HOLOGIC

Recent Canadian studies show that primary screening with the mRNA-based Aptima HPV assay reduces false positives and saves costs

FOCAL-DECADE study shows that primary screening with the mRNA-based Aptima HPV assay has a similar long-term risk as a DNA-based assay.[1,2] Based on the outcomes of a health economic model for Ontario, primary screening with the Aptima HPV assay has the potential to save >$17m annually in Canada.[3]

Results from the model show that the choice of HPV test is important when implementing a primary HPV screening program. The use of the mRNA-based Aptima® HPV assay for primary screening reduces overall screening costs, unnecessary colposcopies and early recall.

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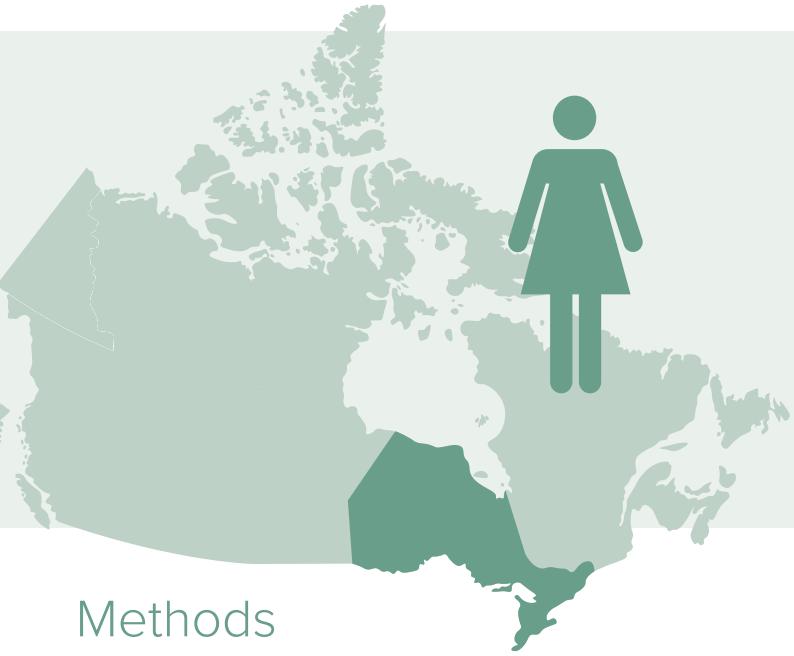
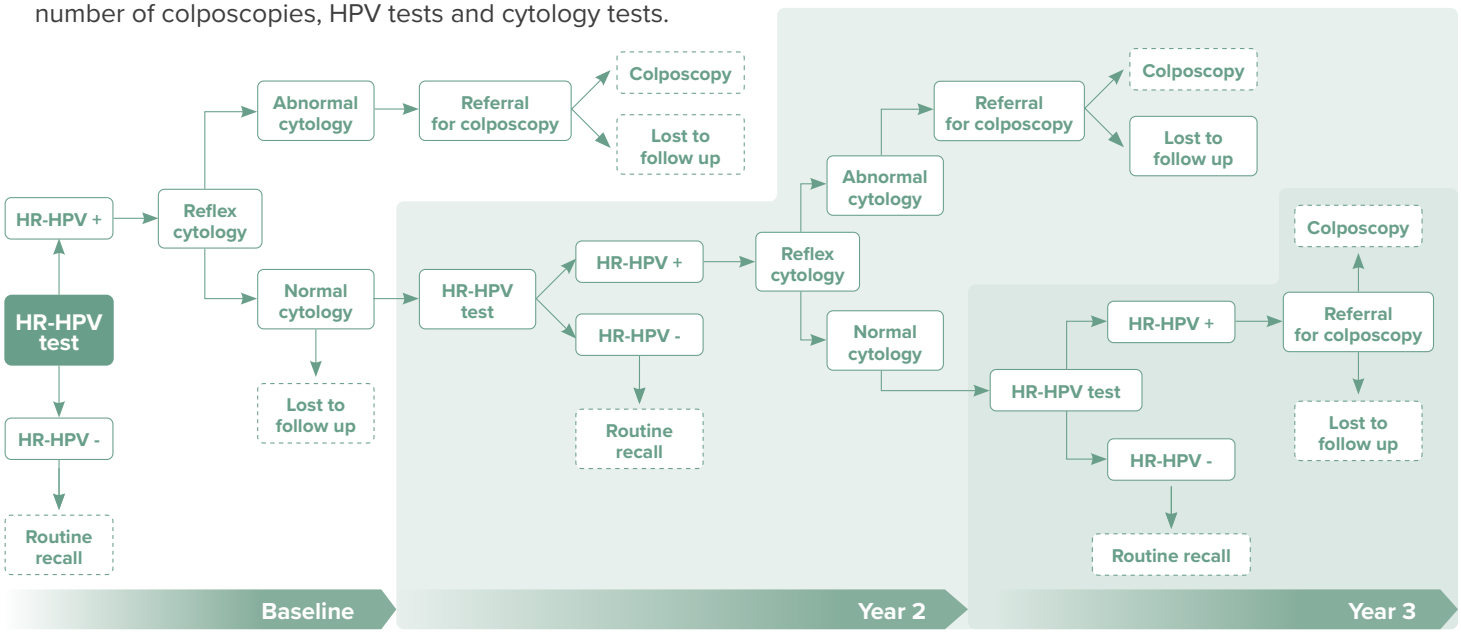


Introduction

- Ontario is one of the first regions in Canada to consider HPV primary screening.
- The mRNA-based Aptima HPV test has a similar sensitivity and a higher specificity compared with a DNA-based test.[4,5]
- Due to its higher specificity, using the Aptima HPV assay in a cervical cancer screening program results in fewer false positive results, which subsequently reduces the number of unnecessary follow-up cytology tests and colposcopies, thereby saving costs.[1,3]

Methods

- **Objectives:** To model the impact of using two different types of HR HPV tests, the mRNA-based Aptima assay and DNA (Hybrid Capture 2) as part of a hypothetical primary HPV screening program in Ontario, Canada.
- **Study outcomes:** Costs of the screening program, number of colposcopies, HPV tests and cytology tests.
- A decision tree model was adapted from a published UK study, with inputs drawn from published Canadian data.[3,6]
- Total screening population: 2,298,094 women between 30 and 65 years.



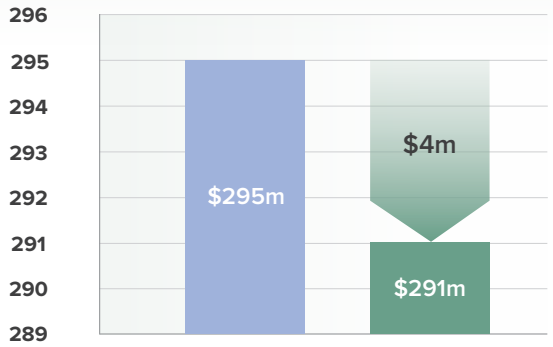
Structure of the decision tree model used to simulate primary HR-HPV cervical screening.[6]

Aptima® HPV Assay

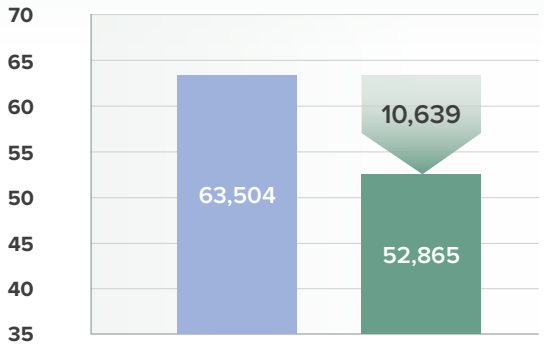
Results

- Fewer false positives with the Aptima HPV assay vs a DNA-based test has the potential to save >$4 million annually in Ontario. The majority of this saving comes from the reduction in unnecessary colposcopies (-10,639) and avoided cytology reflex tests (-38,659).

Costs saved annually with the Aptima HPV assay (▼1.4%)



Colposcopies avoided annually with the Aptima HPV assay (▼16.8%)

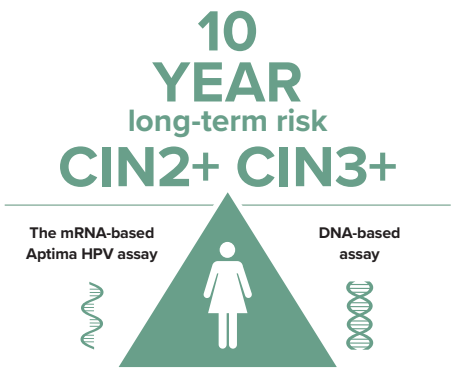


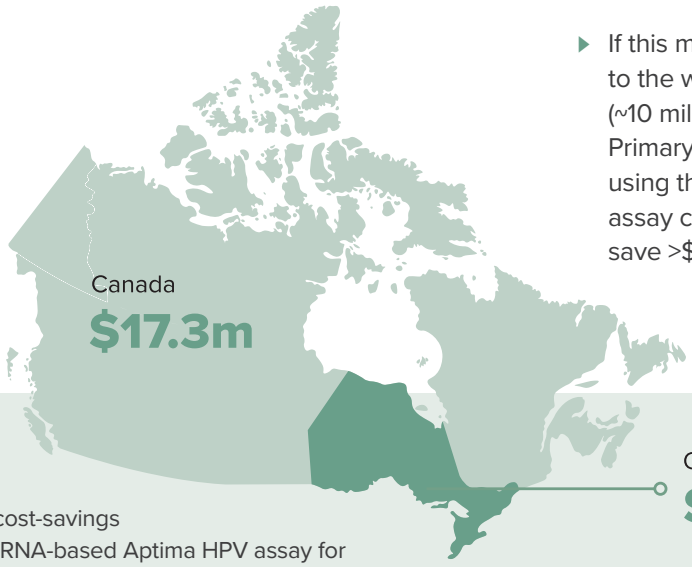
HPV DNA-based assay | The mRNA-based Aptima HPV assay

- The FOCAL trial was a randomized controlled trial evaluating HPV testing for primary cervical cancer screening. The 10-year follow-up, the FOCAL-DECADE, has now shown that women who tested negative for HPV at baseline, the long-term risk of CIN2+ or CIN3+ did not significantly differ regardless of whether a DNA- or mRNA-based (Aptima HPV assay) was used at baseline.[1,2]

Reduced anxiety supporting well-being for women

- Choosing the Aptima HPV assay, the most specific HPV test, reduces false positives and the unnecessary stress and anxiety associated with unnecessary colposcopies and reflex testing, supporting well-being for women.[1]





- If this model was applied to the whole of Canada (~10 million women).[7] Primary HPV screening using the Aptima HPV assay could potentially save >$17 million annually.

Conclusions

The results from this model, highlight the potential cost-savings that can be made by choosing the highly specific mRNA-based Aptima HPV assay for primary HPV screening programs, which will benefit both women and healthcare providers.

FOCAL-DECADE reinforces the use of the Aptima HPV assay for primary screening. Program decisions makers can be confident that for women who test negative for HPV, the Aptima HPV assay shows similar CIN2+ or higher outcomes vs a DNA test over 10 years. At the same time healthcare providers can benefit from cost savings that result from fewer false positives at primary screening.

References: 1. Ogilvie GS, Van Niekerk D, Krajden M, et al. Effect of screening and primary cervical HPV testing vs cytology testing on high-grade cervical intraepithelial neoplasia at 48 months: the HPV FOCAL randomized clinical trial. JAMA 2018:320:43-52. **2.** Strang THR, Gottschlich A, Cook DA, Smith LW, Gondara L et al. Long-term cervical precancer outcomes after negative DNA- or RNA-based human papillomavirus test result. Am J Obstet Gynecol 2021 Jun 1;S0002-9378(21)00606-2.doi: 10.1016/j.ajog.2021.05.038. **3.** Weston G, Dombrowski C, Steben M, Popadiuk C, Bentley J, Adams E. A health economic model to estimate the costs and benefits of an mRNA vs DNA high-risk HPV assay in a hypothetical GPV primary screening algorithm in Ontario, Canada. Prev Med Reports 2021:23:101-448. **4.** Arbyn M, Tommasino M, Depuydt C, Dillner J. Are 20 human papillomavirus types causing cervical cancer? J Pathol [Internet]. 2014 Dec 1 [cited 2018 Nov 27];234(4): 431–5. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1002/path. 4424. **5.** Meijer CJLM, Berkhof J, Castle PE, Hesselink AT, Franco EL, Ronco G, et al. Guidelines or human papillomavirus DNA test requirements for primary cervical cancer screening in women 30 years and older. Int J Cancer 2009:124(3):516–20. Available from: https://doi.org/10.1002/ijc.24010. **6.** Weston G, Dombrowski C, Harvey MJ, Iftner T, Kyrgiou M, Founta C, et al. Use of the Aptima mRNA high-risk human papillomavirus (HR-HPV) assay compared to a DNA HR-HPV assay in the English cervical screening programme: a decision tree model based economic evaluation. BMJ Open 2020 Mar 1 [cited 2020 Mar 12]; 10(3):e031303. Available from: https://bmjopen.bmj.com/content/10/3/e031303. **7.** https://www.statista.com/statistics/444858/canada-resident-population-by-gender-and-age-group/

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