Screening mammography has been the most intensely studied imaging intervention and is certainly the most controversial. It is an issue where scientific considerations are frequently confounded by those of politics and health economics. In North America this is clearly illustrated by the recent recommendations on breast cancer screening of the United States Preventive Services Task Force (USPSTF) in 2009 and the Canadian Task Force on Preventive Health Care (CTFPHC) in 2011 and the response to these recommendations.

Here are the facts—Breast cancer is the most common cancer and the second largest cause of cancer death in North American women. Incidence rises continually with age beginning in the late thirties (Table 1, Column B). Note that about 19 per cent of the breast cancer deaths (Column C) and 30 per cent of the years of life lost to breast cancer (Column D) arise from cancers that are discovered in the 40–49 year age range. About 40 per cent of the deaths and 56 per cent of the years of women’s lives lost come from cancers that emerge between the years 40 and 59.

More facts—The causes of breast cancer are not well understood and no reliable method of prevention is currently available. The probability of successful treatment of the disease is greatest when it is found at an earlier stage, i.e., when the cancer is smaller and the lymph nodes are not occupied by tumour cells. Screening (periodic examination of asymptomatic women) using mammography has been demonstrated to contribute to reduction in mortality from breast cancer in women between 40 and 69 years of age. A mortality benefit of at least 15 per cent is generally accepted, based on results of randomized controlled trials (RCTs). More modern studies point to a reduction of 24 per cent or higher.

Medical tests are not perfect and mammography is no exception. To perform the examination it is necessary to compress the breast and this causes some discomfort. The breast is exposed to x-rays, which themselves have carcinogenic potential, however, for the dose levels used in modern mammography, the risk is considered to be far less than the benefit of the examination. High-quality mammography is capable of detecting 70 to 85 per cent of cancers depending respectively on whether the breast is highly fibroglandular (dense) or fatty in composition, i.e., 15-30 per cent of cancers can be missed. Furthermore, even if cancer is detected, screening will not be helpful for all cancers. Some will grow so quickly that they will not be found before they have metastasized to the lymph nodes or beyond and others will grow so slowly that they likely would not pose a threat of lethality. Despite these limitations, detection of a subset of “effectively treatable” cancers from the spectrum of all breast cancers contributes to the overall expected mortality benefit of screening of 24 per cent or higher. To address the limited sensitivity of film-based mammography in the dense breast digital mammography was developed. While its contribution to mortality reduction has not been directly tested, it has been demonstrated to provide a marked improvement in the detectability of cancers in women with dense breasts and those under 50.

In addition to the benefits of lives and years of life saved, earlier detection can allow reduction in the morbidity associated with treatment, by affording the possibility of surgery by lumpectomy rather than by a more extensive mastectomy or by being able to avoid chemotherapy. Most clinicians and patients consider this to be a major benefit.

The recommendations on screening for breast cancer detection released in 2011 by the CTFPHC closely followed those published two years earlier in the US in suggesting that less screening be done. Specifically, the CTFPHC recommended against: 1) routine screening by mammography for

<table>
<thead>
<tr>
<th>Age</th>
<th>(B) Risk of Developing Breast Cancer in the Next 10 years</th>
<th>(C) % of Deaths From Breast Cancer Surfacing in This Decade</th>
<th>(D) % of Total Woman-Years of Life Lost From Cancer in (C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>40s</td>
<td>13 per 1000</td>
<td>18.7</td>
<td>30</td>
</tr>
<tr>
<td>50s</td>
<td>23</td>
<td>21.4</td>
<td>25.6</td>
</tr>
<tr>
<td>60s</td>
<td>29</td>
<td>19.3</td>
<td>15</td>
</tr>
<tr>
<td>70s</td>
<td>31</td>
<td>18.6</td>
<td>8</td>
</tr>
</tbody>
</table>

Source: (B) Public Health Agency of Canada, (C, D) SEER Data
About 40 per cent of the deaths and 56 per cent of the years of women’s lives lost come from cancers that emerge between the years 40 and 59.

women in their 40s, 2) clinical breast examination (CBE), 3) MRI for screening women at average risk for breast cancer and 4) teaching breast self examination to women. It also suggested that, 5) screening of women over the age of 50 should take place at two to three year intervals, an increase from previous recommendations of one to two years and current practice of two years in most Canadian programs. This final guidance went beyond the American recommendations, which suggested extending the interval from one to two years.

It should be mentioned that both the Canadian and U.S. task forces support mammography screening of women over the age of 50 and that no randomized trial was performed to support the recommendations of increasing the screening interval (from one to two years in the U.S. and from typically two years to two-three years in Canada). This change was based primarily on computer modeling.

The recommendations were framed with the message that while “routine” screening was not recommended for women in their 40s or screening with CBE for any age group, women should make a decision to partake in one of those interventions or not based on consultation with their primary health care provider. It is suggested that if women decide to be screened with one of those interventions, this can be done “in the community”. While superficially this approach is attractive it suffers from two major difficulties. The first is that it is assumed that the health care provider has been sufficiently and accurately informed to be able to provide appropriate advice to the woman. As discussed below, the CTFPHC itself doesn’t appear to clearly understand all of the issues around screening and includes some erroneous information in its report. This suggests that there are likely to be major knowledge gaps among the health care providers, many of whom rely on Task Force guidelines for their information.

The second problem is that, particularly under the current tight economic conditions, screening programs are under pressure to cut costs. Those programs that currently do not provide the services that are not recommended by the CTFPHC are unlikely to start now. In fact, existing services provided by some provinces and territories may be threatened. At the same time, there are compelling arguments that if screening is to be done at all, it should be done under the framework of an organized program where an invitation and recall system and quality assurance is in place. Opportunistic screening within the community is not to be encouraged.

The CTFPHC approached the process of developing its recommendation as a balancing of benefits versus harms of screening interventions. This is a reasonable approach. The process involved an initial systematic evidence review by a separate group responsible for grading and analyzing evidence. This was followed by the synthesis of the recommendations by the CTFPHC. Unfortunately, both processes were carried out by individuals who did not have specific familiarity with the issues of breast cancer detection, diagnosis or treatment. This was justified through the principle of avoiding conflicts of interest, but in this case, at the price of serious scientific errors in evaluating the usefulness of the evidence and assigning values to benefits and harms.

For example, to estimate benefit, results from studies that used mammography from the 1960s, 70s and 80s were pooled by those who conducted the evidence review. The accuracy and ability to find early cancers from the mammography in use decades ago does not represent the performance level of modern film mammography, and certainly does not consider the impact of digital mammography.

A critical question for the CTFPHC is, what is the tradeoff between the value of a life saved through earlier detection of a cancer and the possible harms? As part of the value assessment for screening women in their 40s, the CTFPHC estimated that it would be necessary to screen 2,108 women for 10 years to save a life. This number is incorrect and actually refers to the number of women who would need to be invited to a randomized controlled trial per life saved; the number needed to screen is about 750, almost three times lower than the Task Force estimate.

One of the harms identified is what the CTFPHC refers to as a “false positive” result of screening. In reality, this is a request for a woman to return after an equivocal screening examination for further noninvasive imaging to increase the certainty that cancer is not present. On a woman’s first screening exam this may occur in 10–15 per cent of examinations, but on subsequent screens is about five to seven per cent. This often induces stress, but this can be mitigated by timely and appropriate counseling. Some studies found that anxiety disappeared rapidly after the definitive imaging was performed, although the literature is somewhat inconsistent.

Only about one per cent of women screened receive a needle biopsy, of whom 16–35 per cent will have breast cancer. It is extremely rare for breast cancer surgery to be performed on women who do not have breast cancer. Certainly, some of the cancers that are treated are not destined to be lethal, but currently it is not possible to reliably define that group. Once it is known how to do this, treatment can and will become considerably more selective.

So, here is a summary of the numbers. For every 750

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women in their 40s who are screened for 10 years we can avert a death due to breast cancer, saving, on average 30 years of life and possibly avoiding more difficult treatment. These are the benefits. Against this we must consider costs and harms. Over those 10 years about 150 women would be called back for noninvasive imaging, there would be about 75 biopsies and 20 cancers detected. So 75–20 =55 biopsies (mostly needle biopsies) would be performed on women without cancer and this is the main harm of screening. To save a year of life, it would be necessary, over a 10-year period, to recall about 150 women for noninvasive imaging and two unnecessary biopsies would be performed.

Overall, each year, screening women in Canada in their 40s would prevent about 200 premature deaths due to breast cancer and save about 6,000 woman-years of life.

In developing its recommendations, the CTFPHC did not reveal the algorithm that it used to weight the negative of these recalls and biopsies against the saving of life. The benefits associated with screening have been supported by RCTs and backed up by data from observational studies. The data that were accepted on harms come only from observational studies and from anecdotal information. My impression is that in formulating its recommendations on screening the CTFPHC grossly overweighted the negatives and downplayed the saving of life.

In the U.S., the Secretary of Health and Human Services and Congress rejected the Task Force recommendations and asked insurance companies not to deny coverage of mammography screening for women in their 40s.

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