Maternal age–based prenatal screening for chromosomal disorders

Attitudes of women and health care providers toward changes

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Abstract

Objective To explore views of women and health care providers (HCPs) about the changing recommendations regarding maternal age–based prenatal screening.

Design Mixed-methods design.

Setting Ontario.

Participants A sample of women who had given birth within the previous 2 years and who had attended a family medicine centre, midwifery practice, or baby and mother wellness program (n = 42); and a random sample of family physicians (n = 1600), and all Ontario obstetricians (n = 694) and midwives (n = 334) who provided prenatal care.

Methods We used focus groups (FGs) to explore women’s views. Content analysis was used to uncover themes and delineate meaning. To explore HCPs’ views, we conducted a cross-sectional self-completion survey.

Main findings All FG participants (42 women in 6 FGs) expressed the importance of individual choice about prenatal screening modality, regardless of age. They described their perception that society considers women older than 35 to be at high obstetric risk and raised concerns that change in the maternal age–related screening policy would require education. The HCP survey response rate was 40%. Results showed 24% of HCPs agreed that women of any age should be eligible for invasive diagnostic testing regardless of prenatal screening results; 15% agreed that the age for diagnostic testing should be increased to 40 years, 14% agreed that diagnostic testing should be reserved for women with positive prenatal screening results, and 45% agreed that prenatal screening should remain unchanged.

Conclusion Maternity care organizations have recommended that maternal age–based prenatal screening is no longer appropriate. Informed choice is of paramount importance to women and should be part of any change. Health care providers need to be engaged in and educated about any change to screening guidelines to offer women informed choices.

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EDITOR’S KEY POINTS
• Traditionally, women have been offered prenatal diagnostic testing when they are 35 years of age or older at their estimated delivery date. Recent recommendations state that all women should be offered prenatal screening and that maternal age alone should not be used as a basis for recommending invasive testing when noninvasive prenatal screening for aneuploidy is available.

• In the focus group study, all participants expressed the importance of individual choice about prenatal screening modalities, regardless of age. Participants discussed how age 35 seemed to be accepted by society as the age at which the risk of chromosomal abnormalities increases. Participants strongly recommended that any changes to maternal age–related prenatal screening policy that had the potential to decrease access to these services must be communicated clearly and in a timely manner to both women and health care providers (HCPs).

• The HCPs were unsure of how maternal age–based screening should change. Two-thirds disagreed with the increase to 40 years as the age at which women would have direct access to diagnostic testing. A similar proportion disagreed with eliminating age as a criterion altogether, offering diagnostic tests based on results of screening tests. There likely is a growing awareness among HCPs that maternal age–based prenatal screening is no longer appropriate, but our data suggest a disconnect between the views of experts in the field and HCPs.
Dépistage prénatal des anomalies chromosomiques en fonction de l'âge de la mère

Attitude des femmes et des membres du personnel soignant au regard des modifications éventuelles

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Résumé

Objectif Déterminer ce que pensent les femmes et le personnel soignant (PS) des nouvelles recommandations sur le dépistage prénatal en fonction de l'âge de la mère.

Type d’étude Étude utilisant plusieurs méthodes.

Contexte L’Ontario.

Participants Un échantillon de femmes ayant accouché au cours des 2 années précédentes et qui avaient été vues dans un centre de médecine familiale ou une clinique de sages-femmes, ou qui avaient participé à un programme de bien-être pour la mère ou le bébé (n=42); et un échantillon aléatoire de médecins de famille (n=1600) plus tous les obstétriciens (n=694) et les sages-femmes de l’Ontario qui avaient prodigué des soins prénataux (n=334).

Méthodes On a utilisé des groupes de discussion (GD) pour obtenir l’opinion des femmes. Une analyse de contenu a permis d’extraire les thèmes et d’en préciser la signification. L’opinion du PS a été estimée à l’aide d’une enquête transversale auto-répondue.

Principales observations Les participantes aux GD (42 femmes réparties dans 6 GD) ont toutes souligné l’importance de laisser à chacune le choix du mode de dépistage prénatal, quel que soit leur âge. Elles ont mentionné être conscientes du fait que la société considère que les femmes de plus de 35 ans présentent un risque obstétrical plus élevé et se sont dites préoccupées par le fait qu’une modification de la politique de dépistage en fonction de l’âge nécessiterait des efforts d’information. Le taux de réponse à l’enquête auprès des membres du PS était de 40 %. Les résultats ont montré que 24 % de ces derniers étaient d’accord avec l’idée que les femmes devraient avoir droit à un examen diagnostic invasif quel que soit leur âge ou les résultats du dépistage prénatal; 15 % estimaient qu’on devrait augmenter à 40 ans l’âge où une femme doit avoir directement accès au test diagnostique. Une proportion semblable n’était pas d’accord avec l’idée d’éliminer complètement l’âge comme critère, suggérant plutôt d’offrir les tests diagnostiques selon les résultats des tests de dépistage. Il semble que les membres du PS sont de plus en plus conscients du fait que le dépistage prénatal basé sur l’âge de la mère n’est plus approprié, mais nos données donnent à croire en une disparité entre l’opinion des experts du domaine et celle des membres du PS.

Conclusion Selon les recommandations des organisations responsables des soins de santé maternelle, un dépistage prénatal basé sur l’âge de la mère n’est plus approprié. Tout changement devrait insister sur l’importance de donner aux femmes la possibilité d’un choix éclairé. Les membres du PS devront être engagés et informés à l’égard de tout changement dans les directives concernant le dépistage, de façon à permettre aux femmes de faire un choix éclairé.
In North America, women have traditionally been offered prenatal diagnostic testing when they are 35 years of age or older at their estimated date of delivery. This cutoff was selected for several historical reasons, including limited availability of providers undertaking amniocentesis and chorionic villus sampling (CVS), cost-benefit analyses, the increased risk of Down syndrome with advancing age, and data suggesting that at the age of 35 years, a woman has a similar chance of delivering a child with a numeric chromosomal anomaly as experiencing a miscarriage after amniocentesis. Recently, several publications and maternity care organizations have questioned eligibility for invasive testing based on maternal age. The Society of Obstetricians and Gynaecologists of Canada (SOGC) has recently recommended that all pregnant women should be offered prenatal screening and, generally, only those with screening test results above a predetermined cutoff should be offered invasive testing. They state,

Maternal age alone is a poor minimum standard for prenatal screening for aneuploidy, and it should not be used as a basis for recommending invasive testing when non-invasive prenatal screening for aneuploidy is available.

Before this, the SOGC had recommended maternal age of 40 at delivery as an indication for direct access to invasive diagnostic testing (amniocentesis or CVS). These new recommendations have arisen partly in response to the improved detection rate of trisomy 21 and 18 with improved screening protocols incorporating multiple biochemical and ultrasound markers, such as integrated prenatal screening and first-trimester screening. In addition, the change was recommended to reduce unintended fetal loss resulting from miscarriage following invasive diagnostic testing. In contrast, the American College of Obstetricians and Gynecologists (ACOG) and others have suggested that, irrespective of age, a woman should be allowed to choose the screening or diagnostic test that best meets her needs and that age 35 should be removed as the threshold for offering diagnostic testing. Proponents of this approach cite the importance of individual values in decision making, the increased accuracy of prenatal screening tests, and lower miscarriage rates associated with amniocentesis compared with earlier studies (1 in 300 to 500 compared with as low as 1 in 1600) as factors that might affect women's decision making. Wilson suggests that the SOGC recommendation is more of a “public health approach” in a publicly funded health care system with limited resources, while the ACOG recommendation is one that supports “individual choice” in a private-payer system.

Using the age at which the risk of miscarriage from diagnostic testing equals the risk of a baby being born with a chromosome anomaly as the threshold for offering diagnostic testing implicitly assumes that women value these 2 outcomes equally and independently. Studies have shown that women vary substantially in how they view these and other outcomes of prenatal testing decisions relative to one another. Maternal age-based screening also has considerable resource implications, as there has been a dramatic change in the age distribution of pregnant women. Using advanced maternal age (≥35 years) as the sole determining factor to offer amniocentesis would result in the offer of an invasive prenatal diagnostic procedure to approximately 17% of pregnant women in Canada.

With calls for a new approach to prenatal screening but with different recommendations as to how this might occur, our purpose was to determine the views of women and health care providers (HCPs) on these new recommendations about maternal age-based screening for chromosomal disorders.

METHODS

This study used a mixed-methods design and drew from a larger project with 2 components. One component explored women's attitudes and opinions about a new educational resource, “A Guide to Understanding Prenatal Screening Tests—for Women and their Families,” which detailed the available methods of prenatal screening in Ontario. The other component of the study explored HCPs' attitudes to a new educational resource titled “Reference Guide for Health Care Providers. Prenatal Screening Tests for the Detection of: Down Syndrome, Trisomy 18 and Open Neural Tube Defects.” To explore women's views, we used the qualitative method of focus groups (FGs). Because the proposed changes to maternal age-based prenatal screening are new and complex, we believed FGs would allow for the necessary explanations and enable exploratory discussion. The only eligibility criterion was that women had to have given birth within the previous 2 years. Letters of invitation were sent to all eligible women who attended 3 urban academic family medicine centres (FMCs), 2 urban–suburban midwifery practices (MWPs), and 1 rural baby and maternal wellness program (MatWP) in northern Ontario. All those who were able to attend on the chosen dates were included. Focus groups were conducted by a member of the team with qualitative research expertise. A semistructured
A research interview guide was created and piloted. Focus group conversations were audiorecorded and transcribed verbatim. The analysis followed an iterative process, with core team members (S. Tobin, J.C., and A.R.) meeting after each FG to discuss findings requiring clarification or further discussion. To facilitate data coding, management, and analysis, NVivo software, version 2.0, was used. Content analysis was used to uncover themes and delineate meaning with feedback from the full research team. The themes described in this paper reached saturation.

To examine HCPs’ views, we conducted a self-completion survey of a random sample of Ontario FPs (1600 from the Ontario College of Family Physicians database), all Ontario obstetricians (OBs; 694 from the Scottsinfo Medical Lists of Ontario physicians) and all Ontario midwives (MWs; 334 from the College of Midwives of Ontario database). We used a modified Dillman tailored design method, with initial mailing of the survey followed by a postcard reminder 2 weeks later and re-mailing of the survey 8 weeks later. Health care providers were eligible if they provided prenatal care. Data were entered in a Microsoft Excel spreadsheet and imported into SPSS, version 15.0, for analysis. Frequency distributions and means were generated for all variables and chi-square tests were used to assess differences between provider groups.

Ethics approval was obtained from the research ethics boards of Mount Sinai Hospital, Toronto East General Hospital, and North York General Hospital, all in Toronto, Ont. The study was conducted in 2007 and was funded by the Women’s Health Council of the Ontario Ministry of Health and Long-Term Care.

RESULTS

Focus group study of women’s experiences

Demographic characteristics of the 42 women who participated in the 6 FGs are listed in Table 1. There was a great deal of confusion among the participants about maternal age–related screening and proposed changes to the screening guidelines. It was necessary for the moderator to explain the background briefly and ask specifically, “Should the age at which diagnostic testing is available be increased from 35 to 40?” and “Should everyone, at any age, have the option of diagnostic testing?” The themes that emerged were individual choice, societal expectations, and recommendations on how to handle any change in maternal age–related prenatal screening policy.

Individual choice. All participants expressed the importance of having individual choice about prenatal screening modalities, regardless of age.

I think it would be better if it was regardless of age. I think if you wanted to know, it would be nice to have the option of choice, being able to find out regardless of how old you are, to know for sure. (FG 6, MWP)

These are all personal decisions. They should all be an option, as far as I’m concerned. (FG 3, MatWP)

Participants also described some of the factors that influenced individual choice. They described the different choices about prenatal screening that women might make, depending on their feelings about disability. They said that feelings about disability might be unrelated to the age of the birth mother, again supporting individual choice of prenatal screening modality regardless of age: “If you’re the one that has to raise that child and it’s got a disability, I think it could be more of a burden for a younger person or an older person. It could be either way.” (FG 3, MatWP)

Women acknowledged that in the Canadian system, the full range of choices at any age might entail additional costs: “I guess there’s a fee you have to be charged if you want that option.” (FG 1, FMC)

Societal expectations. Participants discussed how age 35 seemed to be accepted by society as the age at which the risk of chromosomal abnormalities

Table 1. Demographic characteristics of FG participants: N = 42.

<table>
<thead>
<tr>
<th>CHARACTERISTICS</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (range), y</td>
<td>33 (22-43)</td>
</tr>
<tr>
<td>Offered prenatal screening, n (%)</td>
<td></td>
</tr>
<tr>
<td>• Yes</td>
<td>41 (98)</td>
</tr>
<tr>
<td>• No</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Had prenatal screening, n (%)</td>
<td></td>
</tr>
<tr>
<td>• Yes</td>
<td>33 (80)</td>
</tr>
<tr>
<td>• No</td>
<td>7 (17)</td>
</tr>
<tr>
<td>• Not sure</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Highest level of education, n (%)</td>
<td></td>
</tr>
<tr>
<td>• High school</td>
<td>3 (7)</td>
</tr>
<tr>
<td>• College</td>
<td>11 (26)</td>
</tr>
<tr>
<td>• University</td>
<td>13 (31)</td>
</tr>
<tr>
<td>• Postgraduate degree</td>
<td>11 (26)</td>
</tr>
<tr>
<td>• Professional degree</td>
<td>4 (10)</td>
</tr>
</tbody>
</table>

FG—focus group.
increases. They raised the concern that this age is well known, suggesting that it could be a difficult perception to change.

I went into it going, well, I’m over 35, I’ve got to have these tests—I’m going to have these tests. Maybe it is just ... societally, it’s slammed into our mind now that if you’re 35 you’re past your due date and you should ... it was lodged in my head, anyway, enough to act on it. (FG 5, FMC)

[The] bottom line is, your risk goes up when you’re over 35—that’s a fact, that’s been scientifically proven. Amnio[centesis] should be available to you if you want it. (FG 3, MatWP)

**Recommendations on handling age policy change.** Participants strongly recommended that any changes to maternal age–related prenatal screening policy that had the potential to decrease access to these services must be communicated clearly and in a timely manner to both women and HCPs.

I think you should phase it in ... because I think it would be very distressing for a woman who got caught—who was, say, 37—and if all of a sudden tomorrow the ministry of health announces, “Guess what, you’ve got to be 40.” (FG 4, MWP)

If the age was to be pushed up to 40 then it would have to be partnered with a policy of ensuring that health care providers ... get this information to people well in time so they can ... get the testing done if they want to. (FG 6, MWP)

**Provider survey**

Once ineligible or unavailable surveys were removed, the overall response rate was 40% (946 of 2380): 39% of FPs (569 of 1469), 36% of OBs (213 of 592), and 51% of MWs (164 of 319). **Table 2** shows provider demographic characteristics. **Table 3** shows HCPs’ responses to proposed changes to maternal age–based prenatal screening. At the time of the study, pregnant women were still eligible for amniocentesis or CVS if they were 35 years of age or older at their expected delivery date, had a positive prenatal screening test (equivalent to the risk of a 35-year-old or greater), or if they had a family history of genetic disease or abnormal ultrasound findings. Overall, the findings suggested a range of views on issues of eligibility for invasive prenatal diagnostic testing, with some differences in response patterns between the 3 professional groups. In summary, about a quarter of all responding HCPs agreed or strongly agreed with removing age as a criterion for invasive prenatal diagnostic testing, with MWs (18%) less often in favour, and OBs (32%) more often in favour. Overall, 15% agreed or strongly agreed that the eligible age for prenatal diagnostic testing should be increased to 40 years, with MWs (32%) most and FPs (6%) least in agreement. In all, 14% agreed or strongly agreed that amniocentesis should be reserved for women with positive screening results for Down syndrome. Finally, 45% of all respondents agreed or strongly agreed that “the current situation should remain as is.” About half of FPs agreed with this statement, while about a third of OBs and MWs agreed.

**DISCUSSION**

The findings from the FGs suggest that women support the importance of choice in prenatal screening and that all options should be available regardless of age, with appropriate counseling. There was a strong message from these participating women that they perceived age 35 to be recognized by society as the age at which pregnancy becomes “high risk”; any change in policy, whether restricting direct access to diagnostic testing to those older than 40 years or to those

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**Table 2. Demographic characteristics of HCP respondents**

<table>
<thead>
<tr>
<th>CHARACTERISTICS</th>
<th>ALL HCPs</th>
<th>FPs</th>
<th>OBs</th>
<th>MWs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD) age, y</td>
<td>43.6 (9.3)</td>
<td>42.9 (8.3)</td>
<td>48.5 (10.6)</td>
<td>40.2 (8.9)</td>
</tr>
<tr>
<td>Sex, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Male</td>
<td>288 (32)</td>
<td>181 (33)</td>
<td>107 (54)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>• Female</td>
<td>624 (68)</td>
<td>375 (67)</td>
<td>91 (46)</td>
<td>158 (100)</td>
</tr>
<tr>
<td>Self-defined practice location, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Metropolitan city or suburb</td>
<td>588 (65)</td>
<td>349 (64)</td>
<td>149 (75)</td>
<td>90 (58)</td>
</tr>
<tr>
<td>• Small city, town, or rural area</td>
<td>316 (35)</td>
<td>199 (36)</td>
<td>51 (25)</td>
<td>66 (42)</td>
</tr>
</tbody>
</table>

HCP—health care provider, MW—midwife, OB—obstetrician.
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Table 3. Survey responses of HCPs to options for prenatal testing eligibility

<table>
<thead>
<tr>
<th>STATEMENTS AND OPTIONS</th>
<th>ALL HCPs, N (%)</th>
<th>FP's N (%)</th>
<th>OBS, N (%)</th>
<th>MWs, N (%)</th>
<th>P VALUE*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women of any age should be eligible for amnio or CVS (regardless of prenatal screening result)</td>
<td>552 (61)</td>
<td>319 (58)</td>
<td>117 (58)</td>
<td>116 (74)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>• Disagree or strongly disagree</td>
<td>141 (15)</td>
<td>109 (20)</td>
<td>20 (10)</td>
<td>12 (8)</td>
<td></td>
</tr>
<tr>
<td>• Neutral</td>
<td>216 (24)</td>
<td>123 (22)</td>
<td>65 (32)</td>
<td>28 (18)</td>
<td></td>
</tr>
</tbody>
</table>

The age at which women are eligible to request amnio or CVS should be increased to ≥ 40 y <.001

| • Disagree or strongly disagree | 609 (67) | 426 (77) | 121 (60) | 62 (40) | |
| • Neutral | 161 (18) | 91 (17) | 28 (14) | 42 (28) | |
| • Agree or strongly agree | 134 (15) | 34 (6) | 51 (26) | 49 (32) | |

Only women with positive screening results for Down syndrome should be offered amnio (age should not be a criterion) <.001

| • Disagree or strongly disagree | 613 (68) | 391 (71) | 130 (65) | 92 (60) | |
| • Neutral | 162 (18) | 98 (18) | 26 (13) | 38 (25) | |
| • Agree or strongly agree | 129 (14) | 61 (11) | 45 (22) | 23 (15) | |

The current situation should remain as is <.001

| • Disagree or strongly disagree | 163 (18) | 68 (12) | 64 (32) | 31 (21) | |
| • Neutral | 331 (37) | 194 (36) | 68 (34) | 69 (46) | |
| • Agree or strongly agree | 399 (45) | 283 (52) | 66 (34) | 50 (33) | |

Amnio—amniocentesis, CVS—chorionic villus sampling, HCP—health care provider, MW—midwife, OB—obstetrician.

*χ² test.

with positive screening results, or offering diagnostic testing to women of all ages, must be accompanied by education and explanation. This theme of “informed choice” has been found in many studies of women’s experiences of prenatal screening.26–29

Less than half of the participating HCPs agreed that maternal age–based prenatal screening should not change. However, our findings suggest that the other participating HCPs are unsure what change they would prefer. Most disagreed with the ACOG recommendation that women of any age should be eligible for diagnostic testing, if they wish it. Two-thirds disagreed with the increase to 40 years as the age at which women would have direct access to diagnostic testing (2007 SOGC recommendation).7 A similar proportion disagreed with eliminating age as a criterion altogether, offering diagnostic tests based on results of screening tests (2011 SOGC recommendation).9 The remaining respondents seemed to be unsure or have no strong views either way. Findings were significantly different between the HCP groups (P<.001). Possible explanations include differing approaches to evidence, policies, or shared decision making among different practitioners. Future study is needed to understand the reasons for these differences. These findings suggest the need for discussion with HCPs about proposed policy changes along with education about the reasons for such changes. There likely is a growing awareness among HCPs that maternal age–based prenatal screening is changing but our data suggest a disconnect between the views of experts in the field and HCPs; this should be addressed.

In contrast to the SOGC position, the ACOG approach offers the full choice of options to all
women. Many studies highlight women’s desire for informed choice, although women require information and attention to their values and supports to assist with decision making. 26–31 There are limited data on the preferences of women younger than 35 years regarding diagnostic testing. 6 The extent to which this would be chosen, once women were educated about all available options, remains to be determined.

The recent SOGC approach 9 would require that women be informed about prenatal screening options, and that invasive testing would generally be offered to women based on the results of prenatal screening tests. There is some evidence that women will accept screening-directed diagnosis, 5,32–34 The challenge of this approach, as outlined by Hodges and Wallace, is that “it is often difficult to ‘remove’ access to an element of health care once it is established.” 15 Our qualitative findings support the challenges of making “40 ... the new 35” 35 or removing age-based screening entirely. The Canadian health care system generally does not permit private purchase of additional tests, but this might have to be considered in the future.

Limitations
This study has limitations. It was conducted in 2007, concurrent with changing guidelines. However, even at present, some but not all Canadian centres have changed the age at which they offer diagnostic testing to age 40 and older. Screening recommendations are likely to change in the future, particularly with the advent of noninvasive approaches to screening and diagnosis through the analyses of fetal cells or nucleic acids in maternal circulation. 10 The findings of the current study highlight the educational challenges for the public and providers that accompany changes in clinical practice recommendations.

The qualitative study involved the difficult concept of maternal age-based screening versus diagnostic testing embedded in a larger study of women’s experience of prenatal screening and feedback on an educational guide. These were well-educated women with a high uptake of prenatal screening. Our findings might not be generalizable to all women but offer some insight into women’s responses to the proposed changes in maternal age-related screening. Certainly they raise issues to be considered when educating women about prenatal screening. The provider survey had a 40% response rate and might not reflect the views of nonrespondents. We compared demographic characteristics of our survey respondents to the 2007 National Physician Survey (NPS) 36 of Ontario FPs, demographic characteristics of Ontario OBs in 2001 to 2002, 37 and HealthForceOntario 2008 38 data for MWs, as these were the best comparators we could obtain. Our FP respondents were slightly younger (study mean age 43 years vs NPS mean age 50 years) and more likely to be women (study 67% vs NPS 39%), but had similar practice locations (study 64% urban vs NPS 71% urban). Our OB respondents were of similar age (study mean age 48.5 years vs Ontario mean ages 42 [women] and 53 [men] years), and were more likely to be women (study 46% vs Ontario 33%). Midwives were of similar age (study mean age 40 years vs Ontario mean age 41 years) and of the same sex (study 100% female vs Ontario 100% female). The results strongly indicate a need to engage providers if policy changes are being implemented regarding age-based prenatal screening.

Conclusion
It is clear that maternity care organizations and experts in the field believe that maternal age–based prenatal screening is no longer appropriate. Informed choice is of paramount importance to women and should be part of any policy change. Health care providers will need to be engaged in and educated about any policy change in this area to offer informed choices to pregnant women.

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Contributors
All authors contributed to the concept and design of the study; data gathering, analysis, and interpretation; and preparing the manuscript for submission.
Competing interests

Dr Blaine is a member of, and has received funding from, the Strategic Advisory Panel of the Centre of Excellence in Personalized Medicine in Montreal, Que. None of the other authors has any competing interests to declare.

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