Author's response to reviews

Title: Evaluation of non-invasive prenatal testing (NIPT) for aneuploidy in an NHS setting: A Reliable Accurate Prenatal non-Invasive Diagnosis (RAPID) protocol

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Dear Professor Begley,

We hope that you will consider the accompanying manuscript “Evaluation of non-invasive prenatal testing (NIPT) for aneuploidy in an NHS setting: A Reliable Accurate Prenatal non-Invasive Diagnosis (RAPID) protocol” for publication as a study protocol in BMC Pregnancy and Childbirth.

Non-Invasive Prenatal Testing (NIPT) for fetal aneuploidy has the potential to transform prenatal care for women by bringing safe, accurate testing for Down syndrome and other aneuploidies. This test is currently being offered through commercial companies and is available privately in many countries. Thorough evaluation of service delivery requirements are needed to facilitate NIPT being offered more widely within state funded healthcare systems such as the UK’s National Health Service (NHS). In this manuscript we describe a study protocol that aims to evaluate offering NIPT as a contingent screening test in an NHS setting. The results of this study are important to inform best practice for future service delivery and will make a significant contribution to policy decisions around the implementation of NIPT for aneuploidies within the UK NHS and act as a guide for the implementation of NIPT in other countries. The goal of the study is to provide the UK’s National Screening Committee (NSC) with comprehensive data on test uptake, NHS and patient costs and acceptability to key stakeholders. This data will be used by the NSC to determine how NIPT should to be included in the Down syndrome screening programme. The introduction of NIPT into the NHS will result in safer prenatal testing for aneuploidies by reducing the number of invasive tests required. The laboratory standards for testing and reporting, education materials and guidelines for best practice developed as part of the study will support the implementation of NIPT into NHS practice.

The material contained in the manuscript has not been submitted for publication or published elsewhere. The authors have no conflicts of interest to declare. All authors have read and approved the submission. Our ethical approval and funding documentation have been forwarded to BMCSeriesEditorial@biomedcentral.com. Our study is funded by the NIHR under the Programme Grants for Applied Research programme (RP-PG-0707-10107) and has undergone peer review. The study is ongoing; recruitment is underway and will continue until 31/12/2014. The results of this study have not been published or submitted to any journal.

Yours sincerely,

Dr Melissa Hill and Professor Lyn Chitty

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