Reviewer's report

Title: Protocol for the evaluation of a free health insurance card scheme for poor pregnant women in Mbeya region in Tanzania: a controlled-before and after study

Version: 4  Date: 2 December 2014

Reviewer: Nancy L L Sloan

Reviewer's report:

• Major Compulsory Revisions

I realize the authors have had a series of reviews and comments, however as this is my first reviewed of the protocol, I find there are a few small points that require attention (some of major and others of minor essential importance). I expect the authors would be able to complete the modifications in a few minutes and if made, I recommend publication.

1. Page 7 and Ethical Issues section: The authors do not state that the participants (patients) will be asked for their consent to participate prior to observation of provider care of the patient (which is essential). (The authors might also wish to move or add on page 7 the statement that consent will be obtained prior to focus group participation – this is stated on page 8, but it seems reasonable to describe the consenting for all facility-based data collection from women in one place.)

2. The baseline facility-based eligibility is an uninsured status. This means the assessment is of efficacy, not effectiveness. This may limit generalizability (and comparability with other assessments of demand side financing). More importantly, it also appears to be discrepant from the household survey data which is limited to women giving birth in the prior 3 months. If the household sample is also to be limited to those without insurance, this should be stated in the protocol. Either way, there should be consistency in the types of women sampled in the facility-based and household surveys (or some explanation of why they should be discrepant should be included).

3. The household sampling and power calculations are a bit confusing. If there are 3,000 households (is this total or per study group?), and 1,500 per round (does round mean baseline and X months after the intervention is implemented?) then what is the expected sample of women delivering in each study period? It seems this what the power calculations should be based on (e.g., denominator n required per group should be deliveries not households). Without this information it is difficult to determine whether the study design is adequate to test the hypothesis.

4. Impact indicators: Should include stillbirth, and the facility statistics should include caesarean section rates. When C-section rates go from low to recommended levels, there can be a striking impact on reducing the stillbirth rate.
Minor Essential Revisions

1. Will the wealth classification be by simple trichotomies from the sample? If so, please state. If not, almost everyone may end up in the "poor" category, which will not be helpful.

2. The economic assessment is not very specific. Will this be an assessment of incremental costs and incremental cost-effectiveness? (And, for the analysis, please specify, will this be conducted using Monte Carlo simulations as is often done?)

3. Data management: Should be "locked" not "lockable"

• Discretionary Revisions


2. Page 5: The other barriers associated with transportation (lack of transportation, distance, decision to seek care due to hassle, danger at night time, etc.) may be barriers as much as the costs of transportation. It will be important to assess this issue in the household surveys of why women did not seek institutional care and/or focus groups.

3. Data management: Believe the more common term is de-identified (not "made anonymous").

Level of interest: An article of outstanding merit and interest in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

'I declare that I have no competing interests