MENSTRUAL HEALTH LITERATURE REVIEW

UNIVERSITY OF WASHINGTON STRATEGIC ANALYSIS,

RESEARCH & TRAINING (START) CENTER

REPORT TO THE BILL & MELINDA GATES FOUNDATION

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START CENTER

STRATEGIC ANALYSIS, RESEARCH & TRAINING CENTER

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Photo: Blood:Water

PROJECT BACKGROUND

Globally ~500 million menstruators experience compromised menstrual health related to insufficient access to high-quality and affordable products[1].

A more robust understanding of how menstrual health affects women's health, especially as it relates to reproductive tract infections and the use of different menstrual health products, is needed. In particular, greater knowledge about the burden of negative health outcomes related to menstrual products is of key interest.

The output of this work will help to inform the work and strategy for the Women's Health Innovation Team.

PROJECT OBJECTIVE

To conduct a literature review to understand the effect of menstrual health product use on infectious outcomes (sexually transmitted infections, urogenital infections, & bacterial vaginosis), and identify corresponding gaps in the literature.

PROJECT DEFINITIONS[2]

- **Menstrual Pads:** includes commercial sanitary napkins, sanitary pads, or panty liners only worn during menstruation. May include scented or unscented products. Pads were assumed to be disposable, unless reuse was specified.
- **Reusable Pads**: cloth based menstrual pads, intended for reuse for one year or more.
- **Menstrual Cups**: insertable silicone-based menstrual cups that are intended for reuse.
- **Homemade Alternatives:** strips of fabric or other absorbents (e.g. cotton wool) repurposed for menstrual absorbency. May be used/reused and washed/ unwashed. Also termed cloths/rags in studies.

METHODS

- This literature review searched 3 databases for relevant studies published globally up to March 26, 2024 (Figure 1; Appendix 4).

Our Population, Intervention/Exposure, Comparator, and Outcome (PICO) criteria[3] were:

- **P:** menstruators of any age group, located in any geography
- **I**: Reusable or disposable menstrual pads, menstrual cups, and homemade alternatives (e.g. cloths/rags) only worn for menstruation.
- **C**: Other menstrual products or none.
- **O**: Reproductive and Urinary Tract Infections including: HPV, HIV, Syphilis, Gonorrhea, Chlamydia, Bacterial Vaginosis (BV), Urinary Tract Infections (UTI), Vaginitis, & Candidiasis.

Two reviewers screened each article and assessed each full text for eligibility in Covidence[4].

Two subject matter experts (Appendix 1) also reviewed our findings for credibility.

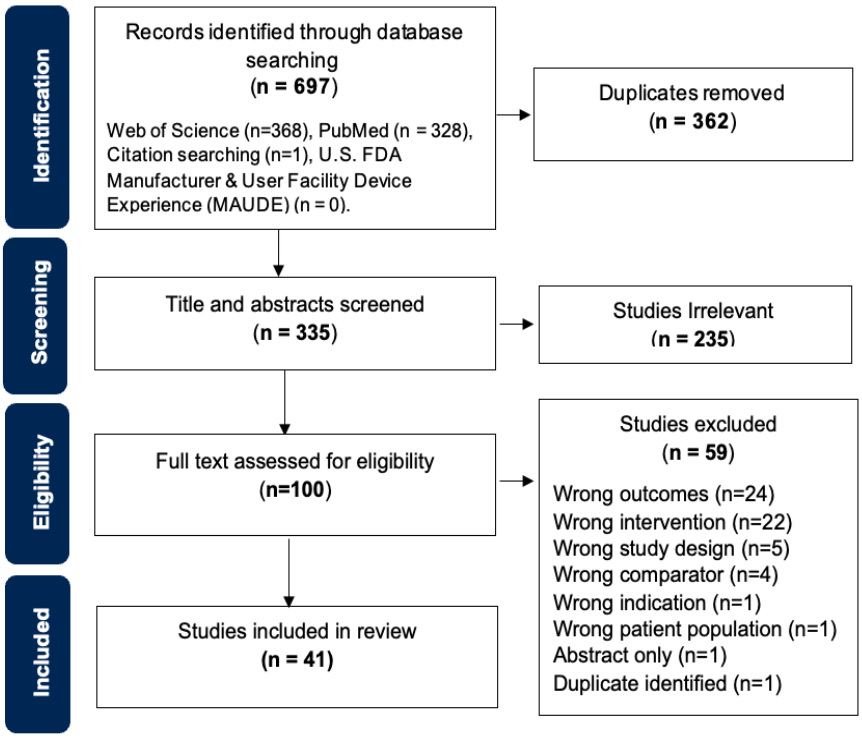


Figure 1: Overview of Project Literature Review

SUMMARY OF INITIAL FINDINGS

Our review identified 41 studies from 14 countries published between 1984-2023. One third (34.1%) of studies were from India, and in total 71.7% of non-review studies were from low-and middle-income countries (LMICs) (see Appendix). Most studies (69.0%) included participants of multiple age groups (e.g., 11-19 years, 20-29 years, 30-39 years, 40-49 years, and ≥50 years). Two thirds (66.7%) of studies included adolescents in the 11-19 years age group, and less than one fifth (19.0%) included women over 50 years of age (Fig 2). Four studies did not report their participants' ages. Some studies did not report exact sample sizes for the outcomes of interest, especially if these were secondary outcomes, and involved between 29 - 27,983 for a total 50,904 participants including controls. This large number of participants is partially due to the number of cross-sectional (survey) studies that were included, notably one nationally representative survey in India[5]. Interestingly 27 studies did not report on participants socioeconomic status despite its importance to menstrual product and health care access[6]. The many factors impacting product access and health outcomes are detailed in Appendix 1. In total our review included 22 cross-sectional, eight case-control, six randomized control trials, two systematic reviews, and one cohort, case series, and non-randomized study, respectively. All studies were assessed as being low to moderate quality evidence (levels 2-4, Figure 3). Overall, the most frequent menstrual products included in studies were disposable pads (81.0%), homemade alternatives (71.4%), menstrual cups (21.4%), reusable pads (11.9%), and other unspecified types (2.4%). Tampons were not captured in this review due to their low use in LMICs[7].

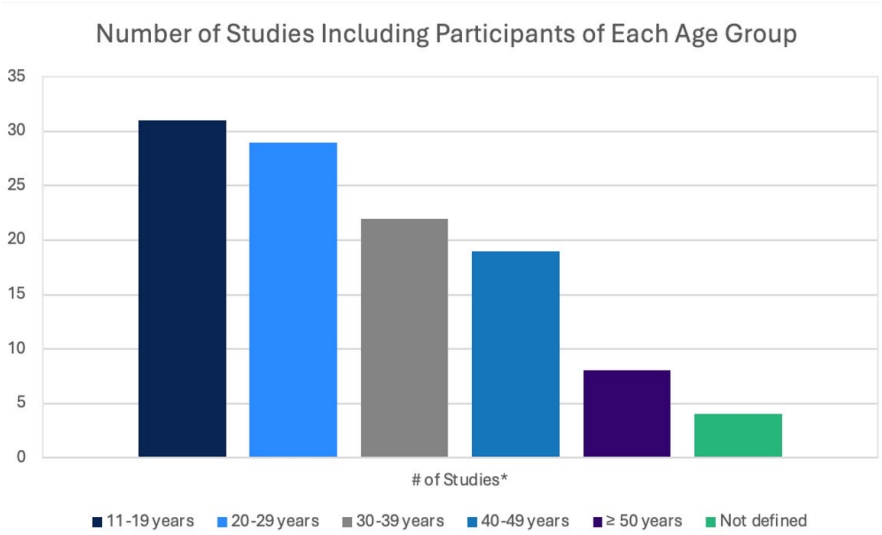
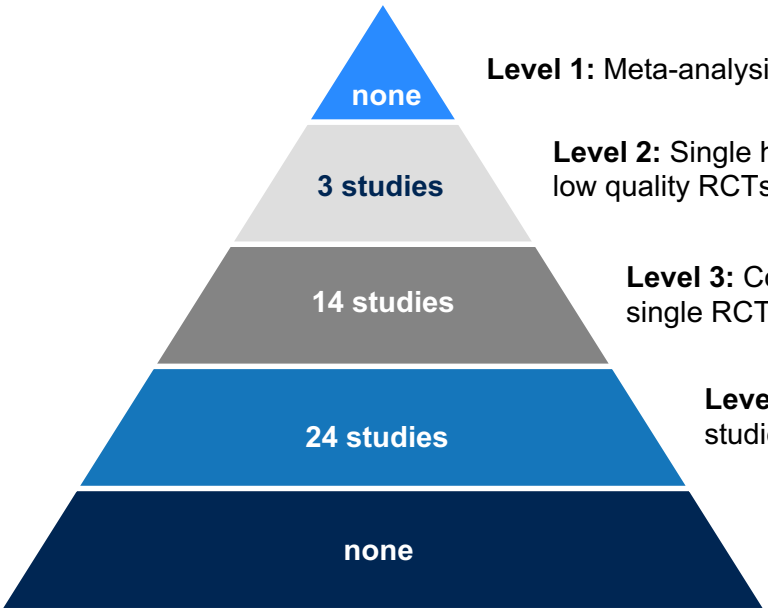


Figure 2: Number of studies including participants of different age groups. *number of studies exceeds total number of included studies (N=41) as most studies included ≥1 age group.

EVIDENCE GAPS

This review did not identify any high-quality systematic reviews on menstrual health product use and the reproductive tract infections of interest. A majority (58.5%) of articles included in this review were cross-sectional or Level 4 evidence, indicating lower quality evidence that does not determine cause and effect. The findings reported in this review should be interpreted with these limitations in mind.



Level 1: Meta-analysis and systematic reviews of high quality RCTs

Level 2: Single high-quality RCTs, or a meta-analysis/systematic review of low quality RCTs/other types of studies

Level 3: Cohort, case control studies, quasi-experimental studies, or a single RCT with methodology deficiencies/limitations

Level 4: Descriptive studies including case series, ecological studies, or cross-sectional studies

Level 5: Expert opinion, case report or clinical examples or experiences

Figure 3: Number of studies by evidence ranking. Ranking adapted from Sackett's Evidence Based Medicine Framework[8].

PRODUCT SPECIFIC FINDINGS

The following pages will summarize the relevant outcome findings for the menstrual products included in this review (menstrual pads, menstrual cups, reusable pads, and homemade alternatives). Only findings from higher quality studies (n= 9), based on evidence ranking and methodology, are emphasized below. Additional detail on why these studies merit the greatest attention is available in Appendix 3. As each study did not include all four menstrual products of interest, only relevant studies for each product are reported in their respective section.

MENSTRUAL PADS

Disposable menstrual pads, also known as 'sanitary napkins' or 'panty liners', are increasingly used in LMICs for menstrual hygiene management[9]. Despite this increasing use, there is limited high-quality evidence examining associations of disposable pads with infectious outcomes, such as reproductive tract infections (RTIs), urinary tract infections (UTIs), sexually transmitted infections (STIs), and bacterial vaginosis (BV).

KEY FINDINGS

1. **Thirty-three articles** for disposable menstrual pads were identified, with studies enrolling between 43 – 27,983 participants. Study designed included cross-sectional (n=19), case-control (n=7), RCTs (n=3), cohort (n=1), case series (n=1), quasi-experimental (n=1), and systematic review (n=1). Non-systematic reviews originated from India (n=12), United States (n=6), Kenya (n=4), The Gambia (n=3), China (n=1), Israel (n=1), Rwanda (n=1), Tanzania (n=1), Sweden (n=1), Ethiopia (n=1), and the Czech Republic (n=1).

2. **No definitive association to adverse outcomes of interest:** The Sumpter 2013 systematic review included no papers with a significant increase in BV when comparing disposable menstrual pads to reusable/traditional absorbents. Similarly, the Phillips-Howard 2016 pilot RCT found no significant difference in BV prevalence when pads were compared to cloths, underwear, or sponges. Phillips-Howard 2016 also observed a lower prevalence of STIs with both pads and cups compared to controls; however, differences between pads and cups were not significant. Of the four high-quality case-control studies, none found a statistically significant association between usage of disposable menstrual pads and infectious outcomes and their symptoms after adjusting for multiple factors. However, Das 2015 found that reusable cloths were associated with a significantly higher risk of symptomatic urogenital infections and combined BV or UTI infections compared to disposable pads.

3. **Research Focus Shift Recommended:** Future research, focusing on insertable products, could provide more valuable insights by as they may present a higher risk of infection when compared to external pads.

LIMITATIONS AND FUTURE RECOMMENDATIONS

There is a lack of high-quality evidence associating disposable menstrual pads with infectious outcomes of interest, including RTIs, UTIs, STIs, and BV. Only six of the reviewed studies met the criteria for high-quality evidence, while 17 out of the 33 studies were cross-sectional and thus unable to provide insight on considerations of temporality. Specific study details on page 4.

There is a lack of geographic variability among the included studies, with a majority being conducted in either India or the United States.

There is a lack of research comparing menstrual pads to insertable products, such as menstrual cups. This research would be necessary to determine if insertable menstrual products carry a higher risk of infection due to their mode of use. At present, the majority of published research focuses on comparing disposable versus reusable menstrual pads or cloths.

CONCLUSION

Overall, the current body of peer-reviewed literature, aside from one study by Das, 2015, indicates no significant association between disposable pad use and increased risk of STIs, RTIs, bacterial vaginosis, or candidiasis. Limitations in study design, exposure/outcome assessment, and small sample sizes in some studies highlight a possible role for further research to draw more definitive conclusions.

MENSTRUAL PADS (CONT.)

Table 1: ARTICLES WITH HIGHEST QUALITY EVIDENCE FOR MENSTRUAL PADS

LoE	Study	Design	Comparison Arms	Outcome	Findings
2	Sumpter (2013, multi-country)	Systematic review	'good' menstrual absorbents 'bad' menstrual absorbents	Confirmed BV	Pooled OR for **BV** for higher quality studies: good vs. bad menstrual absorbents: 1.07 (95% CI: 0.52–2.24, p = 0.85) *good absorbents included disposable pads, bad absorbents included reusable cloths
3	Phillips-Howard (2016, Kenya)	3-arm, single-site, open cluster randomized controlled pilot study	Treatment Arm 1: Menstrual Cups (n = 144) Treatment Arm 2: Commercial Sanitary Pads (n=202) Treatment Arm 3: Usual practice, no menstrual cups or sanitary pads provided (n=156)	Prevalence of RTIs > 9-months of follow-up, Prevalence of STIs > 9-months of follow-up. Est. adjusted prevalence ratios (aPR)	**BV** with pads vs. cloths/underwear/sponges: 19.8% vs. 20.5% (PR: 0.97, 95% CI: 0.65-1.44, p = 0.86) **BV** with cups vs. pads: 14.6% vs. 19.8% (PR: 0.74, 95% CI: 0.51-1.08, p = 0.12) **STI** Prevalence with pads: 4.5% vs. control: 7.7% (aPR: 0.62, 95% CI: 0.37-1.03, p = 0.063) **STI** Prevalence with cups: 4.2% vs. pads: 4.5% (aPR: 0.93, 95% CI: 0.56-1.55, p = 0.78)
3	Janoowalla (2019, Rwanda)	Prospective cohort study	Intervention group: single-use biodegradable pads for 6 months (n= 120) Control group: not provided with pads, not currently using menstrual pads, & no plans to change habits during study (n=120)	Positive Urine Culture Urinary Symptoms Vulvovaginal Symptoms	**Pos. urine culture**: Pad use: 5.5% vs. control: 3.2% (aOR: 2.09, 95% CI: 0.89-4.91, p=0.090) **Urinary symptoms**: Pad use: 52.3% vs. control: 56.6% (aOR: 1.02, 95% CI: 0.66-1.58, p=0.934 **Vulvovaginal symp**: Pad use: 46.8% vs. control: 51.0%; (aOR 0.89, 95% CI: 0.52-1.52, p=0.669) **Adjusted for multiple MHM, SES, and health history factors.*
3	Das (2015, India)	Hospital based case-control study for women seeking out-patient care	Cases: symptomatic women seeking care for vaginal discharge, genital burning/itching /sores, burning with voiding (n=228) Controls: asymptomatic women seeking care for menstrual/breast health (n=258) Ref. group is disp. pads	Urogenital Infection Symptoms BV/UTI (lab confirmed) UTIs (lab confirmed) BV (lab confirmed)	aOR for **symptomatic cases** with reusable cloths vs. disposable pads (ref): 2.26 (95%CI: 1.5-3.4, p<0.001) aOR for **BV or UTI** with reusable cloths vs. disposable pads: 2.8 (95%CI: 1.7-4.5, p<0.001) aOR for **UTI** with reusable cloths vs. disposable pads: 2.0 (95%CI: 1.0-4.0, p = 0.06) aOR for BV with reusable cloths vs. disposable pads: 1.23 (95%CI: 0.8-2.0, p = 0.4) *note study used terms reusable cloths, reusable pads, & reusable cloth pads interchangeably.
3	Geiger (1996, United States)	Case-control among university students	Cases: reported vulvovaginal symptoms & had a positive vaginal culture for yeast (n=64) Controls: university women mailed a survey (n=431)	Vulvovaginal Candidiasis	Crude OR for **Candidiasis** for any sanitary napkin use during last menses cases vs. controls: 0.89 (95% CI: 0.44-1.82) aOR for **Candidiasis** for any sanitary napkin use during last menses cases vs. controls: 1.30 (95% CI: 0.58-2.91) **Adjusted for multiple factors, including race.*
3	Foxman (1995, United States)	Case-control among university students	Cases: women referred for urine testing (n=86) Controls: registered female university students (n=288)	First- time UTI	aOR: 1.0 (ref group) for **first-time UTI** with only sanitary napkins use in past 2 weeks. aOR: 0.57 (95% CI: 0.25-1.28) for **first-time UTI** with both sanitary napkin & tampon in past 2 weeks. **Adjusted for frequency of vaginal intercourse.*

PRODUCT SPECIFIC FINDINGS

MENSTRUAL CUPS

Menstrual cups offer several advantages over traditional menstrual health products, including lower costs and the potential for discreet reuse that can facilitate reductions in stigma associated with menstrual health management. Previous studies have shown acceptability of menstrual cups when compared to other products; however, the safety of these products across diverse settings has been understudied. **To address this gap, we conducted an analysis of peer-reviewed, published literature to summarize our understanding of the associations between menstrual cup use and various safety outcomes, including urogenital infections and changes to the vaginal microbiome.**

KEY FINDINGS

1. **Nine relevant articles were identified**. Study designs included randomized controlled trials (RCTs) (n=3), systematic reviews (n=2), RCT-nested observational studies (n=2), and cross-sectional studies (n=2). Non-systematic reviews originated from Kenya (n=4), India (n=2), and Canada (n=1).
2. **At the present time, researchers have not established a definitive association between menstrual cups and adverse health outcomes.** Results from observational and interventional studies are mixed and do not unequivocally establish a change in STI acquisition risk or the development of RTIs following menstrual cup use.
3. Additional research, including improved implementation of RCTs, is necessary to formally draw causal conclusions.

Table 2: ARTICLES WITH HIGHEST QUALITY EVIDENCE FOR MENSTRUAL CUPS

LoE	Study	Design	Comparison Arms	Outcome	Findings
2	Zulaika (2023, Kenya)	Four-group, cluster RCT	Arm 1: Menstrual cup (ITT: n=915; PP; n=828) Arm 2: Conditional cash transfers (CCT) (ITT: n= 891; PP: n=811) Arm 3: Menstrual cup and conditional cash transfers (ITT: n=913; PP: n=861) Arm 4: Usual practice (ITT: n=813; PP: n=791)	Cumulative Incidence of HIV Infections Est. adjusted relative risks (aRR)	In **intention-to-treat analysis**: • MC vs. Usual Practice (1.2% vs. 1.4%; aRR = 0.88 (95% CI: 0.38,2.05); p=0.7735) • Combined MC and CCT vs. Usual Practice (1.0% vs. 1.4%; aRR = 0.80 (95% CI: 0.33, 1.94); p=0.623 In **per-protocol analysis**: • MC vs. Usual Practice (1.0% vs. 1.3%; aRR = 0.76 (95% CI: 0.30,1.93); p=0.5687) • Combined MC and CCT vs. Usual Practice (0.9% vs. 1.3%; aRR = 0.82 (95% CI: 0.32, 2.10); p=0.685)
3	Phillips-Howard (2016, Kenya)	3-arm, single-site, open cluster randomized controlled pilot study	Treatment Arm 1: Menstrual Cups (n = 144) Treatment Arm 2: Commercial Sanitary Pads (n=202) Treatment Arm 3: Usual practice without menstrual cups or sanitary pads provided (n=156)	Prevalence of STIs > 9-months of follow-up, Prevalence of RTIs > 9-months of follow-up. Est. adjusted prevalence ratios (aPR)	Prevalence of **STIs (presence of either *C trachomatis, T vaginalis, or N gonorrhoea*)**: • MC vs. Control (4.2% vs. 7.7%; aPR = 0.48 (95% CI: 0.24-0.96); p=0.04) • Pooled MC + Pads vs. Control (4.3% vs. 7.7%; aPR = 0.54 (95% CI: 0.34-0.87); p=0.012) Prevalence of **RTIs (presence of either BV *or C albicans*)**: • MC vs. Control (21.5% vs. 26.9%; aPR = 0.79 (95% CI: 0.48-1.30); p=0.356) • Pooled MC + Pads vs. Control (25.7% vs. 26.9%; aPR = 0.93 (95% CI: 0.66-1.31); p=0.675)
3	Mehta (2023, Kenya)	Prospective Analysis Nested within a cluster RCT (Zulaika, 2023)	Menstrual cup Arm (n=213; n=193 @ 30 months follow-up) Control Usual practice Arm (n=223; n=202 @ 30 months follow-up) *trial treated symptomatic & asymptomatic BV	Bacterial Vaginosis STI Incidence Vaginal Microbiome Abundance	aOR of **BV** • MC vs. Control: OR = 0.82 (95% CI: 0.51-1.32); p=0.421 aRR of **STIs** (composite of CT, NG, and/or TV): • MC vs. Control: RR = 0.77 (95% CI: 0.62-0.95) aOR of occurrence of ***Lactobacillus crispatus*–dominated vaginal microbiome**: • MC vs. Control: OR = 1.42 (95% CI: 1.21-1.67)

RCT = randomized controlled trial, STI = sexually transmitted infection, RTI = reproductive tract infection, BV = bacterial vaginosis
OR = odds ratio, RR = relative risk, ITT = intention to treat, PP = per protocol, MC = menstrual cup, CCT = conditional cash transfers

MENSTRUAL CUPS (CONT.)

SUMMARY OF THE EVIDENCE

- Systematic reviews (Sumpter 2013; Daher 2022) highlight a pronounced **gap in relevant literature on menstrual cups and related health outcomes prior to 2016**.
- In a four-group, cluster RCT by Zulaika 2023, there was **no significant difference in risk of incident HIV** comparing either menstrual cup users (aRR = 0.88; 95% CI: 0.38,2.05) or pooled menstrual cup/conditional cash transfer users (aRR = 0.80; 95% CI: 0.33, 1.94) when compared to the control arm. However, COVID-19 impacted study follow-up and may have biased results towards the null.
- Phillips-Howard 2016 (aPR = 0.48; 95% CI: 0.24,0.96) and Mehta 2023 (RR = 0.77; 95% CI: 0.62-0.95) both observed **an associated reduced risk between menstrual cup use and composite prevalence or incidence of STIs, respectively**. Importantly, in Mehta 2023, after adjusting for age, SES, school WASH score, and sexual activity at baseline a significant difference in STI risk was found.
- **The association between menstrual cups and RTIs or bacterial vaginosis were mixed**, with Phillips-Howard 2016 (aPR = 0.79; 95% CI: 0.48,1.30) and Mehta 2023 (OR = 0.82, 95% CI: 0.51,1.32) reporting non-significant associations. However, Mehta 2023 found that menstrual cup users had greater odds of *L. crispatus*-dominated vaginal microbiomes (OR = 1.42; 95% CI: 1.21,1.67) when compared to the control arm, which is associated with decreased risk for bacterial vaginosis.
- Howard 2011, Chakrabarty 2023, Juma 2017, and Parikh 2022 assessed for menstrual cup use in Canada, Kenya, and India. However, these studies either 1) did not directly assess for differences in burden of STIs or other urogenital infections or 2) were not powered to assess for differences given small sample sizes.

LIMITATIONS AND FUTURE RECOMMENDATIONS

Future studies evaluating the association between menstrual cups and incident urogenital infections, changes to the vaginal microbiome, and other safety outcomes **must account for the duration of menstrual cup use and how differences in use over time impact susceptibility** to negative health outcomes.

Incidence and prevalence of STIs and RTIs within longitudinal studies have only been assessed at enrollment and close-out. Future studies should conduct testing for infections at more frequent timepoints **to better understand how risk for urogenital infections changes over time**.

Methodological considerations for how to best assess menstrual cup use in RCTs should be discussed, given the **reliance on self-reported measures** (i.e., intention-to-treat versus per-protocol analysis).

Differences in underlying STI and RTI burden, in combination with social and cultural norms, may limit generalizability of findings across diverse geographic areas. **Decisions on the design of future studies should be specific to the study population under review**, including those around selection of adjustment covariates and implementation strategies.

CONCLUSION

Overall, the current body of peer-reviewed literature indicates varying levels of uncertainty between menstrual cup use and reductions in STIs and RTIs, increased occurrence of *Lactobacillus crispatus*, or general promotion of a healthy vaginal microbiome. Limitations in study design, exposure/outcome assessment, and small sample sizes highlight the need for further research to draw more definitive conclusions.

REUSABLE PADS

Reusable pads are cloth-based menstrual absorbents, intended for wash and reuse for one year or more. These products are developed specifically for menstrual absorbency unlike other cloth-based absorbents described in the homemade alternatives section. Only studies which specified use of reusable pads (versus pads, disposable pads, or sanitary napkins) are discussed below. Studies which may have used the term reusable pad when reporting findings but explicitly defined their product using descriptions of homemade alternatives are reported in the next section.

KEY FINDINGS

1. **Five relevant articles were identified.** Study designs included case-control (n=2), cross-sectional (n=2), and a systematic review (n=1). Non-systematic reviews originated from India (n=3) and Mali (n=1). The systematic review reported on findings from a cross-sectional study, which upon further investigation into supplemental materials analyzed cloths (captured in the homemade alternative product section) and not reusable pads. Thus, only one higher quality study is reported for reusable pads.
2. Although the evidence base is very limited, reusable pads appear to be associated with a higher odds of RTI symptoms, BV or UTIs, and Candidiasis among users. Of importance, all outcomes have biological plausibility.
3. Reusable pads, when adequately washed and dried, are considered hygienic; however, **limited access to safe water and sanitation may hinder adequate maintenance of these products.**

Table 3: ARTICLE WITH HIGHEST QUALITY EVIDENCE FOR REUSABLE PADS

LoE	Study	Design	Comparison arms	Outcomes	Findings
3	Das (2015, India)	Hospital based case-control study for women seeking out-patient care *note study used reusable cloths and reusable pads/reusable cloth pads interchangeably. No product definitions provided.	Cases: symptomatic women seeking care for vaginal discharge, genital burning/itching /sores, burning with voiding (n=228) Controls: asymptomatic women seeking care for menstrual/breast health (n=258) Ref. group is disp. Pads	Urogenital Infection Symptoms BV/UTI (lab confirmed) UTIs (lab confirmed) BV (lab confirmed)	aOR for **symptomatic cases** with reusable cloths vs. disposable pads (ref): 2.26 (95% CI: 1.5, 3.4; p<0.001) aOR for **BV or UTI** with reusable cloths vs. disposable pads: 2.8 (95% CI: 1.7, 4.5; p<0.001) aOR for **UTI** with reusable cloths vs. disposable pads: 2.0 (95% CI: 1.0, 4.0; p = 0.06) aOR for **BV** with reusable cloths vs. disposable pads: 1.23 (95% CI: 0.8, 2.0; p = 0.4)

LIMITATIONS AND FUTURE RECOMMENDATIONS

Definitions of reusable pads varied across studies and may differ in material, frequency of change, or be conflated with reusable cloths. The lack of high-quality studies in diverse populations and geographies limits the generalizability of these findings.

Further research on reusable pads and RTIs should be encouraged in other settings. Although it did not meet our product definition criteria for reusable pads, the methods used for washing and drying reusable products may merit further exploration based on the potential increased Candidiasis risk from homemade alternatives dried in the house compared to outside as reported by Torondel, 2018 (Level 4).

Access to sanitation should be included in the causal pathway, as the hygienic use of these products relies on access to safe water and toilets.

CONCLUSION

While limited to only one higher quality study, the evidence suggests a plausible association between Candidiasis, BV, UTIs, and reusable pads. Further high-quality research in other geographies, using clear reusable pad product definitions, could help broaden the knowledge base regarding reusable pads and the risk of RTIs, including washing and drying of these products which may impact risk for Candidiasis.

PRODUCT SPECIFIC FINDINGS

HOMEMADE ALTERNATIVES

Women lacking access to commercially produced menstrual products may rely more on homemade alternatives for their menstrual absorbency needs. These products are often repurposed strips of fabric, cloths, or rags and differ from reusable pads, which we define as being made expressly for menstrual absorbency. In the literature homemade alternatives were described as washed/unwashed, used/reused, and unhygienic or bad suggesting additional factors to consider with these products. Homemade alternatives remain a commonly used menstrual material globally, particularly among menstruators from more rural, lower socioeconomic, or marginalized backgrounds[5,22].

KEY FINDINGS

1. **Twenty-five relevant articles were identified.** Study designs included cross-sectional (n=17), case-control (n=3), cohort (n=1), observational study nested in a cluster RCT (n=1), quasi-experimental (n=1), and a systematic review (n=1). Non-systematic reviews originated from India (n=13), Kenya (n=4), The Gambia (n=3), China (n=1), Ethiopia (n=1), Rwanda (n=1), and Tanzania (n=1).
2. Although no significant association with UTIs was found, one study suggests the vaginal microbiome may impact the association between the use of homemade alternatives and BV.
3. As the consequences of cloth use as a menstrual product have been primarily explored in low-resource settings, the effects of cloth use on health outcomes may be related to **socioeconomic status and access to sanitation**.

Table 4: ARTICLES WITH HIGHEST QUALITY EVIDENCE FOR HOMEMADE ALTERNATIVES

LoE	Study	Design	Comparison Arms	Outcomes	Findings
2	Sumpter (2013, multi-country)	Systematic review	'good' menstrual absorbents 'bad' menstrual absorbents	Confirmed BV	Pooled OR for **BV** for higher quality studies: good vs. bad absorbents: 1.07 (95% CI: 0.52, 2.24; p = 0.85) *good absorbents included disposable pads; bad absorbents included reusable cloths
3	Janoo-walla (2019, Rwanda)	Prospective cohort study	Intervention group: single-use biodegradable pads for 6 months (n= 120) Control group: not provided with pads, not using menstrual pads, & no plans to change habits during study (n=120)	Positive Urine Culture Urinary Symptoms Vulvovaginal Symptoms	**Pos. urine culture**: Pad use: 5.5% vs. control: 3.2% (aOR: 2.09, 95% CI: 0.89-4.91, p=0.090) **Urinary symptoms**: Pad use: 52.3% vs. control: 56.6% (aOR: 1.02, 95% CI: 0.66-1.58, p=0.934 **Vulvovaginal symp**: Pad use: 46.8% vs. control: 51.0%; (aOR 0.89, 95% CI: 0.52-1.52, p=0.669) **Adjusted for multiple MHM, SES, and health history factors.*
4	Mehta (2021, Kenya)	Cross – sectional (N= 436)	Arm 1: Cloth use during last period Arm 2: No cloth use during last period	BV	OR: 1.59 (95% CI: 1.17, 2.17) for ***L. iners* dominant VMB** for cloth use during last period (p <0.01) OR: 1.72 (95% CI: 1.03, 2.86) for ***G. vaginalis dominant VMB*** for cloth use during last period (p <0.05)
4	Torondel (2018, India)	Hospital based cross-sectional study for women seeking out-patient care *note study uses reusable cloths & reusable pads interchange-ably. Product definitions in supplement defined as old cloths/fabric.	Arm 1: Reusable cloths (includes old cotton, nylon, & silk) Arm 2: Disposable pads (ref. group) *specific sample sizes not reported for this analysis	BV prevalence Candidiasis prevalence *Trichomonas Vaginalis* (TV) prevalence aPRR: adjusted prevalence rate ratios	aPRR for **BV** with reusable vs. disposable pads (ref): 1.23 (95% CI: 1.0, 1.54; no p-value) aPRR for **Candidiasis** with reusable vs. disposable pads: 1.54 (95% CI: 1.21, 2.00) aPRR for **Candidiasis** among individuals drying reusable materials inside their house/hidden in toilet compartment vs. in the sun: aPRR 1.78 (95% CI: 1.34, 2.38) aPRR for **Candidiasis** among individuals drying reusable materials inside their house/hidden in toilet compartment vs. in a changing room cupboard: aPRR 1.96 (95% CI: 1.49, 2.57) aPRR for **TV** with reusable vs. disposable pads: 1.78 (95% CI: 0.81, 3.90) **adjusted for age, education*

SUMMARY OF THE EVIDENCE

- **Definitions for cloth-based products,** whether reusable pads or homemade alternatives, are diverse or poorly defined in the literature. Das, 2015 and Torondel, 2018 are examples of otherwise higher quality studies that use the terms reusable cloths and reusable pads/reusable cloth pads interchangeably. The former did not include any product definitions in their article and the latter only included these details in supplementary information. The lack of consistent and clear product definitions limits comparability of study findings as well as accurate understandings of any product associated risk and was also identified as an issue by Sumpter in 2013.

- **A high percentage of menstruators in LMICs continue to use homemade alternatives** as reported in multiple recent cross-sectional surveys and other study designs[5,23]. While use of homemade alternatives is assumed to be associated with lower socioeconomic status (SES), most of studies that included homemade alternatives in this review did not report any specific socioeconomic status (SES) information for their populations, although may have adjusted for related factors such as education. As most studies were conducted in LMICs, sanitation was also frequently assessed in parallel with menstrual health outcomes.

- **Sumpter's systematic review reported no significant difference** in the odds of BV comparing unhygienic product (cloths/rags) use with hygienic menstrual product use (disposable pads). Using a prospective cohort design, **Janoowalla 2019** found no significant difference in the odds of incident UTI comparing disposable pads with homemade alternatives. However, among the most relevant cross-sectional studies, **Mehta 2021** found a significantly higher presence of BV in cloth users with *G. vaginalis* and *L.* iners dominant VMB, in comparison with *L.crispatus* dominant VMB, thus suggesting a role of VMB composition on risk for development of relevant health outcomes.

LIMITATIONS AND FUTURE RECOMMENDATIONS

Several studies (not discussed above) did not confirm their outcomes with formal lab testing and are therefore subject to misclassification as they instead relied on symptom self-report. Product definitions also vary or are not defined limiting comparisons and understandings of reported findings.

Further research on homemade alternatives and RTIs should be encouraged, given their continued high prevalence of use in LMICs. Access to sanitation and the vaginal microbiome should also be considered in the causal pathway. The methods used for washing and drying reusable products may merit further exploration based on the potential increased Candidiasis risk from products dried in the sun compared to in the house, as reported by Torondel 2018 (Level 4 evidence).

CONCLUSION

The use of homemade alternatives, whether hygienic or unhygienic, for menstruation remains widespread in many low-resource settings. Current evidence points to a possible association between the use of homemade alternatives and the occurrence of BV. Future research should consider harmonizing product and exposure definitions, or at least the reporting of these definitions as standard practice, as well as including critical factors such as access to safe water and proper sanitation and socioeconomic status in their study designs.

RESULTS

The following table 5 summarizes the number of studies that reported on each exposure and outcome of interest for each level of evidence. Some studies included multiple exposures (products) as well as outcomes and so the total number of studies are not unique studies. Bacterial vaginosis was the most frequently assessed outcome followed by candidiasis/vaginitis, both of which are outcomes that could theoretically be more plausibly associated with menstrual product use. None of the included studies reported findings for syphilis, which was included as an outcomes of interest.

It is important to note that for the level four evidence, these studies were survey based and thus had no longitudinal follow-up. They therefore assessed for the prevalence of various outcomes of interest while also asking about menstrual product usage. Some of these studies relied on participants self-report of an outcome which can contribute to misclassification, while a few conducted lab testing. In some cases, STIs were not defined just reported under the term STI. Due to all these limitations, conclusions about cause and effect can not be drawn from these level four studies. In addition, three case-control studies examined associations between cervical cancer and various behavioral risk factors including reported use of menstrual products among women with known cervical cancer. These outcomes are not included in the table below due to concerns about the studies methodology and lack of plausibility for any cervical cancer associations drawn relating to menstrual product use since no longitudinal follow-up was involved that would align with the natural history of cervical cancer and because cervical cancer associated bleeding may necessitate the use of various menstrual products.

Table 5: NUMBER OF STUDIES REPORTING ON EACH OUTCOME OF INTEREST

	Outcomes of Interest						TOTAL # OF STUDIES
Menstrual Product	Bacterial Vaginosis	Sexually Transmitted Infections*	Candidiasis or Vaginitis	Urinary Tract Infections	HIV	HPV	
LEVEL 2 EVIDENCE							
Disposable Pads	1		1				2
Reusable Products	2		2				1
Menstrual Cups					1		1
LEVEL 3 EVIDENCE							
Disposable Pads	3	1	1	3			8
Reusable Products	2			2			4
Menstrual Cups	1	2	1				4
LEVEL 4 EVIDENCE							
Disposable Pads	7	6	5	3	2	1	23
Reusable Products	6	4	5	1	2	1	19
Menstrual Cups							
TOTAL # OF STUDIES	**22**	**13**	**15**	**9**	**5**	**2**	

*STIs in this column includes Syphilis, Gonorrhea, Chlamydia, & Trichomonas.

DISCUSSION

Our review sought to identify literature investigating the effect of menstrual product use on menstruators reproductive and urinary tract infectious outcomes and identify corresponding gaps in the literature. Studies assessing the relationship between menstrual product use and changes in the vaginal microbiome that may not have a defined health outcome are being examined separately from this review. Despite the specific focus of our review, it is important not to lose sight of the broader multi-dimensional context impacting these health outcomes. Menstrual health and management are related to complex social, biological, and behavioral relationships and thus any findings must be considered with this context in mind (Fig 4 & Appendix 1). Simply considering use of more modern materials may ignore women's broader menstrual health needs[7]. A recent systematic review recommends the use of comprehensive and multi-sectoral approaches, that may include addressing access to clean products and sanitation, to improve menstruators health and human rights[35]. While also outside the scope of this review, it should be noted that menstruator's ability to appropriately manage their menstrual hygiene, which includes access to products, has major social benefits including reduced stigma and greater freedom of movement that can include remaining in school or employ[35].

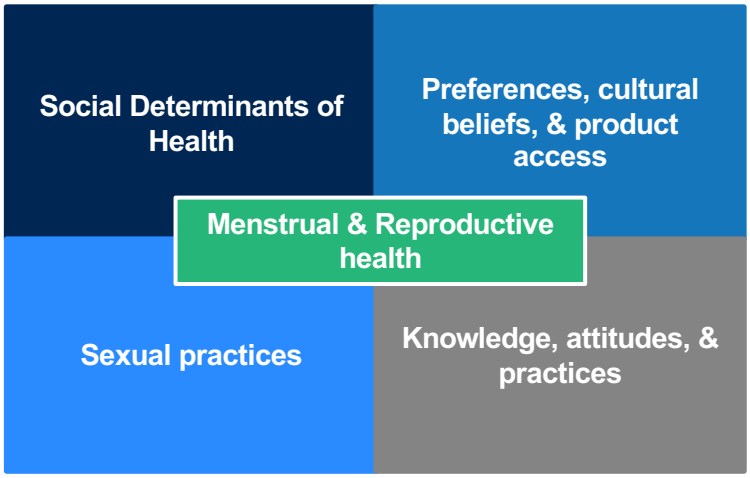


Figure 4: Factors influencing menstrual and reproductive health.

Key takeaways from this literature review include that there is a lack of high-quality evidence regarding menstrual health product use and reproductive and urinary tract infections. Thus, conclusions about cause and effect cannot be drawn from the existing evidence base. Sumpter and Torondel's 2013 systematic review remains the highest quality evidence we identified, and in line with our findings they also reported overall low study quality and variable methodologies on the topic of menstrual health and hygiene management[10]. Most of the higher quality safety data comes from recent trials for menstrual cups. Due to the increased risk for toxic shock syndrome from some tampons[11], interest to investigate the safety of menstrual cups as a newer insertable menstrual product was understandable. Notably, toxic shock syndrome was outside the scope of this review and therefore will otherwise not be discussed. In addition to our review of published literature, we also searched the United States (U.S.) Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database for any reports of malfunction, injury, or death from users of any of the menstrual products included in this review, which returned zero results. This may be suggestive of overall menstrual product safety, although the infectious outcomes of interest may not be typically captured by this database so the lack of results should be interpreted with caution. MAUDE is also a U.S. based database, so may be less relevant for populations residing in LMICs where menstrual product use is more often commercial pads and absorbent cloths[7].

More direct associations between candidiasis, vaginitis, urinary tract infections, and bacterial vaginosis could be considered for further exploration with higher quality research. If pursued, additional research investigating associations between menstrual product use and sexually transmitted would need to be designed to account for confounding factors such as sexual behaviors.

Disposable pads

Studies rarely included product definitions and for our review we assumed that pads, unless otherwise specified were disposable commercial products. Sumpter and Torondel reported contradictory evidence for bacterial vaginosis and menstrual product use from the studies they reviewed and otherwise found the quality of evidence to be too poor to assess any potential association between disposable pad use and the reproductive and urinary tract infections of interest[10]. In addition to Sumpter and Torondel's review, we identified six higher quality studies assessing this association as summarized on page 4. Disposable pads were found to be associated with a significantly lower risk of laboratory confirmed bacterial vaginosis and UTIs, when compared to reusable cloths[12], and no significant risk of culture confirmed UTI when compared to non-pad use which may be related to the small number of culture confirmed cases included in this study[13]. Additional pad related results are reported on the next page in comparison to reusable cloth-based products.

DISCUSSION

Menstrual cups

A 2019 systematic review on menstrual cup safety did not identify any increased risk of RTI compared with other menstrual products among menstruators in both high- and lower-income countries[14]. Our review identified five subsequent studies, four in LMICs, assessing menstrual cup safety [5, 15-18]. None identified any safety issues related to RTIs, and one large-scale trial in Kenya suggested that menstrual cups could be protective against herpes simplex 2 (Zulaika, 2023). Another identified a significantly lower risk of bacterial vaginosis when compared to pads (Philips-Howard, 2016).

Reusable cloth-based products

A 2021 systematic review on reusable pad safety did not identify any objective reports of genitourinary infection from these products, as all studies included in their review relied on symptom self-report[19]. This review was limited to commercially produced reusable menstrual pads and excluded homemade alternatives. In addition, safety, which captured a range of adverse events from infections, skin irritation, allergies, and pain/discomfort, was only one of their six outcomes of interest. Our review used a broader definition of reusable products and identified several studies with formally measured genitourinary outcomes. An increased risk of bacterial vaginosis[12,20,21], candidiasis[20], and urinary tract infection[12, 13] was identified among reusable material users compared to disposable products, although the strength of these associations is limited. The review by Daher, 2022 reported contradictory results from only two studies when considering reusable product use and risk of bacterial vaginosis[15]. Findings for reusable pads and homemade alternatives are discussed together as definitions for cloth-based products were identified as being diverse and generally poorly defined in the literature in our review. In addition, any potential risk from cloth-based products are thought to be similar, apart from cloth-related cleanliness and maintenance which was not always reported.

Limitations

Our review was limited to three databases, two for peer-reviewed literature and one for product safety reports to the U.S. FDA. Curiously two systematic reviews by van Eijk[14,19] on menstrual product safety that were listed in the work order were not captured by our search terms despite being available in PubMed. This could suggest that our search strings may benefit from further refinement, the addition of other databases, and/or reference searching of included articles. We did conduct initial exploratory searches across five additional potential databases (CINAHL, Cochrane Library, Global Index Medicus, Scielo, and Embase) in our initial literature review process, and identified PubMed and Wed of Science as being the best fits based on the relevance and number of articles identified. We sought to minimize bias in article selection by having two reviewers screen each article and full text. Almost a third (31.7%) of the studies included in this review were not sufficiently powered to detect the associations of interest as they were not the primary outcomes of those studies[5,18,24-34]. As discussed throughout this report and identified by previous reviews, in general there is limited quality evidence regarding menstrual health product use and reproductive and urinary tract infections outcomes limiting conclusions that can be drawn about cause and effect between these exposures and the outcomes of interest. Multiple studies of lower quality, also did not adjust for important confounders in their analyses including sexual practices, water, sanitation, and hygiene, age, and socioeconomic status. In addition, lack of clearly defined menstrual product exposures, including type of product, frequency of product change, and cleanliness or washing and drying practices for these products, limits understandings of potential mechanisms of action. Finally, results from studies involving less generalizable cohorts, such as American university students, may be of less relevance to LMICs.

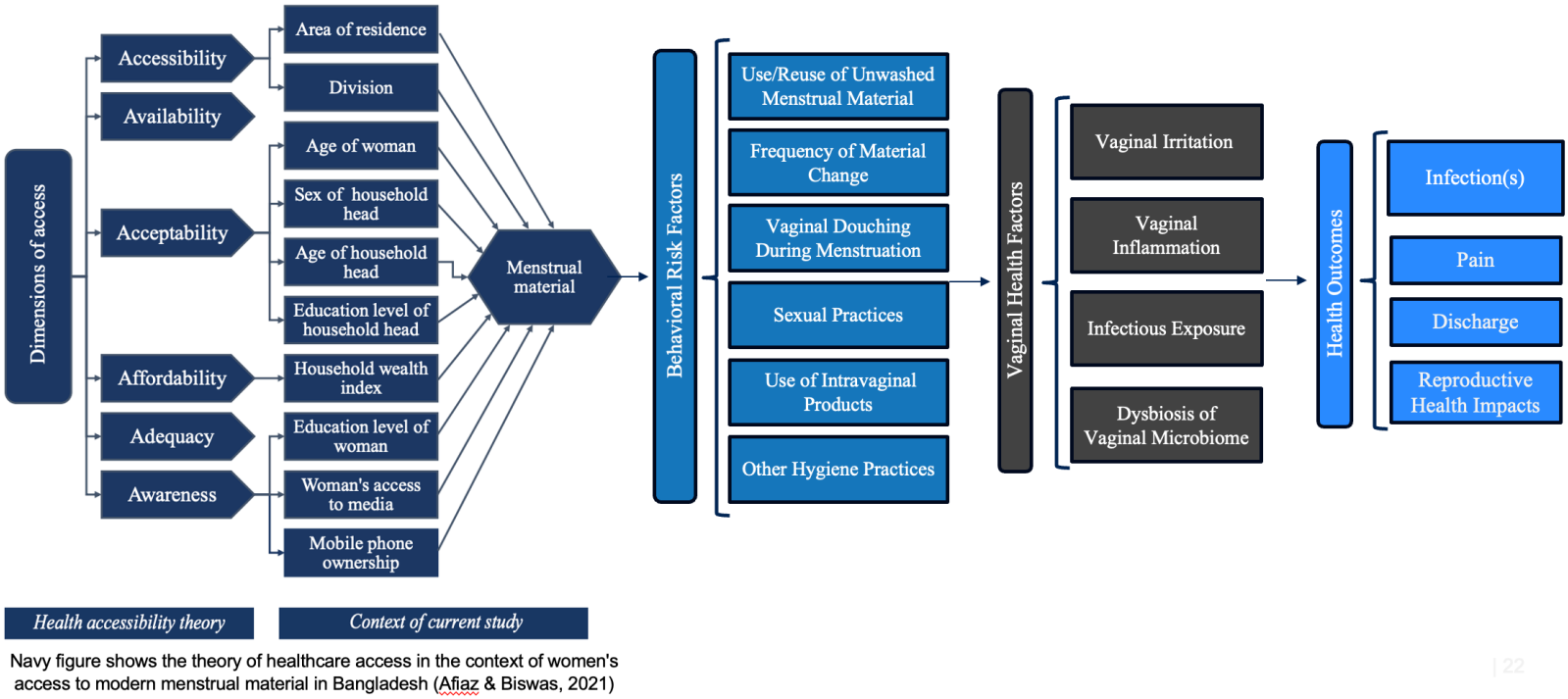
Conclusion

The evidence on menstrual product use and the reproductive and urinary tract infections of interest is mixed and of low to moderate quality involving diverse or poorly defined product exposures. The majority of higher quality safety data comes from recent trials for menstrual cups, as a newer insertable menstrual product. While product safety is important, menstruators health outcomes are influenced by multi-dimensional factors. In order to correctly evaluate product safety, studies must evaluate the effect of multi-dimensional confounding factors. These include social and behavioral determinants such as sexual practices, including transactional sex.

Photo: UN Women

APPENDIX 1

A study in Bangladesh developed a theory of healthcare access in the context of women's access to modern menstrual material/products as displayed below in navy. We expand upon this theory to include behavioral risk and vaginal health factors contributing to the health outcomes of interest to demonstrate the complex social biological, and behavioral relationships involved in menstrual product use and health outcomes.



Navy figure shows the theory of healthcare access in the context of women's access to modern menstrual material in Bangladesh (Afiaz & Biswas, 2021)

Figure 5: Theorized pathway of menstrual product access, use and reproductive and urinary tract outcomes. Expanded from Afiaz and Biswas (2021), which is the figure in navy on the left[23].

SUBJECT MATTER EXPERTS

As described in the methods section on page 1, two subject matter experts from the University of Washington faculty reviewed the findings summarized in this report for credibility.

CONSULTED SUBJECT MATTER EXPERTS
Dr. Stephen E. Hawes • Professor of Epidemiology and Global Health at the University of Washington • Expertise in HIV, HPV, STIs, and the Vaginal Microbiome
Dr. R. Scott McClelland • Professor of Epidemiology, Global Health, and Medicine at the University of Washington • Expertise in women's reproductive health, STIs, and HIV

APPENDIX 2

Table 6: Number of articles by country, World Bank income grouping, and publication year

Country	World Bank Income Grouping*	Menstrual Products of Focus†	Outcomes of Interest	Number of Articles	Publication Years
Canada	High-income	• Menstrual Cup	• Urogenital Infection Prevalence	1	2011
China	Upper-middle income	• Menstrual Pads • Cloths/rags	• HPV Prevalence • # of HPV Infections	1	2017
Czech Republic	High-income	• Menstrual Pads	• Bacterial Vaginosis Prevalence • Urogenital Infection Prevalence	1	2007
Denmark	High-income	• "Other types" (not tampons)	• Bacterial Vaginosis Prevalence	1	1985
Ethiopia	Low income	• Menstrual Pads • Cloths/rags		1	2019
Gambia (The)	Low income	• Menstrual Pads • Cloths/rags	• Bacterial Vaginosis Prevalence • Bacterial Vaginosis Incidence • # of Bacterial Vaginosis Infections • HIV Prevalence • Urinary Tract Infection Prevalence	3	2005 x2 2021
India	Lower middle-income	• Menstrual Cup • Menstrual Pads (disposable & reusable) • Cloths/rags	• Bacterial Vaginosis Prevalence • # of Bacterial Vaginosis Infections • Cervical Cancer Associations • # of Reproductive Tract Infections • STI Prevalence • # of STI Infections • Urogenital Infection Prevalence • # of Urogenital Infections	14	2012 2013 2015 2017 x2 2018 2019 2020 2021 x2 2022 x3 2023
Israel	High-income	• Menstrual Pads	• Urinary Tract Infection Prevalence	1	1984
Kenya	Lower middle-income	• Menstrual Cup • Menstrual Pads (disposable & reusable)	• Bacterial Vaginosis Prevalence • # of Bacterial Vaginosis Infections • HIV Prevalence • # of HIV Infections • HIV Incidence • STI Prevalence • # of STI Infections	6	2015 2016 2017 2021 2023 x2
Mali	Low income	• Menstrual Pads (disposable & reusable)	• Cervical Cancer Associations	1	2002
Rwanda	Low income	• Menstrual Pads • Cloths/rags	• Urinary Tract Infection Incidence	1	2019
Sweden	High-income	• Menstrual Pads	• Urinary Tract Infection Prevalence	1	1998
Tanzania	Lower middle-income	• Menstrual Pads • Cloths/rags • Cotton wool/toilet paper	• Bacterial Vaginosis Prevalence	1	2009
United States	High-income	• Menstrual Pads	• Bacterial Vaginosis Prevalence • # of Urogenital Infections • STI Prevalence • Urinary Tract Infection Prevalence	6	1995 1996 1998 2010 x2 2011
Multi-country	Varies	• Menstrual Cup • Menstrual Pads (disposable & reusable) • Cloths/rags	• STI Prevalence • Bacterial Vaginosis Incidence	2	2013 2022

*Per current World Bank Income groupings which may not reflect a country's income grouping at the time of each study.
†Menstrual pads were assumed or defined as disposable unless specifically indicated to be reusable.

APPENDIX 3

Table 7: Highest quality studies identified in our review, listed alphabetically by author name

Study	Study Design	Comments on Study Methodology	Key Information of Interest & Comments
Daher 2022	Systematic Review	• PRISMA Guidelines followed; three databases searched, 265 articles screened. • Included literature up to January 2021 • Quality of studies assessed & none deemed low quality. • Of the 15 studies included for health outcomes: eight cross-sectional, three RCT, three case control, one cohort. • One used lab testing. • No meta-analysis due to data heterogeneity. • Products: no explicit product definitions. Used terms reusable absorbent material and reusable absorbent pads to report findings from Torondel (2018) and Das (2015) respectively.	• Risk of Candidiasis, UTI, or BV • Qualitative synthesis. Less rigorous than Sumpter's review. • Only two studies cited for our outcomes of interest.
Das 2015	Case Control	• Study designed to assess the association between different menstrual health management and BV & UTI. • Formal swabs/lab testing used for outcome measures. • Hospital based study. Cases (n=228) and controls (n=258) selected based on presence of symptoms. • Adjusted for age, education and wealth index, but not sexual practices. • Controls slightly older than cases (significant finding). • Included in Daher 2022 systematic review • Products: study used reusable cloths and reusable pads/reusable cloth pads terms interchangeably. No product definitions provided.	• Odds of BV or UTI • Residual confounding from sexual practices not captured.
Foxman 1995	Case Control	• Study designed to assess the relationship between women's sexual & health behaviors & first-time UTI. • Associations stratified by multiple sexual behaviors and race. Excluded women who had been catheterized in previous 2 weeks. • Only asked about past 2 weeks of behaviors to limit impact of recall bias. • Formal swabs/lab testing used for outcome measures. • Smaller number of cases (n=86) compared to controls (n=288). • Students using free university health services. • Products: no explicit definitions, described as sanitary napkins, tampons, or combined use for menstrual protection. 'Deodorant napkins or tampons' also assessed but separated from menstrual protection and not discussed so unclear if used for purposes other than menstruation.	• Risk factors associated with first time UTI • Results may be less generalizable as university student population. • Captured a variety of sexual practice history
Geiger 1996	Case Control	• Study designed to test the association between several hypothesized risk factors (sexual behavior, contraceptive practices, feminine hygiene habits, & clothing patterns) and symptomatic culture-positive vulvovaginal candidiasis. • Formal swabs/lab testing used for outcome measures. • Adjusted for oral sex in past 2 weeks, race, and history of candidiasis. • Smaller number of cases (n=64) compared to clinic controls (n=196) and population controls (n=431) • Products: not explicitly defined, described as tampon (any or deodorant) and sanitary napkin (any, deodorant, baking-soda treated) use during last menses, stratified by categories in brackets.	• Candidiasis • Results less generalizable as university student population with free healthcare access & demographics not fully balanced between cases & controls.

Table 7: Highest quality studies identified in our review, listed alphabetically by author name (cont.)

Study	Study Design	Comments on Study Methodology	Key Information of Interest & Comments
Janoowalla 2019	Prospective cohort study	• Study designed to determine rates of UTI in adolescent users of pads. • 209/240 participants completed study, ½ using pads and ½ not, • Results reported using person-visits • Not randomized due to the concern for crossover contamination at each site. • Formal swabs/lab testing, and self-report used for outcome measures. • Pad use analyses adjusted for school, sexual activity, running water, having money, baseline MHM method, history of STI, and frequency of changing pad. • Study also captures knowledge & other behaviors around menstruation. • Products: provided single-use biodegradable pads made from banana fibers (pad-use) in intervention group vs. "not provided pads, were not currently using menstrual pads, & planned not to change their MHM", however per Table 3 at baseline 5% were using commercial pads, 12.5% were using rag made pads, 35% were using cloths, 42.5% were using commercial pads in combination with another method, & 5% were using a combination of non-commercial products.	• Incidence of UTI • Study may have been underpowered to detect a small difference in the rate of UTI. Intervention not randomized.
Mehta 2023	Sub-study of a cluster randomized trial (Zulaika 2023)	• Study designed to estimate the effect of the "Mooncup" menstrual cups on girls' risk of BV as the primary outcome in Kenya. • Formal swabs/lab testing used for outcome measures. • Longitudinal follow-up of participants x 30 months. • Large sample, N=2,048 for primary and N=1,116 for secondary outcomes • Adjusted for baseline sexual behavior, socioeconomic status, and WASH. • Documented antibiotic treatment also captured. • Also captured vaginal microbiome data. • Treated asymptomatic & symptomatic BV despite no indication to treat asymptomatic cases. • Products: silicone Mooncup vs. usual practice (71.6% reported use of sanitary pads, 3.3% used cloths, 25.1% reported combined pad/cloth use, & 3.5% missing data). No further definitions	• BV prevalence & incidence • Gonorrhea, chlamydia, and trichomoniasis pr evalence & incidence (secondary outcomes)
Philips-Howard 2016	Pilot feasibility open cluster randomized trial	• Study designed to assess the effect of menstrual hygiene on school attrition (primary outcomes) • Secondary outcomes: sexually transmitted infection (STI) (Trichomonas vaginalis, Chlamydia trachomatis, Neisseria gonorrhea), reproductive tract infection (RTI) (BV, Candida albicans); safety. • 3-arm (menstrual cup, sanitary pads, & usual practice) single-site study • Longitudinal follow-up of participants x ≥9 months. • Adjusted for age, reported sexual behavior, & SES. • Sample size for outcomes of interest vary between n=43-244 depending on f/u period and product. • Product: silicone Mooncup vs. Always sanitary pads vs. usual practice (not defined)	• Not powered to detect small-to-moderate differences in outcomes between study arms

Table 7: Highest quality studies identified in our review, listed alphabetically by author name (cont.)

Study	Study Design	Comments on Study Methodology	Key Information of Interest & Comments
Sumpter 2013	Systematic Review and Meta-analysis	• The only meta-analysis identified, authors were only able to include six studies in this analysis. • Study designed to summarize and critically assess peer-reviewed and published evidence on the health and psycho-social outcomes of the methods of menstrual hygiene management in LMICs and assess the evidence for existing interventions such as educational programs and absorbent distribution. • PRISMA Guidelines followed; three databases searched & 1,924 articles screened. • Included literature up to May 2012 • Quality of studies assessed by two reviewers. • Of the 14 studies included for health outcomes, 11 were cross-sectional, two were case control, and one was a cross-over. • Five studies relied on self-report of symptoms vs. Six used lab testing. • Products: highlighted inconsistent definitions in literature. 'Good menstrual hygiene management (MHM)' included disposable sanitary pads, reusable cloths if washed hygienically and dried in the sun, 'bad MHM' included reusable cloths, cotton, cotton wool, toilet paper.	• Meta-analysis of association between BV & menstrual hygiene management • Quality of studies included was identified as being low overall.
Zulaika 2023	Cluster randomized trial	• Study designed to assess the impact of "Mooncup" menstrual cups or cash transfers conditioned on school attendance, or both, on schoolgirls risk of HIV, HSV-2 and school dropout in western Kenya. • Large trial in Kenya 4,106 girls completed the trial, across 96 schools. • 4 treatment arms (menstrual cup + soap; cash; menstrual cup + cash; usual practice + soap) • Formal swabs/lab testing used for outcome measures. • Adjusted for socioeconomic status, WASH, & captured sexual behavior information. • Trial was paused due to COVID-19 pandemic & some missing HIV data. • Product: silicone Mooncup; usual practice (71.6% reported use of sanitary pads, 3.3% used cloths, 25.1% reported combined pad/cloth use, & 3.5% missing data). No further definitions.	• HIV incident infection • Results may be less generalizable as schoolgirl population

Additional cross-sectional studies by Mehta et al. (2021) and Torondel (2018) were noted to be stronger designs and were also considered for some products. However, since they only report findings from a specific point in time, conclusions about cause and effect cannot be drawn. The product definitions in Mehta were cloths use vs. no cloth use, but no further definitions provided in terms of use/re-use. Torondel included definitions in additional file one, where absorbent materials were classified as disposable (disposable sanitary pads) vs. reusable cloths/towels (old cotton fabric and old silk/nylon fabric).

APPENDIX 4

Outcome	Search String	Initial Results	Kept Articles
PUBMED			
Bacterial Vaginosis	("Menstrual Hygiene Products"[MeSH] OR "menstrual product*"[MeSH] OR "menstrual napkin*"[Title/Abstract] OR "period product*"[Title/Abstract] OR "feminine hygiene product*"[Title/Abstract] OR "feminine hygiene"[Title/Abstract] OR "feminine product*"[Title/Abstract] OR "feminine napkin*"[Title/Abstract] OR "sanitary pad*"[Title/Abstract] OR "menstrual cup"[Title/Abstract] OR "menses cup"[Title/Abstract] OR "menstruation cup"[Title/Abstract] OR "vaginal cup"[Title/Abstract] OR "menstrual cups"[Title/Abstract] OR "menses cups"[Title/Abstract] OR "menstruation cups"[Title/Abstract] OR "vaginal cups"[Title/Abstract] OR "reusable pad*"[Title/Abstract] OR ("menstrual" AND "cloths") OR ("menses" AND "cloths") OR ("menstruation" AND "cloths") OR ("vaginal" AND "cloths") OR ("menstruation"[Title/Abstract] AND "management"[Title/Abstract]) OR (("menstruation"[Title/Abstract] OR "menstrual"[Title/Abstract]) AND "product*"[Title/Abstract] AND "safety"[Title/Abstract]) OR "catamenia") AND ("Bacterial Vaginosis"[MeSH Terms] OR "bacterial vaginosis"[Title/Abstract] OR "BV"[Title/Abstract] OR "vaginal bacteriosis"[Title/Abstract] OR "Gardnerella"[Title/Abstract] OR "vaginal flora imbalance"[Title/Abstract] OR "vaginal dysbiosis"[Title/Abstract])	32	32
Urinary Tract Infections	("Menstrual Hygiene Products"[MeSH] OR "menstrual product*"[MeSH] OR "menstrual napkin*"[Title/Abstract] OR "period product*"[Title/Abstract] OR "feminine hygiene product*"[Title/Abstract] OR "feminine hygiene"[Title/Abstract] OR "feminine product*"[Title/Abstract] OR "feminine napkin*"[Title/Abstract] OR "sanitary pad*"[Title/Abstract] OR "menstrual cup"[Title/Abstract] OR "menses cup"[Title/Abstract] OR "menstruation cup"[Title/Abstract] OR "vaginal cup"[Title/Abstract] OR "menstrual cups"[Title/Abstract] OR "menses cups"[Title/Abstract] OR "menstruation cups"[Title/Abstract] OR "vaginal cups"[Title/Abstract] OR "reusable pad*"[Title/Abstract] OR ("menstrual" AND "cloths") OR ("menses" AND "cloths") OR ("menstruation" AND "cloths") OR ("vaginal" AND "cloths") OR ("menstruation"[Title/Abstract] AND "management"[Title/Abstract]) OR (("menstruation"[Title/Abstract] OR "menstrual"[Title/Abstract] OR "catamenia"[Title/Abstract]) AND "product*"[Title/Abstract] AND "safety"[Title/Abstract])) AND ("Urinary Tract Infections"[MeSH] OR "UTI"[Title/Abstract] OR "urogenital infections"[Title/Abstract] OR "urinary infection*"[Title/Abstract] OR "bladder infection*"[Title/Abstract])	19	18
Sexually Transmitted Infections	("Menstrual Hygiene Products"[MeSH] OR "menstrual product*"[MeSH] OR "menstrual napkin*"[Title/Abstract] OR "period product*"[Title/Abstract] OR "feminine hygiene product*"[Title/Abstract] OR "feminine hygiene"[Title/Abstract] OR "feminine product*"[Title/Abstract] OR "feminine napkin*"[Title/Abstract] OR "sanitary pad*"[Title/Abstract] OR "menstrual cup"[Title/Abstract] OR "menses cup"[Title/Abstract] OR "menstruation cup"[Title/Abstract] OR "vaginal cup"[Title/Abstract] OR "menstrual cups"[Title/Abstract] OR "menses cups"[Title/Abstract] OR "menstruation cups"[Title/Abstract] OR "vaginal cups"[Title/Abstract] OR "reusable pad*"[Title/Abstract] OR ("menstrual" AND "cloths") OR ("menses" AND "cloths") OR ("menstruation" AND "cloths") OR ("vaginal" AND "cloths") OR ("menstruation"[Title/Abstract] AND "management"[Title/Abstract]) OR (("menstruation"[Title/Abstract] OR "menstrual"[Title/Abstract]) AND "product*"[Title/Abstract] AND "safety"[Title/Abstract]) OR "catamenia") AND ("Sexually transmitted disease"[MeSH Terms] OR "Gonorrhea"[Title/Abstract] OR "Syphilis"[Title/Abstract] OR "Chlamydia"[Title/Abstract] OR "Sexually transmitted infections" [Title/Abstract])	36	29
HIV	("Menstrual Hygiene Products"[MeSH] OR "period product*"[Title/Abstract] OR "feminine hygiene product*"[Title/Abstract] OR "feminine hygiene"[Title/Abstract] OR "feminine product*"[Title/Abstract] OR "feminine napkin*"[Title/Abstract] OR "sanitary pad*"[Title/Abstract] OR "menstrual cup"[Title/Abstract] OR "vaginal cup"[Title/Abstract] OR "menstrual cups"[Title/Abstract] OR "menses cups"[Title/Abstract] OR "vaginal cups"[Title/Abstract] OR "reusable pad*"[Title/Abstract] OR ("menstrual"[All Fields] AND "cloths"[All Fields]) OR ("menses"[All Fields] AND "cloths"[All Fields]) OR ("menstruation"[All Fields] AND "cloths"[All Fields]) OR ("vaginal"[All Fields] AND "cloths"[All Fields]) OR ("menstruation"[Title/Abstract] AND "management"[Title/Abstract]) OR (("menstruation"[Title/Abstract] OR "menstrual"[Title/Abstract]) AND "product*"[Title/Abstract] AND "safety"[Title/Abstract]) OR "catamenia"[All Fields]) AND ("HIV"[MeSH] OR "hiv infections"[MeSH] OR "HIV"[All Fields] OR "Human Immunodeficiency Virus"[All Fields] OR "hiv infections"[All Fields])	60	45

*Kept articles refers to the removal of duplicate articles

APPENDIX 4

Outcome	Search String	Initial Results	Kept Articles
PUBMED CONTINUED			
Human Papilloma Virus	("Menstrual Hygiene Products"[MeSH] OR "period product*"[Title/Abstract] OR "feminine hygiene product*"[Title/Abstract] OR "feminine hygiene"[Title/Abstract] OR "feminine product*"[Title/Abstract] OR "feminine napkin*"[Title/Abstract] OR "sanitary pad*"[Title/Abstract] OR "menstrual cup"[Title/Abstract] OR "vaginal cup"[Title/Abstract] OR "menstrual cups"[Title/Abstract] OR "menses cups"[Title/Abstract] OR "vaginal cups"[Title/Abstract] OR "reusable pad*"[Title/Abstract] OR ("menstrual"[All Fields] AND "cloths"[All Fields]) OR ("menses"[All Fields] AND "cloths"[All Fields]) OR ("menstruation"[All Fields] AND "cloths"[All Fields]) OR ("vaginal"[All Fields] AND "cloths"[All Fields]) OR ("menstruation"[Title/Abstract] AND "management"[Title/Abstract]) OR (("menstruation"[Title/Abstract] OR "menstrual"[Title/Abstract]) AND "product*"[Title/Abstract] AND "safety"[Title/Abstract]) OR "catamenia"[All Fields]) AND ("Human Papillomavirus Viruses"[MeSH] OR "Human Papillomavirus"[Title/Abstract] OR "Human Papillomavirus Virus"[Title/Abstract] OR "HPV"[Title/Abstract])	23	16
All terms	("Menstrual Hygiene Products"[Mesh] OR "menstrual hygiene"[tiab] OR "menstrual product*"[tiab] OR "menstrual materials"[tiab] OR "period product*"[tiab] OR "feminine product*"[tiab] OR "feminine hygiene product*"[tiab] OR "feminine napkin*"[tiab] OR "sanitary pad*"[tiab] OR "sanitary napkin*"[tiab] OR "vaginal cup"[tiab:~1] OR "vaginal cups"[tiab:~1] OR ((menstrual[tiab] OR menses[tiab] OR menstruation[tiab] OR catamenia[tiab] OR "feminine hygiene"[tiab]) AND (cup[tiab] OR cups[tiab] OR cloth*[tiab] OR pad[tiab] OR pads[tiab]))) AND ("HIV"[MeSH] OR "HIV Infections"[MeSH] OR "HIV"[tiab] OR "human immunodeficiency virus*" OR "Syphilis"[Mesh] OR syphilis[tiab] OR "Gonorrhea"[Mesh] OR "Neisseria gonorrhoeae"[Mesh] OR gonorrhea[tiab] OR gonococcus[tiab] OR gonorrhoeae[tiab] OR "Chlamydia"[Mesh] OR chlamydia[tiab] OR "Urinary Tract Infections"[Mesh] OR "urinary tract infection*"[tiab] OR "urogenital infection*"[tiab] OR bacteriuria*[tiab] OR pyuria[tiab] OR "Vaginosis, Bacterial"[MeSH] OR "bacterial vaginosis"[tiab] OR "BV"[tiab] OR "Human Papillomavirus Viruses"[Mesh] OR papilloma*[tiab] OR HPV[tiab])	158	71
TOTAL PubMed Articles		**328**	**211**

*Kept articles refers to the removal of duplicate articles

We would like to acknowledge the support of the University of Washington Librarians, including Teresa Jewell, for her help with our initial exploratory searches across seven potential databases and in helping to develop the searches for PubMed and Web of Science.
ChatGPT was also used to help refine some search strings and to translate one article from Czech (Unzeitig, et al. 2007).

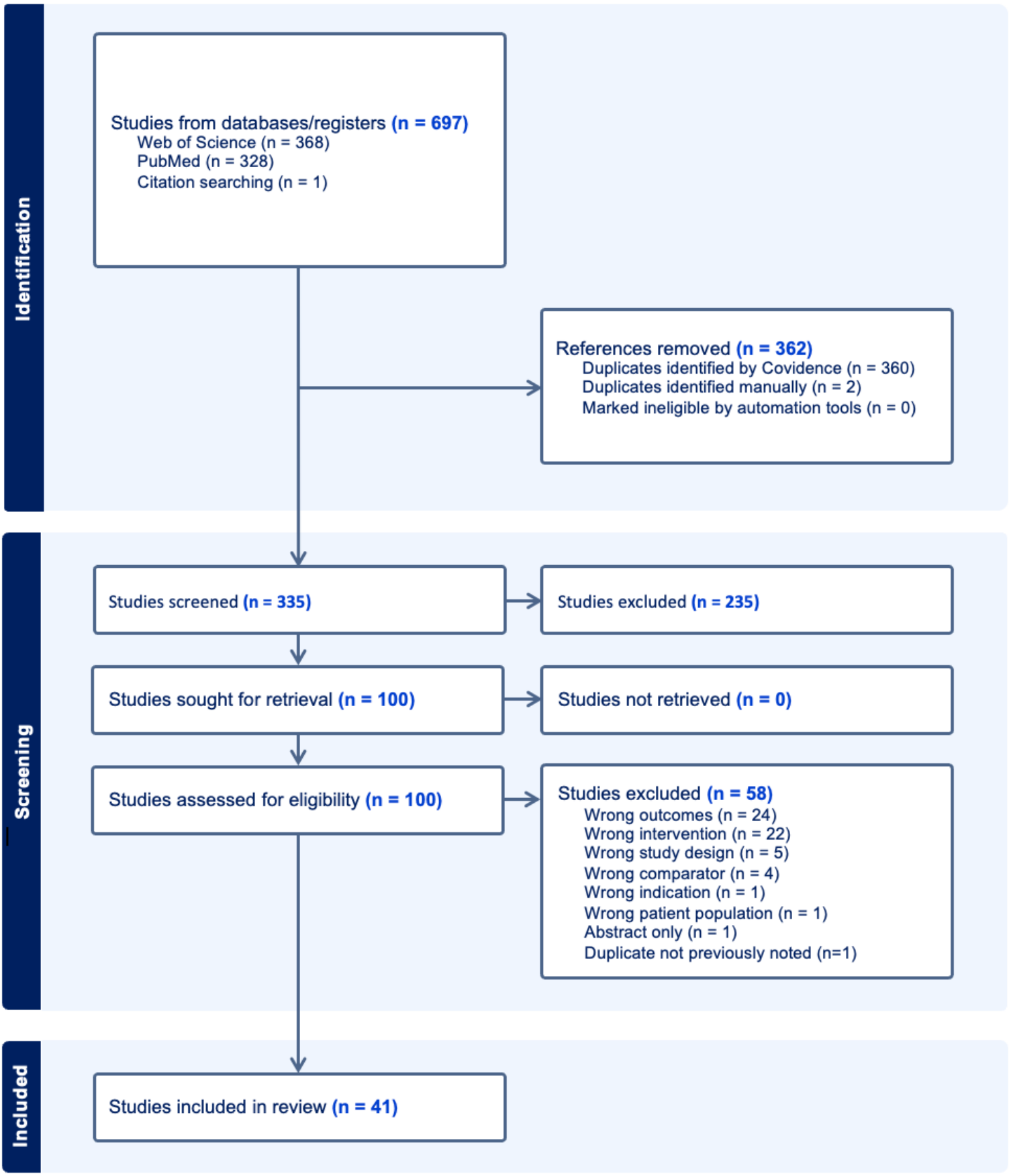
APPENDIX 4

Outcome	Search String	Initial Results	Kept Articles
	WEB OF SCIENCE		
Bacterial Vaginosis	(TS=("Menstrual Hygiene Products" OR "period product*" OR "feminine hygiene product*" OR "feminine hygiene" OR "feminine product*" OR "feminine napkin*" OR "sanitary pad*" OR "menstrual cup" OR "vaginal cup" OR "menstrual cups" OR "menses cups" OR "vaginal cups" OR "reusable pad*") OR TS=(menstrual AND cloths) OR TS=(menses AND cloths) OR TS=(menstruation AND cloths) OR TS=(vaginal AND cloths) OR TS=("menstruation" AND "management") OR TS=(("menstruation" OR "menstrual") AND "product*" AND "safety") OR TS=catamenial) AND TS=("Bacterial Vaginosis" OR "BV" OR "bacterial vaginosis" OR "vaginal bacteriosis"OR "Gardnerella"OR "vaginal flora imbalance"OR "vaginal dysbiosis")	60	19
Urinary Tract Infections	(TS=("Menstrual Hygiene Products" OR "period product*" OR "feminine hygiene product*" OR "feminine hygiene" OR "feminine product*" OR "feminine napkin*" OR "sanitary pad*" OR "menstrual cup" OR "vaginal cup" OR "menstrual cups" OR "menses cups" OR "vaginal cups" OR "reusable pad*") OR TS=(menstrual AND cloths) OR TS=(menses AND cloths) OR TS=(menstruation AND cloths) OR TS=(vaginal AND cloths) OR TS=("menstruation" AND "management") OR TS=(("menstruation" OR "menstrual") AND "product*" AND "safety") OR TS=catamenial) AND TS=("Urinary Tract Infections" OR "UTI" OR "urinary infection" OR "bladder infection")	16	10
Sexually Transmitted Infections	(TS=("Menstrual Hygiene Products" OR "period product*" OR "feminine hygiene product*" OR "feminine hygiene" OR "feminine product*" OR "feminine napkin*" OR "sanitary pad*" OR "menstrual cup" OR "vaginal cup" OR "menstrual cups" OR "menses cups" OR "vaginal cups" OR "reusable pad*") OR TS=(menstrual AND cloths) OR TS=(menses AND cloths) OR TS=(menstruation AND cloths) OR TS=(vaginal AND cloths) OR TS=("menstruation" AND "management") OR TS=(("menstruation" OR "menstrual") AND "product*" AND "safety") OR TS=catamenial) AND TS=("sexually transmitted infection" OR "STI" OR "syphilis" OR "gonorrhea" OR "chlamydia" OR "sexually transmitted disease" OR "STD")	27	3
HIV	(TS=("Menstrual Hygiene Products" OR "period product*" OR "feminine hygiene product*" OR "feminine hygiene" OR "feminine product*" OR "feminine napkin*" OR "sanitary pad*" OR "menstrual cup" OR "vaginal cup" OR "menstrual cups" OR "menses cups" OR "vaginal cups" OR "reusable pad*") OR TS=(menstrual AND cloths) OR TS=(menses AND cloths) OR TS=(menstruation AND cloths) OR TS=(vaginal AND cloths) OR TS=("menstruation" AND "management") OR TS=(("menstruation" OR "menstrual") AND "product*" AND "safety") OR TS=catamenial) AND TS=("HIV" OR "hiv infections" OR "Human Immunodeficiency Virus")	69	27
Human Papilloma Virus	(TS=("Menstrual Hygiene Products" OR "period product*" OR "feminine hygiene product*" OR "feminine hygiene" OR "feminine product*" OR "feminine napkin*" OR "sanitary pad*" OR "menstrual cup" OR "vaginal cup" OR "menstrual cups" OR "menses cups" OR "vaginal cups" OR "reusable pad*") OR TS=(menstrual AND cloths) OR TS=(menses AND cloths) OR TS=(menstruation AND cloths) OR TS=(vaginal AND cloths) OR TS=("menstruation" AND "management") OR TS=(("menstruation" OR "menstrual") AND "product*" AND "safety") OR TS=catamenial) AND TS=("Human Papillomavirus Viruses" OR "Human Papillomavirus" OR "Human Papillomavirus Virus" OR HPV)	19	5
All terms	TS=("menstrual hygiene" OR "menstrual product*" OR "menstrual materials" OR "period product*" OR "feminine product*" OR "feminine hygiene product*" OR "feminine napkin*" OR "sanitary pad*" OR "sanitary napkin*" OR "vaginal cup" OR "vaginal cups" OR ((menstrual OR menses OR menstruation OR catamenia OR "feminine hygiene") AND (cup OR cups OR cloth* OR pad OR pads))) AND TS=("HIV" OR "human immunodeficiency virus*" OR syphilis OR gonorrhea OR gonococcus OR gonorrhoeae OR chlamydia OR "urinary tract infection*" OR "urogenital infection*" OR bacteriuria* OR pyuria OR "bacterial vaginosis" OR "BV" OR papilloma* OR HPV)	123	16
TOTAL Web of Science Articles		**245**	**125**

*Kept articles refers to the removal of duplicate articles

APPENDIX 4

COVIDENCE PRISMA FLOWCHART



In addition to the peer-reviewed literature captured in the PRISMA flowchart, we searched the U.S. Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) for reports of malfunction, injury, or death for our products of interest since 2019 when a systematic review conducted a similar search.

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