Reviewer's report

Title: Record linkage to obtain birth outcomes for the evaluation of screening tests in pregnancy: a feasibility study

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Reviewer: Điva Novak Antolic

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Record linkage to obtain birth outcomes for the evaluation of screening tests in pregnancy: a feasibility study

I congratulate the authors for showing that it is feasible to use record-linkage of a laboratory database with population perinatal health databases and obtain results comparable to other methods. Compulsory revisions are there only to stress the importance of your work.

Ad 1.
Yes, but not in the abstract. It is defined at the end of “Background”, p 5.

Ad 2.
methods: it is not clear who and how de-identified data set of the laboratory results to be able to match with birth outcomes
outcomes: in the abstract, authors only refer to “fetal loss” (i.e. one of three outcomes); afterwards they write of four different outcomes, they add stillbirths. Fetal loss can not be divided into fetal loss and stillbirth.
Definitions in different countries are quite different so it should be stated it is 24 weeks. In Europe, it is usual to consider 22 weeks (EURO-PERISTAT Report 2008, www.europeperistat.com ). Where the definitions of stillbirths the same in the cited studies?

Ad 3.
It should be stated how the data from the laboratory and the data in health databases are audited (ref 28, 29; explain ref 30). Costs of auditing? Where the used data cleaned (cf p 11)?
Table 2: 78 preterm births? In the text: 2 + 16 + 52 =70. Explain.
Is it true that only 75.8% of preterm birth reports are correct?
Is it true that only 98.3% of stillbirth reports are correct?

Ad 4.
What is probabilistic linkage? What is translational research?
Ad 5.
Discussion: “Traditional” methods will be needed for various reasons; only one is that not every country has such a good data linkage system with data protection.
Conclusions: how did you prove it is less expensive? Did you consider expenses for establishing databases, centre for linkage, data protection, auditing all these constantly?
Biases are minimized IF the data in databases are good.

Ad 6.
More or less; explain why traditional research methods are needed.

Ad 7.
I am not sure who performed the blood sample analyses.

Ad 8.
No (see the explanation below).

Ad 9.
Yes.

DISCRETIONARY REVISIONS (authors can ignore)
A possibility of change in the title: which screening tests (PAPP-A, fbeta HCG)
“pathology data” – it is laboratory data
methods: it is not clear who and how de-identified data set of the laboratory results to be able to match with birth outcomes
Is this really a new method?
Explain what is probabilistic linkage? What is translational research?
Who performed laboratory work – acknowledgement?

MINOR ESSENTIAL REVISIONS
Whole text: explain what you mean by effective, efficacious, efficient, cost efficient, cost effective and use words consistently. Predictive tests; use predictive value of tests. Sample (not spectrum). Screening factors? Screening tests.

Abstract: the aim of the study is to test feasibility. The results should be written about that.

Write about 4 outcomes (fetal loss and stillbirths separately)

Background: 2nd paragraph: it should be clear that the data cited are not from Australia (ref 5).

It should be stated how the data from the laboratory and the data in health
databases are audited.

Methods, 2nd paragraph: pregnant women were expected to deliver (not pregnancies); the same in Results.

Table 1 is not appropriately explained in the text (only 0.26, and 0.28 are explained; 0.49 and 0.92 are not). Why?

Table 1: free beta HCG – differently written in the same table
5.3% and 3.5%: is it correct that this is not significant difference?

Table 2: 78 preterm births? In the text: $2 + 16 + 52 = 70$.

The meaning is not clear, please rewrite:
Page 9: “potential pregnancy screening factors”
Page 9: the sentence that starts “With a sample size…”.

How did you prove it is less expensive? Was an economic analysis performed? Did you consider expenses for establishing databases, centre for linkage, data protection, auditing all these constantly?

References: cite in the same way (e.g. American Journal of Obstetrics & Gynecology; sometimes Am J Obstet Gynecol)

MAJOR COMPULSORY REVISIONS
Define the aim of the study in the abstract as it is defined in Background (p5) and change the title (this is not evaluation of screening test but about feasibility). You have shown that there is consistency with results in other studies and this should be stressed.

Discussion: discuss mainly about feasibility; compare results with results of studies done in different ways (do not discuss the predictive value of screening tests).

2nd paragraph: screening tests are NOT diagnostic tests.

Is it true that only 75.8% of preterm birth reports are correct?
Is it true that only 98.3% of stillbirth reports are correct?
Discuss if this can influence your results in comparison to other studies.

Discuss why traditional research methods will still be necessary.

Level of interest: An article of importance in its field

Quality of written English: Acceptable
Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:
'I declare that I have no competing interests'