January 4, 2012

**STROBE CHECKLIST:** For manuscript # BMJ.2011.001082

**Title:** Uterotonic Drug Quality: An Assessment of the Potency of Injectable Uterotonic Drugs Purchased by Simulated Clients in Three Districts in Ghana

| Item | Item # | Recommendation | Description of Manuscript Content |
|---|---|---|---|
| **Title and Abstract** | 1 | Study design indicated with commonly used terms in title or abstract;<br>Provide in abstract informative/balanced summary of methods and results | Our title describes study design: Uterotonic Drug Quality: An Assessment of the Potency of Injectable Uterotonic Drugs Purchased by Simulated Clients in Three Districts in Ghana;<br>Study Method is described in non-technical language. Basic results are provided regarding the potency of the two drugs studied. |
| **Introduction** | | | |
| Background/ rationale | 2 | Explain the scientific background and the rationale for the study | The introduction summarizes the use of uterotonic drugs in poor countries, the current programmatic priority for postpartum hemorrhage prevention and previous studies of uterotonic quality. Pages 5-6 |
| Objectives | 3 | State objectives and pre-specified hypotheses | 2 objectives are clearly specified. There were no pre-specified hypotheses re: results. See 1st paragraph of page 7 |
| **Methods** | | | |
| Study design | 4 | Present key elements of study design | Detailed steps of the study design are presented in chronological order. See pages 7 – 1st 2 paragraphs of page 9. |
| Setting | 5 | Describe setting, relevant dates, recruitment, follow up and data collection | On pages 7 and 8, the dates of the sampling frame compilation and data collection are provided. Data collection procedures, drug handling procedures and details regarding the chemical assays are provided on pages 7-9; |
| Participants | 6 | Cross-sectional study: provide eligibility criteria and sources and methods for the selection of participants | In this study, sample selection of facilities replaces eligibility criteria for study participants. As described on page 7, in 2 of 3 districts, all pharmacies identified in the sampling frame were eventually selected to participate in the study. |
| Variables | 7 | Clearly define all outcomes, predictors, etc. | The main outcome is the percent of active ingredient in the drug assayed, and it is compared against manufacturer specification (described on pages 12-13). Other variables are simple descriptors: region, pharmacy type and registration status – which are all self-explanatory. |
| Data sources/ measurement | 8 | Provide sources of data and | The chemical assays are described in detail. See page 9. |

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| | | measurement methods | |
| Bias | 9 | Describe efforts to assess sources of bias | The simulated client method prevents bias in the selection of ampoules chosen for chemical assay since the pharmacists/drug seller does not know that the drugs will be tested (2nd paragraph, page 15). The authors discuss possible bias due to a sampling frame that may not have been 100% complete due to the informal nature of some points of drug sale. However, they note that the results are so overwhelmingly similar that they are unlikely to have resulted from sampling error. |
| Study size | 10 | Explain how study size was arrived at | The Methods section describes the plan of selecting 25 points of sale in each district. In the Discussion, this sampling plan, which was based on practical and budgetary considerations and resulted in a relatively small sample size is cited as a limitation of the study. However, the overall sample (101 ampoules) in this study does not compare unfavorably to existing community-based studies identified in the literature. |
| Quantitative variables | 11 | Explain how quantitative variables were handled, grouped and the rationale for grouping | The key outcome variable (% active ingredient) was compared against the manufacturer's specifications (90%-110%). Additional groupings (0%, 1-39, 40-59, 60-89%) were selected simply to show the distribution. 0% was shown to identify possible cases of counterfeit drug. |
| Statistical methods | 12 | Describe all statistical methods | As stated in the Methods section, only simple descriptive statistics are used in this paper (% distributions, means). There was no reason to assess confounders in this observational study based on our objectives. Missing data are shown in the tables. |
| **Results** | | | |
| Participants | 13 | Report n of participants at each stage of the study; Give reasons for non-participation, Consider use of a flow diagram | As described in #6 above, the selection of points of sale replaces recruitment of study participants in this study. Our sampling procedure is described under Methods and the results of our sampling procedure is described under Results (see page 11). |
| Descriptive data | 14 | Give characteristics of study participants, indicate participants with missing data | In this case, points of sale are the equivalent of study participants, and within points of sale, ampoules were selected for assay. Points of sale are described by region (no missing data)and type (data were missing on type of point of sale for 1 ampoule – this is noted in Tables 3 and 4.) |

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| Outcome data | 15 | Cross-sectional study: Report numbers of outcomes events or summary measures | N's and percentages and means are presented for potency; that is, outcome data on the % of active ingredient in each ampoule. |
| Main results | 16 | Report n of participants at each stage of the study; Give reasons for non-participation; Consider use of a flow diagram | As described in #6 above, the selection of points of sale replaces recruitment of study participants in this study. Our sampling procedure is described under Methods and the results of our sampling procedure are described under Results (see page 11).<br>The n's for all ampoules tested are shown in Tables 4 and 5. |
| Other analyses | 17 | Report on other analyses conducted (sub-group, etc) | No additional analyses were conducted. |
| **Discussion** | | | |
| Key results | 18 | Summarize key results with reference to study objectives | The key results are summarized in four concise statements in the first paragraph of the Discussion section. |
| Limitations | 19 | Discuss limitations of the study, including possible biases, imprecision and direction and magnitude of such | Possible biases are discussed in the 1st paragraph of page 15 (including the low likelihood that an incomplete sampling frame could have qualitatively changed the key results). The fact that it was not possible to address one of our objectives (ie, quantify results for the need for a prescription for uterotonic drugs) is also discussed openly. |
| Interpretation | 20 | Give a cautious overall interpretation considering objectives, results form similar studies and other relevant evidence | The results are presented as: uterotonic drug quality is likely a serious problem in these three districts. There is no other comparable evidence from Ghana against which one can compare these results. However, reports referring to other types of low quality drugs in Ghana are cited. |
| Generalizability | 21 | Discuss generalizability of study results | Authors were cautious in over-interpreting generalizability of results regarding drug quality in this paper. However, the authors do draw attention to issues discussed in this paper regarding drug quality study design which are generalizable to other poor countries. |
| **Other information** | | | |
| unding | 22 | Provide source of funding and role of funders | A statement regarding the funding of the study and the role of the funders is included on page 10, in the paragraph preceding Results. |