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Using an implementation research tool to guide the implementation of non invasive prenatal screening

cffDNA screening has changed the landscape of prenatal screening. In Canada, 2 provinces and 1 territory are covering its cost through the public health care system for women with a high probability of having a fetus with trisomy 21. For the rest of the country, the situation is similar to the one in the United States: some insurers cover it while many women are paying out of pocket. While cffDNA screening has been on the market for nearly a decade, it has not reached its limits yet: various stakeholders are calling for broader use, not only to screen for trisomy 21, but rather to screen an expanded list of chromosomal anomalies.

This presentation will focus on the normative evaluation of the implementation of cffDNA screening. Using research translation as a theoretical framework, we argue that it is currently being implemented as a novel intervention. It needs to be evaluated accordingly before it moves forward. Decision-makers must consider three pathways before implementing cffDNA screening:

1. Make it available through private means to those willing to pay for it;
2. Make it available to a restricted number of pregnant persons (such as those with a higher probability of carrying a fetus with an aneuploidy or other chromosomal anomaly) through public financing;
3. Make it available to all pregnant persons through public financing.

These pathways have different aims and outcomes and cannot be considered as a unique implementation process. We propose to analyze the ethical, legal and social issues of the

third pathway. To do so, we are applying the Consolidated Framework for implementation Research (CFIR) to the implementation of cffDNA screening in the Canadian context as a case study. The CFIR is a validated tool used to evaluate contextual factors for a successful implementation of an intervention. It has never been applied to cffDNA screening. While, the CFIR has been used mostly to analyze the impact of interventions post-implementation, researchers have also been using it pre-implentation.

We argue that the CFIR strength resides in its ability to identify barriers and facilitators to implementation preemptively. Using four out of its five domains, we hope to identify cffDNA screening issues on:

- its relative advantages compared to other screening methods;
- its cost and the impact on resources management for healthcare services;
- the needs and resources of patients;
- the pressure healthcare services are dealing with to implement it swiftly;
- the training needed by healthcare practitioners to prescribe and describe the intervention to patients.

By using the CFIR to identify factors that will influence the implementation of cffDNA screening in practice, this work will help decision-makers select the implementation strategy most likely to be successful with the data emerging from stakeholders. This strategy should be adapted to the pathway chosen by decision-makers and it should take into account the barriers and facilitators unique to this pathway.