

the WHI ( $20 \times 0.77\% = 15.4\%$ ). We could use both the approaches described above. For the crude approach, the risk difference is now approximately  $15.4\% \times 0.32$  or  $4.93\%$  and the NNT  $100/4.93$  or just slightly above 20. Using the hazard ratio approach for this patient also yields an NNT of just over 20.

As we have shown here, differences between naïve approaches to calculating NNT based on event rates and more sophisticated approaches based on survival analysis may not be large enough to change clinical decisions. We suggest that clinicians who are interested in using the NNT to help guide their practice should not be overly concerned about inaccuracies that may arise from estimating the NNT from event rates, especially when using data from large, randomized trials with high rates of follow-up. What they must avoid is applying NNTs from trial data without considering how their patient's baseline risk may differ from that of the patients in the trial. That mistake could lead to serious miscalculations of the NNT that *would* have implications for clinical decision-making.

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DOI:10.1503/cmaj.1041709

## How to diagnose diabetes

In their commentary on the impact of new guidelines for glucose tolerance testing, Andrew Lyon and associates<sup>1</sup> argue against increased use of the oral glucose tolerance test (OGTT) on the grounds of poor reproducibility, cumbersome and questionable cost-effectiveness. They rightly conclude that devoting resources to programs that can help patients to modify their risk for diabetes is preferable to performing more OGTTs. However, it would have been appreciated if they had considered the simplified or abbreviated version of the glucose tolerance test<sup>2,3</sup> in terms of its suitability for detecting new cases of diabetes; this form of the test would be both reliable and less expensive.

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DOI:10.1503/cmaj.1041707

Andrew Lyon and associates<sup>1</sup> point out that the Canadian Diabetes Association's new clinical guidelines may increase the burden on laboratories because of increased use of the OGTT. I would like to add that the diagnosis of diabetes is mainly initiated by family doctors, but they may be too busy to implement any screening or to follow up appropriately once diabetes has been identified.<sup>2</sup> The burden on family practitioners to initiate mass testing and

manage patients afterward (with lifestyle advice and oral therapy<sup>3,4</sup>) is potentially huge.

The prospect of targeted screening (as supported by Lyon and associates) warrants consideration. Screening tools with different predictive abilities (75% to 80% sensitivity and 50% to 76% specificity<sup>5,6</sup>) are available, which could be used anywhere in the community. These tools take into account major risk factors such as family history, exercise levels, age, body mass index, waist circumference, dietary habits, medication history and history of dysglycemia; however, they perform poorly as stand-alone tests.<sup>7</sup>

A 2- or 3-stage screening test (e.g., the combination of a questionnaire and random capillary blood glucose testing, which yields 58% sensitivity and 94% specificity<sup>8</sup>) might be a more efficient use of resources, ensuring that OGTTs are not performed unnecessarily. Other combinations of near-patient tests and scoring tools that might be used in community settings should be studied, similar to the successful assessment in local pharmacies of people at risk of hypertension.<sup>9</sup> It would be entirely possible, using a mixture of community-based measurements such as scoring tools for diabetes risk, fasting capillary blood glucose readings and near-patient testing of hemoglobin A<sub>1c</sub> to target individuals who should undergo an OGTT. This might reduce the potential burden on both laboratories and family physicians.

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DOI:10.1503/cmaj.1041724

## Clinical trial budgets

In May 1991, Ian Rusted chaired a 2-day workshop sponsored by the National Council on Bioethics in Human Research (now the National Council on Ethics in Human Research) entitled "Ethics of Clinical Trials for Research Ethics Boards."<sup>1</sup> The participants were representatives of the pharmaceutical industry, the Medical Research Council of Canada, Health and Welfare Canada and the Royal College of Physicians and Surgeons of Canada, as well as members of research ethics boards from across Canada.

On reading the viewpoint by Lorraine Ferris and David Naylor,<sup>2</sup> the spirited response by Salim Yusuf<sup>3</sup> and the rebuttal by Ferris and Naylor,<sup>4</sup> I experienced a sense of déjà vu: the points of view expressed in this exchange mirror the conclusions of the 1991 workshop. Unfortunately, although the Tri-Council drafting committee had access to the workshop recommendations for financial accountability and conflict of interest, they were not incorporated in the Tri-Council policy statement.<sup>5</sup> The authors and *CMAJ* are to be commended for revisiting the subject.

At the heart of the matter are issues critical to both patient care and clinical research. Both of these activities are dependent upon public trust, which must be earned through openness and integrity.

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*Competing interests:* Dr. Klassen is a past president of Canadian Society for Clinical Investigation and National Council on Ethics in Human Research.

DOI:10.1503/cmaj.1041762

We commend Salim Yusuf for his reply<sup>1</sup> to the call by Lorraine Ferris and David Naylor<sup>2</sup> for additional monitoring of clinical trials. Yusuf's point on the increasing complexity of regulation for clinical trial research is well taken, as is the point that complying with complex regulations creates significant costs. Although one of us (J.A.C.D.) has previously argued against an excessive reliance on clinical trials,<sup>3</sup> it is clear that they represent the modern gold standard. Given this reality, it is essential that we not choke off this important type of research.

Increasing costs through the requirement to deal with nontransparent and complex regulations actually makes it harder for independent researchers to do research. We have recently seen the consequences of restricting clinical trials to large drug companies<sup>4</sup> rather than independent academic investigators. It would seem more appropriate to have well-trained auditors who could iden-