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### [The authors respond:]

The finding of higher rates of preventable deaths in hospitals with high mortality in the study by Dubois and colleagues<sup>1</sup> applied only to the analysis of deaths from pneumonia, for which the physician reviewers exhibited very poor agreement ( $\kappa = 0.11$ ). Moreover, in citing Dubois and colleagues in our commentary,<sup>2</sup> we did not presuppose that process problems constitute the gold standard for quality indicators. However, process change represents the major aspect of health care delivery under providers' control. If hospital standardized mortality ratios correlate poorly with the need for process changes (as in the study by Dubois and colleagues and a recent study from Ontario<sup>3</sup>), it remains unclear how hospital standardized mortality ratios can serve as a useful screen for quality problems.

Few would argue there are quality problems in the Canadian health care system. The Canadian Adverse Event Study found preventable events in every hospital studied.<sup>4</sup> Ideally, all hospitals would accept these results as fact and undertake vigorous efforts to look for quality problems rather than wait for the results of their hospital standardized mortality ratios analysis. Given that this does not occur, one might argue for the use of a screening test, to engage hospitals.

However, as we outlined in our commentary, the hospital standardized mortality ratio has both low sensitivity and poor specificity for quality problems.<sup>2</sup> This is not unheard of among screening tests. Despite terrible performance characteristics, the fecal occult blood test improves detection of colon cancer, presumably because the results of annual application of this test randomly scare sufficient numbers of patients into undergoing the test they should have agreed to undergo in the first place, namely colonoscopy.

Unfortunately, whereas colon cancer

really does reside in the colon, most quality problems do not manifest themselves in the charts of deceased patients.<sup>5</sup> Thus, rather than engaging hospitals in vigorous and effective detection of quality problems, promotion of hospital standardized mortality ratios focuses hospitals' attention on chart reviews of in-hospital deaths, which has all the inconvenience of colonoscopy but not comparable benefits.

### Kaveh G. Shojania MD

Department of Medicine, Sunnybrook Health Sciences Centre, Toronto, Ont.

### Alan J. Forster MD MSc

Clinical Epidemiology Program, Ottawa Health Research Institute Ottawa, Ont.

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## Smoking cessation trials

I submit that the meta-analysis by Mark Eisenberg and colleagues on pharmacotherapies for smoking cessation<sup>1</sup> is grounded in a false premise, namely that researchers were somehow able to hide the onset of nicotine withdrawal symptoms from control group members, whose previous quitting history had taught them exactly how withdrawal felt (a rising tide of anxieties, anger, dysphoria, concentration difficulty and sleep fragmentation within 24 hours of quitting), and that researchers found a way to mask the reduction of withdrawal syndrome for intervention group members. Mooney and colleagues found that studies of nicotine replacement therapies are generally not blind in that participants correctly

guess assignment at rates significantly above chance.<sup>2</sup> When this finding is combined with the meta-analytic finding by Eisenberg and colleagues that smoking cessation with pharmacologic treatment is nearly always more successful than cessation without pharmacologic treatment in clinical trials and the fact that cessation with pharmacologic treatment has failed to be more successful than cessation without such treatment in nearly all of real-world surveys conducted to date,<sup>3</sup> it strongly suggests that the pharmacologic treatment of chemical dependency may be the only known research area in which blinding is impossible.

Mooney and colleagues warned that the validity of the results of clinical trials of nicotine replacement therapies could be questioned if future studies failed to assess the integrity of study blinding.<sup>2</sup> This warning has not been heeded. How badly can study blinding fail? Dar and colleagues found that control group members were 3.3 times more likely to correctly guess that they had received placebo than to incorrectly guess that they had received nicotine (54.5% v. 16.4%).<sup>4</sup>

In the era in which pharmacologic therapies are used for smoking cessation, the decline in smoking rates seen previously has come to a screeching halt.<sup>5</sup> Although excitement about varenicline should briefly improve cessation rates, Canadian policy-makers must realize that toying with chemicals that stimulate the dopamine pathway is not more effective than teaching those hooked on nicotine how to quickly and more comfortably adapt to natural stimulation.

### John R. Polito JD

Nicotine Cessation Educator,  
Mount Pleasant, South Carolina, USA.

**Competing interests:** John Polito is the editor of *WhyQuit*, a forum on abrupt nicotine cessation. He was compensated by the State of South Carolina for presenting 63 prison programs on abrupt nicotine cessation in 2007 and 2008.

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### [Six of the authors respond:]

We thank John Polito for his discussion of the importance of blinding in clinical trials. Blinding is undoubtedly a key component of the validity of inferences drawn from randomized controlled trials. For this reason, it is included in tools to assess the quality of clinical trials, such as the Jadad scale.<sup>1</sup> In our meta-analysis of randomized controlled trials of smoking cessation pharmacotherapies, we restricted our study to double-blind trials so that only trials of the highest quality would be included.<sup>2</sup> We agree with Polito that maintaining blinding may be difficult, particularly if study participants experience withdrawal symptoms. However, although the importance of blinding is well established, assessing the integrity of blinding remains more controversial.

In a recent analysis of randomized controlled trials that reported tests for the success of blinding, Hróbjartsson and colleagues found that less than 2% of trials reported such testing.<sup>3</sup> Others have reported this percentage to be as high as 8%.<sup>4</sup> One reason few trial reports include tests for blinding is that it is unclear what these tests actually measure. Some have argued that such tests are often biased.<sup>5</sup> These tests often do not test blinding but rather test the participant's or physician's belief regarding the efficacy of the treatment.<sup>6</sup> Thus, the fact that patients who are randomly assigned to receive placebo and subsequently resume smoking correctly guess their allocated treatment may not be a reflection of the blinding

itself but rather of their belief that the placebo is not efficacious.

Blinding plays an important role in ensuring the validity of clinical trial results. However, improved methods are needed to assess the success of blinding. Until such methods are developed, incomplete blinding is a potential limitation to most clinical trials.

#### Kristian B. Filion MSc

Department of Epidemiology, Biostatistics and Occupational Health, McGill University

#### Patrick Bélisle MSc

Division of Clinical Epidemiology, McGill University Health Centre

#### Lawrence Joseph PhD

#### Gilles Paradis MD MSc

Department of Epidemiology, Biostatistics and Occupational Health, McGill University, Montréal, Que.

#### Stéphane Rinfret MD MSc

Division of Cardiology, Laval Hospital, Québec City, Que.

#### Mark J. Eisenberg MD MPH

Divisions of Cardiology and Clinical Epidemiology, Sir Mortimer B. Davis Jewish General Hospital, Montréal Que.

**Competing interests:** Mark Eisenberg is a member of the Varenicline Advisory Board of Pfizer Canada Inc. No competing interests declared by Kristian Filion, Patrick Bélisle, Lawrence Joseph, Gilles Paradis or Stéphane Rinfret.

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### Correction

In a recent research article on stable angina,<sup>1</sup> a sentence in the "symptoms and prognosis" section of Results that read "Among South Asian people with atypical pain, the symptom score was associated with coronary outcomes (Figure 3, unadjusted log rank test  $p = 0.30$ )" should have read "South Asian people with atypical pain were as likely as white people with atypical pain to experience a coronary outcome (Figure 3; unadjusted log rank test  $p = 0.88$ ).

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