Reviewer’s report

Title: The STRIPES Trial - Support to Rural India's Public Education System

Version: 2 Date: 28 September 2009

Reviewer: Tim Peters

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I’m aware that essentially the protocol is finalised, and have no fundamental concerns. However, I offer the following comments that hopefully will help either in fine-tuning the plans and/or in improving the manuscript. Generally in order of the relevant section rather than importance:

1. Might it be worthwhile somewhere in the manuscript explicitly saying why a factorial design of the two elements of the STRIPES intervention was not employed? In any case, for the design adopted, what implications would there be for the primary comparison (all intervention vs. control villages) if there were to be marked differences apparent in the secondary comparison (i.e. that the additional “kit” was effective for girls) – noting that the power for the (secondary) intervention-gender interaction will almost certainly be low?

2. Like most of the manuscript the Background section is well written, although the phrase “the returns to education” in the fifth paragraph would benefit from a brief explanation in this context. In addition, the third sentence in the “Aims of the trial” section needs rewriting. The style is comparatively much less flowing in the latter stages and could do with some attention (notably for Administrative structures and the Discussion sections), plus I wasn’t sure why the full details of the (standard) Uniform requirements for authorship needed to be given. I only spotted one typographical error – “INTERVVENTION” in Figure 1.

3. Cost-effectiveness is mentioned on pages 7 and 8 but virtually no details are given of the methodology being employed for this aspect of the trial.

4. It is clearly stated that only enumerated children (i.e. those present for the baseline survey) will be followed up for the trial, and that secondary analyses will explore inclusion of those without baseline test scores. In contrast the last sentence of the paragraph on “Dealing with migration” implies otherwise, although this could be due to missing baseline scores amongst enumerated children. This needs to be clarified, and perhaps some more detailed explanation given for the approach adopted?

5. Related to this, but arguably more importantly, further details if available should be provided about the recruitment process – in particular if there is any evidence of differential recruitment of children within clusters across the trial arms. Similarly, is there any reason to consider that the presumed follow-up rate of 80% is realistic, and how will any differential attrition be handled despite the best efforts adopted to avoid it? Moreover, for the sample size justification, on
what grounds was 0.14 SDs considered worthwhile detecting (other than that it has been observed), and from where was the ICC of 0.03 derived?

6. In the analysis, even if just as a secondary (multi-level) analysis, would it not be worth considering the effects of clustering at the level of the school as well as the village? Also, the randomisation was stratified by distance to a main centre and “tribal status” – strictly speaking these should be adjusted for in the primary analysis.

7. While not personally an expert in ethics, I am convinced by the details relating to formal ethics approval for these trials, including the procedures for obtaining consent. The arrangements for independent scrutiny of the trial are less well developed, however, since the Trial Steering Committee does not appear to be constituted with any independent members or Chair. As a corollary, the justification for dispensing with a Data Monitoring Committee would be strengthened if some independent oversight were involved on the TSC.