

Peripartum outcomes: non-adjuvanted v. adjuvanted H1N1 vaccination

Pregnant women are at higher risk for complications from pandemic H1N1 virus infection. In *CMAJ*, Mahmud and colleagues¹ showed a seroprevalence of 8.6% among pregnant women in Manitoba in 2009. In that year, over 1 million pregnant Canadian women received either the AS03-adjuvanted or nonadjuvanted H1N1 pandemic influenza vaccine. The safety of adjuvanted vaccine use in pregnancy has been studied,² but has not been systematically compared with the nonadjuvanted vaccine.

We recently completed a study of pregnant women who received either the nonadjuvanted (CSL Limited) or adjuvanted (GlaxoSmithKline Pandemrix) H1N1 vaccine at prenatal hospital clinics at Mount Sinai Hospital, St. Michael's Hospital, Sunnybrook Health Sciences Centre (all in Toronto, Ontario) or Kingston General Hospital. More details can be found at www.stmichaelshospital.com/pdf/research/mapped-tables.pdf.

The composite outcome of peripartum complications was more common in women who received the nonadjuvanted (41.7%) than adjuvanted (25.1%) vaccines (adjusted odds ratio 1.55, 95% confidence interval 1.01–2.39). Other outcomes we measured did not differ significantly (see Table 2 at www.stmichaelshospital.com/pdf/research/mapped-tables.pdf).

Our study was underpowered to detect infrequent outcomes. Because limited safety data were available at that time, the nonadjuvanted vaccine was generally recommended to women who were less than 16 weeks' gestation, and the adjuvanted was recommended to women past that gestational age. That the nonadjuvanted H1N1 vaccine was associated with more peripartum complications is of interest. Influenza infection in the second and third trimesters of pregnancy is a rela-

tively common event¹ and there is no evidence for transplacental transmission of the virus.³ It remains to be determined if it is the adjuvanted vaccine itself, or its differential protection against H1N1, that might modulate the manner in which labour progresses.

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Regulating e-cigarettes as drugs is not the best solution

The *CMAJ* editorial, in which Stanbrook¹ calls for e-cigarettes to be regulated as drug-delivery devices, raises important issues about this controversial new product.

Stanbrook¹ asserts that Health Canada's laws governing e-cigarettes are "among the most restrictive in the world." Yet, tobacco companies promote e-cigarettes to youth in Canada as much as they do in the United States, and e-cigarettes that contain nicotine are openly sold at retailers.

Having strict regulations but turning a blind eye to violations sends a mixed message and does a disservice to both smokers and health practitioners seeking guidance on smoking cessation products. So, too, do misleading assertions from the health community, such as Stanbrook's¹ statement that a recent ran-

domized controlled trial of e-cigarettes published in *The Lancet* "... failed to show superiority over a nicotine patch ..."² Equally true is the assertion that e-cigarettes were found to be as effective as the patch in helping smokers quit.²

Support for e-cigarettes is not predicated merely on "... the assumption that their availability will lead to cessation of tobacco use,"³ but rather on a growing body of research evidence that includes two published randomized controlled trials.^{2,3}

The most effective way to maximize the potential of e-cigarettes as cessation aids, while minimizing the risks they pose to successfully denormalize tobacco use, is to regulate all e-cigarettes as tobacco products. The federal, provincial and territorial governments should impose the same restrictions on all e-cigarettes (i.e., those that contain nicotine and those that do not) that they impose on tobacco products. This would mean that e-cigarettes could not legally be sold to minors; could not be marketed via prominent retail displays, lifestyle advertising or celebrity endorsements in magazines and on television; would be subject to limits on youth-friendly flavourings and to meaningful warnings on relative risk; and could not be used in schoolyards, workplaces and other public places where smoking is banned.

It will be some years before we have definitive answers regarding e-cigarettes. In the meantime, Health Canada needs to enforce basic consumer safety standards to reduce risks from faulty products. Governments need to finance more research on safety and efficacy of e-cigarettes as cessation aids; and, critical tobacco-control gains must be protected by subjecting e-cigarettes to the same regulatory controls as tobacco products.

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Expanding scope of pharmacists

We thank Tannenbaum and Tsuyuki¹ for their review in *CMAJ*. In addition to what the authors have already highlighted, it is also well known that clinical pharmacy services improve patient outcomes and reduce mortality in the inpatient setting and that professional collaboration is key to successful clinical pharmacy service provision.^{2,3}

An example of this collaborative practice model is the Antimicrobial Stewardship Program (ASP) at the Children's Hospital of Winnipeg, in Manitoba. Antibiotics are commonly prescribed to children admitted to hospital, are often associated with prescribing errors, and their misuse drives antimicrobial resistance.⁴ ASPs help minimize inappropriate antimicrobial use, and guidelines on their development have been published.⁵ Accreditation Canada includes ASPs as a Required Organization Practice (ROP) in their accreditation standards. ASPs are "support" teams; core members include a physician and a clinical pharmacist with training in infectious diseases.⁶ Antimicrobial use is reviewed by the ASP team at both patient and system levels in order to promote safe and quality care. Teams interact with the prescribing clinician at the time of antibiotic prescribing; this face-to-face feedback from an ASP pharmacist allows for reciprocal communication in a timely, collaborative fashion, which affects the quality of care provided.

Real-world application of pharmacist-led ASPs has been shown to have the ability to lower overall inpatient antimicrobial use.⁷ At our institution, prescribers are open to feedback from colleagues of different professional backgrounds. We hope that this example of physician-pharmacist collaboration encourages others to explore options to synergistically improve patient care regardless of their practice setting.

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Patient advocacy

I read the *CMAJ* Salon article by Arya¹ with interest and some degree of self-assessment. The author not only provides a fascinating array of physician-based advocacy, but also touches upon the delicate balance between advocacy and empowerment.

Looking at my own practice and those of some of my colleagues, I can appreciate three reasonably distinct styles of physician-based advocacy: advocacy for health-related issues, for non-health-related issues and nonspecific advocacy.

Arya¹ cites obvious samples of advocacy to "promote the health of individuals, communities or populations." This includes direct and indirect health initiatives. Clearly, this unique contribution of physicians is the natural extension of training and expertise as medical practitioners. Not surprisingly, such advocacy remains generally uncontested and powerful.

Physician advocacy for non-health-related issues may be just as powerful, but may not be a natural extension of training and expertise. Furthermore, it

may be far more contentious, depending upon the geopolitical milieu in which the advocacy occurs. In the context of divergent opinions regarding such advocacy, one could reasonably question the appropriateness of physician advocacy for non-health-related issues. However, nonspecific advocacy appears to be on the rise and is more troubling. I sometimes see physicians uncritically reiterating what their patients say, often without corroborating evidence, and at times, inconsistent with the expected course of events. A common example is the physician who advocates on behalf of a patient who is pursuing long-term disability benefits in the context of remote soft tissue injuries that have long-since healed. Although the physician has the best intentions, such advocacy may not be what is physically or psychologically best for the patient. This difficult issue was addressed some time ago by the American Medical Association.

As difficult as it may be, we must, with understanding and compassion, objectively assess impairment and not confuse our role as the patient's advocate with our responsibility for objectivity.²

More and more, I see physicians equating advocacy for health-related issues with nonspecific advocacy. However, we must ensure that when we advocate on behalf of our patients, our actions are consistent with available clinical evidence and are truly based upon the principle of "promoting health interests," rather than simply fulfilling expectations.

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Some letters have been abbreviated for print. See www.cmaj.ca for full versions and competing interests.