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Title **Antenatal Screening for Hemoglobinopathies in Primary Care: A Cohort Study and Cluster Randomized Trial to Inform a Simulation Model. The Screening for Hemoglobinopathies in First Trimester (SHIFT) Trial**

Agency **NETSCC, HTA, NIHR Evaluation and Trials Coordinating Centre**
Alpha House, University of Southampton Science Park, Southampton, SO16 7NS, United Kingdom;
Tel: +44 2380 595 586, Fax: +44 2380 595 639; hta@soton.ac.uk, www.hta.ac.uk

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Aim

To assess the effectiveness, acceptability, and feasibility of offering universal antenatal sickle cell and thalassaemia (SCT) screening in primary care when pregnancy is first confirmed; and to model the cost effectiveness of early screening in primary care versus standard care.

Conclusions and results

Offering antenatal SCT screening as part of pregnancy-confirmation consultations significantly increased the proportion of women screened before 10 weeks (70 days), from 2% in standard care (SC) to between 16% and 27% in primary care (PC), but additional resources may be required to implement this. No evidence supported offering fathers screening at the same time as women. For 1441 eligible women in the cohort phase, the median (interquartile range [IQR]) gestational age at pregnancy confirmation was 7.6 weeks (6.0-10.7 weeks) and 74% presented in primary care before 10 weeks. The median gestational age at screening was 15.3 weeks (IQR 12.6-18.0 weeks). Only 4.4% were screened before 10 weeks. The median delay between pregnancy confirmation and screening was 6.9 weeks (4.7-9.3 weeks). In the intervention phase, 1708 pregnancies from 25 practices were assessed for the primary outcome measure. The proportion of women screened by 10 weeks (70 days) was 9/441 (2%) in SC, compared with 161/677 (24%) in PC with parallel testing, and 167/590 (28%) in PC with sequential testing. The proportion of women offered screening by 10 weeks (70 days) was 3/90 (3%) in SC, compared with 321/677 (47%) in PC with parallel testing, and 281/590 (48%) in PC with sequential testing. The proportion of women screened by 26 weeks (182 days) was similar across the three groups: 324/441 (73%) in SC, 571/677 (84%, 0.09) in PC with parallel testing, and 481/590 (82%, 0.148) in PC with sequential testing. The screening uptake of fathers was 51/677 (8%) in PC with parallel testing, and 16/590 (3%) in PC with sequential testing, and 13/441 (3%) in SC. The predicted average total cost per pregnancy of offering antenatal SCT screening was estimated to be 13 pounds sterling (GBP) in standard care, GBP 18.50 in primary care with parallel testing, and GBP 16.40 in primary care with sequential testing. The incremental cost-effectiveness ratio (ICER) was GBP 23 in PC with parallel testing and GBP 12 in PC with sequential testing when compared with SC. Women offered testing in PC were as likely to make an informed choice as those offered screening by midwives later in pregnancy, but less than one-third of women overall made an informed choice about screening.

Recommendations

See Executive Summary link www.hta.ac.uk/project/1401.asp.

Methods

See Executive Summary link www.hta.ac.uk/project/1401.asp.

Further research/reviews required

The following recommendations are equally weighted: 1) The principal value of early testing is that it provides carrier couples with the option of prenatal diagnostic testing in the early stages of pregnancy and, for those found to have an affected pregnancy, the option of a termination at an early stage. Evidence regarding the strength of value attached to earlier terminations is weak. It would be useful to determine the impact of gestational age at screening on uptake of prenatal diagnostic testing and reproductive decisions following the detection of affected pregnancies.

Written by Professor Theresa Marteau, Kings College London, NETSCC, United Kingdom

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