the public.

The *New England Journal of Medicine* must take first place in this rogue's gallery with publication of the US physician's study (stopped for futility but published as a positive trial after



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retrospective rearrangement of the primary end point).<sup>3</sup> Then comes the *Lancet* with the HOT study, which recommended aspirin despite the study being neutral on its primary end point and retrospectively redefining the criteria for myocardial infarction.<sup>4</sup> And again with the PEP study, which showed a significant excess of fatal and non-fatal myocardial infarction when aspirin was used for prophylaxis of deep venous thrombosis after hip fracture but this worrying finding was not highlighted in the conclusions.<sup>5</sup>

The shortcomings of the aspirin meta-analysis have not been well publicised, although the *BMJ* has not stifled the debate totally.<sup>2</sup> However, Belch and colleagues' conclusion—"aspirin should, however, still be given for secondary prevention of cardiovascular disease in people with diabetes mellitus, when the evidence base is convincing, and the results of this study must not detract from this important standard of care?"—should have specified the duration of aspirin prophylaxis after a vascular event for which there is evidence of benefit (about 6-12 weeks). There is no evidence of a longer term benefit with aspirin and some concern that there may be harm.

We should assess aspirin in the same way as any other therapeutic intervention. No trial shows that contemporary doses of aspirin used long term reduce mortality. Is it not time for an adequately powered study comparing short with long term aspirin 75mg/day after a vascular event?

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## SHARED ELECTRONIC RECORDS

### What have we really learnt?

Greenhalgh and colleagues see the shared electronic record as having to respond to existing ways of working and established practices, not the other way round.<sup>1</sup> My take is this:

- Powerful forces in established ways of working in the NHS are hostile to technological changes that threaten established and possibly dysfunctional and wasteful practices. As a taxpayer, this is not acceptable, especially when we need to explore better ways of using tax revenues when times are likely to be hard
- The scale of complex IT projects empowers dissident critics to feed political interest in their failings. That these projects frequently focus on purely internal (to the NHS) goals and objectives makes them largely inscrutable with respect to benefits that may accrue to patients and their failure more damaging as there are no milestones for delivering taxpayer value. It is better to think of flexible, networked, and distributed approaches—a school of fish adjusting easily to changes in its environment versus a supertanker that is much harder to control. Politicians would be better responding to the benefits that large scale IT projects bring to the public than to internal NHS efficiencies that may result
- Introducing new technologies must have some consequences, and these are not necessarily helped by protecting incumbents and legacy systems from threat.

The lack of a patient held smart card for health, for instance, maintains the control of information in the hands of the clinicians and the provider infrastructure. Giving patients complete and total ownership of their health record is a critical way of driving quality improvement.

My fear is that the sunk costs are already so great that a rethink is unthinkable and that we cannot cut our losses and start again. In politics this would be a U turn, requiring another innovation called courage.

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- 1 Greenhalgh T, Stramer K, Bratan T, Byrne E, Mohammad Y, Russell J. Introduction of shared electronic records: multi-site case study using diffusion of innovation theory. *BMJ* 2008;337:a1786. (23 October.)

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## Disruptiveness of Google Health

Such is the pace of modern technology that the paper by Greenhalgh and colleagues is already out of date.<sup>1</sup> They did not mention the launch of Google's web based personal health record on 20 May 2008 or the collapse of the NHS records system.<sup>2</sup>

Web 2.0 technology will no doubt disrupt the grand aspirations of the NHS IT project. Technosavvy patients using Google style applications might soon ask doctors to access their personal health records on the web.

Like the music industry, the NHS seems to have become self importantly complacent. We are deluding ourselves if we think that "the world is waiting to see" how the NHS IT programme unfolds. The world has already seen that, six years into the programme, NPfIT is overbudget and behind schedule. The NHS isn't the global gold standard. Instead, it is a hugely wasteful, inefficient, and bloated monopoly that needs some serious competition. Did record companies ever imagine that one day music could be downloaded for free?

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## MANDATORY FLU VACCINATION

### Patient care drives mandatory vaccination

Both sides debating mandatory flu vaccination for healthcare workers canvass central arguments,<sup>1,2</sup> but key issues require further exploration. Neither side acknowledged that health care differs fundamentally from other work. Its primary aim is not individual protection but protection of patients by reducing nosocomial flu. John Stuart Mills would support, not oppose, a mandatory programme.<sup>2</sup>

The autonomy argument focuses on individual rights of healthcare workers, ignoring the rights of others. Ethical assessment requires us to balance competing rights, and should include a patient's right to a safe healthcare environment. Australian States and Territories already require hepatitis B vaccination for those who are not immune and provide patient care. Individual autonomy is not catered for, with healthcare workers exercising their right to choose more fundamentally: either work in health care and minimise the risk of infecting patients or work elsewhere.

Increasing flu vaccine coverage among healthcare workers is possible using incentives and signed declination, but results are better<sup>1</sup> and cost less to implement with mandatory requirements. Better coverage at a lower price makes a mandatory programme dominant in health economic terms before consideration of improved outcomes.

Most developed industrialised countries have workplace health and safety laws that require workers to be "free from risk of death, injury or illness caused by any workplace."<sup>3</sup> Flu is an annual and predictable workplace danger that universal vaccination of healthcare workers can reduce. How can mandatory programmes not be required under such laws?

Given that vaccinating eight healthcare workers can prevent the death of one patient,<sup>4</sup> how can healthcare workers continue to oppose mandatory flu vaccination?

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Competing interests: SBL has been an investigator on industry sponsored vaccine studies, received a travel grant to attend a conference, and been a member of vaccine advisory boards for GSK and Novartis.

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## ADDRESSING DOCTORS

### Scandinavian solution

I recently started work in Sweden after a UK medical education and several years working in the NHS.

I find the Swedish solution of introductions very appealing: completely do away with titles and address everyone by their first and second names.<sup>1</sup> So my badge says "Alison Godbolt, doctor," and that's how I introduce myself.

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