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 colleagues[1] 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 relatively common event[1] 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.

Joel G. Ray MD MSc, Allison J. McGeer MD MSc, Jennifer M. Blake MD MSc, Gerald Lebovic PhD, Graeme N. Smith MD PhD, Mark H. Yudin MD MSc
Mount Sinai Hospital (McGeer); Sunnybrook Health Sciences Centre (Blake); St. Michael's Hospital, University of Toronto (Ray, Lebovic, Yudin), Toronto, Ont.; Queen's University (Smith), Kingston, Ont.

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Regulating e-cigarettes as drugs is not the best solution

The *CMAJ* editorial, in which Stanbrook[1] calls for e-cigarettes to be regulated as drug-delivery devices, raises important issues about this controversial new product.

Stanbrook[1] 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's[1] statement that a recent randomized 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,"[1] 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.

Melodie L. Tilson MA
Director of Policy, Non-Smokers' Rights Association

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