has developed a set of guidelines for industry-sponsored clinical trial and epidemiology contract research in Canada in collaboration with 6 multinational vaccine manufacturers.[5] These guidelines describe the roles of the academic and public health investigator in protocol development, access to data, data management, data analysis, creation of the study report and publication in peer-reviewed journals. The guidelines conform to the recommendations of the ICMJE and aim to ensure that the academic or public health investigators have full and unrestricted access to data and play a leading role in the publication of study results. We hope that these guidelines will address the deficiencies documented in recent evaluations of clinical trial agreements and will serve as a model for the interaction between academia, public health and the pharmaceutical industry.

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Refresher on rubella

The authors of a recent public health column in *CMAJ* state that "women of childbearing age should be given rubella vaccine unless they have proof of immunity, and they should be advised to avoid pregnancy for 3 months after vaccination."[1] However, a public health document cited in the column states that "women of childbearing age should be advised to avoid pregnancy for 1 month after immunization. This recommendation is based on the duration of viremia after natural infection and evidence of vaccine safety."

I recently saw a patient who tested negative for rubella antibodies at her first visit. When recalled for a measles, mumps and rubella vaccination, she told me that she wanted to have a child and did not want to wait too long before trying to conceive. I thought a 3-month wait was required but found the 1-month recommendation[2] when I double-checked the requirement.

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[The author responds:]

I thank Michelle Greiver for her attention to our column on rubella.[1] In the first draft of this article Doug Sider and I quoted the Public Health Agency of Canada's advice[2] (which appeared to be based on information in the 2002 Canadian Immunization Guide[3]) that women should avoid pregnancy for 1 month after receiving the rubella vaccine. However, a peer reviewer challenged this statement because one of the bibles on communicable disease, the *Control of Communicable Diseases Manual*,[4] states that after immunization for rubella women should prevent pregnancy for 3 months. In the end we decided to relay the more cautious message.

When I try to assess and communicate risk, I usually ask 3 questions: Is there a hazard? If so, what is the magnitude of the adverse outcome? What is the likelihood that the adverse outcome will occur? In this case, there is a hazard associated with immunizing a pregnant woman; the magnitude of the adverse outcome is potentially very great (congenital rubella syndrome) but the likelihood that it will occur is extremely low (bordering on theoretical). Because the potential adverse outcome is so serious we decided to relay the more conservative recommendation. However, given the extremely low likelihood that it will occur, one could as easily argue that advising women to avoid pregnancy for 1 month after immunization is appropriate.

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Vitamin B_{12} and homocysteine

In their analysis of the relationship between carotid plaque area and vitamin B_{12} status,[1] Julie Robertson and colleagues define vitamin B_{12} deficiency as a serum concentration of less than 258 pmol/L, with a plasma homocysteine concentration of 14 μmol/L or more or a plasma methylmalonic acid (MMA) level of 271 nmol/L or more. We question the use of these thresholds and the conclusions that are based on them.

Their threshold for vitamin B_{12} deficiency of 258 pmol/L is almost the same as the sample median value of 253 pmol/L . This value is exceedingly high and probably inappropriately labeled many study patients as having a vitamin B_{12} deficiency. Among 11 000 elderly women in Ontario and British Columbia, the mean and fifth centile serum vitamin B_{12} concentrations were 300 and 118 pmol/L, respectively, after