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The consequences of implementing non-invasive prenatal testing in Dutch national health care: a cost-effectiveness analysis

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ABSTRACT

Objective: Non-invasive prenatal testing (NIPT) using cell-free fetal DNA in maternal plasma has been developed for the detection of fetal aneuploidy. Clinical trials have shown high sensitivity and specificity for trisomy 21 (T21) in both high-risk and average-risk populations. Although its great potential for prenatal medicine is evident, more information regarding the consequences of implementing NIPT in a national programme for prenatal screening is required.

Study design: A decision-analytic model was developed to compare costs and outcomes of current clinical practice in The Netherlands using conventional screening only, with two alternatives: implementing NIPT as an optional secondary screening test for those pregnancies complicated by a high risk for T21, and implementing NIPT as primary screening test, replacing conventional screening. Probability estimates were derived from a systematic review of international literature. Costs were determined from a health-care perspective. Data were analysed to obtain outcomes, total costs, relative costs and incremental cost-effectiveness ratios (ICERs) for the different strategies. Sensitivity analysis was used to assess the impact of assumptions on model results.

Results: Implementing NIPT as an optional secondary, or as primary screening test will increase T21 detection rate by 36% (from 46.8% to 63.5%) and 54% (from 46.8% to 72.0%), simultaneously decreasing the average risk of procedure-related miscarriage by 44% (from 0.0168% to 0.0094% per pregnant woman) and 62% (from 0.0168% to 0.0064% per pregnant woman), respectively. None of the strategies clearly dominated: current clinical practice is the least costly, whereas implementing NIPT will cause total costs of the programme to increase by 21% (from €257.09 to €311.74 per pregnant woman), leading to an ICER of k€94 per detected case of T21, when utilised as an optional secondary screening test and by 157% (from €257.09 to €660.94 per pregnant woman), leading to an ICER of k€460 per detected case of T21, when utilised as primary screening test. However, implementing NIPT as triage test did result in the lowest expected relative costs per case of T21 diagnosed (k€141).

Conclusion: NIPT should be implemented in national health care as an optional secondary screening test for those pregnancies complicated by a high risk for T21.

Introduction

Non-invasive prenatal testing (NIPT) using cell-free fetal DNA in maternal plasma has been developed for prenatal detection of fetal aneuploidy [1–3]. Clinical trials have proven its value in both high-risk and average-risk populations, showing high sensitivity and specificity for T21 [4–11].

In the Netherlands, prenatal testing requires a permit under the Population Screening Act and is therefore highly regulated. As of April 2014, the government has provided a license for the pilot introduction of NIPT in Dutch health care. However, for a definitive implementation of NIPT, more information regarding the costs and consequences of the implementation of this novel technology in the national programme for prenatal screening is required.

This study uses decision-analytic modelling to determine outcomes, total costs, relative costs and cost-effectiveness of

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different strategies for prenatal screening and diagnosis of T21. It directly compares current clinical practice, i.e. first-trimester screening (FTS) by first-trimester combined testing (FCT) with invasive diagnostic testing only available for those women at high risk for fetal aneuploidy based on FTS, second-trimester ultrasonographic examination, maternal age or personal or family history, with the two most likely alternatives: implementing NIPT as an optional secondary screening test, to guide further testing for those

(a) Strategy 1) current clinical practice: FTS by FCT, with invasive diagnostic testing offered only to those women at high risk for fetal aneuploidy based on FTS, second-trimester ultrasonographic examination, maternal age or personal or family history.

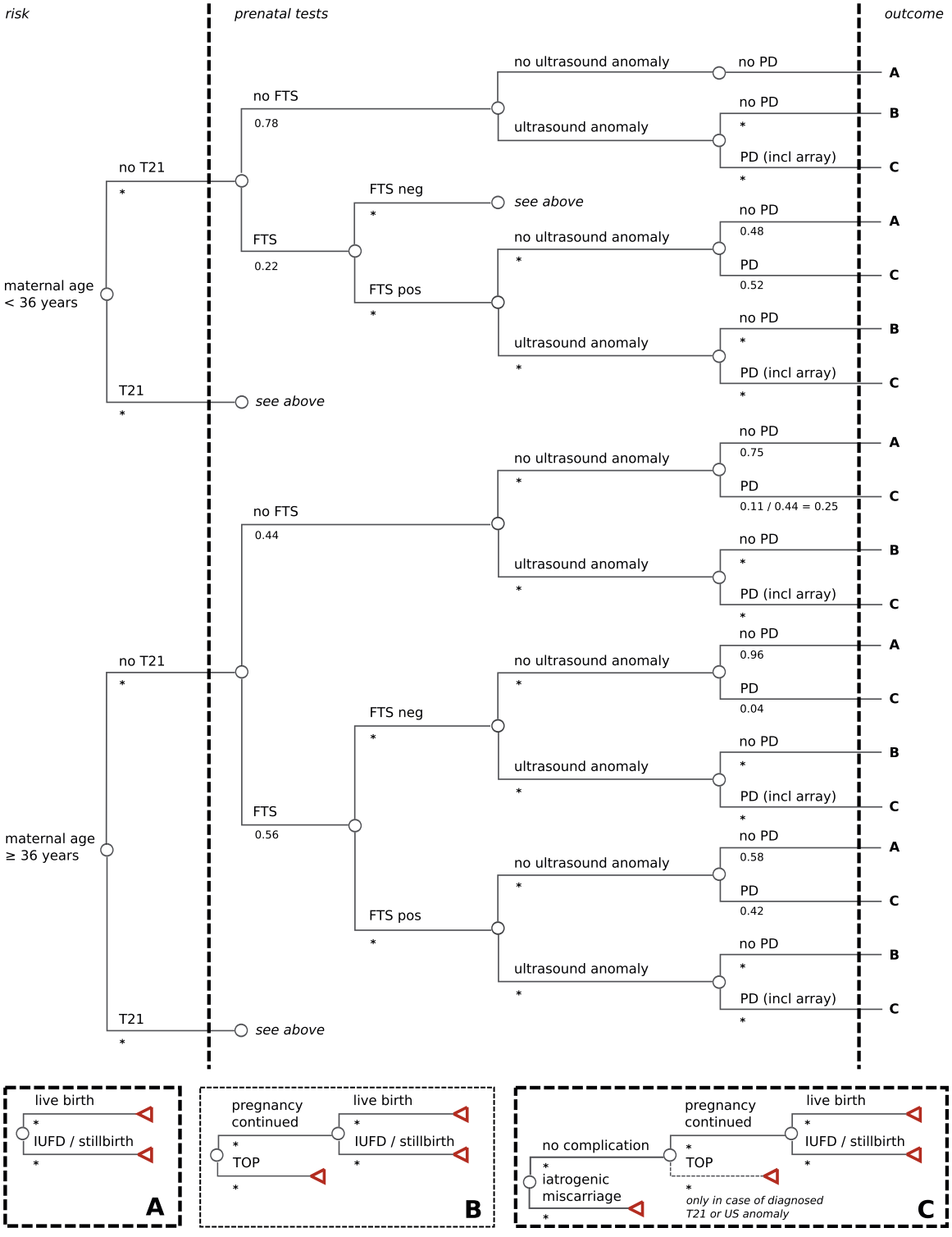

Fig. 1. (a and b) Simplified schematic representation of the decision-analytic model. Not all branches are shown. Participation in prenatal screening and diagnosis indicated below branches where applicable. See Table 1 for probabilities other variables (*).