

Standards/benchmarks for menstrual cups

Nancy Muller

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Speakers

- **Dr. Penelope Phillips-Howard**, Liverpool School of Tropical Medicine
- **Shamirah Nakalema**, WoMena
- **Alethea Osborne**, Mannion Daniels and The Menstrual Cup Coalition
- **Leisa Hirtz**, Women's Global Health Innovations and Bfree Cup
- **Seloi Mogatle**, UNFPA

- **Moderator: Nancy Muller**, RHSC menstrual health workstream co-chair;
Global health consultant

Topics that will be covered

- Existing status of benchmarks
- Key considerations for global benchmarks
 - Safety
 - Evidence in LMIC settings on safety, quality, effectiveness
 - Testing
 - Classification - medical device or consumer product
 - Country regulatory and importation requirements
 - Labeling
- Questions for consideration
- Next steps



Please add your
comments and
questions into
the chat box!

Classification of menstrual cups in global north settings

US FDA: Class 2 medical device

- Does not approve Class 2 medical devices
- Regulates end products only, not materials (eg., silicone)
- Can clear menstrual cups for sale in US (510(k) premarket notification)

EU: Personal hygiene product

- General product safety directive
- CE mark, voluntary confirmation that product meets EU regulations

Global regulations

- ISO 13485 or ISO 10993 - cytotoxicity, irritation, and sensitization
- ISO 14024 - voluntary eco-labeling benchmark for environmentally-friendly product

Australia

- therapeutic goods

What benchmark criteria are most important?

- Manufacturers, CSOs, and advocacy groups are working to create technical benchmarks to guide purchase and use in LMICs
- What criteria are important in ensuring quality, safety, and effectiveness?
- Evidence generation needed in LMIC settings where infrastructure challenges exist



Questions

- Why is it important to have a set of benchmarks for menstrual cups, especially when considering use in LMIC?
- What are we learning from LMIC research about what factors are most important in benchmarks for menstrual cups?



Questions

- What does ISO testing address - what are the most important tests to ensure safety and quality of menstrual cups?
- What are the key benchmarks that should be included for design and materials?



Questions

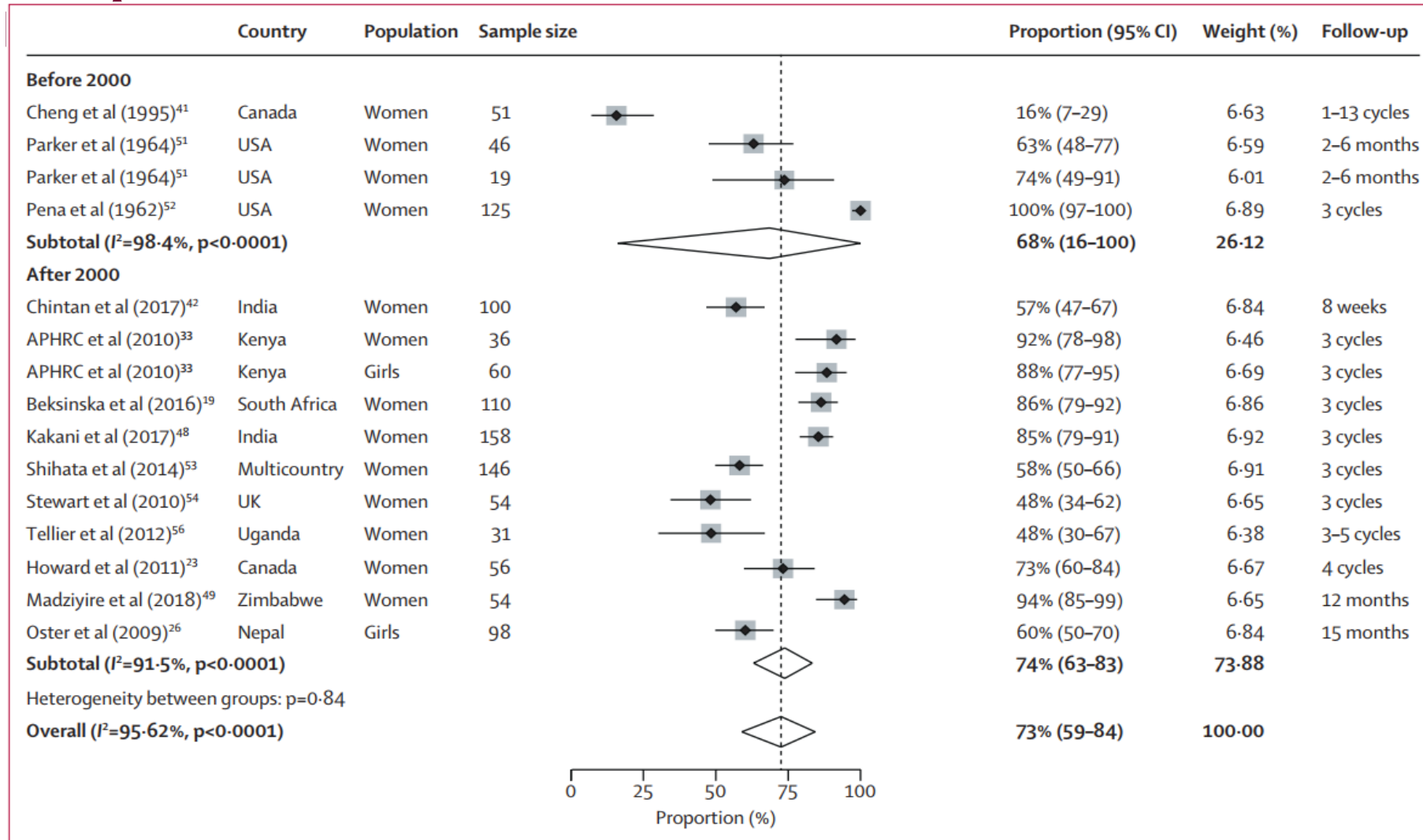
- What information needs to be included in packaging and labeling?
- What is the most appropriate classification for menstrual cups: medical device or consumer product?
- What import regulations do countries apply to menstrual cups?



Dr. Penelope Phillips-Howard

Liverpool School of Tropical Medicine

Key considerations: use/acceptance - global systematic



Studies:

199 brands, in 99 countries (across all incomes)

43 research studies examining use, acceptance, effect, safety in 3319 girls and/or women

- 27 vaginal cups
- 13 cervical

(soft)

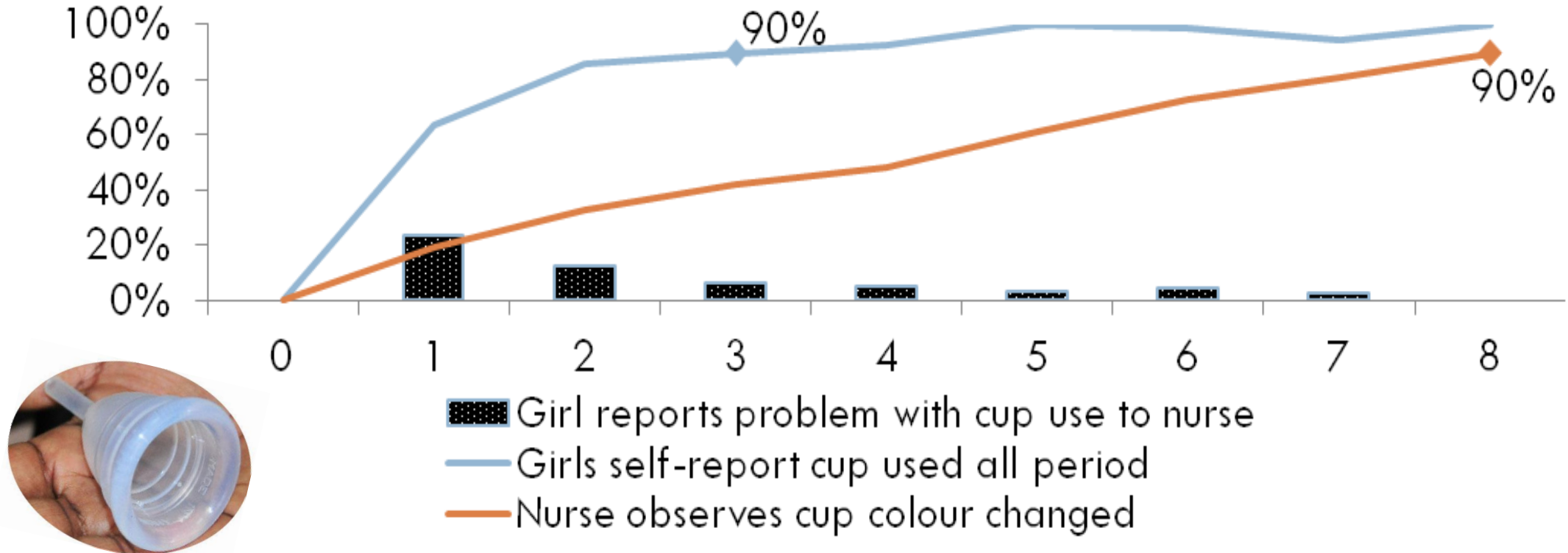
- 11

both/unknown

Source: van Eijk AM, et al. Menstrual cup use, leakage, acceptability, safety, and availability: a systematic review and meta-analysis. *Lancet Public Health*; 4(8), e376-393, [http://dx.doi.org/10.1016/S2468-2667\(19\)30111-2](http://dx.doi.org/10.1016/S2468-2667(19)30111-2) 2019.

Key considerations: use - monitoring Kenyan schoolgirl pilot

Reported v physical evidence of cup use at screening



Sources: van Eijk et al Use of menstrual cups among schoolgirls: longitudinal observations nested in a randomised controlled feasibility study in rural western Kenya *Reproductive Health*, 15:139, 2018; Mason et al, Comparing use and acceptability of menstrual cups and sanitary pads by schoolgirls in rural western Kenya. *Contracep, Reprod, and Health*; 8(8); 2974-82, 2019.

Key considerations: efficacy (leakage) - global

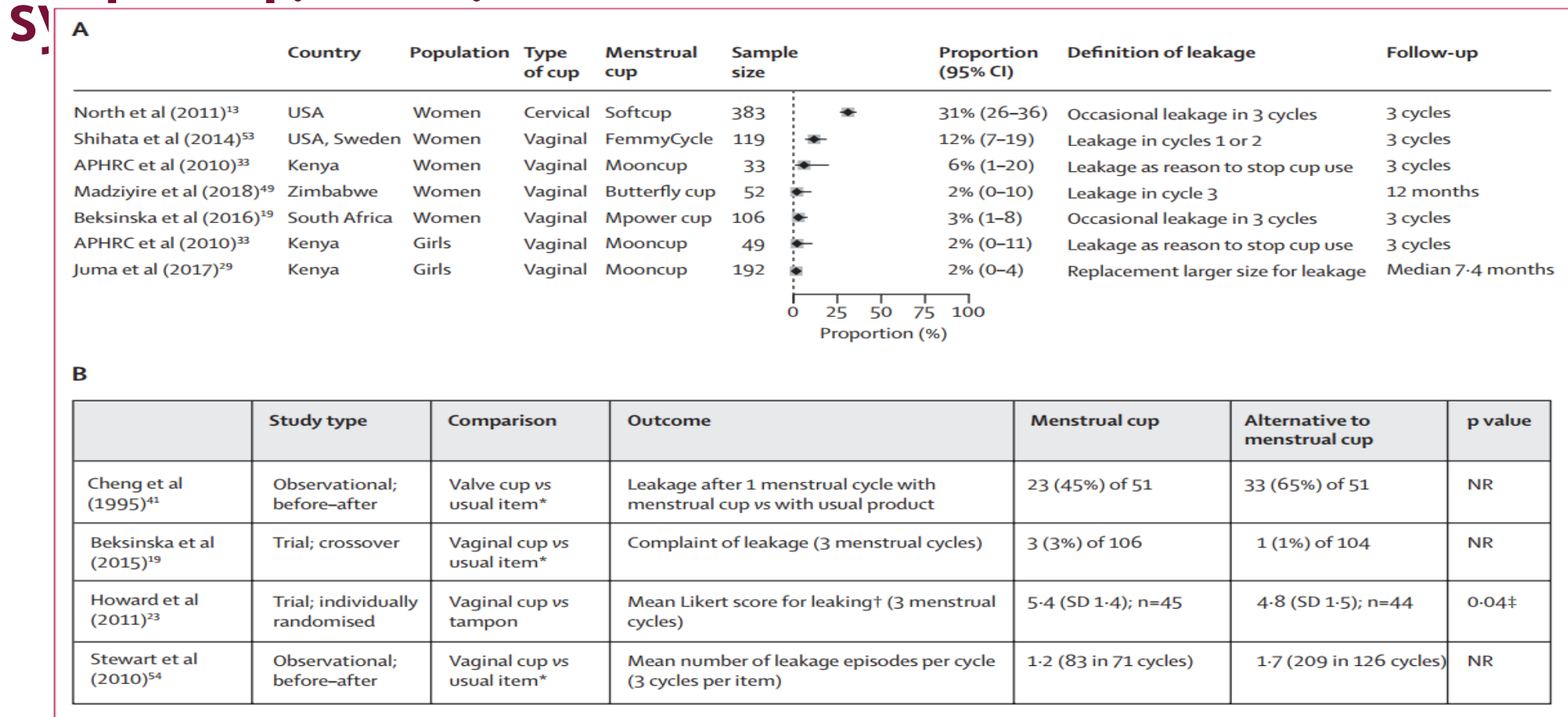


Figure 2: Menstrual cup and leakage

(A) Proportion of participants who had menstrual leakage in seven studies using different types of menstrual cups and definitions. (B) Reports of leakage among menstrual cup users versus users of other menstrual products. APHRC=African Population and Health Research Center. NR=not reported. *Disposable pad or tampon.

†Likert scale: 7-point score, in which 1=terrible and 7=great. ‡p value reported in article for Mann-Whitney test.

Source: van Eijk AM, et al. Menstrual cup use, leakage, acceptability, safety, and availability: a systematic review and meta-analysis. *Lancet Public Health*; 4(8), e376-393, [http://dx.doi.org/10.1016/S2468-2667\(19\)30111-2](http://dx.doi.org/10.1016/S2468-2667(19)30111-2) 2019.

Key considerations: safety - global systematic

Reported events	Number	Studies published on menstrual cups*
Toxic Shock Syndrome	5	2 soft cup (unconfirmed); 1 (with Hashimoto Syndrome), 1 (with IUD), 1 (no co-factors)
Allergies, rashes	6	Allergy in 1 of 150; and rash in 2 of 150 (vaginal cups); 2 cervical cup allergies; 1 silicone allergy (vaginal cup) requiring surgery
Irritation	2	Vaginal/cervical irritation (2) in 2 studies, no clinical consequences
Abnormalities of cervix or vagina	0	Not identified in vaginal examinations in 3 studies (370 women)
Pain, wounds	5	Case reports - Severe pain (3), vaginal wounds (2)
Urinary tract	9	Urinary tract infections; UTI (3), hydronephrosis (3)
Dislodged IUD	13	8 case reports, 5 in one cohort study
Retained cup	49	Cervical (47), vaginal (2) cups required assistance with removal, 47 case reports, and a cohort study
Vaginal flora	0	No disruption to flora with cup use in 4 studies (507 girls/women)

*untreated cups

Source: van Eijk AM, et al. Menstrual cup use, leakage, acceptability, safety, and availability: a systematic review and meta-analysis. *Lancet Public Health*; 4(8), e376-393, [http://dx.doi.org/10.1016/S2468-2667\(19\)30111-2](http://dx.doi.org/10.1016/S2468-2667(19)30111-2) 2019.

Key considerations: safety - Example, longitudinal monitoring of use in schoolgirls in a pilot study in rural Kenya

Severe Events	Cups (188)	Pads (256)	Controls (200)	Total (644)
Deaths recorded through HDSS	0	0	0	0
Participant identified to have symptoms of TSS	0	0	0	0
Visited health facility for TSS; other harms	0	0	0	0
positives			(100)	
Prevalence of staph aureus	9.6%	11.2%	11.3%	10.8%
Presence of TSST-1 in 2 nd survey positives	0/4	2/3	0/3	2/10
	Number of cups	E coli growth prevalence (95% CI) in cups		
All cups sampled	35	37.1% (21.1%-53.1%)		
Cups from new users (less than 6 months)	17	53% (29.3%-76.7%)		
Cups from established users (6 months plus)	18	22.2% (2.9%-41.1%)		

Source: Juma et al Examining the safety of the menstrual cup provided to rural primary school girls in western Kenya, *BMJ Open*, 7:e015429, 2017

Key considerations: costs - findings from a pilot study, Kenya

Study setting: Schoolgirls in Kenya, given menstrual cups or sanitary pads, followed up over one year

Methods: Collect data on costs and effects of menstrual cups, sanitary pads, usual practice (controls)

Costs: materials (cloth, pads, cups, etc.); education and training; soap WASH hygiene; maintaining hygiene (e.g. firewood for boiling, other cleaning); environment costs (disposal)

Effects: health (e.g. infections, psychosocial); education (e.g. absence, dropout, employment, wages)

Results: Compare costs and effects between menstrual cups and pads

- Annual cost (for 1000 girls) for using menstrual cup **\$2,730**; for using sanitary pads **\$22,420**
- Cost to avert infections - 1 disability adjusted life-year (for 1000 girls) **\$2,000** for cups, **\$47,000** for pads
- Cost effect (per 1000 girls) of 5% less absence on wages over 40yrs for pads **\$92,000**, nil for cups

Conclusions: First attempt, more robust data on all menstrual items needed for cost-effectiveness studies

- Menstrual cups are more cost effective compared with sanitary pads for health effects. Explored using absence effect in pad users on long term impact on wages over 40 years
- Measured effect of sanitary pads on reduced absence (~5%), unclear if impacts on long-term wages/employment
- Limitations of study: small pilot sample, primary school, limited follow-up time, psycho-social effects not

Source: *Balsiger MA, Benschaul-Tolonen A, et al. The cost-benefit and cost-effectiveness of providing menstrual cups and sanitary pads to schoolgirls in rural Kenya. CDEP-CGEG WP No. 87. Center for Development Economics and Policy, June 2020.*

Shamirah Nakalema

WoMena



WOMENA

FINDINGS & EXPERIENCE IN UGANDA

SEPTEMBER 2020



What is situation wrt Menstrual Cup Standards in Uganda?

WoMena deeply committed to safeguarding safety – including through development of classification/standards. Have engaged with NDA/UNBS over several years

NDA 2018: not medical devices, refers UNBS, recommends standards. Meanwhile, every batch cleared pre+post shipment - 100% 'regulated' WoMena assists NDA/UNBS concerns: safety, virginity (FAQs [here](#)) acceptability (own reports/global, e.g. van Eijk et al 2019) - beyond distribution (uptake/long-term use/satisfaction, community)

Also international: e.g. discussion UNFPA 2017 -> 2020 standards



Support MC standards in Uganda

- Labelling/relevant information, Language, use and care guidelines and identical from the similar product
- Keen to have standards for products and ready to abide by the regulations
- Safety, taken on very critical context, Hygiene protocol during and after menstruation
- Hymen & virginity Contextual
- Storage materials
- FAQs
- Disposal guidelines for the MC



Alethea Osborne Mannion Daniels & The Menstrual Cup Coalition



Menstrual Cup Coalition



- Over 40 member organisations, from Australia to Zimbabwe.
- A help desk, for information and signposting, in easy and understandable language.
- Website is constantly updated with the latest scientific information.
- Do not endorse one particular brand of cup – promote choice and transparency.
- Offering best practice and guidance for those who want to work with menstrual cups, particularly in the global south.

Leisa Hirtz

Women's Global Health Innovations and Bfree Cup

The Menstrual Cup.....a medical device or a consumer product?



- As a medical device, it is classified as a Class II: Low-to-medium risk devices including contact lenses and the majority of surgically invasive devices (e.g., surgical gloves, needles, magnetic resonance imaging equipment).
- In Europe, it is a consumer product requiring self-guided CE approval.
- All require specific labelling requirements are met.
- Which is the better classification for the end user regarding safety, access, affordability, and proper use?
- Medical Grade silicones are specifically designed, manufactured and purified to meet the strictest requirements of the healthcare industry. These products are made under applicable cGMP (Certified Good Manufacturing Practice) standards in facilities indirectly or directly regulated by US FDA and are typically supported with **Master Access Files**.

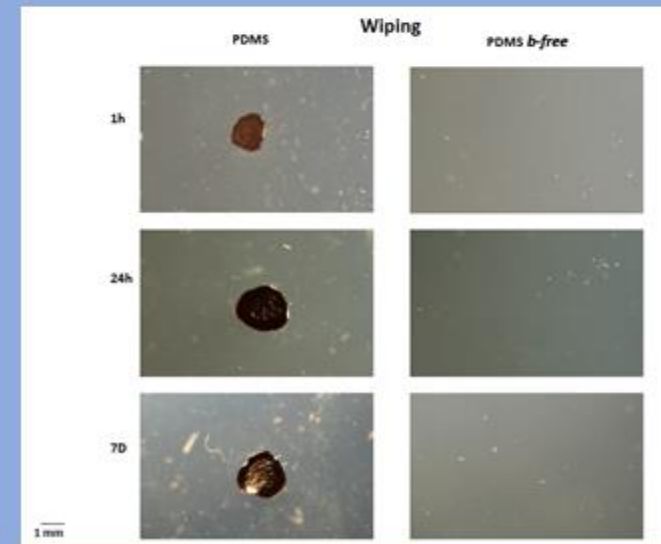
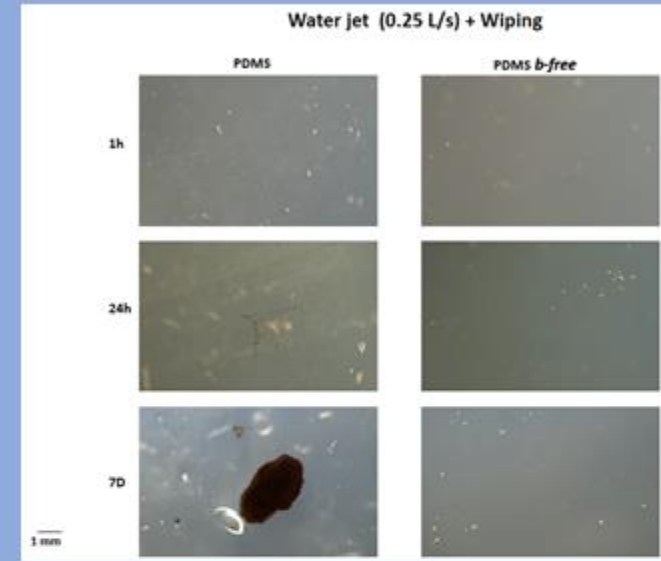
From the perspective of a manufacture....



- Quality and Safety to provide a dignified menstrual product solution that does no harm.
- Know your raw silicone materials. Rely on reputable producers of silicone. Not all silicones are of the same quality. Cheaper silicones may be healthcare approved as opposed to medical grade.
- The menstrual cups of lesser quality may be more affordable, but the design of the cups is such that they are flimsy and do not function optimally often frustrating the user who may give up on menstrual cups.
- Our minimum requirements regarding standards are:
 - a. Manufacturing in an ISO 13485:2016 Certified Facility
 - b. Medical Grade Silicone With Regulatory Testing to Class VI with FDA documentation and Master Access Files.
 - c. Cytotoxicity testing – ISO 10993 for biocompatibility
 - d. Evidence-based experiments to prevent biofilm formation, cleaning experiments, developing design parameters for user benefit for example that the cup inserts easily, opens easily after insertion, is leakproof, and is easy to remove.

Evidence-Based

Cleaning Tests Performed by a Researcher



Labelling Requirements Example



2.1 Interpretation of the Definition of Label

All medical devices must have a **label** which provides the information specified in Section 21(1), (a) to (j) of the Regulations. The definition of **label** as defined in the *Food and Drugs Act* allows flexibility in that the information need not be affixed to the device but may be provided with the device as, for example, **package** inserts, brochures or leaflets.

2.2 Section 21 of the *Medical Devices Regulations* - General Labelling Requirements

Section 21(1)(a) - The name of the device

Section 21(1)(b) - The name and address of the manufacturer

Section 21(1)(c) - The identifier of the device

Section 21(1)(h) - Unless self-evident to the intended user, the medical conditions, purposes and uses for which the device is manufactured, sold or represented

Section 21(1)(i) - The directions for use, unless directions for use are not required, and how to be used safely and effectively

Contraindications for use

Warnings and Cautions

Section 21(1)(j) - Describe any special storage conditions applicable to the device

Seloi Mogatle

UNFPA

Going forward

- Advocate for development of global menstrual cup benchmarks
- Develop criteria based on evidence from LMIC settings
- Engage with manufacturers, researchers, Government regulatory bodies to identify key criteria



Thank you!