

# Non-invasive Prenatal Testing and the Unveiling of an Impaired Translation Process

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## Abstract

Non-invasive prenatal testing (NIPT) is an exciting technology with the potential to provide a variety of clinical benefits, including a reduction in miscarriages, via a decline in invasive testing. However, there is also concern that the economic and near-future clinical benefits of NIPT have been overstated and the potential limitations and harms underplayed. NIPT, therefore, presents an opportunity to explore the ways in which a range of social pressures and policies can influence the translation, implementation, and use of a health care innovation. NIPT is often framed as a potential first tier screen that should be offered to all pregnant women, despite concerns over cost-effectiveness. Multiple forces have contributed to a problematic translational environment in Canada, creating pressure towards first tier implementation. Governments have contributed to commercialization pressure by framing the publicly funded research sector as a potential engine of economic growth. Members of industry have an incentive to frame clinical value as beneficial to the broadest possible cohort in order to maximize market size. Many studies of NIPT were directly funded and performed by private

industry in laboratories lacking strong independent oversight. Physicians' fear of potential liability for failing to recommend NIPT may further drive widespread uptake. Broad social endorsement, when combined with these translation pressures, could result in the "routinization" of NIPT, thereby adversely affecting women's reproductive autonomy. Policymakers should demand robust independent evidence of clinical and public health utility relevant to their respective jurisdictions before making decisions regarding public funding for NIPT.

## Résumé

Le dépistage prénatal non effractif (DPNE) est une technologie remarquable ayant le potentiel d'offrir une multitude d'avantages cliniques, notamment une réduction des fausses couches, grâce à la diminution du nombre d'examen invasifs. Cependant, certains soupçonnent que les avantages économiques et cliniques à court terme du DPNE ont été surévalués, et ses limites et méfaits, minimisés. Il y a donc lieu d'étudier de quelle façon les pressions sociales et les politiques influencent l'application concrète, la mise en œuvre et l'utilisation d'innovations en soins de santé comme le DPNE. Malgré les réserves quant à son rapport coût-efficacité, le DPNE est souvent présenté comme un premier palier d'examen qui devrait être offert à toutes les femmes enceintes. De nombreux facteurs ont contribué à un environnement translationnel problématique au Canada, poussant à l'adoption de cette technologie comme premier palier d'examen. Les gouvernements ont exercé des pressions pour qu'on commercialise le DPNE, en présentant le secteur de la recherche financée par les deniers publics comme un possible moteur de croissance

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économique. Afin d'optimiser la taille de leur marché, les acteurs du secteur ont tout avantage à défendre la valeur clinique de cette technologie pour en vanter les bienfaits pour le plus grand nombre de personnes possible. Nombre d'études sur le DPNE ont été réalisées et financées directement par le secteur privé dans des laboratoires sans supervision indépendante adéquate. Par ailleurs, la crainte pour les médecins d'être tenus responsables s'ils ne recommandent pas un DPNE à leurs patientes peut aussi provoquer l'adoption généralisée de la procédure. Combinée à ces pressions de mise en application, la forte adhésion sociale pourrait mener à une « systématisation » du DPNE et, par conséquent, nuire à l'autodétermination reproductive des femmes. C'est pourquoi les décideurs devraient, avant de prendre des décisions relativement au financement public du DPNE, exiger des preuves solides et indépendantes sur sa pertinence clinique et sanitaire dans leur province ou leur territoire.

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## CONTEXT

The development and potential clinical application of non-invasive prenatal testing (NIPT) have generated an increasing amount of attention in the scientific and health care communities,<sup>1,2</sup> in the media,<sup>3,4</sup> and among policymakers.<sup>5–7</sup> NIPT is an exciting technology with the potential to provide a variety of clinical benefits, including a reduction in the number of women undergoing amniocentesis and chorionic villus sampling and, consequently, a reduction in the number of miscarriages and related health effects caused by invasive procedures.<sup>8,9</sup> Some have suggested that the introduction of NIPT could reduce health care costs and enhance reproductive autonomy by broadening women's choices.<sup>10</sup> However, there is also concern that the economic and near-future clinical benefits have been overstated and the potential limitations and harms underplayed.<sup>11–13</sup> Indeed, multiple forces have created a less than ideal translational environment, one that may be creating pressure to implement NIPT prematurely and utilize it in a manner that is not supported by the best available evidence.<sup>14–16</sup>

NIPT was developed as a commercial screening test in the United States after the discovery that trace quantities of placental DNA are present in the bloodstream of a pregnant woman; placental DNA is largely composed of DNA also shared by the fetus, although this is not the case in confined placental mosaicism.<sup>17,18</sup> NIPT screens for aneuploidies such as trisomy 21 (Down syndrome), trisomy 18, trisomy 13, and other chromosome number abnormalities, without increasing the risk of miscarriage and with

a higher reliability than many current screening tests. However, confirmation of the results using amniocentesis or chorionic villus sampling is required. In Canada, there have been recommendations to publicly fund NIPT.<sup>19</sup> Currently, British Columbia and Ontario have approved funding of NIPT as a second tier screening test—that is, a test for women who have already been identified as having a high-risk pregnancy.<sup>20,21</sup> Professional societies such as the Society of Obstetricians and Gynaecologists of Canada concur with this usage.<sup>22</sup> However, some companies that sell NIPT, as well as some commentators and researchers, have suggested that it should be provided as a first tier screen for all pregnant women, regardless of risk profile.<sup>23–26</sup> Most NIPT currently performed in Canada is provided by companies based in the United States.

Important discussions about the true value of NIPT for couples, health systems, and the public are ongoing.<sup>5,8,11,12</sup> Existing innovation policies and market forces have had an impact on the presentation, adoption, and clinical utilization of NIPT. For example, some have speculated that commercialization pressures may have an impact on the representation and translation of emerging technologies,<sup>27</sup> and that existing patents have already shaped the utilization of NIPT, at least in the United States.<sup>28</sup>

NIPT, therefore, presents an opportunity to explore the ways in which a range of social pressures and policies can influence the translation, implementation, and use of a health care innovation. Here, we discuss the pressures that shape how NIPT is being adopted and funded in Canada and provide recommendations for what needs to change to promote an evidence-based approach that will benefit both Canadians and their public health care systems.

## ASSESSING THE BENEFITS

NIPT is undoubtedly an exciting clinical development, and its effect of reducing the number of invasive procedures is already being felt by the health systems in which it has been implemented. However, independent assessments of this technology have consistently identified reasons to ask for stronger and independent evidence to support some of the claimed benefits. For example, NIPT is increasingly being framed as a possible first tier screen that should be offered to all pregnant women,<sup>23,29,30</sup> while several scientific societies and health technology assessments have argued against such a use because of the lack of unbiased and clear evidence that first tier NIPT would be a good use of health care funding.<sup>31–33</sup> Independent assessments of NIPT have concluded that although there is a high risk of bias in

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