Reviewer’s report

Title: Implementing non-invasive prenatal testing into publicly funded antenatal screening services for Down syndrome and other conditions

Version: 0 Date: 09 Aug 2017

Reviewer: John Williams

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The authors present a discussion of the issues surrounding the implementation of noninvasive prenatal testing (NIPT) as a publicly funded service in Aotearoa New Zealand. Specifically, they address the precautions that should be taken at various levels including: healthcare system, healthcare organizations and personnel to ensure that access to services is equitable and responsive to the needs and concerns of diverse cultural groups, and to safeguard women's rights to make informed decisions. Although the discussion specifically relates to implementation of publicly funded NIPT in New Zealand, the principles and recommendations for engaging groups that traditionally have been disenfranchised or have had limited access to healthcare services is applicable to other countries with ethnically diverse populations. Some comments for the authors are listed below.

On page 1, line 62, the authors state: "...and the mother will likely undergo unnecessary invasive diagnostic testing, which in itself carries around a 1 in 100 chance of a miscarriage." To support this statement, they cite guidelines for antenatal screening published by the Ministry of Health in 2012. However, these guidelines do not cite a reference for this statistic. Statements such as these are inaccurate and misleading because they do not take into consideration the natural baseline risk for miscarriage that is gestational age dependent and that exists for all pregnancies. Recent studies that control for background risk of miscarriage show that the "procedure-related" risks for pregnancy loss with amniocentesis and CVS are 0.1% and 0.2% respectively. (Akolekar R, et al. Ultrasound Obstet Gynecol 2015;45:16-26). Presentation of accurate risks for diagnostic testing during pre-test counseling is essential in helping the patient to make an informed choice.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
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Unable to assess

Are the conclusions drawn adequately supported by the data shown?
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Yes

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