Dense Breasts Canada's Presentation and Submission to the External Expert Review: Modernizing the development of preventive healthcare guidelines in Canada

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DENSE BREASTS CANADA

External Expert Review Consultation

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Dense Breasts Canada

My name is Jennie Dale, and I am the co-founder and executive director of Dense Breasts Canada (DBC). DBC was founded in 2016. DBC raises awareness of breast cancer screening and advocates for equitable and optimal screening, For the past 8.5 years, DBC has been advocating for the reform of the Canadian Task Force on Preventive Health Care (TF) and revision of the breast screening guidelines. We ran petitions signed by 100K Canadians, letter writing campaigns, published op-eds, submitted briefs to federal committees and wrote reports. We also testified to two federal government committees. We have a page on our website devoted to our concerns. We are very pleased this panel has been appointed to examine TF processes and governance and appreciate the opportunity to consult.

QUESTION 1

There are a number of practices that potentially undermine effective governance. One is the practice of basing the TF office at the institution of the Chair and making this institution responsible for providing administrative support and funding. This gives the Chair undue influence over TF activities. Another practice is spreading work out over several bodies attached to different entities. Working groups come together on an ad hoc basis, a science team is attached to the Public Health Agency of Canada (PHAC) and Evidence Review and Synthesis Centres are attached to various universities.

The concerns with the above practices and numerous others are addressed below.

1. The need for independent governance and oversight

- **Designate a public health body to oversee the Task Force**: While it is reasonable from a scientific point of view to have an arms length body, oversight is needed and a public health body should be designated to oversee the Task Force, i.e. PHAC or a College such as the Royal College of Physicians and Surgeons. The Public Health Agency of Canada (PHAC) was notified by the expert advisors to the Ottawa Evidence Review Synthesis Centre (ERSC) that their expert input was being disregarded by the TF. PHAC was also notified of unethical behaviour of both co-chairs. Yet, there were inadequate mechanisms to address the concerns raised.

- **External Expert Review**: This EER panel should not be a one-time review but rather the panel should participate in periodic external reviews of the TF processes to continue to assess the quality of evidence and methodology.
- **Political Accountability:** The TF was asked to testify recently to Committees. The Chair should be required to answer questions by the Standing Committee on Health annually.

2. The need for transparency

Every step in the process must be able to be readily scrutinized by stakeholders to prevent the TF from arbitrary or unreasonable decisions. Errors, either inadvertent or otherwise, can be identified and remedied. The TF should be required to identify decision points and, for each of these, report what information it received, how it assessed this information, and what decision it made based on this information.

- **Conflict of Interest** The ERSC is paid by the TF, and reliant on their funds to perform the evidence review. When there is interference by the TF in this process, this creates a conflict of interest. The ERSC ability to establish an objective evidence base should not be tied monetarily to the Task Force.
- **Working Group Meetings**: These meetings should be open for the public or transcripts should be provided upon request so that the decision-making processes is transparent.
- **Conflict-of-Interest Declaration Review**: Although the TF requires members to disclose potential conflicts of interest at the beginning of their volunteer term, there need needs to be ongoing evaluation of conflict of interest as we witnessed overt bias in articles and webinars the chair continued to produce.
- **Panel Member Removal:** During the 2023/2024 update, the TF chair made statements to the media indicating a prejudicial stance on the recommendations, up to a year before the update process had been completed. She was not removed from an influential leadership position, despite repeated efforts brought to the attention of PHAC.
- **Panel Member Term:** Currently the term is 4 years but members can stay longer**.** Members should be removed after a 4-year term and not be involved in making back-to-back guidelines in a specialty, as is the case for the breast guidelines.
- **Evidence** reviews, data sources, and modelling should be publicly available.

3. The need for specialist expertise on the TF panel

Experts with direct expertise in the area under review should be included in the guideline process in a meaningful manner and should be allowed to vote. TF members lack the necessary expertise to evaluate the significance of evidence, the validity of data, and the most suitable analytical methods concerning the current diagnosis and treatment of relevant diseases. The TF points to the inclusion of four breast cancer experts in its Working Group. The reality: these experts were not allowed to vote on the recommendations. The absence of meaningful involvement by content experts resulted in errors in interpretation of data. Many Canadians assume that the guidelines are made by experts. This is a breach of the public's trust.

- TF and working group membership needs to reflect the diversity of Canada's population, including Indigenous voices, racial minorities, and representatives of vulnerable populations.

4. The need for inclusion of the patient voice

- Patient representatives need to be involved in the guideline development process in a meaningful manner. The TF promoted their inclusion of patients. The reality: the patients had no vote on recommendations. Initially medical and technical terminology was not explained to them. The patients called a meeting to discuss their concerns. One quit, leaving only two. Patients must be included but require training to ensure meaningful input.

5. The need for current evidence and up to date modelling

- **Modern Evidence Incorporation**: It is essential to use the most recent, high-quality research, particularly studies reflecting modern technologies and diverse populations. This was not the case in the recent breast guideline and current evidence was often dismissed. There was also 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 TF must be up to date to reflect technological advances in treatment with improved outcomes. The 2024 draft recommendations did not reveal or release all evidence to support their conclusions. The modelling results are not yet published.

6. The need for more frequent updates to guidelines that would be responsive to the latest research and the changing healthcare environment

- Canadian guidelines are not updated frequently enough. Once the guidelines are published, they remain in place ~7 years. The cervical guideline has actually been in place for 11 years. There needs to be a schedule for updating the recommendations earlier as new research is published, so that they reflect current knowledge and clinical realities. The TF should: Commit to updating guidelines on a regular schedule (e.g., every 3-5 years) to incorporate the latest research and feedback.

7. The need for collaboration with internal and external stakeholders

- **Communication between the different evidence review centres:** There was no communication between the centres resulting in siloing.
- **Consultation**: The only communication we had with the TF was on Twitter when the Chair provided cryptic answers to our questions. There should be formal processes to consult with stakeholders, including advocacy groups, healthcare providers, and provincial/territorial health ministries.
- **Advisory Panels**: Create external advisory panels to review recommendations and provide input before guidelines are finalized.

- **International Comparisons**: There should be a comparison of guidelines from respected international bodies, such as the USPSTF and an understanding of why they made their recommendations, rather than an immediate dismissal of their findings as occurred in May 2023 by the chair.

8. The need for public communication

- **Public Feedback Opportunities**: Allow the public to comment on draft guidelines and incorporate meaningful feedback. The TF released a feedback survey, misleadingly promoting it as a survey for public input. PHAC clarified the TF designed the survey for researchers, doctors and other healthcare providers, using medical and scientific language. It was not designed for the public.
- **Clear Rationale for Recommendations**: Publish user-friendly summaries explaining the reasoning behind recommendations, addressing benefits, risks, and trade-offs. The 1000-person tool is not inclusive and does not include benefits.
- **Education Campaigns**: Actively inform the public and physicians about guideline changes and their implications through transparent and accessible communication channels. There is much confusion amongst both, with the thinking that mammograms are not recommended till age 50.

9. The need for monitoring and evaluation

- **Outcomes Tracking:** The TF needs to monitor the real-world impact of guidelines on health outcomes, equity, and access. There have been worsening outcomes with an increase in the incidence of later-stage breast cancer since 2011 following the recommendation **not** to routinely screen women in the 40s. The US monitored mortality trends after recommending against prostate cancer screening in 2012, and subsequently changed its prostate cancer screening recommendations in 2018. We have no similar monitoring ongoing in Canada.
- **Respond to errors made in previous guidelines.** The TF would not explain why figures for overdiagnosis and the number of breast cancer cases differ significantly from the numbers in the 2018 guidelines.
- **Feedback Loop**: Establish a mechanism for stakeholders and the public to report issues with guidelines and suggest improvements.
- **Performance Metrics**: Evaluate the Task Force's performance based on adherence to transparency, inclusivity, and evidence-based practices. The ECRI performance ratings touted by the TF were not backed up and no score cards could be produced unless one paid $8500.

QUESTION 2

Mandate: The mandate of the TF should be to provide equitable guidelines that meet the needs of diverse populations of Canadians. To do that they must prioritize transparency, inclusivity, and the use of modern evidence. To uphold the highest standards of medical and scientific integrity,

subject matter expertise is essential. There must be a clear governance structure and the TF should be accountable to an independent public health authority, There should be regular external reviews to ensure alignment with current science and best practices and regularly scheduled updates to guidelines to keep pace with evolving research and technological advances. There should be explanations of decision-making processes.

Collaboration The guidelines for each specialty need to be composed of expertise for that specialty but there can also be a cross functional table where a member of each group participates in table to share insights best practices from the Canadian landscape. A jurisdictional analysis including best practices is essential. Experts from other jurisdictions should be included at the table. There should be collaboration with stakeholders including provincial and territorial health authorities, healthcare professionals and international TF members. Currently, we have some provinces following guidelines and others not, creating geographical inequities. There should also be engagement with non-profits and advocacy organizations to integrate public concerns and lived experiences into decision-making.

QUESTION 3

The current process appears to treat subject-matter expertise as an input to be considered, along with other information, by decision-makers. Subject-matter experts must be brought into a more central role- of course with appropriate checks and balances.

One way to address equity and diversity issues is to create a role for a bioethics expert in the guideline development process.

It is essential to remove racial and system discrimination from the guideline making precises. It is evident in the breast screening guidelines**.** The TF gave the highest grade to research performed almost exclusively on white women in Canada and Europe from the 1960s to the 1980s. This ignores the important issues of earlier, more aggressive cancers and poorer outcomes in racialized women and fails to consider Canada's diverse population. To ensure appropriate representation of Canada's diverse population, the panel reviewing the evidence and the research they use should represent Canada's diverse population. The weighting of the evidence should emphasize more modern evidence that includes a diverse population.

The 2023 US breast screening guideline addressed the varying peak incidences among ethnicities by recommending starting screening at age 40. They made a commitment to help reverse the negative impacts of systemic and structural racism, gender-based discrimination, and bias. Canada should do the same.

Thank you to the EER panel for your work.

Presented Virtually with PowerPoint Jan 24, 2025

Good afternoon. My name is Jennie Dale. Ten years ago, I was diagnosed with breast cancer. Two years later, I co-founded Dense Breasts Canada (DBC). We are a volunteer-run, evidence-based organization advocating for better breast screening provincially and Task Force reform federally.

We speak to many women suffering physically and emotionally due to later stage diagnoses, as a result of the Task Force guidelines. Today, I carry their voices and those of the DBC advocates we have needlessly lost.

The Task Force implemented some guideline development changes for the breast screening update. Four breast cancer experts and 2 patients were included in Working Groups but they had no vote on recommendations. Three other experts contributed to evidence reviews, yet much of their input was disregarded. Current evidence was examined but its value diminished. A feedback survey was released to the public but not appropriate. Canadians need real change.

Today, I'd like to share some recommendations for external and ethical oversight, transparency, panel diversification, stakeholder engagement, and inclusivity. The DBC website has further recommendations and rationale.

Aside from governance changes needed, **oversight** of the Task Force's operations is also needed.

- We recommend establishing an independent panel of experts, patients, a bioethicist, and healthcare administrators to biennially assess the Task Force's processes, ensuring transparency, equity, and scientific rigour.
- It's essential to monitor the real-world impact of guidelines on health outcomes and access. Since the 2011 recommendation against breast screening in the 40s, there's been an increase in later-stage breast cancer cases. The guidelines also created inequitable access across Canada.
- There needs to be a commitment to updating the guidelines regularly to incorporate the latest research findings. It's been 11 years for cervical screening.
- The Task Force funds the Evidence and Synthesis Review Centres. This conflict of interest needs to be addressed. The Task Force dictated to the Ottawa evidence review that they had to include outdated RCTs from the 1960s-80s even though the experts disagreed.

Transparency must be increased and we recommend the following:

1. The criteria for which evidence is included and excluded needs to be divulged. Recent Canadian studies, including Statistics Canada data, were not appropriately valued in guideline development.
2. ALL evidence used to support recommendations, such as modeling, must be released. Eight months after the draft breast guidelines, the Task Force has yet to release the modelling.
3. Transcripts of Working Group meetings must be publicly accessible to allow stakeholders to understand the rationale behind decision-making.
4. Inconsistencies in published figures need to be addressed. Overdiagnosis figures and breast cancer numbers in the 2018 versus the 2024 guidelines remain unexplained.

Diversification of the panel

1. We need to diversify the task force. Its essential to include specialists with expertise in the relevant area to accurately evaluate evidence and reduce errors in data interpretation.
2. Its also important because it can minimize bias. Anti-screening bias among Task Force members is evident in media, webinars, articles, and responses to patients on X.
3. Recruitment of Task Force members needs to reflect the diversity of Canada's population,
4. Term limits for members need to be implemented, preventing involvement in back-to-back guidelines, as seen in the 2018 and 2024 breast guidelines
5. There needs to be involvement of diverse patient representatives in the development process, supported by proper training.

To enhance Public and Stakeholder Engagement, advocacy groups representing racial minorities, underserved populations, and also healthcare providers, and health ministries need to be engaged in guideline development. In 2018, stakeholders had the opportunity to review the guidelines before they came out; in 2024, this opportunity was rescinded.

- There should be a process that allows stakeholders and the public to report issues and a portal to upload new evidence.
- Surveys for feedback on the guidelines should be made accessible to the public with language that is not overly scientific. PHAC acknowledged that the recent breast survey was not designed for public use despite being promoted as such.

- Knowledge translation materials should be clear, user-friendly and address both benefits and risks. The current 1,000-person tool is not inclusive.
- The public and physicians need to be clearly informed about guideline changes. Differing guidelines from the Task Force and specialty societies leave physicians and patients unsure of optimal screening- with many believing mammograms are not allowed until age 50.

Inclusivity

When the U.S. Task Force guidelines changed to recommend screening at age 40, they emphasized their new guidelines were inclusive.

Canada also needs contemporary, inclusive guidelines that reflects our diverse population

We need to ensure a space for a bioethics expert in guideline making.

We must also prioritize morbidity and go beyond our focus on mortality for holistic recommendations.

Canadians deserve better.

Thank you for inviting me today and thank you to the panel for your critical work.