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UNIVERSAL SCREENING TO DETECT OVERT HYPOTHYROIDISM IN PREGNANT WOMEN: A FIRST-YEAR INTERIM ANALYSIS

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Objectives: Overt hypothyroidism in pregnant women is a serious concern when left untreated. Routine testing of newborns to detect congenital hypothyroidism has long been part of clinical care in many countries, whereas universal testing of pregnant women is hitherto not implemented. We aimed to study the implementation of a universal screening model to detect overt hypothyroidism in Danish pregnant women.

Methods: A prospective cohort study was initiated in the North Denmark Region on June 17, 2022. Serum residues of blood samples drawn as part of prenatal screening for chromosomal anomalies in early pregnancy (median week 9) were used for measurement of TSH, total T4 (reference interval (RI): 90-180 nmol/L), and free T4 (RI: 10.8-16.8 pmol/L), as well as thyroid peroxidase antibodies (TPO-Ab) (cut-off: <60 U/mL) and thyroglobulin antibodies (Tg-Ab) (cut-off: <33 U/mL). If maternal TSH in the sample was > 6 mIU/L, and thyroid disease in the woman was not known, the general practitioner was contacted and informed about the findings for referral to the endocrine department and initiation of treatment according to the Danish clinical practice guideline. When maternal TSH in the sample was ≤ 6 mIU/L, the findings were not reported.

Results: During the first-year study (June 17, 2022, to June 16, 2023), a total of 6,004 samples were screened in the North Denmark Region, corresponding to 5,475 unique pregnant women (median age 30.3 years) and 10% of the annual number of pregnancies in Denmark. Unknown maternal TSH above 6 mIU/L was identified in 18 of the 5,475 women screened (0.3%), and TSH was above 10 mIU/L in 10 of the screen-positive cases. Median maternal age among screen-positive cases was 28.5 years, and 5 women (27.7%) were of non-Danish origin. TSH ranged from 6.1 to 44.3 mIU/L (median 11.6 mIU/L), total T4 from 54-122 nmol/L (median 86 nmol/L), and free T4 from 6.7-11.2 pmol/L (median 8.4 pmol/L). All screen-positive cases were positive for TPO-Ab and 88.9% additionally for Tg-Ab. In all cases, the general practitioner was immediately informed about the findings for initiation of treatment.

Conclusions: This is the first-year interim analysis of a universal screening model to detect maternal overt hypothyroidism in pregnancy. Results highlight that it was possible to implement the model as part of clinical care, and that 0.3% of Danish pregnant women were found to be screen-positive. Thus, the screening model identifies the expected number of pregnant women with unknown overt hypothyroidism in pregnancy.