

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	MENSTRUAL HYGIENE MANAGEMENT AMONG ADOLESCENT GIRLS IN INDIA: A SYSTEMATIC REVIEW AND META-ANALYSIS
AUTHORS	Van Eijk, Anna Maria; Sivakami, M.; Thakkar, Mamita; Bauman, Ashley; Laserson, Kayla; Coates, Suzanne; Phillips-Howard, Penelope

VERSION 1 - REVIEW

REVIEWER	Prof (Dr) MKC Nair Vice Chancellor, Kerala University of Health Sciences Thrissur, Kerala, India
REVIEW RETURNED	03-Nov-2015

GENERAL COMMENTS	A well conducted systematic review and meta analysis on a topic most relevant to India and other middle income countries. I can appreciate the enormous work involved, particularly taking studies that are not in pubmed and also with reference to socio-economic status data. My only comment would be on the discussion part referring to limitations. The statement "some outcomes were affected, and for these, the pooled estimate may be over- or under estimated". It may be more appropriate to elaborate a bit more with specific examples.
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REVIEWER	Bethany Caruso Emory University, Atlanta, GA USA
REVIEW RETURNED	27-Nov-2015

GENERAL COMMENTS	Summary 1. Please clarify timing: 'Half of the girls reported being informed about menarche (PP 48%, 95% CI 43-53%, n=88 studies).' Assume authors mean girls were informed prior to menarche, but do not want to have readers assume. Please also make necessary change in body of text. 2. Please indicate when studies published (i.e. include a range of years): "Data from 138 studies involving 193 subpopulations were extracted." I realize authors searched for papers between 2000 and present, but clarify if papers were found from 2000 as well. Please also make necessary change in body of text. 3. Authors note that girls face many restrictions and note 'missing school' as an example. Missing school is not noted as a restriction on body of paper. Please clarify in text: is this a restriction or a behavioral adaptation? Restrictions are often imposed by others
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	<p>thus limiting personal agency, and adaptations are an exercise of personal agency. Are others (even a social norm) influencing this behavior or is something girls do to cope/adapt? Something to consider as you list out varied restrictions.</p> <p>Methods</p> <p>1. The authors note that observational studies were sought. Please elucidate as to whether or not your criteria allowed for the inclusion of qualitative observational studies and (if so) if/how they were analyzed any differently (i.e. use of meta-synthesis to code findings?). If qualitative studies were included as, please report on the proportion that were qualitative.</p> <p>2. Great that study quality was assessed. It is recommended that the authors explicitly describe how the applied scores were eventually used in the synthesis. Were scores used as weights in any way? Merely as something to report back on? How study rigor was applied is noted in limitations, but can be described in more depth in methods.</p> <p>Results</p> <p>1. Qualitatively, I know that caste has an influence on restrictions related to menstruation. Was caste ever controlled for in the models? If not, please indicate decision not to include caste in discussion.</p> <p>Discussion</p> <p>1. As a result of this very exhaustive synthesis, it would be useful to know what major gaps were noted. For example, in the results, the authors note that most of studies were from Maharashtra. If most studies came from one area, what regions were not or under-represented? What themes explored had the least amount of information or the poorest quality of information? What questions did you have in mind initially that you were not able to explore because of the data quality. It is an accomplishment to be able to draw some inferences based on the research that does exist. Discussion of what inferences cannot be drawn, what other information would be useful, etc. would be a valuable contribution as well.</p>
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REVIEWER	Seyed M Hosseini London Health Sciences center
REVIEW RETURNED	28-Nov-2015

GENERAL COMMENTS	<p>Congratulations to the authors for very well-written paper. I think their findings are very helpful for local health systems to improve primary prevention for urogenital diseases. Menstrual hygiene is very important to control and prevent gynecological diseases. This study also looked at the association between cultural/geographical variables and menstrual hygiene.</p> <p>The limitations of the study is not adequately explained. The search strategy for grey literature also needs more clarification. Pooled estimates calculated using meta regression appear to be clear; however I suggest further assessment by statisticians.</p>
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REVIEWER	Dr Marrison Martyn-St James University of Sheffield UK
REVIEW RETURNED	16-Dec-2015

GENERAL COMMENTS	<p>The authors present a systematic review and meta-analysis of a large body of evidence. However, there are some aspects of the data acquisition and synthesis that need addressing as follows:</p> <p>ABSTRACT</p> <ol style="list-style-type: none"> 1. The methods section of the abstract should report that methodological quality of the included studies was assessed and that between-study heterogeneity was assessed. 2. The results section of the abstract should report the number of participants. 3. A summary of methodological quality and heterogeneity should also be included in the results section of the abstract. <p>METHODS</p> <ol style="list-style-type: none"> 4. The review authors report that data extraction was undertaken by two reviewers, but do not report if independent double data extraction or data checking was undertaken, which is important in a systematic review to minimise DE errors. 5. The authors have assessed the methodological quality of their included studies but do not cite the instrument they have used. If the authors have created their own quality assessment instrument, this should be clearly stated along with any validation of the instrument the authors have undertaken. 6. The authors report using metaprop in Stata to pool data across studies and that they pooled prevalence data as proportions. The authors need to make it clear for the reader if any transformation of data occurred and how this was undertaken, along with how the authors dealt with missing data statistically. 7. The authors assess between-study heterogeneity using the I-squared statistic. 8. The I-squared statistic is usually seen in a pair-wise meta-analysis of RCT data (metan, RevMan) so it would be useful to explain for the reader its appropriateness when pooling proportion data. <p>DISCUSSION</p> <ol style="list-style-type: none"> 9. The discussion is heavily front-loaded in terms of discussion the subject area, rather than following the structure for a discussion of a systematic review and meta-analysis that has used robust methods. I would suggest restructuring the discussion as the following paragraphs: summarise the overall results, including methodological quality and heterogeneity; describe limitations of the included studies review and hence the reliability of the results, i.e., couching the review findings in the context of the methodological quality and heterogeneity; describe the strengths and weaknesses of the systematic review methods, e.g., data were not double extracted or checked; set the results in context of other knowledge on the topic; provide conclusions, and then any implications for current practice and particularly for future research. The review authors touch on some of this in the penultimate paragraph, but a lot of this is played down. For example, why exactly did the authors anticipate statistical heterogeneity? The authors should consider the literature on spurious I-squared values from pooling observational studies.
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Prof (Dr) MKC Nair
Vice Chancellor, Kerala University of Health Sciences

A well conducted systematic review and meta analysis on a topic most relevant to India and other middle income countries. I can appreciate the enormous work involved, particularly taking studies that are not in pubmed and also with reference to socio-economic status data. My only comment would be on the discussion part referring to limitations. The statement "some outcomes were affected, and for these, the pooled estimate may be over- or under estimated". It may be more appropriate to elaborate a bit more with specific examples.

Response: We thank the reviewer for the appreciation, and have elaborated further in the discussion section under limitations as follows: "To evaluate the potential effect of study quality, we assessed outcomes against the quality score and presence of random sample. Some outcomes were affected, e.g. a higher quality score of a study was associated with a lower use of commercial pads; the pooled estimate which includes studies with lower scores may thus overestimate the prevalence of commercial pad use. A self-administered questionnaire was associated with a lower prevalence of absenteeism, so the pooled estimate for absenteeism may be overestimated."

Reviewer: 2
Bethany Caruso
Emory University, Atlanta, GA

Summary

1. Please clarify timing: 'Half of the girls reported being informed about menarche (PP 48%, 95% CI 43-53%, n=88 studies).' Assume authors mean girls were informed prior to menarche, but do not want to have readers assume. Please also make necessary change in body of text.

Response: We have changed this as suggested in the abstract (page 1) and throughout the manuscript where applicable (page 4, page 5).

2. Please indicate when studies published (i.e. include a range of years): "Data from 138 studies involving 193 subpopulations were extracted." I realize authors searched for papers between 2000 and present, but clarify if papers were found from 2000 as well. Please also make necessary change in body of text.

Response: We added this information to the characteristics table (Table 1).

3. Authors note that girls face many restrictions and note 'missing school' as an example. Missing school is not noted as a restriction on body of paper. Please clarify in text: is this a restriction or a behavioral adaptation? Restrictions are often imposed by others thus limiting personal agency, and adaptations are an exercise of personal agency. Are others (even a social norm) influencing this behavior or is something girls do to cope/adapt? Something to consider as you list out varied restrictions.

Response: We realized that the text in the abstract is indeed misleading, because missing school is not necessarily an example of a restriction. For this reason we added religious restrictions as an example of restriction to the abstract, and report missing from school separately. This is changed as

follows (Page 1): “Menstruating girls experienced many restrictions; three quarter reported restrictions for religious activities (PP 0.77, 0.71-0.83, n=67). A quarter (PP 24%, 19-30%, n=64) reported missing school during periods.”

Please note that school absenteeism is reported as a separate section under results, whereby all the different reasons identified in the literature are mentioned as follows (page 5): “Girls’ reasons for absence were physical discomfort or pain, lack of water, hygiene and disposal facilities in school toilets, fear of staining their clothes, and restrictions imposed by relatives or teachers (table S2.8).”

Methods

1. The authors note that observational studies were sought. Please elucidate as to whether or not your criteria allowed for the inclusion of qualitative observational studies and (if so) if/how they were analyzed any differently (i.e. use of meta-synthesis to code findings?). If qualitative studies were included as, please report on the proportion that were qualitative.

Response: We did not include papers that were solely qualitative. We included studies with “mixed designs” as mentioned in the methods section (14 studies had a mixed design). However, only the quantitative components were systematically extracted and analysed. We corrected table 1 (the characteristics table) to display this information and added the following sentence to the methods section to clarify this issue (page 3): “No systematic data extraction or analysis were conducted for qualitative components present in included studies with mixed designs.”

No systematic data extraction or analyses were conducted for qualitative components present in included studies with mixed designs.

2. Great that study quality was assessed. It is recommended that the authors explicitly describe how the applied scores were eventually used in the synthesis. Were scores used as weights in any way? Merely as something to report back on? How study rigor was applied is noted in limitations, but can be described in more depth in methods.

Response: Please note that quality-assessments methods are detailed in supplement S1, and the use of the score under data-synthesis (“For sensitivity analysis, we examined the effect of self-administered questionnaire versus study staff interview, study quality assessment as a continuous or dichotomous variable [quality score > 4 versus ≤4], and the effect of random sampling.”) Scores were not used as weights, but their associations with outcomes were examined using meta-regression as reported in the methods section under analysis (last sentence of this section, page 4-5: “For sensitivity analysis, we examined the effect of self-administered questionnaire versus study staff interview, study quality assessment as a continuous or dichotomous variable (quality score > 4 versus ≤4), and the effect of random sampling using meta-regression.” We added the following sentence (page 4): “Quality scores were not used as weights in analyses.”

We added the following sentence to the Study Quality section in the main paper to make clear what the quality score was based on: “Quality-assessments of included studies were conducted by the same reviewers based on the following criteria: presence of a sample size calculation, randomness of sample, description and appropriateness of inclusion and exclusion criteria, presence of a description of the number of persons approached but not enrolled, or enrolled but data not used, completeness of outcome data for the number which was presented, presence of study characteristics and of multivariate analysis for the outcome of the paper. The results were added to obtain an overall quality score ranging from 0-7 for each study.”

Results

1. Qualitatively, I know that caste has an influence on restrictions related to menstruation. Was caste ever controlled for in the models? If not, please indicate decision not to include caste in discussion.

Response: Thanks, the reviewer raises a good point. Caste was not controlled for in the models, because few studies reported information by caste. Similarly, we would have liked to control for socio-economic status, but again, this was reported erratically, and results were often not stratified by socio-economic status. We added this now to the discussion in the limitations section on page 8 as follows: "Further, our review was limited by the information available; not all included studies focussed solely on MHM and not all studies presented basic information on age, or socio-economic status. This limited exploration of the effect of factors such as socio-economic status, caste or maternal education on the outcomes."

Discussion

1. As a result of this very exhaustive synthesis, it would be useful to know what major gaps were noted. For example, in the results, the authors note that most of studies were from Maharashtra. If most studies came from one area, what regions were not or under-represented?

Response: With regards to regions, the Central region states, and Eastern region states to some extent, are under-represented which we briefly reported in Table 1. To make this clear, we added the states without surveys to Table S2.1. We had a map showing all the study locations, but because of the political sensitivities (in particular Jammu and Kashmir) we decided not to include this. We have now highlighted the under-representation of some states in the limitation section in the discussion as follows (page 7): "Not all studies reached scientific rigor, and states in the Central and Eastern region are under-represented as few studies have been conducted in these regions."

Not all studies reached scientific rigor, and states in the Central and Eastern region are under-represented as few studies have been conducted in these regions.

What themes explored had the least amount of information or the poorest quality of information?

Response: The quality assessment was for the study overall and not specific for a theme. However, as reported in the discussion, we would have liked to examine associations between outcomes such as commercial pad use or school absenteeism with socio-economic status or maternal education, but information was too incomplete to use. Further, with regards to school absenteeism we were unable to control for WASH variables as these were erratically reported, which we note may confound reported absence (Page 7).

What questions did you have in mind initially that you were not able to explore because of the data quality. It is an accomplishment to be able to draw some inferences based on the research that does exist. Discussion of what inferences cannot be drawn, what other information would be useful, etc. would be a valuable contribution as well.

Response: The themes that we had in mind to examine are listed in the proposal (Protocol: page 4, section 12 – data items). The quality of information on the reaction of girls to menarche or how a girl cleans herself during her period, the frequency of changing menstrual materials, and the obstruction girls face was generally too poor to use. We added this on page 8 to the manuscript in the discussion section under limitations.

Reviewer: 3

Seyed M Hosseini
London Health Sciences center

Congratulations to the authors for very well-written paper. I think their findings are very helpful for

local health systems to improve primary prevention for urogenital diseases. Menstrual hygiene is very important to control and prevent gynecological diseases. This study also looked at the association between cultural/geographical variables and menstrual hygiene.

The limitations of the study is not adequately explained. The search strategy for grey literature also needs more clarification. Pooled estimates calculated using meta regression appear to be clear; however I suggest further assessment by statisticians.

Response: We added an explanation of grey literature as follows: "We searched 'grey literature' (e.g. reports from UNICEF about school sanitation retrieved in Google Scholar), conference abstracts, and manually reviewed reference lists of eligible publications."

We changed the first section of the limitations as follows: "There was high heterogeneity between studies, which may be explained by the different methodology of the studies and the different settings where the studies were conducted. We used metaregression to explore factors that affected the outcomes, and indeed the setting (urban or rural), the region, time and quality of the study were regularly associated with the outcomes examined. (Supplement 2)".

Reviewer: 4

The authors present a systematic review and meta-analysis of a large body of evidence. However, there are some aspects of the data acquisition and synthesis that need addressing as follows:

ABSTRACT

1. The methods section of the abstract should report that methodological quality of the included studies was assessed and that between-study heterogeneity was assessed.
2. The results section of the abstract should report the number of participants.
3. A summary of methodological quality and heterogeneity should also be included in the results section of the abstract.

Response: Comment 1-3 were incorporated in the abstract. Because of the restrictions on number of words of the abstract, we could not add that between study heterogeneity was assessed using the I-square. The abstract reads now as follows (page 1):

“Objectives: To assess the status of menstrual hygiene management (MHM) among adolescent girls in India to determine unmet needs

Design: Systematic review and meta-analysis. We searched PubMed, The Global Health Database, Google Scholar and references for studies published from 2000 to September 2015 on girls' MHM.

Setting: India

Participants: Adolescent girls

Outcome measures: Information on menarche awareness, type of absorbent used, disposal, hygiene, restrictions, and school absenteeism was extracted from eligible materials; a quality score was applied. Meta-analysis was used to estimate pooled prevalence (PP), and meta-regression to examine the effect of setting, region, and time.

Results: Data from 138 studies involving 193 subpopulations and 97,070 girls was extracted. In 88 studies, half of the girls reported being informed prior to menarche (PP 48%, 95% CI 43-53%, I² 98.6%). Commercial pad use was more common among urban (PP 67%, 57-76%, I² 99.3%, n=38) than rural girls (PP 32%, 25-38%, I² 98.6%, n=56, p<0.0001), with use increasing over time (p<0.0001). Inappropriate disposal was common (PP 23%, 16-31%, I² 99.0%, n=34). Menstruating girls experienced many restrictions, especially for religious activities (PP 0.77, 0.71-0.83, I² 99.1%, n=67). A quarter (PP 24%, 19-30%, I² 98.5%, n=64) reported missing school during periods. A lower prevalence of absenteeism was associated with higher commercial pad use in univariate (p=0.023) but not in multivariate analysis when adjusted for region (p=0.232, n=53). Approximately a third of girls changed their absorbents in school facilities (PP 37%, 29-46%, I² 97.8%, n=17). Half of the girls'

homes had a toilet (PP 51%, 36-67%, I2 99.4%, n=21). The quality of studies imposed limitations on analyses and the interpretation of results (mean score 3 on a scale of 0-7).

Conclusions: Strengthening of MHM programmes in India is needed. Education on awareness, access to hygienic absorbents, and disposal of MHM items need to be addressed.”

METHODS

4. The review authors report that data extraction was undertaken by two reviewers, but do not report if independent double data extraction or data checking was undertaken, which is important in a systematic review to minimise DE errors.

Response: We changed the second sentence in the section “Study selection, data extraction” as follows (page 3): “Data extraction of eligible material and the quality assessment was conducted independently by two reviewers (AMvE and MS or AB) using a data extraction framework (supplement S1) and standardized pretested extraction forms.”

5. The authors have assessed the methodological quality of their included studies but do not cite the instrument they have used. If the authors have created their own quality assessment instrument, this should be clearly stated along with any validation of the instrument the authors have undertaken.

Response: We did not use a pre-existing instrument, but scored for common factors relevant for bias in a survey, and many components are part of the Strobe checklist (<http://strobe-statement.org/index.php?id=available-checklists>). The method used was not validated. This was added to the method section as follows (page 3): “This quality score was not based on a pre-existing instrument, and has not been validated in other studies.”

6. The authors report using metaprop in Stata to pool data across studies and that they pooled prevalence data as proportions. The authors need to make it clear for the reader if any transformation of data occurred and how this was undertaken, along with how the authors dealt with missing data statistically.

Response: If data was missing for a certain outcome in a study, this study was not included in the analysis of that outcome. The Freeman-tukey double arcsine transformation was used as reported in the methods section, and this is used as a specification in the stata program.

7. The authors assess between-study heterogeneity using the I-squared statistic.

8. The I-squared statistic is usually seen in a pair-wise meta-analysis of RCT data (metan, RevMan) so it would be useful to explain for the reader its appropriateness when pooling proportion data.

Response: The I2 statistic is used to assess heterogeneity between studies. An I2 of 0%, would indicate that all variability in the pooled prevalence estimate was due to sampling error within studies, and not to heterogeneity between studies. However, given that there are many methodological and participant differences between the studies, we anticipated a high heterogeneity. It is recommended that the sources of heterogeneity are examined, e.g. by using meta-regression. We added this to the discussion as follows (page 7): “There was high heterogeneity between studies as indicated by the I2 statistic, which was regularly over 90%. This may be explained by the different methodology of the studies and the different settings where the studies were conducted. We used metaregression to explore factors that affected the outcomes, and indeed the setting (urban or rural), the region, time and quality of the study were regularly associated with the outcomes examined (Supplement 2).”

DISCUSSION

9. The discussion is heavily front-loaded in terms of discussion the subject area, rather than following the structure for a discussion of a systematic review and meta-analysis that has used robust methods.

I would suggest restructuring the discussion as the following paragraphs: summarise the overall results, including methodological quality and heterogeneity; describe limitations of the included studies review and hence the reliability of the results, i.e., couching the review findings in the context of the methodological quality and heterogeneity; describe the strengths and weaknesses of the systematic review methods, e.g., data were not double extracted or checked; set the results in context of other knowledge on the topic; provide conclusions, and then any implications for current practice and particularly for future research. The review authors touch on some of this in the penultimate paragraph, but a lot of this is played down. For example, why exactly did the authors anticipate statistical heterogeneity? The authors should consider the literature on spurious I-squared values from pooling observational studies.

Response: Please see above on how we changed the sentence regarding our expectation of a high heterogeneity. We have restructured the discussion, by moving some sections in the discussion. It is now as follows: summary of results, results in context, limitations and implications for current practice and future research and conclusion.

We agree that the I-square is just the proportion of observed dispersion, and that other measures may be more informative about the variation in results when the I-square is high, e.g. the range in proportions, or a standard deviation of the pooled proportion. For this reason we have regularly added the range of proportions when results are presented.

VERSION 2 – REVIEW

REVIEWER	Prof (Dr) MKC Nair Kerala University of Health Sciences, India Developmental pediatrics and adolescent care counselling
REVIEW RETURNED	29-Jan-2016

GENERAL COMMENTS	The authors have modified the article according to the comments of the reviewer and may be accepted for publication.
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REVIEWER	Bethany Caruso Emory University, Atlanta, GA USA
REVIEW RETURNED	04-Feb-2016

GENERAL COMMENTS	The authors have addressed all of my previous comments well and I congratulate them on a strong paper.
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REVIEWER	Seyed M Hoseini-Moghaddam Department of Medicine Western University, LHSC
REVIEW RETURNED	31-Jan-2016

GENERAL COMMENTS	I think the revision is well done.
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REVIEWER	Dr Marrison Martyn-St James University of Sheffield
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REVIEW RETURNED	26-Jan-2016

GENERAL COMMENTS	No further comments
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