

Researchers evaluate cost-effectiveness of noninvasive prenatal screening in Quebec

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Adding non-invasive prenatal genetic screening (NIPS) for fetal chromosomal abnormalities to the current prenatal testing strategy in Quebec would be more cost-effective than current approaches based on blood tests and amniocentesis, according to research presented at the American Society of Human Genetics (ASHG) 2016 Annual Meeting in Vancouver, B.C.

Healthy human body cells contain 23 pairs of chromosomes, for a total of 46. However, errors during the cell replication process can cause the chromosomes to distribute unevenly, a condition known as aneuploidy. Led by Francois Rousseau, MD, MSc, Professor of Medicine at the Université Laval in Quebec City, Quebec, a diverse group of scientists, physicians, health economists, and laboratory physicians used a complex computer simulation to compare the cost-effectiveness of 13 protocols for [prenatal testing](#) for fetal aneuploidies such as Down syndrome: Six that are commonly used in countries around the world; six that add NIPS, a [blood test](#) of cell-free DNA in the mother's blood, to those common procedures; and one that uses NIPS only. Current protocols generally start with a blood test, followed by [amniocentesis](#) if the blood test indicates high risk of aneuploidy.

NIPS is less invasive than amniocentesis and thus less risky for pregnant women and fetuses, but unlike amniocentesis, it is not a definitive diagnostic test, Dr. Rousseau explained. "In addition to being safer, we wanted to find out whether the introduction of NIPS as a first- or second-tier test would be more cost-effective than current options in the context

of the health system in Quebec," he said.

To answer this question, Dr. Rousseau and colleagues developed a computer simulation for each of the 13 protocols they studied. Based on real data from the Ministry of Health on 113,000 pregnancies in Quebec in 2014, they created decision trees of the steps that would have been taken in those pregnancies if each protocol was followed, accounting for real-world factors such as families that opt out of the screening program and loss to follow-up. They then assigned a cost to each procedure followed and computed the total cost to the healthcare system for each protocol. This was divided by the number of Down syndrome cases detected to calculate the cost per case detected. For the protocols with NIPS, the researchers also calculated the incremental cost per case detected - the extra cost per case detected that would not have been detected without NIPS.

Each simulation was run 1000 times to evaluate the consistency of the results. This was followed by sensitivity analyses, in which the researchers tried changing variables such as participation rates and costs of NIPS to measure whether the relative cost-effectiveness of protocols changed as a result.

"Using these measures, we found that a Serum Integrated option, followed by NIPS for women at high risk, was the most cost-effective," Dr. Rousseau said. This approach entails a blood test at 10 weeks into gestation, followed by a second blood test at 12-14 weeks. For blood test results indicating high risk (about 1 in 300), NIPS is performed within a week, and when NIPS confirms there is a risk, amniocentesis is performed and a diagnosis is made as appropriate. This approach would reduce the number of amniocentesis procedures performed by about 90 percent.

A Serum Integrated option without the intermediate step of NIPS, the

approach currently used in Quebec, was second-most cost-effective. In contrast, the universal NIPS option was least cost-effective. The sensitivity analyses showed that these results held even if the cost of NIPS was halved.

In addition to accounting for a range of possibilities in Quebec, the sensitivity analysis data may help other health jurisdictions extrapolate the findings to their own areas, Dr. Rousseau noted. Costs of procedures and participation rates can vary geographically, and prenatal screening decisionmakers can use the scenarios closest to their own context to evaluate the cost-effectiveness of various protocols with and without NIPS.

"Ours was the first study to compare the cost-effectiveness of NIPS approaches in the Quebec context, and the simulations were a great way to evaluate so many options head to head," Dr. Rousseau said. They accounted for many real-world challenges in the program, which were validated by two independent groups of experts.

"The next steps would be to perform a budget impact analysis and to do a pilot test or clinical trial of the one or two most promising options to see how these results play out in the health care system," he said.

More information: Dr. Rousseau will present his research on Wednesday, October 19, 2016, from 10:15-10:30 a.m., in Room 109 of the Vancouver Convention Centre, West Building.

Provided by American Society of Human Genetics

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