



Most over-the-counter drugs have CRCs. There is often no choice in packaging.

CRCs are not just a problem for seniors. We have a large population of semiliterate as well as non-English-speaking people. For many of them, CRCs remain a mystery.

I wonder whether the association is claiming credit where credit is not due. Simply because there has been a reduced incidence of accidental poisoning in children coincident with the introduction of CRCs does not necessarily mean there is a causal connection. Is it possible that the reduction is the result of a better educated population?

**Lynette E. Sutherland, MD, PhD**  
North York, Ont.

## Calcium supplementation for the nation

The timing of the symposium on the prevention and management of osteoporosis (*Can Med Assoc J* 1996;155:921-65) was appropriate because of the immense magnitude of this problem in Canada.

One of the articles, "Calcium nutrition and osteoporosis" (*Can Med Assoc J* 1996;155:935-9), by Dr. Timothy M. Murray, drew attention to the need for calcium supplementation.

It seems ironic that the simple supplementation of ordinary orange juice with tricalcium citrate is not available to the Canadian public. For at least the past 10 years this calcium-supplemented orange juice has been available throughout the US. In that country, a glass of orange juice supplies as much calcium as a glass of milk. Calcium-supplemented orange juice is available at the same price as regular juice. The containers are specially marked with blue print and the screwtop on the container is also blue.

This calcium-fortified juice is available from every major producer of orange juice in the US. The same brands are available in Canada, but without the option of calcium supplementation. I wonder why Canadians nation wide are denied access to this product.

**Walter P. Bobechko**  
Dallas, Tex.

### [The author responds:]

Dr. Bobechko raises an important point. Supplementation of food products such as orange juice is an important source of calcium, particularly for those who cannot or will not consume dairy products. Such products can be supplemented at a level higher than the calcium level in vegetable sources. We have been aware of the availability of calcium-supplemented orange juice in the US for some time, and we would like to see such products available in Canada. Indeed, the Osteoporosis Society of Canada has endeavoured to help make such products available in Canada, in keeping with its view that informed and educated consumers should be able to obtain dietary calcium from a variety of food choices. The society has advocated the introduction of such products to the Canadian market by consulting with corporate partners in the food and beverage industry and with the Health Protection Branch of Health Canada. However, the issue is a complicated one that still awaits regulatory approval. Topics that need to be addressed include upper safety limits for calcium intake in the general population, whether health claims can be made for such products with regard to osteoporosis, the scope of the population at risk for osteoporosis, which products should be supplemented and the benefits of harmonization with US policies. We would like to see more consumer choice

and greater calcium availability through a wider variety of food sources.

**Tim Murray, MD**  
Professor of Medicine  
Metabolic Bone Clinic  
St. Michael's Hospital  
Toronto, Ont.

## Checking random assignment with claims data

Dr. Norman F. Boyd ("The review of randomization in the Canadian National Breast Screening Study: Is the debate over?," *Can Med Assoc J* 1997;156:207-9) refers to our analysis of health insurance data on the Manitoba women enrolled in the National Breast Screening Study (NBSS).<sup>1</sup> One of the objectives of our study, which was funded by the National Cancer Institute of Canada, was to determine whether there was independent evidence supporting criticism of the random assignment procedures used in the NBSS. In Manitoba, we could construct a medical history for each woman before her entry into the trial with the use of a database generated as part of that province's health insurance system. The database includes claims data from the billing cards sent to Manitoba Health by fee-for-service physicians. Each card must include the reason for the visit (diagnosis) for the claim to be accepted and the physician paid.

The NBSS provided identifying information for each of the 9477 women who attended the screening centre in Manitoba, which we then linked with each woman's claims data. We retrieved all procedures and diagnoses related to the breast in the 24 months before each woman's entry into the NBSS. As Boyd notes, we identified 9 women who had a claim for breast cancer



during that period. Of these 9 women, 3 had no other breast-related claims, 2 were referred for a mammogram, 2 had a biopsy and 2 had both a mammogram and a biopsy. None had surgery or other form of cancer treatment during the 24 months before their enrolment. Only 1 of these women subsequently had breast cancer diagnosed and treated, several years after the closure of the NBSS centre. We verified this with files provided by the NBSS, which documented all cases with a cancer diagnosis during the trial or the follow-up period. We also determined that these women had continuous coverage under Manitoba Health from 1980 to 1995, suggesting that none of them had left the province or had been diagnosed or treated elsewhere.

Eight of the 9 women with a prior claim for breast cancer (4 of whom were in their 40s and 4 of whom were in their 50s) were randomly assigned to the mammography arm of the NBSS. We reported a probability value of 0.06 for this comparison, based on Fisher's exact test. Boyd re-

analysed the data and found a  $p$  value of 0.05, but he used the  $\chi^2$  test. It should be recognized, when interpreting these results, that the study examined a large number of comparisons between women in the 2 arms of the trial. The finding of a  $p$  value close to 0.05 did not control for multiple comparisons and should be treated with caution.

In interpreting these results, one needs to be aware of the nature of the health insurance system in Manitoba. A tentative diagnosis may be entered on a claims card as the reason for the visit and any further diagnostic procedures. Even if the results are negative — as was presumably the case for these 9 women — the original claims card remains in the system. The physicians of these women probably wrote “query breast cancer” or “rule out breast cancer” on the claims cards.

Despite the limitations of the claims data, they were generated independently from the NBSS and provide a unique method of checking the random assignment process used in this trial.

**Marsha Cohen, MD**

Clinical Epidemiology Unit  
Sunnybrook Health Science Centre  
North York, Ont.

Department of Community Health  
Sciences

University of Manitoba  
Manitoba Centre for Health Policy  
and Evaluation

Winnipeg, Man.

Department of Health Administration  
University of Toronto  
Toronto, Ont.

**Pat Kaufert, PhD**

Department of Community Health  
Sciences

University of Manitoba  
Winnipeg, Man.

**Leonard MacWilliam, MNM, MSc**

Manitoba Centre for Health Policy  
and Evaluation

Winnipeg, Man.

**Robert Tate, MSc**

Department of Community Health  
Sciences

University of Manitoba  
Winnipeg, Man.

Received via e-mail

**Reference**

1. Cohen MM, Kaufert PA, MacWilliam L, Tate RB. Using an alternative data source to examine randomization in the Canadian National Breast Screening Study. *J Clin Epidemiol* 1996;49:1039-44.

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