

Understanding interventions to improve menstrual health in low and middle income countries: evidence and future directions.

Julie Hennegan

Department of Social Policy & Intervention, University of Oxford

Green Templeton College

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List of Abbreviations

CI	Confidence Interval (95%)
EBP	Evidence-based Practice
LMICs	Low and Middle Income Countries
M	Mean
MHM	Menstrual Hygiene Management
N	Number
NGO	Non-governmental Organisation
OR	Odds Ratio
RCT	Randomised Controlled Trial
cRCT	Cluster Randomised Controlled Trial
RR	Risk Ratio
RTI	Reproductive Tract Infection
SD	Standard Deviation
SDG	Sustainable Development Goal
SMD	Standardised Mean Difference
STI	Sexually Transmitted Infection
UTI	Urinary Tract Infection
WASH	Water Sanitation and Hygiene

Understanding interventions to improve menstrual health in low and middle income countries: evidence and future directions.

Julie Hennegan
Green Templeton College, University of Oxford
DPhil Social Intervention
Hilary Term, 2017

Abstract

Background. Menstrual health has emerged as an under recognised barrier to women and girls' dignity, health, education, and psychosocial wellbeing in low and middle income contexts. Interventions targeting this issue have seen increasing dissemination, despite little evidence for their effectiveness and sparse research to inform intervention development or evaluation.

Objectives. 1) Appraise current evidence for the effectiveness of menstrual health interventions; 2) Evaluate the effectiveness of a reusable sanitary pad and puberty education intervention for girls' school attendance; and, 3) Expand understanding of menstrual health to inform future research and practice.

Methods. The multiple objectives of this thesis were addressed through a range of methodological approaches, reported across six manuscripts. The first collates and critically appraises existing evidence in a systematic review, while the second provides a broader overview in a position piece advocating for an evidence-based approach to menstrual health. The third paper reports on a cluster quasi-randomised control trial of reusable sanitary pad and puberty education interventions undertaken in Uganda. The fourth and fifth papers report secondary analyses of the trial survey data to investigate the prevalence and consequences of menstrual hygiene, and schoolgirls' experiences with menstrual absorbents. The final manuscript presents a qualitative, framework analysis to describe and compare the menstrual experiences of 27 schoolgirls in the controlled trial.

Results. Systematic review identified eight controlled trials of menstrual health interventions. There was emerging evidence for the effectiveness of both education and product provision interventions, although methodological quality was poor. The controlled trial of reusable sanitary pad and puberty education provision found both interventions were similarly effective in reducing school absenteeism, with a moderate effect size. Follow-up quantitative papers provided insights into girls' menstrual experiences. In the first of these, the prevalence of inadequate menstrual hygiene was estimated to be 91% when measured consistently with the consensus definition, and did not differ between those using trial-provided reusable sanitary pads and those using existing methods. Aspects of menstrual hygiene were associated with shame, reduced school engagement, and health concerns. In the second follow-up, girls rated the trial-provided reusable sanitary pads favourably. However, greater perceptions of reliability did not translate into reduced rates of soiling or odour in the last menses. Finally, qualitative work provided process evaluation and nuanced understanding of the interventions' change mechanisms. Reduced fears of soiling improved school attendance for those provided with absorbents, while improvements in social support may have mediated the impact of the puberty education on attendance.

Conclusions. This thesis represents a significant step forward in the emerging field of menstrual health research. The work provides critical appraisal of existing studies and new evidence for the effectiveness of interventions to improve outcomes for girls' in low and middle income contexts. Further, new insights on the prevalence and consequences of menstrual hygiene, girls' appraisal of menstrual absorbents, and qualitative exploration of girls' experiences provide guidance for the development of future interventions and evaluations.

Publications and presentations arising from the thesis

Peer-review publications

Hennegan, J., & Montgomery, P. (2016). Do menstrual hygiene management interventions improve education and psychosocial outcomes for women and girls in low and middle income countries? A systematic review. *PLOS ONE*, 11(2), e0146985. <http://dx.doi.org/10.1371/journal.pone.0146985>

Hennegan, J. (accepted). Menstrual hygiene management and human rights: the case for an evidence-based approach. *Women's Reproductive Health (Special Issue. Menstrual health: a matter of human rights)*.

Montgomery, P., **Hennegan, J.**, Dolan, C., Wu, M., Steinfeld, L., & Scott, L. (2016) Menstruation and the cycle of poverty: a cluster quasi-randomised control trial of sanitary pad and puberty education provision in Uganda. *PLOS ONE*, 11(12), e0166122 <http://dx.doi.org/10.1371/journal.pone.0166122>

Hennegan, J., Dolan, C., Wu, M., Scott, L., & Montgomery, P. (2016). Measuring the prevalence and impact of poor menstrual hygiene management: a quantitative survey of schoolgirls in rural Uganda. *BMJ Open*, 6, e012596. <http://dx.doi.org/10.1136/bmjopen-2016-012596>

Hennegan, J., Dolan, C., Wu, M., Scott, L., & Montgomery, P. (2016). Schoolgirls' experience and appraisal of menstrual absorbents in rural Uganda: a cross-sectional evaluation of reusable sanitary pads. *Reproductive Health*, 13, 143-155. <http://dx.doi.org/10.1186/s12978-016-0260-7>

Hennegan, J., Dolan, C., Steinfeld, L., & Montgomery, P. (under review). Soiling, soap, and support. A qualitative understanding of the effects of reusable sanitary pads and puberty education: implications for future research and practice. *Reproductive Health*.

Conference presentations

Montgomery, P., **Hennegan, J.**, Dolan, C., Wu, M., & Scott, L. (2016, September). Menstruation and the cycle of poverty: a cluster quasi-randomised control trial of sanitary pad and puberty education provision in Uganda. *60th Annual Scientific Meeting of the Society for Social Medicine*, York, UK.

Hennegan, J., Dolan, C., Wu, M., Scott, L., & Montgomery, P. (2016, September). Measuring the prevalence and impact of poor menstrual hygiene management: a quantitative survey of schoolgirls in rural Uganda. *36th Annual Society for Reproductive & Infant Psychology Conference*, Leeds, UK.

Hennegan, J., & Montgomery, P. (2015, September). Do menstruation management interventions improve education and psychosocial outcomes for women and girls in low and middle income countries? A systematic review. *59th Annual Scientific Meeting of the Society for Social Medicine*, Dublin, Ireland.

Poster Presentations

Montgomery, P., **Hennegan, J.**, Dolan, C., Wu, M., & Scott, L. (2016, October). Menstruation and the cycle of poverty: a cluster quasi-randomised control trial of sanitary pad and puberty education provision in Uganda. *5th Virtual Conference on MHM in WASH in Schools*, New York, USA.

CHAPTER 1

Introduction and aims

Menstruation is the cyclic monthly shedding of the uterine lining. It is a natural process, integral to women's reproductive health. The management of menstrual bleeding has varied over time, and differed with available resources, cultural traditions, and preferences. Effective and hygienic management is essential for women to participate in society with dignity and comfort. Facilitating adequate menstrual management represents a significant challenge, and an opportunity to address gender inequalities and improve health, education, employment, and wellbeing outcomes for women and girls.

Taboo and stigma have resulted in poor representation of menstrual management issues across public and private sectors (United Nations, 2013). However, in recent years there has been increased recognition of women's menstrual needs (Sommer & Sahin, 2013; Sommer et al., 2016a). Governments and international organisations have launched programs such as the distribution of sanitary products or puberty education (Proctor & Gamble, 2010; Kristof, 2010; Garg, Goyal, & Gupta, 2012; Sommer, Hirsch, Nathanson, & Parke, 2015; Ameade & Majeed, 2015). Whilst such initiatives represent a significant step forward, menstrual health is severely under-researched. There is an urgent need to improve understanding of poor menstrual health, and its causes and consequences, and for rigorous evaluations of proposed interventions. This thesis seeks to fill some of these substantial gaps in the existing evidence base.

The thesis has been undertaken through the standalone papers route and includes six manuscripts submitted for peer-review publication. In addition, Introduction and aims (Chapter One) and Discussion (Chapter Eight) chapters provide background, narrative, and summarise findings from the work.

Chapters One, Two, and Three, work together to summarise and critically appraise current evidence in the field of menstrual health. The Introduction (Chapter One) defines key terms, describes the theoretical framework, and provides a broad overview of menstrual health. It also summarises the aims and manuscripts included in the thesis. The appraisal of existing evidence is continued in a systematic review of intervention studies (Chapter Two, paper #1) and a critical review and position paper advocating for an evidence-based approach to menstrual health (Chapter Three, paper #2). A new evaluation of the effectiveness of menstrual health interventions commences in Chapter Four, which reports the findings of a cluster quasi-randomised control trial undertaken in rural Uganda (paper #3). A suite of three follow-ups to the trial in Chapters Five, Six, and Seven, provide novel advances in the field. The first of these addresses measurement issues and the relationship between menstrual hygiene and proposed consequences (paper #4), while the second reports on girls' preferences and experiences with menstrual absorbents (paper #5). The final follow-up reports on a qualitative study investigating pathways of effect in the trialled interventions (paper #6). Finally, the Discussion (Chapter Eight) distils the contributions of the work and provides recommendations for future research and practice.

Chapter overview

Chapter One provides a broad introduction to menstrual health and the theoretical framework for the thesis. It will define key terms and outline considerations for an evidence-based practice approach. This will be followed by an overview of the importance of menstrual health for the lives of women and girls in low and middle income countries (LMICs) and description of the problem theory. The chapter will then provide a concise summary of the program theories underlying proposed interventions. It should be noted that structured critical appraisal of the quality of existing intervention studies is provided in the systematic review reported in Chapter Two (paper #1), and an evaluation of the quality of menstrual health research across studies is provided in Chapter Three (paper #2). The final sections of Chapter One outline the research questions for the thesis and detail the role of the candidate.

Key definitions

Menstrual hygiene management (MHM)

A unified definition of “*menstrual hygiene management*” (MHM) was developed in 2012 by the Joint Monitoring Program (JMP) of the World Health Organisation (WHO), with MHM defined as “*women and adolescent girls using clean menstrual management material to absorb or collect blood that can be changed in privacy as often as necessary for the duration of the menstruation period, using soap and water for washing the body as required, and having access to facilities to dispose of used menstrual management materials.*” (Sommer & Sahin, 2013, p.1557). This definition captures consensus around the essential physical requirements for the effective and hygienic management of menstruation. As addressed extensively in Chapter Five, detailed characteristics capturing ‘adequate’ and ‘inadequate’ MHM have yet to be well defined.

Menstrual health

Since “*MHM*” emerged as a recognised term, many have extended the strict definition to encompass other challenges of managing menstruation. Some have noted that information, education, and awareness are important preconditions for the uptake of physical facilities, and thus MHM (e.g., Winkler & Roaf, 2015). Further, that within a human rights framework, women and girls must be able to meet the conditions of MHM with dignity, without fear of stigmatisation or shame. It has been noted that women and girls with physical or mental disabilities may need additional facilities in order to manage menstruation hygienically and effectively (Winkler & Roaf, 2015; House, Mahon, & Cavill, 2012). As such, MHM is increasingly recognised as a term to refer to women’s unmet needs for managing menstruation and menstrual issues more generally. The term has been used in advocacy (e.g., “*Menstrual Hygiene Day*”, Menstrual Hygiene Day, 2017), and to refer to the field of research investigating menstruation in LMICs.

More recently, however, there has been push-back against the use of “*MHM*” in this way. Many uses of the term described above extend far beyond its formal definition. In response, the term “*menstrual health*” has been introduced as a way of capturing such extensions to “*MHM*”. Following review of the field, Geertz and colleagues (2016) proposed menstrual health as “*an encompassing term that includes both menstrual hygiene management as well as the broader systemic factors that link menstruation with health, well-being, gender, education, equity, empowerment, and rights.*” (p. 2). Whilst this serves as one origin of the term in its current use, this definition lacks clarity as to what constitutes a state of menstrual health. A better description of menstrual health may incorporate the definition of health adopted in the WHO constitution (1946, p.1) as “*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.*”

Use of terms in this thesis

Terminology in the study of women’s menstrual needs has evolved over the past few years and this evolution will likely continue. At present, many terms are used interchangeably and there is a lack of clarity around core concepts and definitions. This was identified as a priority problem for the field in a recent meeting of experts at the University of Oxford (described in Chapter Eight). This thesis has sought to use terms consistent with the strict version of their definition. “*MHM*” is used to refer to the physical requirements for managing menstruation as defined by the JMP (2012) above. The term “*menstrual health*” is used to refer to the physical management of menstruation in addition to mental and social needs such as education, reduced stigma, and empowerment. In the Introduction and aims and Discussion chapters (Chapters One and Eight) the term menstrual health has been adopted when referring to this field of research. However, it should be noted that this term was defined and incorporated as part of the lexicon in this field in late 2016. As such, manuscripts included in the thesis submitted for peer-review before that time (e.g., Chapter Two and Three, paper #1 and

paper #2) do not refer to “*menstrual health*”. Other terminology such as “*menstrual management*” or “*the management of menstruation*” are used to refer more simply to women managing their menses without additional connotations of hygiene requirements. “*Menstrual needs*” are conceptualised as all the needs women have to manage menstruation; physical, psychological, and socio-cultural.

Theoretical framework for the thesis

Evidence-based practice (EBP)

The evidence-based practice (EBP) model is defined as clinical decision making based on the conscientious, explicit and judicious use of best available evidence, integrated with client values and professional expertise (Sackett, Richardson, Rosenberg, & Haynes, 2000; Loumas, 2005; Haynes, Devereaux, & Guyatt, 2002; Gambrill, 2006). While this approach stems from evidence-based medicine (Evidence-Based Medicine Working Group, 1992), there is increasing recognition that social and public health programmes often fail to achieve positive outcomes, wasting limited resources, or worse, causing harm (Chalmers, 2003; Chalmers, 2005; Macintyre & Petticrew, 2000; Lorenc & Oliver, 2013). In response, many disciplines beyond medicine have moved towards an EBP approach. The EBP model has been visually represented by Haynes and colleagues (2002) as displayed in Figure 1.1. While it's medical origins are apparent in the terminology used, these can easily be adapted to other fields such as the study of menstrual health. For menstrual health, the EBP terminology could be adapted to advocate for the integration of high-quality evidence with an understanding of women and girls' experience, the need to address human rights, the specific contextual circumstances, and expertise in the field, as displayed in annotations on Figure 1.1.



Figure 1.1. Revised evidence-based practice model, with annotations for application to menstrual health (adapted from Haynes, Devereaux, & Guyatt, 2002).

In 2000, Sackett and colleagues outlined five steps in EBP:

“Step 1: Formulate an answerable question

Step 2: Track down the best evidence with which to answer that question

Step 3: Critically appraise the available evidence for its validity (closeness to the truth), impact (size of the effect), and applicability (usefulness in practice)

Step 4: Integrate the critical appraisal with practitioner expertise, patient preferences and with the context and circumstances

Step 5: Evaluate the effectiveness and efficiency in executing Steps 1-4 and improve them for next time” (p.4)

These steps provide a useful framework for practitioners and promote an approach to practice and policy that emphasise the use of high-quality research evidence. In this way, an EBP approach is dependent on the availability of high-quality evidence which can be critically appraised and integrated with other aspects of the model in order to make the best practice decision for the population (or patient) of interest.

Standards of evidence

In recognition of the need for high-quality evidence, much attention has been given to improving the rigorous conduct and appraisal of research. In the EBP tradition, hierarchies of research evidence have been employed to guide practitioners in the identification of the 'best evidence' (step 2 and 3) (Shekelle, Woolf, Eccles, & Grimshaw, 1999; Sackett et al., 2000; Flay et al., 2005). The traditional hierarchy focused on research of interventions and the designs which offered the lowest risks of bias in estimating treatment effects, as displayed in Figure 1.2.

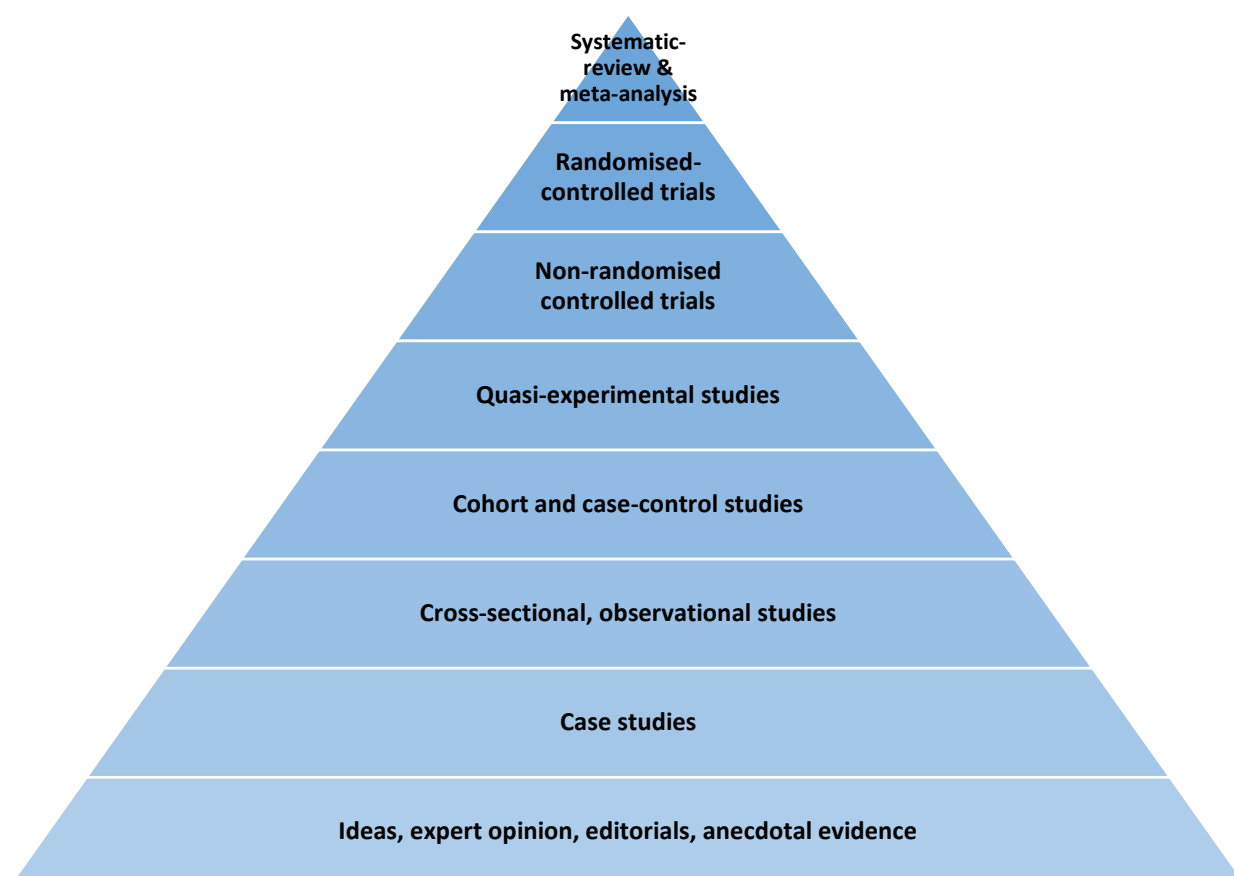


Figure 1.2. Hierarchy of evidence (adapted from Shekelle et al., 1999)

This hierarchical approach has come under criticism for failing to account for the appropriateness of different research designs for answering different questions. This has been a particularly pertinent concern in disciplines such as public health or social work, and the study of complex interventions where evaluations must ask questions beyond

effectiveness, or, “*does it work*” (Rychetnik, Frommer, Hawe, & Shiell, 2002; Petticrew & Roberts, 2002; Walach et al., 2006; Gottfredson et al., 2015; Moore et al., 2015; Petticrew, 2015). In response, some have suggested that rather than a fixed hierarchy, researchers should look to typologies of research and select methods most appropriate to their question (Rychetnik et al., 2002; Petticrew & Roberts, 2003). Petticrew and Roberts (2003) gave one such example where the appropriateness of different research methods were considered according to the type of research question (see Table 1.1). In this table, the top row summarises methods for the evaluation of ‘effectiveness’ and is consistent with the original evidence hierarchy. Other rows list additional key questions in the evaluation of complex interventions. Petticrew (2015) has recently emphasised the importance of such additional considerations in the study of complex interventions, suggesting researchers move from asking “*what works*” to “*what happened*”.

Table 1.1 An example of a typology of evidence, adapted from Petticrew & Roberts (2003) and Muir (1996).

Research Question	Qualitative research	Survey	Case-control studies	Cohort studies	RCTs	Quasi-experimental studies	Non experimental evaluat's	Systematic reviews
Effectiveness <i>Does this work?</i>				+	+++	+		+++
Process of service delivery <i>How does this work?</i>	++	+					+	+++
Salience <i>Does it matter?</i>	++	++						+++
Safety <i>Will it do more good than harm?</i>	+		+	+	++	+	+	+++
Acceptability <i>Will the intended audience be willing or able to take up the service/program</i>	++	+			+	+	+	+++
Cost effectiveness <i>Is it worth buying this service/program?</i>					++			+++
Appropriateness <i>Is this the right service for this population?</i>	++	++						++
Satisfaction with the service <i>Are users, providers, and other stakeholders satisfied with the service?</i>	++	++	+	+				+

Complex interventions

As noted above, interventions in many fields such as social work, public health, and public policy are complex. Researchers have increasingly emphasised the importance of the degree of complexity of an intervention and the additional considerations then needed in evaluation and implementation (Craig, Dieppe, MacIntyre, & Michie, Nazareth, & Petticrew, 2008; Hawe, 2015). The United Kingdom Medical Research Council (MRC) has conceptualised complexity across multiple dimensions. An intervention is considered to have increasing degrees of complexity according to the (Craig et al., 2008):

- *Number of interacting components within the experimental and control interventions*
- *Number and difficulty of behaviours required by those delivering or receiving the intervention*
- *Number of groups or organisational levels targeted by the intervention*
- *Number and variability of outcomes*
- *Degree of flexibility or tailoring of the intervention permitted*

These characteristics provide a useful reference point when considering the complexity of an individual intervention. However, others have argued that complexity needs to be conceptualised not only in terms of the intervention, but also as a characteristic of the system in which an intervention may be implemented (Hawe, Shiell, & Riley, 2009; Hawe, 2015). In this way, interventions which appear straightforward may reveal higher levels of complexity when considered in context. Interventions to improve menstrual health and hygiene typically have multiple interacting components, seek to alter human behaviours, and interact with a complex environment of resource unavailability and social stigma. Thus, under both approaches, interventions for improving menstrual health can be considered complex. In guiding approaches to

menstrual health research, and in the development and evaluation of interventions for this complex problem, it is useful to turn to established guidance for studying complex interventions.

The Medical Research Council guidance for complex interventions

This thesis draws on the MRC guidance for the development and evaluation of complex interventions (Craig et al., 2008) as a framework with which to appraise the state of menstrual health research, and to situate the components of the thesis into the broader picture of intervention development and evaluation. The MRC framework is displayed in Figure 1.3.

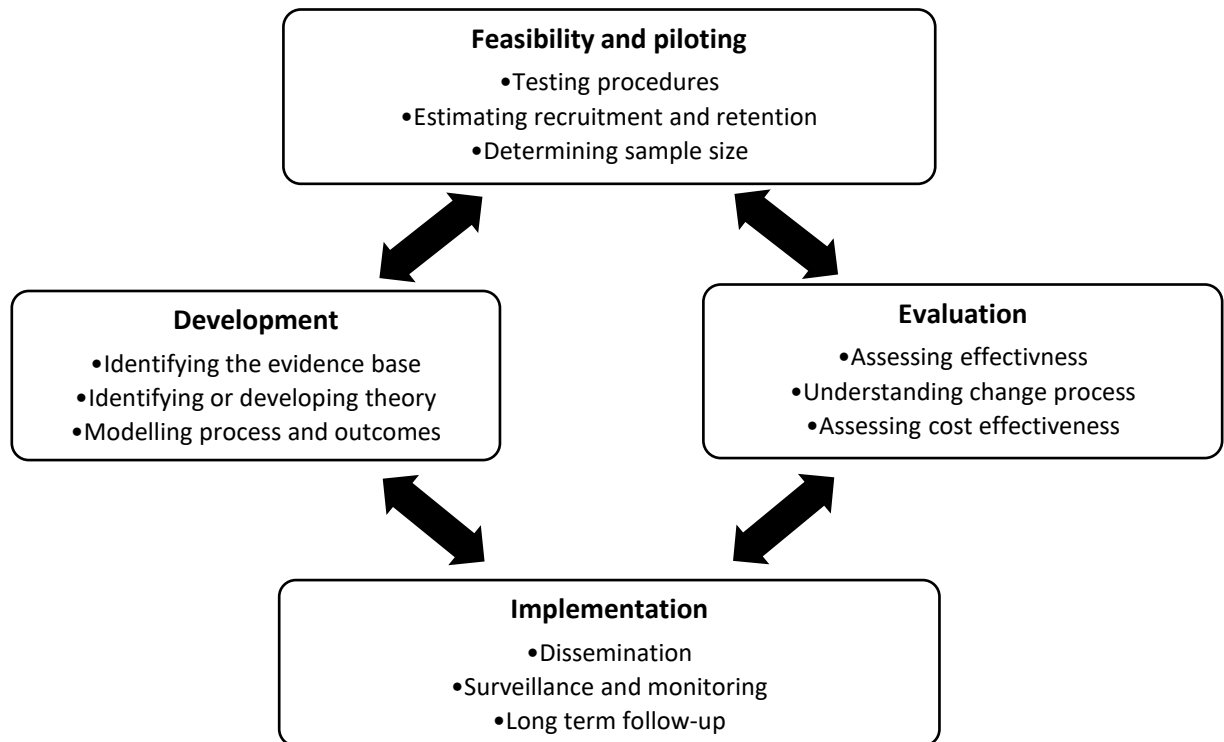


Figure 1.3. MRC framework for the development and evaluation of complex interventions (Craig et al., 2008)

In order to efficiently and rigorously develop and evaluate interventions, this framework promotes a cyclic process emphasising the importance of understanding the problem an intervention seeks to address and then understanding how an intervention

elicits change when evaluating effectiveness. Lessons learned from evaluations and their implementation are then fed back into further development. The work proposed for this thesis focuses most heavily on the phases of development and evaluation. The development phase includes gaining an understanding of existing interventions and their effectiveness, developing a thorough understanding of the problem, modelling the processes within the intervention, and identifying suitable outcomes and outcome measures (Craig et al., 2008). After piloting the testing procedures, full-scale evaluation seeks to provide an estimate of effectiveness. Further, evaluations seek to assess the underlying theory of the intervention. In both development and evaluation phases, Craig et al. (2008) stress the importance of modelling the problem and change process of the intervention. The MRC framework also emphasises the iterative nature of intervention research and the capacity for different phases of the process to inform and improve the others. Similarly, the work of this thesis falls under different phases of the framework, and findings are used to provide recommendations for the future development and evaluation of menstrual health interventions.

Why study menstrual health?

Menstruation is a near-universal experience for women and girls from early adolescence until menopause. Most women menstruate between two and seven days every 21 to 35 days (NICE, 2007). That is, on average, a total of 65 days per year. In 2017, there are over 1.5 billion females aged between 15 and 49 in United Nations defined Less Developed Countries (Census Bureau, 2017). There has been no large-scale assessment of menstrual health among these women, however associated indicators and pooled estimates from small-scale studies suggest that menstrual health is poor (Loughnan, Bain, Rop, Sommer, & Slaymaker, 2016). A systematic review of research in India found that across 88 studies, a pooled prevalence of 48% of girls had been informed that menstruation would happen to them prior to menarche (van Eijk et al., 2016). If this figure is generalizable, of the 55 million girls between 10-14 in India in 2017 who may reach menarche in the coming years, 26.4 million will be unaware of menstruation before it commences (Census Bureau, 2017). Beyond menstrual knowledge, women and girls lack resources to manage their menses. In the same review, van Eijk and colleagues (2016) found that across studies in India a pooled prevalence of 67% of girls in urban areas, and only 32% of girls in rural areas used commercial sanitary pads. A recent review of water, sanitation and hygiene (WASH) coverage in sub-Saharan African countries using Demographic Household Survey or Multiple Indicator Cluster Survey data estimated that an average 4.2% of the population have access to WASH at the 'basic' target level for the Sustainable Development Goals¹ (SDG) (Roche, Bain, & Cumming, 2017). In addition, Loughnan and colleagues (2016) have suggested that the half a billion women (13%) globally estimated to practice open

¹ Water within 0-30 minutes from dwelling; handwashing facility observed; presence of soap, detergent, or other cleansing agent at the specific place for handwashing.

defecation, according to JMP data, are highly likely to lack menstrual hygiene and health. Thus, estimates of absorbent, WASH, and latrine coverage suggest that many women and girls do not have access to the necessary requirements for managing menstruation.

Prevalence

Limited research has investigated the prevalence of menstrual health and MHM. Only in the last decade have studies of women and girls' experiences, and the consequences of poor menstrual management been published. Much of this work is limited. Most studies have been surveys of approximately 100-400 adolescent girls, and have asked basic questions about their management practices (e.g., Santina, Wehbe, Aizde, & Nehme, 2013; Arora, Mittal, Pathania, Singh, Mehta, & Bungler, 2013; Adinma & Adinma, 2008). Perhaps reflecting the recency of a unified definition of MHM, many of these capture only one aspect of management such as the type of absorbents used or body washing practices. The systematic review noted above, identified 138 survey studies in India (van Eijk et al., 2016). Studies were found to be of low quality and largely limited to research questions concerning the type of menstrual absorbent used. A smaller selection of studies is available outside of India, and high rates of unhygienic absorbent use have been documented (Chandra-Mouli & Patel, 2017). In Nigeria, of 550 schoolgirls surveyed, 56% reported using unsanitary menstrual absorbents, most often toilet paper (Adinma & Adinma, 2008). Wilson and colleagues (2014) reported similar findings in Kenya, with 51% of 302 girls across 10 schools reporting using disposable sanitary pads, while 40% used cloth, wool or blanket, and 8% used toilet paper. In a higher-income sample of student nurses from training schools in Nigeria, Moronkola and Uzuegbu (2006) found 70% used sanitary pads as menstrual absorbent. Of 245 college students in Islamabad Pakistan aged 16-21, 50% reported using commercial sanitary pads, with 50% using home-made menstrual absorbents (Aflaq & Jami, 2012).

Far fewer studies have assessed menstrual management in adult women. Work conducted by the Business Social Responsibility (BSR) '*HERproject*' has noted poor MHM to be a significant issue for supply chain factory workers in a number of countries (BSR, 2006; 2011; 2012). Reports from site visits at over 40 factories in India stated that most women used and reused cloth absorbents, often dirty cloth found on the factory floor (BSR, 2006). In Afghanistan, 91% of women disclosed in focus groups or individual interviews that they used old cloth as menstrual absorbent (ACTD, 2013).

The variation in estimates of menstrual absorbent use reflects the variety of contexts assessed as well as the diverse practices of MHM in LMICs. Studies assessing correlates of sanitary pad use have suggested that rural location, current school enrolment, caste or socio-economic status, and education level predict use of unhygienic absorbents (Tegegne & Sisay, 2014; El-Gilany, Badawi, & El-Fedawy, 2005; Anand, Unisa, & Singh, 2015). Prevalence variations may also reflect different methods used to assess absorbent use as no standardised or validated measures have been developed. No studies have used a comprehensive measure of MHM capturing all aspects of the consensus definition (Sommer & Sahin, 2013) and it should be noted that studies assessing absorbent use do not adequately capture the full state of MHM (for further discussion see Chapter Five). As such, it is likely that the prevalence of poor MHM is much higher than has been reported.

Additional aspects of MHM have been assessed in some studies which have reported variable access to privacy for changing, genital washing or adequate washing and drying of absorbents. A cross-sectional study of urban and rural public schoolgirls in Egypt found that poor hygiene was prevalent despite 67% of girls using sanitary pads. Pads were changed infrequently and rarely at school, and 29% of girls reported not bathing during menstruation (El-Gilany, Badawi, & El-Fedawy, 2005). In Pakistan, Ali and Rizvi (2010) found using interviews, surveys, and focus groups that nearly 50% of girls did not bathe during menstruation. Tegegne and Sisay (2014) reported on the most

aspects of MHM in a single study to date. Authors found in a sample of 595 school girls in northeast Ethiopia that 55.6% of girls used cloth as menstrual absorbent. Only 37% of girls washed absorbents with soap and water, 61% with water only. 20% dried absorbents in the sun. Most girls (55%) bathed only after menstruation was complete. 42% washed external genitalia with soap and water. 77% disposed of absorbents in a latrine, 33% in an open field (Tegegne & Sisay, 2014).

Such studies provide a useful estimate of the state of MHM across different groups. However, as noted above, few studies provide a comprehensive survey of menstrual practices. In addition, most studies fail to report the questions used to assess practices making it difficult to judge the item quality. The taboo nature of menstruation, and tendency for socially desirable responding mean poorly designed questions are unlikely to accurately capture practices. Further, few studies disclose sampling methods or refusal rates. Of reviewed studies in India rated on quality from 0-7, van Eijk and colleagues (2016) found only 19.6% of studies met five or more quality criteria (e.g., description of inclusion and exclusion criteria, number of non-respondents, multivariate analysis for outcomes). Many of the studies cited above were unclear in their research questions, beyond simple description of girls' practices. In sum, while current evidence is incomplete, existing studies suggest that large proportions of women and girls across LMICs do not have adequate menstrual hygiene or menstrual health.

Consequences

Poor menstrual management has been hypothesised to have detrimental effects on physical health, education, employment, and psychological wellbeing.

Health

Inadequate MHM can lead to discomfort, irritation and infection (Mahon & Fernandes, 2010; House, Mahon, & Cavill, 2012). Poor hygiene has been proposed to be linked to reproductive tract infections (RTIs), bacterial vaginosis and vulvovaginal candidiasis, as well as urinary tract infections (UTIs) (see Table 1.2). These conditions can cause considerable discomfort, and have also been linked to increased vulnerability to sexually transmitted infections including HIV (Sweet, 2000; Atashili, Poole, Ndumbe, Adimora, & Smith, 2008; Johnson & Lewis, 2008). In Pakistan, a survey of 556 women found 33% reported irritation, and 10% infection attributable to poor MHM (IRSP, 2013). The use of unclean menstrual absorbents, menstrual absorbents which have not fully dried, and failure to wash external genitalia during menstruation have all been hypothesised to contribute to such irritation and infection. An early study in India surveyed urban and rural girls and found 76% of 611 participants used old cloth as absorbent, with almost a third self-reporting symptoms of RTIs (Khanna, Goyal & Bhawsar, 2005). Sumpter and Torondel (2013) conducted a systematic review of studies assessing these associations and found mixed evidence for associations between MHM and RTIs. Many included studies assessed aspects of menstrual hygiene and classified menstrual absorbents or 'hygiene indexes' differently, and populations varied widely.

Table 1.2. Description and symptoms of non-sexually transmitted reproductive and urinary tract infections (adapted from House, Mahon & Cavill, 2012, Toolkit One ,T1.3.4, p.230-232)

Condition	Description	Symptoms
Bacterial Vaginosis	The normal balance of bacteria in the vagina becomes disrupted and there is an overgrowth of specific types of bacteria.	Pain, fishy odour, white or grey vaginal discharge, itching, burning sensation on urination. There may also be no symptoms.
Vulvovaginal Candidiasis (thrush)	A common fungal infection that occurs when there is overgrowth of the fungus (or yeast) called Candida. Candida usually lives in the vagina in small quantities without causing symptoms. A change in the vaginal pH or hormonal changes can lead to an overgrowth of the fungus.	Genital itching or burning, often with a watery, white, lumpy vaginal discharge.
Urinary tract infections	The majority of urinary tract infections (UTIs) are caused by E. coli infections – often introduced into the urethra (the tube that leads from the bladder to allow the passage of urine) from the rectum.	Burning sensation or pain when passing urine. Urge to urinate frequently. Raised temperature. There is no vaginal discharge. Lower urinary tract infections can cause blood in urine and an inability to urinate despite the urge.

Education

A negative influence on education has been the consequence of poor MHM most prominently discussed. Qualitative and quantitative work have suggested that a lack of access to MHM leads to school absenteeism, distraction, and disengagement (Lloyd & Young, 2009; Grant, Lloyd, & Mensch, 2013). A World Bank report (2005) asserted that 10-20% of school-days were missed by girls in LMICs due to menstruation, and whilst other reports repeat this figure, most lack substantiating evidence (e.g., World Bank, 2005; House, Mahon, & Cavill, 2012; UNESCO, 2014). Evidenced estimates of the association between menstruation and school absence have varied. A study in rural Malawi of 717 girls aged 14-16 reported that after adjusting for sociodemographic

characteristics and other reasons for school absenteeism, menstruation did not predict absence (Grant, Lloyd, & Mensch, 2013). In contrast, a study of 595 school girls in northeast Ethiopia found that even after adjustment for residence, household income, and parental education, girls who did not use disposable sanitary pads had 5.37 times higher odds of school absenteeism during menses than those using disposable pads (Tegegne & Sisay, 2014). An RCT conducted in Nepal used girls' menstrual calendars (self-kept) and attendance records to estimate that only 0.4 days in 180 were missed due to menstruation (Oster & Thornton, 2011). In contrast, a pilot non-randomised trial in Ghana found that the provision of sanitary pads and education improved attendance by 9% after 5 months (Montgomery, Ryus, Dolan, Dopson, & Scott, 2012). No studies have used a comprehensive assessment of MHM consistent with the consensus definition and assessed association with school attendance.

A primary criticism of studies which seek to establish the relationship between menstruation and education, and intervene to improve outcomes, has been a myopic focus on attendance (e.g., Dolan, Ryus, Dopson, Montgomery, & Scott, 2013). As qualitative studies have highlighted, even if girls are present at school during their menses, being concerned about leaking through absorbents, soiling/soiled outer garments, odour, and the secrecy of their menstrual status is likely to hinder concentration and engagement in the classroom (Sommer, 2010; McMahon et al., 2011; Caruso et al., 2013; Crichton et al., 2013; Sommer et al., 2014). This was noted by Caruso and colleagues (2013) in a report of WASH in Sierra Leone. They found that whilst girls were typically active classroom participants, they would disengage during menstruation, sitting in the back of the classroom concerned about odour or soiling clothes. Girls may also miss parts of the school day to manage menstruation, not reflected in attendance records. In Malawi, a survey and site evaluation study found girls estimated missing one or two hours per day during their menses due to body washing, changing stained skirts, and other menstrual concerns (Pillitteri, 2011).

It was recently estimated that 60% of countries have not reached gender parity in primary and secondary education (UNESCO, 2010). In many regions improvements have been more pronounced in primary education than secondary, despite strong evidence for the benefits of secondary education (UNESCO, 2010). Menstrual health advocates argue that menstruation may be one of many contributors to this ongoing inequality (Sommer et al., 2016a). Negative impacts on girls' education have immediate and long-term consequences for girls in LMICs. Benefits of staying in school include improved literacy and self-efficacy as well as delayed sexual debut, marriage, and exposure to STIs (LeVine, LeVine, Rowe, & Schnell-Anzola, 2004; Lloyd & Young, 2009). Further, educational attainment has been linked to positive long-term outcomes for women's labour force participation and earnings, increased involvement with household decisions, and health for women and their family (Herz & Sperling, 2004; Kirk & Sommer, 2006; Rihani, Kays, & Psaki, 2006; World Bank, 2007; Lloyd & Young, 2009).

Workplace difficulties

As noted above, there is a dearth of literature concerning the impact of MHM on adult women. The few evaluations conducted suggest menstruation represents a barrier to work attendance and engagement (BSR, 2011; 2012). Focus groups from a factory in Pakistan suggested that women missed up to three days' work per month due to menstruation (BSR, 2012). Menstrual pain was emphasised more frequently by factory workers than hygiene management, although it should be noted that many factories had provided free sanitary pads as part of *HERproject*, with site evaluations reporting improved health and attendance as a result (however, few specific measures were taken and the project included multiple health-care elements, making it difficult to isolate the effects of different components). Recent call to action in this area (Sommer, Chandraratna, Cavill, Mahon, & Phillips-Howard, 2016b) highlighted that women in LMICs are often employed in the informal sector which lacks safety regulations and

standards, and within which women may lack the political power to change WASH or facility standards in their workplace. This paper called for increased attention to this issue in order to understand and address inadequacies (Sommer et al., 2016b).

Psychosocial consequences

The impact of menstrual management on psychological wellbeing and adjustment was first highlighted through qualitative research and NGO reports (e.g., Sommer, 2009a; 2009b; McMahon et al., 2011; Crichton et al., 2012; Mason et al., 2013; Long et al., 2013; Sommer et al., 2014). However, relatively few in-depth qualitative studies of the psychosocial impact of menstruation have been conducted. In 2013, Crichton and colleagues identified two qualitative studies of the psychosocial impacts of menstruation in resource-poor settings, in a systematic search of peer-reviewed literature (Sommer, 2009a; 2009b; McMahon et al., 2011). Authors conducted a subsequent qualitative investigation of schoolgirls' experiences (Crichton et al., 2013). Since this time, a number of additional qualitative studies have been published, situated in Nepal (Crawford, Menger, & Kaufman, 2014), Kenya (Mason et al., 2013), and a comparative study across Tanzania, Ghana, Cambodia, and Ethiopia (Sommer et al., 2014). These studies have consistently reported negative psychological effects, predominantly shame, fear (and fear of stigma), distraction, anxiety, and low mood. Themes capturing the psychosocial consequences of poor menstrual management are summarised in Table 1.3.

Table 1.3. Psychosocial consequences of menstruation identified in qualitative studies

Study	Population	Key Themes
Sommer 2009a/b;	In-school and out-of-schoolgirls (n=16) aged 16-19 in Tanzania	Worries about physiology of menstruation Worries about fulfilling adult role Worries regarding sexual attention (generally safety concerns) Shame and confusion upon reaching menarche (lack of pragmatic knowledge of management) (Sommer, 2009a) Fear, shame and confusion around menses (Sommer 2009b) Disengagement from school due to discomfort associated with menstruation Author conclusions suggest inadequate facilities have negative impacts on empowerment, confidence and wellbeing
McMahon et al., 2011	28 primary schoolgirls from six rural schools in Western Kenya	Shame, fear, distraction, confusion and powerlessness describe feelings towards menstruation. Concerns regarding unwanted attention (sexual or ridicule/teasing) Feelings that menstruation is 'bad' Societal expectations regarding secrecy despite deficits in understanding Lack of self-efficacy/confidence and feeling incapable of managing menses Stigma and fear of stigma associated with menstruation
Crichton et al., 2013	15 individual interviews and 10 focus groups with girls aged 12-17 (in-school and out-of-school) in Nairobi	Social stigma (bullying by friends, boys) Fear of stigma associated with menstruating status, leaking and odour Embarrassment, anxiety, low mood Feelings of isolation and self-imposed reduced social activities Distraction, lack of concentration and reduced participation in the classroom Participants used terms including "feeling bad", "stressed" "fearful" and "wanting to cry" to describe emotional distress.
Mason et al., 2013	120 girls aged 14-16 through 11 focus groups conducted in rural western Kenya	Unprepared for menarche, resulting in feelings of anxiety and shock Fearing menstruation as an illness Feeling alone or isolated (pressures of secrecy) Fear and anxiety regarding physical management and stigma as well as sexual advances Fear and shame most prominent feelings Disengagement in class and self-imposed withdrawal from activities
Crawford et al., 2014	University students and adult women (n = 19) from Nepal	Fear, secrecy and shame experienced at menarche Emotional distress and 'feeling upset' at menarche and afterwards during menses Culturally sanctioned restrictions and expectations during menstruation Experiencing stigma and fear of stigma Shame
Sommer et al., 2014	Focus groups with a total of approximately 150 girls in each country (Ghana, Cambodia and Ethiopia) with results also compared to findings from Tanzania (Sommer 2009a/b)	Fears regarding stigma and cultural taboos Secrecy and needing to conceal menstrual status and menstruation management from others Fear of sexual expectations/advances Confusion, anxiety, worry about managing menstruation Embarrassment and fear of ridicule/stigma Lack of confidence to manage menstruation

Both physical hygiene management, and broader socio-cultural aspects of menstruation appear to contribute to psychosocial consequences. Soiling outer-garments and odour have been identified as foremost concerns amongst adolescent girls (Dolan et al., 2013; House, Mahon, & Cavill, 2012). Few studies have quantified the extent of this issue. In Ghana, Dolan and colleagues (2013) found that over three quarters of schoolgirls surveyed reported soiling outer garments during their last menses.

Poor understanding of menstruation and its management has been noted as particularly detrimental at menarche if girls are unprepared, leading to fear and worry (Deo & Ghattargi, 2005; Ali & Rizvi, 2010). Kumar and Srivastava (2011) reported that 29% of girls from residential areas and 55% of girls from slum areas were frightened and cried at menarche, and 32.5% reported feeling disgusting (Kumar & Srivastava, 2011). Again, few studies have quantitatively assessed the relationships between MHM, socio-cultural factors, and proposed consequences. Aflaq and Jami (2012) provided some analysis in a survey of 245 college girls in Islamabad. Positive experiences of menstruation were associated with being able to share and discuss with others and being able to move freely in home and school settings. Positive experiences and attitudes were negatively correlated with feeling self-conscious in social situations, depressed mood, and avoiding physical activities. Notably, girls using premade disposable pads reported more positive attitudes towards menstruation (Aflaq & Jami, 2012).

There is emerging evidence that menstrual needs may indirectly affect wellbeing, with reports suggesting girls engage in transactional sex in order to purchase sanitary pads (House, Mahon, & Cavill, 2012; Mason et al., 2013), or receive unwanted sexual attention after disclosure of their menstrual status (Abrahams, Mathews, & Ramela, 2006; Crichton et al., 2013).

What contributes to poor menstrual health?

Material and psychosocial deprivations have been hypothesised to contribute to poor menstrual health (Crichton et al., 2013). As reflected in the definition of MHM, there are a number of conditions required for adequate and hygienic menstrual management. These physical conditions must be combined with knowledge and information, and are embedded within a social and cultural context. In a recent summary of menstrual health literature, Geertz and colleagues (2016) conceptualised menstrual health as a mix between these physical deprivations (sanitation and products), awareness, and community and societal level factors, displayed in Figure 1.4.

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Figure 1.4. Menstrual health framework (Geertz et al., 2016)

Material deprivation

Clean absorbents

Clean menstrual absorbents may take many forms, from commercially produced sanitary pads, tampons, and menstrual cups to locally made re-usable sanitary pads, home-made pads, or cloth (if cleaned appropriately). Menstrual absorbents must be comfortable, safe, and fit for the purpose of absorbing menstrual blood providing protection against soiling garments (Winkler & Roaf, 2015; Tamiru, Mamo, Acidria, Mushi, Ali, & Ndebele, 2015). Women and girls may use different products depending on available resources, personal and cultural preference, for example, vaginally inserted absorbents may not be considered acceptable for adolescent or unmarried girls (House, Mahon, & Cavill, 2012). The cost and availability of sanitary products is a fundamental barrier to MHM and menstrual health in LMICs (Pillitteri, 2011; House, Mahon, & Cavill, 2012; van Eijk et al., 2016). Commercial products are frequently unavailable, and these are often too expensive for women and girls to afford (Dasgupta & Sarkar, 2008; Crofts & Fisher, 2012; House, Mahon, & Cavill, 2012; Pillitteri, 2011; Garg, Goyal, & Gupta, 2012). El-Gilany and colleagues' (2005) found in Egypt that higher socio-economic status and urban residence predicted disposable sanitary pad use. Similarly, school girls from families with higher reported monthly expenditure were more likely to use disposable sanitary pads in northeast Ethiopia (Tegegne & Sisay, 2014).

WASH facilities and privacy

Adequate WASH facilities are necessary for MHM and for managing menstruation with dignity and comfort. The ability to wash both the body and reusable absorbents to a hygienic standard requires access to a reliable water-supply and soap which can be used discretely and in private (Sommer & Sahin, 2013). Travelling long distances to collect water may inhibit women's ability to change absorbents as needed. It may also be an obvious sign that a woman is menstruating, attracting unwanted

attention and stigma (Sommer et al., 2009; House, Mahon, & Cavill, 2012). Hygiene guidelines recommend changing absorbents every two to six hours dependent on blood flow, thus facilities are needed at home and in schools or workplaces (House, Mahon, & Cavill, 2012). Across low income contexts, many schools and homes lack adequate WASH facilities. In 2013, UNICEF estimated that basic water and sanitation facilities were lacking in over 50 per cent of primary schools in least developed and low income countries. The cost of soap also presents a barrier to the hygienic and effective use of improvised absorbents (Tegegne & Sisay, 2014; Tamiru et al., 2015).

Where toilets are available, their design often fails to meet women and girls' physical and psychological needs (Fisher, 2006; Dolan, Ryus, Dopson, Montgomery, & Scott, 2013). Latrines lacking doors or locks may threaten safety and cause embarrassment (Abrahams, Mathews, & Ramela, 2006; Lloyd & Young, 2009). Open pit latrines mean blood or used sanitary products often reveal when a woman is menstruating, resulting in embarrassment and stigma (Fisher, 2006; Mahon & Fernandes, 2010). A site evaluation in Malawi found that girls reported waking early in the morning to shower or use toilets before others could see. Girls reported not using the 'special' cubicle toilet with a tap as it was a clear sign they were menstruating, and 25% stated they practiced open defecation rather than using school toilets so that others would not see menstrual blood (Pillitteri, 2011). A lack of female teachers, and sensitivity to girls' need to excuse themselves and find time to change absorbents during breaks further contributes to an environment in which managing menstruation is difficult (Lloyd & Young, 2009).

Beyond access to sanitation facilities and private spaces for changing menstrual absorbents at school, home environments may also fail to provide sufficient facilities for MHM. For the many women and girls using reusable menstrual absorbents, home may represent a more comfortable place to clean used absorbents. To facilitate this, women and girls need consistent access to water, soap, and a private space to wash and dry

absorbents. The taboo nature of menstruation means many girls have reported distress in finding a private space to wash absorbents adequately, or finding places to dry absorbents (House, Mahon, & Cavill, 2012). Hygiene guidelines have recommended drying absorbents in the sun to benefit from the antimicrobial properties of UV light, however, many girls report drying absorbents under mattresses or in other, hidden locations that are unlikely to facilitate hygienic drying (House, Mahon, & Cavill, 2012; Tegegne & Sisay, 2014).

Disposal

The ability to dispose of single use menstrual absorbents has been an overlooked aspect of menstrual health in research to date. Few studies have investigated disposal practices, even when implementing single-use product interventions. Used menstrual absorbents present potential negative environmental impacts. In absence of waste management strategies, used products may be thrown into pit latrines, fields, or present blockages to sanitation systems (Geertz et al., 2016). Beyond environmental impacts, access to disposal facilities presents an additional challenge to women and girls. Throwing used absorbents into latrines or public waste areas may reveal menstrual status or incur embarrassment. Further, cultural taboos around others seeing menstrual blood, or the burning of menstrual blood, discussed below, add further strain to find adequate disposal options (House, Mahon, & Cavill, 2012; Geertz et al., 2016).

Psychosocial deprivation

Understanding menstruation

Adolescent girls have been found across a range of countries to lack knowledge of the function, origin, and management of menstrual bleeding (Ali & Rizvi, 2009; House, Mahon, & Cavill, 2012; Sommer, 2010, 2011; Crichton et al., 2013; van Eijk et al., 2016; Chandra-Mouli & Patel, 2017). Adinma and Adinma (2008) found that few Nigerian girls

(aged 15-17) knew the location or function of their reproductive organs, with many believing menstrual blood originated from abdominal organs. A qualitative study in India found that despite recent government efforts to provide sanitary pads to girls in rural areas, few had an understanding of the use or disposal of sanitary products (Chothe et al., 2014). Whilst mothers were often the primary source of menstrual knowledge, they too lacked accurate information (Chothe et al., 2014). Reshmi and colleagues (2015) found poor understanding of menstruation and management in a sample of 400 adult women in India. In two sample sites, only 26% and 21% of women knew that foul smell in menstrual discharge was abnormal (Reshmi et al., 2015). In a study of 200 schoolgirls in India, 56% were under the misconception that menstruation was a disease or physical problem and 28% lacked understanding regarding the timing of the menstrual cycle (Dube & Sharma, 2012). In Egypt, 84% of girls surveyed stated they needed more information regarding MHM (El-Gilany, Badawi, & El-Fedawy, 2005). A recent scoping review of studies of menstrual knowledge across LMICs described a similar pattern of findings (Chandra-Mouli & Patel, 2017). It should be noted that this review had a number of limitations. The review identified only 81 studies, when another systematic review of cross-sectional studies found 138 English-language papers on India alone (van Eijk et al., 2016). Chandra-Mouli and Patel (2017) failed to undertake any quality assessment of included studies. Rather, they provided a narrative summary of menstrual knowledge and sources of information across LMICs without commenting on the inadequacy of measures or methods in the included papers. They found that the proportion of girls with knowledge of menstruation prior to menarche was highly varied across countries, but often below 60%. Mothers were overwhelmingly identified as the source of menstrual information, followed by other family members.

Preparation and support at menarche

The shroud of silence around menstruation typically leaves girls unprepared for menarche and prohibits them from asking questions, or discussing management openly

(Dasgupta & Sarkar, 2008; Sommer & Kirk, 2008; Sommer, 2009; McMahon et al., 2011; Marvan & Molina-Abolnik, 2012). Ali and Rizvi (2010) reported that in Pakistan, less than 50% of girls surveyed received information about menstruation prior to menarche, and only 15% information about management. In West Bengal a higher 68% of girls surveyed were aware of menstruation prior to menarche, but 51% were ignorant regarding the use of sanitary pads (Dasgupta & Sarkar, 2008). The relationship between pre-menarche training and outcomes has received limited assessment. In a study of Nigerian schoolgirls, Aniebue and colleagues (2009) found that girls without pre-menarche training were more likely to report adverse effects of menstruation in multiple domains including schooling, social-life, unhygienic practices and menstrual pains. A study conducted in three different public schools in Mexico found discussing the emotional aspects of menstruation (generally with mothers) prior to menarche was associated with a more positive attitude towards menstruation (Marvan & Molina-Abolnik, 2012). Both studies were cross sectional and retrospectively assessed preparation for menarche and management practices, limiting the strength of conclusions drawn. The aforementioned review by Chandra-Mouli and Patel (2017), concluded that mothers in many contexts did not discuss menstruation with daughters until after menarche. Authors echoed the finding that girls felt unprepared for menarche and frequently reported negative reactions to their first menses.

Cultural restrictions and taboos

Cultural beliefs and taboos may contribute to poor menstrual health through misinformation or unhygienic customs, in addition to perpetuating stigma and shame around menstruation. A comparative study of girls in Tanzania, Ghana, Cambodia and Ethiopia found similarities in the taboos reported. Many concerned the disposal of menstrual blood, with beliefs that if animals or others came in contact with used absorbents this would lead to infertility or curses (Sommer, Ackatia-Armah, Connolly, & Smiles, 2014). Other studies have documented cultural practices including social

restrictions, restrictions to bathing, and taboos around others seeing menstrual blood (Pillitteri, 2011; Deo & Ghattargi, 2005; Kumar & Srivastava, 2011; Santina, Wehbe, & Ziade, 2012; ACTD, 2013). Few papers have quantified these restrictions. Deo and Ghattargi (2005) found in a sample of 168 Indian schoolgirls that only 4.3% of urban girls and 21.6% of rural girls reported not practicing any taboo. In Lebanon, Santina and colleagues (2012) reported that 67% of girls did not shower until the third day of menstruation, consistent with taboos. Other restrictions included 35.5% changing eating habits, 19% not walking barefoot, and 18% not participating in social activities. It should be noted that the full impact of cultural restrictions on the behaviour of adult women has been questioned by some authors, with findings that although restrictions on daily activities may be adhered to by adolescents, they were less likely to be followed by adult women (Garg et al., 2012). The recent scoping review of studies across LMICs found estimates of avoiding physical or social activities varied from 4.9% to 76.6% across 17 studies, and estimates of abstaining from religious activities ranged from 43.4% to 94.2% in the 11 studies measuring this restriction (Chandra-Mouli & Patel, 2017).

Broader context and gender inequalities

Both material and psychosocial barriers to menstrual hygiene and health exist within a context of broader disadvantage and gender inequality. This must be taken into account when considering the relationship between more immediate barriers and menstrual health, as well as pathways in interventions. For example, whilst access and the cost of sanitary pads or soap for washing represent a significant barrier to MHM, women are often not in control of household spending (Winkler & Roaf, 2015; UN Committee on Economic, Social and Cultural Rights, 2005; UDHS, 2011). Male-headed households may place a lower priority on women's needs, meaning that even if finances are available they may not be allocated to hygiene items such as sanitary products. Further, women may lack access to opportunities for gainful employment and economic advancement meaning they are unable to purchase products themselves.

Psychosocial barriers to MHM may be enhanced by a lack of female teachers, limiting understanding of needs during menstruation in the school environment, and teaching on girls' reproductive issues. As noted above, toilets may not be designed with girls or menstruation in mind and gender-based violence makes seeking private locations or walking distances to access water dangerous (Harmann et al., 2015). To achieve gender equality in WASH, different requirements may need to be met in order to adequately meet the needs of men and women (Winkler & Roaf, 2015). Such differences may be overlooked by male-dominated decision making locally, at a government or national level, and within development agencies. Cultural attitudes about the role of women, the significance of menstruation, and reproductive viability may further limit girls' opportunities for hygienic management, education, and employment after menstruation commences (or their menstrual status becomes known). Sexual and reproductive aspects of menstruation cannot be ignored in analysis of the hygiene, education or employment consequences of menstruation (Joshi, Buit, & Gonzalez-Botero, 2015).

Female genital mutilation (FGM) presents an additional barrier to menstrual health. FGM comprises *“all procedures involving partial or total removal of the external female genitalia or other injury to the female genital organs for non-medical reasons”* (WHO, UNICEF, UNFPA, 1997; WHO, 2008 p.4). There are four types of FGM, summarised in Table 1.4. The WHO estimates between 100 and 140 million girls and women to have undergone FGM worldwide (WHO, 2008). The practice is concentrated in low income countries with Types I, II and III documented in 28 countries in Africa, with some reporting near universal rates of FGM, as well as some countries in Asia and the Middle East (WHO, 2008). FGM is associated with short and long-term health risks to women. With regard to MHM, FGM may leave women more susceptible to irritation and infection. Chronic pain and scarring may result in far greater pain and discomfort during menstruation. Further, Type III FGM which includes near-complete sealing off of the

vagina and urethra may substantially interfere with urination and menstruation (WHO, 2008).

Table 1.4 Classifications of female genital mutilation/cutting (WHO, 2008)

Classification	Description
Type I	Partial or total removal of the clitoris and/or the prepuce (clitoridectomy).
Type II	Partial or total removal of the clitoris and the labia minora, with or without excision of the labia majora (excision).
Type III	Narrowing of the vaginal orifice with creation of a covering seal by cutting and appositioning the labia minora and/or the labia majora, with or without excision of the clitoris (infibulation).
Type IV	All other harmful procedures to the female genitalia for non-medical purposes, for example: pricking, piercing, incising, scraping and cauterization.

Menstrual symptoms and disorders

Individual physiological aspects of menstruation contribute to menstrual health. Symptoms which accompany menstruation for high proportions of women include; menstrual cramping, diarrhoea, mastalgia (sore breasts), nausea, and headaches. Further, menstrual conditions such as endometriosis, severe dysmenorrhea, menorrhagia, and premenstrual syndrome, summarised in Table 1.5, represent significant challenges to health and wellbeing, differentially disadvantaging some women. Studies conducted in LMICs to date, and indeed the definition of menstrual hygiene and menstrual health, have largely ignored menstrual disorders and symptoms. Arguably, this approach separates the physical management of the normative process of menstruation (managing menstrual blood), from conditions and symptoms for which severity and treatment differs substantially. Whilst this distinction has merit, it may overlook the important role of discomfort in establishing negative consequences of menstruation on education or psychosocial wellbeing, and in intervention.

Table 1.5. Disorders/symptoms associated with menstruation

Condition	Definition and symptoms
Normal Menstruation	Mean interval of 28 days. Mean duration is 4-5 days (with most females menstruating 3-7 days). Menstrual blood loss varies considerably between women, but studies have shown a rapid adverse change in blood chemistry at two levels, 60mL and 120mL. (NICE, 2007)
Amenorrhoea	Absence of menses; can be primary or secondary (absence of three consequent menstrual cycles, after regular periods have been established)
Dysmenorrhoea	Painful periods. Secondary dysmenorrhoea is classified when pain is associated with a diagnosable condition (e.g., endometriosis, see below), and primary dysmenorrhoea when there is no known cause of pain (Marjoribanks et al., 2010).
Menorrhagia	Prolonged or excessive uterine bleeding occurring at regular intervals.
Metrorrhagia	Uterine bleeding at irregular but frequent intervals, the amount being variable
Oligomenorrhoea	Infrequent, irregular bleeding at >45-day intervals
Polymenorrhea	Uterine bleeding occurring at regular intervals of <21 days
Endometriosis	Endometriosis is a condition in which endometrial tissue grows outside of the uterus, most commonly around the pelvis, uterus, ovaries, colon, bladder and distal ureter. This tissue induces a chronic inflammatory reaction as it thickens and is shed consistent with the menstrual cycle. (Dunselman et al., 2014; Kennedy et al., 2005) Symptoms and severity vary, the most common of which are pain and infertility. Symptoms include cyclical pelvic pain, post-coital bleeding, dysmenorrhea, dyspareunia, intestinal complaints, bloating, diarrhoea, constipation, and fatigue. (Ballard et al., 2008)
Premenstrual syndrome	“a condition which manifests with distressing physical, behavioural and psychological symptoms, in the absence of organic or underlying psychiatric disease, which regularly recurs during the luteal phase of each menstrual (ovarian) cycle and which disappears or significantly regresses by the end of menstruation” (Magos & Studd, 1984 cited in RCOG, 2007). Symptoms include: mood swings, irritability, depression, feeling out of control, breast tenderness (mastalgia), bloating, headaches, reduced visuospatial ability, reduced cognitive ability, and increase in accidents (RCOG, 2007).

It should be noted that high income countries are yet to adequately tackle issues surrounding menstrual symptoms and disorders. Despite a high prevalence of menstrual conditions, menstrual dysfunction is not included in global burden of disease estimates and is severely under researched with regard to aetiology, symptoms, and treatments (AbouZahr & Vaughan, 2000; Latthe, Latthe, Say, Gulmezoglu, & Khan, 2006). The reported prevalence of dysmenorrhea has ranged from 1.7 to 97% of menstruating women (Latthe et al., 2006). Studies show prevalence of between 4 and 51.6% of women experience heavy menstrual bleeding, which has been found to affect quality of life (NICE, 2007). The Royal College of Obstetricians and Gynaecologists (RCOG, 2007) state that approximately 5% of women experience very severe premenstrual symptoms which impact significantly their personal, social and professional lives. The poorly-understood condition of endometriosis has an estimated prevalence of 2-10% in the female population, from estimates in predominantly high-income contexts (Dunselman et al., 2014). Lack of awareness and understanding of this condition has led to an 8-year median delay in diagnosis in the United Kingdom (Dunselman et al., 2014). The recent EndoCOst study estimated the annual societal burden of endometriosis-associated symptoms for Europe to be between 0.8 million and 12.5 billion euros (Nnoaham et al., 2011; Simoens et al., 2012; Dunselman et al., 2014).

These issues have been neglected more severely in LMICs. Harlow and Campbell (2004) conducted a review of menstrual disorders in LMICs and found that prevalences were comparable to those in high income countries. Studies included in the review described self-reported rates of dysmenorrhea between 15 and 70%, with an included WHO multi-country study reporting a prevalence of 25-58% of women experiencing menstrual pain in the past three months. These proportions were higher in studies of adolescent girls, with menstrual symptoms thought to decrease over time (Harlow & Campbell, 2004).

Suggested treatments for menstrual disorders include; diet and exercise, vitamin supplementation (such as magnesium or vitamin B6), heat applied to the abdomen, use of hormonal contraceptives or hormone replacement therapies, non-steroidal anti-inflammatory drugs (NSAIDs), and radical treatments such as hysterectomy for severe conditions (RCOG, 2007; Marjoribanks et al., 2010; Dunselman et al., 2014). The most recent Cochrane review for the use of NSAIDs, the front line treatment for dysmenorrhea, found NSAIDs to be more effective than placebo at reducing pain but also found that these drugs had significantly greater adverse effects of which patients needed to be aware (Marjoribanks et al., 2010). For women and girls in LMICs, access and affordability of painkillers, knowledge of the association between menstruation and other symptoms, and diagnosis for menstrual conditions is severely limited.

Menstrual symptoms and conditions represent additional challenges for women in LMICs. Investigations into the antecedents of menstrual health should also integrate an understanding of the role of menstrual conditions, noting that there may be substantial individual differences between women. Nevertheless, it may be necessary to differentiate between the adequate provision and facilitation of MHM, and the management of associated conditions which vary between women, and where evidenced treatments vary substantially. In large part, the role of menstrual disorders and symptoms is beyond the scope of this thesis.

Socioecological perspective

A socioecological perspective to menstrual health is useful in acknowledging the many barriers and layers of influence discussed above (Bronfenbrenner, 1979; Whitehead, Dahlgren & Gilson, 2001). Conceptualising barriers to menstrual health as part of a multi-level system emphasises the complexity of the issue (Haver et al., 2013; Long et al., 2013) and can assist consideration of pathways for intervention, as well as the potential challenges to their implementation (see Figure 1.5).

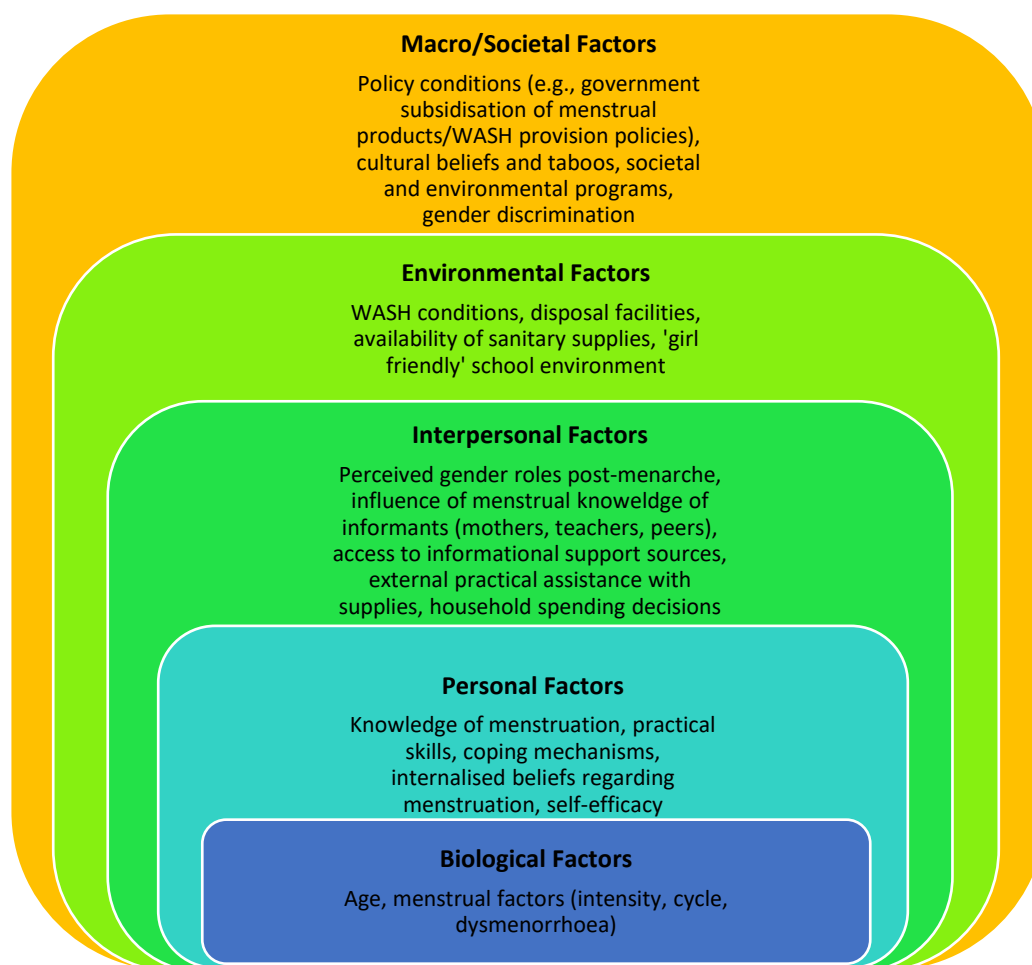


Figure 1.5. Socioecological framework for menstrual health (derived from Haver et al., 2013; Long et al., 2013).

Problem theory and menstrual health

Poor menstrual health is a multifaceted issue, with contributing factors ranging from individual physiology to societal gender inequalities. Material and psychosocial deprivations have emerged as two key proximal contributors to inadequate management, although studies to date have failed to adequately test proposed associations. MHM has been identified as a contributor to poor health, education, work and psychosocial outcomes for women and girls. This background section has provided an overview of extant literature on the contributors to, and consequences of, poor MHM. These factors represent the problem theory of menstrual health. Problem theory maps the underlying causes of an issue; its aetiology, risk and protective factors, and level of

impact (Fraser, Galinsky, Richman, & Day, 2009). As detailed in earlier sections of this chapter, the development of complex interventions should be driven by a strong problem theory (Craig et al., 2008). Social interventions may fail to be effective, or worse do harm, if their design is not based on a clear understanding of the antecedents of the problem (Glanz & Bishop, 2010). As has been highlighted above, there are significant gaps in the research of menstrual health problem theory. Thus in seeking to provide recommendations for future menstrual health interventions, Objective 3 of this thesis focuses on filling gaps in the problem theory of menstrual health.

Interventions to address menstrual health

A growing list of specialist charities, governments, international organisations and NGOs have started to invest in menstrual health. Acknowledgement of women's menstrual needs have led to a variety of interventions. This has included the development of national guidelines (e.g., Government of India, 2015), and government initiatives to provide free or subsidised pads (e.g., India; Garg, Goyal, & Gupta, 2012; Ghana; Boateng, 2014; Ameade & Majeed, 2015). Menstrual Hygiene Day, launched in 2014 by WASH United, currently lists a total of 380 partner organisations as official allies (Menstrual Hygiene Day, "The Alliance", 2017). Many of these organisations include programs specifically devoted to menstrual health (e.g., sewing or providing reusable sanitary pads, providing menstrual cups, providing online or printed educational materials). Most of these organisations were founded in the last decade and already advertise extensive reach. For example, Days for Girls, founded in 2008 state they provide menstrual kits in over 100 countries, with 720 Global Chapters (Days for Girls, 2017). Similarly, Zana Africa, founded in 2007, reports providing 20,000 girls in East Africa with sanitary pads and health education since 2013 (ZanaAfrica Foundation, 2017). Private sector involvement has also expanded, with a new cohort of social enterprises seeking to tackle menstrual hygiene through a range of novel products, for example, AFRIPads founded 2010 (AFRIPads, 2017), Be Girl founded 2012 (Be Girl, 2017), Femme International founded 2013 (Femme International, 2017). This sharp increase in the number of organisations seeking to intervene and address menstrual health needs means ever increasing numbers of women and girls are being presented with menstrual health interventions. Consistent with the EBP approach of this thesis, it is imperative to provide these organisations with rigorous evidence on program effectiveness to inform practice.

Program theory and menstrual health interventions

Program theory; how and why an intervention is hypothesised to work, is essential in clearly developing and evaluating an intervention (Fraser et al., 2009). Fraser and colleagues (2009) have distinguished between general program theory (broad conceptualisation of how the intervention works) and theory of change (which seeks to specify all aspects of the intervention, including intermediary steps and implementation). This meticulous consideration of intermediary steps and underlying assumptions in the creation of an intervention forces developers to reach consensus about what they are trying to do and think through possible issues (Weiss, 1995; Fraser et al., 2009). Explicit theory also sets the stage to evaluate why a program works and ‘understand the change process’ as emphasised in the evaluation phase of the MRC framework (Craig et al., 2008; Figure 1.2). A lack of a theory of change has been a common issue in complex interventions, termed the ‘black box’ problem. Even though a rigorous RCT can establish if a program is effective, understanding the change process is essential for 1) interpreting positive and null results (if they are due to the intervention or implementation issues), 2) providing plausibility to findings, 3) providing information about how the intervention worked for future replication or refinement, and 4) providing generalizable information about problem and program theory (Weiss, 1995; Bonell et al., 2012).

Program theory has been hypothesised for menstrual health interventions, with interventions proposed to target material and/or psychosocial deprivations. However, just as the problem theory surrounding the predictors and consequences of menstrual health and hygiene has not been quantitatively tested, intervention trials have typically failed to include any investigation of their proposed theory of change.

Interventions seeking to address menstrual health may target material and/or psychosocial deprivations through:

- 1) *Hardware interventions* designed to address material deprivations, including the provision of sanitary products, improved WASH, or 'girl friendly' environments, and adequate disposal facilities; and,
- 2) *Software interventions* to address psychosocial deprivations, particularly knowledge, by providing education on menstruation and management.

Hardware interventions

The provision of clean sanitary products (e.g., commercial or home-made pads) has been the most prominent hardware intervention proposed. A range of products exist as displayed in Table 1.6. Many of these products have been distributed by NGOs, governments or local organisations to try and improve girls' menstrual health. Improving access to absorbents addresses one of the material deprivations contributing to inadequate menstrual hygiene and poor menstrual health. Fit-for-purpose products offer improved absorbency and protection against soiling under and outer garments. Moreover, providing absorbents in sufficient quantity is expected to allow girls to change their absorbent with adequate frequency. Improved absorbents may reduce stigma, ridicule, and embarrassment arising from soiling or odour, which deters women and girls from attending school or work (Geertz et al., 2016; House, Mahon & Cavill, 2012).

Table 1.6 Types of menstrual absorbent and use (source: Menstrupedia, 2017)

Sanitary pads (disposable)

[Images removed for online version]

Sanitary pads (reusable)

[Images removed for online version]

Tampons (applicator)

[Images removed for online version]

Tampons (non-applicator)

[Images removed for online version]

Menstrual cups (hard)

[Images removed for online version]

Menstrual cups (soft)

[Images removed for online version]

(source: Softcup, 2017)

A range of menstrual products have been provided in menstrual health interventions. Each absorbent type entails different advantages and disadvantages. Single-use products present challenges in monthly distribution and environmental challenges for disposal. In contrast, reusable products require access to water, soap and drying facilities, but have a longer lifespan and have been proposed to be more affordable in the long-term. Inserted products, such as menstrual cups or tampons, require cultural sensitivity and training, particularly for younger girls who may not feel confident to insert a product, or where concepts of virginity are important to maintain prior to marriage. Tampons have not been distributed by menstrual health organisations due to concerns around toxic shock syndrome. As discussed in more detail in Chapter Six (paper #5), women and girls' preferences have also driven intervention agendas, although there is highly limited published academic literature in this domain. A recent study in India found that among 150 women interviewed in slums of Hyderabad, 36% exclusively used cloth as their menstrual absorbent, with a further 8% using a combination of cloths and pads. Of these women 52% reported a willingness to use sanitary pads, and of these 94% stated that they would find a reusable pad preferable. Authors suggest this preference was driven by a comfort with current habits of cleaning and concerns around taboos of disposing of menstrual blood (Garikipati & Boudot, 2017). Preferences are likely to differ across contexts, making scoping research prior to intervention essential. Qualitative studies preceding menstrual cup interventions have typically reported high acceptability of these products, despite initial apprehension (e.g., Mason et al., 2015; Phillips-Howard et al., 2016).

The majority of hardware interventions for menstrual health have focussed on providing absorbents. However, other hardware interventions improving WASH facilities, privacy, or disposal would address core contributors to poor menstrual hygiene and health. Providing WASH access in schools, and private spaces for changing are hypothesised to reduce rates of inadequate MHM and associated psychosocial stress

associated with finding private spaces to change or wash absorbents (Sahoo et al., 2015). Such facilities improve the ability to clean reusable absorbents and genitals to a hygienic standard, reducing discomfort, infection, and embarrassment. Similarly, 'girl friendly' environmental changes such as gender-separate latrines, locks on toilets, discrete facilities for menstrual management or washing would also enable better and easier MHM. Such changes would address privacy and safety concerns, leaving girls more comfortable to attend school or work. Safer environments may also reduce secondary negative consequences, such as the threat of sexual violence, which may also directly impact psychological wellbeing and school attendance (Gonsalves, Kaplan, & Paltiel, 2015; Grant, Huggett, & Willetts, 2016)

Software interventions

Improving understanding of menstruation including knowledge of cycle length, requirements for hygiene, origin and location of menstrual bleeding, is hypothesised to improve hygienic practices, self-efficacy, and reduce anxiety (Kirk & Sommer, 2006; McMahon et al., 2011; Sommer, 2011; House, Mahon & Cavill, 2012). Educational interventions seek to address the knowledge deficits around menstruation discussed in previous sections (Chandra-Mouli & Patel, 2017). Understanding the physical process and purpose of menstruation is proposed to dispel fears of illness or supernatural punishment that may be perpetuated when girls are unprepared for menarche or subject to myths around menstrual bleeding. Further, practical strategies for management and information about hygiene practices has been proposed to address knowledge gaps and empower girls to improve their MHM and menstrual health. Thus, through improved practices, and lowered stress, education interventions are hypothesised to improve school attendance and health. Education is also predicted to reduce psychosocial consequences by normalising menses, and reducing anxiety and shame. Improving understanding of menstruation may have longer term impacts, with accurate information

passed to the next generation and integrated at a societal level reducing misconceptions and restrictive taboos.

The effectiveness of menstrual health/hygiene interventions will be summarised and critically appraised in Chapter Two through a systematic review of trials.

Thesis aims and format

As has been described in this chapter, the management of menstruation has emerged as an under-recognised barrier to women's dignity, equality, and human rights. But despite recent enthusiasm, menstrual health is severely under-researched. An evidence-based approach has not driven the agenda to date. Research efforts have followed after government policies (e.g., Garg, Goyal, & Gupta, 2012), large funder initiatives (e.g., Proctor & Gamble, 2010), NGO action, experts' opinions, and media attention (Kristof, 2010; Sommer, Hirsch, Nathanson, & Parke, 2015). As a result, research programs have been reactionary, leading to a disjointed literature. There is an urgent need for research improving understanding of poor menstrual health, and its causes and consequences, and for rigorous evaluations of proposed interventions.

This thesis seeks to fill substantial gaps in the existing evidence base by applying rigorous methodologies to core questions in the menstrual health field. The work draws on guidance from the MRC framework for the development and evaluation of complex interventions, and focuses on aspects of development and evaluation (see Figure 1.6) (Craig et al., 2008). The work seeks to address three broad objectives; 1) Collate and critically appraise current evidence for the effectiveness of menstrual health interventions; 2) Evaluate the effectiveness of a reusable sanitary pad and puberty education intervention for girls' school attendance; and, 3) Expand understanding of menstrual health problem and program theory to inform future research and practice.

This thesis contains six manuscripts submitted for peer-review publication. These studies represent a significant contribution to advancing the understanding of menstrual health and interventions in LMICs. Each paper includes a background and justification for the conduct of the research within the broader literature. The first papers summarise and critically appraise current evidence in the field of menstrual health, both for interventions (paper #1) and the field more broadly (paper #2). Critical review of past

literature highlighted significant gaps in the conduct of menstrual health research and guided a number of subsequent research questions. The remaining four papers are situated within the *Menstruation and the Cycle of Poverty* trial. The third paper reports on the methods and primary outcomes of this cluster quasi-randomised control trial undertaken in rural Uganda. The fourth and fifth papers present secondary analyses of survey data collected as part of the final follow-up in the trial. Paper #4 seeks to address the significant limitations of the measurement of MHM in studies undertaken to date, this paper also tests associations between a comprehensive measure of MHM and hypothesised consequences. Paper #5 focuses on the experiences of girls in the trial and their menstrual absorbent preferences. This paper seeks to go beyond past work which has proposed that commercially produced products (in this case, reusable sanitary pads) will improve girls' menstrual health, but failed to investigate girls' preferences and experiences of using these absorbents. The study compares perceptions of absorbent reliability and management practices between girls using reusable sanitary pads provided in the trial and girls using existing improvised measures (predominantly cloth). Finally, this study compares girls' self-reported avoidance of daily activities during menstruation. This extends the trial results by investigating differences beyond school attendance. The final paper (paper #6) reports on a qualitative follow-up to the trial and compares the menstrual experiences of girls across the four trial conditions. This serves to investigate the change pathways in the interventions, intervention implementation, and the interaction of the intervention with the local context. In this way, the trial paper and follow-up papers serve together to advance understanding of menstrual health and provide evidence for the potential of interventions to meet girls' needs.

Papers and their individual objectives are listed below:

Paper #1: Systematic review of MHM interventions

Objective: 1) Summarise and critically appraise extant evidence for the effectiveness of menstrual hygiene interventions in improving women and girls' education, work, and psychosocial wellbeing in LMICs

Paper #2: Arguing for an evidence-based approach to menstrual health

This paper sought to fill a significant gap in existing works by highlighting quality issues in the study of menstrual health. The paper advocates for a more evidenced approach in a field where advocacy and emotive approaches have largely driven the agenda. The content was tailored to a special issue on *Menstrual Health and Human Rights* in the journal *Women's Reproductive Health*.

Objectives: 1) Argue for the imperative of an evidence based approach to menstrual health. 2) Provide an integrated critical appraisal of the state of menstrual health research to a broad audience of academics, actors, and advocates.

Paper #3: Results of the *Menstruation and the Cycle of Poverty* trial.

Objectives: 1) Report the findings of a cluster quasi-randomised control trial testing the effectiveness of providing sanitary pads and/or puberty education for improving girls' school attendance and psychosocial outcomes. 2) Provide transparent reporting of the strengths and weaknesses of the trial, and include implications for future work.

Paper #4: Estimating the prevalence of menstrual hygiene and its relationship with hypothesised health, education and psychosocial consequences.

Objectives: 1) Describe the menstrual hygiene practices of girls in rural Uganda. 2) Assess the prevalence of MHM consistent with the concept definition. 3) Compare the prevalence of MHM between girls using trial-provided reusable sanitary pads and those using existing methods. 4) Test the associations between aspects of MHM, and the pooled MHM measure, and health, education, and psychosocial wellbeing.

Paper #5: Assessing the acceptability and experience of different menstrual absorbents.

Objectives: 1) Describe girls' access to, and use of, menstrual absorbents in the *Menstruation and the Cycle of Poverty* sample. 2) Compare perceptions of absorbents between girls using reusable pads provided in the trial and girls using existing improvised methods. 3) Compare self-reported freedom of activity between girls using the reusable pads provided in the trial and those using existing improvised methods.

Paper #6: Describe and compare girls' menstrual experiences at the conclusion of the *Menstruation and the Cycle of Poverty* trial.

Objectives: 1) Describe girls' experiences of menstruation in the *Menstruation and the Cycle of Poverty* trial sample. 2) Compare the menstrual experiences of girls across the intervention conditions in the trial. 3) Identify pathways of effect in the interventions. 4) Identify interactions between the intervention and the context, and the barriers and facilitators to effectiveness.

As previously stated, this thesis draws on guidance from the MRC framework. Figure 1.6 provides a conceptual diagram of the thesis chapters and their contribution to different aspects of this framework. The figure also summarises the data used for each section of the thesis.

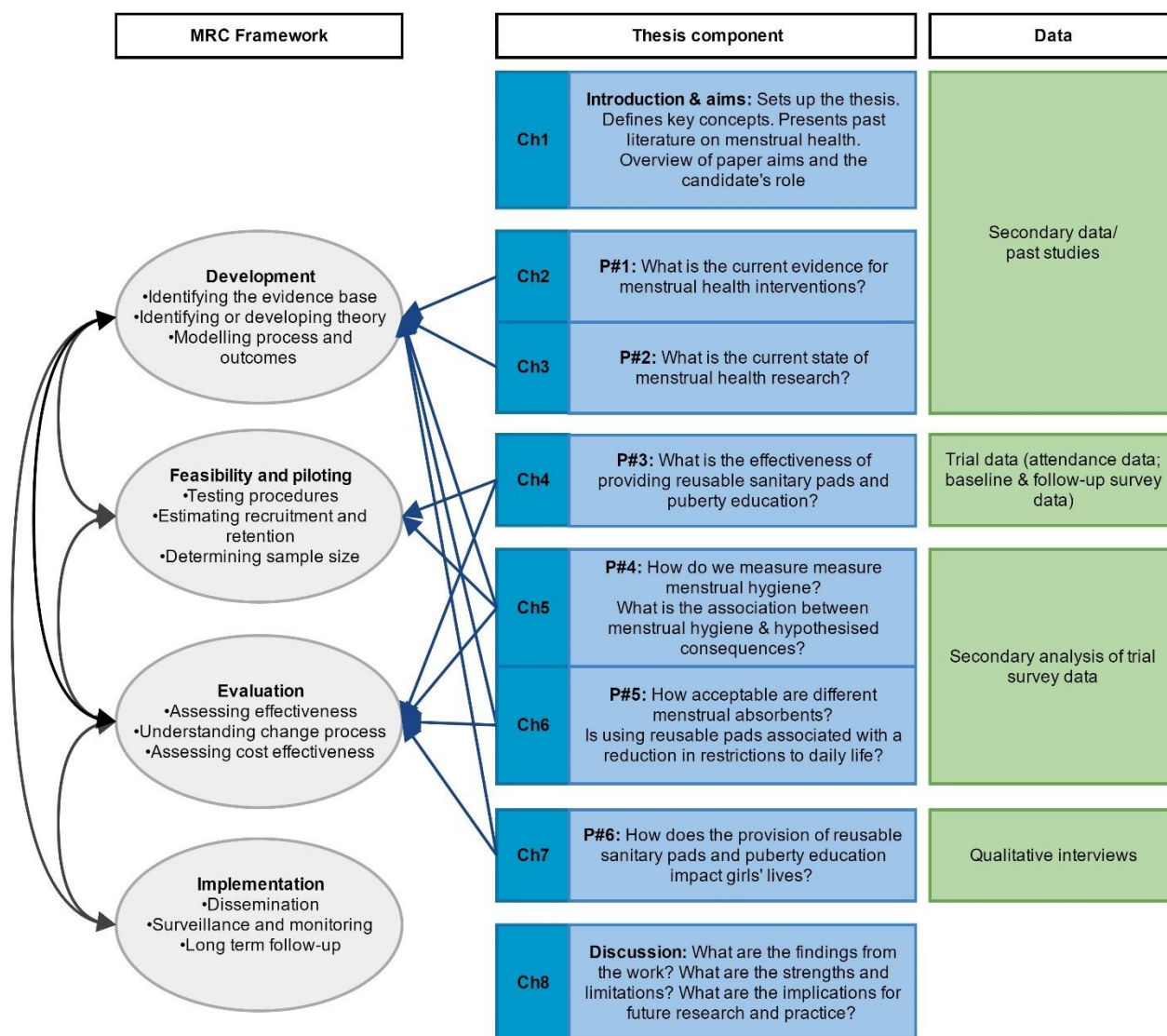


Figure 1.6. Conceptual diagram of the links between the MRC framework, chapters and research questions, and data used in the thesis.

The *Menstruation and the Cycle of Poverty* project

The DPhil research reported in this thesis is situated within a broader program of work being undertaken in the *Menstruation and the Cycle of Poverty* project. This project represents a collaboration between the Department of Social Policy & Intervention and Saïd Business School at the University of Oxford, as well as SOAS at the University of London. This project is funded by a DFID-ESRC (Economic and Social Research Council) grant (Grant ref: ES/I034145/1). The work was undertaken in partnership with a partner Non-Governmental Organisation (NGO), *Plan International* (and *Plan Uganda*).

The methods of the main trial are reported in Chapter Four (paper #3). The trial was undertaken between January 2012 and December 2014. Copies of the original ethical approvals for the project are provided in Appendix 1.1.

Setting

Uganda has a population of 37.58 million, and is considered a low income country by the World Bank (World Bank, 2014). Whilst Uganda has made substantial gains in education and gender equality there is significant progress yet to be achieved. Uganda has a three-tier education system, with seven years of primary school (official ages 6-12 years), six years of secondary education (4 ordinary and 2 advanced; official ages 13-18 years), and tertiary/university education (official ages 19-24) (DHS Program, 2011). High levels of enrolment in primary school drop off sharply in secondary school (UNESCO 2008; World Bank, 2013; UDHS, 2011). Enrolment in secondary education remains low, with 2013 figures suggesting only 22% of school-aged girls are enrolled in secondary school (UNESCO, 2015; UDHS, 2011). School enrolment and gender parity in school enrolment differs across regions, with lower enrolment and greater disparity with increasing rurality (UDHS, 2011).

Water, sanitation and hygiene (WASH) in Uganda continues to be a challenge in rural areas. The 2014 Water, Environment Sector Performance report stated that 74.6%

of the rural population have household latrine coverage. Access to hand-washing facilities at toilets was reported to be only 32.7%, with districts reporting that 38% of primary schools had hand washing facilities (Ministry of Water and Environment, 2014).

Women remain disadvantaged in Uganda. They have fewer economic and employment opportunities than men. The recent Ugandan Demographic and Health Survey reported that 53% of married women who earned cash were a main decision maker in how the cash was used. Control over earnings increased with education and socioeconomic status. Approximately four in ten women were reported to own a house or land (mostly jointly with their husband). Only 38% of currently married women reported participating in all three of; decisions regarding their own health care, major household purchases, and visits to their family or relatives (UDHP, 2011). 60% of women reported believing that wife beating is justified for at least one reason (e.g., refusal of sexual intercourse, arguing, going out without telling husband). 25% of married women in the Demographic and Health Survey reported being in a polygynous union (UDHP, 2011), with higher proportions reported in rural areas. Compared to other countries in the region, the prevalence of FGM is very low in Uganda. Legislation banning FGM was passed in 2010, and UNICEF estimates of a prevalence of 1% for any type of FGM for women aged 15-49 (UNICEF, 2014).

Site selection

The main trial took place in the Kamuli district of Uganda (see Figure 1.7). Kamuli was selected after a small scoping study during spring 2010. Plan Uganda, a part of the partner NGO, had a number of well-established girls' education and women's health promotion programmes through-out Uganda, with several programs within the Kamuli area. The Kamuli district was selected due to its poor performance across a range of key education, health and welfare indicators, with a literacy rate below the national average (Uganda Bureau of Statistics, 2002).

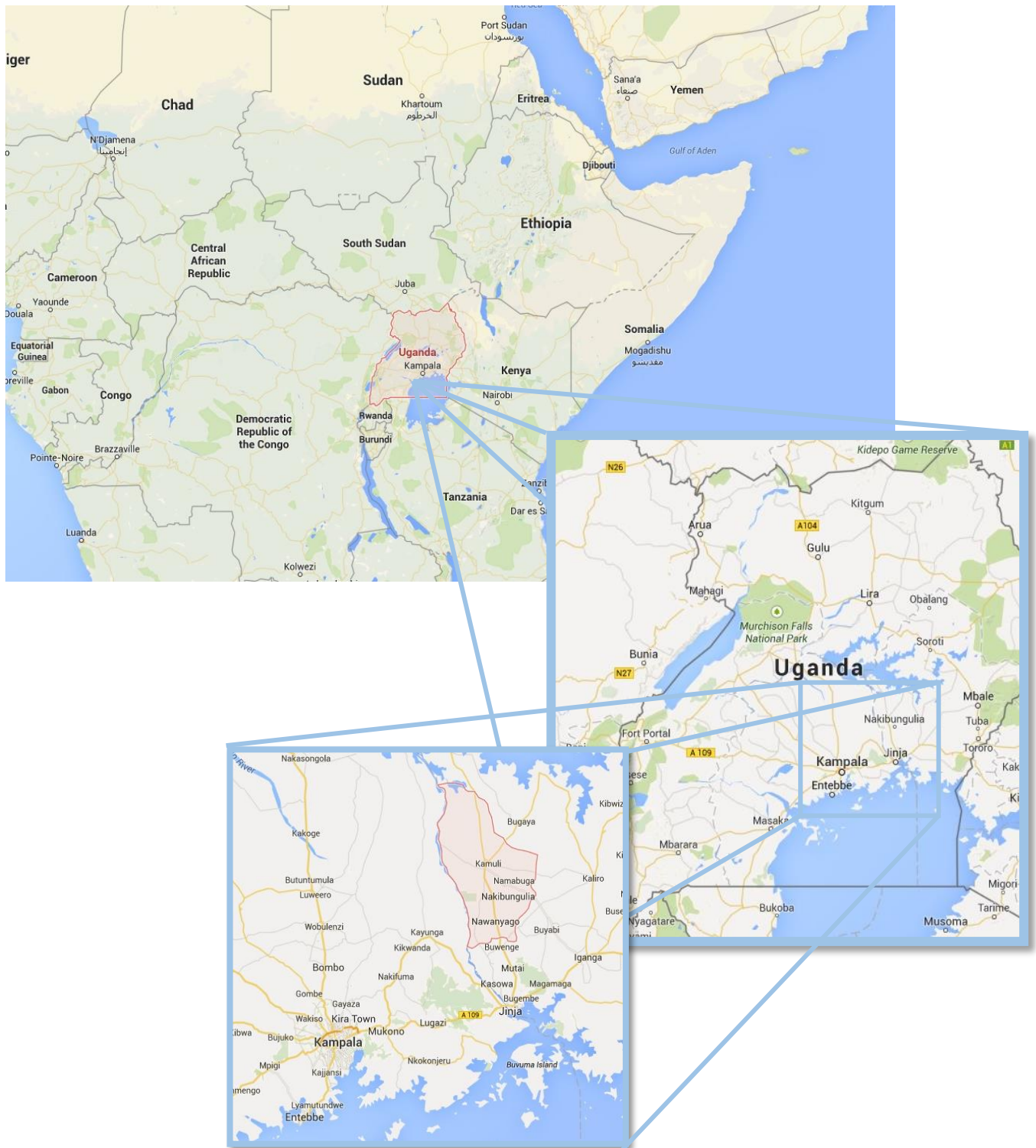


Figure 1.7 Kamuli district of Uganda (Source: Google Maps, 2015)

The candidate's role

I proposed both the systematic review (paper #1) and position paper (paper #2) and these were undertaken independently of the *Menstruation and the Cycle of Poverty* project, although the findings from this work were integral in informing the primary research presented in subsequent papers.

I commenced my DPhil study in October 2014, towards the end of the *Menstruation and the Cycle of Poverty* trial. I was not involved in developing or setting up the trial, although was able to add some additional items to the final follow-up survey. In October 2014, I travelled to the study sites in Uganda to assist in the final attendance data collection and survey. At this time, I also undertook interviews with girls from the trial (methods reported in paper #6). The trial suffered from a number of significant failings, which I helped to identify after its conclusion. From February 2015 to December 2015, I was involved in identifying errors in the trial conduct and data (see Chapter Four, paper #3 – protocol deviations). I undertook data cleaning and management for all data collected over the trial which included baseline attendance data and survey, follow-up attendance data and survey. Further, I pursued missing data from the trial, such as attendance registers from education sessions and sanitary pad delivery registers. There was no analytic protocol for the trial. I developed and conducted analyses for the trial and authored the trial manuscript.

I proposed and designed all three follow-up papers based on the available data and survey items. Each study was designed to address a significant deficit in the field of menstrual health research, and to maximise use of the survey data collected as part of the trial. For qualitative interviews undertaken in October 2014, I had proposed all questions related to menstrual experience which are featured in paper #6. I selected and applied a qualitative approach to answer my research questions. As noted in the manuscript, other interview questions concerned girls' broader experiences and socio-

cultural contributors to school attendance. I also conducted these parts of the interviews, however these have been analysed in a separate qualitative paper which is not part of this thesis.

Health and Safety risk assessment for the candidate's fieldwork in Uganda is included in Appendix 1.2.

Co-author's confirmation that the manuscripts included in the thesis represent the majority work of the candidate are presented in Appendix 1.3 for each paper.

For the papers presented in the thesis the author contributions were as follows.

Paper #1

Author contributions: Conceived and designed the experiments: JH PM. Performed the experiments: JH PM. Analysed the data: JH. Wrote the paper: JH. Commented on the paper: PM.

Paper #2

Author contributions: Conceived the paper: JH. Wrote the paper: JH. Commented on the paper: PM

Paper #3

Author contributions: Conceived and designed the experiments: PM CD LS. Performed the experiments: PM CD MW LSt LSc. Analysed the data: JH. Wrote the paper: JH. Commented on the paper: PM CD MW LSt LSc.

Paper #4

Author contributions: Conceived and designed the experiments: JH PM CD LS. Performed the experiments: PM CD MW LS. Analysed the data: JH. Wrote the paper: JH. Commented on the paper: PM CD MW LS.

Paper #5

Author contributions: Conceived and designed the experiments: JH PM CD LS.

Performed the experiments: PM CD MW LS. Analysed the data: JH. Wrote the paper:

JH. Commented on the paper: PM CD MW LS.

Paper #6

Author contributions: Conceived and designed the experiments: JH CD PM LS.

Conducted interviews: JH LS. Performed the analyses: JH. Wrote the paper: JH.

Commented on the paper: PM CD LS.

Chapter Summary

This chapter has defined core terms used in the thesis. It has outlined the theoretical framework for the thesis and noted the importance of menstrual health for women and girls' physical health, education, employment, and psychosocial wellbeing. The chapter included discussion of the role of problem and program theory in the development and evaluation of complex interventions such as those for menstrual health. The general theory underlying different intervention types was discussed. This chapter provided some critical appraisal of menstrual health and hygiene research to date, however, as noted in the overview, this is expanded in Chapter Two (paper #1) and Chapter Three (paper #2). Finally, this chapter provided an overview of the work presented in the thesis, outlining the research questions and manuscripts. This chapter also provided a brief description of the broader trial context, and stated the candidate's role and author contributions for the included manuscripts.

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CHAPTER 2

Paper #1: Systematic review of interventions

Do menstrual hygiene management interventions improve education and psychosocial outcomes for women and girls in low and middle income countries? A systematic review

Julie Hennegan¹

Paul Montgomery¹

¹ Centre for Evidence-Based Intervention, University of Oxford, Oxford, UK

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Abstract

Background. Unhygienic and ineffective menstrual hygiene management has been documented across low resource contexts and linked to negative consequences for women and girls.

Objectives. To summarise and critically appraise evidence for the effectiveness of menstrual management interventions in improving women and girls' education, work and psychosocial wellbeing in low and middle income countries.

Methods. Structured systematic searches were conducted in peer-reviewed and grey literature to identify studies evaluating education and resource provision interventions for menstruation management. Individual and cluster randomised controlled trials were eligible for inclusion, as were non-randomised controlled trials. Study characteristics, outcomes and risk of bias were extracted using a piloted form. Risk of bias was independently assessed by two researchers.

Results. Eight studies described in ten citations were eligible for inclusion. Studies were highly heterogeneous in design and context. Six included assessment of education-only interventions, and three provided assessment of the provision of different types of sanitary products (menstrual cups, disposable sanitary pads, and reusable sanitary pads). A moderate but non-significant standardised mean difference was found for the two studies assessing the impact of sanitary pad provision on school attendance: 0.49 (95%CI -0.13, 1.11). Included studies were heterogeneous with considerable risk of bias. Trials of education interventions reported positive impacts on menstrual knowledge and practices, however, many studies failed to assess other relevant outcomes. No trials assessed or reported harms.

Conclusions. There is insufficient evidence to establish the effectiveness of menstruation management interventions, although current results are promising. Eight trials have been conducted, but a high risk of bias was found and clinical heterogeneity

precluded synthesis of most results. Whilst trials provided some indication of positive results, further research is needed to establish the role of menstrual hygiene management in education performance, employment and other psychosocial outcomes. This review provides a concise summary of present trials and highlights improvements for future work.

Introduction

The effective, hygienic management of menstruation is essential for women and girls to participate in society with dignity and comfort. Effective menstrual hygiene management (MHM) includes access to clean absorbents, with facilities to change, clean or dispose of these as needed, and access to soap and water for cleaning the body and absorbents (Sommer & Sahin, 2013). Studies across low and middle income countries (LMICs) have reported that more than 50% of girls have inadequate MHM, with higher proportions reported in rural areas (Dasgupta & Sarkar, 2008; Khanna, Goyal, & Bhawsar, 2005; El-Gilany, Badawi, & El-Fedawy, 2005; Adinma & Adinma, 2009).

Health and social research has only recently sought to address the neglect of MHM as a significant development issue and barrier to achieving gender equality. Both qualitative and quantitative work have suggested that poor MHM results in school absenteeism, distraction, and disengagement (Lloyd & Young, 2009; Grant, Lloyd, & Mensch, 2013). There is a shortage of literature addressing the impact of MHM on adult women, but poor MHM is also likely a barrier to occupational attendance and engagement (Business for Social Responsibility, 2011;2012). Focus groups from a factory in Pakistan suggested that women missed up to three days' work per month due to menstruation (Business for Social Responsibility, 2012).

Other programs of qualitative work have reported psychosocial consequences of poor MHM (e.g., Sommer, 2009). Feelings of shame, fear (and fear of stigma), anxiety, and distraction have been described across a range of contexts (Crichton, Okal, Karibu, & Zulu, 2013; Sommer, Ackatia-Armah, Connolly, & Smiles, 2014). Few studies have quantified the relationship between MHM and psychosocial consequences. Studies that have been conducted have often focused on menarche, reporting that high proportions

of girls feel unprepared and afraid at this time (Ali & Rizvi; Kumar & Srivastava, 2011; Deo & Ghattargi, 2005).

MHM Interventions

Interventions to address MHM have been categorised into two groups; *hardware interventions* designed to address material deprivations such as the provision of absorbents, or improved Water, Sanitation and Hygiene (WASH) facilities; and *software interventions* which address deficits in knowledge of menstruation and management by providing education.

Hardware interventions

The cost and availability of sanitary products, and underwear in which to wear them, is a fundamental barrier to MHM (Pillitteri, 2011; House, Mahon, & Cavill, 2012; Montgomery, Ryus, Dolan, Dopson, & Scott, 2012). Commercial absorbents are frequently unavailable or too expensive (Dasgupta & Sarkar; Pillitteri, 2011; House, Mahon & Cavill, 2012; Crofts & Fisher, 2012; Garg, Goyal, & Gupta, 2012). The provision of clean sanitary products (e.g., commercial or home-made pads) addresses this material deprivation and is hypothesised to reduce discomfort, and concerns regarding soiling outer garments. Improved management and comfort may also reduce associated stigma, ridicule, and embarrassment which deters women and girls from attending school or work. In Ghana, Dolan and colleagues (2013) found that over three quarters of schoolgirls surveyed reported soiling outer garments during their last menses, and found that school attendance improved by 9% after 5 months with the provision of disposable sanitary pads (Montgomery et al., 2012).

Inadequate WASH represents a barrier to MHM, particularly the ability to clean absorbents, and the body, in private (Das et al., 2015). The design of toilets often fails to meet women's physical and psychological needs (Dolan et al., 2013; Fisher, 2006). Latrines lacking doors or locks may threaten safety and cause embarrassment (Lloyd &

Young, 2009; Abrahams, Mathews, & Ramela, 2006). Hygiene guidelines recommend changing absorbents every two to six hours dependent on blood flow, thus facilities are needed both at home and in schools or workplaces (House, Mahon, & Cavill, 2012). Improvements to WASH access may enable women to clean reusable absorbents and genitals hygienically, as well as reduce discomfort and embarrassment. Open pit toilets or toilets without disposal facilities mean blood or used sanitary products reveal when a woman is menstruating, resulting in embarrassment and stigma (Fisher, 2006; Mahon & Fernandes, 2010). 'Girl friendly' changes such as gender-separate latrines, locks on toilets, discrete facilities for changing absorbents or washing have also been hypothesised to enable improved MHM.

Software interventions

Adolescent girls have been found across a range of countries to lack knowledge of the physiology and management of menstrual bleeding (Adinma & Adinma, 2009; Ali & Rizvi, 2010; Chothe et al., 2013). Ali and Rizvi (2010) reported that in Pakistan, less than 50% of girls surveyed received information about menstruation prior to menarche, only 15% information about management. Cultural beliefs and taboos may also contribute to poor MHM through the perpetuation of misinformation or unhygienic customs. Studies across contexts have reported taboos around the disposal of menstrual blood, and practices including restrictions to bathing and participation in social activities (Sommer et al., 2014; Kumar & Srivasta, 2011; Deo & Ghattargi, 2005; Pillitter, 2011; Santana, Wehbe, & Ziade, 2012).

Improving understanding of menstruation, such as knowledge of cycle length and requirements for hygiene, is hypothesised to improve management practices, self-efficacy, and reduce anxiety (House, Mahon, & Cavill, 2012; Kirk & Sommer, 2006; McMahon et al., 2011; Sommer, 2011). In this way education interventions may facilitate school attendance and engagement in the classroom through improved ability to effectively manage menstruation, and confidence in management methods. This

education may also reduce negative psychosocial consequences by normalising menses and dispelling myths (Montgomery et al., 2012; Dolan et al., 2013).

Previous reviews

Sumpter and Torondel (2013) conducted the only systematic review of MHM interventions, focusing on health outcomes. The review included some education and social outcomes, but had a number of limitations. First, pre-post comparisons and observational studies were synthesised alongside randomised controlled trials despite representing different risks of bias. Second, the review searched only peer-reviewed journals thus missed the wider 'grey' literature. Third, only limited terms 'school' and 'educat*' were used to search for education outcomes. Only 'social restrictions' such as restricting diet or interactions during menstruation, rather than psychosocial consequences described in the literature, were included. The review did not discuss the inclusion or exclusion of WASH interventions. Finally, the review search was conducted in May 2012, with at least two trials published since this time (Montgomery et al., 2012; Wilson, Reeve, & Pitt, 2014; Wilson, Reeve, Pitt, Sully, & Julious, 2012).

Two other relevant reviews have been conducted. Birdthistle and colleagues (2011) and Jasper and colleagues (2012) focused on WASH interventions. Neither identified all relevant studies, nor appraised the risk of bias in included studies.

The present review

Hardware and software interventions have been employed by governments, international organisations and local charities seeking to address poor MHM and associated consequences (Garg, Goyal, & Gupta, 2012; Ministry of Health & Welfare, 2012). These programs have been enacted in the absence of evidence for their effectiveness. Given the weak evidence base and ongoing plans to implement MHM interventions, the present work will provide an essential appraisal of eligible studies and highlight implications for future research.

This review will summarise and critically appraise evidence for the effectiveness of hardware and software interventions for MHM aimed at improving education, employment or psychosocial outcomes for females in LMICs.

Methods

This review was conducted according to the requirements of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (see Appendix 2.1; Moher, Liberati, Tetzlaff, & Altman, 2009). Review protocol was registered on PROSPERO (CRD42014010631)

http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42014010631.

Criteria for selecting studies

Individually and cluster randomised controlled trials (RCTs/cRCTs) were eligible for inclusion, representing the most rigorous evidence with the ability to infer causality (Higgins & Green, 2011). Non-randomised controlled trials and controlled before-after studies were also included despite greater potential for bias, due to the lack of available trials and difficulty conducting RCTs in LMICs (Effective Practice and Organisation of Care Group (EPOC), 2013). Cross-sectional studies and pre-post designs which did not include a control group were ineligible.

Studies were eligible if they reported on outcomes for menstruating females from LMICs as defined by the World Bank (2014) (<http://data.worldbank.org/about/country-classifications>).

Eligible interventions

Hardware interventions

1. The provision of clean absorbents/sanitary products (disposable or reusable),
2. Improved WASH or girl-friendly facilities. Key aspects of WASH interventions relevant to menstruation were derived from the WHO (Adams, 2009) report on *Water, Sanitation and Hygiene standards for schools in low-cost settings*, the UN Gender, Water and Sanitation Policy Brief (Inter-agency Task Force on Gender &

Water, 2006) Studies could include any number of these aspects where authors' hypothesised that the intervention was sufficient to improve MHM practices:

- a. Improved clean water supply for menstruation management (e.g., access to water within latrine or private areas);
- b. Provision of soap or disinfectant for body and absorbent cleaning;
- c. Improved absorbent disposal facilities;
- d. Improvements to latrine privacy or safety.

Software interventions

Interventions that delivered sufficient education to provide an understanding of the biological process of menstruation (e.g., the cyclic nature of menses, origin of menstrual blood), and which authors hypothesised was sufficient to improve either MHM practices or misconceptions and confusion. Information could be provided in person or via printed or electronic resources.

Eligible outcomes

Primary outcomes

Education. School attendance (full or partial days) from school records or self-reported.

Employment. Self- or employer-reported attendance/absenteeism (full or partial days).

Psychosocial Outcomes. Outcomes were derived from qualitative literature identifying psychosocial consequences of poor MHM and included; anxiety, confusion, depression, embarrassment, emotional distress, fear, powerlessness, self-confidence, self-efficacy, shame, stigma, worry, and self-imposed withdrawal from activities such as playing sport. Externally enforced restrictions (e.g., not attending religious ceremonies) were not eligible outcomes as interventions were not hypothesised to impact such traditions.

Secondary outcomes

Education. Academic achievement and school engagement.

Employment. Measures of productivity, engagement, and worker satisfaction.

Psychosocial outcomes. Other measures of attitudes related to menstruation.

Menstrual knowledge and management. Knowledge of menstruation and improved management practices.

Search methods

Searching strategy was based on inclusion criteria and developed with reference to searches reported in previous reviews (Crichton et al., 2013; Sumpter & Torondel, 2013; Birdthistle et al., 2011). Searches were conducted in English, but no restrictions were set for language, date, or publication type. Searching strategy for PsycINFO is displayed in Box 2.1.

The following databases were searched from inception to present in January 2015:

- ASSIA (Applied Social Science Index and Abstracts)
- CENTRAL (Cochrane Central Register of Controlled Trials)
- CINAHL
- EMBASE
- Global Health
- IBSS (International Bibliography of the Social Sciences)
- MEDLINE
- OpenGrey
- POPLINE
- PsycINFO
- Science Citation Index
- Social Sciences Citation Index (SSCI)
- TRoPHI (Trials Register of Promoting Health Interventions)
- WHOLIS
- World Bank e-library

Box 1. PsycINFO search strategy

Search #1: exp menstruation/ OR (menstrual period OR menstru* or menses OR catamenia OR menarche).mp.

Search #2: hygiene/ OR water deprivation/ OR water safety/ OR water supply/ OR health education/ OR exp school facilities/ OR exp intervention/ OR (Management OR hygiene OR hygienic OR product* OR absorb* OR WASH OR sanitary OR sanitation OR toilet facilities OR bathroom facilities OR toilet* OR latrine* OR privy OR water closet OR lavatory* OR girl friendly OR wom#n friendly OR gender-separate OR privacy OR private OR dispos* OR waste OR intervention*).mp.

Search #3: employee absenteeism/ OR school attendance/ OR exp school dropouts/ OR exp student engagement/ OR exp academic achievement/ OR exp occupational success/ OR exp productivity/ OR academic failure/ OR education/ OR academic self concept/ OR distraction/ OR colleges/ OR exp schools/ OR job performance/ OR employee efficiency/ OR employee productivity/ OR employee retention/ OR employee motivation/ OR employee engagement/ OR (absent* OR academic achievement OR academic performance OR attend* OR attention OR college* OR disengage* OR distract* OR educat* OR employee absenteeism OR employee engagement OR employee productivity OR engage* OR job OR productivity OR school* OR university OR vocation* OR work).mp.

Search #4: agency/ OR anxiety/ OR depression, emotion/ OR distress/ OR embarrassment/ OR empowerment/ OR Health Knowledge/ OR Health Attitude/ OR shame/ OR fear/ OR mental health/ OR self determination/ OR exp interpersonal control/ OR exp self concept/ OR self confidence/ OR self efficacy/ OR self esteem/ OR self perception/ OR social isolation/ OR social acceptance/ OR exp stress/ OR well being/ OR (agency OR alone OR anxiety OR anxious OR attitude* OR confidence OR confused OR confusion OR depress* OR distress OR exclu* OR embarrass* OR empower* OR fear OR fearful OR isolation OR knowledge OR mood OR mental health OR psycholog* OR psychosocial OR restrict* OR secrecy OR shame OR social OR stress OR stigma OR self confidence OR self-efficacy OR self efficacy OR self-esteem OR self esteem OR upset OR understanding OR well-being OR well being OR worry OR worries).mp.

Search #5: Search #3 OR Search #4

Search #6: Search #1 AND Search #2 AND Search #5

Searching other resources

Government departments and multilateral organisations were identified through the *Menstrual Hygiene Matters* report (House, Mahon, & Cavill, 2012) co-publishing agencies, and websites and databases were searched. Handsearching was conducted in two key journals, reference lists of included studies, and the *Menstrual Hygiene Matters* report (House, Mahon, & Cavill, 2012). Subject experts were contacted to identify published, unpublished, or ongoing research.

Data collection and analysis

Two reviewers independently screened titles, abstracts and full text articles. Included articles were determined by consensus. Data were extracted regarding participants, methods, intervention, analyses, outcomes, and risk of bias using a piloted form.

Risk of bias was assessed independently by both authors using the tool outlined in the *Cochrane Handbook* (Higgins & Green, 2011). Additionally, three domains recommended by the Cochrane EPOC group (2013) were used to assess threats to validity; imbalance of the outcome measures at baseline, comparability of intervention and control group characteristics at baseline, and protection against contamination. These were incorporated due to the inclusion of non-randomised studies and risk of contamination in software interventions.

Narrative synthesis is presented for included studies with standardised measures of effect calculated to aid comparison. For studies with multiple intervention groups, data were extracted for all comparisons. Where interventions were comparable (e.g., education by different providers), groups were combined to generate an average intervention effect.

Due to intervention and methodological heterogeneity data synthesis was possible for only one comparison, with two studies. Randomised and non-randomised

studies were considered separately, as these designs represented different levels of risk of bias (Higgins & Green, 2011). Review Manager 5.3 (2012) was used to conduct meta-analysis using the generic inverse variance method to enable inflation of standard errors for clustering. Intra-cluster correlation coefficients (ICCs) were obtained from study reports or requested from authors. There were insufficient trials to conduct subgroup or sensitivity analyses.

Results

After duplicates were removed a total of 10,674 titles and abstracts were screened (see Figure 2.1).

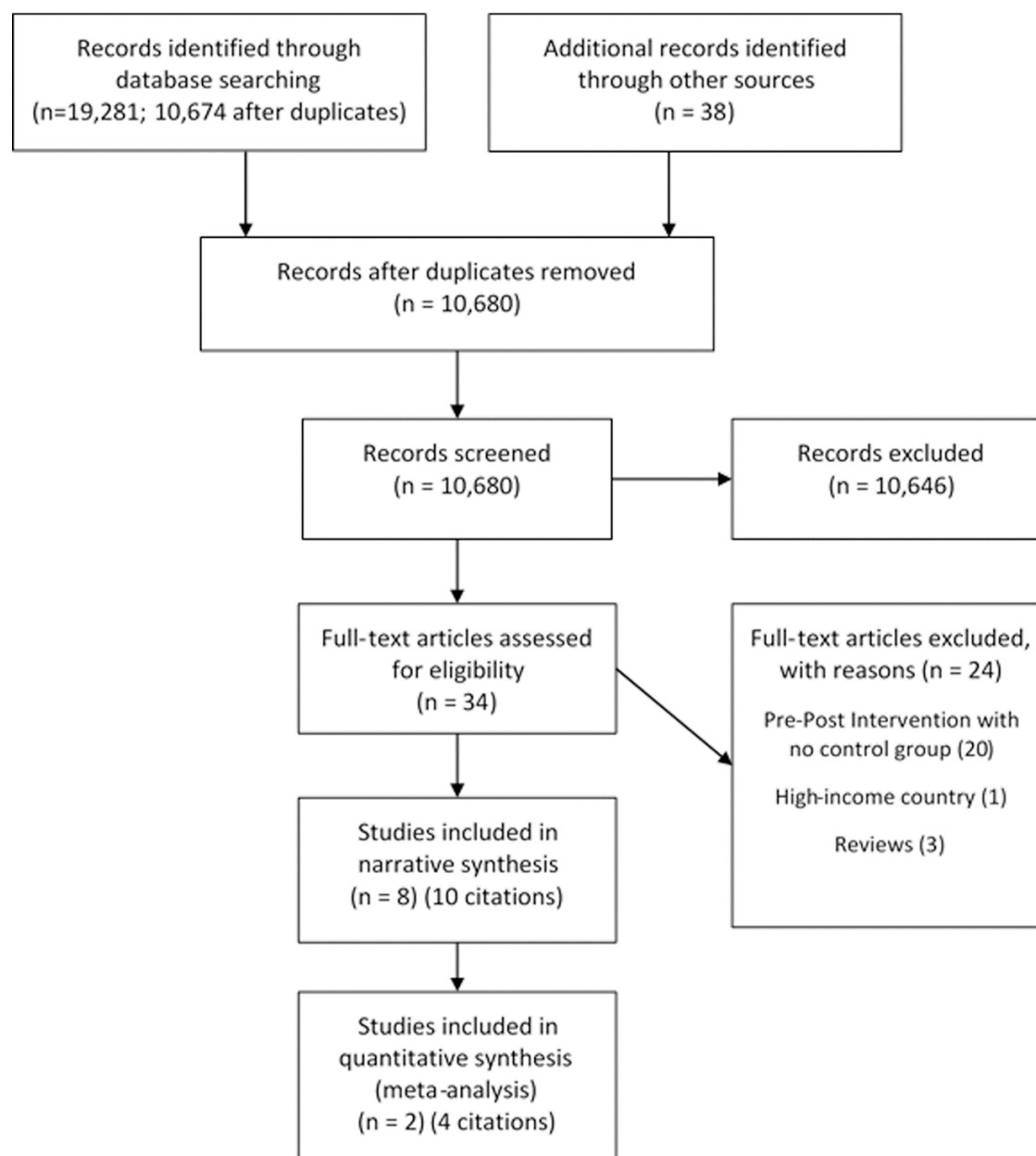


Figure 2.1. Study Flow Diagram (Moher et al., 2009)

Included studies

Full text studies excluded, with reasons, are presented in Appendix 2.2.

Eight trials were eligible for inclusion. Five evaluated education interventions, two the impact of providing sanitary products, and one included both interventions. One study assessed menstrual knowledge for both males and females. Authors were contacted, but unable to provide separated comparisons (Mbizvo et al., 1997). To provide an overview of available interventions, this study was retained although no outcomes could be reported.

Study characteristics are presented in Table 2.1. Six countries were represented; Iran (3), Saudi Arabia, Zimbabwe, Ghana, Nepal, and Kenya. Sample sizes ranged from 120 to 1823. Five studies included only girls post-menarche (Montgomery et al., 2012; Wilson, Reeve, & Pitt, 2014; Abedian, Kabirian, Mazlom, & Mahram, 2011; Fakhri, Hamzehgardeshi, Golchin, & Komili, 2012; Fetozy, 2007). Exclusion and non-participation rates were typically not reported, although the majority of papers implied that few invited girls declined to participate. Studies typically included school-aged girls, (approximately 11-18 years). Wilson and colleagues reported an age range of 11-26, although the study was set in a secondary school with a mean participant age of 16 years (Wilson, Reeve, & Pitt, 2014; Wilson et al., 2012). One study focused on university students (Abedian et al., 2011). This study included only students who reported experiencing dysmenorrhea (three menstrual cramps in the past six months).

Limited information was provided regarding the content of education interventions, but all papers reported including key information such as the origin of menstrual bleeding and menstrual management. The amount of education varied, as did the timing of outcome assessment. The trial by Djalalinia and colleagues (Djalalinia, Tehrani, Afzali, Hejazi, & Peykari, 2012) in particular failed to describe education content or duration. The three hardware intervention trials differed in the products tested. One

provided disposable sanitary pads (Montgomery et al., 2012), one self-made re-usable pads (Wilson, Reeve, & Pitt, 2014), and one reusable menstrual cups (Oster & Thornton, 2011). All trials compared intervention groups to no-intervention controls.

The timing of outcome assessment varied, from immediately after a 120-minute intervention to two-years post intervention. Primary psychosocial outcomes were only assessed in one study (Montgomery et al., 2012; Dolan et al., 2013). Most software trials reported only secondary outcomes of attitude towards menstruation and menstrual knowledge. One study (Abedian et al., 2011) used a previously validated menstrual attitude questionnaire (MAQ; see Brooks-Gunn & Ruble, 1980), however, this did not capture vital psychosocial constructs reflected in background literature. Knowledge of menstruation was assessed via study-specific questionnaires, for which comparability is unclear. Whilst Fakhri and colleagues (2012) assessed many relevant outcomes, including self-reported school attendance, authors reported only a single collapsed 'menstrual health' variable and did not report menstrual attitude outcomes according to intervention or control group.

Hardware Interventions						
Oster 2010	iRCT	Nepal/Urban and peri-urban schools	198 females aged 12-16 (87% post-menarche)	Provision of menstrual cup and instructions on how to use it	15 months	Girls and their mothers in the intervention group were provided with a menstrual cup (MoonCup) and instructions on how to use the cup were provided by a nurse. Timing of outcome assessment: 15-months throughout the intervention Outcomes assessed: School attendance records. Self-reported attendance, and self-recorded menstrual calendars. <i>School attendance:</i> Overall attendance, attendance during menstrual and non-menstrual days.
Wilson 2014	NRS. Non-randomised cluster control trial	Kenya/Non-urban primary and secondary schools	302 post-menarche females aged 11-26 (mean 16 years)	Provision of a training session and materials to make reusable sanitary pads	1 session	A training session on how to make a reusable sanitary pad and provision of enough equipment to make three pads. Girls were given a printed hand-out, adapted from the original pad pattern, to remind them how to make the pad. Instructions about washing and drying and information on the risk of infection or irritation of a damp or poorly washed pad was included. (The workshop did not include general menstrual health education) Timing of outcome assessment: 1-month after initial training Outcomes assessed: self-report questionnaire: <i>School attendance:</i> self-reported. <i>Menstrual hygiene practices:</i> including use of pads, adequate washing

iRCT: individually randomised controlled trial, cRCT: cluster randomised controlled trial, NRS: non-randomised study

¹All interventions were compared to no-treatment controls

Ongoing studies

Two eligible ongoing study were identified, see Appendix 2.3.

Risk of bias in included studies

Risk of bias assessments for included studies are summarised in Figure 2.2, and discussed below. Justification for included study risk of bias ratings are reported in Appendix 2.4.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Imbalance of outcome measures at baseline	Comparability of intervention and control group characteristics at baseline	Protection against contamination	Other bias
Abedian 2011	?	?	-	-	-	?	+	+	-	+
Djalalinia 2012	?	?	-	-	-	?	+	+	-	+
Fakhri 2012	-	-	-	-	+	-	?	+	+	+
Fetohy 2007	?	?	-	-	+	?	+	+	+	+
Mbizvo 1997	?	?	-	+	+	?	+	+	+	+
Montgomery 2012	-	-	-	+	+	+	+	+	+	+
Oster 2010	+	+	-	+	+	?	+	+	+	+
Wilson 2014	-	-	-	-	-	?	+	+	+	+

Figure 2.2. Review authors' judgements about methodological items for each included study

Three studies were non-randomised, representing a high risk of selection bias (Higgins & Green, 2011). Positively, these studies assessed and reported good comparability of intervention and control group characteristics at baseline. Wilson and colleagues (2012;2014) reported that all outcomes were comparable at baseline. The primary outcome of school attendance was balanced at baseline in the study by Montgomery and colleagues (2012), however, psychosocial outcomes were not balanced, representing a high risk for these outcomes. Of randomised studies, only one (Oster & Thornton, 2011) adequately reported methods of randomisation and allocation concealment. Of the three individually allocated studies, two were vulnerable to contamination (Abedian et al., 2011; Djalalinia et al., 2012). Education provided to girls in the same university dormitories or school could have easily been passed to friends in the control condition.

All studies had a high risk of bias due to blinding, as it would not be possible to conceal the intervention from those providing or receiving education or sanitary products. Similarly, the majority of outcomes were self-reported by participants and most included items (e.g., attitudes) vulnerable to self-report biases, and may have been influenced by the lack of blinding. Two studies (Montgomery et al., 2012; Oster & Thornton, 2011) were considered to have a low risk of detection bias as they used official school attendance records. Whilst attendance data may not be highly reliable in the context of LMICs, both studies reported triangulating school records with researcher visits (Montgomery et al., 2012) or girls' own attendance diaries (Oster & Thornton, 2011) and noted a high level of attendance record reliability. It should be noted that for attitude items reported in Dolan et al. (2013) a high risk of detection bias is present. Mbvizo and colleagues (1997) tested menstrual knowledge by assessing students' answers to questions about menstruation; judged to represent low risk of bias as the ability to answer accurately was unlikely to be altered by lack of blinding. There was considerable attrition in Wilson et al. (2012;2014) as authors were unable to follow-up

one intervention school. Djalalinia and colleagues (2012) stated in text that 5% of the sample was lost to follow-up, however reported N's deviate from this figure with 1231 participants of 1823 (67.5%) reported on at two-years post intervention, with even smaller numbers displayed in results tables. Abedian et al. (2011) reported modest attrition, but failed to employ an intention-to-treat analysis. Fetohey (2007) assessed outcomes immediately after the education session, resulting in no attrition. Despite a 15-month duration, Oster and Thornton (2011) reported negligible drop out (one participant), and employed an intention-to-treat analysis. Some missing outcome data was reported by Montgomery et al. (2012; Dolan et al., 2013) but this was judged to be low risk in light of analytic approaches, including imputing missing values. Only one study reported trial registration (Montgomery et al., 2012). Of the remaining studies, five reported all outcomes included in methods. One study (Fakhri et al., 2012), reported only an aggregated outcome, and one (Mbizvo et al., 1997) did not include a list of measured outcomes in methods.

No other sources of bias were identified, although the suitability of outcome measures and study quality varied and are highlighted further in discussion.

Effects of interventions: software interventions

Results of software intervention trials are summarised in Table 2.2.

Education

Only one study assessed the impact of education on school attendance (Montgomery et al., 2012). When comparing the education-only school (n=25) to the control school (n=35) a medium effect (SMD=0.63 95%CI 0.11-1.16) was found. Although a broad confidence interval, and comparison of single clusters cautions against over-interpretation (EPOC, 2013).

No studies assessed secondary education measures of achievement, or engagement.

Employment

No studies assessed the impact of MHM interventions on employment.

Psychosocial outcomes

Primary psychosocial outcomes were assessed in one study (Montgomery et al., 2012; Dolan et al., 2013). Authors reported that outcomes of shame, lack of self-confidence, insecurity, and difficulty concentrating did not improve in the education-only arm of the study (Dolan et al., 2013).

Djalalinia and colleagues (2012) evaluated primary outcomes of fear and confusion specific to menarche. Authors reported that negative psychological effects of menarche were lower in the groups which received the intervention. However, insufficient data were reported to calculate an effect size, and findings should be interpreted with caution in light of unclear attrition and analyses.

Most software trials reported only secondary outcomes of attitude towards menstruation, or menstrual knowledge and practices (Table 2.2). Abedian et al. (2011) found a large positive impact of education on menstrual knowledge. On average, scores on the 10-item test designed by study authors increased from 3.86 to 8.99. The study used the MAQ (Table 2.1) to assess attitudes and found medium to large effects on most sub-scales (Table 2.2). Fetohy (2007) found a large positive effect of education on menstrual attitudes compared to controls, however menstrual attitude was conceptualised as attitude towards healthy practices which fails to capture attitudes towards experiencing menstruation and is not comparable to other studies. Fetohy (2007) found a large difference in menstrual knowledge post-education, with intervention and control groups differing by approximately 10-points on a test scored from 0 to 33. Similarly, there was a large standardised mean difference between intervention and control students in self-reported hygiene behaviours (Fetohy, 2007). However, this outcome was measured immediately after a single session of education, leaving

students no time to have changed behaviours. Thus this result is likely to represent recall bias or social desirability effects, and demonstrates the biases inherent in self-reported behavioural outcomes, particularly where blinding to condition is not possible. Fakhri and colleagues (2012) found a significant impact of their intervention on the inappropriately collapsed 'menstrual health' variable which included a wide range of practices.

Table 2.2. Effects of software interventions

Study ID	Design	Age, N per condition	Intervention ¹	Eligible Outcome/s	Measure of Effect SMD ² (95%CI)	Adjustments
Abedian 2011	iRCT	19-25 years. 104 intervention, 61 control	Peer-led and health-provider-led 'self-care' education (collapsed)	Menstrual knowledge	2.29 (1.88, 2.69)	No adjustment
				<i>Menstrual Attitude:</i>		No adjustment
				Menstruation as debilitating	-1.26 (-1.61, -0.92)	
				Menstruation as bothersome	-0.40 (-0.72, -0.08)	
				Menstruation as natural	0.66 (0.34, 0.99)	
				Prediction of onset of menstruation	0.22 (-0.10, 0.53)	
				Denial of effect of menstruation	0.76 (0.43, 1.08)	
Djalalinia 2012	iRCT	11-15 years. Total 1823 (intervention and control N's not reported)	Parent-led or school health trainer-led menstruation education (collapsed)	Feelings at menarche (confusion, scared, uncomfortable feeling, good feeling)	Unable to calculate measures of effect. N's and percentages not adequately reported in study table and text. Authors report control participants were more likely to experience negative feelings at menstruation (confusion, being scared, feeling uncomfortable) than those in the health trainers groups ($p<.001$).	No adjustment
				Hygiene practices	The trained groups were more likely to take appropriate actions at menarche than controls but this was not significant. Authors report continuing to exercise during menstruation was most common amongst the health trainers group ($p<.05$)	No adjustment

Fakhri 2012	Cluster Controlled before after	14-18 years. 349 intervention, 349 control	Youth and School Health Department-run puberty and menstrual health education	Menstrual health (collapsed outcome) (Risk ratio of good or excellent ‘menstrual health’ in contrast to ‘average’ or ‘poor’ menstrual health).	RR=1.30 (1.04, 1.64) ³ Control RR=1.00	No adjustment
				Usual bathing during menstruation	RR=1.29 (1.10, 1.51) ³ Control RR=1.00	
				Attitude toward menstruation	Not reported by intervention and control group (data requested, not provided)	
Fetohy 2007	cRCT	14-17 years. 124 intervention, 124 control	Menstrual education sessions	Menstrual knowledge	2.23 (1.98, 2.62)	No adjustment
				Menstrual attitude	1.82 (1.52, 2.11)	
				Menstrual practices	0.97 (0.70, 1.23)	
Mbizvo 1997	cRCT	10-19 years. 1159 intervention, 530 control (51% female)	Puberty education through posters and pamphlets	Menstrual knowledge	No comparable outcomes. Outcomes reported collapsed for males and females (authors unable to provide stratified data)	

Montgomery 2012	NRS cluster control trial	12-18 years. 25 education only intervention, 35 control	Puberty education alone condition	School attendance	0.63 (0.11, 1.16)	No adjustment
				<i>Psychosocial outcomes:</i> shame, lack of self-confidence, insecurity, difficulty concentrating	Dichotomous outcomes. Risk ratios could not be calculated. Clusters varied widely at baseline. Control group psychosocial outcomes were not assessed at follow-up and test-retest reliability of measures was not reported/evaluated (therefore difference scores could not be compared). Authors reported pre-post analysis for each cluster. Authors reported psychosocial outcomes of shame, self-confidence, insecurity and difficulty concentrating did not improve in the education- alone condition	No adjustment

¹All interventions were compared to no-treatment controls

² Standardised Mean Difference (Cohen's *d*) calculated from means and standard deviations and data provided in text (for guidance; small 0.2, medium 0.5, and large 0.8 effects)

³RR = Risk Ratio, calculated from reported study frequencies for dichotomous outcomes.

Effects of interventions: hardware interventions

Education

School attendance was assessed in all three trials. In accordance with review protocol, randomised studies (Oster & Thornton, 2011) were not combined with non-randomised studies. Thus two studies (Montgomery et al., 2012; Wilson, Reeve, & Pitt, 2014) were eligible for meta-analysis. Intervention heterogeneity was high as studies differed in the products provided and education was included alongside pads in one study (Montgomery et al., 2012). Random-effects meta-analysis with standard-errors corrected for clustering revealed a moderate non-significant pooled effect (SMD=0.49, 95%CI -0.13, 1.11), see Figure 2.3. Statistical heterogeneity was negligible ($\text{Chi}^2=0.04$, $df=1$, $p=0.84$, $I^2=0\%$).

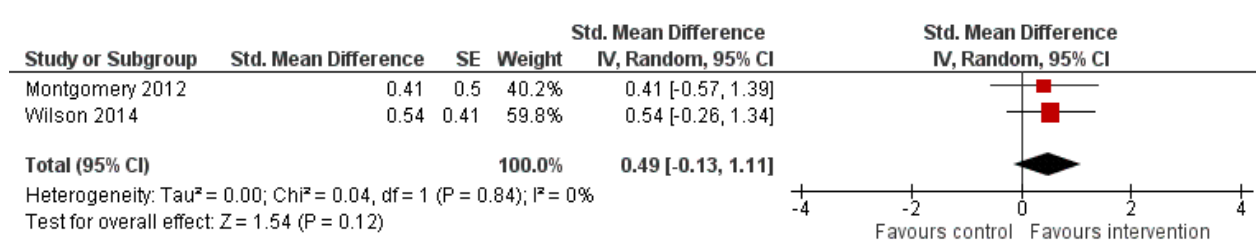


Figure 2.3. Hardware intervention compared with no treatment on school attendance

Oster and Thornton (2011) reported education outcomes using days rather than participants as the unit of analysis. For a 180-day school-year, authors report that provision of a menstrual cup resulted in a small but non-significant improvement ($\beta=0.14$, $p>.05$). The interaction between receipt of a menstrual cup and days of school missed during menstrual periods was investigated and also found to be a small non-significant effect ($\beta=0.02$, $p>.05$).

Psychosocial outcomes

One study (Montgomery et al., 2012; Dolan et al., 2013) reported on psychosocial outcomes. Psychosocial outcomes varied significantly between clusters at baseline. In addition, these outcomes were not evaluated in the control cluster at follow-

up, and test-retest reliability of scales was not reported (or evaluated). Dolan et al. (2013) were only able to report pre-post intervention changes in psychosocial outcomes for each cluster. Authors reported that for both sites where pads and education were provided, shame, lack of confidence, insecurity, and difficulty concentrating were improved following the intervention, with many outcomes (including shame, insecurity and difficulty concentrating) reported by approximately 25% fewer girls in each site at follow-up (Dolan et al., 2013). These findings represent a much higher risk of bias as they were not compared to a control group, and it may be the case that negative psychological consequences of menstruation decrease naturally over time.

Discussion

This review identified six software, and three hardware trials of MHM interventions. Whilst heterogeneous with regard to intervention, context and delivery, software interventions were generally found to improve knowledge of menstruation (Abedian et al., 2011; Fakhri et al., 2012). Menstrual knowledge is hypothesised to improve girls' MHM and reduce negative psychosocial consequences (House, Mahon & Cavill, 2012; Kirk & Sommer, 2006; McMahon et al., 2011; Sommer, 2011). Some supporting evidence for these outcomes was found, with management practices reported to have been improved by education in three studies (Fakhri et al., 2012; Fetohy, 2007; Djalalinia et al., 2012). However, unclear measures and self-report biases mean results should be interpreted with caution. In terms of psychosocial outcomes, more positive attitudes towards menstruation were found for girls who had received education in two studies (Abedian et al., 2011; Fetohy, 2007). One study (Abedian et al., 2011) used a previously validated menstrual attitude questionnaire (MAQ; Brooks-Gunn & Ruble, 1980). However, this measure was developed in a high-income, US-context. Survey items, for example, *'menstruation is an obvious example of the rhythmicity which pervades all of life'* and *'a woman who attributes her irritability to her approaching menstrual period is neurotic'* (Brooks-Gunn & Ruble, 1980) do not reflect the fear and stigma facing women in LMICs (Sommer, 2009; Crichton et al., 2013). Only two studies measured primary psychosocial outcomes. One RCT found a positive influence of education on feelings at menarche (Djalalinia et al., 2012), in contrast to a non-randomised study (Montgomery et al., 2012; Dolan et al., 2013) which found no improvements in shame, self-confidence, or insecurity following education. This same software intervention found positive effects on school attendance (Montgomery et al., 2012). However, the non-randomised pilot study was small, with single clusters compared.

School attendance was assessed in all three hardware trials. Moderate, but non-significant, improvements in school attendance were found for hardware interventions providing varied sanitary products. One iRCT found no significant impact of providing menstrual cups (Oster & Thornton, 2011). Context should be taken into account in interpreting results of this study. Very high attendance was reported at baseline, so minimal changes may reflect a ceiling effect. Further, uptake of menstrual cups may have been difficult to capture as these could be difficult to use for young girls. Meta-analysis of two non-randomised studies providing disposable sanitary pads (Montgomery et al., 2012) and reusable home-made pads (Wilson et al., 2014) revealed a moderate non-significant effect. Given the small sample and cluster sizes of the studies, both pilots, this may be due to a lack of power. Larger trials are needed to determine the true effectiveness of MHM hardware interventions. In such trials, assessment of supplementary outcomes such as achievement or engagement would triangulate findings. Only one study (Montgomery et al., 2012; Dolan et al., 2013) assessed hardware intervention impact on psychological outcomes, with reductions in shame, lack of confidence, insecurity, and difficulty concentrating reported. However, as noted previously only pre-post analysis of individual clusters was possible.

High risk of bias was present in the included studies. Three non-randomised studies were included. Positively, appraisal using additional items suggested by the EPOC group (2013) showed intervention and control groups in non-randomised studies to be comparable at baseline on characteristics assessed. Risk of contamination was an issue in two individually randomised studies (Abedian et al., 2011; Djalalinia et al., 2012). Studies suffered from inadequate reporting with many items in risk of bias assessments 'unclear'. Further, few studies reported implementation, or analytic strategies, for appraisal.

A lack of appropriate outcome assessment limits the conclusions which can be drawn currently. No software trials assessed academic outcomes, and only two studies

(Montgomery et al., 2012; Djalalinia et al., 2012) assessed primary psychosocial outcomes. Whilst such outcome measurement is challenging in LMIC contexts, no studies evaluated potential harms (Moher et al., 2009). Stigma, harassment, and unwanted sexual attention arising from the disclosure of menstrual status have been documented (Sommer & Sahin, 2013; Pillitteri, 2011; House, Mahon, & Cavill, 2012). The identification of menstruating females through interventions may 'out' girls' menstrual status, resulting in negative effects on attendance or psychological harm.

This review has highlighted many weaknesses in the existing body of evidence for MHM interventions. The challenges of conducting rigorous evaluations in LMICs should not be overlooked when considering the value of these findings. Furthermore, large gaps in MHM research more broadly contribute to the difficulty of conducting intervention trials. As noted, the lack of measures specific to MHM limits the reliability of outcome measures. Similarly, accurately assessing education outcomes may be challenging due to the differing reliability of school attendance registers or comparability of achievement measures across contexts. Sparse data exists regarding optimal genital cleaning practices for women and girls during menstruation, or the contribution of menstrual absorbent types to genital infection, comfort, or psychosocial outcomes (Das et al., 2015). Age of menarche differs contextually, and targeting interventions to the correct age group may be difficult in absence of population-specific data (Anderson, Dallal & Must, 2003; Parent et al., 2003; Sommer & Mmari, 2015). Finally, as qualitative research has revealed, menstruation represents a taboo topic for many, and accurately capturing practices, attitudes or disseminating education to communities may fail if strategies lack cultural sensitivity (Sommer et al., 2014).

The present review comprehensively searched peer-reviewed and grey literature. Searches identified a large number of studies, most of which were of poor quality. All papers included in past reviews were identified. In addition, many excluded studies were not captured in previous reviews (Sumpter & Torondel, 2013) although were likely to

have met their broader inclusion criteria. Publication bias could not be assessed as the evidence base is still limited. This review did not include interventions to address dysmenorrhoea, painful menses in women with normal pelvic anatomy (Avasarala & Panchangam, 2008), which has been identified as an issue affecting attendance at work (Business for Social Responsibility, 2011), school (Ali & Rizvi, 2010; Santina, Wehbe, & Ziade, 2012; Tavallaee, Joffres, Corber, Bayanzadeh, & Rad, 2011), and contributing to negative experiences of menstruation (Ali & Rizvi, 2010; Saintina, Wehbe, & Ziade, 2012). However, background searching suggested interventions targeting dysmenorrhoea in LMICs are yet to be trialled.

The use of school attendance, rather than achievement or engagement, as the primary education outcome could be criticised. Authors have argued that a singular focus on attendance is a limitation of present literature (Pillitteri, 2011; McMahon et al., 2011; Sommer, 2010; Haver et al., 2013). However, no studies reported on academic achievement so this would not have affected the conclusions of the review.

Implications for future practice and research

There is insufficient evidence to determine the effectiveness of MHM interventions, although some positive indicators are emerging. In seeking to implement programs, practitioners and policy-makers should consider comprehensive evaluations. This review has provided a summary and critical appraisal of interventions and assessment methods used to date, which may aid the development of such evaluations. Larger, randomised trials are needed to determine the impact of MHM interventions. In such trials, cRCTs are likely to be most appropriate for avoiding contamination issues. Trials must compare the various intervention strategies proposed; including both hardware and software interventions and the interaction between them. To aid this process, interventions should be based on a clear theory of change which includes the various individual and contextual factors which contribute to women and girls MHM. Such theories should be tested, and mediators and moderators of effects identified, for

example the distribution of reusable sanitary pads may not be effective in the absence of improvements to WASH. Absorbent sustainability, acceptability, comfort, and risk of reproductive tract infections must all be considered when selecting sanitary products appropriate for interventions. A reliable and consistent assessment of all aspects of MHM (Sommer & Sahin, 2013) in observational studies and trials may serve to draw attention to the various aspects of MHM contributing to outcomes.

As noted above, there is a lack of research capturing MHM practices or quantifying the health, education, and psychosocial consequences of different MHM practices. Providing data on the hypothesised causes and consequences of poor MHM would help guide the development and evaluations in future. These trials should seek to use validated measures of psychosocial constructs and measures of women's wellbeing specific to, or which include, MHM. This would improve comparability across studies, enabling researchers to grasp the severity of distress caused by unmet menstrual needs, and the influence of interventions.

Studies are needed on the impact of MHM on adult women, and potential WASH interventions as no trials were identified. Future trials must evaluate potential harms of interventions, particularly consequences of 'outing' menstruating girls in contexts with high levels of stigma associated with menstruation.

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CHAPTER 3

Paper #2: Advocating for an evidence-based approach to menstrual health

Menstrual hygiene management and human rights: the case for an evidence-based approach.

Julie Hennegan¹

¹ Centre for Evidence-Based Intervention, University of Oxford, Oxford, UK

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Note: To comply with journal requirements, U.S. spelling is used in this chapter.

Abstract

Menstrual hygiene has emerged as an under-recognized barrier to human rights. Activism and preliminary research have highlighted the challenge women face managing their menses in resource-limited contexts. However, despite enthusiasm in the field and the dissemination of a variety of interventions, menstrual management is severely under-researched. This article argues that a human rights approach to menstrual hygiene necessitates an evidence-based approach. It will critically appraise the current state of the evidence in understanding the problem, and developing and evaluating interventions. This will highlight present inadequacies, unanswered questions, and propose avenues for future improvement.

Introduction

A human rights approach to menstrual hygiene management (MHM) means acting as swiftly and effectively as possible to improve conditions for women and girls. It also means doing so in an ethical manner, without iatrogenic effects. This article argues that understanding MHM through appropriate methods and rigorously evaluating interventions, an evidence-based approach, is vital to achieving this outcome. As described below, links between MHM and human rights have been described. However, a much stronger case for these relationships can be made when claims are supported by rigorous research. Further, an evidence-based approach ensures interventions are built on a detailed understanding of the issue, identifying potential problems, minimizing resource waste, and maximizing effectiveness. In a climate of limited resources and increased recognition for the ethical imperative of evidence-based practice and policy making, we cannot expect governments and other organizations to place the considerable and necessary investment into MHM without rigorous estimates of the prevalence and consequences of poor MHM, or the effectiveness of MHM interventions. Such findings must be reported in papers compliant with current reporting standards, where methods can be adequately critiqued. This paper argues for the imperative of an evidence-based approach to MHM for human rights and provides a critical appraisal of the state of MHM research.

What is menstrual hygiene management?

Menstruation is the natural, cyclic shedding of the uterine lining that occurs in women from menarche in adolescence until menopause in middle age. Despite the ubiquity of menstruation, its occurrence and management have been stigmatized across cultures and contexts (Mahon & Fernandes, 2010, Crichton, Okal, Kabiru, & Zulu, 2013; Sommer, Ackatia-Armah, Connolly, & Smiles, 2014). Menstrual hygiene management (MHM) is the term used to describe the hygienic and efficient management of

menstruation, defined as *“women and adolescent girls using clean menstrual management material to absorb or collect blood that can be changed in privacy as often as necessary for the duration of the menstruation period, using soap and water for washing the body as required, and having access to facilities to dispose of used menstrual management materials.”*(Sommer & Sahin, 2013, p.1557). This definition captures the physical requirements for management. In addition, education and awareness are preconditions for the use of physical facilities, and women and girls must be able to meet MHM conditions with dignity, and without fear or shame (House, Cavill, & Mahon, 2012; Winkler & Roaf, 2015).

Menstrual hygiene management and human rights

MHM is integral to women’s dignity, and links to multiple human rights. Winkler and Roaf (2015) have described the contribution of a human rights approach to MHM. Their work provides extensive detail situating MHM within a human rights framework. They link MHM to articles from the Universal Declaration of Human Rights (General Assembly, 1948) and subsequent agreements including the Convention on the Elimination of all Forms of Discrimination Against Women (General Assembly, 1979) and International Covenant on Economic, Social and Cultural Rights (1966). It is clear that MHM has implications for rights to: dignity, privacy, health, gender equality, education, and work and working conditions, as well as the right to water and sanitation, explicitly recognized in 2010 (General Assembly, 2010).

Briefly, MHM relates to human rights both directly and indirectly; via access to the facilities required for adequate MHM, and then through rights infringed upon as a consequence of inadequate MHM. As a challenge specific to women, gender equality is a key aspect of MHM in all respects. As described above, there are a number of necessary preconditions for the hygienic management of menstruation which present a particular challenge in resource-poor contexts. Access to soap and water for washing the body and absorbents, have clear implications for women’s human right to water and

sanitation, and right to privacy. Inadequate sanitation, privacy and disposal facilities necessary for menstruation in schools or workplaces represent structural inequalities compromising women's right to equality, education and work (Winkler & Roaf, 2015). Social taboos and inadequate information about menstruation also contribute to an environment in which women's rights to dignity and equality are compromised due to menstruation. Human rights to health, education, work and rights at work, and non-discrimination are all impacted by inadequate MHM (Winkler & Roaf, 2015; Sommer, Chandraratna, Cavill, Mahon, & Phillips-Howard, 2016). Poor MHM may contribute to absence or disengagement from school or work, infringing upon rights to education and work. Irritation, discomfort and potential reproductive and urinary tract infections resulting from inadequate MHM have implications for rights to health. Stigma and marginalization following soiling outer garments or odors resulting from poor MHM undoubtedly impact women's dignity and equality.

What is an evidence-based approach?

Social and public health programs frequently fail to achieve positive outcomes, wasting limited resources, or worse, causing harm (Chalmers, 2003; Chalmers, 2005; Macintyre & Petticrew, 2000; Craig, Dieppe, MacIntyre, Mitchie, Nazareth, & Petticrew, 2008; Lorenc & Oliver, 2013; Wight, Wimbush, Jepson, & Doi, 2015). An evidence-based approach in which decisions are made based on best available research evidence, integrated with client preferences, local contextual knowledge, and clinical expertise has been increasingly recognized as the ideal for efficient and effective intervention (Sackett, Richardson, Rosenberg, & Haynes, 2000; Loumas, 2005; Haynes, Devereaux, & Guyatt, 2002; Gambrill, 2006). In the case of MHM, this means high-quality evidence considered alongside an understanding of women and girls' experience, the need to address human rights, the specific contextual circumstances, and expertise in the field.

Evidence-based MHM

The need for an evidenced approach to MHM was recognized in the recent *MHM in Ten* report (Columbia University & UNICEF, 2014). Of five priorities for achieving MHM in schools by 2024, the working group set the first as '*building a strong cross-sectoral evidence base for MHM in schools for prioritization of policies, resource allocation and programming at scale*' (Columbia University & UNICEF, 2014, p.3). To meet this objective there are two broad domains in which evidence is needed. The first is in understanding the problem; including the prevalence, severity, causes and consequences of MHM. The second is to use this knowledge to develop appropriate interventions and rigorously evaluate their effectiveness (Craig et al., 2008). Finally, as noted in the *MHM in Ten* report, this evidence must be translated across sectors and integrated with local knowledge and circumstances (Columbia University & UNICEF, 2014; Sackett et al., 2000).

Those most affected by poor MHM are disadvantaged and marginalized populations of girls and women. An evidence-based approach is a particular ethical imperative in such resource-limited and disenfranchised populations. The types of interventions suggested for MHM may ask women and girls to change their vaginal care practices and use unfamiliar menstrual products (e.g., menstrual cups). These interventions are presented to resource-poor populations where alternative options are limited. Such changes to practice may present risks to health, comfort, dignity, stigma, and psychosocial outcomes. From both feminist and human rights perspectives it should be imperative that these interventions are implemented following thorough evaluations. Trials require full informed consent and ethical approval. Through monitoring and evaluation, rigorous studies can identify potential harms and benefits of interventions before they are disseminated on a larger scale. In this way an evidence-based approach prevents vulnerable women from being put at risk by untested interventions which may waste scarce resources, or worse, risk being harmful.

As in many areas of public health and social work, an evidence-based approach has not driven the MHM agenda to date. Research efforts have followed after government policies (e.g., Garg, Goyal, & Gupta, 2012), large funder initiatives (e.g., Proctor & Gamble, 2010), NGO action, experts' opinions, and media attention (Kristof, 2010; Sommer, Hirsch, Nathanson, & Parke, 2015). As a result, research programs have been reactionary, perhaps contributing to the disjointed nature of the literature discussed below. The state of evidence-based practice in MHM was well captured when Sommer and colleagues (2015) discussed the role of research in promoting MHM as a public health issue and, without critical comment, stated that *"research drew upon participatory and feminist methodologies rather than the traditionally accepted gold standard of randomized control trials"* (p.e4). Whilst women and girls' must be central to our agenda, it is difficult to imagine that using gold standard research methods to establish hypothesized relationships and identify effective, rather than harmful, interventions does not constitute a feminist approach to MHM. The need for each aspect of this evidence-based approach to MHM will be expounded in this work and the current gaps and weaknesses highlighted.

Understanding the Problem

A history of neglect means MHM research is in its infancy. Systematic reviews have found a paucity in intervention and background evidence (Hennegan & Montgomery, 2016 [Thesis Chapter Two]; Sumpter & Torondel, 2013). There is an urgent need for rigorous research revealing the prevalence, causes, and consequences of MHM across contexts. This would primarily include low-and-middle-income countries (LMICs), but also low-income or homeless populations in high income countries, as well as refugee and conflict settings. Reliable studies describing the prevalence of MHM would add weight to links made to human rights and bring visibility to this largely hidden issue. Cross-sectional and longitudinal studies demonstrating the negative consequences of poor MHM are critical for effective advocacy, and understanding the etiology of MHM key to developing effective interventions (Craig et al., 2008).

Describing the problem: prevalence

Establishing the prevalence of MHM in different populations, and sub-groups is a key first step in research, and essential for advocacy and funding (e.g., Bill & Melinda Gates Foundation, 2016). Most quantitative studies of MHM have been those surveying girls' hygiene practices. A selection of studies from a range of contexts, many frequently cited in academic literature and advocacy as MHM prevalence, are displayed in Table 3.1. As shown in the table, studies have captured a few aspects of MHM, but none report on all components (Sommer & Sahin, 2013) and none include a summary prevalence estimate of poor MHM consistent with the consensus definition. There is no consistency, and a paucity of reporting on how questions were asked. Frequently cited papers such as Adinma and Adinma (2008) state that 55.7% of girls were classified as using unsanitary menstrual absorbent, but do not report how menstrual absorbents used were reported by participants, and did not distinguish between clean, used, or found cloth. This paper reported a single item for 'multiple materials' (10.7% of girls) without

stating what these materials may be. Similarly, El-Gilany and colleagues (2005), cited over 100 times, did not report how questions were asked to capture absorbent use. Authors report categories such as *'re-usable cloth after boiling or washing'*, *'old cloth thrown away after single use'*, with no items that might capture alternate strategies such as if old cloth was re-used. It is unclear if these categories were collapsed from separately reported items, or if these were the response options presented to girls. Dasgupta & Sarkar (2008), cited over 150 times, reports on menstrual hygiene in India. Again example items, or information about the structure of questions were not reported.

Table 3.1. Selection of studies across LMICs reporting on MHM practices

Study	Population	Methods	MHM
MIDDLE EAST			
Santina, Wehbe, Aizde & Nehme, 2013	389 adolescent girls aged 13-19 at 5 high schools in Sidon city and surrounding suburbs, Lebanon.	Survey	100% used disposable sanitary napkins, 51.5% changed pads every 8-10 hours, 40.4% every 3-4 hours. 66.9% did not shower in first three days of menstruation. 40.9% used only water for cleaning genitalia, 42.2% used soap and water.
SOUTH ASIA			
Adhikari, Kadel, Dhungel & Mandal, 2007	150 adolescent girls aged 13-15 years from 3 schools of Shivanagar and Pathani village development committees of Chitwan district, Nepal	Survey	94% used sanitary pads for absorbents, but only 11.3% disposed 'adequately'.
Aflaq & Jami, 2012	245 female adolescents studying at intermediate to postgraduate levels in postgraduate colleges for women in Islamabad, Pakistan (age 16-21)	Survey	50% using ready-made sanitary napkins, 50% using home-made napkins.

Ali & Rizvi, 2010	1275 female adolescents in urban Karachi, Pakistan	Interview, survey, and focus groups	79% used unhygienic menstrual absorbent (old cloth, none, other –except sanitary pad and clean cloth). 50% did not bath during menstruation.
Amirtha, Premarajan, Sarkar & Lakshminarayan, 2013	325 adolescent girls (12-15) in two urban primary schools in Pondicherry, India	Survey	94.8% used sanitary pads, 2% reused cloth after washing and drying in the sun. 82% changed pads less than 3 times per day.
Choudhary & Rahman, 2015	200 girls aged 10-19 who were slum living at Rajshahi City Corporation	Survey	82.5% had unhygienic menstrual management (did not use sanitary pad or clean cloth).
Dasgupta & Sarkar, 2008	160 adolescent girls at a secondary school in Singur, West Bengal	Survey	11% of girls reported using sanitary pads, 43% old cloth and 6% new cloth. 15% cleaned external genitalia daily.
Mudey, Kesharwani, Mudey, & Goyal, 2010	300 school going adolescent girls (10-19) in the Wardha district, Maharashtra, India	Survey	46.7% used cloth as menstrual absorbent, 15.7% used sanitary pads. Cleanliness of external genitalia was unsatisfactory (nil or <2 times per day) for 34.3% of girls. Only 59% used soap and water for cleaning genitalia. 56.6% satisfactorily disposed of used cloth or sanitary napkins.
Nemade, Anjenaya & Gujar, 2009	217 adolescent girls from Kalamboli, Navi-Mumbai, Maharashtra, India	Survey (baseline of intervention study)	15.7% used cloth only, 40.6% sanitary pads only and 43.7% used both cloth and sanitary pads. Of those using cloth: 51.3% used only water (48.7% soap and water) to clean it. 68.37% used the same cloths for 1 year.
Reshmi, Gupta, Kumar & Visengrawala, 2015	400 women 20-40+ (Mean 32 years) in the Kolar district of Karnataka, India.	Survey/ interviews	76% of women used cloth as menstrual absorbent.
Salve, Dase, Mahajan & Adchitre, 2012	189 rural and 132 urban school girls from 8 th to 10 th standard grades.	Survey	Percentage of using market available sanitary napkins was more in urban girls 60% compared to rural girls 6% whereas homemade sanitary napkins were used by 94% rural girls.

Sudeshna & Aparajita, 2012	190 adolescent girls of a rural secondary school in West Bengal, India	Survey	62.6% used only cloth, 13.2% used only sanitary napkins. Mean times absorbent changed per day was 2.27. Reusable cloth was dried in sunlight by 63%. 64.2% cleaned cloth with soap. Disposal of sanitary pads was inappropriate (53% pond, 40% garden, 5% landfill, 2% latrine). Reusable cloth used on average 3.1 cycles. Genitalia cleaning mean of 0.70 times per day during last menses.
Thakre, Thakre, Reddy, Rathi, Pathak & Ughade, 2011	387 school going girls in the field practice area of the Rural Health Unit and Training Centre, Saoner, Nagpur, India	Survey	49.4% used sanitary pads, 45.7% old cloths. Satisfactory cleaning of external genitalia practiced by 33.9% (satisfactory = more than two times a day during menstruation). Cleaning external genitalia: only water 40.6%, water & soap 58%. 11.37% changed pad during school.
AFRICA			
Abioye-Kuteyi, 2000	352 randomly selected healthy Nigerian school girls in Ile-Ife (South Western Nigeria)	Survey	66.3% used unsanitary menstrual absorbent (cloth, tissue paper and 'other' considered unhygienic).
Adinma & Adinma, 2008	550 menstruating schoolgirls in Onitsha (south eastern) Nigeria	Survey	55.7% classified as using unsanitary menstrual absorbents (toilet tissue, cloth).
El-Gilany, Badawi, & El-Fedawy, 2005	664 girls from public secondary schools in rural and urban areas aged 14-18 in Mansoura, Egypt.	Cross-sectional survey	Absorbents were: 66.8% sanitary pads (single use), 15.9% re-usable cloth after boiling or washing, 12.0% old cloth thrown away after use, 5.3% other (cotton, tissue). 29% of girls reported not bathing during menstruation.
Guya, Mayo & Kimwaga, 2014	149 girls from 12 secondary schools in Kinodoni and Bagamoyo districts in Tanzania.	Survey	97.3% using disposable sanitary pads. 1.3% cloth. 48.3% use water only to clean genitalia.

Moronkola & Uzuegbu, 2006	120 student nurses from two schools of nursing in Ibadan, Nigeria	Survey	70% used sanitary pads as menstrual absorbent. 43% cotton wool, 13% toilet paper, 10% clothing material, 10% tampons.
Tegegne & Sisay, 2014	595 adolescent school girls in Northeast Ethiopia	Survey	37.6% used sanitary pads as menstrual absorbent, 55.6% used homemade cloth and 9% used underwear as absorbent. 91.8% of those using cloth or underwear reused the absorbent. 85.5% did not change their menstrual absorbent at school. 37% used washed reusable cloth with soap and water. 54.9% washed their body when they finished their menstrual period but not during.
Umeora & Egwuatu, 2009	1692 females 17-56 from south east Nigeria.	Survey	Menstrual absorbent: 27.4% sanitary pads, 31.4% toilet tissue, 68.6% cloth/towel, 0.4% tampons.
Wilson et al 2014	302 school girls from 10 schools in rural Nyanza province in Western Kenya (baseline of an intervention study)	Survey	Menstrual absorbent: 24% cloth, 8% toilet paper, 7.7% cotton wool, 7.8% mattress or blanket, 51% disposable sanitary pads.

These studies are not named to disparage valuable work in understanding MHM, but to point out that there are significant gaps in current knowledge and inadequacies in reporting. Failure to report items capturing key variables of interest means papers are not compliant with established reporting standards such as the STROBE statement (Strengthening The Reporting of OBservational studies in Epidemiology, von Elm et al., 2007) which expects *“for each variable of interest, give source of data and details of methods of assessment (measurement).”* From the information available in current literature we do not know if measures are comparable. Items such as *“What do you most frequently use to absorb your menstrual blood?”*, may yield different responses to *“What absorbent do you currently use to absorb your menstrual blood?”*, or questions that

capture which types of absorbents girls have “*ever used*”. Questions about the reliability of self-report or of different question structures and formats are yet to be asked in the literature. Few studies have sought to provide details such as if girls use different absorbents at home than at school, or at different times in the menstrual period. These same queries apply to self-reports of disposal, washing the body, and the frequency of absorbent change. Although more detailed questions may be outside of the scope of all studies, improved reporting of items used would allow the field to reflect critically on what we do and do not know about girls’ behavior. These questions are not only important for prevalence estimates, but also when using measures of MHM to predict consequences (highlighting human rights violations) or test predictors of MHM.

Measuring MHM

Establishing the prevalence, causes and consequences of poor MHM, is contingent on being able to validly and reliably measure MHM in a way that is consistent with the established concept. The need for global standards was mentioned by the *MHM in Ten* report (Columbia University & UNICEF, 2014) which proposed the need for guidelines capturing what MHM-friendly schools would look like. The report, however, was unclear on how such guidelines would be developed within the limits of current evidence. It did not note the importance of measures of MHM for individuals, beyond schools, and for use in research. A validated measure of MHM would allow for comparability across studies, including studies of prevalence, epidemiology, and intervention studies. Whilst it is beyond the scope of this article to describe all the issues inherent in the development of a standardized assessment tool for MHM, such an assessment would need to report on all aspects of the consensus definition (Sommer & Sahin, 2013) and thus include;

1. Menstrual management material used to absorb or collect blood
2. Privacy for changing absorbents
3. Frequency at which absorbents are changed

4. Use of soap and water for washing the body (and absorbents)
5. Access to facilities to dispose of used menstrual management materials

As discussed above, questions would need to be piloted and asked in a way that truly captured women and girls' practices. There are specific questions for each aspect. For example, *'what should be classified as a clean menstrual absorbent?'* *'What is an adequate frequency for changing (which may vary individually and over the menstrual period)?'* *'What is an adequate and hygienic frequency for washing the body and genitals?'* It is unlikely that each point could be captured with a single question. The structure and wording of questions would also likely impact on reporting. Whilst there are MHM-specific issues in the development of these measures, challenges in reliably assessing self-reports of facilities and behaviors are not new to public health or psychology, and past literature is available on the development of reliable measures and examples in fields of handwashing, safe sex, and maternal health care. It may be that consideration of core outcome measures such as those developed via the Comet Initiative (<http://www.comet-initiative.org/>) may be of assistance to the field.

The ability to present rigorous prevalence estimates which stand up to the scrutiny required in more established areas of public health is vital to placing MHM in its rightful place on health, WASH, and development agendas. Provoking swift action and providing evidenced strategies to combat the threat that poor MHM poses to women and girls' rights world-wide is surely a goal aligned with feminist scholarship and MHM advocates.

Consequences of poor MHM

Poor MHM has been hypothesized to have a range of detrimental effects on health, education, employment, and psychosocial wellbeing. Evidence for these consequences is vital to substantiating claims of human rights violations, prompting

action from states and agents in the field, and developing interventions targeting relevant outcomes.

Health

Inadequate MHM has been stated to result in discomfort, irritation, and infection (Mahon & Fernandes, 2010; House, Mahon, & Cavill, 2012). However, there are few studies testing the links between MHM practices, absorbents, and infections (Sumpter & Torondel, 2013). There is little information on the adequacy of self-reported symptoms and studies to inform guidelines on best MHM practices. Das and colleagues (2015) found that the relationship between disposable and reusable pads and confirmed genital infections was complex, and that many aspects of MHM such as washing, privacy and demographic factors all played a role. The study observed differences in the effects of different MHM practices on different health outcomes, but noted that more studies, and studies in varied contexts, are needed to broaden our understanding (Das et al., 2015). Whilst gold-standard measures which require genital swabs are difficult to obtain, studies incorporating these outcomes are highly relevant to the human rights and MHM agenda. It is difficult to make recommendations to governments and agents, or for guidelines for school or workplace MHM adequacy when we have a very limited understanding of the practices which contribute to health (and discomfort). Developing validated self-report items for health symptoms, may reduce the need for future invasive studies and provide more comparability in the field.

Education

Qualitative and quantitative work has suggested that poor MHM leads to school absenteeism, distraction, and disengagement (Lloyd & Young, 2009; Grant, Lloyd, & Mensch, 2013). In 2005, a World Bank report asserted that 10-20% of school-days were missed by girls in LMICs due to menstruation, and whilst other reports repeat these or similar figures, most lack substantiating evidence (e.g., World Bank, 2005; House,

Mahon, & Cavill, 2012; UNESCO, 2014). Evidenced estimates of the association between menstruation and school absence have varied. An RCT conducted in Nepal, used girls' menstrual calendars (self-kept) and attendance records to estimate that only 0.4 days in 180 were missed due to menstruation (Oster & Thornton, 2011). In contrast, a pilot non-randomized trial in Ghana found that MHM intervention (provision of sanitary pads and education) improved attendance by 9% after five months (Montgomery, Ryus, Dolan, Dopson, & Scott, 2012). Different figures are quoted in academic literature and press. For example, in a recent article for a popular audience on MHM and human rights in the Huffington Post, Chatterjee and Din (2016) casually stated that *“Overall, studies estimate that 61 per cent of girls miss school annually due to lack of menstruation hygiene facilities in their primary schools”*. The ‘studies’ referred to a single article describing a qualitative study which undertook focus groups with a total of 53 participants in a large city in Kenya (Jewitt & Ryley, 2014). However, this figure was absent in the text of that published paper. Whilst this number may be interpreted as simply representative of the spread and severity of the issue, it does not serve the goal of improving MHM if figures are inconsistent, with unclear or disparate definitions used across advocacy and academic literature. If the aim is for a historically marginalized issue to be recognized as a significant global public health concern, the rigor of research and reporting must reflect this. Figures such as *‘61 per cent of girls miss school annually’* are not meaningful without reference to country, rurality, how often girls miss school (e.g., 1 day per year), or clarity in what is meant by a *‘lack of menstrual hygiene facilities’*. Rigorous methods and assessment of MHM and its contribution to education are sorely needed to advocate for attention and justify claims of human rights violations.

Employment

There is a dearth of literature concerning the impact of MHM on adult women. It has been suggested that workplaces lack adequate facilities to support MHM and that poor MHM presents a barrier to work and engagement. This has been linked to women's

rights for work and just and favorable working conditions (Winkler & Roaf, 2015; Boosey & Wilson-Smith, 2014). The only evidence for these links come from a limited number of site reports and focus groups (BSR, 2011; 2012; Boosey & Wilson-Smith, 2014). Focus groups from a factory in Pakistan suggested that women missed up to three days' work per month due to menstruation (BSR, 2012). Menstrual pain was emphasized more frequently by factory workers than MHM, although it should be noted that many factories had provided free sanitary napkins as part of HERproject, with site evaluations reporting improved health and attendance as a result (however few specific measures were taken). Studies quantifying links between inadequate WASH, MHM and work absences or difficulties would be invaluable in understanding and advocating for attention (and possible intervention) for menstrual issues at work. As populations of women in LMICs increasingly move into formal employment settings, managing menstruation in workplaces is likely to be a growing issue.

Psychosocial consequences

The impact of poor MHM on psychosocial wellbeing has been well documented by qualitative research (e.g., Sommer, 2009; McMahon et al., 2011; Crichton et al., 2013; Long et al., 2013; Sommer et al., 2014). This has been the strongest area of research, with cross-context and comparative studies consistently reporting girls' experience of shame, fear, distraction, anxiety, and disengagement. Such studies provide a clear link between rights to dignity and equality and MHM. The literature is far less convincing when trying to quantify these associations. Here the failure to measure MHM in a reliable or consistent way is again inhibitory. Similarly, measures of fear, shame or anxiety have been highly generalized. Scale items are often not reported, preventing appraisal and consistency across studies (e.g., Tamiru et al., 2015). Valid and reliable measures of relevant constructs are important both for observational and intervention studies when trying to assess changes in these outcomes. Systematic reviews (Sumpter & Torondel, 2013; Hennegan & Montgomery, 2016 [Thesis Chapter

Two]) have revealed that some intervention trials to date have used the now outdated *menstrual attitude questionnaire* (MAQ: Brooks-Gunn & Ruble, 1980) to evaluate outcomes. This questionnaire, with five subscales: menstruation as a debilitating event, menstruation as a bothersome event, menstruation as a natural event, anticipation and prediction of the onset of menstruation, and denial of any effect of menstruation, was developed in a high-income US context. Survey items, for example, '*menstruation is an obvious example of the rhythmicity which pervades all of life*' and '*a woman who attributes her irritability to her approaching menstrual period is neurotic*' (Brooks-Gunn & Ruble, 1980) do not reflect the experience of women in low income contexts, and do not fit with the psychosocial consequences of poor MHM identified in the qualitative literature (Sommer, 2009; Crichton et al., 2013). Dolan and colleagues (2013) sought to measure more relevant outcomes such as shame and insecurity in their pilot study of sanitary pad provision and puberty education in Ghana. Whilst these were more relevant outcomes, they used single item questions to which responses varied widely across sites at baseline. Items were not described in full in the paper (Dolan, Ryus, Dopson, Montgomery & Scott, 2013). While some of these deficiencies may be due to journal requiring short papers, authors might consider putting their measures in supplementary materials and on project websites.

Reliable and valid measurements of psychosocial constructs related to menstruation, perhaps specific MHM quality of life scales, may be of use to the field. This would provide a standardized assessment, comparable across contexts with known test-retest reliability, relationship to social desirability and validity (convergent and divergent). The field could also better employ previously validated measures of psychosocial constructs, wellbeing, and quality of life. This would allow comparison to existing public health work in other areas (e.g., the 36-Item Short-Form Health Survey; Ware & Sherbourne, 1992), or education interventions on emotional states (e.g., modified Positive and Negative Affect Schedule; Watson, Clark, & Tellegen, 1988).

Predictors of MHM

Understanding the predictors of MHM is vital to the menstrual health and human rights agenda. First, demonstrating hypothesized links between human rights such as WASH and privacy and MHM adds weight to advocacy and urgency to calls for action. Second, developing a thorough working theory of the problem is crucial to developing and testing interventions (Glanz & Bishop, 2010; Campbell et al., 2007). Just as a biological understanding of illnesses is necessary to development of appropriate medication, a clear understanding of the antecedents of complex health and social issues, like MHM, is essential to developing interventions and policies which are effective and minimize the potential for unintended harm (Johnson, Baur, & Meissner, 2011; Bonell, Jamal, Melendez-Torres, & Cummins, 2015). Existing work has started to build a theory of the predictors of poor MHM, although quantitative studies are limited. Proximal predictors of MHM have been divided into two categories: material and psychosocial deprivations (Crichton et al., 2013).

Material deprivations

The resource and physical requirements of MHM are well captured in its definition (Sommer & Sahin, 2013). Deficits in absorbents availability, access to water and sanitation, as well as privacy all pose a threat to women's MHM. However, assessments of these contributors to MHM have been sparse. Studies consistently report high rates of inadequate absorbent use in rural compared to urban populations (van Eijk et al., 2016), but there has been limited comparison of how other facilities and material deprivations contribute collectively to MHM. There is also an under-acknowledged lack of evidence for best practice. There is little guidance to suggest the optimal frequency of body washing, adequate cleaning for reusable absorbents, or the use of soap on genitals specific to contexts affected by poor MHM (Das et al., 2015).

Psychosocial deprivations

Our understanding of the psychosocial predictors of poor MHM largely qualitative. Studies have found that both women and girls lack knowledge of menstruation before it happens, the function and location of reproductive organs, or information about menstrual management leading to inadequate MHM (e.g., Chothe et al., 2014; Ali & Rizvi, 2009; House, Mahon, & Cavill, 2012; Crichton et al., 2013). Similarly, cultural beliefs and taboos may contribute to poor MHM by perpetuating misinformation or unhygienic customs (Sommer et al., 2014). Whilst the evidence base is more substantial here than in other aspects of MHM, there is little transparency in the questions asked or where reported quantitative percentages originate. For example, in the recent *Waterlines* issue on MHM, one paper reported baseline survey results from a project involving 141,000 adolescent girls (Tamiru et al., 2015). Despite this large sample, the paper failed to report the number of participants who responded to baseline surveys. The paper then reported that 80% of girls had knowledge of puberty in general but 66% of girls had not known about menstruation. No details were reported on the way questions were asked, or how percentages were derived. There was little break down by country, or by what factors may have contributed to knowledge of MHM, despite the study including 5 countries and multiple contexts. Studies must go beyond simply reporting if girls' had a knowledge of menstruation, but explore what type of knowledge they had, where information was received, and what additional information is needed to significantly improve MHM and associated outcomes.

Multivariable models

Most quantitative studies to date have focused on rough prevalence of poor MHM as discussed above. These studies have often documented a high rate of material and psychosocial deprivations alongside poor MHM, but have failed to explicitly test links using appropriate statistical techniques or confounder adjustment. Two good examples of multivariable approaches have been published, but more work is needed.

One study assessed the relative contributions of proposed predictors of MHM in West Bengal. Findings from a survey of 190 girls revealed that having a sanitary latrine at home, a mother who was literate, knowledge of menstruation prior to menarche, and exposure to advertisements for sanitary products all significantly predicted adequate MHM in a multivariable model, supporting assertions that both material and psychosocial deprivations uniquely contribute to effective management (Sudeshna & Aparajita, 2012). Another study, located in Northeastern Ethiopia found that in a multivariable model, area of residence, living away from parents, mothers' (but not fathers') education and monthly expenditure predicted sanitary pad use (Tegene & Sisay, 2014). Both these multivariable studies make valuable contributions in estimating the way that different factors contribute to MHM, and identifying avenues for intervention. Prospective longitudinal studies, for example studies capturing the timing of puberty information delivery, and studies testing factors at multiple ecological levels, would provide a clearer picture of the contributors to poor MHM.

Understanding the Solutions: MHM Interventions

Case studies are not enough

The ability to implement effective and ethical programs to improve the MHM of women and girls in low-resource contexts as swiftly as possible should be the primary objective of a human rights approach to MHM. Awareness raising, understanding the problem, and building a defensible evidence base are of little use to populations of women and girls if these do not result in action.

Agents in the field have needed to act in absence of a strong evidenced base. As a result, many case studies of single programs for MHM have been recorded. These provide invaluable practical information, an opportunity for research and a chance for agents in the field to learn from each other about feasibility, practical challenges, and implementation. However, these reports are insufficient for rigorous estimates of intervention effectiveness or to imply causation. For a true evidence-based approach and to advocate for large-scale intervention, trials are needed. Case studies feature very low on the hierarchy of evidence for interventions, see Figure 3.1. They represent an initial step in developing an evidence-based intervention, but are recognized as the least rigorous designs for estimating its true effect (Chalmers, 2003; Flay et al., 2005; Craig et al., 2008). Case studies are open to a plethora of biases. Unfortunately, few studies of MHM interventions have moved beyond case study, or pre-post-test designs. In order to meet the standards of evidence set out in more established areas of public health (see Flay et al., 2005), MHM research must employ designs with lower risk of bias to evaluate interventions. Systematic reviews have revealed that there is some trial evidence available for MHM interventions (Sumpter & Torondel, 2013; Hennegan & Montgomery, 2016 [Thesis Chapter Two]), however, none have provided evidence sufficient to meet standards of research evidence, and most have been pilot studies (Flay et al., 2005; Gottfredson et al., 2015).

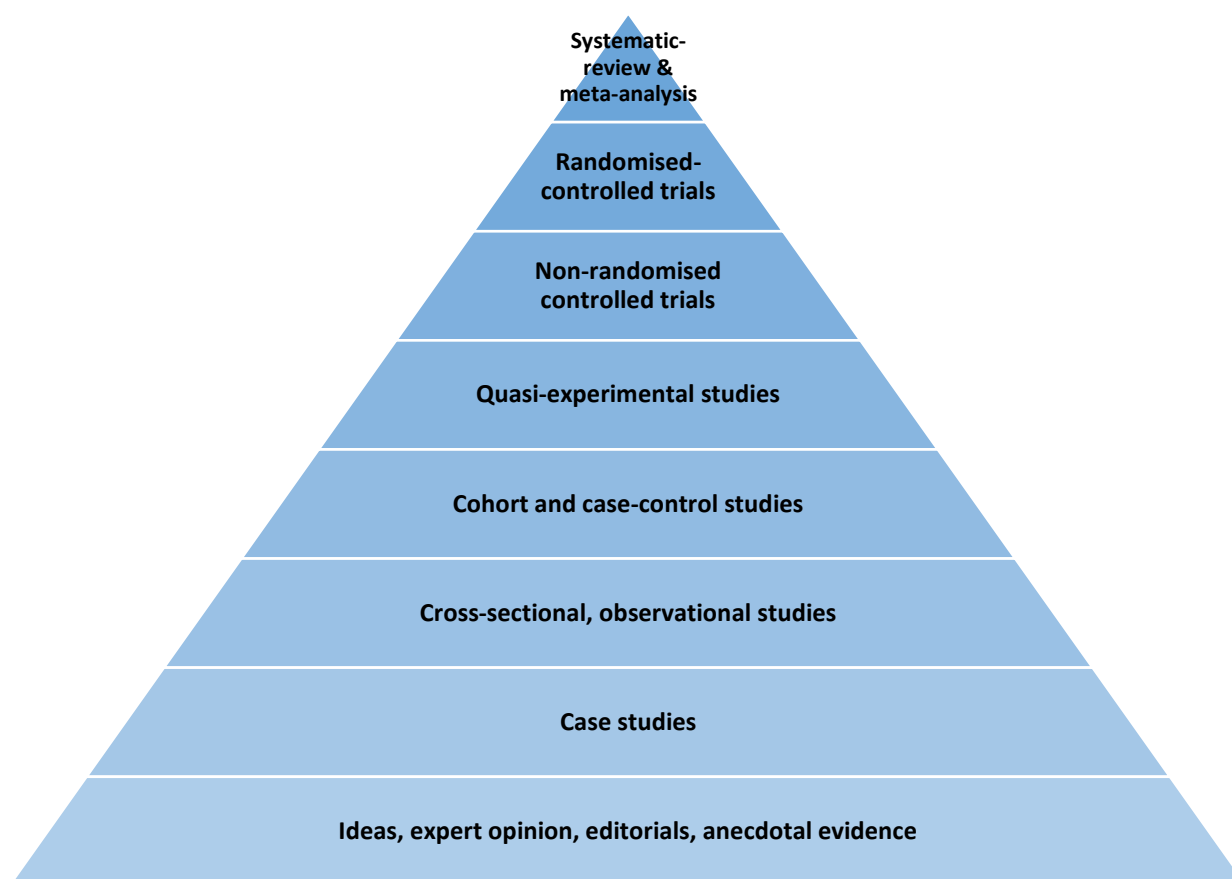


Figure 3.1. Hierarchy of evidence (adapted from Shekelle, Woolf, Eccles, & Grimshaw, 1999)²

The Medical Research Council framework

The Medical Research Council (MRC) (Craig et al., 2008) guidelines for the development and evaluation of complex interventions is a useful framework for assessing the current state of MHM intervention research, and to indicate next steps. This framework, displayed in Figure 3.2, promotes a cyclical process emphasizing the

²Note that this hierarchy is specific to the evaluation of intervention effectiveness. A variety of methodologies are required to understand MHM, as described in previous sections, and to understand in greater detail the results of intervention studies, cultural appropriateness and acceptability. Different research methods are needed to answer different questions. For this, I direct readers to the helpful matrix of research questions and appropriate methodologies proposed by Petticrew and Roberts, 2003.

importance of understanding the problem an intervention seeks to address, piloting, and rigorous evaluation including full assessments of the change process of the intervention. Each stage is expanded upon below.

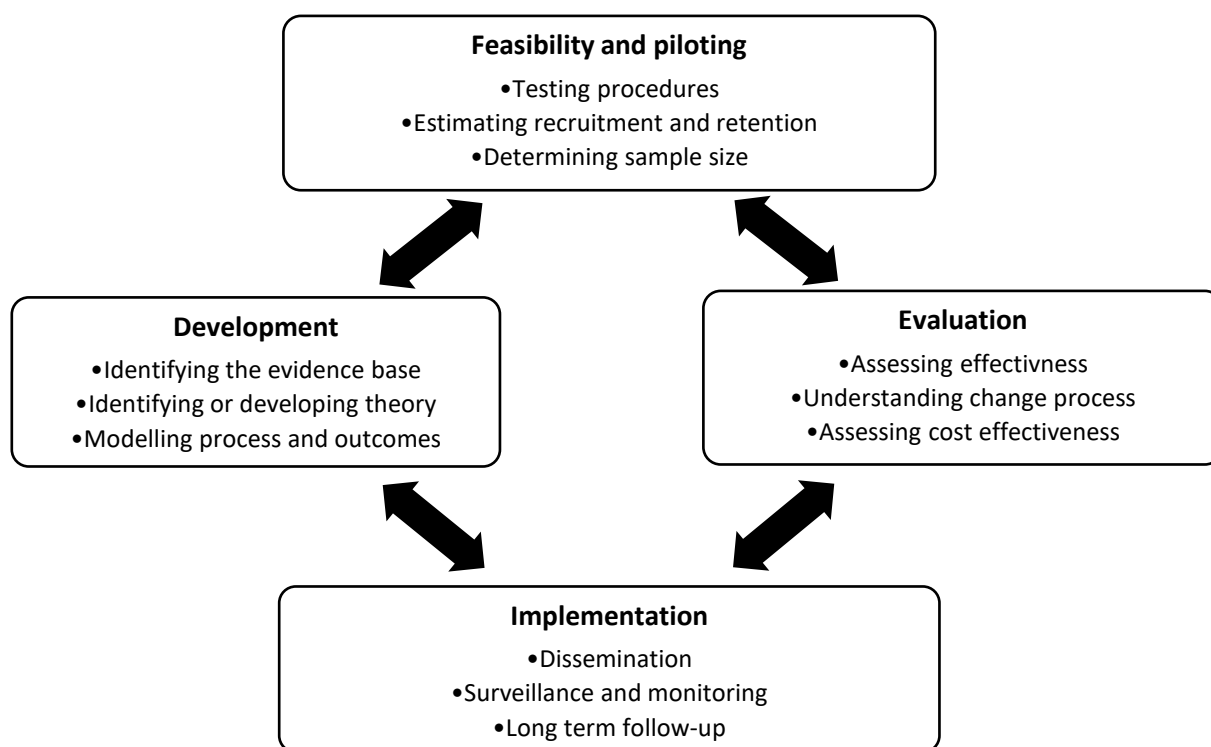


Figure 3.2. MRC framework for the development and evaluation of complex interventions (Craig et al., 2008)

Development

The development of a complex intervention involves; identifying the evidence base, identifying or developing theory, and modelling processes and outcomes. As has been discussed above, primary MHM research is yet to adequately address any of these points. The qualitative literature has provided a substantial base to build upon, understanding the issues, ensuring women and girls' views and embedding an initial rights perspective. However, an improved epidemiological evidence base is needed to guide intervention development and evaluation as detailed in the previous sections. Stronger evidence for the key outcomes to be considered, and adequate measurement of these would allow trials to report on validated, comparable outcomes. Modelling

processes and outcomes in development allows researchers to explore potential pathways of intervention effect (which can be later tested through mediation analyses in interventions), as well as anticipate avenues for unintended harm (Craig et al., 2008).

Feasibility and piloting

To ensure resources are not misspent on full-scale trials hampered by issues such as acceptability, compliance, delivery and sample sizes appropriate to estimated effect sizes (Craig et al., 2008), pilot studies and feasibility testing lay groundwork for the conduct of rigorous trials. This approach has been taken by two ongoing evaluations of MHM interventions (Montgomery et al., 2012; Wilson, Reeve, & Pitt, 2014). Pilot trials of sanitary pad provision in Ghana (Montgomery et al., 2012), and reusable sanitary pad construction lessons in Western Kenya (Wilson, Reeve, & Pitt, 2014) have both provided valuable lessons in outcome assessment, the feasibility of intervention and effect size estimates which can be used to estimate sample requirements for full trials. Both showed promising effects, and complimented quantitative trial research with qualitative work to understand the local context, mechanisms for change, and attend to girls' human rights (Dolan et al., 2013). Oster and Thornton (2011), in contrast, commenced their assessment of the effectiveness of menstrual cup provision in Nepal with a full-scale trial. The individually randomized control trial found no benefit of menstrual cup provision on school attendance, however girls' baseline school attendance was high, presenting a ceiling effect and there was incomplete uptake of the cups (60% at study conclusion) (Oster & Thornton, 2011).

Case studies can also contribute in the domain of feasibility and piloting. They provide insights into how different populations may react to MHM interventions, and the types of interventions which warrant further evaluation. Acceptable forms of menstrual absorbent, or language with which to discuss menstruation can be essential lessons learned from these studies. Increased exposure of the findings of these case studies, and greater collaboration between agents in the field and researchers would increase

the speed at which full scale trials, and thus stronger evidence for the effectiveness of MHM interventions, can be provided.

Evaluation

In 2010, the Government of India proposed the scheme to improve MHM through the provision of subsidized sanitary pads. There is no record of piloting or formal assessment of this initiative, although studies referencing the policy have suggested that multiple issues with implementation, acceptability, and education about the use of sanitary pads, meant the policy was ineffective (Garg, Goyal, & Gupta, 2012; Chothe et al., 2014). Further evidence on the scheme may yet be published, however, at present it appears to represent a missed opportunity for researchers and agents in the field to learn from a large-scale attempt to intervene in MHM. It may also support the assertion that despite the best of intentions, we fail to address threats to girls' human rights if programs that are implemented are ineffective.

A range of methods have been used to assess the effectiveness of MHM interventions. As noted above there is an abundance of case studies, and most trials so far have lacked control conditions (see Hennegan & Montgomery, 2016 [Thesis Chapter Two]). Eight controlled-trials (5 randomized) have been conducted; six of these assessing the effectiveness of puberty education interventions and three assessing the effectiveness of different types of menstrual product provision (Hennegan & Montgomery, 2016 [Thesis Chapter Two]). Some promising effects have been identified, however, study quality has been poor. In particular, there have been issues with the assessment of appropriate outcomes. Most studies of education-focused interventions measured only self-reported MHM intentions or knowledge as outcomes. Whilst this represents a useful step towards improving MHM, such measurements fall short of providing evidence for intervention effectiveness on girls' actual MHM and the consequences of poor MHM.

The MRC framework emphasizes the importance of understanding the change process of interventions. Presenting an explicit intervention ‘theory of change’, explication of *how* an intervention is designed to work, can help both in development, in selecting outcomes for assessment, and in understanding how the intervention worked or did not work. Explicit tests of theory; such as individually comparing how the effect of education and sanitary product provision contribute to our understanding of the *active ingredients* of interventions. For example, the pilot MHM intervention trial conducted in Ghana compared sites providing puberty education alone with sites providing puberty education and sanitary pads to schoolgirls and found that after five months both interventions were equally effective in improving school attendance (Montgomery et al., 2012). For MHM interventions that target specific consequences (e.g., school attendance), assessments of whether improvements in MHM mediated observed changes in school attendance or other outcomes adds weight to the case that it is poor MHM which causes these outcomes (improving our understanding of the problem, and weight to the argument that poor MHM threatens human rights to education). Cost-effectiveness evaluations are also essential in presenting a case for the gains achieved by targeting MHM, and in providing as much detail as possible for agents and policy makers to implement programs. Comprehensively understanding MHM interventions and their effectiveness will assist in integrating MHM interventions with other reproductive health and education programs which may increase the dissemination of these programs (Columbia & UNICEF, 2014), maximizing opportunity to empower girls’ and target rights affected by MHM.

There has been no assessment of iatrogenic effects of any proposed MHM intervention (Hennegan & Montgomery, 2016). The potential for harm has not been adequately acknowledged. Stigma, harassment, and unwanted sexual attention arising from the disclosure of menstrual status have all been documented (Pillitteri, 2011; House, Mahon, & Cavill, 2012). In identifying menstruating females by providing them

with interventions, in some cases distributing menstrual products, there is a high risk of 'outing' girls' menstrual status. This could result in increased stigmatization or unwanted sexual attention having unintended negative consequences for school attendance, dignity, and psychosocial outcomes. In scaling-up to a policy level, where implementation may not be closely monitored, the potential for these negative effects may be even greater. MHM interventions would not be the first gender empowerment intervention to be beset with potential risks. Trials of micro-finance interventions have identified the potential for increased intimate partner violence following enrolment, and thus have suggested that additional intervention needs to be provided alongside these interventions to ensure a net positive impact (Madhani, Tompkins, Jack, & Fisher, 2015). The potential for harm through MHM interventions furthers the case that a human rights approach to MHM necessitates the use of an evidence-based approach where potential harms are evaluated through randomized trials prior to dissemination.

Implementation

Dissemination, long-term follow up, and integration of MHM interventions into school curriculum and other WASH interventions will be important for sustained impact. Building communication between researchers and agents in the field, improving knowledge transfer, and disseminating research findings in understandable ways to a broad audience will all be important in ensuring that MHM is given attention commensurate with the size of the issue. In this way researchers, advocates and stakeholders must work together to improve the quality of the evidence, and integrate findings into practice. It is also important that the strength of the research evidence is considered before implementation (Craig et al., 2008). For example, following the results of the very small pilot study (of only 120) girls in Ghana (Montgomery et al., 2012), the Ghanaian Government responded by spending a considerable sum on a free sanitary pad program that was implemented despite multiple warnings in the publication on the pilot trial that longer-term follow-up and full-scale evaluation were needed (Boateng,

2014). Consistent with MRC guidance, academics must work alongside agents in the field to ensure monitoring and quality in dissemination (Craig et al., 2008).

Discussion

Women and girls' dignity, equality, and human rights are threatened by inadequate MHM. Poor MHM threatens human rights to dignity, privacy, health, gender equality, water and sanitation, education, and work (General Assembly, 1948; Winkler & Roaf, 2015). An evidence based approach to menstrual management is essential to the human rights agenda. Rigorous research demonstrating the prevalence, causes and consequences of poor MHM is crucial to establishing the scope of the issue and validating assertions of human rights violations. This is key to advocacy, attracting funding, and ensuring the development of efficient and effective interventions. These interventions must then be evaluated in a way that stands up to scrutiny and complies with our ethical imperative to 'do no harm'. By using gold-standard methodology to understand how and why interventions work, and ensure that there are no iatrogenic effects, we provide the strongest case for effective, ethical interventions to improve MHM. Interventions can then be confidently disseminated. Further, rigorous studies would provide the necessary support to advocate for the integration of MHM interventions with other reproductive health and WASH programs.

Limitations of an evidence-based approach

It is important to acknowledge the inherent challenges in taking in evidence-based approach to MHM. The first is the delay caused by waiting for the funding, conduct, and publication of the necessary research. The development of standardized measures, use of longitudinal studies, intervention development, piloting, effectiveness trials, scale-up and implementation assessment, all take time. Activists, policy makers and agents in the field cannot sit waiting for a full body of research to be published before acting to improve MHM and associated violations of human rights. As such, there is a conflict between acting (and advocating for immediate action), and upholding an ethical imperative to deliver evidenced interventions, without harms, to vulnerable

populations. In moving forward, the limitations of the evidence base to date should provoke a swift increase in funding and research in this field. Targeted studies, collaboration, and interdisciplinary work between academics in this area, agents in the field, and other stakeholders will be essential in bridging the current evidence gaps. Improved knowledge transfer between academic work and those in the field will also be essential in developing an approach to MHM which is responsive to, and utilizes, best evidence and at the same time is sensitive to local needs.

A second challenge for an evidence based approach to MHM from a human rights perspective is the risk of placing too much focus on outcomes such as education (school attendance) or employment. If studies, and thus practice, focus only on these outcomes, we run the risk of failing to act to address MHM if evidence does not support hypothesized links or intervention effectiveness for education or employment outcomes. This concern was perfectly voiced by Emily Wilson (2014) in observing that *“If the world was run by women we would not have to justify investment in good menstrual hygiene in terms of long term educational and economic benefits. We would assume it as a right because it is part of the minimum requirements of enabling us to participate in society with dignity.”* The challenge that MHM presents for women’s dignity must be central in both research and practice. A feminist approach to scholarship should ensure that this is emphasized in reported studies, and further that outcomes such as comfort and psychosocial wellbeing are measured and reported when testing interventions. Similarly, focusing on education and employment outcomes in quantitative studies may overlook key subgroups such as disabled women who need additional provision to manage menstruation. This was highlighted by Winkler and Roaf (2015) as an essential challenge to the human right to dignity for these women.

Conclusions

This article has demonstrated that in order to ‘first, do no harm’, and to act as swiftly, effectively, and efficiently as possible to address the threat that MHM presents to human rights, it is imperative that we take an evidence-based approach. The current state of research, and many significant gaps have been noted. The contributions that different studies make, from prevalence through to intervention development and evaluation, have been discussed and linked to their implications for women’s human rights. To attract attention commensurate with the size of the threat that MHM poses to women’s dignity and human rights, it is essential that researchers in this field build a strong and considered evidence base. We must conduct and report studies comparable with the level of rigor in more established areas of global public health. The research community has a responsibility to substantiate claims of human rights violations and push for interventions with evaluations that stand up to scrutiny. Funding bodies, advocates, policy makers, researchers and agents in the field have an ethical imperative to invest in MHM and ensure that resources are not wasted on ineffective or harmful interventions.

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CHAPTER 4

Paper #3: Results of the *menstruation and the cycle of poverty* trial

Menstruation and the cycle of poverty: a cluster quasi-randomised control trial of sanitary pad and puberty education provision in Uganda

Paul Montgomery¹

Julie Hennegan¹

Catherine Dolan²

Maryalice Wu³

Laurel Steinfield⁴

Linda Scott⁵

¹ Centre for Evidence-Based Intervention, University of Oxford, Oxford, UK

² SOAS, University of London, London, UK

³ Applied Technologies for Learning in the Arts and Sciences, University of Illinois, Urbana-Champaign, US

⁴ Bentley University, Waltham, MA, USA

⁵ Said Business School, University of Oxford, Oxford UK

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Abstract

Background. Poor menstrual knowledge and access to sanitary products have been proposed as barriers to menstrual health and school attendance. In response, interventions targeting these needs have seen increasing implementation in public and private sectors. However, there has been limited assessment of their effectiveness.

Objectives. Assess the impact of providing reusable sanitary pads and puberty education on girls' school attendance and psychosocial wellbeing outcomes.

Methods. A cluster quasi-randomised controlled trial was conducted across 8 schools, including 1124 girls, in rural Uganda. Schools were allocated to one of four conditions: the provision of puberty education alone; reusable sanitary pads alone; puberty education and reusable sanitary pads; and a control (no intervention). The primary outcome was school attendance. Secondary outcomes reflected psychosocial wellbeing.

Results. At follow-up, school attendance had worsened for girls across all conditions. Per-protocol analysis revealed that this decline was significantly greater for those in the control condition $d=0.52$ (95%CI 0.26-0.77), with those in control schools having a 17.1% (95%CI: 8.7-25.5) greater drop in attendance than those in any intervention school. There were no differences between the intervention conditions. High rates of school drop-out and transfer meant the trial suffered from substantial participant drop-out. Intention-to-treat analyses using two different imputation strategies were consistent with the main results, with mean differences of 5.2% attendance in best-case and 24.5% in worst-case imputations. Results were robust to adjustments for clustering. There was no impact of the interventions on girls' self-reported shame or insecurity during menstruation.

Conclusion. Results of the trial support the hypothesised positive impact of providing sanitary pads or puberty education for girls' school attendance in a developing country

context. Findings must be interpreted with caution in light of poor participant retention, intervention fidelity, and the attendance measures used.

Trial Registration. Pan African Clinical Trials Registry PACTR201503001044408

Background

Educating girls has been proposed as the world's highest yielding investment for developing countries (Sperling & Winthrop, 2015). Improved educational attainment has been consistently linked to economic growth and productivity (OECD, 2012; Barro & Lee, 2013). For women and girls, increased education has been associated with benefits including: health for women and their children, literacy, delayed sexual debut and marriage, self-efficacy, improvements in labour force participation, and involvement with household decision making (Sperling & Winthrop, 2015; LeVine, LeVine, & Rowe, 2004; Kirk & Sommer, 2006; Lloyd & Young, 2009; Gakidou, Cowling, Lozano, & Murray, 2010; Montenegro & Patrinos, 2014). These benefits rise substantially with increasing years of schooling (Sperling & Winthrop, 2015).

Global improvements in gender parity in school enrolment have been considerable. UNESCO (2015) has reported that at the end of 2015, 69% of countries with data had achieved or were likely to reach gender parity in primary education. Disparities are greater in secondary education where less than 50% of countries are projected to reach gender parity (UNESCO, 2015). Poverty deepens disparities, with poor girls the least likely to enter or complete primary and secondary schooling. In Uganda, the context of the present study, high levels of enrolment in primary school drop off sharply in secondary school (UNESCO, 2010; World Bank, 2014; Uganda Demographic and Health Survey (UDHS), 2011). In 2013, figures suggested only 22% of school-aged girls were enrolled in secondary school in comparison to a 91% enrolment rate in primary school (Montenegro & Patrinos, 2014; UDHS, 2011; World Bank, 2015). Gender parity in school enrolment differed by area, with disparity increasing with rurality (UDHS, 2011). While enrolment figures represent easily available and comparable statistics, it is the quality of education as well as attendance and engagement at school which contribute to girls' ability to learn effectively when enrolled, and thus garner the

benefits of education (Sperling & Winthrop, 2014; UNESCO, 2015; Clinton Foundation, 2015).

Many barriers to girls' school attendance, participation, and retention have been identified (Lloyd & Young, 2009; UNESCO, 2010). Cultural expectations, household responsibilities, early pregnancy and marriage, and prioritisation of boys' education have all been discussed (UNESCO, 2015; Lloyd & Mensch, 2008). Further, school environment barriers to education for girls include a lack of female teachers, sanitation and hygiene facilities, and gender-based violence (Lloyd & Young, 2009; Parkes & Heslop, 2013). Menstruation has emerged as an additional gender-specific barrier to school participation amongst adolescent girls (Sommer, Sutherland, & Chandra-Mouli, 2015). Particularly for poorer girls, the most disadvantaged in access to education, the management of menses presents a significant obstacle to health, comfort, and engagement with school.

Qualitative studies have revealed the construction of menstruation as embarrassing, shameful, and dirty across many contexts (McMahon et al., 2011; Sommer & Kirk, 2008; Sommer, Ackatia-Armah, Connolly, & Smiles, 2014). Taboos around the topic mean many adolescent girls are unprepared for menarche, and that management practices are not discussed openly (McMahon et al., 2011; Sommer & Kirk, 2008; Dolan, Ryus, Dopson, Montgomery, & Scott, 2013). In the confined school environment, with a lack of access to adequate latrines or separate latrines for males and females, menstrual management presents a significant challenge. Absorbents such as cloth are used and can often leak, soiling uniforms or outer garments. In addition, cleaning and changing absorbents pose significant challenges. Girls interviewed have described feelings of shame, fear and distraction associated with menstruation. Both girls and teachers have expressed the view that menstruation is a barrier to school attendance and engagement (McMahon et al., 2011; Sommer et al., 2014).

Quantitative work has begun to support these assertions, although estimates have varied. A study of 595 school girls in northeast Ethiopia found that after adjustment for residence, household income and parental education, girls who did not use disposable sanitary pads had 5.37 times higher odds of school absenteeism during menses than those using disposable pads (Tegegne & Sisay, 2014). In contrast, a survey study in rural Malawi of 717 girls aged 14-16 reported that after adjusting for sociodemographic characteristics and other reasons for school absenteeism, menstruation did not predict absence (Grant, Lloyd, & Mensch, 2013). Intervention studies have also provided mixed support for the association between menstruation and absenteeism (Oster & Thornton, 2010; Montgomery, Ryus, Dolan, Dopson, & Scott, 2012; Wilson, Reeve, & Pitt, 2014).

Studies have hypothesised that both physical barriers and a lack of menstrual knowledge to support hygienic management of menses contribute to disengagement and absenteeism (Pillitteri, 2011; Crichton, Okal, Kabiru, & Zulu, 2013; Sumpter & Torondel, 2013). Thus the provision of clean menstrual absorbents, and information about the effective and hygienic management of menstruation, have been proposed as simple and efficient interventions to improve the comfort, dignity, and school participation of adolescent girls. Increasingly governments, charities, and development organisations have sought to target menstruation as a barrier to school attendance (Garg, Goyal & Gupta, 2012; Proctor & Gamble, 2010; Sommer, Hirsh, Nathanson, & Parker, 2015). However, there is sparse evidence for the effectiveness of such interventions (Hennegan & Montgomery, 2016 [Thesis Chapter Two]). The first randomised controlled trial, conducted in Nepal, used girls' menstrual calendars (self-kept) and attendance records to estimate that only 0.4 days in 180 were missed due to menstruation (Oster & Thornton, 2011). The study found no improvement in attendance after providing menstrual cups. Conversely, two pilot non-randomised trials in Ghana and Kenya respectively found interventions providing sanitary pads and education, or

materials and education for girls to make their own pads improved school attendance (Montgomery et al., 2012; Wilson, Reeve, & Pitt, 2014). There is a need for larger, randomised trials to provide causal evidence for the link between menstruation and education, as well as the effectiveness of proposed interventions (Hennegan & Montgomery, 2016 [Thesis Chapter Two]).

In 2009 this research group undertook a pilot trial of sanitary pad provision and puberty education in peri-urban and rural Ghana. The non-randomised cluster-control trial of 120 schoolgirls (aged 12-18) across four schools tested the effectiveness of the provision of disposable sanitary pads and/or a puberty education class on school attendance over a 5-month period. Results were promising with a 9% increase in attendance found for those receiving pads and education (see Montgomery et al., 2012). Qualitative work indicated improvements in shame and self-confidence (Dolan et al., 2013). Whilst findings of the pilot were positive, they were limited by a lack of randomisation, small sample size, comparison of single clusters, and short study duration. In addition, the trial raised questions with regard to the effectiveness of providing sanitary pads in contrast (or addition to) education, and the need to identify the individual impact of these interventions (Montgomery et al., 2012).

The present study represents a scale-up from the initial pilot to a cluster quasi-randomised control trial of reusable sanitary pad and puberty education provision. A Latin-square design meant four different conditions were compared to isolate the individual and combined effect of pad provision and puberty education. Clusters received one of the following interventions: reusable pads alone, education alone, reusable pads and education, or a no-intervention control.

Objectives

This trial aimed to assess the impacts of providing reusable sanitary pads and puberty education on school attendance and psychosocial outcomes for girls in Uganda. In addition, the study seeks to isolate the impact of resource provision (pads) and education as potential interventions to reduce menstrual-related absence and consequences for psychosocial wellbeing.

Methods

The trial was registered with the Pan African Trials Registry (PACTR201503001044408), included in Appendix 4.1. Administrative challenges meant the trial was not registered until after follow-up. The trial was registered prior to the analyst receiving any data, and details were recorded consistent with the protocol prior to the start of the trial to ensure transparency around deviations, noted below. The authors confirm that all ongoing and related trials for this intervention are registered. Outcomes reported in the paper are the same as those registered in the protocol. The trial is reported in accordance with CONSORT (cluster RCT) guidance (Campbell, Piaggio, Elbourne & Altman, 2012) (for checklist see Appendix 4.2).

Context

The intervention took place in Kamuli district, located in the eastern-central region of Uganda, where the partner NGO (Plan International) operates several health and education programmes. The district was selected due to its poor performance across a range of key education, health and welfare indicators, with the district characterised by “high school dropouts, high illiteracy rates, high levels of morbidity and mortality, early marriages, high fertility rates, intermittent food shortages and malnutrition, and poor housing” (Republic of Uganda, 2008). The district’s literacy rate continues to lag behind the national average (61.8% vs 70%, respectively), with significant disparities between the literacy of girls (54.6%) and boys (69.7%) (Republic of Uganda, 2008). Poor literacy rates are particularly pronounced among children; the District has the 3rd lowest rates of primacy school literacy in the country (14% compared to 28% nationally) (Uganda Development Series, 2013). Approximately a third of students never complete primary school, and the majority of those who do, do not progress to secondary school (Nakabugo, 2013).

Design

The trial was conducted between January 2012 and December 2014. The initial sample size included in the protocol ($n=560$) was calculated based on the effect size (partial-eta squared = 0.094) and drop-out (15%) from the Ghana pilot (Montgomery et al., 2012) to achieve 80% power at a 5% α -level, but clustering was not accounted for. Eight rural primary schools were recruited into the study through the partner NGO. Budget limitations precluded the enrolment of additional schools. Schools were purposively selected from the Kamuli district as described above. Schools were required to be within reasonable distance from the partner NGO, and to be comparable in major characteristics such as degree of rural location and distance from services, size, educational provision, toilet facilities, and education quality based on the extensive local knowledge of the partner NGO. Additional summary of school facilities is provided in Appendix 4.3. School clusters were selected to have sufficient geographical separation so as to reduce risks of contamination. In each school, girls in primary grades 3 to 5 (ages approx. 10-13, but extending above this) were enrolled in the study. Girls were not excluded based on menstrual status as the trial aimed to capture both menstruating girls and those who were likely to commence menstruating during the study (a very early protocol deviation). Written consent for participation was sought from girls and a parent/caregiver; none declined to participate. A total of 1124 girls were recruited into the trial prior to baseline.

The study was a four-armed cluster quasi-randomised control trial. After baseline attendance data collection and the baseline survey had been completed (see below), schools were grouped into pairs maximising the distance between the clusters. The four clusters were then quasi-randomised to conditions (two schools per condition). Clustered schools were allocated sequentially in alphabetical order of the first school in the pair to one of the four conditions:

1. The provision of puberty education
2. The provision of reusable sanitary pads (AFRIPads)
3. The provision of puberty education and reusable sanitary pad (AFRIPads)
4. A control condition (receiving no pads or education).

After allocation, neither the intervention delivery team nor participants were blind to intervention condition. The clustered design prevented contamination of education or pad distribution, and prevented social and ethical issues which may have arisen by unequally distributing resources to some girls and not others in a single community. Cluster sizes varied depending on the number of pupils in each school, as all girls in primary grades 3-5 were included.

Intervention

Development

The trial followed a pilot in Ghana, however, many modifications were made. In particular, the change from commercial disposable sanitary pads, to a locally-made, reusable AFRIPad. Among the key limitations of the pilot work were the environmental consequences of pad disposal (Dolan et al., 2013; Montgomery et al., 2012). Further, the cost of monthly provision of disposable pads was substantial. A reusable product was believed to be more sustainable, both from a cost and environmental perspective. Prior to selecting AFRIPads, an acceptability study was conducted comparing three different types of reusable pads, the results of which have been reported elsewhere (Scott, Montgomery, Steinfield, Dolan, & Dopson, 2013). Girls in the study reported that the reusable pads were more reliable and stable than their previous methods of menstrual absorption (e.g., cloth, underwear alone), and AFRIPads were thus selected as the product of choice for the trial.

AFRipads

Girls in the conditions receiving pads were provided with a pack of AFRipads, 3 pairs of underwear, and a small quantity (one sachet, 45grams) of Omo (soap) with which to wash the pads. Pads were distributed in October 2012, and again in March 2014. When distributing the pads, girls were also taught about their correct use and cleaning by locally trained NGO research assistants. AFRipads are a washable, reusable cloth pad produced in Uganda. They are manufactured by a social business in Uganda that specializes in locally-produced, eco-friendly sanitary pads. Pads are made of quick-drying fleece and sold in a kit that includes two soil-resistant plastic-lined 'base' pads that fasten securely to underwear, three attachable winged liners, three straight liners and two small bags for carrying. AFRipads can be reused for 12 months (Scott et al., 2013; <http://www.afripads.com/>).

Puberty education

Locally trained community health nurses from the partner NGO administered the education intervention in October 2012. Education sessions were conducted in each school and lasted approximately 1.25hrs. Education followed the Straight Talk training guide developed by the Straight Talk Foundation Uganda (<http://straighttalkfoundation.org/>). Education covered puberty changes, menstruation, early pregnancy, life skills, prevention of HIV, strategies for avoiding sexual assault, healthy relationships, and friendship formation and goal setting. This education programme was selected for its high face-validity concerning the topics of puberty in the study. It has a small but promising evidence base, and available community health nurses had familiarity with the program. It was deemed contextually appropriate and endorsed by project stakeholder groups. The manual from the program can be downloaded from the intervention program page ([http://www.spi.ox.ac.uk/fileadmin/documents/PDF/Straight Talk Plan.pdf](http://www.spi.ox.ac.uk/fileadmin/documents/PDF/Straight_Talk_Plan.pdf)).

Intervention delivery and protocol deviations

The sample size recruited was larger than reported in the original protocol. Based on the results of the pilot study, power analysis calculated the total sample size requirement to be 560 girls across the eight schools. However, attendance was taken for all girls in the assigned classes (primary grades 3 to 5). As there was a much higher rate of drop-out over the 2-year study period than in the pilot (only 5 months), this additional data collection meant sufficient numbers were still available at the 24-month follow-up to detect an effect. Far fewer girls were reached for survey at the final time-point than intended, despite the administration of a drop-out survey and attempt to follow up girls who were no longer in the study schools. Resource restrictions limited the amount of time that could be dedicated to finding girls who had dropped out of the study schools, thus assessments of those who did and did not drop-out are limited to baseline measures. There was a very early change to the protocol to include menstruating and non-menstruating girls, as noted above, in an attempt to reach girls before their first menses.

Significant errors in intervention delivery occurred across the trial. The intended protocol was for all girls in education conditions to receive the education, and all girls in pads conditions, regardless of menstrual status, to receive the two deliveries of AFRipads. Interventions were delivered by the partner NGO. AFRIPad delivery was problematic. After the conclusion of the trial it was revealed that pads may only have been delivered to girls who reported that they had reached menarche; a very small proportion at baseline. The second pad delivery was found to be delayed from the initial intended mid-point (12 months after the first delivery), to March 2014. The names of girls receiving pads were recorded. These lists were manually matched to participants to estimate which girls in the trial received pads. This number was very low. Reports from local research assistants, however, suggested pads were left with head teachers at the schools for additional distribution. Additionally, many more pads were reported to be

distributed than the number of girls listed as having received them. Thus it is highly likely that more girls received pads than those listed.

The education sessions were only run once in each school, meaning girls absent on the day of the sessions missed them. Attendance was taken and, on average, only half of all girls included in the trial were present. It is possible some names were missed, recorded incorrectly, or had been changed as part of religious practices, and so were unable to be matched to study participants. Thus, the per-protocol and intention-to-treat analysis are likely to capture more girls who did receive the interventions than displayed in the study flowchart. Nevertheless, poor fidelity was a significant issue in the trial.

Measures

School attendance

As in the pilot study (Montgomery et al., 2012) and similar studies of menstrual hygiene management interventions (Oster & Thornton, 2011; Montgomery et al., 2012; Wilson, Reeve, & Pitt, 2014), attendance was selected as the primary outcome. In contrast to measures such as performance, attendance is comparable across sites and other trials.

Baseline attendance: Baseline school attendance was collected prior to quasi-randomisation by copying school attendance records for two full school terms (Term 1 and 2 of 2012). Teachers received training from the partner NGO to improve the accuracy of school records. Local research assistants from the partner NGO took copies of these records each fortnight.

Follow-up attendance: The attendance data collection strategy was modified for follow-up in light of budget considerations and to further improve accuracy. Research assistants from the partner NGO conducted attendance data collection for a single week (week 4) across the three follow-up terms, with research assistants calling attendance rather than copying school registers. This was collapsed across terms 1, 2 and 3 of 2014

to form a continuous follow-up measure. Due to the change in procedure, only corresponding weeks in the baseline data (weeks 3-6 of Terms 1 and 2) were used to be comparable to the week 4 attendance collected at follow-up. Site visits and reports from local research assistants noted that school attendance varies greatly over the term due to school-fee demands and agricultural practices.

Drop-out: Throughout baseline and follow-up, if girls were absent for a full weeks' recordings, research assistants asked other students and teachers to report if girls were simply absent from school that week or if they had dropped out of school or transferred to a new school. Student and teacher reports were checked again at subsequent data collection weeks and notes on girls' whereabouts recorded. In instances of drop-out or transfer, research assistants recorded the name of the school the student had transferred to, or the reason a girl had dropped out of school (e.g., death in the family, pregnancy, marriage). Girls' whereabouts were corroborated by those reached at the time of the drop-out survey, and were markedly consistent across repeated collections. Further, extensive efforts were undertaken in data cleaning phases to ensure only girls that had truly left the study schools, rather than those absent on the days assessed, were considered to have dropped out.

Survey

Surveys captured socio-demographics, menstrual practices, and psychosocial outcomes.

Surveys were administered at baseline, mid-point, and conclusion of the study. Trained local research assistants from the partner NGO verbally administered the surveys in the local language (Lusoga) and recorded answers on iPads (using the program SurveyDeck) into an English copy of the questionnaire. Each question was required to be answered (or marked as 'no answer') by research assistants before it was possible to proceed to the next question, ensuring there was no accidental missing data.

Survey responses were then uploaded from SurveyDeck to online collection tool, SurveyGizmo. For the final round of surveys, SurveyGizmo was available for offline use so answers were recorded on iPads directly into SurveyGizmo.

The trial employed a Solomon 4-group design, surveying only a computer randomised 25% subset (n=281) of participants at baseline. This design was employed to reduce the bias introduced to trials by researcher interference and repeated measurement (McCambridge, Butor-Bhavsar, Witton, & Elbourne, 2011; McCambridge, Witton, & Elbourne, 2014). In the context of the present study, there was significant concern that repeated questioning on menstrual issues would lead to additional education being provided, causing contamination. The mid-point assessment sought to follow-up only the subset of girls surveyed at baseline. However, response rates were poor and outcomes at mid-point are not reported. Survey of the full sample was attempted at the conclusion of the trial, including girls who had dropped out of school.

Menstrual practices. Girls self-reported if they had reached menarche. To assess knowledge of menstruation, interviewers asked girls to describe to them what menstruation was. Girls were considered to have passed if they revealed knowledge that menstruation was a biological process linked to reproduction, with blood lost through the vagina. Interviewers asked girls to elaborate when necessary to judge their knowledge. Additional questions captured menstrual practices. These included questions about current absorbent use, disposal, changing and washing absorbents, as well as bathing practices and girls' access to water, soap and underwear. The survey also included items capturing how girls obtained menstrual absorbents (e.g., from parents, purchased themselves).

Psychosocial outcomes. The self-report version of the Strengths and Difficulties Questionnaire (SDQ; Goodman, Meltzer, & Bailey, 1998) was used to assess overall psychosocial wellbeing. This questionnaire is a brief screening tool typically used to identify child mental health problems. The questionnaire consists of 25 items scored on

a 3-point Likert scale from 0 'not true' to 2 'true', with a midpoint of 1 'somewhat true'. Questions form five subscales; hyperactivity, conduct problems, emotional problems, peer problems and prosocial behaviour, with the summative total difficulties score used in the present study. The total difficulties score includes the hyperactivity, conduct, emotional and peer problems scales summed and has a range of 0-40. For 4-17-year-olds, current 4-band categorisation based on a UK survey population are; average (0-14), slightly raised (15-17), high (18-19), very high (20-40) (see <http://www.sdqinfo.com/d0.html>). The SDQ has been well validated and broadly used in both high-income contexts as well as in low and middle income countries (e.g., Syed, Hussein, Azam, & Khan, 2009). The questionnaire has been translated into more than 75 languages.

Wellbeing in relation to menstruation was assessed through a series of single-item questions seeking to capture shame and insecurity associated with menstruation (e.g., *"During your MP, do you feel ashamed? Or do you feel about the same as when you are not on your MP?"*). Girls indicated if they felt more ashamed or insecure during menstruation or if they felt the same as usual.

Analysis

Analyses were conducted using SPSS 22 and Stata 14.0.

Participant characteristics. Descriptive statistics were used to assess demographic characteristics. Differences in baseline demographics, psychosocial functioning, and menstrual practices across conditions were examined using the appropriate tests (see results reported). Chi-square comparisons and one-way analysis of variance were used to assess the proportion of girls who dropped out of the study for differing reasons.

Primary outcome at baseline: school attendance. Baseline school attendance was compared across conditions using a one-way analysis of variance. Attendance

varied significantly, thus, subsequent analyses needed to account for baseline attendance and attendance change scores were used as the primary outcome.

Primary outcome: effect of drop-out. Variation in drop-out and reasons for drop-out across intervention conditions were assessed through one-way analysis of variance and independent samples t-tests. In addition, differences in attendance at baseline between those who dropped out of the study and those who were retained were assessed using one-way analysis of variance and independent samples t-tests.

There was considerable, and unanticipated, drop-out over the study. Due to the high proportion and reasons for drop-out, imputation would be highly unreliable and open to bias. It would have been inaccurate to assume data were missing-at-random, further it would not be theoretically justifiable to use multiple imputation for attendance scores for girls who had dropped out of school. Thus, per-protocol analysis is presented as the main analysis for the paper. Intention-to-treat analysis, described below, using two different imputation strategies is also provided.

Intervention effectiveness: primary outcome. The main study analysis was a per-protocol analysis conducted on the sample of all girls who were quasi-randomised to conditions and were still in school at the start of the attendance follow-up period. This excluded girls who had dropped out of the study schools between baseline and follow-up as there were no attendance data for these participants. Independent-samples t-tests were used to compare girls in any intervention condition to those in the control condition. One-way analysis of variance assessed differences between all four conditions, with follow-up t-tests with Bonferroni adjustment for familywise error assessing differences between the conditions.

Robustness checks. The analytic strategies outlined above did not take account of the clustered nature of the data. Whilst the preferred method of analysis would have been a multilevel model, capturing both the data clusters and individual participant

variation, the very small number of clusters meant this analysis would have been inappropriate. Intra-cluster correlation coefficients were calculated to estimate the impact of clustering. In addition, the robustness of findings to adjustment for clustering was assessed through analysis of variance conducted at the cluster level ($n=8$). Secondly, linear regressions with cluster-adjusted standard errors were estimated. However, these standard methods for bias correction from clustering are problematic in the context of small numbers of clusters (Cameron, Gelbach, & Miller, 2008) and the results were re-estimated accounting for small cluster numbers (Gelbac & Miller, 2009) as a robustness check.

Intention-to-treat analyses. Intention-to-treat analyses were conducted on the full sample of 1008 participants allocated to a condition. The large amount and nature of the missing data meant multiple imputation methods, which assume data is missing-at-random, were inappropriate. Instead, data were imputed using a realistic best case and a worst case scenario for girls' school attendance. In the best-case, baseline observations were carried forward for missing follow-up data. In the worst-case imputation, it was assumed that girls with missing data attended school 0 days (0%). The high proportion (42.5%) and non-random nature of the missing data means these estimates are likely to be more biased than the per-protocol analysis. Nevertheless, the best-case and worst-case imputation provides a measure of the impact of missingness on the paper's conclusions. After imputation, one-way analysis of variance was used to compare change scores between those who received any intervention and controls, and across all four conditions. Further, regressions with adjustment for the small number of clusters were undertaken as a further check of the robustness of these results to clustering.

Intervention effects for menstruating, compared to non-menstruating girls. At the conclusion of the trial, the follow-up survey indicated that less than half of the sample had reached menarche. The provision of sanitary products and education about

menstruation should only benefit the school attendance of those who had started menstruating. Thus, follow-up analyses were conducted to test the impact of the intervention on girls who self-reported that they had started menstruating, and those who had not. One-way analysis of variance and independent samples t-tests were conducted on menstruating and non-menstruating sub-groups. These analyses could only be conducted for the smaller sub-sample of girls who completed the final survey (see study flow chart).

Intervention effectiveness: secondary outcomes. Psychosocial outcomes were compared between the conditions using chi-squared tests and one-way analyses of variance. These were compared between the groups at follow-up as there were no differences identified at baseline, and only a 25% sub-set of the sample was surveyed at baseline.

Ethics

Ethical approval for the study was received from the Social Science & Humanities Inter-Divisional Research Ethics Committee at the University of Oxford (Ref No.: SSD/CUREC1/11-056), the AIDS Support Organisation (TASO) Institutional Review Committee Uganda (TASOIRC/022/14-UG-IRC-009), and the University of Illinois (#12236).

Results

Participant flow chart

A total of 1124 girls were recruited into the study. By the conclusion of the two-term baseline attendance data collection, 116 girls had dropped out of the schools (reasons included dropping out of school, transferring to another school, or leaving the school for an unknown reason), leaving a sample of 1008 girls across the eight schools when quasi-randomisation occurred. A participant flow chart is displayed in Figure 4.1. As noted in methods, the reported number of participants receiving the intervention are conservative.

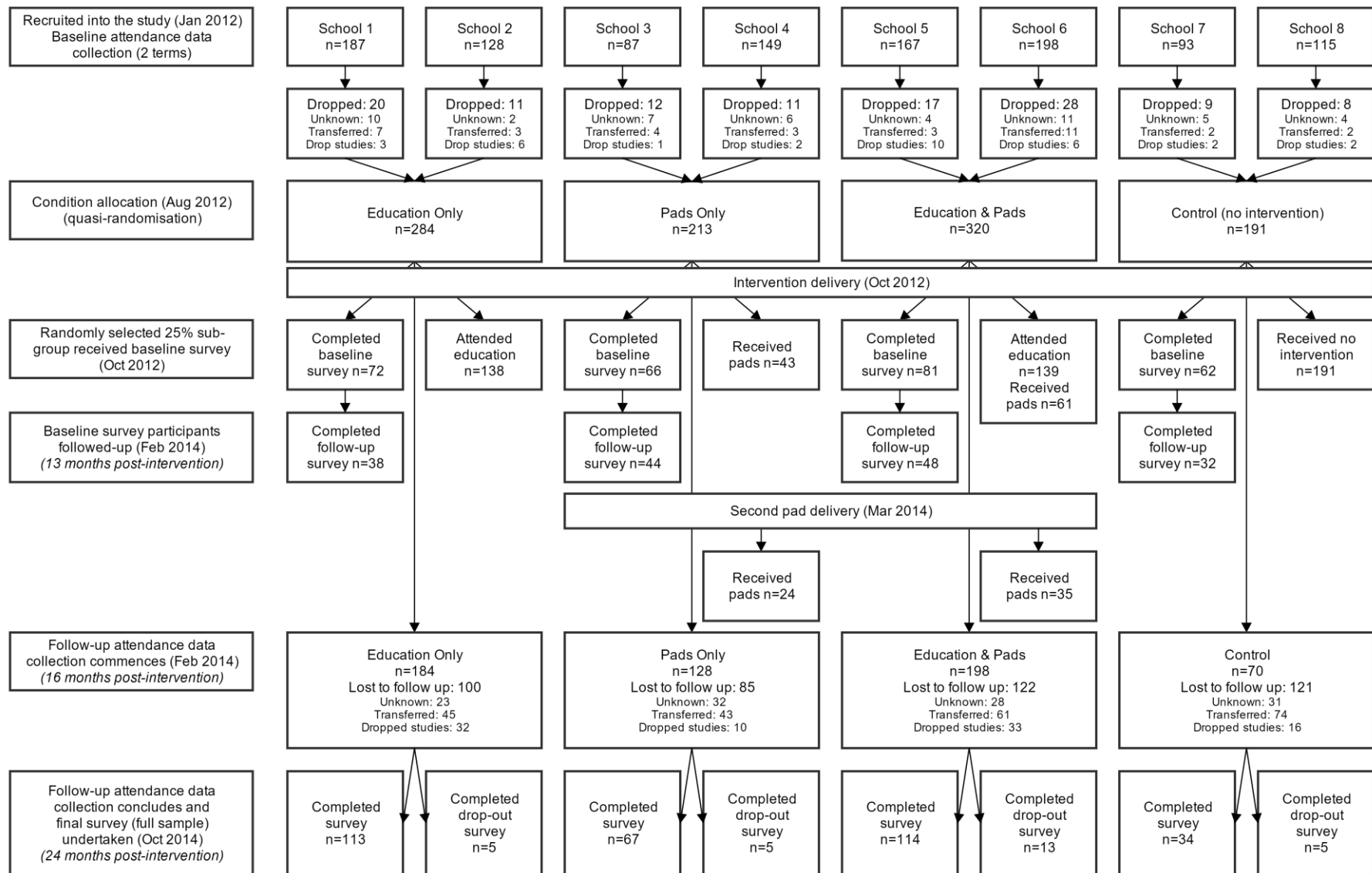


Figure 4.1. Participant flow chart.

Participant drop-out over the study period was substantial. Consistent with low secondary school enrolment, many girls dropped out of school over the trial. Additionally, the population of girls in rural Uganda was highly mobile and many girls transferred to other schools during the trial period. At follow-up, 580 girls remained in school and 428 had dropped out of the study, a retention rate of 57.5%. Based on the reports of students and teachers, of participants lost to follow-up; 91 had dropped out of school, 223 had transferred to a new school, and 114 had unknown school enrolment status (95 were stated to have moved to a new town with unclear school enrolment, and 19 girls were no longer in school but no more information was available). A breakdown of girls' school status across conditions at follow-up is displayed in Table 4.1 and Figure 4.2.

Table 4.1. School status at follow-up according to condition (n=1008)

	Education only % (N)	Pads only % (N)	Education & Pads % (N)	Control % (N)
Retained	64.8 (184)	60.1 (128)	61.9 (198)	36.6 (70)
Transferred to a new school	15.8 (45)	20.2 (43)	19.1 (61)	38.7 (74)
Dropped studies	11.3 (32)	4.7 (10)	10.3 (33)	8.4 (16)
Unknown school status (moved to another town, or unknown status)	8.1 (23)	15.0 (32)	8.8 (28)	16.2 (31)

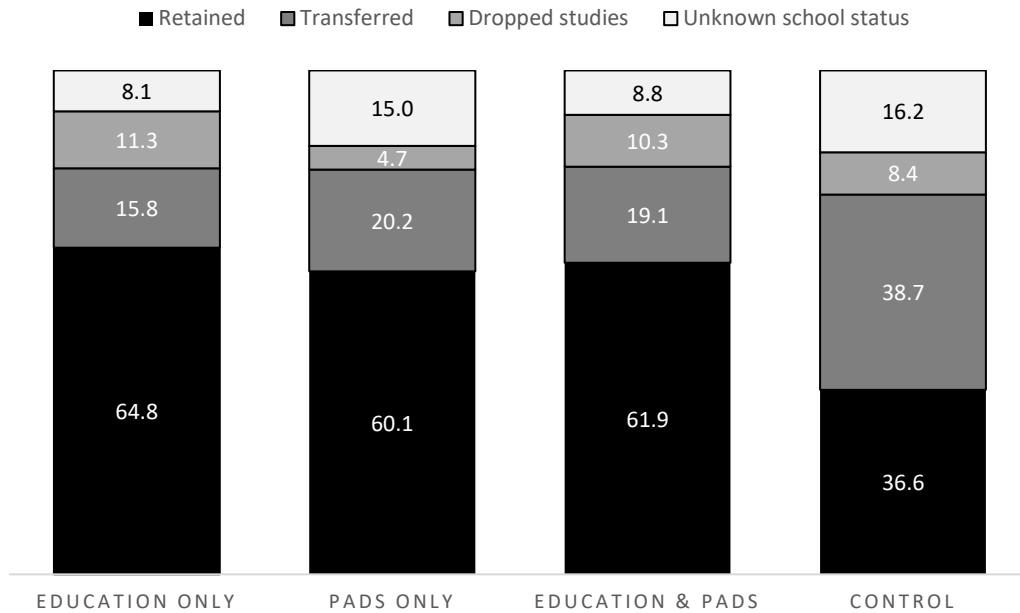


Figure 4.2. School status at follow-up according to condition (%) (n=1008)

Sites differed significantly in retention rates $\chi^2(3) = 43.26$, $p < .001$, with girls in the control condition far less likely to be retained in the study (36.6%) than in any intervention condition (62.4%), $\chi^2(1) = 41.05$, $p < .001$. This difference was driven by the number of transfers out of the control schools, with girls in the control condition significantly more likely to transfer (38.7%) than those in intervention schools (18.2%), $\chi^2(1) = 36.60$, $p < .001$. Girls in the control condition were no more likely to drop out of school than those in intervention conditions (8.4% vs 9.2%, respectively), $\chi^2(1) = 0.04$, $p = .842$, and were significantly less likely to have an unknown school status (16.2 vs 10.2%, respectively), $\chi^2(1) = 5.10$, $p = .024$.

Participant characteristics

In line with the Solomon 4-group design, a random 25% sub-sample completed the baseline survey. Table 4.2 displays the sample's characteristics by intervention condition. Girls who completed the baseline survey reported being between 7 and 18 years of age ($M = 11.44$, $SD = 1.71$). Girls in the pads only schools were, on average, older than those in the control condition ($p = .012$). There were no significant differences

according to school grade, repeating the current school grade, or being at the same school the preceding year. There was significant variation in the amount of time girls estimated it took to walk from home to school across the conditions $\chi(6) = 17.45, p = .008$. With over half the girls in the pads only and control conditions reporting it took them less than 30 minutes, in contrast to education only and education and pads conditions where almost one third of girls reported that it took longer than one hour. The mean SDQ total difficulties score was high for girls across all conditions ($M = 19.50, SD = 5.84$), but did not differ significantly between conditions. Scores were in the high categorisation range based on children (aged 4-17) in the UK (Goodman, Meltzer, & Bailey, 1998). Although it should be noted that scores on the pro-social scale were also very high, but in the positive direction ($M = 9.26, SD = 1.13$).

Of girls surveyed, 61.4% knew what menstruation was, and 20.6% had started menstruating. These proportions did not differ significantly by condition. Of girls who were menstruating ($n = 58$), 55.2% reported knowing about menstruation before it happened to them. 87.9% used cloth as menstrual absorbent with only 3 girls reporting using sanitary pads, and 4 reporting using just underwear. Almost all girls (96.6%) had access to water at home, and 86.2% of girls reported having access to soap at home. In contrast, only 15.5% reported having access to soap at school. When asked how much of a problem it was to change their sanitary protection at school 43.9% of menstruating girls stated that it was '*not a problem at all*', 26.3% that it was '*a little bit of a problem*', and 29.8% reported it was '*a big problem*'. Most girls (70.7%) felt more ashamed and insecure whilst menstruating than when they were not. In the sample of 58 menstruating girls, no responses significantly differed between conditions.

55.2% of girls reported that their menstruation caused them to miss school. This did not differ significantly according to condition, although proportions did vary substantially (see Table 4.2), in the small sample. In a similar pattern, the number of days girls reported missing from school during their menses varied across conditions,

$F(3,54)=3.05$, $p=.036$. Girls in the education only condition reported missing significantly fewer days of school than those in the control condition ($p=.026$), with no other significant differences between conditions. For the 58 menstruating girls, the self-reported mean days of school missed per menses was 1.43 days ($SD=1.61$).

Table 4.2. Baseline characteristics across intervention conditions in the 25% subsample

(n=281)

	Education only (72) % (N)	Pads only (66) %(N)	Education & pads (81) %(N)	Control (62) %(N)
Age (self-report) (M/SD)*	11.68 (1.71)	11.89 (1.76)	11.20 (1.64)	10.97 (1.61)
Grade				
P3	37.5 (27)	28.8 (19)	30.9 (25)	43.5 (27)
P4	31.9 (23)	31.8 (21)	34.6 (28)	25.8 (16)
P5	30.6 (22)	39.4 (26)	34.6 (28)	30.6 (19)
Are you repeating this grade?				
Yes	27.8 (20)	42.4 (28)	25.9 (21)	29.0 (18)
No	72.2 (52)	57.6 (38)	74.1 (60)	71.0 (44)
Did you go to the same school last year?				
Yes	72.2 (52)	78.8 (52)	74.1 (60)	85.5 (53)
No	27.8 (20)	21.2 (14)	25.9 (21)	14.5 (9)
How long does it take you to walk to school?**				
Less than 30 mins	37.5 (27)	57.1 (36)	37.0 (30)	51.6 (32)
30 mins to 1 hour	30.6 (22)	25.4 (16)	35.8 (29)	40.3 (25)
1 hour or more	31.9 (23)	17.5 (11)	27.2 (22)	8.1 (5)
Strengths & Difficulties Questionnaire Total Score (0- 40)	19.96 (6.49)	19.55 (5.65)	18.67 (4.88)	20.03 (6.38)
Menstruating girls	19.4 (14)	21.2 (14)	17.3 (14)	25.8 (16)
Does your menstruation ever cause you to miss school ¹ (Yes)	35.7 (5)	50.0 (7)	50.0 (7)	81.3 (13)
Self-reported days missed per period (M/SD) *	0.93 (0.25)	1.59 (0.43)	1.60 (0.43)	2.31 (1.82)

*p<.05, **p<.01, ***p<.001, ¹ of menstruating girls (N=58)

Primary outcome at baseline: school attendance

Attendance across the baseline period varied significantly by intervention condition $F(3,1004)=9.923$, $p<.001$. Education alone ($M=78.02$, $SD=23.51$) and control conditions ($M=76.09$, $SD=21.50$) did not significantly differ in mean attendance, but both had significantly higher attendance than pads alone ($M=68.36$, $SD=26.30$) or education and pads conditions ($M=69.35$, $SD=25.65$), ($p<.05$). Education and pads, and pads alone conditions did not significantly differ in baseline attendance. Some impact of clustering was identified. Intra-cluster correlation coefficient (ICC) was calculated to be 0.026 which represents a small impact of clustering (Campbell et al., 2012; Chromy, 2014).

Primary outcome: effect of drop out

Baseline attendance significantly differed between those who were retained or dropped out of the study $F(3,1004)=2.82$, $p=.038$. However post-hoc tests revealed only those who had an unknown school enrolment status at follow-up had significantly lower baseline attendance ($M=67.00$, $SD=24.79$) than those who were retained at follow-up ($M=74.29$; $SD=24.43$), $p=.025$, with no other significant differences amongst the groups. However, these results varied when drop-outs were assessed within each condition. For those in the control schools, girls who dropped out of the study (for any reason) had significantly lower baseline attendance ($M=72.23$, $SD=23.26$) than those who were retained at follow-up ($M=82.78$, $SD=16.12$), $t(182.83)=-3.69$, $p<.001$. Similarly for girls in the education schools drop-outs had significantly lower attendance at baseline ($M=73.94$, $SD=24.44$) than those who were retained in the study ($M=80.24$, $SD=22.76$), $t(191.36)=-2.12$, $p=.035$. In contrast, for the pads only schools drop-outs did not have significantly lower attendance ($M=71.13$, $SD=25.62$) than those who were retained ($M=66.53$, $SD=26.68$), $t(185.09)=1.26$, $p=.208$. The same was true in the education & pads schools where there was no difference in baseline attendance between drop-outs ($M=67.05$, $SD=27.00$) and those remaining the study ($M=70.77$, $SD=24.74$), $t(239.28)=-1.24$, $p=.217$. When compared across all reasons for drop-out only those in the control

condition were found to vary in their baseline attendance $F(3,187)=4.75$, $p=.003$, with post-hoc comparisons revealing both those who transferred from the control school, and those with unknown school status at the start of the follow-up period had significantly lower baseline attendance, ($p=.006$ and $p=.039$, respectively).

The above findings have some implications for interpreting the trial findings. The main trial analyses (per-protocol) were conducted including girls who were still attending the study schools at follow-up. Since girls with lower attendance were significantly more likely to drop-out of the control and education only conditions, it is likely that drop-outs would have *reduced* the average attendance in the control group, increasing the disparity between the intervention and control conditions. Thus the results of the per-protocol analysis may be conservative.

Intervention effectiveness: school attendance

Per-protocol analysis of girls retained in the sample at follow-up was undertaken as the primary assessment of interventions' effectiveness on school attendance ($n=580$). Table 4.3 reports the mean percentage attendance at baseline, follow up, and the percentage change between baseline and follow up for girls in the control condition, intervention conditions, and a pooled total for those in any intervention condition.

Table 4.3. Mean percentage attendance at baseline, follow-up and change scores across conditions ($n=580$)

		Baseline %	Follow-up %	Change %
	N	M (SD)	M (SD)	M (SD)
Education Only	184	80.24 (22.76)	76.56 (27.47)	-3.68 (28.07)
Pads Only	128	66.53 (26.68)	65.63 (29.78)	-0.90 (35.43)
Education & Pads	198	70.77 (24.75)	64.31 (26.71)	-6.46 (32.82)
Any intervention	510	73.12 (25.15)	69.06 (28.30)	-4.06 (31.90)
Control	70	82.78 (16.12)	61.62 (29.93)	-21.16 (33.35)

Change scores differed significantly between those in the control (-21.16%) and those in an intervention condition (-4.06%), $t(87.25)=-4.04$, $p<.001$. This represented a moderate effect of any intervention in comparison to control $d=0.52$ (95%CI 0.26-0.77). Attendance worsened across all conditions, however, in the intervention groups this effect was mitigated by 17.1% (95%CI: 8.7-25.5) (see Figure 4.3). This represents an extra 2.5 days in school in the 15-day (3 week) follow-up assessment period that would have otherwise been lost.

Intervention effectiveness was then compared between the four conditions. There was a significant difference amongst the groups, $F(3,576)=6.63$, $p<.001$, $\eta^2=.033$. Follow-up comparisons with Bonferroni adjustment for familywise error revealed no significant differences between any of the intervention groups ($p>.05$). However, comparing the control group to each intervention, there was a significantly greater drop in attendance for the control compared to the education only ($p=.001$), pads only ($p<.001$) and education and pads ($p=.006$) conditions. This effect is presented in Figure 4.3.

As noted in Methods, this comparison does not take account of the clustered nature of the data. The intra-cluster correlation coefficient (ICC) for follow-up attendance data was 0.058, which represents a small impact of clustering (Campbell et al., 2012; Chromy, 2014).

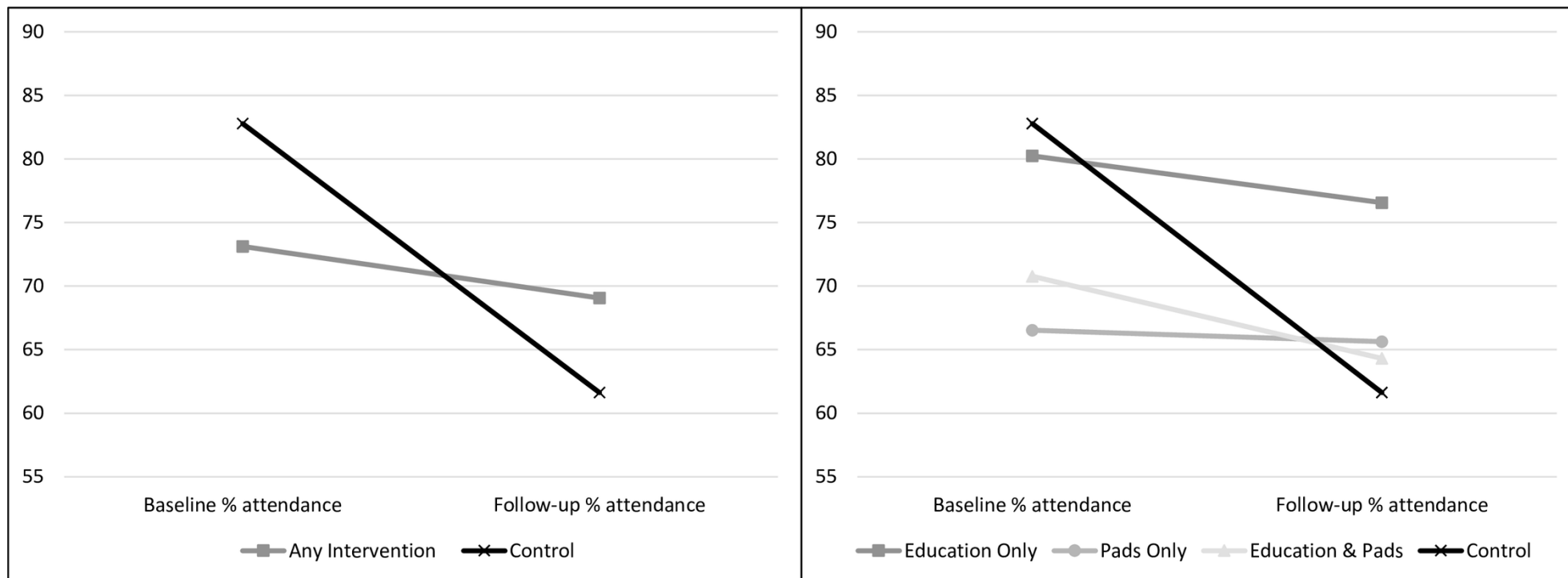


Figure 4.3. Mean percentage attendance at baseline and follow-up for all interventions combined, and each condition, compared to control. Presented for the sample of girls retained in schools at follow-up (n=580).

Robustness checks

While above analyses provide easily interpretable estimates of intervention effects, they do not adjust for clustering. Additional analyses were undertaken with adjustment for clustering, bearing in mind the small number of clusters.

Ordinary least squares regression with adjustment for clustering compared the three intervention conditions to the control. Again there was an overall effect of condition $F(3,7)=14.00$, $p=.002$, $R^2=0.03$. Each intervention condition; education alone ($b=17.48$, $SE=4.69$, $95\%CI=6.40-28.56$), pads alone ($b=20.26$, $SE=3.18$, $95\%CI=12.75-27.78$), and education and pads ($b=14.70$, $SE=3.58$, $95\%CI=6.23-23.17$) significantly differed from the control. With adjustment for clustering, considering the small number of clusters, there was also an overall effect of the intervention. Each intervention condition; education alone ($b=17.48$, $SE=4.69$, $95\%CI=8.29-26.67$), pads alone ($b=20.26$, $SE=3.18$, $95\%CI=14.02-26.49$), and education and pads ($b=14.70$, $SE=3.58$, $95\%CI=7.68-21.73$) differed significantly from the control. Similarly, adjustment for clustering demonstrated the robustness of results where any intervention was compared to the control. Results were corroborated with ordinary least squares regression with cluster adjustment, where there remained an effect of any intervention ($b=17.10$, $SE=3.45$, $95\%CI=8.95-25.25$) compared to the control $F(1,7)=24.64$, $p=.002$, $R^2=0.03$, and in regression with adjustment for clustering accounting for the small number of clusters ($b=17.10$, $SE=3.45$, $95\%CI=10.34-23.86$).

One-way analysis of variance at the school/cluster level ($n=8$) found an overall significant difference between conditions, $F(3,4)=6.80$, $p=.048$, however, follow-up tests with Bonferroni adjustment were not significant. This is to be expected in light of the lack of power to detect effects at the cluster level only ($n=8$). All intervention conditions, education alone ($p=.164$), pads alone ($p=.080$) and pads and education ($p=.246$), trended toward a significant difference from the control condition.

Worst case imputation

When 0% attendance was imputed for all girls who had dropped out of the study the mean percentage attendance at follow-up decreased dramatically (Table 4.4).

Consistent with per-protocol analyses there was a significantly greater drop in attendance for girls in the control condition than those in the intervention condition

$t(328.52)=-7.98, p<.001$. This was a moderate effect $d=0.62$ (95%CI 0.46-0.78).

Similarly, a one-way ANOVA identified a significant difference between group change scores when individual interventions were considered $F(3,1004)=17.09, p<.001$,

$\eta^2=0.05$. Post hoc tests found no significant differences amongst the intervention

conditions, but all intervention conditions had a significantly smaller drop in attendance than those in the control condition ($p<.001$ for all analyses). Regression with adjustment

for the small number of clusters demonstrated the robustness of results to clustering,

finding when compared to the control, the change in attendance percent was mitigated

by 24.5% in the intervention conditions ($b=24.51, SE=2.25, 95\%CI=20.10-28.91$).

Table 4.4. Mean percentage attendance at baseline, follow-up and change scores across conditions for best and worst case imputations (n=1008)

		Worst case imputation			Best case imputation	
		Baseline %	Follow-up %	Change %	Follow-up %	Change %
	N	M (SD)	M (SD)	M (SD)	M (SD)	M (SD)
Education Only	284	78.02 (23.51)	46.60 (42.78)	-28.42 (42.98)	75.64 (26.43)	-2.39 (22.64)
Pads Only	213	68.36 (26.30)	39.44 (39.61)	-28.93 (46.91)	68.82 (28.26)	-0.54 (27.43)
Education & Pads	320	69.35 (25.65)	39.79 (37.67)	-29.56 (42.55)	65.35 (26.81)	-4.00 (25.98)
Any intervention	817	72.11 (25.45)	43.11 (40.24)	-29.00 (43.83)	69.57 (27.41)	-2.54 (25.28)
Control	191	76.09 (21.50)	22.58 (34.81)	-53.51 (36.80)	68.33 (26.33)	-7.76 (22.55)

Best case imputation

An intention to treat analysis with last observations (baseline attendance) carried forward was also conducted. Consistent with main analyses, there was a significantly greater drop in attendance for girls in the control condition than those in the intervention condition $t(311.80)=-2.81$, $p=.005$, $d=0.21$ (95%CI=0.05-0.37). When intervention groups were compared separately there remained a significant difference in change scores amongst the groups $F(3,1004)=3.13$, $p=.025$, $\eta^2=0.01$, however, post hoc tests found only the pads alone schools had a significantly smaller drop in attendance than those in the control schools ($p=.021$). These results were also robust to the impact of clustering with any intervention mitigating the drop in percent attendance by 5.2% ($b=5.22$, $SE=1.83$, 95%CI=1.63-8.81).

Both scenarios indicate a more pronounced decrease in the control group attendance compared to the intervention groups, consistent with the pattern of results for the per-protocol analysis. This suggests the positive effect of the interventions represents a real difference, but that the precise amount of attendance saved by the interventions may vary. Whilst per-protocol analysis observed a difference of 17.1% (95%CI=8.7-25.5) between interventions and control, conservative imputation estimated 5.2%, and worst-case imputation estimated 24.5%. These results were robust to adjustment for clustering.

Outcomes according to menstrual status

As noted in methods, the trial included girls both pre- and post-menarche with the aim of delivering the intervention before menstruation commenced. However, fewer girls had reached menarche than anticipated in the final survey (although those who had dropped out of school and were not reached for survey are likely to be older and to have reached menarche so figures in the final survey may be an underestimate). Thus, additional comparisons were undertaken for girls who completed the final survey

($n=356$) and reported that they had reached menarche ($n=164$), and those who had not ($n=192$). These analyses also served as an additional check in light of the small number of clusters in the trial. If the same pattern of results was observed for girls pre- and post-menarche it may have suggested that unidentified cluster-level factors may have been driving identified effects. Table 4.5 displays the percentage attendance and change scores for girls in each condition, or who received any intervention, according to whether they self-reported that they had or had not reached menarche at the time of the final survey.

For girls who had commenced menstruation by the time of the final survey, receiving any intervention was associated with a significant difference in attendance change score, $t(14.35)=-2.59$, $p=.021$, $d=0.93$ (95%CI 0.37-1.49), a mean difference of 24.7% (95%CI 10.07-39.38). When distinguishing between the interventions there was an overall difference in change scores, $F(3,160)=4.19$, $p=.007$, $\eta^2=0.07$, and follow-up comparisons revealed no significant differences between the intervention groups. But that education ($p=.045$), pads ($p=.003$) and education and pads ($p=.017$) conditions all experienced a significantly smaller drop in attendance than the control condition. For girls who had not yet reached menarche at the time of the final survey, receiving any intervention was not associated with a significant difference in the changed attendance percentage between baseline and follow-up, $t(41.06)=-1.55$, $p=.128$, $d=0.25$ (95%CI -0.17-0.67). There was also no significant difference in change scores when distinguishing between the intervention types $F(3,188)=1.92$, $p=.128$, $\eta^2=0.03$. Interestingly, change scores revealed a slight increase in attendance for these girls. Results are also shown in Figure 4.4.

Table 4.5. Mean percentage attendance at baseline, follow-up and change scores across conditions for menstruating and non-menstruating girls at follow-up (n=356)

		Baseline %	Follow-up %	Change %
	N	M (SD)	M (SD)	M (SD)
<u>Girls post-menarche at follow-up (N=164)</u>				
Education Only	40	84.29 (19.14)	82.83 (22.23)	-1.46 (16.55)
Pads Only	40	74.10 (23.83)	79.33 (21.18)	5.23 (29.48)
Education & Pads	70	72.38 (23.02)	72.19 (22.81)	-0.19 (27.66)
Any Intervention	150	76.02 (22.70)	76.93 (22.57)	0.92 (25.70)
Control	14	85.71 (13.85)	61.90 (27.10)	-23.81 (34.82)
<u>Girls pre-menarche at follow-up (N=192)</u>				
Education Only	78	83.99 (19.85)	87.95 (13.89)	3.96 (21.64)
Pads Only	32	65.38 (26.14)	80.21 (16.63)	14.82 (28.24)
Education & Pads	57	67.88 (27.66)	73.22 (19.78)	5.34 (30.56)
Any Intervention	167	74.93 (25.33)	81.44 (17.79)	6.51 (26.42)
Control	25	85.03 (13.80)	85.07 (13.09)	0.04 (18.14)

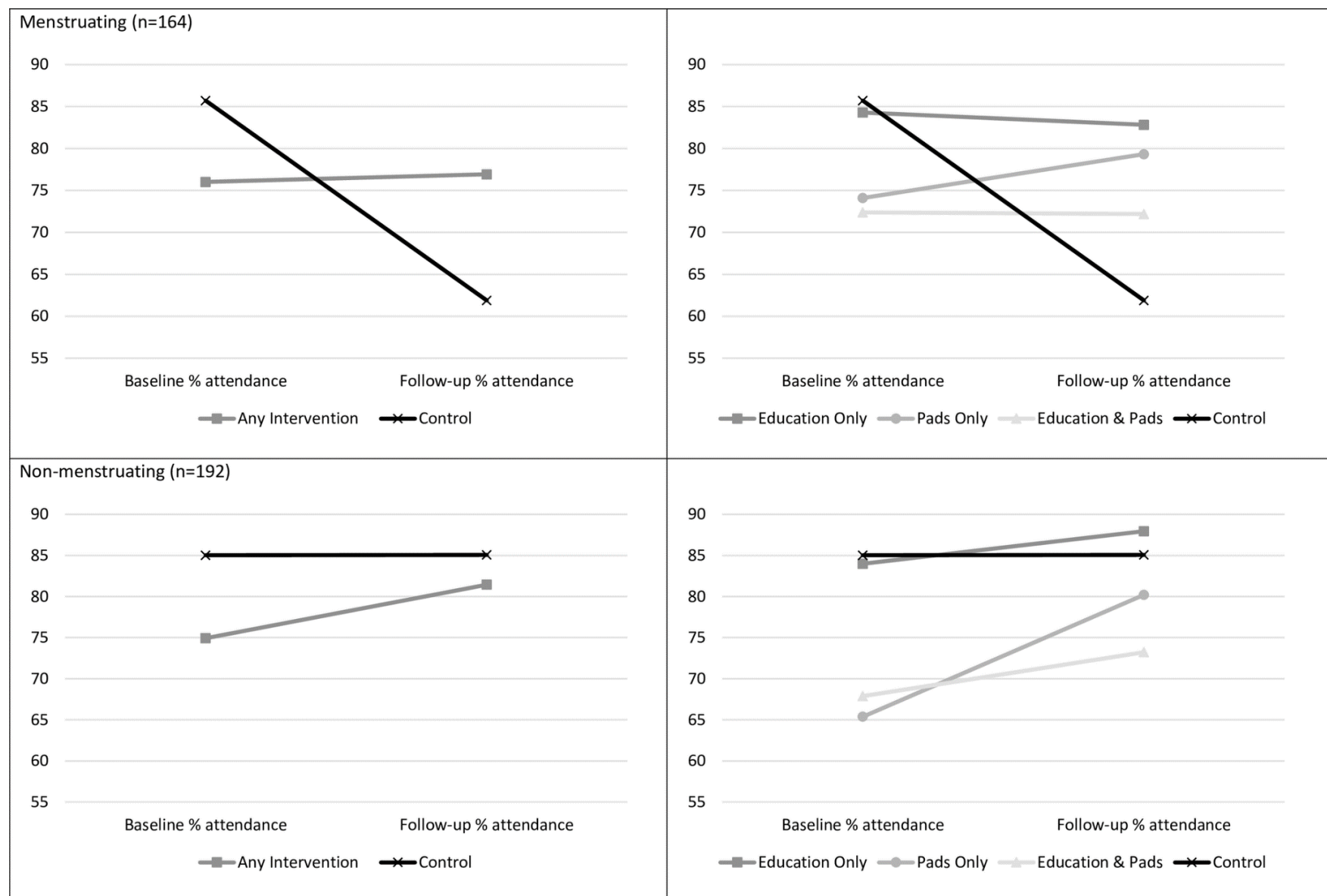


Figure 4.4. Mean baseline and follow-up percentage attendance according to girls' menstrual status at study conclusion (n=356)

Intervention effectiveness: psychosocial wellbeing

A total of 356 girls from the trial completed a final survey. Of these, 328 completed the full follow-up survey, and 28 girls who had dropped out of school completed a shorter 'drop-out' version of the survey. The mean self-reported age of this sample was 13.23 (SD=1.43). 46.1% of girls surveyed at the end of the study had started menstruating. Since psychosocial wellbeing constructs were balanced across the groups at baseline, follow-up scores were compared. Table 4.6 displays the self-reported SDQ total score, and feelings of shame and insecurity during menstruation across the four conditions. Of girls who completed the follow-up surveys, a higher proportion were menstruating in the pads only and education and pads schools, compared to the education only and control schools $\chi(1)=14.57$, $p<.001$. For girls who were menstruating, there were no differences across the conditions on any outcome, including feelings of shame or insecurity during menstruation.

Table 4.6. Psychosocial wellbeing across intervention conditions (n=356)

	Education only (118)	Pads only (72)	Education & pads (127)	Control (39)
	% (N)	%(N)	%(N)	%(N)
Accurate knowledge of menstruation ¹	58.5 (55)	71.2 (42)	67.7 (65)	63.3 (19)
Strengths & Difficulties Questionnaire Total Score ² (0-40) <i>M(SD)</i>	18.41 (4.75)	19.39 (5.39)	18.61 (4.90)	17.18 (5.62)
Menstruating girls ^{3***}	33.9 (40)	55.6 (40)	55.1 (70)	35.9 (14)
Feels more ashamed during menstruation ⁴	77.5 (31)	65.0 (26)	61.4 (43)	64.3 (9)
Feels more insecure during menstruation ⁴	75.0 (30)	65.0 (26)	68.6 (48)	71.4 (10)
Does your menstruation ever cause you to miss school? ⁵ (Yes)	20.0 (7)	8.8 (3)	23.6 (13)	11.1 (1)
Self-reported days missed per period ⁵ <i>M(SD)</i>	0.37 (0.88)	0.24 (0.86)	0.38 (0.81)	0.33 (1.00)

*p<.05, **p<.01, ***p<.001

¹of girls who completed the full follow-up survey, 12 girls did not answer, for 35 there was an ipad error (n=279)²of girls completing full follow-up survey, 2 girls did not provide responses (n=326)³of girls completing full follow-up or drop-out survey (n=356)⁴of menstruating girls who completed either full follow-up or drop-out survey (n=164)⁵of menstruating girls who completed full follow-up survey (n=133)

Discussion

Main study findings

This trial assessed the effectiveness of providing reusable sanitary pads or puberty education for improving girls' school attendance in rural Uganda. Consistent with the pilot study in Ghana, the trial found both education and reusable sanitary pads to be equally effective in improving school attendance compared to no-intervention. For all girls still in the study schools at follow-up, attendance had dropped substantially from the baseline. However, those in the control schools had a 17.1% (95%CI: 8.7-25.5) greater drop in attendance than those who received the interventions in per-protocol analyses. This represents an extra 2.5 days in school in the 15-day (3 week) follow-up assessment period that would have otherwise been lost. The moderate effect size found in this study ($d=0.52$ 95%CI=0.26-0.77) was comparable to the pooled standardised mean difference revealed by meta-analysis of the two pilot trials of sanitary pad and education provision to date ($d=0.49$; Montgomery et al., 2012; Wilson, Reeve, & Pitt, 2014; Hennegan & Montgomery, 2016 [Thesis Chapter Two]). In this trial, the provision of education or reusable pads alone, and these interventions combined, were found to have similar effectiveness in improving attendance. For policy makers, this suggests that even in absence of resources to provide sanitary pads, the inclusion of adequate and gender-sensitive puberty education in school curriculum could improve attendance and target gender inequalities. Regressions with adjustment for clustering demonstrated the robustness of the findings. The trial suffered from significant drop-out (42.5%). Only a sub-set of girls were surveyed at baseline, precluding multiple imputation based on this survey. Further, the nature of the participant drop-out meant that imputed attendance scores would be misrepresentative. Thus two intention-to-treat analyses with different imputation strategies were undertaken. The first, or worst-case scenario, assumed all drop-outs had 0% school attendance, while the second, best-case scenario, presented a highly conservative estimate where baseline attendance scores were carried forward for

all drop-outs. In both scenarios, the pattern of results observed in the per-protocol analyses were replicated and the interventions were found to have a significant positive effect on attendance (5.2% in the best-case, and 24.5% in the worst-case estimates).

The frequency at which girls dropped out of school or transferred to another school was unanticipated. While school absences attributable to menstrual management may be an additional factor involved in drop-out, menstruation alone was not hypothesised to lead to drop-out and drop-out was not considered as an outcome variable in the study. The distribution of participant drop-out for various reasons was similar across sites. There were no differences in the rate dropping out of school or moving away, however the proportion of girls transferring to another school during the study was substantially higher in the control condition. Follow-up assessment revealed this was spread across both control schools. There were no patterns in the recorded destination schools for transfer. Interventions may have been protective against school transfer, as improved attendance may have meant girls were better equipped to pass school exams and to progress through the school at the expected rate, reducing motivation to transfer. It is also possible that the presence of the partner NGO in those schools delivering pads or education provided extra incentive to stay, although the additional attention should only have occurred very early in the study and should not have been sufficient to influence school choice. Given the small number of clusters it is also possible an unmeasured factor influenced the substantial transfer from the control schools.

The study included girls in upper primary school (ages 10-18, with a mean of 11.44 at baseline) and sought to intervene before menarche. Only 20% of the sample had commenced menstruating at the time of intervention. Despite age at menarche estimates of 12-14 (Anderson, Dallal, & Must, 2003; Freedman et al., 2002), only 46% of girls self-reported having commenced menstruation at the conclusion of the trial. This may reflect the variability of menarche with environmental factors such as nutrition, and

means the intervention was well-timed to educate girls and provide products prior to menarche, but that the follow-up period was not long enough for most girls to have started menstruating. It is also likely that girls who had been lost to follow-up were older and more likely to have reached menarche, thus the survey figure is an underestimate. The measured effect of the intervention is therefore likely to be conservative as the provision of pads or education should make little difference to girls prior to menarche.

To provide an estimate of the intervention effectiveness amongst girls who had reached menarche, additional analyses were undertaken separately for menstruating and non-menstruating girls. These analyses were restricted to the smaller sample of girls who had completed the follow-up surveys. In addition to estimating the effectiveness of the interventions for those who had reported reaching menarche in the follow-up surveys, these analyses served to check for variations in attendance which may have been caused by individual school level factors. Moreover, to assess the consistency of the school attendance measures which were changed between baseline (teacher-recorded attendance) and follow-up (partner-NGO recorded attendance) and could have introduced bias. Analysis according to menstrual status supported the interpretation of the per-protocol analysis, finding a significant, 24.7% (95%CI 10.07-39.38) drop in attendance in the control conditions for girls' post-menarche compared to the intervention conditions, which did not differ from one another. In contrast, there was no effect of the interventions, and no drop in attendance amongst girls who reported not yet menstruating. Findings support the interpretation of the study results that intervening in menstrual management was responsible for observed differences in school attendance. Further, findings support the hypothesised link between menstruation and school absence (Sommer, Sutherland, & Chandra-Mouli, 2015; Tegegne & Sisay, 2014), although these differences may also reflect other age-related absences, such as increased obligations to paid work or household chores.

Secondary outcomes

There were no significant differences in the psychosocial outcomes assessed across conditions at follow-up. Reductions in shame and insecurity in the conditions providing sanitary pads in the pilot study were not replicated (Dolan et al., 2013). It should be noted that only a small proportion of girls in the study completed the follow-up survey, and single item measures of shame and insecurity may have been influenced by social-desirability, particularly as the survey was administered verbally by research assistants. Similarly, the SDQ total difficulties score (Goodman, Meltzer, & Bailey, 1998) did not differ across groups. Very high total difficulties scores were noted. These high scores may reflect the study population. Recent systematic review, including studies using the SDQ, concluded that considerable levels of mental health problems exist among children and adolescence in sub-Saharan Africa (Cortina, Sodha, Fazel, & Ramchandani, 2012). Higher scores on subscales of the SDQ have been noted in studies in the Democratic Republic of Congo (Kashala, Elgen, Sommerfelt, & Tylleskar, 2005) and refugee children in the UK (Fazel & Stein, 2003), although these were both in younger populations of children than the present study. Interestingly, in this study, scores on the pro-social scale were also very high, but in the positive direction. This may reflect some bias towards affirmative responses, perhaps again reflective of the verbal administration of the survey. There was no difference in girls' knowledge of menstruation at follow-up, however, the measurement of this construct was poor. During the survey girls were asked to describe menstruation and research assistants provided a pass/fail rating based on criteria that girls reported menstruation to be a biological process associated with reproduction. This menstrual knowledge measure fails to capture many important aspects of menstrual management, and may be biased based on girls' confidence to describe the process or research assistants' subjective assessment of the response adequacy. Improved measurement is needed in future trials.

The trial failed to assess potential harms of the interventions. The identification of menstruating girls through education and the provision of sanitary products has the potential to expose these girls' menstrual status, leading to increased stigmatisation, teasing, or unwanted attention. To date, no studies of menstrual management interventions have assessed potential harms (Hennegan & Montgomery, 2016 [Thesis Chapter Two]), and there is an urgent need for future work to more thoroughly investigate this possibility.

Implications for menstrual hygiene intervention and research

Results of the study support the assertion that the management of menstruation presents a gender specific barrier to education (Sommer et al., 2015). They also support the provision of menstrual absorbents and information about menstruation as effective avenues for intervention. It should be noted, however, that the effective and hygienic management of menstruation requires more than knowledge or reusable absorbents (Sommer & Sahin, 2013). The interventions assessed in this trial did not address needs for adequate latrines, access to water for washing the body and absorbents, access to soap (beyond a small quantity provided initially with reusable pads in some conditions), access to privacy or methods for disposal. Each of these factors contributes to dignity and enables adequate menstrual management (Sommer & Sahin, 2013; Winkler & Roaf, 2014). Access to these other requirements for menstrual management were comparable across schools. Follow-up qualitative work to be detailed elsewhere, and reports from the field revealed that girls cleaned absorbents at home rather than at school, and that changing practices were associated with individual school cultures around latrine use rather than any variation in facilities. In taking a holistic view of girls' needs, it is important to consider the way access to other requirements for management may further contribute to school attendance, and to psychosocial wellbeing, which was not improved by the tested interventions. Furthermore, as a reusable sanitary pad was provided in this

intervention, the effectiveness of this product is contingent on the resources to wash and dry it appropriately.

Girls' psychosocial wellbeing, dignity, comfort, and ability to manage menstruation without shame are all essential considerations in seeking to provide girls with their full right to menstrual health in low income contexts. Whilst there was only limited measurement of these outcomes in the present trial, the lack of an effect is disappointing and means that there is more work to be done for the development and evaluation of interventions to address this challenge. Increased primary epidemiological research capturing girls' behaviours, attitudes, and barrier to menstrual hygiene, as well as improved measurement of negative effects on wellbeing or comfort would provide much needed knowledge and tools for intervention research.

Limitations of the current trial should be addressed in future studies. A-priori analytic strategies for high levels of participant drop-out are needed where this is expected. For girls who have dropped out of school, no attendance can be expected. These cases may zero-inflate data and fail to capture the true nature of effects. Trials with a larger number of clusters are needed to enable adequate samples for multi-level models. Full baseline survey may be necessary to adequately compare lost and retained participants, however the risks of bias associated with multiple testing or the impromptu education provided through asking questions about menstruation in studies of the effectiveness of puberty education must be considered. Menstrual diaries may allow for more specific menstrual-attendance measures but may also represent an intervention if girls had not previously recorded their cycles, and risk greater quantities of missing data where diaries are not returned.

Contextual considerations and implementation

This paper reports on the primary quantitative outcomes of the *Menstruation and the Cycle of Poverty* trial. The study took place in a complex environment and many

factors should be considered to maximise understanding of the barriers and facilitators of girls' schooling in rural Uganda, and lessons for future trials of sanitary pad provision or puberty education. Forthcoming qualitative and quantitative work [Thesis Chapters Five, Six, and Seven] will seek to elucidate further complexities of improving girls' menstrual management and access to schooling. In brief, these include the role of teachers, whether or not girls used the provided pads or if they were sold to combat other barriers to schooling such as school fees, the acceptability of a reusable absorbent, and girls cleaning practices. The interaction of the intervention with the other considerations for menstrual management noted above, including how girls managed menstruation when only education was provided, disposal or the adequacy of cleaning methods for the reusable pads provided, and the role of access to water, sanitation and hygiene and privacy with regard to school latrines, are all important considerations in understanding how the interventions worked and what adaptations to the interventions may be needed if relocated to different contexts. Current results do not have sufficient explanatory power for why education alone, pads alone, and education in addition to pads did not differ in their effectiveness for improving school attendance or psychosocial outcomes.

Broader contextual considerations for this study include the roll-out of the partner NGO, Plan International's well-known '*Because I am a girl*' campaign (<https://plan-international.org/what-we-do/because-i-am-girl>) which may have influenced community attitudes regarding girls' education. The effect of the campaign should have been comparable across conditions, however, an increased emphasis on girls' education may have impacted the self-reported psychosocial and menstrual practice findings. Girls' reports must be interpreted in light of this program. An unanticipated contextual issue was the practice of labial elongation in the trial population. This will be discussed further in forthcoming qualitative work, however, reports from girls in the study suggested that

uptake of the reusable sanitary pads may have been limited by discomfort, perhaps associated with this practice.

Study strengths and limitations

This trial was the largest to date assessing the impact of menstrual management interventions on girls' school attendance. The use of a clustered design prevented contamination, while allocation to the four conditions provided a contrast between the different intervention components of education and sanitary pad provision, compared to a no-intervention control. The sequential allocation of clusters to conditions alphabetically represented quasi-randomisation, potentially resulting in a higher risk of selection bias (Higgins & Green, 2011). However, despite this sub-optimal randomisation in comparison to more rigorous methods such as computer randomisation, the school names in alphabetical order is unlikely to have biased allocation. There were few differences in participant characteristics between the conditions measured at baseline. The study did not adjust for slight differences in mean age and the distance walked from school as only a portion of the participants were surveyed at baseline, age is highly collinear with menstrual status, and there was no evidence to suggest the distance walked to school would have any significant interaction with the intervention. The small number of clusters limits the generalisability of findings and meant the trial was vulnerable to external factors which may have influenced any of the small number of sites. The high rate of drop-out, and inability to follow-up girls who dropped or transferred out of study schools also restricted the validity of the intention-to-treat analysis and ability to capture the pattern of attendance for the full sample.

The change in attendance data collection methods was a significant limitation of the study. Despite receiving training and repeated checks to try and ensure the accuracy of teacher-recorded attendance, changing the follow-up measure to three, single-week attendance data collections by research assistants may have introduced bias. The drop in attendance between baseline and follow-up may be a true effect, but may also reflect

this change in method. The impact of the change should be the same across schools, and should not limit the interpretation of the effect sizes as demonstrated in sub-group analyses of girls pre- and post-menarche. The use of only two time points (1 week of attendance data per term for the follow-up year), means more nuanced changes in attendance over time could not be investigated (for example, if there was an initial increase in attendance following intervention delivery or if education took longer to achieve a change as was found in the pilot study). Similarly, restriction of school attendance records to weeks in the middle of the term means results may not be representative of other times when attendance may vary more substantially. It should be noted that this study assessed attendance across all days, not only attendance during menstruation. Poor follow-up survey coverage limits the study from being able to test mediating effects such as the role of changed menstrual practices which may have resulted from education interventions as sample sizes of menstruating girls who completed the follow-up survey were highly limited.

Weaknesses in intervention delivery also severely limit the reliability of results found. Although estimated, it is unclear what proportion of girls received the assigned interventions. Intervention implementation through a local NGO brought strengths to the study, providing access to the local language, age appropriate research assistants to administer surveys and rapport with local communities and schools. However, issues with delivery and long-armed management from the UK resulted in poor intervention implementation and inadequacies in participant follow-up.

Conclusions

This cluster quasi-randomised controlled trial provides initial evidence for the effectiveness of providing reusable sanitary pads or puberty education for improving girls' school attendance in rural Uganda. Given the limitations of the trial, and need to assess potential harms of menstrual management interventions, more research and replication is needed. Challenges identified in this trial represent important

considerations for future work. The study adds to an emergent body of evidence suggesting that interventions to assist girls in better managing their menses may be effective in improving girls' access to education and reducing gender inequality.

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CHAPTER 5

Paper #4: Prevalence and impact of poor menstrual hygiene

Measuring the prevalence and impact of poor menstrual hygiene management: a quantitative survey of schoolgirls in rural Uganda.

Julie Hennegan¹

Catherine Dolan²

Maryalice Wu³

Linda Scott⁴

Paul Montgomery¹

¹ Centre for Evidence-Based Intervention, University of Oxford, Oxford, UK

² SOAS, University of London, London, UK

³ Applied Technologies for Learning in the Arts and Sciences, University of Illinois, Urbana-Champaign, US

⁴ Said Business School, University of Oxford, Oxford UK

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Note: for the thesis references have been updated to APA style.

Abstract

Objectives. The primary objective was to describe Ugandan schoolgirls menstrual hygiene management (MHM) practices and estimate the prevalence of inadequate MHM. Secondly, to assess the relative contribution of aspects of MHM to health, education, and psychosocial outcomes.

Design. Secondary analysis of survey data collected as part of the final follow-up from a controlled trial of reusable-sanitary pad and puberty education provision was used to provide a cross-sectional description of girls' MHM practices and assess relationships with outcomes.

Setting. Rural primary schools in the Kamuli district, Uganda.

Participants. Participants were 205 menstruating schoolgirls (10-19 years) from the eight study sites.

Primary and secondary outcome measures. The prevalence of adequate MHM, consistent with the concept definition, was estimated using dimensions of; absorbent used, frequency of absorbent change, washing and drying procedures, and privacy. Self-reported health, education (school attendance and engagement), and psychosocial (shame, insecurity, embarrassment) outcomes hypothesised to result from poor MHM were assessed as primary outcomes. Outcomes were measured through English surveys loaded on iPads and administered verbally in the local language.

Results. 90.5% (95%CI 85.6-93.9) of girls failed to meet available criteria for adequate MHM, with no significant difference between those using reusable sanitary pads (88.9%, 95%CI 79.0-94.4), and those using existing methods, predominantly cloth (91.5%, 95%CI 85.1-95.3), $\chi^2(1)=0.12, p=.729$. Aspects of MHM predicted some consequences including shame, not standing in class to answer questions, and concerns about odour.

Conclusions. This study was the first to assess the prevalence of MHM consistent with the concept definition. Results suggest that when all aspects of menstrual hygiene are considered together, the prevalence is much higher than has previously been reported based on absorbents alone. The work demonstrates an urgent need for improved assessment and reporting of MHM, and for primary research testing the links between menstrual management and health, education, and psychosocial consequences.

Strengths and limitations of this study³

- Offers a working example of the quantitative assessment of MHM, using best available evidence to assess each aspect
- Provides the first prevalence estimate of adequate menstrual hygiene management consistent with its definition
- Multivariable comparisons demonstrate the importance of multiple aspects of menstrual hygiene in predicting hypothesised health, education and psychosocial consequences
- Self-reported menstrual hygiene behaviours, health, education, and psychosocial outcomes are vulnerable to biases, particularly social-desirability
- The cross-sectional nature of the study limits causal inference, and the analyses are limited by the lack of ability to adjust for potential socio-demographic confounds, the small sample size, and lack of existing literature on which to base power analyses

³ This section is a journal requirement of *BMJ Open*

Background

Menstrual hygiene management (MHM) has received increasing attention as a public health issue. After a history of silence, stakeholders from governments to local charities have started to speak about the barrier that the management of menstruation presents to gender equality, and the potential for programs to address the problem. Qualitative research has documented challenges girls face in managing their menses and indicated health, education and psychosocial wellbeing consequences of poor management (House, Mahon, & Cavill, 2012; Crichton, Okal, Karibu, & Zulu, 2013; Dolan, Ryus, Dopson, Montgomery, & Scott, 2013; Sommer, Ackatia-Armah, Connolly, & Smiles, 2014). However, quantitative studies of the associations between MHM and health, education and psychosocial outcomes are scarce (Hennegan & Montgomery, 2016 [Thesis Chapter Two]). With regard to health, few studies have assessed associations between infection and MHM. In the most comprehensive work to date, a case-control study concluded that there was evidence for an association between reusable pad use and lab-confirmed urogenital infection compared to disposable pads, but noted the complex range of MHM practices, and the need for more research (Das et al., 2015). Other physical and health outcomes including irritation, discomfort and urogenital symptoms, even if not confirmed infections, are also important potential consequences of poor MHM which impose on women's ability to participate in society with dignity (Winkler & Roaf, 2015; Kerubo et al., 2016).

School absenteeism and disengagement have been emphasised as important consequences of poor MHM. Quantitative evidence for links between MHM and attendance have been mixed, although studies have almost exclusively looked at absorbent type, rather than all MHM practices discussed below (Tegegne & Sisay, 2014; Grant, Lloyd, & Mensch, 2013; Montgomery, Ryus, Dolan, Dopson, & Scott, 2012; van Eijk et al., 2016). Studies have focused on attendance (Hennegan & Montgomery, 2016 [Thesis Chapter Two]), and additional work is needed to capture the impact of

menstruation on concentration and engagement, even if girls are at school (Crichton et al., 2013; Caruso et al., 2013). Psychosocial consequences including shame, insecurity, anxiety, and fear of stigma are well-documented correlates of menstruation in qualitative studies (e.g., Crichton et al., 2013; Sommer et al., 2014). Such negative psychosocial outcomes have been hypothesised to arise from poor MHM such as inadequate absorbent use (Dolan et al., 2013). They may also result from a lack of knowledge and information about menstruation (Deo & Ghattargi, 2005), cultural stigma and taboos (Sommer et al., 2014), and as a result of transactional or coercive sex undertaken to meet MHM needs (Phillips-Howard et al., 2015). More quantitative evidence is needed to unpack the roles of these different contributors to wellbeing, and associations between MHM and wellbeing outcomes. As argued below, it may be inaccurate to label all of these predictors as MHM.

Menstrual hygiene management: definition, use, and measurement

A unified, working definition of MHM was developed by the Joint Monitoring Program of the World Health Organisation and UNICEF in 2012, defining MHM as: *“Women and adolescent girls using a clean menstrual management material to absorb or collect blood that can be changed in privacy as often as necessary for the duration of the menstruation period, using soap and water for washing the body as required, and having access to facilities to dispose of used menstrual management materials”* (Sommer & Sahin, 2013). This captures aspects of the physical requirements for hygienic, effective management of menstrual bleeding. Use of the term has proliferated; however, operationalisation has been inconsistent. As per the above definition, adequate MHM would require:

- Clean absorbents
- Adequate frequency of absorbent change
- Washing the body with soap and water
- Adequate disposal

- Privacy for managing menstruation

Studies to date have only reported a few of these aspects (see Hennegan, accepted [Thesis Chapter Three]). Prevalence studies, and quantitative assessments of predictors and consequences of poor MHM have focused on the type of absorbent used, the first aspect of MHM (e.g., Choudhary & Rahman, 2015). Some include one or two additional components, such as washing the body, or disposal of absorbents (e.g., Wilson, Reeve, & Pitt, 2014; Guya, Mayo, & Kimwag, 2014). None have included all aspects of MHM or considered a pooled, comprehensive prevalence estimate requiring all conditions to be met. Overextension of the term has also occurred with studies reporting a lack of knowledge about menstruation, or cultural taboos as aspects of MHM, rather than contributors to MHM (e.g., van Eijk et al., 2016).

One barrier to the full assessment of MHM is the lack of evidence and consensus of what constitutes adequacy in each aspect. In a systematic review of MHM practices and infections, Sumpter and Torondel (2013) found no consistent standard in the application of 'good' and 'bad' MHM. They found that most studies used only absorbent type to predict consequences, and even with this simplified criterion, did not agree on the adequacy of absorbents such as cloth. Single use absorbents such as sanitary pads are easily classified as clean, however reusable absorbents such as cloth or reusable pads (homemade or commercially produced) could be considered hygienic if cleaned appropriately (Sumpter & Torondel, 2013). MHM literature is yet to provide evidenced guidance for washing and drying absorbents. Washing with soap may be one important criterion. Drying practices are also important, with exposure to UV through sunlight known to have a microbiocidal effect (Bloomfield et al., 2011). Leaving fabrics damp has been found to encourage microbial survival, and wearing absorbents wet has frequently been considered unhygienic, with some evidence for greater infection risk and discomfort (House, Mahon, & Cavill, 2012; Das et al., 2015; Bloomfield et al., 2011). Similarly, there is little rigorous evidence to guide absorbent change frequency. The

Menstrual Hygiene Matters report suggested changing absorbents every 2-6hrs dependent on blood flow (House, Mahon, & Cavill, 2012). However, there is a lack of evidence on the irritation and infection risk associated with prolonged wear, and women's perceptions of the adequate frequency for changing for comfort and risk of soiling. There is no clear guidance on optimal washing frequency, or correct use of soap and water on the body and genitals. Similarly, disposal method adequacy is likely to be contextually dependent and relies on latrine capacity, cultural appropriateness of burning absorbents, and other waste disposal methods. Finally, whilst the concept definition stresses the need to change absorbents in privacy, women and girls need privacy for all aspects of MHM, such as washing the body and absorbents (Winkler & Roaf, 2015). Each of these aspects must be considered in trying to estimate the prevalence of MHM, establish relationships between predictors and consequences of poor MHM, and evaluate interventions aimed at improving MHM.

Recent calls for action, such as the *MHM in Ten* report (Sommer et al., 2016), state the need for a strong quantitative evidence base. This is difficult to achieve without consistent, transparent reports of MHM as defined. Prevalence estimates are needed to assess the distribution of the issue, and to advocate effectively for MHM to be addressed by governments, non-government organisations, and other interest groups. Assessment of all aspects of MHM is needed to identify the relevant contributors to the problem, and establish quantitative links between MHM and consequences. For example, a recent systematic review of MHM studies in India reported that in multivariable models, the use of sanitary pads did not predict school attendance (van Eijk et al., 2016). It is inaccurate to conclude from this finding that MHM does not predict attendance, but only that the type of absorbent used may not. Similarly, trials to date have focused on education and sanitary product provision (Hennegan & Montgomery, 2016 [Thesis Chapter Two]). No studies have reported if addressing these contributors to MHM, that is, education informing girls how to manage menstruation hygienically, and

the provision of clean absorbents as a resource to improve one aspect of MHM (clean absorbents), actually improves MHM overall. Given the many components of MHM detailed above, it is likely that the provision of menstrual products without attention to other factors is insufficient to improve MHM. This has implications for our expectations and interpretations of intervention outcomes. Trials to date assume that improvements in school attendance or psychosocial outcomes observed are the result of improved MHM, but none have tested this. It may be that other factors such as reductions in menstrual stigma, improved pain management strategies, or improved social support amongst classmates contribute to these improvements. While important aspects of managing menstruation, these factors do not fall under the MHM definition. They risk being minimised if studies focus only on MHM, or being mishandled if inaccurately labelled as MHM, which may further complicate its definition and make measurement more difficult. Thus there is a need to understand how proposed interventions affect MHM and to establish the role of MHM, in contrast to other aspects of managing menstruation, in hypothesised consequences.

The present study

This study employs secondary data analysis of the final survey data from the *Menstruation and the Cycle of Poverty* trial undertaken in rural Uganda from January 2012 to December 2014 (Pan African Clinical Trials Registry PACTR201503001044408). The trial methods and outcomes of school attendance and psychosocial wellbeing are described elsewhere (see Montgomery, Hennegan, Dolan Wu, Steinfield, & Scott, 2016 [Thesis Chapter Four]). Briefly, eight primary schools (including primary school grades 3 to 7) located in Kamuli district, Uganda, an area characterised by poor performance on education and health indicators, were quasi-randomised to one of four conditions, the provision of: puberty education alone, AFRIpads alone, puberty education and AFRIpads, or a no-intervention control. Schools were paired to maximise distance between the four conditions and the risk of

contamination. Pairs were allocated sequentially in alphabetical order to conditions. Schools were recruited through the partner NGO and selected to be comparable on characteristics such as size, educational provision and quality (see Montgomery et al., 2016 [Thesis Chapter Four]). While water sources were closer to some schools than others, water, sanitation and hygiene (WASH) for MHM was comparable across schools. All girls in the schools in primary school classes 3 to 5 at baseline were included in the trial, regardless of menstrual status.

Girls in the reusable pad conditions were provided with one pack of AFRipads and small quantity (one sachet, 45 grams) of Omo soap in October 2012, and again in March 2014. Girls were taught about the correct use and cleaning of AFRipads by local research assistants from the partner NGO upon each delivery (Montgomery et al., 2016 [Thesis Chapter Four]). AFRipads are a washable, reusable cloth sanitary pad produced in Uganda (<http://www.afripads.com/>). Deluxe packs provided to girls included two soil-resistant plastic-lined 'base' pads, three attachable winged liners, three straight liners and two small bags for carrying. AFRipads can be reused for 12 months. Girls in the puberty education conditions received an education session (in October 2012) lasting approximately 1.25 hrs (see Montgomery et al., 2016 [Thesis Chapter Four]). Girls who transferred into the study schools during the trial were included in intervention delivery (if attending school at those times) alongside those in the trial and follow-up surveys as not to identify or stigmatise girls in the trial or discriminate against those transferring after the baseline from receiving resources. While girls transferring into the school could not be included in trial outcomes compared across conditions, their responses were incorporated into the final survey data set for secondary analyses. This maximised cross-sectional sample size in the survey data set.

The present study employs the final survey data from the trial to provide the first estimate of MHM consistent with the concept definition. This was used to estimate the association between poor MHM and health, education, and psychosocial outcomes,

alongside an assessment of the relative contribution of aspects of MHM to these experiences. MHM prevalence was assessed separately for those using the AFRIPads provided in the intervention, and girls using other existing methods. The present study uses data from the final follow-up survey of the trial but does not compare across trial conditions, the work provides cross-sectional assessment of practices as reported in the survey and their associations with health, education and psychosocial wellbeing.

Research Questions

1. What are the self-reported MHM practices of girls in rural Uganda?
2. What is the prevalence of MHM consistent with the concept definition?
3. Is adequate MHM greater amongst those using reusable sanitary pads?
4. How do aspects of MHM, and pooled MHM, comparatively predict health, education, and psychosocial wellbeing?

Methods

This study was conducted and reported according to best practice guidelines in the Strengthening the Reporting of Observational studies in Epidemiology (von Elm et al., 2008). Checklist for cross-sectional studies is reported in Appendix 5.1

Participants

435 schoolgirls across the 8 study schools completed follow-up surveys. This included girls who had been involved in the trial, and girls in the same classes who had joined the school after the trial commenced. All girls were surveyed to avoid selectively identifying those menstruating or involved in the trial, potentially stigmatising these girls. 205 girls who reported in the survey that they had reached menarche were asked questions about menstrual management, and are included in this study. There were no a-priori power analyses for this cross-sectional assessment as the study seeks to demonstrate the calculation of a prevalence estimate of MHM, and there was no past evidence from which to draw effect size estimates between aspects of MHM and health, education and psychosocial wellbeing outcomes assessed.

Survey design

The survey was administered in November 2014. Trained local research assistants from the partner NGO (Plan International) used an English version of the survey loaded on iPads in the app *SurveyGizmo*. iPads were used in the field offline and data was uploaded to the online service *SurveyGizmo* at the end of each day once an internet connection could be established. Research assistants, all young women, verbally administered surveys in Lusoga (the local language) and inputted answers in English into the instrument. Girls were surveyed individually in a private place on the school grounds, for menstruating girls this lasted approximately 30-40 minutes.

Survey items were designed following a pilot trial and qualitative research in Ghana (see Montgomery et al., 2012; Dolan et al., 2013), where a number of similar items were also used. Additional questions were developed following feasibility and acceptability work leading to the selection of AFRipads for the intervention study (Scott, Montgomery, Steinfield, Dolan, & Dopson, 2013), and in consultation with stakeholders and partner NGO staff. To support best practice and transparency in reporting, a full list of survey items used is reported in Appendix 5.2.

MHM measure

MHM practices

Girls self-reported MHM practices through structured questions. To assess absorbent use, girls were asked: *“What do you usually use to catch/absorb your menstrual period (MP)?”*, and their free responses were recorded by research assistants as AFRipad, cloth, toilet roll, sanitary pad, or other. Few girls reported use of toilet roll so this was recoded to other, along with use of underwear alone and using mattress or sponge. In a follow-up question girls were asked where they (or the person who gives them the absorbent) obtain it. This item was used to determine if girls were using old or new cloth. Girls were also asked: *“How frequently do you change your sanitary protection?”* with guidance from research assistants that per-day meant in 24hrs.

For girls who reported using AFRipads or cloths, follow-up questions captured washing and drying procedures. Girls responded yes/no to items: *“Did you ever wash the AFRipad/cloth?”*, and to the follow-up: *“Did you use soap?”*. To assess drying girls were asked: *“Where did you hang the cloth to dry?”* with responses including; under the bed, outdoors, in the school dorm rooms, and in a secret place. Free text responses to the question included: in the bathroom, behind the toilet, in the grass, and behind the house. Responses were back-coded into three categories: outside, hung inside, or

hidden inside. Girls were then asked: *“How often did you wear the cloth/AFRIpad damp?”* with response options *never*, *sometimes*, and *usually*.

Girls were asked: *“What do you usually do with your used sanitary protection when you have to change at home/school?”* with response options *throw in latrine*, *throw in bush*, *dispose at community rubbish heap*, *bury*, and *burn*. When asked about disposal at school, listed responses also included *go home to change*. *Wash and reuse* was a listed option for home disposal. For both questions girls volunteered information and research assistants selected the appropriate category.

Those using reusable absorbents were asked: *“Do you worry about being observed when washing the cloth/AFRIpad?”* with yes/no response options.

MHM criteria

Self-reported MHM behaviours were used to generate a pooled, aggregate estimate of MHM consistent with the concept definition discussed in the background. Criteria for available aspects of MHM are detailed below, and the pooled estimate included; absorbent cleanliness, adequate change frequency, hygienic washing and drying, and privacy. Criteria for each step were derived from background literature, although existing evidence is sparse. Each criterion was added sequentially and the number of girls considered to have adequate or inadequate MHM at each step reported in results. Absorbents were considered clean if they were AFRIpads, new cloth or sanitary pads, with old cloth and other items such as toilet paper, mattress, sponge, or underwear alone considered inadequate. Changing absorbents 3 or more times per 24hrs was required to be considered adequate MHM, consistent with recent work (Tegegne & Sisay, 2014), and guidance (House, Mahon, & Cavill, 2012). For reusable absorbents, MHM was considered inadequate if not washed with soap. Absorbents were considered to be hygienically dried if dried outside, rather than hung up or hidden inside. Never wearing absorbents damp was also required for adequate MHM. Finally, girls

needed to report they were not worried about privacy for washing their absorbents. There were no appropriate items in the survey capturing washing the body or genitals, or items on the ability to change absorbents in privacy, which would have improved the MHM estimate. Whilst disposal methods were reported, there was no consistent guidance on what could be considered an adequate method, so this item was not included in the overall estimate. These aspects were considered the *minimal* requirements for MHM, using best available evidence.

As criteria for MHM could be debated given the lack of evidence, an additional measure of MHM was used for comparison. For this pooled total more *relaxed* criteria were used. Both new and old cloth were considered to be adequate absorbents at step one, with the concession that if washed appropriately, old cloth could be considered an adequate absorbent. Girls were only required to change their sanitary protection twice per day, although were still required to wash absorbents with soap and water. To meet criteria as having adequate MHM in the relaxed model girls needed to dry absorbents outside or hung up inside; only those who dried their absorbent hidden away were considered to have poor MHM. The criteria that girls never wear absorbents damp remained unchanged, as did the requirement they felt they had adequate privacy to wash reusable absorbents. Girls were required to meet all relaxed criteria to be considered to have adequate MHM in this model.

Survey measures

Additional survey measures assessed participant characteristics and hypothesised consequences of poor MHM.

Participant characteristics

Girls self-reported their age, grade in school, and how long it took them to walk to school. Data were also collected concerning access to water and soap at home and

schools as yes/no responses to items asking *“Do you have regular access to (water/soap) at (school/home)?”*.

Health

Girls were asked to report if during their *last* period they experienced: skin irritation or rashes in the pelvic area with a yes/no response. They were also asked if since the beginning of the school year they had experienced *“any itching or burning in the pelvic area”*, or *“any white or grey discharge from their [your] vagina”* and could report if this was while on their period, at only other times, or both during their period and at other times. All girls reported that this was experienced either only during their period, or during their period and at other times, so only a dichotomous *experienced* response was used. Girls were asked: *“Do you worry that other people can smell your menstrual period?”* with yes/no responses.

Education

Girls reported if they felt their menstruation ever caused them to miss school or not to do their homework as part of a longer list of activities (including other items such as participating in sports or being around males). Girls were asked: *“Do you avoid standing in class to answer questions while on your menstrual period?”* and *“Do you find it difficult to concentrate at school when you have your menstrual period?”* with yes/no options. The latter was followed with a multiple response item capturing the reasons for difficulties concentrating, listed in results tables.

Psychosocial wellbeing

Girls reported if during their *last* period they experienced embarrassment. They also reported if during their menstruation they felt ashamed or insecure or if this was the same as when they were not menstruating. Psychosocial wellbeing was assessed using the total score from the Strengths and Difficulties Questionnaire (SDQ: Goodman, Meltzer, & Bailey, 1998). The SDQ consists of 25, 3-point Likert scale items from 0 *not*

true' to 2 '*true*', with a midpoint of 1 '*somewhat true*'. The total score (0-40) uses summed scores from the four problem subscales of; hyperactivity (e.g., "*I am easily distracted.*"), conduct problems (e.g., "*I usually do as I am told*"), peer problems (e.g., "*I would rather be alone than with people of my age*"), and emotional problems (e.g., "*I have many fears. I am easily scared.*"). The total difficulties score can range from 0-40. For 4-17-year-olds, current 4-band categorisation based on a UK survey population are; average (0-14), slightly raised (15-17), high (18-19), very high (20-40). The questionnaire has been well validated and was a secondary outcome in the *Menstruation and the Cycle of Poverty* trial (see Montgomery et al., 2016 [Thesis Chapter Four]), with norms for different countries available online (www.sdqinfo.com).

School attendance

Attendance data was recorded for girls participating in the *Menstruation and the Cycle of Poverty* trial from baseline. For the present study, only follow-up attendance data was used. Research assistants from the partner NGO collected attendance for the fourth week of each of the three terms in 2014. This was collapsed to create a continuous variable: the percent attendance out of the 15 days recorded. Week four of the school term was selected to avoid very-low attendance periods coinciding with school fee collection at the start of term or agricultural practices, based on advice from site visits and local agents. Girls were not asked to record menstrual cycles, so attendance includes menstruating and non-menstruating days. Attendance was linked to survey responses through participant ID.

Analyses

Analyses were conducted using Stata 14.0. Participant characteristics were detailed using descriptive statistics, as were the prevalence of MHM practices and consequences. Combined measures of MHM were reported using descriptive statistics, including 95% confidence intervals (CI) of the total proportions of those with adequate

and inadequate MHM. The chi-square statistic was used to compare the pooled MHM between those using AFRIpads and using other existing methods. Bivariate correlations were used to test the overlap of MHM aspects prior to use in multivariable models.

Univariate logistic regressions assessed the relationships between MHM practices and health, education, and psychosocial outcomes. Washing absorbents (with or without soap) was not used as a predictor in these comparisons as almost all girls reported doing so. All of the girls who reported never wearing their absorbent damp had also dried their absorbent outside, so only the location of drying was used as a predictor in the models. All four aspects of MHM were included in multivariable logistic regressions to assess the individual contribution of each to hypothesised consequences. Univariate logistic regressions assessed the relationship between the combined measures of MHM and outcomes. For continuous outcomes of school attendance and total SDQ score, independent samples t-tests were used.

Ethics

Ethical approval for the study was received from the Social Science & Humanities Inter-Divisional Research Ethics Committee at the University of Oxford (Ref: SSD/CUREC1/11-056), the AIDS Support Organisation (TASO) Institutional Review Committee Uganda (TASOIRC/022/14-UG-IRC-009), and the University of Illinois (#12236). To participate in the trial, girls and their parent/caregiver provided written consent. Schools provided consent for participation throughout the duration of the study. At the start of the survey girls provided verbal consent to participate. No girls declined participation. They were informed that they were free not to answer any question in the survey.

Results

Participant characteristics

A total of 205 menstruating girls were included in this study. 145 (70.7%) had been attending the schools in the trial at baseline. Of the 145 trial girls, 96 (66.2%) had received one of the tested interventions (puberty education alone: 36 (24.8%), pads alone: 40 (27.6%), and education and pads: 27 (18.6%). Of the 60 girls who had not been in the trial schools at baseline, 20 (33.3%) had received pads alone and 1 had received the education intervention. Interventions were identical for all girls, including transfers. Transfer girls received the interventions alongside girls in the trial from baseline to ensure there was no stigmatisation of either group. 81 girls in the full sample had received no intervention, this included girls in the control condition, as well as girls who failed to receive their assigned intervention. Girls in this study were compared according to their self-reported menstrual hygiene practices.

Girls ranged from a self-reported age of 10-19 years ($Mean=14.20, SD=1.12$). The average age at menarche was 12.82 years ($SD=1.28$). Table 5.1 describes the participant characteristics for this study.

Table 5.1. Participant characteristics (n=205)

	%	N
Grade		
P3	0.5	1
P4	8.3	17
P5	21.5	44
P6	44.9	92
P7	24.9	51
Age		
10	0.5	1
11	0.5	1
12	1.0	2
13	21.5	44
14	44.9	92
15	20.5	42
16	8.8	18
17	1.0	2
18	1.0	2
19	0.5	1
Did you go to the same school last year?		
Yes	94.6	194
No	5.4	11
How long does it take you to get to school?		
10 minutes or less	19.8	33
11-30 minutes	37.7	63
31-60 minutes	37.7	63
>1hr	4.8	8
<i>No answer</i>		38
Do you have regular access to:		
Soap at home (n=200)	94.0	188
Water at home (n=200)	99.0	198
Soap at school? (n=199)	27.1	54
Water at school? (n=199)	44.2	88

Menstrual hygiene management (MHM) practices

Table 5.2 describes the girls' MHM practices. Four did not report the type of absorbent used, therefore were not asked follow-up questions. Thus the table reports on 201 girls, unless otherwise indicated. Almost 36% of the sample were using AFRIPads received as part of the intervention study as their primary absorbent. Of girls not using AFRIPads, most used cloth as absorbent. Of those using reusable absorbents, almost all reported washing them and using soap for every wash. Half of those who washed absorbents hid them to dry, most commonly under the bed. 23% reported wearing absorbents wet at least once. No girls reported disposing at community rubbish heaps, burning, or burying pads.

Table 5.2. Self-reported menstrual hygiene management practices (n=201)

	%	N
Absorbent		
What do you usually use as menstrual absorbent?		
AFRIpad	35.8	72
New cloth	14.9	30
Old cloth	30.9	62
Sanitary pad	9.0	18
Other (incl. toilet paper, underwear, mattress, sponge)	9.5	19
How frequently do you change your sanitary protection?		
1x per day	6.1	12
2x per day	33.2	65
3x per day	49.0	96
4x per day	9.7	19
5+ times per day	2.0	4
Missing		5
Washing reusable absorbents		
Did you wash the absorbent? (n=158)¹		
Yes	95.7	154
No	1.9	3
No answer/don't know	2.5	4
Did you use soap? (n=154)²		
Never	0	0
Sometimes	1.9	3
Every time	98.1	151
Drying reusable absorbents		
Where did you dry the absorbent? (n=154)²		
Hidden inside (e.g., under bed)	47.4	73
Hung up inside (e.g., girls dorm, bathroom)	11.0	17
Outside	41.6	64
How often did you wear the absorbent damp? (n=154)²		
Never	77.3	119

Sometimes	6.5	10
Usually	16.2	25
Absorbent disposal		
What do you usually do with your used sanitary protection when you have to change at school? (n=158)³		
Throw in latrine	12.3	19
Take home to wash or dispose	85.7	132
<i>Other</i>	12.0	3
What do you usually do with your used sanitary protection when you change at home? (n=199)		
Throw in latrine	11.6	23
Put in trash	0.5	1
Wash and reuse	87.9	175
Privacy		
Do you worry about being observed when washing the absorbent? (n=154)²		
Yes	73.4	113
No	26.6	41

¹ Of girls using reusable menstrual absorbents (AFRipads, cloth)

² Of girls using reusable menstrual absorbents (AFRipads, cloth) who reported washing their absorbent

³ Only asked of girls who reported they 'couldn't go whole day at school without changing absorbent'

Prevalence estimate: menstrual hygiene management

By adding each available aspect of MHM assessed, the overall prevalence of MHM was estimated. Table 5.3 displays the proportion of girls who met criteria at each step. That is, the proportion of girls remaining after the introduction of that requirement for MHM. Each additional aspect of MHM resulted in fewer girls qualifying. There were particularly large drops following the introduction of changing frequency, drying, and privacy. After the inclusion of available aspects, only 9.5% of the sample qualified as having adequate MHM using minimal criteria. The prevalence of inadequate MHM did not differ between those who used AFRIpads (88.6%) and those using existing methods (90.5%), $\chi^2(1)=0.12$, $p=.729$.

As noted previously, there is a lack of evidence for MHM criteria. Thus, more relaxed criteria were applied for comparison (Table 5.3, right columns). Despite these changes, the overall prevalence of poor MHM remained high and there was no significant difference between those using AFRIpads (80.6%) and those using existing methods (76.7%), $\chi^2(1)=0.20$, $p=.655$.

Table 5.3. Estimated prevalence of menstrual hygiene management, using minimal and relaxed criteria

MHM criteria (minimal)			MHM criteria (relaxed)		
	AFRIpad users N=72	Usual practice N=129		AFRIpad users N=72	Usual practice N=129
	application of criteria % (n) retained			application of criteria % (n) retained	
Clean absorbent	(criteria: AFRIpad, new cloth, or sanitary pad) 100 (72)			(criteria: AFRIpad, old or new cloth, sanitary pad) 100 (72)	
Changed frequently	(criteria: 3 times or more) 66.7 (48)			(criteria: 2 times or more) 93.1 (67)	
Washed with soap ¹	(criteria: washed absorbent with soap) 65.3 (47)			(criteria: washed absorbent with soap) 90.3 (65)	
Dried adequately ¹	(criteria: absorbent dried outside) 29.2 (21)			(criteria: absorbent dried outside or hung inside) 56.9 (41)	
	(criteria: absorbent never worn damp) 29.2 (21)			(criteria: absorbent never worn damp) 56.9 (41)	
Privacy for washing ¹	(criteria: not worried about being observed washing absorbent) 11.1 (8)			(criteria: not worried about being observed washing absorbent) 19.4 (14)	
Meet available criteria:	% [95%CI] (n)	% [95%CI] (n)		% [95%CI] (n)	% [95%CI] (n)
Prevalence of poor MHM:	11.1 [5.6-21.0](8)	8.5 [4.7-14.8] (11)		19.4 [11.7-30.5](14)	23.3 [16.7-31.4](30)
	88.9 [79.0-94.4](64)	91.5 [85.2-95.3](118)		80.6 [69.5-88.3](58)	76.7 [68.6-83.3](99)
Met available criteria:	Total % [95%CI] (n)			Total % [95%CI] (n)	
Prevalence of poor MHM:	9.5 [6.1-14.4] (19)			21.9 [16.7-28.2] (44)	
	90.5 [85.6-93.9] (182)			78.1 [71.8-83.3] (157)	

¹If reusable absorbent (AFRIpad, new/old cloth)

While the study aimed to use each aspect of MHM to predict outcomes, almost all girls reported washing absorbents with soap. Thus groups were not large enough for reliable comparison in chi-square or logistic regression so this criterion was dropped from analysis of association with outcomes. As noted in the analysis section, drying criteria were collapsed. The minimal MHM criteria from Table 5.3 (i.e., new cloth, AFRIPad or sanitary pads considered clean absorbent, and outside alone considered adequate drying), were used for comparison with health, education and psychosocial outcomes.

To check for multicollinearity and associations between the different aspects of MHM, bivariate correlations were compared between the clean absorbents (AFRIPad, new cloth, sanitary pad), frequency of absorbent change (3+ times), drying adequately (outside), and having adequate privacy. There was only one significant correlation between girls feeling they had adequate privacy to wash absorbents and drying absorbents adequately (outside), $r=0.42$, $p<.001$. All other associations were very low ($r<.08$).

Consequences of poor MHM

Table 5.4 presents the proportion of girls reporting negative health, education, and psychosocial outcomes. Approximately half of the sample reported discomfort, possibly indicating health consequences. Less than 20% of girls stated that menstruation caused them to miss school, although over half reported not standing in class to answer questions, and finding it difficult to concentrate when menstruating. Discomfort, fear of soiling, and menstrual pain were the most common reasons for difficulty concentrating. Many girls reported embarrassment, shame, and insecurity associated with menstruation.

Table 5.4. Prevalence of proposed consequences of poor MHM (n=201)

	%	N
Health/comfort		
Skin irritation/rashes in pelvic area during last MP (n=153) ¹	54.3	83
Itching or burning in the pelvic area (since start of the school year) (n=199)	60.3	120
White or green discharge (since start of the school year) (n=199)	47.2	94
Do you worry people can smell your MP? (yes)	70.2	141
Education		
Does your MP ever cause you to: (n=185) ¹		
Miss school	18.4	34
Not do your homework	7.6	14
School attendance at intervention follow-up (n=144) <i>M (SD)</i>	81.06	(18.58)
Do you avoid standing in class to answer questions on your MP (n=198)	64.7	128
Do you find it difficult to concentrate at school when you have your MP? (n=198)	51.0	101
Reasons it is difficult to concentrate during MP (n=101)		
Actual soiling	24.8	25
Fear of soiling	72.3	73
Scent	15.8	16
Discomfort	49.5	50
Actual teasing	4.0	4
Fear of teasing	21.8	22
Cramps	54.5	55
Psychosocial wellbeing		
Strengths & Difficulties Questionnaire (SDQ) total score <i>M (SD)</i>	19.11	(5.31)
Did you experience embarrassment during your last MP (n=153) ¹	45.8	70
During your MP do you feel ashamed?	69.2	139
During your MP do you feel insecure?	69.2	139

¹ n's lower than 201 resulted in part from iPad issues where, in about 40 cases, the appropriate page froze or failed to load, additional missing resulted from girls not providing an answer to the question

Relationships between MHM aspects and proposed consequences

Table 5.5 displays the univariate and multivariable relationships between MHM aspects, pooled MHM estimates (minimal and relaxed), and health, education, and psychosocial wellbeing.

There were no significant associations with itching or burning, despite a consistently higher rate of report among those with poorer MHM. Drying outside had the reverse relationship to discharge than expected, with less white or green discharge reported amongst those drying inside or hidden. This unexpected direction of effect was also found for girls' fears that others could smell their menses. Unclean absorbents and inadequate privacy were associated with increased concerns about odour in multivariable comparison.

Only one aspect of MHM was associated with school attendance, with those changing 3 times a day or more having a higher attendance rate. Unclean absorbents and privacy were associated with higher odds of avoiding standing in class to answer questions, as were pooled MHM estimates. Only adequate privacy for washing absorbents was associated with difficulties concentrating, although having a clean menstrual absorbent trended towards significance with an almost 10% difference in reports. Drying practices were associated with shame in the opposite direction to that expected. Adequate privacy for washing was associated with shame and insecurity.

Despite very large percentage differences in the reports of consequences between those categorised as having adequate and inadequate MHM, the small number of girls with adequate MHM meant there was insufficient power to demonstrate statistically significant effects. Percent differences should be noted, however, with the potential for large effect sizes to be identified in larger samples.

Table 5.5. Univariate and multivariable comparisons of aspects of MHM, combined measures of MHM, and hypothesised consequences.

	Absorbent type		Absorbent change		Absorbent drying		Privacy (for washing)		MHM (minimal)		MHM (relaxed)	
	Clean	Unclean	3+ times	<3 times	Outside	Inside/hid	No concern	Concern	Adequate	Inadequate	Adequate	Inadequate
	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)
	OR (95%CI)		OR (95%CI)		OR (95%CI)		OR (95%CI)		OR (95%CI)		OR (95%CI)	
Health/comfort												
Itching or burning in the pelvic area (since start of the school year)	59.7 (71)	61.3 (49)	60.2 (71)	60.5 (49)	58.6 (58)	62.0 (62)	54.4 (43)	64.2 (77)	52.6 (10)	61.1 (110)	54.6 (24)	61.9 (96)
	1.07 (0.60-1.91)		1.01 (0.57-1.81)		1.15 (0.65-2.04)		1.50 (0.84-2.67)		1.41 (0.55-3.65)		1.36 (0.69-2.67)	
OR _{adj} (95%CI)	1.10 (0.61-1.98)		0.98 (0.54-1.76)		0.96 (0.51-1.82)		1.54 (0.80-2.93)					
White or green discharge (since start of the school year)	44.5 (53)	51.3 (41)	48.3 (57)	45.7 (37)	53.5 (53)	41.0 (41)	44.3 (35)	49.2 (59)	31.6 (6)	48.9 (88)	47.7 (21)	47.1 (73)
	1.31 (0.74-2.31)		0.90 (0.51-1.59)		0.60 (0.34-1.06)		1.22 (0.69-2.15)		2.07 (0.75-5.69)		0.98 (0.50-1.91)	
OR _{adj} (95%CI)	1.36 (0.76-2.43)		0.80 (0.45-1.44)		0.47* (0.24-0.88)		1.78 (0.92-3.43)					
Worry people can smell your MP?	65.8 (79)	76.5 (62)	68.9 (82)	73.0 (59)	74.3 (75)	66.0 (66)	58.2 (46)	77.9 (95)	63.2 (12)	70.9 (129)	59.1 (26)	73.3 (115)
	1.69[†] (0.90-3.20)		1.16 (0.62-2.15)		0.68 (0.37-1.24)		2.52** (1.36-4.69)		1.42 (0.53-3.80)		1.90[†] (0.94-3.81)	
OR _{adj} (95%CI)	1.88[†] (0.96-3.68)		0.94 (0.49-1.81)		0.34** (0.16-0.73)		4.51*** (2.09-9.77)					

Adequate absorbent OR=1.00; Changed frequently OR=1.00; Drying outside OR=1.00; Don't worry about privacy OR=1.00; Adequate MHM strict OR=1.00; Adequate MHM relaxed OR=1.00

OR_{adj}: Odds ratio for multivariable models where all aspects of MHM were included in the model.

* $p < .05$, ** $p < .01$, *** $p < .001$, [†] $p < .10$

	Absorbent type		Absorbent change		Absorbent drying		Privacy (for washing)		MHM (minimal)		MHM (relaxed)	
	Clean	Unclean	3+ times	<3 times	Outside	Inside/hid	No concern	Concern	Adequate	Inadequate	Adequate	Inadequate
	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)
	OR (95%CI)		OR (95%CI)		OR (95%CI)		OR (95%CI)		OR (95%CI)		OR (95%CI)	
Education												
School attendance <i>M</i> (<i>SD</i>) (<i>n</i> =144)	82.10 (18.33)	79.39 (19.04)	84.89 (14.28)	76.40** (22.23)	79.00 (21.54)	83.19 (14.82)	80.12 (21.14)	81.67 (16.86)	86.19 (13.95)	80.51 (18.98)	81.96 (20.07)	80.79 (18.19)
Do you avoid standing in class to answer questions on your MP?	59.3 (70)	72.5 (58)	63.6 (75)	66.3 (53)	59.6 (59)	69.7 (69)	53.2 (42)	72.3 (86)	26.3 (5)	68.7 (123)	45.5 (20)	70.1 (108)
		1.81 (0.98-3.34)		1.13 (0.62-2.04)		1.56 (0.87-2.81)		2.30** (1.26-4.17)		6.15** (2.11-17.91)		2.82** (1.42-5.60)
OR _{adj} (95%CI)		1.97* (1.05-3.71)		1.05 (0.56-1.95)		1.14 (0.58-2.22)		2.31* (1.18-4.53)				
Do you find it difficult to concentrate at school when you have your MP? (n=198)	46.6 (55)	57.5 (46)	49.2 (58)	53.8 (43)	52.5 (52)	49.5 (49)	39.2 (31)	58.8 (70)	42.1 (8)	52.0 (93)	31.8 (14)	56.5 (87)
		1.55 (0.87-2.75)		1.20 (0.68-2.12)		0.89 (0.51-1.55)		2.21** (1.24-3.95)		1.49 (0.57-3.87)		2.78** (1.37-5.66)
OR _{adj} (95%CI)		1.69[†] (0.93-3.05)		1.05 (0.58-1.91)		0.55 (0.29-1.07)		3.03** (1.54-5.99)				

Adequate absorbent OR=1.00; Changed frequently OR=1.00; Drying outside OR=1.00; Don't worry about privacy OR=1.00; Adequate MHM strict OR=1.00; Adequate MHM relaxed OR=1.00

OR_{adj}: Odds ratio for multivariable models where all aspects of MHM were included in the model.

p*<.05, *p*<.01, ****p*<.001, [†]*p*<.10

	Absorbent type		Absorbent change		Absorbent drying		Privacy (for washing)		MHM (minimal)		MHM (relaxed)	
	Clean	Unclean	3+ times	<3 times	Outside	Inside/hid	No concern	Concern	Adequate	Inadequate	Adequate	Inadequate
	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)	% (N)
	OR (95%CI)		OR (95%CI)		OR (95%CI)		OR (95%CI)		OR (95%CI)		OR (95%CI)	
Psychosocial wellbeing												
Strengths & Difficulties Questionnaire <i>M(SD)</i>	18.65 (5.24)	19.80 (5.37)	18.75 (5.42)	19.65 (5.13)	18.91 (5.34)	19.32 (5.29)	18.84 (5.42)	19.30 (5.25)	17.11 (6.30)	19.32 (5.17)	18.25 (5.80)	19.36 (5.16)
Did you experience embarrassment during your last MP (n=153)	47.8 (43)	42.9 (27)	46.2 (42)	45.2 (28)	48.8 (39)	42.5 (31)	54.4 (31)	40.6 (39)	50.0 (6)	45.4 (64)	38.7 (12)	47.5 (58)
OR _{adj} (95%CI)	0.82 (0.43-1.57)		0.96 (0.50-1.84)		0.78 (0.41-1.47)		0.57 (0.30-1.11)		0.83 (0.26-2.70)		1.43 (0.64-3.21)	
During your MP do you feel ashamed? (n=201)	66.7 (80)	72.8 (59)	69.8 (83)	68.3 (56)	72.3 (73)	66.0 (66)	59.5 (47)	75.4 (92)	52.6 (10)	70.9 (129)	56.8 (25)	72.6 (114)
OR _{adj} (95%CI)	1.34 (0.72-2.49)		0.93 (0.51-1.72)		0.74 (0.41-1.36)		2.09* (1.13-3.84)		2.19 (0.84-5.70)		2.01* (1.01-4.03)	
During your MP do you feel insecure?	68.3 (82)	60.4 (57)	69.8 (83)	68.3 (56)	68.3 (69)	70.0 (70)	60.8 (48)	74.6 (91)	63.2 (12)	69.8 (127)	61.4 (27)	71.3 (112)
OR _{adj} (95%CI)	1.10 (0.60-2.03)		0.93 (0.51-1.72)		1.08 (0.59-1.97)		1.90* (1.03-3.48)		1.35 (0.50-3.60)		1.57 (0.78-3.15)	
	1.16 (0.62-2.16)		0.86 (0.46-1.60)		0.78 (0.39-1.54)		2.16* (1.09-4.28)					

Adequate absorbent OR=1.00; Changed frequently OR=1.00; Drying outside OR=1.00; Don't worry about privacy OR=1.00; Adequate MHM strict OR=1.00; Adequate MHM relaxed OR=1.00

OR_{adj}: Odds ratio for multivariable models where all aspects of MHM were included in the model.

* $p < .05$, ** $p < .01$, *** $p < .001$, † $p < .10$

Discussion

Prevalence of poor MHM

This study was the first to provide a prevalence estimate for MHM consistent with the concept definition; *“women and adolescent girls using a clean menstrual management material to absorb or collect blood that can be changed in privacy as often as necessary for the duration of the menstruation period, using soap and water for washing the body as required, and having access to facilities to dispose of used menstrual management materials.”* (Sommer & Sahin, 2013). 90.5% (95%CI 85.6-93.9%) of the sample had inadequate MHM. This did not differ between those using reusable pads and those using other existing methods (71.3% cloth, 14.0% disposable sanitary pads, 14.7% other methods including toilet paper and underwear alone). Even when more relaxed criteria were used (use of sanitary pad, AFRIPad, old or new cloth, that was changed 2 or more times per day, with absorbents washed with soap and dried hung outside or inside, absorbents never worn damp, and girls reporting they were not worried about being observed washing their absorbent), the prevalence of poor MHM was 78.1% (95%CI 71.8-83.3%), and did not differ for those using reusable pads. By employing the current definition of the concept, this work has shown that reporting individual aspects of MHM alone underestimates the extent of deprivation. Furthermore, when MHM is considered as a whole, girls using reusable sanitary pads provided as part of the intervention trial did not report a lower prevalence of poor MHM. As such, the use of reusable sanitary pads alone may not improve girls' menstrual hygiene.

MHM behaviours reported by the sample are consistent with the rural context and poverty in the study area. The sample may be more disadvantaged, at least in terms of menstrual hygiene, than some past studies. A higher proportion of girls (who did not use AFRIPads) reported using cloth compared to studies of girls in rural India (pooled prevalence: 63%, van Eijk et al., 2016), and single-study estimates from East Africa

(24% in rural Kenya, Wilson, Reeve, & Pitt, 2014; 56% in Ethiopia, Tegegne & Sisay, 2014). A similarly high rate of cloth use (87%) was recently reported in the Rukungiri district of Uganda (Boosey, Prestwich, & Deave, 2014). There are far fewer studies with which to compare reports of washing or drying practices. Past studies have also failed to adequately report questions used to capture MHM practices, which limits comparison (see Hennegan, accepted [Thesis Chapter Three]). This study focused on the absorbent girls reported using most frequently.

Facilities for MHM were comparable across all study schools. Latrines were gender-separated but had few adequate doors or locks, and no access to water. Girls reported going home to change absorbents, and all stated that they washed and dried reusable absorbents at home, rather than at school. No survey items asked about transporting menstrual absorbents home for cleaning, which may have presented an additional challenge for girls and resulted in anxiety or stigma. Improvements to facilities for changing and cleaning absorbents at the schools may have improved MHM. While advocates have increasingly focused on the provision of facilities at school for MHM (Sommer et al., 2016), this was not the focus of the present study and the washing and drying practices reported in this sample were undertaken at home, rather than at school.

Consequences of poor MHM

High rates of negative outcomes were observed. Many girls reported genital irritation, discharge, and concerns about odour. Whilst self-reported symptoms may not be the best predictor of laboratory-confirmed infections (Kerubo et al., 2016), girls' discomfort and symptoms which may cause distress, represent important health outcomes. Over half the sample reported not standing to answer questions and difficulties concentrating in school. 69% of girls reported shame and insecurity during menstruation. High SDQ scores in the sample have been discussed elsewhere, in part consistent with high scores reported in low-income contexts, and a possible bias towards affirmative responses (see Montgomery et al., 2016 [Thesis Chapter Four]).

Large percent differences were observed using the pooled MHM measures for all consequences assessed. Unfortunately, the small proportion of girls with adequate hygiene meant there was insufficient power to detect many effects. Nevertheless, findings support the value of considering all aspects of MHM together.

There were few associations between aspects of MHM and health symptoms. As noted above this may reflect the poor validity of girls self-reports (Kerubo et al., 2016). Concerns about odour were associated with absorbent type, drying practices and privacy. AFRIpads provided as part of the *Menstruation and the Cycle of Poverty* trial were approximately 7-8 months old at the time of follow-up survey. As AFRIpads last 12 months, the deterioration of the pads is unlikely to have contributed to outcomes. However, if poorly maintained, the pads may not have been a clean absorbent, or associated with reduced irritation and infection.

Using unclean absorbents was associated with concerns about odour, difficulties in school concentration, and standing to answer questions. Actual soiling or fear of soiling and odour may mediate the identified relationship with school participation, and should be investigated in future work. Drying absorbents adequately was associated in an unanticipated direction with both odour concerns and reports of discharge. There may be multiple explanations for this finding. Firstly, girls drying absorbents outside may place them on unclean surfaces or on the ground, which may increase contamination. Drying outside may provoke concerns that absorbents will be seen, thus they may not be left to dry adequately. Consistency of reports between drying outside and never wearing absorbents damp, however, works against this interpretation. Whilst replication would be needed, findings have interesting implications for interventions which encourage outside drying. If conditions outside are unclean, this may cause unintended harm.

Concerns about privacy for washing absorbents were associated with many consequences including shame, insecurity, and disengagement at school. The privacy

item captured worry about privacy for washing absorbents, so associations may have been driven by girls' trait anxiety. However, it would be difficult to measure privacy more objectively, as adequacy is in many ways subjective (Winkler & Roaf, 2015). Girls' feelings of safety are likely to reflect some individual differences. In interpreting the associations between privacy for washing and outcomes, one explanation may be that girls who felt they were likely to be observed did not wash absorbents as well as those without this pressure. As noted above, high rates of reported washing with soap 'a/ways' are likely to be misleading. This also did not capture the quality of washing. Those washing absorbents quickly may have been unable to get them clean and properly prepared for future use and minimal odour. More research is needed to investigate the validity and reliability of these measures, and provide recommendations on criteria for adequate washing for health and odour prevention. Reports of perceived privacy for changing and drying absorbents represent important parts of the MHM concept definition which were not able to be captured by available measures in this study.

Only the frequency of absorbent change was significantly associated with school attendance, although the sample size was limited. Consistent with guidelines for MHM, girls changing their absorbents 3 or more times per day had a greater percentage of school days attended. This may be due to a lower rate of soiling, or concerns about soiling, amongst these girls as they used a fresh absorbent more often. This group of girls may feel more confident to change their absorbents at school, leading to greater attendance. Past literature (e.g., Pillitteri, 2011) and reports from local agents in the field in this study suggest many girls go home to change their absorbents. Interventions proposing to improve the quality of facilities for changing at school may therefore be effective in improving attendance for more girls. It should be noted that in order for girls to change three or more times per day they must have access to sufficient absorbents (cloth or pads) to do so, thus this may represent a more advantaged group and this study was unable to adjust for such sociodemographic confounds.

Strengths and limitations

The present study was undertaken in a difficult-to-reach population of adolescent girls in rural Uganda. The use of local research assistants and language improved access to the population and facilitated comfort with the interviewers. The prevalences of MHM behaviours are heavily dependent on the reliability of girls' reports and questions used, an issue that pervades MHM studies. The study found almost universal washing with soap. Whilst girls report that soap and water is available to them at home, qualitative interviews, site reports, and reports from the field suggest always washing absorbents with soap to be unlikely. Social desirability is likely to have influenced self-reported behaviours, urogenital symptoms, and the impact of menstruation on schooling. Interviewers were from the local NGO, well known in the area, with a recent campaign focused on girls' education (<https://plan-international.org/what-we-do/because-i-am-girl>). In addition, many had been involved in delivering the AFRipads to the girls. It is unclear if written surveys would have reduced social-desirability in responses, and may have introduced other biases given the low levels of literacy in the area. Additionally, this would have required costly translation of surveys and girls' responses.

The use of an objective measure of school attendance meant this was not subject to girls' self-reports, however, means this data reflects attendance across all days including both menstruating and non-menstruating days. This means effect sizes are limited, and the impact of confounds on attendance which pervade across non-menstrual days may have a greater influence than if only menstruating school days were compared. Future studies of menstrual-specific absence would provide a more specific measurement of menstrual and MHM-related absenteeism, but may be difficult to obtain as they are reliant on receiving girls' self-reports of their cycle. The distribution of AFRipads and education in the sample mean that the prevalences of MHM behaviours and consequences reported may not reflect practices prior to the interventions. As noted previously, a proportion of girls (n=60) not included in the *Menstruation and the Cycle of*

Poverty trial results were included in this study. While these girls were not included in the trial sample, many had been attending the study schools from very near the baseline assessment, and were comparable to girls in the trial, with many also receiving the interventions alongside the trial girls. This study used best available evidence to guide criteria for MHM estimates and predictive models; however, as noted, there is a dearth of literature to guide hygiene recommendations and research.

The cross-sectional and correlational nature of the research precludes causal inference. With regard to the prevalence of menstrual hygiene, this study compared girls who reported using AFRIPads provided in the trial as their primary absorbent to those using other methods when calculating MHM prevalence. While this presents a cross-sectional assessment of menstrual hygiene when using a reusable product, it does not reflect the effectiveness of providing reusable pads in an intervention. Girls' were not compared across the intervention arms, rather across the primary absorbent used. Those in the reusable pad arms who may have received AFRIPads but not used them, were grouped according to the absorbent they used most often. Cross-sectional relationships between MHM and health, education, and psychosocial wellbeing outcomes are limited by the inability to adjust for socio-demographic confounds. It is likely that greater access to resources is associated both with better MHM, and proposed consequences. Girls with greater access to resources are likely to have better health outcomes, family support for school attendance, fewer other challenges to psychosocial wellbeing. Thus, the study would have been greatly improved by the ability to adjust for socio-demographic factors such as parental education and poverty (van Eijk et al., 2016). The small sample size further limited these analysis. As this work was exploratory, and the first to estimate a combined measure of MHM and assess multiple aspects of MHM and their relationship to outcomes, there was very limited literature on which to base a-priori power analyses and none were undertaken. This study provides some indication of expected effect sizes to enable power analyses in future studies.

The nature of, and need for, a pooled estimate of MHM could be questioned. As argued in the background to this paper, this is useful for establishing the state of MHM in different populations and advocating for attention. It also promotes use of the MHM term consistent with its definition, and provides greater clarity around what should be considered predictors and consequences of MHM, rather than aspects of it. This highlights the need for alternate terminology capturing other factors such as menstrual taboos that impact on girls' menstrual management but are not MHM. Until evidenced-guidelines are developed, and comparable measures of MHM have been tested and used across studies, it is not advised to present only pooled estimates. The individual aspects that make up MHM will always be important individual factors, as indicated by the differential relationships with outcomes identified in this work. This paper presents a worked example of how the MHM concept could be operationalised. The aspects of the definition, placing equal value on each of these, and the cut off points used in this work could all be debated. More work is needed to guide research and practice.

Finally, the individual items available to appraise MHM in this study could be improved. MHM literature has paid insufficient attention to measurement issues and there are presently no validated questionnaires for assessing practices such as absorbent washing and drying (Hennegan, accepted [Thesis Chapter Three]). The measures in the present study could be improved upon in future work. Questions often asked about how girls '*usually*' dry or dispose of absorbents which may result in greater social desirability in responses than asking about the last menstrual period. Response options for drying items need improvement. Field work in the study found that girls drying absorbents outside would often do so under another piece of fabric which may reduce the UV benefits of drying outside. Drying pads 'hidden' lacks specificity which could be improved on in future work.

Implications for research and practice

Recent calls for action on MHM state the need for a strong quantitative evidence base (Sommer et al., 2016). This cannot be achieved without consistent reporting of MHM as defined. Prevalence estimates are needed to advocate effectively for action, establish hypothesised consequences, and measure improvements in intervention trials. Slow movement to address MHM deficits to date may reflect the present absence of quantitative prevalence figures and links to consequences. Confusion between what represents a predictor or aspect of poor MHM will continue without guidance and tools for measuring MHM as defined. This delays the development of a detailed, and quantitatively supported, problem theory of MHM. There is an urgent need for guidelines detailing the MHM concept, and criteria for adequacy in each aspect, as well as research guidance to establish a rigorous primary evidence base in this field.

Minimal correlations between aspects of MHM, and differential associations between aspects and consequences in multivariable models demonstrate unique impact of each facet. Findings suggest all MHM aspects must be considered in testing links with hypothesised consequences. Null results, particularly for psychosocial consequences, suggest more predictors may need to be considered. Hygiene management is not the only menstruation related challenge facing girls in low income contexts. Fear around menstruation due to lack of understanding, taboos and stigma may contribute to these outcomes. Whilst properly defining and measuring aspects of MHM, future studies must also investigate these other contributors to outcomes.

The present study suggests that using AFRIpads was not associated with a higher prevalence of adequate MHM. Whilst this study does not compare intervention conditions, findings suggest that improving only one aspect of MHM, the absorbent used, may not improve MHM overall. The *Menstruation and the Cycle of Poverty* trial did find that across conditions the provision of AFRIpads was effective in improving school attendance (Montgomery et al., 2016 [Thesis Chapter Four]). Thus, it may be that

addressing only one aspects of MHM is sufficient to improve outcomes, as suggested by differential associations in this study, but is insufficient to provide girls with their full right to MHM (Winkler & Roaf, 2015). The provision of a reusable product may have a negligible impact on MHM due to their dependency on washing, drying and privacy facilities which are unaffected by product-provision interventions. In the present study it may be that girls needed additional training in AFRIPad use beyond what was provided, to improve cleaning practices. Providing disposable pads, which do not require washing or drying and may be quicker to change, might have a larger impact on MHM. This should be investigated in future work. Inserted products including menstrual cups and tampons were not considered culturally appropriate in this population, but may present another alternative to reusable pads for future studies (Scott et al., 2013; Oster & Thornton, 2011; Mason et al., 2015; Averbach et al., 2009; Beksinska et al., 2015; Tellier, Hyttel, & Glad, 2012). In interpreting the primary trial results, which found improvements in school attendance following reusable pad provision (Montgomery et al., 2016 [Thesis Chapter Four]), it is likely that improvements to unmeasured aspects of menstrual management such as improving teachers' awareness of girls' needs or improved social support by prompting girls to discuss menstruation, may have contributed to these effects. More quantitative epidemiological studies and in-depth analysis of trial results, such as mediation analyses, are needed to fully understand the pathways of effect in interventions and maximise their future effectiveness.

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CHAPTER 6

Paper #5: Experience and appraisal of menstrual absorbents

Schoolgirls' experience and appraisal of menstrual absorbents in rural Uganda: a cross-sectional evaluation of reusable sanitary pads.

Julie Hennegan¹

Catherine Dolan²

Maryalice Wu³

Linda Scott⁴

Paul Montgomery¹

¹ Centre for Evidence-Based Intervention, University of Oxford, Oxford, UK

² SOAS, University of London, London, UK

³ Applied Technologies for Learning in the Arts and Sciences, University of Illinois, Urbana-Champaign, US

⁴ Said Business School, University of Oxford, Oxford UK

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Abstract

Background. Governments, multinational organisations, and charities have commenced the distribution of sanitary products to address current deficits in girls' menstrual management. The few effectiveness studies conducted have focused on health and education outcomes but have failed to provide quantitative assessment of girls' preferences, experiences of absorbents, and comfort.

Objectives. First, to quantitatively describe girls' experiences with, and ratings of reliability and acceptability of different menstrual absorbents. Second, to compare ratings of freely-provided reusable pads (AFRIPads) to other existing methods of menstrual management. Finally, to assess differences in self-reported freedom of activity during menses according to menstrual absorbent.

Design. Cross-sectional, secondary analysis of data from the final survey of a controlled trial of reusable sanitary pad and puberty education provision.

Methods. Participants were 205 menstruating schoolgirls from eight schools in rural Uganda. 72 girls who reported using the intervention-provided reusable pads were compared to those using existing improvised methods (predominately new or old cloth).

Results. Schoolgirls using reusable pads provided significantly higher ratings of perceived absorbent reliability across activities, less difficulties changing absorbents, and less disgust with cleaning absorbents. There were no significant differences in reports of outside garment soiling (OR 1.00 95%CI 0.51-1.99), or odour (OR 0.84 95%CI 0.40-1.74) during the last menstrual period. When girls were asked if menstruation caused them to miss daily activities, there were no differences between those using reusable pads and those using other existing methods. However, when asked about activities avoided during menstruation, those using reusable pads were less likely to report avoiding physical sports, working in the field, fetching water, and cooking.

Conclusions. Reusable pads were rated favourably. This translated into some benefits for self-reported involvement in daily activities, although reports of actual soiling and missing activities due to menstruation did not differ. More research is needed comparing the impact of menstrual absorbents on girls' daily activities, and validating outcome measures for menstrual management research.

Plain language summary⁴

Governments and charity organisations have proposed providing resources, such as reusable pads, to address the barrier that managing menstruation may present to girls' dignity, health, education, and psychosocial wellbeing. However, studies of sanitary product provision to date have not quantitatively tested girls' perceptions and experience of such products.

This study describes and compares schoolgirls' experiences of different menstrual absorbents. The work provides a follow-up to a controlled trial of reusable sanitary pad and puberty education provision which tested improvements in school attendance. By comparing the experiences between girls who received reusable sanitary pads as part of the trial and girls using other existing methods of menstrual absorption (predominantly cloth), this study provides insight into girls' comfort and preferences. A sample of 205 schoolgirls, from eight schools in rural Uganda were included in the study. 72 girls who were using the reusable pads provided in the intervention study were compared with those using existing improvised methods. A few girls were using disposable sanitary pads, and their results are displayed separately. Results found that girls rated the reusable pads positively. Girls using the reusable pads were more likely to report they were easy to change, and were not disgusting to clean. Those using the reusable pads rated them as more reliable to keep them from soiling during a range of activities. Despite more positive perceptions, there were no differences in girls' reports of soiling outer garments or experiencing odour during the last menstrual period. Results of the study are important in understanding girls' preferences and experiences of menstrual absorbents in low income contexts.

⁴ This section is a journal requirement of *Reproductive Health*

Background

Menstruation is a healthy and natural process for women and adolescent girls. The management of menstruation has varied over time and differs with available resources, cultural traditions, and preferences. There is increasing recognition that in low-income contexts, women struggle to manage menstruation in effective and hygienic ways (Sommer, Hirsch, Nathanson, & Parker, 2015). This has been linked to negative impacts on health, education and wellbeing (Winkler & Roaf, 2015; Das et al., 2015). A lack of clean and reliable menstrual absorbents has received much of the attention, with interventions focussed on the provision of these products to improve poor menstrual hygiene and associated consequences (Sumpter & Torondel, 2013; Hennegan & Montgomery [Thesis Chapter Two]). There has been a proliferation of programs and organisations providing girls with menstrual absorbents, most frequently reusable or disposable pads (Proctor & Gamble, 2010; Garg, Goyal, & Gupta, 2012; Ameade & Majeed, 2015). A recent systematic review of studies evaluating the effectiveness of such interventions found few rigorous trials had been conducted (Hennegan & Montgomery, 2016 [Thesis Chapter Two]). The review identified only 3 studies of menstrual product provision, each assessing a different product; menstrual cups (Oster & Thornton, 2010), disposable sanitary pads (Montgomery, Ryus, Dolan, Dopson, & Scott, 2012), and home-made reusable pads (Wilson, Reeve, & Pitt, 2014).

Whilst results of these trials seem promising with regard to school attendance, some have criticised menstrual management research for taking for granted the inadequacy of existing local methods (Joshi, Buit, & Gonzalez-Botero, 2015). Further, focus on hygiene and education outcomes may have minimised the importance of women and girls' right to dignity and comfort during menstruation (Winkler & Roaf, 2015). Trials and observational studies have often overlooked girls' perceptions of absorbent acceptability, reliability and comfort, as well as absorbents' impact on self-efficacy. These outcomes are critical for many reasons. Firstly, school absenteeism

during menstruation is frequently attributed to soiling or the fear of garment soiling. As a result, trials providing menstrual absorbents may assume that observed improvements to school attendance result from a reduced risk of soiling, but none have reported on this outcome explicitly or tested it as a mediating pathway. Secondly, menstrual management programs typically provide only one type of product, which may be delivered alongside explicit education or proscriptive norms which discourage the use of existing improvised absorbents such as cloth. This could be seen as limiting girls' choices for menstrual management, particularly in comparison to high-income contexts where women and girls may use a range of different products during menses. This places more pressure on ensuring the acceptability and adequacy of the products provided before interventions are implemented at scale. Further, if trials focus exclusively on school attendance and fail to report on other outcomes which have been neglected to date such as comfort, acceptability, or self-efficacy, sanitary product distribution interventions may be abandoned if education provision alone is found to be equally effective in improving attendance, as has been the case in recent studies (Montgomery et al., 2012; Montgomery, Hennegan, Dolan, Wu, Steinfeld, & Scott, 2016 [Thesis Chapter Four]).

Girls' dignity must be kept at the forefront of primary research and intervention studies of menstrual management. Assessment of reliability, comfort, and satisfaction with activities such as changing and washing absorbents put girls' agency and preferences at the centre of program evaluation. The present study is the first to do this quantitatively, providing a cross-sectional follow-up to the *Menstruation and the Cycle of Poverty* trial (Montgomery et al., 2016) and evaluates reusable pads as an alternative to existing improvised methods. Reusable pads are assessed in terms of girls' experiences, preferences and self-reported leaking, odour, and avoidance of daily activities during menses. The study compares ratings between those using reusable pads provided as part of the trial, and those using existing improvised menstrual

absorbents (including cloth, toilet paper, and underwear alone). A small group of girls reported using commercially produced sanitary pads and their ratings are displayed separately.

Past trials of menstrual product provision have addressed some of these questions with qualitative reports or field observations of product acceptability and uptake (Oster & Thornton, 2010; Wilson, Reeve, & Pitt, 2014; Dolan, Ryus, Dopson, Montgomery, & Scott, 2013). The *Menstruation and the Cycle of Poverty* trial (Montgomery et al., 2016) assessed here, conducted a pilot assessment of menstrual products. Prior to trial implementation girls in a different region provided feedback on proposed absorbents for intervention compared to each other and existing methods such as cloth or underwear alone (see Scott, Montgomery, Steinfield, Dolan, & Dopson, 2013). While reported reusable pad acceptability was high, only 44% of the sample reported they would switch from their existing methods (possibly due to a high baseline rate of disposable sanitary pad use). Other studies have found qualitative evidence of acceptability of menstrual cups, but it is unclear if these would be preferred to other methods if offered (Mason et al., 2015). A recent study of women in a high income context, where other products such as pads and tampons are available, found only 55% reported they would continue using a menstrual cup after an acceptability study (Stewart, Greer, & Powell, 2010). Whilst some positive endorsement is evidenced here, findings indicate individual differences in preferences, and that acceptability and experience measures must be taken into account in trials of product provision interventions beyond preliminary qualitative studies. Quantitatively reported outcomes would allow comparison between different products trialled. While some have suggested that large trials of multiple products may be needed to best maximise outcomes for women and girls (Sumpter & Torondel, 2013; Mason et al., 2015), quantitative reports across studies of girls' experiences would also allow for comparisons and help identify products which have a demonstrated benefit for health and education outcomes, as well

as girls' comfort. This evaluation is needed to provide agents in the field and policy makers with the breadth of information necessary for large-scale dissemination of programs to be considered.

The present study

This paper follows-up the *Menstruation and the Cycle of Poverty* trial with a secondary analysis of data from the surveys conducted at the end of the trial. The trial and primary outcomes have been described elsewhere (see Montgomery et al., 2016 [Thesis Chapter Four]). In brief, the study was conducted between January 2012 and December 2014 in Kamuli district, Uganda, in rural areas characterised by poor performance on health and education indicators, and a literacy rate below the national average (Montgomery et al., 2016; Republic of Uganda, 2008). Eight schools were quasi-randomised (in alphabetical order) to one of four conditions: puberty education alone, reusable pad provision alone, puberty education and reusable pad provision, or no intervention control. The education provided was a 1.25hr session following the Straight Talk training guide (see Montgomery et al., 2016 [Thesis Chapter Four]). While the pilot study in Ghana (see Montgomery et al., 2012) provided disposable pads for improved school attendance, the *Menstruating and the Cycle of Poverty* trial tested reusable pads (AFRIPads, described in methods). This change followed environmental concerns and difficulties disposing of single-use pads in the pilot, as well as the high cost and limited availability of disposable pads for long-term provision (Scott et al., 2013).

This paper presents a secondary analysis of the final survey data to extend upon the trial findings by providing a detailed assessment of girls' perceptions of the pads provided, their comfort, as well as the impact of the reusable pads on daily activities beyond school attendance.

Objectives

1. To describe girls' access and use of existing menstrual absorbents in the survey sample.
2. To compare the experience, including the ease of changing and cleaning menstrual absorbents, between those using reusable pads and those using existing improvised methods.
3. To compare girls' ratings of absorbent reliability in different situations between reusable pads and existing improvised methods.
4. To test if girls using reusable pads felt greater freedom to participate in daily activities than those using existing methods.
5. To provide a brief description of girls' appraisals of the reusable pads including how much they liked them and if they would purchase the pads if not freely available.

Methods

This study was conducted and reported according to best practice guidelines in the Strengthening the Reporting of Observational studies in Epidemiology statement (von Elm et al., 2008). The checklist for cross-sectional studies is reported in Appendix 6.1.

Participants

Girls attending the trial schools at baseline were recruited into the *Menstruation and the Cycle of Poverty* trial. In addition, girls who transferred into the study schools during the trial were included in intervention delivery (of reusable pads and education) and in the final survey as not to stigmatise trial girls or discriminate against non-trial girls in resource provision. Similarly, non-menstruating girls were surveyed as not to identify menstruating girls. While those who transferred to the study schools could not be included in the intention-to-treat analyses of primary trial outcomes, they were incorporated in the final survey data set for secondary analyses.

Across the eight schools, 435 girls completed the final follow-up survey of the *Menstruation and The Cycle of Poverty* trial. Of these, 205 had reached menarche at the time of survey and were included in the present study.

In the present study, 145 girls (70.7%) were attending the trial schools at baseline and a part of the *Menstruating and the Cycle of Poverty* trial intention-to-treat sample. Of these, 67 (46.2%) received the reusable pads. A further 60 girls who had not been attending the study schools at baseline, but transferred into these schools during the trial are also included in the present study. Of these girls, 20 (33.3%) had received reusable sanitary pads. Of the 205 girls included in this study, 64 (31.2%) had received the education intervention. Girls were compared according to the menstrual absorbent they reported using, irrespective of trial condition.

Materials

Reusable pads were provided to girls in four of the eight trial schools (for the reusable pads alone, and reusable pads and puberty education conditions). These were provided in October 2012, and March 2014. Girls were given a single pack of AFRIPads, underwear, and a small quantity of omo soap (1 sachet, 45 grams). AFRIPads are a reusable cloth pad produced locally in Uganda. Packs provided included soil-resistant 'base' pads that fastened to underwear, 3 winged pads, and 3 straight pads, along with 2 bags for transporting pads (see <http://www.afripads.com/>). This was considered the 'deluxe menstrual kit' by AFRIPads at the time of delivery (see Figure 6.1). Instructions on using and cleaning the reusable pads were provided by trained local research assistants alongside delivery.



Figure 6.1. AFRIPads menstrual kits, 2012 (source: <http://afripads.com/>)

Measures

The follow-up survey was administered in November 2014. English surveys were loaded on iPads (using an offline app for *SurveyGizmo*) and delivered verbally in the local language (Lusoga), with trained research assistants from the partner NGO inputting responses in English. Research assistants were local young women, and

visited the study schools in teams. For the survey, girls were taken aside to a private space and interviewed individually. If girls were absent on the day of interview, additional school sweeps were undertaken to survey all girls. Survey items required a response before progressing, or interviewers could indicate a '*don't know/no answer*' response if girls' did not provide an answer. Survey interviews lasted approximately 30-40 minutes for menstruating girls.

The survey was developed by the research team in consultation with stakeholders and the partner NGO. Core items had been piloted in Ghana (Montgomery et al., 2012). Qualitative feasibility and acceptability work was undertaken prior to trial implementation, both in the local area, and similar regions (see Scott et al., 2013). This further shaped question development, as did existing menstrual hygiene literature. For transparency all survey items are reported in full in Appendix 5.2.

Participant characteristics

Girls self-reported their age, school grade, and how long it took them to get to school each day.

Menstrual absorbent use

Menstrual absorbent use was captured through the item: "*What do you usually use to catch/absorb your MP (menstrual period)?*" and girls provided a free response and resulted in the following responses: AFRIPad, cloth, sanitary pad or other items including toilet paper, underwear alone, mattress, or sponge. Follow-up items asked girls who provided their menstrual absorbent as a free response, responses included: the girls' mother, another family member, or herself. Girls were asked where absorbents were obtained which was used to code if new or old cloth was being used. The menstrual absorbent categories are the same as reported in an additional secondary analysis paper on menstrual hygiene practices (Hennegan, Dolan, Wu, Scott, & Montgomery, 2016 [Thesis Chapter Five]).

Girls provided number responses to questions: *“how many pieces of cloth do you have?”* and *“how many pieces of cloth do you use a day?”*. They were also asked to report (Yes/No) if they shared cloth with anyone in their household. Girls provided yes/no responses to indicate whether or not they had underwear, and if they wore underwear with their menstrual absorbent.

Cleaning and changing absorbents

Girls provided a numbered response to the question: *“How many minutes does it take for you to change your sanitary protection?”*. They were asked if they were able to *“go for a full day without changing protection”* with response options *“no, never”*, *“yes, on some days”* and *“yes, always”*. Girls were asked to rate on a 3-point Likert scale if changing their absorbent at school was *“not a problem at all”*, *“a little bit of a problem”* or *“a big problem”*. Girls provided yes/no responses to items asking if they washed their absorbents, used soap, used clean water for washing, and if water was hot or cold. Girls also provided a yes/no response to the item *“Did you feel disgusted by washing the pad/cloth?”*. Absorbent drying time was reported as the number of hours the pad or cloth took to dry, and girls reported if they wore their absorbent damp *“never”*, *“sometimes”*, or *“often”*.

Absorbent reliability

Girls were asked: *“Do you feel you can rely on this method [most frequently used absorbent] to keep you from soiling when you have to...”* followed by the list of activities reported in results tables. They reported that leaking when using their absorbent was *“not at all a problem”*, *“a little bit of a problem”* or *“a big problem”*. Girls reported if they worried about odour: *“never”*, *“rarely”*, *“sometimes”*, *“often”* or *“all of the time”*. This was followed by a question asking girls to report on the situations in which they worried about odour. Girls provided yes/no responses to if they had experienced a list of events during their *last menstrual period*, including odour, and outside garment soiling.

Restrictions due to menstruation

Girls were asked if their menstruation *ever causes* them to miss or avoid certain activities. Interviewers read a list of activities such as physical exercise or being around males and girls reported if their menstruation caused them to miss or avoid this activity. Similarly, girls provided a yes/no response to the item: “*are there any activities or settings that you avoid while on your menstrual period?*”. For those who indicated that there were, girls were asked to list them. Girls were also asked: “*do the boys you know tease girls about their MP (menstrual period)?*”, and provided yes/no responses.

Reusable pad ratings

For girls who reported that they had received reusable pads, items captured how much they liked them (from “*dislike very much*” to “*like it very much*” on a 4-points scale). Girls were asked how likely they would be to purchase such pads if they had the resources to do so (from “*not at all likely*” to “*extremely likely*” on a 5-point scale, with mid-point of “*moderately likely*”).

Analyses

Analyses were conducted with Stata 14.0. Descriptive statistics captured participant characteristics and schoolgirls’ satisfaction with reusable pads. Description of girls’ experiences and reliability ratings are presented for each type of absorbent (reusable pads, new or old cloth, disposable sanitary pads, or other which included toilet paper, mattress, and underwear alone). However, there was insufficient power to compare differences in experience and reliability across the 5 absorbent types. It was not deemed appropriate to group commercial sanitary pads, as a purpose-built menstrual absorbent, with other improvised methods such as cloth. Thus, the existing improvised absorbents (new or old cloth, or other absorbents including toilet paper, mattress, and underwear alone) were compared with girls using the reusable pads received as part of the *Menstruating and the Cycle of Poverty* trial. Additional sensitivity

analyses (available from corresponding author on request) included girls using disposable sanitary pads in the comparison group as a treatment-as-usual comparison and found no difference in the pattern of observed effects. Experiences of girls using disposable sanitary pads are retained in tables but there was insufficient power to test statistically significant differences for this group. Girls using reusable pads were compared to those using improvised methods using binary logistic regressions for dichotomous outcomes, and *t*-tests for continuous outcomes. Reference categories for logistic regressions were selected to favour positive odds ratios for more intuitive interpretation for readers.

Ethics

Ethical approval was received from: the Social Science & Humanities Inter-Divisional Research Ethics Committee at the University of Oxford (Ref: SSD/CUREC1/11-056), the AIDS Support Organisation (TASO) Institutional Review Committee Uganda (TASOIRC/022/14-UG-IRC-009), and the University of Illinois (#12236). When completing the survey girls provided verbal consent. Those who participated in the trial provided written-consent, as did their parent/caregiver. No girls declined participation. Girls were informed that they could decline to answer any question in the survey. Schools provided consent for participation throughout the trial.

Results

Participant characteristics

Girls' self-reported age ranged from 10 to 19 years ($Mean=14.20, SD=1.12$), with the majority (86.9%) aged 13 to 15. The average age at menarche was 12.82 years ($SD=1.28$). Most girls were in upper primary school (Primary class (P) P5: 21.5%, P6: 44.9%, P7: 24.9%) and attended the same school last year (94.6%). When asked how long it took them to get to school 37.7% reported an 11-30-minute walk, 37.7% a 31-60-minute walk, and smaller proportions reported a walk less than 10 minutes (19.8%) or longer than 1 hour (4.8%).

Menstrual absorbents

201 girls answered questions about the type of absorbent they used most frequently. Of these, 72 girls (35.8%) used reusable pads, 30 (14.9%) new cloth, 62 (30.9%) old cloth, 18 (9.0%) disposable sanitary pads, and 19 (9.5%) 'other' methods including toilet paper, underwear alone, mattress, or sponge. 100% of girls in the sample stated that they had underwear and 97.6% reported that they wore underwear with sanitary protection. Table 6.1 describes girls' access to the different menstrual absorbents. For girls who did not receive reusable pads, new cloth was more often provided by mothers, and old cloth more often obtained by girls themselves. Girls using new cloth reported having more cloth, and using more pieces per day. Few girls reported sharing cloth.

Table 6.1. Schoolgirls' self-reported access to absorbents

	Reusable pad N=72	New cloth N=30	Old cloth N=62	Disposable sanitary pad N=18	Other N=19
	%(N)	%(N)	%(N)	%(N)	%(N)
Who provides you with your absorbent?					
Obtain myself	-	13.3 (4)	59.7 (37)	5.6 (1)	31.6 (6)
Mother	-	76.7 (23)	32.3 (20)	72.2 (13)	26.3 (5)
Other household member	-	6.7 (2)	8.1 (5)	5.6 (1)	10.5 (2)
AFRIPads (intervention)	100 (72)	-	-	-	-
Other (hospital doctor)	-	3.3 (1)		16.7 (3)	5.3 (1)
<i>Don't know/no answer</i>					26.3 (5)
Anyone else in your house use this absorbent?					
Yes	-	53.3 (16)	45.2 (28)	72.2 (13)	36.8 (7)
No	-	40.0 (12)	50.0 (31)	27.8 (5)	36.8 (7)
<i>Missing or Not Applicable</i>	100 (72)	6.7 (2)	4.8 (3)	0 (0)	26.3 (5)
How many pieces of cloth do you have?					
1-2		7.7 (2)	25.9 (15)		
3-4		50.0 (13)	37.9 (22)		
5+		42.3 (11)	36.2 (21)		
How many pieces of cloth do you use a day?					
1-2		38.5 (10)	53.5 (31)		
3+ (max reported 6)		61.5 (16)	46.6 (27)		
Do you share cloth with anyone else in your household?					
Yes		0 (0)	3.4 (2)		
No		100 (26)	96.6 (57)		

Experience of cleaning and changing menstrual absorbents

Table 6.2 displays girls' changing and cleaning practices. The left side of the table compares reusable pads to existing improvised methods combined, while the right section of the table presents the proportion of behaviours broken down across absorbent types. Girls using reusable pads reported that it took them less time to change, and were more likely to report that it was "*not a problem at all*" to change at school. They were less likely to report that they could go a whole day without changing their absorbent.

Of girls using reusable absorbents (AFRIPads, cloth), almost all (98.0%) reported washing them. Of those, 98.0% reported using soap every time. Almost all (98.7%) reported using clean water, and most reported that it was cold (89.0%). Girls using the reusable pads were more likely to report that they were not disgusted by washing their absorbent, in contrast to those using cloth. Although those using the pads reported longer drying times, they were more likely to report never wearing them damp.

Table 6.2. Experience of changing and cleaning absorbents compared between those using reusable pads and existing improvised methods

	Reusable pad N=72	Existing improvised methods N=111	OR (95%CI) (Existing method OR= 1.00)	Existing improvised methods (disaggregated)			Sanitary pad N=18
				New cloth	Old cloth	Other	
				N=30	N=62	N=19	
Changing absorbents							
How many minutes does it take for you to change your sanitary protection? (n=178)							
Minutes <i>M(SD)</i>	6.36 (11.75)	10.85 (13.96)	d=0.35 (0.04-0.64)	9.17 (13.94)	11.46 (14.54)	11.61 (12.43)	10.44 (12.27)
	%(N)	%(N)		%(N)	%(N)	%(N)	%(N)
0-4 minutes	69.6 (48)	49.5 (54)	2.24 (1.19-4.23)	53.3 (16)	50.8 (31)	44.4 (8)	44.4 (8)
5+ minutes	30.4 (21)	50.5 (55)	1.00	46.7 (14)	49.2 (30)	55.6 (10)	55.6 (10)
Are you able to go to school for a full day without changing your protection? (n=180)							
No, never	70.8 (51)	50.9 (55)	1.00	53.3 (16)	49.2 (30)	52.9 (9)	61.1 (11)
Yes, on some days	13.9 (10)	23.2 (25)	0.43 (0.23-0.80)	16.7 (5)	31.2 (19)	5.9 (1)	11.1 (2)
Yes, always	15.3 (11)	25.9 (28)		30.0 (9)	19.7 (12)	41.2 (7)	27.8 (5)
How much of a problem is it to change your sanitary protection at school? (n=140) ¹							
Not a problem at all	41.0 (25)	7.6 (6)	8.44 (3.18-22.43)	14.3 (3)	4.2 (2)	10.0 (1)	38.5 (5)
A little bit of a problem	29.5 (18)	32.9 (26)	1.00	38.1 (8)	31.3 (15)	30.0 (3)	46.2 (6)
A big problem	29.5 (18)	59.5 (47)		47.6 (10)	64.6 (31)	60.0 (6)	15.4 (2)

Cleaning absorbents							
	%(N)	%(N)		%(N)	%(N)	%(N)	%(N)
Did you feel disgusted by washing the absorbent?							
(n=154) ²							
Yes	22.5 (16)	48.2 (40)	1.00	65.4 (17)	40.4 (23)		
No	77.5 (55)	51.8 (43)	3.20 (1.58-6.46)	34.6 (9)	59.7 (34)		
How long did it take the absorbent to dry completely? (n=151) ²							
2hrs or less	26.1 (18)	48.8 (40)	1.00	50.0 (13)	48.2 (27)		
3-4hrs	30.4 (21)	29.3 (24)		23.1 (6)	32.1 (18)		
5-6hrs	26.6 (17)	11.0 (9)	2.74 (1.35-5.55)	11.5 (3)	10.8 (6)		
7hrs +	18.8 (13)	11.0 (9)		15.4 (4)	8.9 (5)		
How often did you wear the absorbent damp? (n=154) ²							
Never	85.9 (61)	69.9 (58)	2.63 (1.16-5.95)	61.5 (16)	73.7 (42)		
Sometimes	6.9 (5)	6.0 (5)	1.00	11.5 (3)	3.5 (2)		
Usually	6.9 (5)	24.1 (20)		26.9 (7)	22.8 (13)		

¹ Of girls who reported they could not go a whole day without changing their absorbent at school,

² Of girls who reported washing and reusing their absorbent, and not asked of girls using disposable sanitary pads or 'other' absorbent

Absorbent reliability

Girls' ratings of perceived reliability and their experience of using their absorbent are displayed in Table 6.3. Again, the left side of the table displays comparison between those using the reusable pads and a pooled total of those using existing improvised methods, which are broken down by absorbent type in the right section of the table. The ratings for the few girls using commercial disposable sanitary pads are displayed in the far right column for comparison.

Girls using reusable pads reported significantly higher perceptions of reliability across all listed activities than those using existing methods. They were also much more likely to report that leaking was "*not a problem at all*". Despite large differences in the self-reported belief that they could rely on the reusable pads to keep them from soiling across situations, there were no differences in reports of experiencing actual panty or outer garment soiling, odour, or fear that sanitary protection would fall out of underwear. There were also no differences in reported concerns about odour. Follow-up items (not included in the table) found that for those who did worry about odour (n=117), they worried about odour at school (87.2%), around males (39.3%) and in other environments (e.g., church, market) (53.9%).

Table 6.3. Schoolgirls' ratings of absorbent reliability compared between those using reusable pads and those using existing improvised methods

	Reusable pad N=72	Existing improvised methods N=111	OR (95%CI) (Existing method OR=1.00)	Existing improvised methods (disaggregated)			Sanitary pad N=18
				New cloth N=30	Old cloth N=62	Other N=19	
	%(N)	%(N)		%(N)	%(N)	%(N)	%(N)
Do you feel you can rely on this absorbent to keep you from soiling when you have to...							
Walk a long distance	75.7 (53)	37.7 (40)	5.14 (2.62-10.08)	43.3 (13)	37.1 (23)	28.6 (4)	88.9 (16)
Be gone from home for a long time	75.7 (53)	40.6 (43)	4.31 (2.23-8.35)	40.0 (12)	40.3 (25)	42.9 (6)	77.8 (14)
Move quickly or strenuously	73.6 (53)	49.1 (52)	2.90 (1.52-5.54)	46.7 (14)	46.8 (29)	64.3 (9)	72.2 (13)
Sit for a long time	68.1 (49)	35.9 (38)	3.81 (2.02-7.19)	23.3 (7)	38.7 (2)	50.0 (7)	77.8 (14)
Be around males	59.2 (42)	28.6 (30)	3.62 (1.92-6.83)	27.6 (8)	25.8 (16)	42.9 (6)	66.7 (12)
Go to the farm	88.6 (62)	60.0 (63)	5.17 (2.25-11.89)	55.2 (16)	61.3 (38)	64.3 (9)	100 (16)
Go to school	90.1 (64)	53.8 (57)	7.86 (3.30-18.74)	60.0 (18)	51.6 (32)	50.0 (7)	100 (17)
Go to the market	83.3 (60)	43.4 (46)	6.52 (3.15-13.52)	46.7 (14)	40.3 (25)	50.0 (7)	88.2 (15)
How much of a problem is leaking when using this absorbent? (n=174)							
Not a problem at all	55.6 (40)	14.71 (15)	7.25 (3.53-14.87)	4.6 (1)	14.8 (9)	38.5 (5)	72.2 (13)
A little bit of a problem	34.7 (25)	35.3 (36)	1.00	64.3 (18)	27.9 (17)	7.7 (1)	22.2 (4)
A big problem	9.7 (7)	50.0 (51)		32.1 (9)	57.4 (35)	53.9 (7)	5.6 (1)
Do you often worry about odour? (n=181)							
Never	42.3 (30)	40.0 (44)	1.10 (0.60-2.01)	40.0 (12)	41.0 (25)	36.8 (7)	38.9 (7)
Rarely/Sometimes	19.7 (14)	29.1 (32)	1.00	23.3 (7)	32.8 (20)	26.3 (5)	44.4 (8)
Often/All the time	38.0 (27)	30.9 (34)		36.7 (11)	26.2 (16)	36.8 (7)	16.7 (3)
During your last menstrual period did you experience... (n=140)¹							
Fear of panty soiling	60.0 (33)	54.1 (46)	1.27 (0.64-2.53)	54.6 (12)	53.2 (25)	56.3 (9)	61.5 (8)
Odour	29.1 (16)	32.9 (28)	0.84 (0.40-1.74)	31.8 (7)	38.3 (18)	18.8 (3)	23.1 (3)
Outside garment soiling	43.6 (24)	43.5 (37)	1.00 (0.51-1.99)	45.5 (10)	44.7 (21)	37.5 (6)	61.5 (8)
Fear that sanitary protection would fall out of underwear	47.3 (26)	49.4 (42)	0.92 (0.47-1.81)	63.6 (14)	46.8 (22)	37.5 (6)	23.1 (3)

¹ An error in the survey application meant in 38 cases this item failed to load, a further 10 girls did not respond

Freedom to participate in daily activities

A total of 116 girls (63.4%, excluding those using sanitary pads) reported that there were activities or settings they avoided when menstruating. Table 6.4 presents the activities girls reported missing due to menstruation as well as activities or settings they avoid, according to menstrual absorbent. There were no significant differences in the daily activities girls reported their menstruation caused them to miss. Similarly, there was no difference in girls reporting that there were activities or settings they avoided while menstruating. Of those who did report avoiding activities or settings, girls using existing methods were more likely to report avoiding physical sports or exercise, working in the field or garden, fetching water, or cooking. There were no differences in reported avoidance of being around males, playing with other children, or other going to school. Despite a large (almost 10%) difference between the proportion of girls reporting boys teased girls about their menstruation, favouring existing methods, this difference was not significant (although trended towards significance, $p=.208$).

Table 6.4. Comparison of participation in daily activities between reusable pads and existing improvised methods

	Reusable pad N=72	Existing improvised methods N=111	OR (95%CI) (Reusable pad OR= 1.00)
	%(N)	%(N)	
Does your menstruation ever cause you to: (n=169)			
Miss school	17.2 (11)	21.9 (23)	1.35 (0.61-3.00)
Not do your homework	6.3 (4)	8.6 (9)	1.41 (0.41-4.77)
Miss work in the field	17.2 (11)	21.0 (22)	1.28 (0.57-2.85)
Be unable to play with other children	37.5 (24)	41.9 (44)	1.20 (0.64-2.27)
Avoid physical sports/exercise	37.5 (24)	43.8 (46)	1.30 (0.69-2.45)
Avoid being around males	60.9 (39)	49.5 (52)	0.63 (0.33-1.18)
Avoid chores	7.8 (5)	5.7 (6)	0.72 (0.21-2.45)
Avoid sex	39.1 (25)	41.9 (44)	1.13 (0.60-2.12)
Are there activities or settings that you avoid while menstruating? (n=183)			
Yes	67.6 (48)	61.8 (68)	1.00
No	32.4 (23)	38.2 (42)	1.29 (0.69-2.41)
No answer	1	1	
Activity or setting (n=116) ¹			
Serving food and beverages to guests	6.3 (3)	11.8 (8)	2.00 (0.50-7.97)
Being around males	56.3 (27)	45.6 (31)	0.65 (0.31-1.37)
Fetching water	18.8 (9)	41.2 (28)	3.03 (1.27-7.25)
Cooking	8.3 (4)	26.5 (18)	3.96 (1.25-12.59)
Being in a sacred space	0 (0)	7.4 (5)	-
Physical sports/exercise	10.4 (5)	36.8 (25)	5.00 (1.75-14.28)
Playing with other children	35.4 (17)	38.2 (26)	1.13 (0.52-2.43)
Working in the field/garden	2.1 (1)	29.4 (20)	19.58 (2.53-151.85)
Going to school	6.3 (3)	8.8 (6)	1.45 (0.34-6.12)
Doing homework	0 (0)	4.4 (3)	-
Do the boys you know tease girls about their menstruation? (n=183)			
Yes	52.8 (38)	43.2 (48)	1.00
No	47.2 (34)	56.8 (63)	1.47 (0.81-2.66)

¹ Of girls who reported there were activities or settings they avoided while menstruating

Reusable pad use and appraisal

While 72 girls in the sample reported most frequently using the reusable pads as their absorbent, a further 4 received but never used them, 5 received the pads and used them a few times before discontinuing use, and 14 received the reusable pads and continued using them (but did not report them as their main absorbent). Of the 23 girls who reported using reusable pads but did not report these as their primary menstrual absorbent, 6 were using new cloth, 8 were using old cloth, 2 were using sanitary pads and 2 were using other methods.

Of girls who never used the reusable pads, 1 reported this was because they were stolen, 2 because they trusted regular pads more, and 1 because she did not know how to dispose of them. Of those who discontinued pad use, 2 reported that they preferred regular disposable pads, 1 that she had lost them, 1 that she felt the reusable pads burned, and 1 because they “*did not look like they would work well*”. No items captured reasons girls most frequently used alternate absorbents for the 14 who had not reported discontinued reusable pad use.

Table 6.5 displays girls’ appraisal of the reusable pads provided. The table includes girls who reported reusable pads as their usual absorbent, as well as those who had received and used them at least once.

Table 6.5. Schoolgirls' appraisal of the reusable pads (n=91)

	%	N
How much did you like the AFRIPad?		
Dislike it very much	2.2	2
Dislike it a little	1.1	1
Like it a little	4.4	4
Like it very much	92.3	84
AFRIPads cost 15,000 shillings (UGX)¹ and last for a year. Would you be able to afford them?		
No	52.3	46
Maybe	2.3	2
Yes	45.5	40
If you had 15,000 shillings, how likely would you be to buy the AFRIPads?		
Not at all likely	3.4	3
Slightly likely	14.8	13
Moderately likely	1.1	1
Very likely	37.5	33
Extremely likely	43.2	38

¹ for reference, in the local area: school fees for one term 10,000 UGX, exercise book 200 UGX, soap (small piece) 500 UGX, soap (regular bar) 2000 UGX, laundry detergent (small bag) 2500 UGX, petticoat 1500 UGX, maize flour 1kg 1500 UGX, rice 1kg 3000 UGX.

Discussion

The present study was the most comprehensive quantitative assessment to date comparing girls' experiences of different menstrual absorbents in a low income context. Specifically, comparing reusable sanitary pads to existing improvised methods, predominantly cloth, in rural Uganda. The reusable pads tested here, AFRIPads, received favourable ratings. They were reported to be quicker to change, less of a problem to change at school, and less disgusting to wash than other absorbents. Although these pads took longer to dry, girls were less likely to report wearing them damp. This may be a true difference as a result of the accompanying instruction not to wear them damp, or may represent social desirability bias in reporting, as girls knew they were not supposed to wear the pads damp.

Girls reported that they felt the reusable pads were more reliable to keep them from soiling in a variety of settings. Perceptions of reliability ranged from 68-90% for those using reusable pads compared to 29-54% for those using existing improvised methods. Interestingly, among the highest ratings of 90% and 54% reliability were for protection from soiling when going to school. This is highly suggestive of girls providing biased, desired responses. Girls reported the lowest reliability of absorbents when sitting for a long time (68% and 36% for pads and existing improvised methods, respectively), one of the main school activities. Similarly, girls rated reliability when they needed to be gone from home for a long time as 76% and 41% for reusable pads and improvised methods, another aspect of the school day which did not corroborate girls' ratings of absorbent reliability when at school. As AFRIPads were the only product provided in the intervention, this study was unable to test if girls would have rated other provided products more highly (e.g., other types of reusable pad, reusable menstrual underwear, tampons). Only a very small group used disposable sanitary pads, which may have been favoured and showed high ratings. No girls reported using inserted methods. Girls reported liking the reusable pads, although half reported that they would not be able to

afford them. Girls stated they would be likely to spend money on these products if they had the funds available but they were not asked if they would favour other types of products; an important consideration for future research.

The above ratings indicate positive perceptions of reliability of the reusable pads, and may indicate better performance. However, they also highlight issues with current outcome assessment in menstrual management research and discrepancies between girls' perceptions of absorbents and their lived experience (Joshi, Buit, & Gonzalez-Botero, 2015). While girls using reusable pads had 8.44 times higher odds of reporting leaking was not a problem and reported higher perceptions of reliability, there were no differences in reported outer garment soiling during the last menses (44% for both those using reusable pads and those using improvised methods). These high proportions suggest that the provision of better absorbents may not be sufficient to protect against embarrassment. More research is needed on the frequency of soiling and contributing factors (e.g., wearing pads for too long, underwear quality, inadequate absorbents, being unprepared for menstruation and soiling when menstruation commences). It is also difficult to determine from these results if the reusable pads were more reliable absorbents, or only perceived to be so. Future work which collects objective measures of absorbency and fluid retention may answer these questions with regard to product development. Improved outcome measures may capture the time and causes of soiling which may also distinguish between absorbent failure and behavioural predictors of soiling. Similar rates of odour and concern about odour were reported for reusable pads and other absorbents. This could reflect other aspects of menstrual hygiene management such as washing and drying, which were not improved by pad provision (Hennegan et al., 2016 [Thesis Chapter Five]). Differences between perceptions of reliability and actual soiling and odour also highlight the value of quantitative and mixed-methods approaches to assessing absorbents as such discrepancies may not have been identified in qualitative studies.

Girls reported missing activities due to menstruation. Differences in responses to items '*does your menstruation ever cause you to miss/avoid...*' where the list of items was read aloud, and '*are there activities you avoid while menstruating...*' with volunteered responses, further demonstrates the need for more careful and validated outcome assessment in this field. Validity and reliability studies are needed, with lessons from fields with more research such as sexual and reproductive health which also ask for sensitive information about personal experience and practices, with known social desirability. Across a range of domains there is a need for measure development. Further, mixed-methods research may assist in attaining the nuanced measurement of proposed outcomes. Despite issues of outcome assessment, comparison between reusable pads and existing methods revealed fewer differences than expected in daily activities. When girls were asked if their menstruation ever caused them to miss certain activities there were no differences in reports. When asked to volunteer settings avoided while menstruating there were large differences between pads and existing methods on selected items. This may indicate differences in volunteered responses, or being asked if they avoided activities, in contrast to asking if menstruation caused them to miss activities. Girls using existing methods had 5.00 times higher odds of avoiding physical sports and exercise, and were more likely to report avoiding fetching water, cooking or working in the field or garden.

Together study findings reveal the importance of considering the full story of menstrual management when assessing interventions. Primary trial outcomes reporting the same improvements in school attendance following reusable pad provision as puberty education (Montgomery et al., 2016 [Thesis Chapter Four]), do not reveal improvements to girls' confidence in absorbents, disgust in washing, difficulties changing absorbents, or participation in other activities. Findings also suggest that the provision of pads alone may not be sufficient to reduce garment soiling and that more detailed work is needed.

Although not statistically significant, there was an almost 10% higher report of teasing amongst those using the trial-provided reusable pads. No trials to date have assessed potential harms of menstrual management interventions in low income contexts (Hennegan & Montgomery, 2016 [Thesis Chapter Two]), this finding cautions that the provision of sanitary products in schools may leave girls vulnerable to teasing about menstruation if interventions draw attention to, or 'outs', menstruating girls.

Strengths and limitations

This study reported on a sample of girls in rural Uganda. Although the work is cross-sectional, the reusable pads were provided as part of a quasi-randomised trial to girls in 4 of the 8 study schools. Socio-demographic differences are likely to exist between those using the range of other existing methods, however as the reusable pads were distributed free as part of the trial these should not vary according to socio-demographics. It should also be noted that girls who were not included in the trial, but moved to intervention schools by March 2014 may also have received pads or have been surveyed and so were included here. When pads were delivered, they were provided to all menstruating girls as not to discriminate or create known inequality between students. With regard to generalisability of the findings, results of the main trial found those attending school at follow-up and therefore completing follow-up surveys had higher attendance than those who had dropped out by this point (Montgomery et al., 2016 [Thesis Chapter Four]). Thus the present sample is likely to have higher attendance and more favourable circumstances than those who had dropped out of school already.

The use of local research assistants to administer surveys was advantageous in use of the local language and access to the population. Given the low literacy rate in the area, verbal administration of the survey was likely to be more reliable than written surveys, which would have also required costly translation and back-translation efforts. However, this method was vulnerable to social-desirability in girls' reports, as noted

above. Social-desirability in reporting may have been exacerbated by asking questions in the school setting. Although girls were taken aside to ask questions there were many others around which may have primed social norms and led to biases towards expected responses. The local NGO was well known and respected in the area, with recent high-profile campaigns for girls' education (<https://plan-international.org/what-we-do/because-i-am-girl>). Many interviewing research assistants were the same as those who had provided the pads, which may have also biased girls towards favourable reports. These biases are likely to exist in most studies in this area and must be considered in interpreting results.

The sample size of this study was insufficient to assess outcomes across all absorbents. Frequencies suggest that disposable pads may have been more favourable than reusable pads in some areas, but there was insufficient power to compare these. Future studies are needed, with larger sample sizes, and should seek to compare a variety of absorbents. Further, future cross-sectional comparisons would be improved by adjusting for potential socio-demographic confounds.

Conclusions

Results of this study suggest reusable pads are perceived to be more reliable and convenient to manage than girls' existing improvised menstrual absorbents (predominantly cloth) in rural Uganda. Whilst the primary outcomes of the trial found no difference between reusable pads and puberty education in improving school attendance, this follow-up work reveals other important benefits of pad provision. Findings suggest that to fully appraise programs providing sanitary products to girls, a wide range of outcomes must be considered. Girls' comfort and dignity must be kept in the forefront of evaluation and consideration by policy makers when interpreting the results of existing studies. Potential harms from outing girls' menstrual status, or reductions to their choice of menstrual absorbents by restricting them to only one advised product should also be considered. Ideally schoolgirls may be provided with a choice of products, and willingness and ability to pay studies may provide further details on preferences and practices.

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CHAPTER 7

Paper #6: Understanding the impact of pads and puberty education

Soiling, soap, and support. A qualitative understanding of the effects of reusable sanitary pads and puberty education: Implications for future research and practice.

Julie Hennegan¹

Catherine Dolan²

Laurel Steinfield³

Paul Montgomery¹

¹ Centre for Evidence-Based Intervention, University of Oxford, Oxford, UK

² SOAS, University of London, London, UK

³ Bentley University, Waltham, MA, USA

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Abstract

Background. The management of menstruation has come to the fore as a barrier to girls' education attainment in low income contexts. Interventions have been proposed and piloted, but the emerging nature of the field means limited evidence is available to understand their pathways of effect.

Objectives. This work sought to describe and compare girls' experiences of menstruation and school engagement at the conclusion of a controlled trial of sanitary pad and puberty education provision.

Methods. Semi-structured interviews were undertaken with schoolgirls who participated in the menstruation and the cycle of poverty trial in rural Uganda concurrent with the final set of quantitative surveys. A framework approach and cross-case analysis were employed to describe and compare the experiences of 27 menstruating girls across the four intervention conditions (education, reusable sanitary pads, education with reusable sanitary pads, and control).

Results. Themes included: menstrual hygiene, soiling, irritation and infection, physical experience, knowledge of menstruation, psychological, social and cultural factors, and support from others. Those receiving reusable pads experienced improvements in comfort and reliability. This translated into reduced fears around garment soiling and related school absenteeism. Other menstrual hygiene challenges of washing, drying and privacy remained prominent. Puberty education improved girls' confidence to discuss menstruation and prompted additional support from teachers and peers.

Conclusions. This qualitative work provides insights into the quantitative trial results. Findings have important implications for the development and evaluation of future interventions. Results suggest the provision of menstrual absorbents addresses one core barrier to menstrual health, but that interventions addressing broader needs such as privacy may improve effectiveness. Puberty education sessions should increase

attention to body awareness and include strategies to address a wider range of practical menstrual challenges, including pain management. Interviews revealed avenues for improving quantitative surveys in future research.

Trial registration. Pan-African Clinical Trials Registry PACTR201503001044408

Plain language summary⁵

The effective management of menstruation has been identified as an under recognised challenge for girls in low income contexts. In response, there has been increasing emphasis on the potential for interventions addressing this issue to improve girls' health, education, and psychosocial wellbeing. This paper follows up on the results of a controlled trial testing the effectiveness of providing girls in rural Uganda with reusable sanitary pads or puberty education to improve their school attendance. The trial found positive results for both interventions on attendance, but not on psychosocial outcomes such as shame and insecurity. This study uses in-depth interviews with 27 menstruating girls from the trial to better understand how the interventions worked. We describe and compare girls' experiences of menstruation across the four trial conditions (pads and education provision, pads alone, education alone, and control). We found that menstruation presented a significant challenge to school attendance, and that the provision of sanitary pads reduced fears of soiling outer garments allowing better school attendance. However, providing pads did not address other challenges of managing menstruation such as washing and drying the reusable pads. The education intervention was helpful in promoting understanding of menstruation, but more detailed information and practical strategies may improve future education packages. Across the interventions, we found social support from peers and teachers to be an unmeasured driver of intervention effects. Finally, we found that menstrual pain and variations in menstrual experience cause significant distress and suggest some strategies for interventions to address this issue.

⁵ This section is a journal requirement of *Reproductive Health*

Background

Many challenges lie ahead in achieving quality education for all. Investment has seen considerable improvements in education metrics across low and middle income countries (LMICs). However, progress has been uneven and poor girls remain the most disadvantaged, facing an array of barriers to school enrolment, attendance, and attainment (UNESCO, 2015). Among these, menstruation has emerged as a neglected but significant obstacle to education.

Although an individual biological event, the experience of menstruation is entangled within a complex socio-ecological system. Reflecting this, '*menstrual health*' has been suggested as an overarching term for women and girls' menstrual experience encompassing menstrual hygiene, the physical requirements of effective management, as well as broader psychological and socio-cultural elements (Geertz, Iyer, Kasen, Mazzola & Peterson, 2016). Menstrual health is severely under researched. Consequences of inadequate menstrual management have been suggested to extend beyond the classroom to health, dignity, psychosocial wellbeing, employment, and participation in society (Mason et al., 2013; Phillips-Howard et al., 2015). Nuanced understanding of this complex experience is needed in the development of interventions, and in their evaluation (Craig, Dieppe, Macintyre, Michie, Nazareth, & Petticrew, 2008; Hawe, 2015). Programs seeking to improve menstrual health have been implemented, but few high quality trials have been conducted (Hennegan & Montgomery, 2016 [Thesis Chapter Two]).

Across disciplines there is increasing recognition of the value of qualitative research conducted alongside effectiveness trials (Lewin, Glenton, & Oxman, 2009; Moore et al., 2015). Lewin and colleagues (2009) suggest four broad ways qualitative methods can be employed after a trial to enhance evaluation: to explore reasons for the findings; to explain variations in effectiveness across the sample; to examine underlying

theory, and; to generate further questions or hypotheses. Furthermore, in fulfilling these functions qualitative research serves to provide a trial process evaluation by exploring mechanisms of impact in the trial, implementation, and study context (O’Cathain, Thomas, Drabble, Rudolph, & Hewison, 2013). This is highly appropriate in the study of menstruation, where evidence is sparse and interventions are undergoing rapid development and modification.

The present study uses this qualitative approach to describe and compare experiences of menstruation at the conclusion of a controlled trial of reusable sanitary pad and puberty education provision in rural Uganda (Montgomery, Hennegan, Dolan, Wu, Steinfeld, & Scott, 2016 [Thesis Chapter Four]). By comparing girls’ experiences across trial conditions this work aims to elucidate pathways of effect in the interventions and to identify barriers and facilitators of intervention effectiveness and implementation. In this way, the study enhances the quantitative trial evaluation and aims to provide recommendations for future intervention development and evaluations.

The Menstruation and the Cycle of Poverty trial

This study follows-up the *Menstruation and the Cycle of Poverty* trial; a quasi-randomised controlled trial of the impact of reusable sanitary pad and/or puberty education provision on school attendance for girls in rural Uganda. The methods and results have been reported elsewhere (Montgomery et al., 2016 [Thesis Chapter Four]). In brief, eight schools in Kamuli District, located in areas characterised by poor educational attainment and high rates of school drop-out were assigned to one of four conditions. Schools were grouped into pairs based on geographical proximity and assigned alphabetically. Each of the pairs received either puberty education (hereinafter referred to as education) alone, reusable sanitary pads alone, both pads and education, or no-intervention (control). The education comprised a 75-minute session providing information about puberty and managing menstruation, (full program available online [www.spi.ox.ac.uk/fileadmin/documents/PDF/Straight Talk Plan.pdf](http://www.spi.ox.ac.uk/fileadmin/documents/PDF/Straight_Talk_Plan.pdf)). Reusable sanitary

pads were AFRIPads, a locally produced cloth pad, which were provided with a single sachet (45 grams) of Omo soap, three pairs of underwear, and instructions on how to use and clean the pads.

The trial found that the percentage of school days attended dropped substantially in the control schools. This drop was mitigated by a mean 17.1% (95%CI 8.7-25.5) by the provision of either education or reusable pads in the intervention schools (Montgomery et al., 2016 [Thesis Chapter Four]). There were no significant differences in attendance between the intervention conditions, nor between psychosocial wellbeing outcomes, including shame and insecurity during menstruation, when compared at the conclusion of the trial.

Methods

Data collection

Twenty-seven girls were interviewed in October 2014 concurrent with the final quantitative survey data collection in the *Menstruation and the Cycle of Poverty* trial. Girls were eligible for interview if they had been at the school for longer than 2 years (since the start of the trial), and had reached menarche. Participants were sampled at each of the study schools and selected from a range of school grades (primary classes 4-7) and ages. Participants were aged 12 to 17 ($Mean=14.35$, $SD=1.11$) and the time since menarche varied. Interviews were spread between the four intervention conditions of education alone ($n=8$), pads alone ($n=8$), education and pads ($n=6$), and control ($n=5$).

Members of the research team (JH,LS) interviewed girls over approximately one hour at a private location on the school grounds. Lusoga translations were provided by trained female research assistants from the partner NGO. Interviews were digitally recorded. Both English and Lusoga portions were transcribed.

Semi-structured interviews covered a broad range of topics (see Box 7.1 for broad guide; Appendix 7.1 for full interview guide) drawn from interviews undertaken in pilots preceding the trial (Dolan, Ryus, Dopson, Montgomery, & Scott, 2013; Scott, Montgomery, Steinfield, Dolan, & Dopson, 2013), with additions to capture more detail around menstrual experience and trial implementation.

In addition to interview transcripts, notes from school facility assessments, field notes and debrief sessions with the project research assistants were consulted to contextualise interviews. School facility appraisal included the number and condition of the latrines, distance to water, access to water and soap, and school fees and grain requirements.

Box 7.1. Broad interview topic-guide

Broad interview topic-guide

- Household dynamics
- Schooling history
- Payment of school fees and access to resources
- Attitudes/expectations of education and gender
- Menstrual experiences
- Menstrual practices
- Perceptions of menstruation at school and other girls' experiences
- Sources of menstrual information/support
- Knowledge of family planning
- Future ambitions

Analysis

Analyses were conducted using NVivo 11. Interview transcripts were analysed using a framework approach with cross-case analysis to identify differences in experiences between intervention conditions. Framework analysis employs a thematic analytic approach with structured data management for a comprehensive, systematic analysis and data summary. The technique is well suited to large quantities of data, and studies with pre-established research questions.

Framework analysis followed the five steps described by Spencer and colleagues (2014).

- (1) Familiarisation: Four interviews were transcribed by the analyst (JH) and a further three read in their entirety.
- (2) Initial thematic framework: A blended approach of deductive and inductive coding was used. The initial thematic framework was developed based on the intervention theory of change, past literature, and quantitative findings from the trial. This was updated with emerging themes identified in familiarisation, indexing, and sorting (step 3). The final thematic framework is displayed in Table 7.1. Few changes were made from the initial framework.

Privacy was initially listed as a subtheme of menstrual hygiene, but was removed as it was an inextricable part of other aspects of menstrual hygiene (e.g., washing, drying).

- (3) Indexing and sorting: All interviews were coded into the thematic framework, with emerging themes added as described above.
- (4) Reviewing data extracts: Theme and sub-theme coding was reviewed and discussed among the study authors (JH CD LS PM).
- (5) Data summary and display: A framework matrix was generated using NVivo and each cell filled with a written summary and illustrative quotes by the first author. Full framework matrix is included in Appendix 7.2 for the thesis.

Following the framework analysis, cross-case matrices were generated to compare between the trial conditions.

Table 7.1. Final thematic framework

Final thematic framework	
Theme	Sub-theme
Menstrual hygiene	Absorbent
	Changing absorbents
	Washing
	Drying absorbents
	Disposal
Soiling	Soiling
	Absorbent falling out
Irritation & infection	
Physical experience	Menstrual symptoms & management
	Individual menstrual factors
Knowledge of menstruation	
Psychological, social and cultural factors	Coping mechanisms & self-efficacy
	Stigma & shame
	Labia elongation
Support	Teachers
	Friends
	Family
	Others

Ethical approval and consent to participate

Ethical approval was received from: the Social Science & Humanities Inter-Divisional Research Ethics Committee at the University of Oxford (Ref: SSD/CUREC1/11-056), the AIDS Support Organisation (TASO) Institutional Review Committee Uganda (TASOIRC/022/14-UG-IRC-009), and the University of Illinois (#12236). Girls participating in the trial provided written-consent, as did their parent/caregiver. To participate in the qualitative interviews girls provided verbal consent to participate and be recorded. No girls declined participation. Girls were informed that they could decline to answer any question.

Results

Findings are presented using the framework themes (Table 7.1) with differences between conditions discussed within each section.

Menstrual hygiene

Absorbents

Cloth was the most common absorbent for girls who did not receive AFRIPads. Some girls used clean, new cloths such as face towels or large sheets cut into pieces. Such cloths were purchased by or with funds from caregivers. Other girls used their own wages from farming work to purchase cloths. Those who could not afford cloth or pads used found-cloth such as old sweaters or discarded rags. In some cases, girls used underwear alone or multiple pairs of underwear. While girls were usually aware of commercial pads and may have used them, most could not afford them. A few girls reported that parents had purchased pads, but most did so inconsistently.

Unreliable absorbents kept girls from school, particularly where girls were using old or found cloths. Girls with no absorbents were absent. Most girls reported knowing others who struggled to find absorbents and thus stayed home.

"That like now, I began 3 days ago, but I did not come to school those three days, and I have just come back today."

(Participant 16, Pads-only)

"I stay home on the day I start.... Am not ready by that time but the following day I tell mummy to buy me pads...."

Interviewer: "What do you use the first day?"

"I use a cotton cloth."

Interviewer: "Why don't you come to school while using that cloth?"

"I fear that it may leak out."

(Participant 25, Control)

Intervention education sessions taught girls to sew pads from cloth. Girls reported trying to do so, but felt unable to sew the pads properly or lacked resources such as sewing equipment. At one education-alone site girls had more success, forming a group to pool resources and purchase large sheets of fabric and sewing needles to make pads as a joint venture. Parents were supportive, sometimes providing the fabric sheets. These were given to girls in need, or sold to those who could not make their own.

“Those who don’t have admire us and buy from us, others take it to be very important and they want us to be very important and they want us to teach them of which we do.” “...Even hygiene has improved at school. Other girls were using these papers to clean and put in the toilet, you could find the whole toilet dirty. They could use the other leaves, those long ones you have seen. They could use those leaves to clean themselves even plastic papers, so the cleanliness of the toilet was bad, but since we started giving out pads people can contain until they go home...”

(Participant 8, Education-only)

Girls receiving AFRIpads felt they were superior to previous absorbents in comfort and reliability. When using cloth, girls often reported discomfort from wearing multiple pairs of underwear, whereas fewer pairs were worn over the AFRIpads. There were some concerns raised about AFRIpads: a few girls reported that they experienced a burning sensation, or heard that others experienced this, while other girls were concerned about the pad moving or being visible.

“...when you put it on, sometimes when you are walking it keeps on moving that way and backwards. They can protrude behind or in front.”

(Participant 15, Pads-only)

Changing absorbents

The absorbent used, particularly the amount of cloth, impacted changing practices. For some, having few cloths meant that when one was removed it needed to be washed and dried immediately so that it was dry in time to change again. Since no school had washing facilities this required going home.

"... I put [a cloth] on in the morning, I go back during lunch time and I change and even wash it again at 4:00pm. The others [cloths] may be dry and I go and wash, and that is what I put on at night and put the one I washed on in the morning, and again wash the one I used at night"

(Participant 23, Control)

For those with sufficient absorbents to allow for changing at school, practices varied across the schools despite comparable latrines. At one school (education-only), a common bullying practice was to lock other students inside the latrines, compelling all girls interviewed at this school to return home to change. Conversely, at another school (pads-only condition) girls regularly changed absorbents in the latrines, storing used AFRIPads or cloth in a black plastic bag placed into their schoolbag to take home and wash. Going home to change was most common among those in education-only and control schools. Those living close to the school may return after changing, others stay home.

"I go back home at 10am or 1pm and change... I normally come back. But I might spend 45 minutes because it is far."

(Participant 7, Education-only)

In one school (education-alone), girls reported changing, and sometimes washing, absorbents at the home of a female teacher living close to the school, allowing them to return to school quickly after changing.

Washing, drying and disposal

Single-use pads were disposed of in latrines. Girls using AFRIPads or cloth washed, dried and reused them. Two girls who boarded at school washed absorbents in the evening and hid them to dry in the girls' dormitory. Most girls had access to soap, although for some this was inconsistent. Girls developed different strategies for accessing soap including purchasing it themselves, borrowing money, or using a local plant known to act like soap.

"When I do not get soap sometimes I go to a boy who knows us and we also know him and tell him to give me soap that if I get money I will give you"...

"When I borrow I go and get a portion and dig for money and pay back"

(Participant 23, Control)

Girls in pad-provision conditions used the small quantity of Omo soap provided surprisingly sparingly, stretching the 45-grams over nine months in some cases.

"I use omo detergent to clean the pad. When it gets finished I can ask for money to pay for more."

(Participant 9, Pads-only)

When girls lacked soap most would discard the used cloths.

"I throw them away if mother has no soap. I throw them away since I can't keep dirty things and do not want people to see dirty things..."

(Participant 24, Control)

Although girls expressed comfort with having water and their own basin or female-only bathroom area for washing absorbents at home, there were privacy concerns around drying absorbents.

"... if there are no people you can quickly put it outside to dry."

(Participant 4, Education-only)

This did not differ for those using AFRIpads. When drying absorbents outside girls hid them in bushes, put them on top of poultry houses, or hung them on wires. The absorbent was then covered with another thin piece of material to conceal it, a practice reported by some girls drying inside in more private places such as shared bedrooms as well. Girls sharing their bedroom with only females hung absorbents on a nail or wire in the room. For girls boarding at school, there were concerns around boys seeing pads drying, while those drying at home sometimes reported hiding them from parents.

Soiling

All girls expressed fears of soiling. Girls' who received AFRIpads felt these were reliable and experienced greater comfort as a result, with some reporting that they experienced soiling prior to, but not after, receiving AFRIpads. Soiling was a consistent problem for girls with poorer quality absorbents, prompting some to stay home on the heavier days of their period. All girls recalled others soiling at school, and expressed compassion for girls they knew soiled frequently. Fear of soiling often meant girls avoided standing in class to answer questions, and was a barrier to concentration.

"...there is one girl and she experiences leaking almost every month. She gets teased for it, mostly by the boys."

(Participant 9, Pads-only)

"...you cannot settle because you really feel blood is going to soil your uniform any time."

(Participant 23, Control)

One participant was the 'head girl' for her class meaning that others came to her if they had soiled their outer garments. She reported that this happens monthly. Fears

about soiling were amplified by girls' concern that absorbents would fall out of their underwear. Girls described sitting with their legs pressed together in class, and not playing games or skipping to avoid embarrassment.

Despite girls' focus on soiling through absorbents, most reported that soiling at school occurred on the first day of their menses when they were unprepared. One girl noted that she no experienced soiling since receiving AFRIPads, but still might be caught unaware by her period. At one school the uniforms had changed colour in the past year, reducing girls fears of soiling.

"because you may come to school when you are ok and it starts at school then you say "ha" since it has just started it will not come out. You just see at 10am when you stand it has spilled."

(Participant 4, Education-only)

"... this type of uniform has helped us a lot because it is heavy and the colour is not bad. But before when we were in yellow, you could even see someone in class when the uniform is full of blood. But now it is better because we are in this uniform."

(Participant 8, Education-only)

Irritation and infection

Genital irritation was reported across the sample. Some girls' described a burning sensation when using the AFRIPads, associating it with wearing the pad for an extended time. Irrespective of absorbent type, girls described how they were unable to deal with discomfort such as irritation during class, and needed to wait to get away from the classroom or school during a break.

"That sometimes, this begins when the teacher has entered in class. You need to finish the lesson, if you go out you will not get what the teacher has told, it will keep on burning until the teacher goes out."

(Participant 6, Education only)

Many girls had experienced itching and abnormal discharge at least once. They did not have an explanation for why this occurred, nor did they tell or ask anyone about it. Many were embarrassed, or felt that care providers might share the information with others.

Physical experience

Menstrual pain

Menstrual cramping was a focal part of girls' experience across all conditions. They reported school absences and disengagement for themselves and others due to pain. Participants often named two or more girls from their class who experienced significant pain and stayed home.

"I worry a lot about periods because I have serious cramps and the back pains a lot."

(Participant 20, Pads & Education)

"...if they are too much, I don't come and if they are not too much I come."

(Participant 12, Pads-only)

Pain management practices were mixed. Some girls had never taken steps to reduce their pain, while others frequently used paracetamol. Girls' sought to access painkillers through their care providers (without revealing menstruation as the source of pain) or purchased them with funds from their labour. Care providers sometimes provided painkillers. Paracetamol was the most common product, although some girls did not know what tablets they were given. One girl sought help from a health clinic, but only told them that she had stomach pain and was sold an anti-malarial. Girls reported mixed effectiveness of painkillers.

Individual menstrual factors

Girls expressed anxiety about variations in their menstrual patterns, which they feared were abnormal. This was most the common concern girls raised when they were provided the opportunity to ask questions of the interviewer. This was similar across all conditions, and did not seem to be affected by having received the education intervention. In particular, girls were concerned that their bleeding was too heavy, although it was unclear to interviewers if bleeding was truly abnormal.

"I menstruate for a full week, can you help me out?... In the first five days, it is heavy, but light in the last two. It is heavy then in the last two it is somehow light"

(Participant 12, Pads-only)

One girl reported month-long bleeding, and another reported instances where her menses had come two weeks apart. In these cases, girls feared that something was very wrong with them. Girls had sometimes sought advice from female teachers or relatives. Advice received was limited, with others simply encouraging girls that they were normal. Symptomology suggested possible menstrual disorders in a couple of cases.

Knowledge of menstruation

Regardless of intervention condition, many girls had known about menstruation prior to menarche, although were given varying information by mothers, aunts, sisters, or peers. In some cases, girls reported that teachers had first informed them, or had provided missing details. Teacher-provided sessions on menstruation were reported in some control and pad-only schools; some appeared to be special sessions arranged by female teachers, while others were part of classes on reproduction. For a couple of girls, the intervention was the first time they had learned about menstruation. Exposure to the education prompted some girls to start discussions with caregivers about menstruation.

Girls in education conditions were also more comfortable discussing menstruation in interviews. Receiving the pads-alone intervention did not appear to have the same impact, and notably two girls from the pad-only schools expressed fear to describe menstruation or use anatomical terms such as 'vagina'.

Despite being aware of menstruation, many girls reflected on menarche with fear. Although they had been told that menstruation would happen to them, most received little instruction on practical management. A number of girls reported that the intervention education session was the first time they received any demonstration of the use of absorbents. Education sessions provided girls with more practical knowledge than they had before, such as the importance of using cold water for washing. One girl reflected that prior to the education she *"didn't know how to put the pads in the knickers very well"* (Participant 19, Pads & Education). In some instances, girls were told by family members to restrict their activities during menstruation, including not going to school or being around boys. The education sessions informed them otherwise. Disparity between the advice provided by family members or peers and information in the education sessions was a source of stress. This is noted below with regard to practising labia pulling, but was also evident in other decisions such as whether to attend school or engage in other physical activities.

Psychological, social and cultural factors

Anxiety and embarrassment pervaded menstrual experiences across conditions. Girls carried significant anxiety about soiling outer-garments and being embarrassed or teased.

"That mostly when it soils they start bullying you. Both girls and boys."

(Participant 20, Pads & Education)

"Most of the girls they feel shy when they are in their MPs [menstrual periods]."

(Participant 8, Education-only)

This anxiety was reflected in girls' recollections of menarche. Even though they had been told that menstruation would happen, most did not immediately tell care providers or friends about it. Many tried to manage on their own, and waited until carers noticed and asked them about it.

As noted above, the AFRIPads allowed girls to feel more confident that they would not soil garments during menses and girls receiving education more freely discussed menstruation with the interviewers. This confidence appeared to have extended to interactions with others. Girls in the intervention schools reported ease discussing menstruation with peers, albeit with some individual variation. This contrasts with girls in the control schools, two of whom stated that they could not talk to friends about their menses at all.

Across intervention conditions, girls were heavily reliant on external sources to tell them what was normal for their periods and what their management practises should look like. Girls' reliance on others to provide funds for absorbents, soap and basins for washing meant most expressed little control over their ability to manage menses. Furthermore, girls expressed little control over their body. Of notable exception were the few girls whose parents regularly provided disposable pads and funds for painkillers. These girls expressed greater control and lower anxiety.

Labia elongation

Labia elongation emerged as an important cultural practice and avenue through which girls were informed about menstruation. Girls had received instructions from mothers, aunts, teachers and other girls to '*pull*' and elongate their labia minora. Debriefing sessions with the local research assistants revealed that girls were expected to elongate labia prior to menarche at which time labia were believed to become tougher and harder to elongate. The practice came to light in interviews when girls were asked who had told them about menstruation, with girls being told by teachers (male and

female alike) in reproductive classes to pull their labia, or when girls were provided the opportunity to ask questions of the interviewer. Girls were conflicted about whether or not they should engage in the practice, and indicated that the topic had been raised during questions in the education sessions.

"They [teachers] told us that in case you didn't pull the labias, you should pull, and in case you see blood from the vagina do not fear for it is normal"

(Participant 26, Control)

"Our senior woman teacher advised us to pull the labia but when Plan [the partner NGO] came they told us it is nonsense they should not do that."

Interviewer: "What do you think about who is right, Plan or the senior woman teacher?"

"The teacher who heads girls. Because even at home, mother told us the same."

(Participant 4, Education-only)

Support

Teachers

Female teachers were an important source of information and support. Girls often felt they could talk to a female teacher about menstrual issues. Notably, the range of topics and the ease of talking to the female teacher was greater in the intervention conditions than the control, where menstrual education at the school was more limited. While most girls reported positive experiences with teachers, some expressed that teachers of both sexes were not sensitive enough to menstrual issues.

"I was ashamed so I had to leave class and went home, but by that time when I was in class. Madam asked for me and I tried to explain, madam couldn't believe me so I cried again to explain to her in order to believe me."

(Participant 25, Control)

At both education-alone schools, girls felt cared for by a female teacher. At one school, a teacher provided a safe place for changing absorbents at her house nearby, while at another, the teacher provided spare skirts for girls if they had soiled, and took action to dismiss the boys from class first. There were also reports in other intervention schools that teachers provided girls with skirts in case of soiling.

"I tell my friend who is next to me who goes and tell the head girl to go to the madam [senior female teacher], tells her and she gives me a skirt which resembles my uniform and I put on then go home."... "if boys are in madam comes and tells the head girl to send boys out, then she brings the skirt."

(Participant 4, Education-only)

Friends

Across all schools, girls reported checking each other's skirts for leaks, talking about menstruation with others, and providing moral support. There were a few exceptions of girls who did not feel they could trust others with any information about their menses or feared teasing from other girls, interestingly both of these were in the control schools. Teasing was mostly attributed to boys. One girl in a control school reported that since her father provided pads for her she would sometimes share them with her friends. No girls reported sharing the AFRIPads provided in the intervention.

"A teacher might be teaching and then a friend stands up when she has soiled her clothes, you advise her to go out she leads the way and you follow to shadow her up. You get her other clothes to put on"

(Participant 22, Pads & Education)

Family and others

Mother's had often told girls about menstruation and provided money for cloth or painkillers. Where girls did not feel comfortable to discuss menstruation with their mother there was often an aunt, grandmother, or sister they talked to. This varied according to girls' family circumstances such as living arrangements, the presence of other wives and children, and how much time they spent with their mother. The level of detail in information girls' received from family varied. For some, they had been told to keep clean but copied cloth use from their mother or sisters without any formal instruction. In a few cases, aunts had warned against attending school or collecting water while menstruating. Most girls did not talk to fathers about menstruation. There were a couple of exceptions where fathers were the primary care-giver and girls reported that they could ask him directly for help.

Discussion

This qualitative follow-up to the *Menstruation and the Cycle of Poverty* trial extends on the quantitative findings, provides a more nuanced picture of the pathways of effect, and illuminates new considerations for menstrual health interventions and research.

Main findings

Interviews confirmed that among this sample, inadequate absorbents were a source of school absence. This was consistent with past qualitative work (e.g., Mason et al., 2013; Sommer, Ackatia-Armah, Connolly, & Smiles, 2014; Tegegne & Sisay, 2014). The provision of reliable absorbents in the intervention addressed soiling and fears of soiling, and meant girls could more easily attend school during menses. This may have been particularly beneficial for the most disadvantaged girls who struggled to access sufficient clean cloth. Further, the provision of reusable pads meant that girls could direct precious funds spent on pads or cloths to other needs, a potential added benefit. The ingenuity of the girls in one school to pool resources and make pads is testament to the importance of this issue in their lives and likely contributed to the education intervention effectiveness identified in this school. Beyond this group, no other girls sewed their own pads. Other content in the education sessions such as practical suggestions about how to fix absorbents in underwear or use cold water for washing was beneficial for girls' menstrual management.

The intervention did not address the school facilities available for changing absorbents. Despite similar facilities, school culture around latrine use dictated if girls felt comfortable to change absorbents there. Those using AFRIpads may have been able to change faster, as indicated in quantitative findings (Hennegan, Dolan, Wu, Scott, & Montgomery, 2016a [Thesis Chapter Six]), facilitating some girls to change at school in those conditions. Still, many girls using AFRIpads or cloths returned home to change.

None of the schools provided soap or water basins fit for purpose (even if water was available at a reasonable distance). Most girls washed their absorbents at home and felt comfortable doing so. Girls had more concerns about drying. Interviews revealed that when girls dried absorbents outside they covered them with another cloth. This may explain the unexpected quantitative findings that those drying pads outside experienced poorer health (discharge and odour) outcomes (Hennegan, Dolan, Wu, Scott, & Montgomery, 2016b [Thesis Chapter Five]).

More research is needed on the relationships between irritation, infection, and menstrual management (Das et al., 2015; Sumpter & Torondel, 2013). There were no clear variations across the conditions. Some girls reported burning sensations on extended AFRIPad use, which may have reflected an interaction with labia elongation or hygiene. This may also have been symptomatic of a reproductive-tract, or sexually transmitted, infection. Girls attributed any irritation to wearing an absorbent for too long, they did not tell others about it or seek advice. Girls' lack of understanding around vaginal discharge and health may be one source of the poor consistency between self-reported symptoms and laboratory-confirmed reproductive tract infections (Kerubo et al., 2016).

Almost all girls experienced menstrual pain and identified this as a barrier to attendance and engagement in the classroom. While girls in this study seemed aware of medication as a treatment for dysmenorrhea, Crichton et al (2013) found that girls in Nairobi were unaware pharmaceutical options existed. Pain and girls' anxiety about menstrual differences or menstrual disorders have received little attention in interventions to date and recommendations for addressing these are presented below.

In contrast to some past studies (e.g., Mason et al., 2013; Tegegne & Sisay, 2014; Ali & Rizvi, 2010), we found that most girls were aware of menstruation prior to menarche. This may have been due to the widespread practice of labia elongation and/or the presence of the trial. However, findings indicate that girls were under-

informed about practical management and individual variations in menstruation. The education intervention addressed some of this deficit, and provided an opportunity for girls to ask questions and initiate conversations with friends and other support sources. As a result, those in schools receiving the education intervention were more at ease discussing menstruation. Nevertheless, the education fell short in empowering girls to feel in control of their menstrual management. Embarrassment and anxiety around menstruation was evident in girls' willingness to report others' struggles with menstruation and soiled garments, rather than their own. A similar finding was noted by Mason and colleagues (2013), and did not appear to be impacted by the intervention. While studies have suggested that vaginal practices such as labia elongation may be a source of agency (Martin-Hilber et al., 2012), this did not appear to be the case in this study where social pressure and fear pervaded. Unclear and conflicting information about the practice was a source of anxiety among the girls.

Support from peers, teachers and family were integral to girls' experience. The impact of the interventions, and particularly the education, on girls' ability to support each other during menstruation may have been an important, unmeasured variable driving some of the improvements identified. It is unclear if teacher support, such as providing a safe-place for girls to change in their own homes, keeping spare skirts at school for girls, or changing the colour of the school uniforms, were responses to the intervention or actions teachers would have taken independently. However, it is likely that the trial and the involvement of the partner NGO in the school drew attention to this issue.

Trial implementation

Interviews confirmed implementation issues reported in the trial outcomes paper (Montgomery et al., 2016 [Thesis Chapter Four]). If girls were absent during education or pad provision they missed receiving these interventions. Girls shared information from education sessions among themselves, and this study suggests education may have led

to greater openness among peers. Thus other girls in the education conditions likely indirectly benefitted from the intervention. The finding that teachers in non-education schools provided some menstrual information is important in understanding the trial results. While this reflects real-world practice, it is possible the provision of pads in pad-only schools prompted greater attention to this education. In a similar way, the inclusion of instructions on making pads from cloth, combined with the fact that this was undertaken in a group and distributed at one education school, may all contribute to the lack of variation in effects across the interventions in the trial. The inclusion of mediation analyses in future trials would be able to further elucidate pathways of effect. Qualitative findings presented here are consistent with the null findings of the impact of the intervention on shame and insecurity outcomes.

Strengths and limitations

As a follow-up to a trial, this study was able to provide a comparison of experiences following different interventions. Schools were quasi-randomised to conditions and thus interventions were independent of participant characteristics. Participants were purposively sampled to include a range of classes and ages, however, girls who had dropped out of school or were absent on the day interviewers came to the different schools were unable to be selected for interview. NGO staff assisted in translation and selection of participants and may have also introduced bias. Interview transcription included English translations provided verbally during the interviews, in addition to girls' responses translated by different interpreters during transcription. This provided a double-translation of interviews, ensuring accuracy. There were insufficient funds for back-translation efforts, and four interviews had only English transcriptions due to funding limitations. Interviews were subject to self-report biases. This was evident in girls' greater ease in reporting others' difficulties with menstruation rather than their own. The presence of a foreign interviewer may have meant further hesitance to share openly about menstrual experiences.

Implications for research

Interviews highlighted measurement issues in menstrual health research. For school attendance, frequent part-day absences for changing absorbents are missed by most measures which record attendance once per day. Girls did not consider these absences as '*missing school*', so studies reliant on self-reported absences may be biased. Interviews indicated girls used soap very sparingly. The amount of soap used may have implications for the accuracy of menstrual hygiene estimates that rely on yes/no responses to soap use (e.g., Hennegan et al., 2016b [Thesis Chapter Five]). In evaluating menstrual hygiene, current items fail to capture use of soap alternatives, such as local remedies. Further, findings indicate that items capturing drying practices have been too simplistic. These are likely to be insufficient if they only collect information about location but not if absorbents are covered with another cloth. For future studies of menstrual health, questionnaire items asking simply if girls knew about menstruation prior to menarche are insufficient and misleading where girls have substantial deficits in practical knowledge. We recommended that future studies evaluate the reliability and validity of more detailed questions. Asking girls about their most recent menses, rather than what they *usually* do or how they *usually* feel during menstruation may improve the accuracy of self-reports. It may also be useful to ask about others' menstrual practices and compare these with self-reports to identify bias in studies assessing new measures.

Interviews revealed hitherto overlooked items in studies of menstrual experience. These include the way girls record their cycle, with interviews finding girls were often caught unprepared on the first day of their menses. Sources of support including teachers and peers may be important contributors to girls' experience that have not been included in models of school attendance or menstrual experience. The broader impact of interventions, such as personal or family funds saved by the provision of absorbents in interventions, or improvements in girls' feelings of control over their own bodies are outcomes that have not yet been assessed in intervention studies. Future

trials should be of sufficient size, and employ adequate quantitative survey assessment to undertake mediation analyses comparing pathways of effect. This would be invaluable in extending menstrual health theory and improving interventions.

Implications for practice

Results of this study provide a range of recommendations for practice and future interventions. Beyond providing sanitary products, much of the emphasis in this field has moved towards providing WASH facilities in schools (e.g., Sommer et al., 2016). However, girls in this study expressed comfort washing their absorbents at home. They had access to a personal basin, female-only spaces, and often soap. Interventions addressing WASH facilities at schools may address the needs of those without such resources at home, the most disadvantaged, but may be unnecessary and expensive if girls are comfortable at home. Instead, the provision of soap may more affordably improve the effectiveness of reusable product provision, improve hygiene, and assist girls for whom accessing soap is challenging, or girls currently using soap too sparingly. Conversely, improved facilities at school may be essential to combat issues with absorbent changing, reducing part-day absences. Interventions providing or encouraging use of discrete plastic bags to transport spare absorbents to school and used absorbents home may be sufficient where there are existing changing facilities. Drying presented a challenge to girls' feelings of privacy in this study. Recommendations for menstrual hygiene include drying absorbents outside to benefit from air-flow and the antimicrobial properties of sunlight. However, if this recommendation is implemented with other material put over the top of the absorbent, drying times may be increased, increasing anxiety about discovery, and benefits of direct sunlight lost.

Future education interventions should be improved. In this study, girls' feelings of control over their menstrual management and body remained low. Girls suffered from a lack of information about vaginal discharge, reproductive tract infections, and menstrual irregularities. Future interventions may be improved by providing more detailed practical

information about menstruation and menstrual management, educating support people, and emphasising girls' attention to their own body and experience. Girls were often caught unprepared on the first day of their menses. Encouraging girls to attend to their cycle and bodily cues signalling menses, as well as storing spare absorbents for the first day, may address this issue in the future. Dark coloured school uniforms as implemented in one school may be a way to improve experience and reduce fears of soiling. This study suggests that support from teachers and peers were integral to intervention effectiveness. Education facilitating this communication, such as group exercises during sessions, may therefore be more effective than individual or lecture-based education. Empowering teachers to better inform and support girls by providing education, practical tips and tools for them may boost intervention effectiveness and longevity.

Menstrual pain remains a challenge worldwide. Providing pain relief medications to girls in LMICs would be ethically challenging and difficult to implement without the risk of harm. However, findings from this study hold some alternatives. Many girls did not ask for pain killers, and those that did ask often did not reveal the source of their pain. In some cases, this resulted in the provision (and wasted funds) of the wrong medication. Some girls could report that paracetamol was the drug given. The most recent review has found that non-steroidal anti-inflammatory drugs (NSAID, e.g., Ibuprofen) are effective for the relief of menstrual cramps, and significantly more effective than paracetamol (Marjoribanks, Ayeleke, Farquhar, & Proctor, 2015). Future interventions could be improved by empowering girls to report the source of pain and providing education about the best types of medication. Few girls used other strategies, such as stretching or heat, which could also be suggested in education (Kannan & Claydon, 2014). Finally, interventions which reach parents and caregivers and reduce menstrual stigma more broadly may be important in opening channels of communication so girls can openly talk about their needs.

Conclusions

In sum, this qualitative work has enhanced understanding of the change process and implementation of the *Menstruation and the Cycle of Poverty* trial. Findings are consistent with the quantitative findings of the trial in suggesting that both education and pads were effective interventions to reduce menstrual-related absenteeism. The provision of sanitary pads reduced fears of outer garment soiling, although did not address other menstrual challenges. The education was successful in improving understanding and comfort with menstruation, but more practical information was needed. Social support from peers and teachers was an important driver of effects across both conditions. Implications for research and practice have been highlighted.

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CHAPTER 8

Discussion

Chapter Overview

Attending to women and girls' menstrual needs is an emerging avenue to address gender inequalities and human rights. Despite calls for an evidence-based approach to this issue (e.g., Sommer et al., 2016), menstrual health research has been disjointed and often methodologically poor. This thesis represents a timely investigation into a series of interconnected research questions which take stock of current work, extend the evidence for the effectiveness of proposed interventions, and seek to better understand menstrual health to inform future research and practice.

Chapter Eight distils the contributions of this thesis across the six included manuscripts and provides additional discussion of their strengths and limitations. The chapter then turns attention towards future directions and recommendations. This begins with a short advocacy for the reduction of research waste. It is followed by a summary of the methods and findings from a scientific meeting undertaken at the conclusion of the DPhil program to share findings within the field and gain additional insights into what is needed to improve menstrual health research. Finally, drawing on the lessons from the thesis work, and the scientific meeting, Chapter Eight concludes by summarising recommendations for future menstrual health research and practice.

Contributions and caveats

This thesis drew on the Medical Research Council (MRC) framework (Craig, Diepe, MacIntyre, Michie, Nazareth, & Petticrew, 2008) for the development and evaluation of complex interventions for guidance. Figure 8.1 (also shown as Figure 1.6), situates the thesis chapters within this framework. As seen here, most parts of the thesis contribute to more than one aspect of the process. Lessons learned from the work have implications for the development and evaluation of interventions.

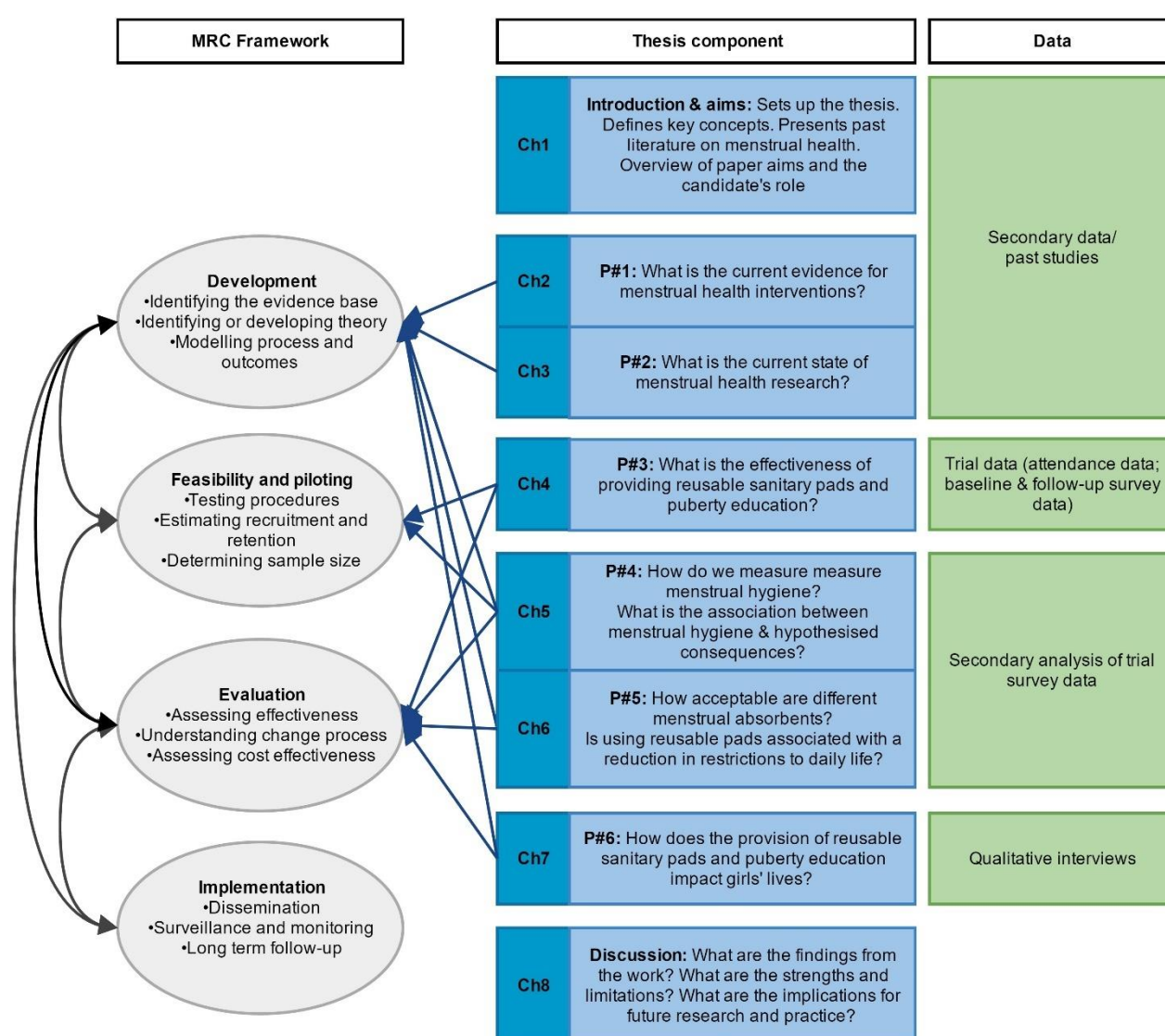


Figure 8.1. Conceptual diagram of the links between the MRC framework, chapters and research questions, and data used in the thesis.

The thesis had three broad aims:

- (1) Summarise and critically appraise current evidence for the effectiveness of menstrual health interventions;
- (2) Evaluate the effectiveness of a reusable sanitary pad and puberty education intervention for girls' school attendance; and
- (3) Expand understanding of menstrual health to inform future research and practice.

Findings for each objective are discussed below.

(1) Summarise and critically appraise extant research on menstrual health

Contributions

The systematic review presented in Chapter Two identified eight eligible trials of menstrual health interventions. Studies were heterogeneous in design and context and had considerable risk of bias. The effectiveness of software (education) interventions was tested within six of the trials, and the effectiveness of hardware interventions (provision of menstrual cups, disposable sanitary pads, or reusable sanitary pads) was tested in three studies. Despite extensive searching, there were no trials of other hardware interventions such as improvements to water, sanitation and hygiene (WASH) facilities (e.g., water access in latrines). Trials of software interventions were typically of poor quality. Most found positive effects on girls' knowledge of menstruation. While this outcome is hypothesised to improve girls' menstrual hygiene management (MHM) practices and reduce negative psychosocial consequences (e.g., anxiety), few studies tested these outcomes. Two studies tested effects on fear and shame and found mixed results. Trials of hardware interventions provided some evidence for positive effects of product provision on school attendance. Two of these were pilot studies, with short durations (e.g., 5 months) and small sample sizes ($n = 120$ and 306). In sum, the

systematic review revealed a lack of evidence for the effectiveness of menstrual health interventions.

Beyond summarising current estimates of effectiveness, critical appraisal of intervention trials in the systematic review revealed limitations in the literature. This was continued in Chapter Three, in a broader appraisal of extant evidence. This paper highlighted weaknesses in past studies which have had a narrow focus on surveys of girls' menstrual absorbent use. Review of past literature in these two chapters revealed that menstrual hygiene and health studies suffer from a lack of validated assessment tools, poor questionnaire design, inadequate reporting, and deficits in consensus around core concepts. Further, the field lacks research demonstrating the causes and consequences of poor menstrual health. As a result, detailed program and problem theory are lacking. By identifying and describing current deficits, Chapters Two and Three of the thesis aimed to provoke critical reflection in the field and direct future research efforts to address these issues. Further, critical appraisal of past research informed subsequent chapters.

Discussion

Commencing the work of the thesis with a systematic review and thorough engagement with past literature provided a solid foundation from which to pursue subsequent research questions with primary data. Moreover, this approach sought to minimise repeating past mistakes and to address current deficits in the field. Using a systematic review as a starting point was consistent with recent emphasis on the importance of review in advance of trials to reduce research waste (e.g., Moher et al., 2016).

In light of growing dissemination of menstrual health interventions, and the absence of past reviews, the Cochrane-style systematic review (Higgins & Green, 2011) undertaken in Chapter Two was appropriate to address a question of effectiveness.

However, it should be noted that, the primacy of Cochrane-style reviews has been questioned for the study of complex social interventions, (e.g., Greenhalgh, Wong, Westhorp, & Pawson, 2011; Petticrew, 2015; Oliver & Dickson, 2016). Critics have argued that summarising evidence for intervention effectiveness is not sufficient to understand or transport complex interventions. The need for broader questions which incorporate context, implementation, and *how* the intervention works, or the mechanisms of the intervention, have been emphasised (Wong, Greenhalgh, Westhorp, Buckingham, & Pawson, 2013a;b; Petticrew, 2015). Structured investigation into the components of menstrual health interventions would be a valuable undertaking, however, through conduct of the systematic review it was clear that poor reporting and low quality trials meant there would be insufficient material for this kind of review. None of the reviewed trials included any process evaluation, and only the Montgomery et al. (2012) study included a qualitative component. Changing the criteria for included studies to include pre-post assessments of interventions would have introduced substantially greater risk of bias into the estimate of effectiveness provided in the review. From broader review of these studies in Chapters One and Three, it was clear that these designs suffered from similarly poor quality and reporting deficiencies as the controlled studies. It is highly doubtful their inclusion would have provided any more insight into the change mechanisms or contextual factors at play in menstrual health interventions. Future reviews of menstrual health studies may provide greater depth than the systematic review undertaken in Chapter Two as more research becomes available. Nevertheless, the review provided an important starting point, demonstrating the need for more evidence on the effectiveness of menstrual health interventions and highlighting current methodological issues.

As for any systematic review, conclusions drawn from Chapter Two were limited by the number and quality of available trials. This paucity is likely to be reduced over the coming years. Since publication of the systematic review, two trials of menstrual health

interventions have been published, the trial reported in Chapter Four (paper #3) and a feasibility study of menstrual cup provision in Kenya (Phillips-Howard et al., 2016a). Moreover, a full-scale follow-up to the Wilson et al (2014) pilot is soon to be reported (for protocol see Wilson, Smith, Julious, Flight, & Reynolds, 2015). Two new studies focussed on menstrual hygiene are underway, the MENISCUS trial led by the London School of Hygiene and Tropical Medicine in Uganda (Research Councils UK, 2017) and a Population Council run trial in Kenya funded by the Bill and Melinda Gates Foundation (Population Council, 2017). Finally, a trial testing the effectiveness of menstrual cup provision and cash transfers for reducing reproductive tract infections (RTIs) and school drop-out has been registered and is listed as currently recruiting participants in Kenya (Clinical Trials, 2017). Forthcoming studies appear to represent an improvement in methodological quality and reporting, and to include qualitative components which could be used to provide further insight into change processes (e.g., the qualitative follow-up to the Menstruation and the Cycle of Poverty trial reported in Chapter Seven, paper #6).

Broader critical appraisal of the menstrual health literature presented in Chapter Three of the thesis (paper #2) enabled dissemination of insights from the systematic and background literature review to a new audience of menstrual health and hygiene researchers and activists. As noted in the Introduction and review chapters, there has been a heavy reliance on single case studies to demonstrate effectiveness within menstrual health. There has also been significant duplication of studies which do not advance understanding of the causes and consequences of menstrual health. Indeed, much of the energy dedicated to menstrual health has been in advocacy, rather than primary research. Chapter Three advocates for greater attention to the need for evidence to inform effective action, while acknowledging the imperative to act immediately to improve access to human rights and address menstrual needs.

It should be noted that two recent publications, published after the submission of Chapter Three (paper #2), have advocated for improved menstrual health research

(Sommer et al., 2016; Phillips-Howard, Caruso, Torondel, Zulaika, Sahin, & Sommer, 2016b). Many of the weaknesses noted in these papers, and their recommendations for future work, are consistent with the issues highlighted in Chapters Two and Three. Unfortunately, while both recent papers propose a series of important research questions that must be addressed by those researching menstrual health, they neglect pervasive methodological issues highlighted in this thesis. These papers do not address issues of measurement, over-reliance on case studies, or the assessment of harms which were identified as significant issues in Chapters Two and Three.

(2) Evaluate the effectiveness of a reusable sanitary pad and puberty education intervention for girls' school attendance

Contributions

As shown by the systematic review reported in Chapter Two, there is little evidence for the effectiveness of menstrual health interventions. The *Menstruation and the Cycle of Poverty* trial was well timed to address this need and to investigate two potential interventions (puberty education and the provision of reusable sanitary pads). Using a Latin 4-square design, the trial compared the effectiveness of both interventions, separately or in combination, to the wait-list control, and the interventions to one another. The trial found the provision of puberty education or reusable sanitary pads to be similarly effective in maintaining school attendance compared to the control. Findings were robust to different imputation strategies used to address participant drop out (discussed in Chapter Four, and below), although the size of the effect estimate varied with imputation strategies. There was no impact of either intervention on psychosocial outcomes such as shame, insecurity, or the total difficulties score of the Strengths and Difficulties Questionnaire (Goodman, Meltzer, & Bailey, 1998).

The qualitative follow-up reported in Chapter Seven (paper #6) served to further understanding of intervention effectiveness, as well as the context and pathways of

change. This study contributed to both assessing the effectiveness of the intervention (Objective 2), and enhancing understanding of menstrual health (Objective 3). Findings from the qualitative interviews supported the quantitative conclusions that providing education and/or sanitary pads enabled school attendance. In both conditions, improved social support from peers and teachers contributed to this effect. For girls receiving education sessions alone, this was paired with some improvement in practical skills. For girls receiving the reusable pads, greater confidence in the reliability of absorbents facilitated attendance. It was unclear from the qualitative work why no additive effect of these interventions was observed, this may have been due to variations across the small number of included schools (n=8). Qualitative findings also supported the lack of positive effects on shame and insecurity. The psychosocial stress of menstruation remained evident in interviews. Neither puberty education nor the provision of pads was sufficient to reduce concerns around management practices such as obtaining soap or drying absorbents. Girls worried about practical aspects of management, individual variations in menstrual patterns or discharge, and pain.

Discussion

A strength of the *Menstruation and the Cycle of Poverty* trial was the use of a Latin 4-square design to estimate and compare the individual, and combined, effectiveness of puberty education and sanitary pad provision. Without this separation, it would be difficult to estimate the extent to which a combined intervention effect is dependent on each component. This is particularly relevant for practitioners and policymakers who may consider the implementation of only one intervention due to funding or other constraints. Comparing multiple intervention components and identifying active ingredients, is also consistent with MRC guidance for the evaluation of complex interventions, which emphasises the importance of understanding pathways of change (Craig et al., 2008). Change pathways must be further investigated through a range of methods, as discussed below and addressed in the third objective of the thesis. As

discussed in Chapter Five and Chapter Seven, current menstrual health interventions do not attend to infrastructure needs for private changing and washing of menstrual absorbents. Additional intervention components such as these may be needed to better address women and girls' needs. A comprehensive understanding of the effectiveness of different possible intervention components, as well as their pathways of change, is important for optimising future menstrual health intervention packages. Effective intervention components could be identified and combined. Moreover, understanding the different possible components means that contextually appropriate packages can be delivered in response to local needs. Finally, comprehensively understanding menstrual health interventions facilitates their integration into other reproductive health or education packages, which may increase dissemination.

As noted in Chapter Four, there were substantial limitations in the *Menstruation and the Cycle of Poverty* trial conduct. This presented many challenges for the candidate who joined the project in the final stages of the trial (as described in Chapter One). Long-armed management of the project and high staff turnover within the partner NGO meant that many issues were not identified until after the conclusion of the project. These included; that many girls did not reach menarche during the trial, high rates of drop-out, and poor record keeping and implementation of the interventions as designed. Had such issues been identified earlier, it may have been feasible to provide additional education sessions so that more girls were able to attend, to direct funds towards following up girls who had dropped out of the study, or to extend the final time points of the intervention to ensure more girls had commenced menstruation over the trial. Conduct of a systematic review, such as the one reported in Chapter Two, prior to commencing the trial would have highlighted some of the potential issues in implementation and measurement. Similarly, improved data on the age of menarche within different populations is sorely needed to inform recruitment for menstrual health trials (Sommer, Sutherland, & Chandra-Mouli, 2015).

Although the *Menstruation and the Cycle of Poverty* trial followed a feasibility and pilot trial in Ghana, many issues arose as the study was transported to Kamuli, Uganda. Additional piloting was conducted to determine appropriate products for distribution, a strength of the study (see Scott, Montgomery, Steinfeld, Dolan & Dopson, 2013), however, there was no piloting of some survey measures or, importantly, the attendance data collection method. School attendance records were reliable, and high quality in the Ghana pilot (Montgomery et al., 2012; Dolan, Ryus, Dopson, Montgomery, & Scott, 2013). This was not the case in Kamuli. Changing the attendance data collection method part-way through the trial was a substantial limitation. Inadequacy in school attendance records should have been identified prior to the trial. A plan for ongoing spot-checks to supplement and triangulate attendance data over the course of the study would have been favourable to mid-way changes in data collection methods. The trial did not adequately plan for difficulties in attendance data collection, nor did it address many of the measurement issues (e.g., aspects of menstrual hygiene, or psychosocial outcome variables) identified in systematic review and review of past literature (Chapters Two and Three).

Full coverage of the baseline survey would have significantly improved the *Menstruation and the Cycle of Poverty* trial. This was noted in the trial discussion in Chapter Four. There were concerns that multiple surveys regarding menstruation would serve as an intervention and draw attention to the presence of the intervention, increasing risks of the Hawthorne effect (McCambridge, Butor-Bhaysar, Witton, & Elbourne, 2011; McCambridge, Witton, & Elbourne, 2014). While this is a legitimate concern, the infancy of menstrual health research calls for greater explanatory power within trials and investigation of the change mechanisms. Full baseline and midpoint surveys would have enabled the kind of research questions asked in the quantitative follow ups to be explored using the baseline data. Further, hypothesised mediators and moderators of intervention effects could have been tested using longitudinal data. For

example, after investigating the prevalence of menstrual hygiene across the sample using baseline data, improvements in hygiene could have been measured and tested as mediators of intervention effects. This would show if improvements in hygiene were responsible for positive impacts of education. Longitudinal data would reveal if the provision of a clean absorbent improved MHM from baseline, and could identify aspects of MHM insufficiently addressed by education and reusable pad provision. If they had been feasible, these kinds of analyses would have provided stronger evidence for hypothesised program theories of menstrual health interventions. Furthermore, full coverage of the baseline survey would have made alternative imputation strategies possible to address participant drop out in primary trial analyses.

In light of the trial limitations, quantitative and qualitative follow-ups were important to triangulate trial findings and contribute towards improving menstrual health research. Consistency between the quantitative and qualitative findings support the interpretation of the trial results. Change mechanisms identified in the qualitative findings as potential drivers of intervention effects can be investigated further, and quantitatively, in future studies. Thus, despite the limitations of the *Menstruation and the Cycle of Poverty* trial, findings remain useful in informing menstrual health research and practice. In addressing the limitations of the trial data, strengths of this thesis are also apparent. These include: qualitative investigation of the trial results; the conservative approach to imputation, transparent reporting of trial challenges and outcomes in Chapter Four, and the theoretical contributions offered by follow-up papers which made best use of available trial data (discussed further below).

In response to the need for methodological approaches that are sensitive to the complexities of social interventions, mixed-methods designs have received increased attention (Johnson & Onwuegbuzie, 2004; Petticrew, 2015). This has led to growing discourse on the variety of mixed-methods approaches (e.g., Leech & Onwuegbuzie, 2009), and strategies to improve the quality and usefulness of qualitative methods

alongside trials (e.g., Lewin, Glenton, & Oxman, 2009). Lewin and colleagues' (2009) review of the use of qualitative approaches alongside trials of complex healthcare interventions revealed that most studies did not include a qualitative component, and those that did failed to integrate the qualitative and quantitative findings. In contrast to these findings, the qualitative paper reported in this thesis commented on links with the quantitative paper, and listed the trial registration alongside the study abstract. However, the findings from the qualitative follow-up, and issues in the conduct of the trial, suggest that a more integrated approach to the two methods may have been beneficial.

Understanding girls' menstrual experiences prior to implementing the interventions would have informed intervention design and evaluation strategies. Issues such as labia-elongation, individual menstrual concerns, and pain would have been identified prior to education sessions. While the trial took a sequential approach to the mixed methods used, a concurrent design in which qualitative findings were also used to inform evaluation design and provided triangulation across time points, may have offered greater explanatory power (Leech & Onwuegbuzie, 2009).

(3) Expand understanding of menstrual health to inform future research and practice

Contributions

The final objective of this thesis was to expand understanding of the antecedents, correlates, and consequences of menstrual health. Through this objective, the work sought to extend the problem theory of menstrual health (Bowling, 2009; Fraser, Galinsky, Richman, & Day, 2009) and thus inform the development of interventions. Within the MRC framework these questions sit in both phases of development, in identifying and developing theory and modelling processes, and in the evaluation phase, where data from the *Menstruation and the Cycle of Poverty* trial were used to better “understand the change process” (Craig et al., 2008).

The first quantitative follow up paper (Chapter Five, paper #4) addressed measurement issues and concept definition in menstrual health. The paper sought to address a significant deficit in menstrual health research to date; the misuse and inadequate measurement of the core concept of menstrual hygiene. Despite a clear definition of menstrual hygiene which encompasses absorbent use, washing, needs for privacy and disposal, the overwhelming majority of studies have focused exclusively on the types of absorbents used. Chapter Five undertook secondary data analysis of the final survey data collected as part of the *Menstruation and the Cycle of Poverty* trial to provide a cross-sectional assessment of the prevalence of MHM consistent with the consensus definition and best available evidence for what constitutes 'adequate' MHM. This demonstrated the inadequacy of single-item measures and suggested that prevalence of poor MHM is underestimated when only the type of absorbent is considered. The paper proceeded to look at the individual and relative contributions of the different aspects of MHM to health, education, and psychosocial consequences. Whilst there were limitations to this analysis, the paper was novel in taking this approach to understanding the consequences of poor MHM and quantitatively testing hypothesised relationships.

The findings of Chapter Five (paper #4) were consistent with those from the qualitative work presented in Chapter Seven, such that providing reusable sanitary pads did not address menstrual hygiene concerns beyond absorbent type, and that privacy for changing and drying absorbents remained an issue for girls in the *Menstruation and the Cycle of Poverty* trial. Associations between aspects of MHM and health, education, and psychosocial consequences supported some hypothesised relationships. Use of a clean absorbent was associated with a reduction in; concerns about odour, avoidance of standing in class to answer questions, and difficulties concentrating in school while menstruating. Each of these mechanisms supports the usefulness of providing sanitary pads or education (if this leads to use of more hygienic/effective absorbents) for

improving attendance and engagement at school. Such findings further supported the interpretation of the trial results (Chapter Four). Associations between other aspects of MHM and hypothesised consequences demonstrated the importance of considering these aspects in studying, and developing interventions for, menstrual health.

The second quantitative follow up paper (Chapter Six, paper #5) expanded outcome assessment from the trial to other daily activities and girls' perceptions of the reliability of menstrual absorbents. This work gave a broader perspective than the primary outcomes of the trial paper and drew attention to the importance of girls' preferences and the acceptability of the products provided in menstrual health interventions. The study found that the reusable sanitary pads provided in the *Menstruation and the Cycle of Poverty* trial were viewed favourably and associated with fewer reports of avoidance of daily physical activities such as exercise. These results are consistent with the trial findings reported in Chapter Four and the qualitative study reported in Chapter Seven. Chapter Six supported one assumed mechanism of the hardware component of the intervention; that supplying a fit-for-purpose product would increase confidence that the absorbent would not leak, reducing school absenteeism. The finding that there was no difference in the self-reported garment soiling of girls using the trial-provided reusable sanitary pads and those using existing methods (mostly cloth) was consistent with insights from the qualitative interviews that girls may be most vulnerable to soiling at school on the first day of their period. Chapter Six also highlighted the lack of assessment of potential harms in the primary or secondary trial outcomes. The study found that a higher proportion of girls' using trial provided sanitary pads reported teasing from boys regarding menstruation. This outcome should have been included in the trial results, although would have been limited by the poor follow-up survey response rate. The study also served to demonstrate issues with outcome assessment in menstrual health research, and the trial survey, showing discrepancies

between different question formats and answers, and self-report biases when asking about school avoidance.

The interconnected themes identified in the qualitative follow-up (Chapter Seven, paper #6) aptly reflect the multi-faceted nature of menstruation in girls' lives. This investigation not only served to assess effectiveness and triangulate the quantitative trial findings, but also to explore the problem theory of menstrual health and program theory of the interventions when seeking to target school attendance. Findings from the qualitative follow-up emphasise the importance of multiple pathways in understanding menstrual health. Physical, psychological and socio-cultural factors all feature in contributing to girls' experience, and to their attendance and engagement at school.

Discussion

Quantitative follow-ups represent an optimised balance between methodological rigor, the ethical imperative to make best use of the collected data, contributing theoretically to the field, and achieving the third aim of the thesis to expand upon problem and program theory for menstrual health. As noted above, the conduct of the systematic review, attention to baseline quantitative findings, full coverage of the baseline survey, and qualitative work at an earlier phase of the *Menstruation and the Cycle of Poverty* trial would likely have improved many aspects of the study, including the ability of the thesis to address Objective 3. Questions addressed by Chapter Five and Six would have been well suited to a full-scale baseline survey. This would also have allowed a longitudinal approach to some of these questions, and the ability to investigate mediators and moderators of intervention effects.

For both quantitative follow-up studies (Chapters Five and Six), the small sample size severely limited statistical power to detect effects. In addition, the population for these studies included girls who were not recruited as original participants for the trial. While these girls were almost identical to those included in the study (and many of them

joined the schools in time for the intervention delivery), this made describing the population more challenging. It also meant that girls were compared cross-sectionally and there was no adjustment for potential clustering effects. For example, a girl who joined a school in which pads were provided but did not receive the pads as she was not present at the time of delivery would have had outcomes compared with girls in the same school who did receive the pads. Effects of education, or contamination from drawing attention to menstruation within pad-provision schools, were not accounted for in these studies. It is unlikely that this introduced systematic biases, and research questions were proposed with this limitation in mind. However, this may have added additional noise to the data. The inability to adjust for socio-demographic and other potential confounds was a significant limitation in Chapter Five (paper #4) when estimating the effect of aspects of MHM on proposed consequences.

Due to the limitations of the data it was not possible to explore the impact of the education intervention on the cross-sectional outcomes assessed in Chapters Five and Six. Ideally, the prevalence of MHM and girls' experience of menstrual absorbents and daily restrictions would have been compared across intervention conditions at follow-up. This would have provided an assessment of the impact of the interventions, including education, on these outcomes. However, the sample size of the final survey was insufficient to undertake this analysis and weaknesses of the trial implementation meant that presenting a cross-sectional analysis was a more conservative approach to the use of this data.

The quantitative follow-up papers reported in this thesis highlighted measurement issues. As noted above, data had already been collected so it was not possible to significantly update the survey design. Many of the survey items used repeated past mistakes. Single item, Likert-scale questions were used to assess psychosocial constructs, and girls were asked broadly about 'general' menstrual

practices. It was not possible to capture all desired aspects of MHM for Chapter Five (e.g., privacy for drying or changing facilities).

In reflecting on outcome assessment, it may be that links to sexual health were overlooked by the work of the trial and in this thesis. Survey items measuring vaginal itching or discharge were used in the thesis studies to capture irritation or infection, targeted at measuring non-sexually transmitted RTIs such as Vulvovaginal Candidiasis. However, these symptoms may have also been indicative of sexually-transmitted infections (STIs). Recent studies have suggested that girls in LMICs may engage in transactional sex in order to obtain sanitary products (Phillips-Howard et al., 2015). Further, a recently published cRCT in rural Kenya found that girls provided with menstrual cups had a lower prevalence of STIs at 11-month follow up than those in the control condition (Phillips-Howard et al., 2016a). Links between menstrual health and sexual health need greater investigation. Sexual health outcomes may be an important consideration in trials of menstrual health interventions and problem theory. At the same time, the mechanisms linking menstrual management to STIs have more steps, and are more complex than those between MHM and non-sexually transmitted RTIs or irritation which are hypothesised to occur due to use of unclean absorbents (Das et al., 2015). As limited studies link transactional sex and menstrual health, more attention to establishing and exploring these associations and pathways of effect in interventions is needed. The study by Phillips-Howard and colleagues (2016a), while encompassing 30 schools and using laboratory confirmed infections as an improvement on previous studies, did not undertake any additional checks to evaluate the pathways of effect between cup provision and STIs.

It may be dangerous to divert attention to STIs as the primary outcome in trials of menstrual health interventions. Menstrual management has been linked to many consequences sufficient to warrant investigations. Indeed, the findings of this thesis support the assertion that menstrual health interventions may have benefits for girls'

school attendance and engagement, and reduce avoidance of many daily activities.

Fixating on STIs as the primary outcome in studies of menstrual management risks limiting attention to these other important issues, and diverting it to an outcome which has limited links to menstrual management and may be better addressed through other types of intervention (e.g., sexual health education). Therefore, it is concerning that at least one of the upcoming trials noted earlier has selected STI infection (human immunodeficiency virus (HIV), genital herpes simplex (HSV-2)) and school drop-out as primary outcomes (Clinical Trials, 2017).

Next Steps

Why prioritise priorities?

In 2014 *The Lancet* series “*Increasing value: reducing waste*” described the multiple phases in which research funding is wasted (Macleod et al., 2014). While the series was based in the biomedical research field, where Chalmers and Glasziou (2009) estimated that 85% of research funding was avoidably wasted, lessons ring true for menstrual health research. Figure 8.2 describes the stages of research production that lead to waste. As captured here, the identification of high priority questions, which are answered with adequate rigor and reporting are essential first steps to prevent waste. In investigating menstrual health, the many cross-sectional studies conducted have already duplicated efforts and failed to answer epidemiological questions needed to advance understanding of menstrual management and its impact on women and girls’ lives. The poor quality of research and reporting has meant further waste.

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Figure 8.2. Stages in research production that lead to waste (Moher et al., 2016).

The identification of high priority questions, answered with rigor and reported with transparency should be the aim of any field trying to prevent waste and make best use of the limited available research resources. To this end, there are increasing efforts to improve the quality of published research. Recommendations have emerged from successful practices across disciplines. In 2014, Ioannidis summarised the prevailing recommendations for how to “*make more published research true*”, displayed below. These recommendations can be used to promote best practice and stimulate the academic community to reflect critically on their own discipline. The recommendations were (Ioannidis, 2014, p. 2):

- *Large-scale collaborative research*
- *Adoption of replication culture*
- *Registration (of studies, protocols, analysis codes, datasets, raw data, and results)*
- *Sharing (of data, protocols, materials, software, and other tools)*
- *Reproducibility practices*
- *Containment of conflicted sponsors and authors*
- *More appropriate statistical methods*
- *Standardization of definitions and analyses*
- *More stringent thresholds for claiming discoveries or “successes”*
- *Improvement of study design standards*
- *Improvements in peer review, reporting, and dissemination of research*
- *Better training of scientific workforce in methods and statistical literacy*

Taking stock of these recommendations, it is clear that the field of menstrual health research has a long way to go. The work presented in this thesis makes steps towards improving research questions and methods. However, there is much more to be done. To further facilitate this process, in the final stages of the thesis the scientific meeting described below was undertaken to bring together leaders in the field of menstrual health research and discuss priority questions and methodological improvements.

Scientific meeting: Priorities for menstrual health research

This meeting sought to advance global priority setting for research on menstrual health. The objective was to engage in discussion around the current literature and projects, highlight existing gaps, and distil priorities for future work. The full meeting report is included in Appendix 8.1. The meeting was funded by Green Templeton College at the University of Oxford through a small grant obtained by the candidate and the candidate’s supervisor.

Process

Prominent researchers in menstrual health were identified and invited to participate in the meeting. Selection prioritised those who had, or were currently, undertaking primary research in menstrual health, and researchers with significant authority in agenda setting (e.g., participation in the annual virtual Menstrual Hygiene Management conference and Menstrual Hygiene Management in 10 meeting (Columbia University & UNICEF, 2017)). The meeting prioritised research methods and thus sought to include predominantly academics, rather than a diverse range of stakeholders or actors in the field. Through this decision, we sought to direct the agenda towards research priorities, rather than priorities for improving menstrual health more generally. The final list of meeting participants is presented in Table 8.1.

Table 8.1. List of meeting participants and institutions

Bethany Caruso	Emory University
Catherine Dolan	SOAS, University of London
Julie Hennegan	University of Oxford
Paul Montgomery	University of Oxford
Penelope Phillips-Howard	Liverpool School of Tropical Medicine
Marni Sommer	Columbia University
Belen Torondel	London School of Hygiene & Tropical Medicine
Leeat Weinstock	Grand Challenges Canada
Helen Weiss	London School of Hygiene & Tropical Medicine
Emily Wilson-Smith	Irise International, University of Sheffield

Prior to the meeting, participants received a package of reading materials and were invited to add papers as they saw fit (the final list of pre-meeting reading is included in the meeting report in Appendix 8.1). It was assumed that all invited

participants would be familiar with the menstrual health literature. The agenda was distributed in advance and participants were assigned topics for short presentations to facilitate discussion. Notes taken during discussions throughout day were used to compile the meeting report and describe emergent themes. A draft report was circulated to participants with the opportunity to provide feedback (Appendix 8.1).

Outcomes

The scientific meeting *“Priorities for research of menstrual management in low and middle income countries”* provided an opportunity to reflect on the current state of research and identify priority questions and guidance for research design and conduct. As a new area of research, there is a great opportunity for studies in this field to benefit from more established disciplines and existing recommendations for improving research practices. The scientific meeting facilitated the identification of some pathways forward, and proposed works of review and guidance to improve future efforts. Many of these were well aligned with current recommendations for best practice discussed above (e.g., Ioannidis, 2014), including promoting collaborative research, sharing data and tools, and standardisation of definitions. Six core themes emerged from the day as actionable avenues to provide guidance and improve research, further summarised in Table 8.2:

- Assessments of **harms** need to be included across study designs.
- Consensus is needed on *what* and *how* to measure indicators and core outcomes across different domains to improve **outcome assessment** in menstrual management research and program monitoring.
- **Equipping in-country teams** with methodological guidance and validated indicators would improve the quality of small scale evaluations and should be a priority to facilitate ongoing monitoring and generate aggregate data for review and larger-scale analysis.
- **Key concepts** should be clearly defined and use of shared language promoted.

- Studies of menstrual management should be informed by explicit **theory**, and should seek to investigate pathways of effect.
- The role of **water, sanitation and hygiene facilities** needs to be considered, measured, and highlighted across studies.

Table 8.2. Research priorities: core themes identified through the scientific meeting

Harms	Outcomes & outcome assessment
Assessments of harms should be included across study designs. More guidance is needed to highlight potential harms of interventions (e.g., dark logic models) and recommend methods for assessment.	Consensus is needed on <i>what</i> to measure, and <i>how</i> to measure constructs. Outcomes in different domains (health, education, psychosocial wellbeing) need to be defined and guidance needs to be provided for their measurement. This must be done recognising the strong demand for hard indicators and current, unacknowledged, biases in reported outcomes.
Equipping in-country teams	Constructs & definitions
Providing better tools, support, and training so that small scale evaluations can contribute to understanding should be a priority. Once agreed metrics are in place, there is potential for results and data to be pooled for mega-analysis. Shared platforms may facilitate this. Linked systematic reviews and Delphi/consensus methods have potential to promote shared understanding.	'Adequate' and 'inadequate' menstrual hygiene need to be defined, informed by evidence. A clear definition of menstrual health is needed as this term sees increased use. Key terms should be defined to promote use of shared language.
Theory	Considering infrastructure
Greater use of theory should be promoted in menstrual management research. This should be used to inform intervention development. Greater attention to mediators and covariates is needed across study types. Future reviews may be able to identify core components of interventions.	Water, sanitation and hygiene (WASH) infrastructure needs must be considered across studies (as covariates and in cost-effectiveness analyses). More studies are needed to draw attention to infrastructure needs.

In addition to the six priorities, suggestions for a number of works of guidance to improve the quality of menstrual health research emerged over the day. The first was to emphasise the need to measure potential harms of interventions. A paper collating different minimal harms that could be assessed in interventions would promote the assessment of these outcomes in studies from large trials to small pre-post assessments. This work could draw on existing guidance for identifying harms of interventions (e.g., Lorenc & Oliver, 2014; Bonell, Jamal, Melendez-Torres, & Cummins, 2015). Lorenc and Oliver (2014) offered typologies of harms which could be applied to menstrual health: direct harms (e.g., injury, infection), psychological harm (e.g., bullying), equity harms (e.g., where interventions increase discrepancies between certain groups), group and social harms (e.g., risks of labelling or targeting in response to the intervention), and opportunity harms (e.g., diverting resources to menstrual health intervention which may be less effective than another type of intervention). To facilitate identification of these harms in testing interventions, Bonell and colleagues (2015) suggest the development of 'dark logic' models to identify all potential harms or paradoxical effects.

The second proposed work of guidance was a paper highlighting outcome assessment issues in menstrual health research. Many of these issues were identified in the work presented in this thesis. Other recent analyses have also suggested that current outcome assessments are inadequate (e.g., van Eijk et al., 2016).

Third, it was suggested that there was a need for published consensus on the core definitions (e.g., menstrual health) and work to define 'good' and 'poor' MHM. To address all of the priorities identified in the meeting, much more work is needed. However, the three suggested works of guidance represent immediately actionable projects to initiate this process.

Beyond the top priority issues for action, there were a number of new areas of inquiry or neglected issues which arose throughout the meeting. While these issues

were not central to the ongoing discussion or the core, actionable themes, they represent important considerations which could be incorporated into future research and are listed in Box 8.1 for completeness.

Box 8.1. Additional research topics, methodological suggestions or new areas of inquiry arising throughout the meeting.

- Pain & pain management
 - The relative contribution of pain to proposed consequences is rarely addressed.
 - Similarly, the importance of improved pain management in comparison to hardware or software interventions has not been considered.
- Gastro-intestinal consequences
 - There are links between menstruation and diarrhoea (and other gastro-intestinal symptoms) that not often discussed in research of girls' experiences or in proposed intervention (e.g., the impact of such symptoms on infrastructure needs or school absence).
- New studies are needed to demonstrate importance of infrastructure/facilities.
- Smartphone apps (e.g., Clue, 2017) represent new potential tools for data collection or education dissemination.
 - These could be used to pilot survey questions, although may be limited to a high-income country population.
- Adult women have not received adequate research attention.
- The needs of disabled populations are rarely considered in menstrual health research.
- Emergency/humanitarian contexts have received limited attention.
- Inequalities in menstrual needs and experiences may need to be explored (e.g., religious requirements of menstruation).
 - Potential inequalities resulting from interventions much be considered.
- Links to contraceptive/reproductive health education should be explored.
- Research is needed to provide guidance on best hygiene practice e.g., change frequency, extent to which some drying practices better than others.
 - Laboratory research may be needed.
- More studies are needed to understand product preferences.
 - These could use purchase data.

Future directions

The work reported in this thesis has many implications for future research and practice. Each paper included a section on implications for both groups, and broad implications of the work for research and practice are collated below.

Research

Outcome assessment

First, improved measurement is needed in the study of menstrual health. The systematic review (Chapter Two), position paper (Chapter Three), and study of the prevalence and consequences of menstrual hygiene (Chapter Five) all stress this issue. Measures need to be reported transparently so they can be critically appraised and compared between studies. Results of this thesis suggest that pilot work, and the use of multiple measurements to triangulate data may be needed. Further, there is a need for studies on the reliability and validity of current approaches to construct measurement in menstrual health research. In addition, researchers need to expand the variables measured when considering menstrual health. Research to date has largely overlooked girls' product preferences, psychosocial experiences, social support, and MHM in full. Studies can no longer fail to report MHM in a way that is inconsistent with the concept definition, compounding the neglect of essential features such as WASH facilities or disposal.

Problem theory

Second, more research is needed to assess and expand the problem theory of menstrual health. To establish menstrual health as a significant threat to human rights and demonstrate its impact on the lives of women and girls, studies must demonstrate hypothesised effects. Further, underrepresented correlates of menstrual health must receive more attention. This includes the role of WASH facilities, menstrual symptoms,

and social restrictions. Greater attention to problem theory is important to guide the development and evaluation of interventions. As demonstrated by the systematic review in Chapter Two, and trials published since the review (Chapter Four), there has been limited attention to the role of hardware interventions beyond sanitary product provision. Epidemiological and trial research on the role of WASH facilities and privacy on women and girls' is of utmost importance if this menstrual need is to be addressed. Similarly, social contributors to menstrual health have received little attention outside qualitative research.

Program theory and development

Third, attention to the program theory of proposed menstrual health interventions, and assessment of this theory in evaluations, is needed to minimise research waste and accelerate the evolution of effective interventions. For example, there has been no published research on the components of menstrual education interventions. Programs vary widely, with much NGO programming taking a more iterative and participatory approach than what was represented in the *Straight Talk* education delivered in the *Menstruation and the Cycle of Poverty* trial. Such diversity in education content and modes of delivery must be recognised when seeking to provide effect estimates that could be generalised across programs. Moreover, as a complex intervention within a complex environment, understanding the core education components and how they impact on behavioural and psychosocial changes is key in understanding effects on outcomes and improving effectiveness for the future. There is some evidence from sexual education studies that greater effect sizes may be achieved when adapting established programs, compared to 'home-grown' programs (Kirby, Laris, & Rolleri, 2006; Fonner, Armstrong, Kennedy, O'Reilly, & Sweat, 2014). Similarities to sexual education for menstrual education mean that identifying and standardising core components of education could be valuable in improving menstrual education interventions. This may improve the effectiveness of programs across contexts, and

reduce the time needed to invest in development; an important consideration for resource-constrained NGOs. Identified core components could be adapted for integration with local needs, consistent with the evidence-based practice paradigm described in Chapter One. Identification of core educational components is not new, UNESCO (2009) guidance for the conduct of comprehensive sexuality education identifies essential aspects of sexuality education. This guidance was recently updated, although education around menstruation remains notably absent (P. Montgomery, personal communication, October, 2016; A. Stahmer, personal communication, October, 2016). This example suggests one way that greater research attention to program theory, and attention to the considered development of interventions may facilitate the dissemination of menstrual health interventions that best meet girls' needs. Beyond greater attention to education programming, similar attention is needed to address other contributors to menstrual health such as WASH facilities or taboo and stigma.

Methodology and reducing research waste

This thesis demonstrates both the value of, and need for, more research on menstrual health. As governments, NGOs, and charities recognise the importance of women and girls' menstrual needs, it is imperative to provide a thorough understanding of menstrual health and guidance on the effectiveness of different intervention strategies to inform practice. There is still a long way to go. As a new field, there is great potential to benefit from existing methodological guidance for the development and evaluation of complex interventions. However, the presence of methodological guidance and knowledge of past mistakes does not guarantee their application. To improve menstrual health research, the field should, first, attend to methodological guidance and reflect critically on existing literature as captured in Chapters Two and Three. Second, the field should identify priority research questions and reduce unnecessary duplication (Ioannidis, 2014). Third, studies should adhere to best-practice reporting guidelines (EQUATOR Network, 2017). Fourth, greater attention to study design and reducing bias

including; use of randomised designs and attention to covariates and confounder adjustment in observational studies is needed (Chapter Two; van Eijk et al., 2016). Fifth, the use of integrated mixed-methods designs may be useful to improve the explanatory power of intervention studies (Leech & Onwuegbuzie, 2009; Lewin, Glenton, & Oxman, 2009). Finally, theory-led designs which seek to contribute to the development of problem and program theory for menstrual health are needed. These research questions need to be built into the design of observational studies and intervention trials.

Practice

There remains limited evidence for the effectiveness of menstrual health interventions. As such, programs should be implemented along comprehensive monitoring or structured evaluations. Most studies have not measured the potential harms of interventions and so practitioners should be particularly vigilant to detrimental effects of product provision, such as, 'outing' girls' menstrual status, introducing inequalities as a result of programmes implemented, and other unintended consequences. In addition to the need for more research, the studies presented in this thesis have implications for practitioners and policy makers seeking to improve menstrual health.

Facilities/infrastructure

As described in Chapter One, the vast majority of menstrual health interventions focus on the provision of menstrual absorbents. The work of this thesis clearly demonstrates that more factors must be considered when seeking to improve the menstrual health of women and girls. Indeed, the provision of improved absorbents may not be sufficient to improve menstrual health as shown in Chapter Five. This means that more comprehensive, or facility based projects may be needed.

Education

As discussed above, there is a significant need for more attention to the development of menstrual education interventions from the research community. Practitioners are already implementing and developing their own programs. Consistent with the evidence-based practice model, the theoretical framework for this thesis, practitioners should be seeking to integrate the available research with their local contextual knowledge to improve programming. The findings from this thesis suggest that more attention to the practical aspects of menstruation are needed during education. This includes information about the physical management of menstruation, more information about vaginal discharge and individual variations in menstruation, and information about the options available for pain management. The *Menstruation and the Cycle of Poverty* trial suggests that education interventions can be effective for reducing school absenteeism for girls, which should encourage attention to education for improving menstrual health. Qualitative work reported in Chapter Seven further illustrated that one of the reasons for the effectiveness of the education intervention may have been improved social support from peers and teachers. As such, providing education in a group setting, and to teachers, may be the most effective method for improving outcomes. Findings of this thesis also suggest that modifications to education interventions may be needed to address stigma and psychosocial consequences of menstruation. Broader programs focussed on the whole community, and which include males, may be needed.

Product acceptability and preferences

Debate around the merits of various menstrual absorbents appears to be intensifying, with proponents of different products, such as menstrual cups or reusable pads, voicing increasingly proscriptive opinions on the topic. With diverse experiences reported in literature to date (e.g., Mason et al., 2015; Joshi, Buit, & González-Botero, 2015; Garikipati & Boudot, 2017) and studies of menstrual practices in high income

contexts indicating individual differences in product preferences (Stewart, Greer, & Powell, 2010), practitioners must be sensitive to girls' needs. It is unlikely that there is a single 'silver bullet' product which should be promoted above all others, indeed a human-rights centred approach should emphasise women and girls' agency and informed choice.

Menstrual pain

Finally, menstrual pain is likely to remain a significant issue in menstrual health practice. As noted in the introduction, menstrual symptoms were largely beyond the scope of this thesis and have received limited attention in menstrual health research in low and middle income contexts. This is likely due to ethical issues of intervention and the lack of options available for the management of menstrual symptoms. Nevertheless, while researchers may be able to sanction this issue as outside the scope of current interventions, it will remain a significant challenge for practitioners. Findings from the qualitative study reported in Chapter Seven, and further research into education programming or options for menstrual pain relief, may offer some solutions. In the interim, careful and informed consideration of this issue by practitioners and policy makers is warranted.

Conclusions

Emboldened by the sustainable development goals, the world seeks to achieve gender equality, education for all, and access to WASH and health. In this endeavour, women's need to manage menstruation can no longer be marginalised as a shameful secret and niche area of inquiry and intervention. The work of this thesis demonstrates that with considered attention to methodological challenges, studies can improve understanding of menstrual health and develop and evaluate interventions which address the limitations imposed on women and girls. While this thesis suggests that the evidence-base in this field has been limited, the work offers hopeful recommendations for the future.

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Appendices

Please see book 2.