Reviewer’s report

Title: Genetic testing of newborns for type 1 diabetes susceptibility: A prospective cohort study on effects on maternal mental health

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Reviewer: Barbro Lernmark

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Thanks for inviting me to review the paper
Genetic testing of newborns for type 1 diabetes susceptibility: A prospective cohort study on effects on maternal mental health
By Kaja K. Aas, Kristian Tambs, Marit S. Kise, Per Magnus, Kjersti S. Rønningen

The paper reports of a study on the mental health of mothers whose newborn children had been identified as having high genetic risk for developing type 1 diabetes. The mothers’ mental health was assessed at 30 weeks of pregnancy and 6 months after delivery - approximately 3 months after the information of increased genetic risk. The mental health of these mothers was compared with the health of mothers who had been informed that their children did not have the increased genetic risk. The result showed that there was no difference in mental health between mothers of children with increased genetic type 1 diabetes risk and mothers of children without this increased risk. There was no difference in concern about that “something was wrong with the child” between mothers whose children had increased genetic risk and mothers of children without the increased risk. However mothers with type 1 diabetes expressed more often concern compared to healthy mothers irrespective of the child’s risk.

The result reported that the mothers with babies at risk did not have a poorer mental health than mothers with babies without risk, was not surprising considering earlier published studies. The novelty of this study was that the baseline data was acquired before delivery i.e. before any information about risk was reported to the mothers.

The major criticism of this paper is that the novelty of this paper is questionable. Even if most other studies with similar questions only have included mothers/parents that have been given the information of their child’s increased genetic risk the methods that have been used are generally well established with reliable results from large study groups for normative comparisons. To suppose that mothers/parents in these studies not would be accurate in their answers is not an established fact.

This paper needs major revisions – especially regarding the results section - before a publication can be considered.
Risk information: As has been shown in other studies the way the information of increased risk is given is critical for how parents perceive the risk. As the children have high risk genes it is not adequate to say Children with “diabetes risk genes”. It needs to be clear if it is reported to the parent that the children have “diabetes risk genes” or “diabetes high risk genes”.

To give extra counselling and support to worried parents are of course an important part of studies like MIDIA. The problem is that it can be a strong confounding factor in relation to the main research question in this study: “To what extent can receiving information about a young child having an increased risk of type I diabetes affect maternal well-being and mental health?” As the follow up data were collected 6 months after delivery - 3-3.5 months after the information - all extra information and support to the mothers during the time between information and collection of data will make the study hypothesis less adequate. Others have shown that increased anxiety and worries decrease after a few months after risk information and the authors should include references to these studies. This decrease can be due to different reasons: time passes and the worry/anxiety level decreases over time or counselling and other types of psychological support will lower the anxiety. Worry and anxiety are the main psychological factors studied, but are important for mental health and well-being of the mothers. This needs to be discussed.

Page 8, 2nd para: The five lines in the end of the paragraph can be deleted (In December …).

The paragraph on page 10: Follow-up of children with high genetic risk in MIDIA is not necessary in this paper. One sentence regarding the follow-up is enough.

The description of the three instruments used in the study is unnecessarily thorough. A heading need to be inserted above the paragraph “Child’s risk status” as it is not factors obtained from the questionnaires. Socio demographic characteristics are part of these factors as well and this needs to be indicated.

A paragraph in the methods section should be moved to the Statistics section or under Results (Page 12 f Handling of missing data…).

The Results section is too brief, a bit confusing why it need to be expanded with more clear interpretations of the results.

To able to compare some of the socio demographic variables with official Norwegian socio demographic statistics is fine even though it is a bit too ambitious to do it by year. A statistical comparison between the two study groups regarding demographics is missing and would have been adequate to present in Table 1. The presentation of characteristics should be in the same order as they are presented in the text.

Maternal income is not commented at all in the results section. What is the point of grouping the characteristics if there is no comparison? What is the point of the 95%CI column in this regard?
The result presented in Table 2 does not correspond to the study question. Statistics of the different mental health measures and differences between mothers of high risk and mothers of non high risk infants should be the main focus and clearly shown in the Table. A comparison over time between the two groups is needed in a more clear way. To me – not being a statistician – the statistical methods chosen don’t seem to be the best alternatives.

The authors need to discuss the validity of comparing a small group of only 166 with more than 7000 individuals. It is not clear that this comparison is fair. A matching of the control group with the study group in some demographic variables should be possible.

It is not clear and confusing why the demographic table show divorced or single mothers as no analysis has been carried out to define if these groups of mothers might be more anxious.

The discussion lacks comments on the increased concern of the mothers with type 1 diabetes.

The last paragraph of the Discussion is not appropriate and could be deleted. The last sentence in the paragraph above the last should be deleted. Instead it is important to state that parents who become and stay worried/anxious, are worried in many aspects not directly related to the test results. These parents often belong to more vulnerable socioeconomic groups like immigrants, lower education or lower income groups as has been shown in other studies.

The language need to be checked and corrected throughout the paper.