Concerns with the 2024 breast screening guidelines and the guideline creation process.

Dense Breasts Canada submission to the House of Commons Standing Committee on Health.







Breast screening experts, breast cancer organizations, the public, and the Health Ministerⁱ have all expressed concern over the recently released Canadian Task Force on Preventive Health Care (Task Force) draft breast screening guidelines. The Task Force underestimates the benefits of breast screening and overstates the harms. It provides misinformation to physicians and Canadians.

Dense Breasts Canada is deeply concerned that the Task Force and its guideline update process lacks accountability, transparency, ethical oversight, scientific rigour, objectivity, and credibility.

1. A lack of accountability

- The Task Force was formed in the 1970s, but disbanded in 2005.ⁱⁱ When it was resurrected in 2010, the design failed to include oversight.
- The conduct of the Task Force, in terms of how members are appointed, how working groups are composed, how evidence is selected, how recommendations are made, etc. requires a governance structure that makes it accountable to Canadians.

2. A lack of transparency

- The Task Force points to the inclusion of four breast cancer experts in its Working Group, but these experts were not allowed to voteⁱⁱⁱ on the recommendations. In addition, the Task Force promoted the inclusion of patients but the two patients had no vote on recommendations.
- The Task Force nondisclosure agreements state that participant signatures are irrevocable. That applies even if experts disagree with the recommendations.
- There was no communication between the different evidence review centres, resulting in siloing.
- The 2024 draft recommendations were released before the results of computer modelling were available.^{iv}
- The Task Force figures for overdiagnosis and the number of breast cancer cases in 2018 differ significantly from numbers in the 2024 draft guidelines, with no explanation given.
- The Task Force released a feedback survey, misleadingly promoting it as a survey for public input. PHAC clarified the Task Force designed the survey for researchers, doctors and other healthcare providers, using medical and scientific language. It was not designed for the public.

3. A lack of ethical oversight

- According to testimony to HESA from expert advisors to the Ottawa Evidence Review Synthesis Centre (ERSC), their expert input was disregarded and the Task Force dictated to them what evidence to consider.^v They insisted on including 40–60-year-old Randomized Controlled Trials (RCTs). The inclusion of these obsolete data does not reflect technology, treatment, or outcomes of breast cancer management today. The inclusion of the old trials misinformed the 2024 guideline update.
- The Task Force states that women should be informed when making a choice about screening. To do so, accurate information is required, but this was not provided about the limitations and benefits of screening. As well, healthcare providers were instructed to use only absolute numbers when providing information, a nonstandard practice.^{vi} This understates the large benefits associated with earlier cancer detection. Data should be presented in both absolute and relative terms.
- Task Force members must have the expertise to evaluate incoming evidence objectively, free from bias, ensuring that family doctors and the public receive impartial information to inform their health decisions. Before the Task Force began its work on this guideline, the co-chair publicly stated that there was no new evidence and that the recommendations did not need to change.^{vii} She demonstrated an anti-screening bias in public statements, a webinar, and published articles, indicating a predetermined outcome for the guidelines.

4. Errors made in the 2018 guidelines have gone unchecked

- The Task Force stated in 2018 that there were 7 cancers in 1000 women 40-49 in 7 years. In the 2024 guideline, they stated that there are 19 cancers in 1000 women in 10 years.^{viii} By stating there were fewer cancers in women 40-49 in 2018, the Task Force diminished the perceived value of screening.
- In the 2018 recommendations, the Task Force presented an inflated value of 48% for overdiagnosis.^{ix} This figure came from the Canadian National Breast Screening Study (CNBSS), which is currently under investigation by the University of Toronto for subverted randomization. More credible reports, ignored by the Task Force, suggested 1-10%. The 48% datapoint was incorporated into the decision tool supplied to primary care providers to use in shared decision-making with patients. It undoubtedly misled many women to decline screening and led to avoidable deaths and suffering.
- The Ottawa ERSC (2024) used multiple trials to arrive at an estimate of overdiagnosis. They found that overdiagnosis was significantly lower. Overdiagnosis was 11% (for both DCIS and invasive cancers) and 6% (for invasive only) when including the discredited CNBSS trial, Without the CNBSS, the corresponding data points were 9% (for DCIS and invasive) and 3% (for invasive only).^x The 2018 error in the value for overdiagnosis devalued screening. In 2024, the Task Force uses the 11% value of overdiagnosis, which includes the CNBSS trial.

5. No meaningful input from content experts results in misinterpretation of data

• Task Force members lack the necessary expertise to evaluate the significance of evidence, the validity of data, and the most suitable analytical

methods for the current diagnosis and treatment of breast cancer. Breast cancer experts are aware of the clinical context and changing data.

- Unlike the US Task Force, the Canadian Task Force continued to use randomized trials whose technology is no longer representative of current practice. This would not have been the case had experts been heeded.
- The Task Force set arbitrary thresholds to assess the data.
- The Task Force used too short an observation time to allow the full impact of the benefits to be measured. The misplaced emphasis on the weight of shortterm (10-year) survival ignored the long-term survival benefit of early detection. ^{xi} Ten years is an inappropriate timeline to determine the benefits of early detection given the long trajectory of breast cancer where risk of recurrence continues 20-30 years after diagnosis, underlying the need for inclusion of disease experts to understand the context of the disease they are studying.
- The Task Force suggestion of a 3-year screening interval for women 40-74 is without solid basis in evidence.
- The Task Force overlooked the benefit of early-stage diagnosis and decreased morbidity of treatment. The only metric used in their knowledge translation tool was decreased mortality, but not the years of life gained (highly important for younger women) or the options to avoid mastectomy, chemotherapy, and armpit surgery. In doing so, they are communicating only half the benefit of screening, but all of the potential risks. Moreover, they wrongly assumed that the mortality benefit was the same for women of all ages, despite evidence showing that women 40-49 have greater benefit.^{xii}
- The Task Force has a dangerous misunderstanding that improved life expectancy is attributable only to better treatment, implying that early detection is unimportant.^{xiii} This is not the case.
- The stage of diagnosis does matter. Some members of the Task Force claim that screening can't save the lives of women with rapidly growing cancers.
 xivStatistics Canada has shown the opposite: when aggressive triple negative cancer is detected at stage one, the five-year survival is 96%, but at stage four, it's only 7%.^{xv}

6. A lack of equitable and accessible breast screening for racialized women

- The Task Force acknowledges the increased risk of breast cancer in racialized women aged 40-49, their increased mortality, and earlier peak incidence and yet the Task Force did not lower the screening age to provide an equitable opportunity for early detection.
- The participants in the historical RCTs (such as the flawed CNBSS) were almost entirely white women. xvi
- The Task Force 1000-person tool is "one-size-fits-all." It should individualize a women's risk to inform her of her own personalized benefit of screening.

7. Task Force did not perform its own evidence review on supplemental screening for dense breasts

• There is a great deal of evidence on the benefits of supplemental screening for women with dense breasts, but the Task Force chose not to do an independent review and used the US Task Force review instead. ^{xvii} The

Edmonton Evidence Review team looking at supplemental screening had no breast cancer screening experts.

- The Task Force diminished the value of RCTs that looked at the benefit of ultrasound and MRI screening in intermediate or high-risk women.
- The RCTs showed adding ultrasound or MRI to mammograms reduced interval cancers—cancers diagnosed by symptoms after a normal mammogram—by 80% and by 50%.^{xviii} Interval cancers often have a worse prognosis than screen detected cancers. An important goal of screening is reducing interval cancers. Reduction of interval cancers is accepted as a surrogate for mortality reduction. However, the Task Force downplayed the statistically significant interval cancer reduction of a factor of 4 seen in the J-Start RCT.^{xix}
- The Task Force disregarded a recent comprehensive 300-page review of supplemental screening done by Ontario Health examining the evidence, benefits and harms, patient preferences, etc. Ontario Health recommended supplemental screening, stating it detected more cases of breast cancer and led to fewer interval cancers. ^{xx} The Edmonton review team disregarded the Ontario evidence review because of differences in eligibility criteria between Ontario and the US Task Force.^{xxi}

8. No auditing of the outcomes of previously released recommendations

 Since the 2011 Task Force recommendation **not** to routinely screen women in the 40s, women aged 40-59 in provinces without access to screening until age 50 were more likely to be diagnosed with more advanced cancers and had poorer survival. ^{xxii} There has been a 10% increase in the incidence of later-stage breast cancer in women in their 40s and 50s between 2011 and 2020 and this has not been acknowledged by the Task Force.^{xxiii}

9. No responsiveness to the rapid evolution of breast cancer detection, research, and treatment

 Once the guidelines are published, they remain in place ~7 + years, as seen in the case of the cervical and prostate guidelines. Recommendations must be updated faster, as new research is published, so that they reflect current knowledge and clinical realities, such as the increasing rate of breast cancer in women under the age of 50. The US Task Force cited this increase as a key reason for lowering the screening age to 40.^{xxiv}

10. A lack of equitable and optimal breast screening across the country

Currently, six provinces and territories screen at 40 (NS, NL, NB, PEI, YT, BC), with two more (ON, SK) scheduled to start in the next six months. AB and NWT screen at 45. Only QC and MB have not yet committed to lowering the screening age. MB states it is following the Task Force. Where a woman lives impacts her ability to screen at 40. Supplemental screening for women with dense breasts is also dependent on where she lives.

11. A lack of up-to-date modelling

• Since additional randomized trials will not be conducted due to ethical considerations, cost and the length of time required, it will be necessary to rely on high-quality simulations, along with available empirical data to inform healthcare policies. The model used by the Task Force must be up to date to reflect technological advances in treatment with improved outcomes.

12. A lack of recommendations for high-risk women

• The Task Force does not provide appropriate guidance for women who have an elevated or high risk of developing breast cancer, such as those with certain genetic mutations, a family history, or dense breasts.

13. No consideration of the cost savings of finding cancer early

- Recently published Canadian research^{xxv} shows that there are large reductions in treatment costs when cancers are detected earlier. One stage 4 patient can cost up to \$500,000.
- A recent Canadian study shows potential savings of hundreds of millions of dollars annually by screening women aged 40-74 and avoiding the need for expensive therapies used for late-stage disease.^{xxvi}

The Task Force guideline creation processes are shown to be flawed. The Task Force must be rebuilt with appropriate accountability, transparency, and ethical oversight. To do anything less will mean the continued avoidable deaths and suffering of Canadian women.

ⁱ <u>https://www.youtube.com/watch?v=qr6DSPO8zak</u>

ⁱⁱ <u>https://canadiantaskforce.ca/about/history/</u>

ⁱⁱⁱ <u>https://canadiantaskforce.ca/breast-cancer-update-draft-recommendations/</u>

^{iv} <u>https://canadiantaskforce.ca/wp-content/uploads/2024/05/BCU_Draft-Rec_Discussion-tool_40-49_FINAL.pdf</u>

^v <u>https://www.ourcommons.ca/DocumentViewer/en/44-1/HESA/meeting-123/evidence</u>

vi <u>https://canadiantaskforce.ca/wp-content/uploads/2024/05/BCU_Draft-Rec_Discussion-tool_40-49_FINAL.pdf</u>

^{vii} <u>https://www.thestar.com/life/health-wellness/some-doctors-patients-want-canada-to-follow-u-s-proposal-for-earlier-mammograms/article_9bfba9c8-2ec7-5c05-ab9b-e906b39bc580.html</u>

viii <u>https://canadiantaskforce.ca/wp-content/uploads/2024/05/BCU_Draft-Rec_Discussion-tool_40-49_FINAL.pdf</u>

^{ix} <u>https://doi.org/10.1503/cmaj.180463</u>

^x https://doi.org/10.1101/2024.05.29.24308154

^{xi} https://doi.org/10.1101/2024.05.29.24308154

^{xii} https://doi.org/10.1101/2024.05.29.24308154

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^{xv} https://www150.statcan.gc.ca/n1/pub/82-003-x/2023001/article/00001-eng.htm

^{xvi} https://www.ourcommons.ca/documentviewer/en/44-1/HESA/meeting-94/evidence

^{xvii} <u>https://canadiantaskforce.ca/wp-content/uploads/2024/05/Comparative-effects-of-mammography-based-screening-strategies-KQ2-Systematic-Review-Preprint.pdf</u>

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^{xx} <u>https://www.hqontario.ca/Portals/0/documents/evidence/reports/recommendation-</u> <u>supplemental-screening-as-an-adjunct-to-mammography-for-breast-cancer-screening-in-</u> <u>people-with-dense-breasts-en.pdf</u>

^{xxi} <u>https://canadiantaskforce.ca/wp-content/uploads/2024/05/Comparative-effects-of-</u> mammography-based-screening-strategies-KQ2-Systematic-Review-Preprint.pdf

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https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/file/supporting_documents/breast-cancer-screening-draft-rec-bulletin.pdf

xxv https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10527628/

xvvi <u>https://acrobat.adobe.com/id/urn:aaid:sc:VA6C2:5fbe1519-efdc-4bc4-9b8d-405ae7781ee7</u>