

Global Research and Learning Agenda:

Building Evidence on Contraceptive-Induced Menstrual Changes for Research, Product Development, Policies, and Programs Globally

November 2021



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LIST OF ACRONYMS

CIMCs	Contraceptive-induced menstrual changes
CSE	Comprehensive sexuality education
DEI	Diversity, equity, and inclusion
FP	Family planning
LGBTQ	Lesbian, gay, bisexual, transgender, queer
MH	Menstrual health
R&D	Research and development
RLA	Research and learning agenda
R4S	Research for Scalable Solutions project
SRHR	Sexual and reproductive health and rights
USAID	United States Agency for International Development
WHO	World Health Organization

THE CONTRACEPTIVE-INDUCED MENSTRUAL CHANGES TASK FORCE

The contraceptive-induced menstrual changes (CIMC) Task Force was launched in April 2021 and brings together 28 menstrual health and family planning experts from 18 organizations and 10 countries. The Task Force is responsible for creating and advancing an agenda for addressing the issue of CIMCs in the family planning (FP) and menstrual health (MH) fields, as well as within the wider sexual and reproductive health and rights (SRHR) sector. Members include:

- Amanda Cordova-Gomez (USAID), Alex Mickler (USAID), Amelia Mackenzie (FHI 360), Barbara Sow (FHI 360), Bellington Vwalika (University of Zambia), Carolina Vieira (University of Sao Paulo), Chelsea Polis (Guttmacher Institute), Chukwuemeka Nwachukwu (USAID), Diana Blithe (Eunice Kennedy Shriver National Institute of Child Health and Human Development), Emily Hoppes (FHI 360), Eva Lathrop (Population Service International), Funmi OlaOlorun (Evidence for Sustainable Development Systems in Africa), Gustavo Doncel (Contraception Research and Development), Hilary Critchley (University of Edinburgh), Jackie Maybin (University of Edinburgh), Julie Hennegan (Burnet Institute), Kate Rademacher (FHI 360), Katie Williams (FHI 360), Katrina Wilson (MSI), Kavita Nanda (FHI 360), Kelle Moley (Bill & Melinda Gates Foundation), Laneta Dorflinger (FHI 360), Lisa Haddad (Population Council), Lucy Wilson (Rising Outcomes), Marni Sommer (Columbia University), Marsden Solomon (FHI 360), Simon Kibira (Makerere University), and Tanya Dargan Mahajan (The Pad Project).

The CIMC Task Force strongly encourages you to share your experiences implementing the CIMC Global Research & Learning Agenda including adaptations, evidence generated, or programs and policies implemented. Please report these experiences and direct all inquiries about this document to Emily Hoppes, Senior Technical Officer, Product Development and Introduction at FHI 360, ehoppes@fhi360.org.



ACKNOWLEDGMENTS

In addition to the contributions and work of the CIMC Task Force, this document was developed in collaboration with several other reviewers, including Alison Edelman (Oregon Health & Sciences University), Candace Tigen (National Institutes of Health), Celia Karp (Performance Monitoring for Action), Dina Sharon (Bill & Melinda Gates Foundation and Massachusetts Institute of Technology), Egbere Theophilus, Farina Abrejo (Aga Khan University), Flora Njelekela (Anuflo Industries Limited & Smile For Community), Gathari Ndirangu (Pathfinder International and MIHR), Heather Guidone (Center for Endometriosis Care), Heidi Moseson (Ibis Reproductive Health), Inga Winkler (Central European University), Jane Cover (PATH), Jenni Smit (MatCH Research Unit), Jessica Sanders (University of Utah), Jully Chilambwe (Jhpiego), Lisa Halverson (National Institutes of Health), Lowri Davies (AFRIPads), Laury Francia (Population Service International Madagascar), Linnea Zimmerman (Performance Monitoring for Action), Luis Bahamondes (University of Campinas Faculty of Medical Sciences), Mandira Paul (Sida), Maureen Baldwin (Oregon Health & Sciences University), Megan Christofield (Jhpiego), Melinda Stanley (Clinton Health Access Initiative), Meridith Mikulich (USAID), Mohamed Isah (West African Institute of Public Health), Mojisola Alere (University of Ibadan), Nancy Muller, Rael Akoru (Kenya Ministry of Health Services and Sanitation), Sara Stratton (Palladium), Shannon Wood (Performance Monitoring for Action), Taryn Barker (Children's Investment Fund Foundation), Teresa Bombas (Portuguese Society of Contraception), and Zelalem Attlee.

The development of this Research and Learning Agenda was funded through the [Innovate FP](#) and [Research for Scalable Solutions](#) projects and is made possible by the support of the American People through the United States Agency for International Development (USAID). The contents of this brief are the sole responsibility of FHI 360 and do not necessarily reflect the views of USAID or the United States Government.



COMMITMENT TO INCLUSION

The CIMC Task Force is committed to diversity, equity, and inclusion (DEI). DEI helps drive innovation, leading to better research and resulting in policies and programs that better reflect the lives and meet the needs of the populations they are intended to reach and assist. Additionally, the Task Force acknowledges the importance of applying an intersectional lens, recognizing the complexity in and intersection of identity that play a role in people's perceptions, experiences, and behaviors. Principles of inclusion are woven throughout this Global Research and Learning Agenda, and they have guided the work of the CIMC Task Force in the following ways:

- Diverse collaboration: In every step of the process, the Task Force has dedicated time and effort to ensuring a diverse group of people from a variety of sectors, countries, perspectives, and stakeholder groups have been meaningfully engaged in this work.
- Terminology: This Research and Learning Agenda and any emanating materials attempt to use inclusive, people-first language. The Task Force recognizes not all girls and women menstruate, and not all people who menstruate identify as girls or women. In addition, not all contraceptive users identify as women or girls. As such, the Research and Learning Agenda uses inclusive terms like “user,” “client,” and “menstruator” whenever possible. This report also uses terminology that not all contraceptive users identify with, such as “uterus” and “menstruation.” If you plan to use this Research and Learning Agenda to inform your work with transgender and gender expansive people, we suggest you engage and partner with these communities about language when designing research, programs, and policies.
- Active engagement: The Task Force enters this work with an open mind, a commitment to learning, and an understanding that the work of inclusion is ongoing. As such, the Task Force provides opportunities for and encourages honest feedback about this document and subsequent work that is undertaken to address CIMCs in contexts around the world.

We strongly encourage all partners who use this Global Research and Learning Agenda to commit to inclusion through diverse collaboration, inclusive language, and active engagement.

EXECUTIVE SUMMARY

Contraceptive-induced menstrual changes (CIMCs) can affect family planning (FP) users' lives in both positive and negative ways, resulting in opportunities and consequences. Despite this, and despite the important linkages between FP and menstrual health (MH),¹ the fields often do not adequately address CIMCs, including in research, product development, policies, and programs. This Global Research and Learning Agenda (RLA) for addressing CIMCs includes four research agendas for: (1) measurement, (2) contraceptive research and development (R&D) and biomedical research, (3) social-behavioral and user preferences research, and (4) programmatic research. The following key recommendations provide a summary of these Global RLA, which can act as a guide for researchers, product developers, health care providers, program implementors, advocates, policymakers, and funders interested in exploring and contributing to a collective understanding of the issue of CIMCs.

- Future CIMC research and programs should develop and utilize a comprehensive and harmonized measurement framework that includes indicators related to biological changes; social environments; facilities and services; user experiences, preferences and behaviors; and impacts on health and life through an integrated and interdisciplinary approach.
- Future contraceptive R&D and biomedical research should focus on: (1) understanding the biological mechanisms that lead to CIMCs and factors that affect them; (2) developing improved prevention and treatment options for undesired CIMCs and options to accelerate and maintain desired CIMCs; and (3) understanding the use of existing and new contraceptive methods to treat menstrual and gynecologic disorders and symptoms. Future contraceptive R&D should integrate users' preferences and needs related to CIMCs into new method development.
- Future social-behavioral research should take an integrated approach to understanding: (1) the nuance and diversity of perceptions, attitudes, and practices related to all types of CIMCs; (2) factors that influence CIMC perceptions, attitudes, and practices, including at the individual, relationship, and wider socio-ecological levels and across the life course; and (3) the impacts of CIMCs on users' lives and their FP and MH decision-making.
- Future programmatic research should aim to identify and scale up cost-effective approaches to addressing CIMCs, including through FP and MH programs and as part of self-care.
- Crosscutting: In all research related to CIMCs: (1) consider the impact of different socio-ecological levels of influence; (2) integrate equity using a rights-based framework including considerations for social and environmental determinants of health; and (3) consider the changing experiences and preferences of users across the life course.
- Cross-cutting: In research related to CIMCs, consider and incorporate the key concepts of informed choice, gender, and self-care.

¹ The terminology used to describe the needs of menstruators continues to evolve. Throughout this paper, "menstrual health" or "MH" will be used and is meant to encompass a comprehensive set of menstrual needs encountered through the life course as defined by Hennegan et al. (2021).

Background and Framing

Development of the Global Research and Learning Agenda

Contraceptive-induced menstrual changes (CIMCs) affect family planning (FP) users' lives in both positive and negative ways, resulting in opportunities and consequences (Polis et al., 2018). Despite this, and despite the important linkages between FP and menstrual health (MH), the fields often do not adequately address CIMCs, including in research, product development, policies, and programs.

Box 1. Meeting Outputs

Overall goal of November 2020 meeting: identify research, product development, policy, and program priorities

Through the two-day meeting, attendees:

- Gained an overview of the existing evidence related to CIMCs and identified key gaps
- Contributed to the development of a Research and Learning Agenda
- Began facilitating new and increased connections between the FP and MH fields
- Identified additional key stakeholders to engage
- Provided input on appropriate global and country forums to advance the CIMC agenda

To help address this gap, a two-day virtual technical consultation was held on November 17–18, 2020. The global event convened experts in the fields of FP, MH, and sexual and reproductive health and rights (SRHR) broadly to review evidence around CIMCs; work collaboratively to identify priorities for research, product development, policies, and programs related to CIMCs; and explore potential ways to produce and move forward a shared CIMC research agenda. This meeting was

coordinated by FHI 360 through the [Research for Scalable Solutions](#) (R4S) and [Envision FP](#) projects with support from the United States Agency for International Development (USAID). Presentations addressed topics related to contraceptive R&D, biomedical research, social-behavioral research, implementation science, policy, and programs. A summary of intended meeting outputs is in Box 1, and the full meeting agenda, goals, objectives, and outputs can be found in Appendix C

Interactive small group sessions organized around key topics related to CIMCs demonstrated a high level of engagement and strong interest in the issue of CIMCs from stakeholders in the FP, MH, and wider SRHR fields. These discussions also demonstrated a need for foundational work and cross-discipline thought leadership to inform future research, product development, policies, and programs around this rich and multifaceted topic. Key recommendations emerging from those discussions, as well as the work of a dedicated Task Force that was convened after the meeting, are synthesized below in this ***Global Research and Learning***

Agenda: Building Evidence on Contraceptive-Induced Menstrual Changes in Research, Product Development, Policies, and Programs Globally.

Contraceptive-Induced Menstrual Changes

WHAT ARE CIMCS?

CIMCs encompass all changes to a users’ menstrual cycle caused by the use of contraception, including:

- Changes in bleeding duration, volume, frequency, and/or regularity
- Changes in blood (and other uterine and cervical effluent) consistency, color, and/or smell
- Changes in uterine cramping and pain
- Changes in other symptoms before, during, and after menstruation (e.g., migraines, breast tenderness, gastrointestinal symptoms)
- Changes in experiences of menstrual and gynecologic disorders and symptoms, such as endometriosis
- Changes over time with continued contraceptive method use
- Short-term changes to the menstrual cycle after contraceptive discontinuation

The terminology used to describe CIMCs can be complex and generally varies depending on the context and audience. For example, the way health care providers discuss CIMCs with FP users and the way users understand these changes can be very different from the terminology used by researchers and contraceptive developers (e.g., Mishell et al., 2007). Likewise, different groups working in the FP and MH fields may have different terminology preferences (Figure 1).

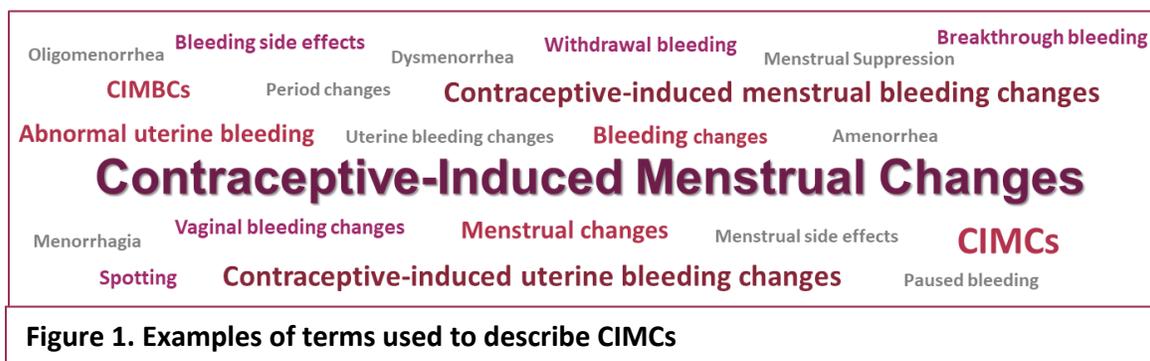


Figure 1. Examples of terms used to describe CIMCs

Although certain groups may have other preferences, “contraceptive-induced menstrual changes” was selected by the November 2020 meeting organizing committee as the recommended terminology. It is intended to be inclusive of how menstruating people understand their standard menstrual cycle and uterine bleeding, and it captures not only bleeding changes, but all other changes caused by contraceptive use detailed above.

WHY ARE CIMCS IMPORTANT?

Globally, users can face barriers to accessing and using FP. Evidence indicates CIMCs can contribute to poor adherence, discontinuation, and non-use of contraception (Castle & Askew, 2015; Folger et al., 2013; Polis et al., 2018; Rosenberg et al., 1995). Some FP users fear that CIMCs can lead to negative health consequences, including infertility. Other myths and misconceptions are also common, including that amenorrhea—or “paused bleeding”—means there is a buildup of “dirty,” “blocked,” or “bad” blood in their bodies that might lead to major health issues or even death (Hindin et al., 2014; Mackenzie et al., 2020; Polis et al., 2018, Wood & Jewkes, 2006). These misconceptions can influence the attitudes and behaviors of providers and affect their communications with clients related to CIMCs (Solo and Festin, 2019). CIMCs can also affect users’ daily lives and activities in important and meaningful ways. This includes effects on users’ menstrual health experiences, especially for those having heavier or longer bleeding, which could lead to unexpected changes in the quantity or type of menstrual products required to manage their menses (Graham et al., 2013; Szarewski and Moeller, 2013). In addition, CIMCs can have significant effects on the ability to participate in daily activities like school, work, sex, and social and religious activities (Higgins and Smith, 2016). For example, in some contexts, bleeding prevents users from participating in important religious practices or partaking in domestic work like cooking (Bhatt and Bhatt, 2005). CIMCs can also have psychosocial impacts caused by the stress of managing these changes and the worry related to hiding CIMCs for those discreetly using FP methods (Kibira et al., 2020). Finally, CIMCs might negatively affect sexual satisfaction and well-being (Higgins et al., 2021).

CIMCs can also have advantages and can be the main reason for contraceptive use for some. Potential lifestyle and wellness benefits associated with reduced bleeding, pain, or cramping, as well as paused bleeding, can include increased freedom to engage in daily activities (e.g., work and school), improved convenience, improved sexual satisfaction and well-being, decreased stress and worry, and reduced costs if fewer menstrual health products are needed (Bahamondes et al., 2015, Brunie et al., 2021). Potential health benefits include the use of some hormonal methods to manage menstrual and gynecologic disorders and symptoms,¹ such as heavy menstrual bleeding, which affects approximately 30 percent of menstruators (El-Hemaidi et al., 2013), and endometriosis, which affects an estimated 176 million individuals worldwide (Zondervan et al., 2020). Contraceptives can also be used to prevent or improve other health conditions, including iron deficiency

¹ In this document, menstrual and gynecologic disorders and symptoms include dysmenorrhea, heavy menstrual bleeding (or menorrhagia), endometriosis, adenomyosis, uterine leiomyomas (or fibroids), uterine polyps, polycystic ovarian syndrome (PCOS), premenstrual syndrome (PMS), and premenstrual dysphoric disorder (PMDD).



anemia, which affects about a third of women of reproductive age globally (WHO, 2019b). Finally, CIMCs can be beneficial for transgender and gender expansive persons who may use contraceptives to induce amenorrhea and reduce the effects menstruation may have on gender dysphoria (Baum et al., 2018).

CIMCs affect the health and well-being of FP users, and it is essential for researchers, product developers, health care providers, program implementors, advocates, policymakers, and funders working in the FP and MH sectors to consider CIMCs to effectively meet mutual public health goals. The added opportunity to promote desirable CIMCs as a way to improve health and promote well-being only adds to the urgency of addressing CIMCs as an important public health issue. High-quality counseling on CIMCs, including information about non-contraceptive benefits, is one intervention that can help users make well-informed decisions about the method(s) that best meet their needs (Keogh et al., 2021, Knowledge SUCCESS, 2021). Such counseling may lead to increased demand, satisfaction, and/or continuation of FP, and reduce the burden of menstruation management. For example, the use of a job aid can be effective in counseling users on CIMCs, including potential health benefits and lifestyle advantages (Rademacher et al., 2018). Addressing CIMCs through counseling is just one of the ways in which the fields of FP and MH can address CIMCs through existing programs and platforms. There are also ways in which the two fields can more effectively integrate to improve the health of menstruators and FP users (e.g., through SRHR education and reduced menstrual-related barriers to FP). See Appendix B and the *Programmatic Research Agenda* for more details on FP-MH linkages and integration.

Cross-Cutting Foundations

Key Recommendations:

- In all research related to CIMCs: (1) consider the effect of different socio-ecological levels of influence; (2) integrate equity using a rights-based framework including considerations for social and environmental determinants of health; and (3) consider the changing experiences and preferences of users across the life course.
- In research related to CIMCs, consider and incorporate the key concepts of informed choice, gender, and self-care.

Theoretical Basis: Socio-Ecological Model, Equity, and Life Course Approach

The concept of CIMCs naturally lends itself to focusing on the individual at a single point in time: What does a current or potential FP user want and need? How are they thinking through their decisions about menstruation and contraception? At the same time, FP users do not experience and make judgments about CIMCs in a vacuum. Experiences and preferences regarding CIMCs affect and are affected by relationships, organizations, communities, and societies. Additionally, CIMCs will affect users differently depending on their age, and more specifically, during important life stages such as during and just after menarche, before and after childbearing (should users choose to have children), and during perimenopause. To understand the breadth and depth of issues surrounding CIMCs, it is best to frame those issues within two important socio-behavioral theories: the socio-ecological model and the life course approach (shown in Figures 2 and 3). Additionally, these theories facilitate and prompt considerations regarding equity in the development of CIMC research, product development, policies, and programs. This includes working with a rights-based framework that considers how social and economic determinants of health might drive inequities, especially for those who have been systematically marginalized or underserved. A more detailed explanation of these theories and their application to CIMCs can be found in Appendix D.

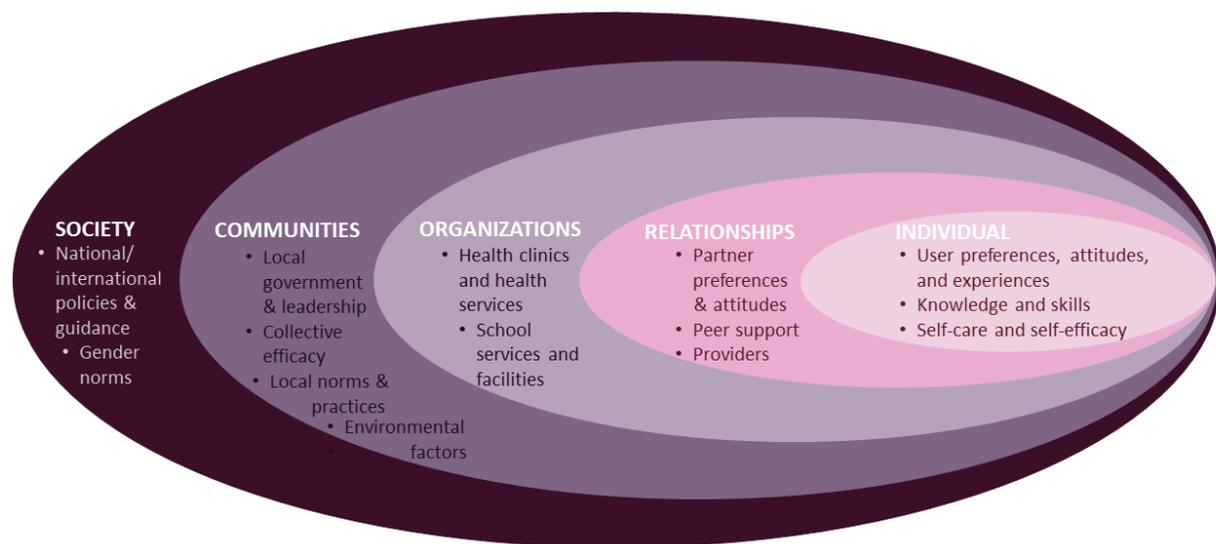


Figure 2. The socio-ecological model and CIMCs

(image adapted to fit the issue of CIMCs from Caprio et al., 2008, and HC3, 2017)

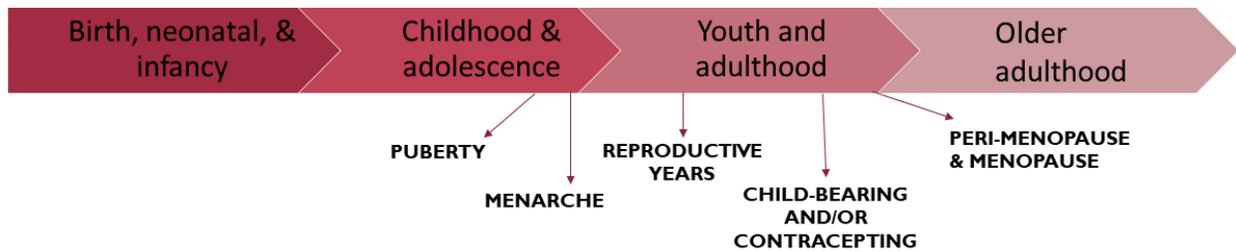


Figure 3. Life course and CIMCs (image adapted from life stages content in Elder et al., 2003)

Other Considerations

The topic of CIMCs is complex and multifaceted, but in all areas, there are cross-cutting considerations that affect multiple aspects of CIMCs and position CIMCs as both an FP and MH issue. These include:

- Choice:** The principle of promoting choice is essential to both FP and MH, and as such, all efforts to address CIMCs must reflect the principles of informed choice and bodily autonomy, which are closely related. In MH, it is important to provide a range of choices for high-quality affordable menstrual products and materials, safe and accessible facilities, effective pain management options, and effective options for the management of menstrual and gynecologic disorders and symptoms to address the unique and evolving needs of menstruators across the life course. In FP, providing contraceptive method choice and the ability to voluntarily choose among a range of methods is essential to meeting users’ needs and preferences. “Menstrual choice” is a comprehensive term intended to reflect the importance of ensuring that menstruators are empowered and able to choose how, when, and where to manage their menses safely and effectively from puberty through perimenopause and are able to choose if, when, and how much they menstruate and experience related symptoms.
- Gender:** To advance both MH and FP outcomes, it is important to carefully and explicitly consider the social and gender norms that affect perceptions of FP and MH practices, as well as sexuality, menstruation, and reproduction more broadly. Gender is foundational to both FP and MH, but it is sometimes overlooked when research and programs focus on the individual and not on context and social influences. With CIMCs, it is important to understand and acknowledge the effect of gender norms and identities for users, partners, families, providers, communities, and health care systems. See above for more on this regarding the socio-ecological model.
- Self-Care:** The World Health Organization (WHO) defines self-care as the ability of individuals, families, and communities to promote health, with or without the support



of a health care provider, which is central to both FP and MH (WHO, 2019a). Self-care is an essential strategy for promoting effective FP and MH, including FP-MH integration and addressing CIMCs. For example, providing young people with puberty education that includes information about the menstrual cycle can improve their ability to take responsibility for their reproductive health (Armour et al., 2019), including accessing FP services later in life if they need them (IRH et al., 2015). Additionally, systematically linking information on CIMCs with the broad range of self-care FP information and products may enhance client confidence and “self-reassurance” around FP choices (Rademacher et al., 2018).

Global Research and Learning Agenda: Addressing CIMCs

This Global RLA for addressing CIMCs includes four research agendas for (1) measurement, (2) contraceptive R&D and biomedical research, (3) social-behavioral and user preferences research, and (4) programmatic research. The Global RLA is meant to bring attention to the urgent need for CIMC research and is designed to guide the work of researchers, product developers, health care providers, program implementors, advocates, policymakers, and funders interested in the issue of CIMCs. It is important that the work of each of these actors is not siloed; thus, each research agenda has a section for “translational considerations: integrating research across disciplines and domains,” which is meant to guide and encourage collaboration across the Global RLA. Note that for all four research agendas, it is essential that research be conducted with diverse populations across different locations, races and ethnicities, socio-economic statuses, ages, abilities/disabilities, sexual orientations, and gender identities. In addition, groups who have been systematically marginalized or underserved should be included in this research, such as youth, perimenopausal people, people with disabilities, people living with HIV, postpartum people, refugees, migrants or other mobile populations, sex workers, people in the LGBTQ (lesbian, gay, bisexual, transgender, queer) community, survivors of abuse and violence, and those who are incarcerated, among others (see Appendix D).

For each of the four research agendas, a table lists research questions categorized by recommended area of research. Because the Global RLA is detailed and attempts to be comprehensive, a “priority” column is included to the right of each research question to guide researchers, implementors, funders, and policymakers on potential timing and prioritization of research. The prioritization categories include “short-term,” “mid-term,” and “long-term,” but these categories do not indicate a distinct amount of time; rather, they

are meant to provide guidance about the sequence and priority of the research. For some research questions that include several steps or a significant amount of work, two prioritization categories were identified.

1) Measurement Framework and Research Agenda

➤ **Key Recommendation:** Future CIMC research and programs should develop and utilize a comprehensive and harmonized measurement framework that includes indicators related to biological changes; social environments; facilities and services; user experiences, preferences, and behaviors; and impacts on health and life through an integrated and interdisciplinary approach.

To move forward a collective measurement research agenda, it is important to align on a framework to identify which aspects of CIMCs need to be measured, and when and how these can potentially be measured. Thus, a basic measurement framework was developed (Figure 4). A list of potential indicator categories for each of the framework domains is listed in Table 1.

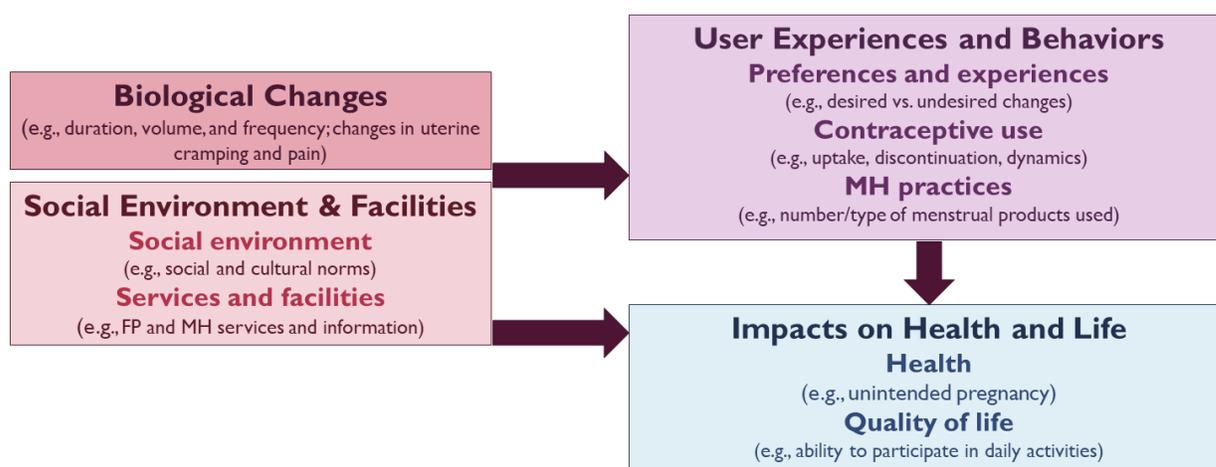


Figure 4. CIMC measurement framework

For CIMCs, both the biological and social-behavioral dimensions of the issue should be measured (Critchley et al., 2020). The CIMC measurement framework captures this within four domains, or major areas, that need to be measured across CIMC activities:

- The *biological changes* include actual changes to the menstrual cycle caused by contraception such as changes in duration, volume, frequency and regularity of bleeding, and amount of uterine cramping and pain.
- The *social environment* includes the influence of socio-cultural norms that shape FP and MH perceptions and practices. *Facilities and services* include infrastructure such



as sanitation, as well as facilities providing health care services and information for FP and MH, and those enabling self-care for CIMCs.

- *User experiences and behaviors* include understanding individuals’ reactions to CIMCs such as their perceptions of CIMCs as desired or undesired and changes to contraceptive use and menstrual practices in response to CIMCs.
- *Impacts* include how biological changes, the environment, and user responses ultimately intersect and influence individuals’ *health and life*.

The arrows in the CIMC measurement framework (Figure 4) indicate directions of influence. The figure shows that an individual’s biological changes and environment influence their experiences and behaviors related to CIMCs. The social environment and facilities can also have a direct effect on health and quality of life, as do users’ experiences and behaviors. For example, a user may be experiencing more frequent bleeding due to use of a contraceptive (*biological changes*) while living in a community where menstrual blood is considered unclean (*social environment*). Combined, this can cause the user to view this CIMC as undesirable and cause the user to stop using their method (*user experiences and behaviors*), which in the end causes an unintended pregnancy (*impacts on health*).

Table 1 reflects the domains in Figure 4 and goes into further depth by listing important indicator categories and current and future measures and tools that can be used to capture the many dimensions of the CIMC framework. This table can be used by stakeholders and interest groups to develop a complete list of indicators for projects or programs. This list and the research agenda described below reflect the need for interdisciplinary teams to work together to measure and integrate understanding across the many aspects of CIMCs.

TABLE 1. INDICATOR CATEGORIES AND EXAMPLES AND MEASUREMENT TOOLS FOR CIMC MEASUREMENT FRAMEWORK	
Biological Changes	
Indicator Categories	Measurement Tools
• Baseline menstrual experience (duration, volume, regularity) prior to contraceptive use	<ul style="list-style-type: none"> ○ Bleeding diaries (at baseline and during use) ○ Menstrual pictograms ○ Menstrual product and/or blood collection and analysis ○ Questionnaires (Menstrual Practices Questionnaire & Menstrual Practices Needs Scale [Hennegan et al., 2020], Mood scales etc.)
• Bleeding changes (duration, volume, frequency, regularity)	
• Changes in blood and effluent (color, consistency, smell)	
• Changes in uterine cramping	
• Changes in other symptoms (gastrointestinal, migraines, acne, weight loss/gain, mood changes and PMS, etc.)	
• Changes in the cervicovaginal microbiome and mycobiome	
• Symptom interactions and changes over time	

<ul style="list-style-type: none"> Menstrual and gynecologic disorders and symptoms (including bleeding and other cycle-related impacts) 	<ul style="list-style-type: none"> Pain scales Ultrasound, blood tests, biopsy, surgery Health apps and digital platforms
Social Environment and Facilities	
Indicator Categories	Measurement Tools
Social Environment	<ul style="list-style-type: none"> Qualitative methods (in-depth interviews, focus group discussions, ranking activities, etc.) Questionnaires/facility level surveys Checklists of service provision and care, and water and sanitation infrastructure National/cross-national surveys Health apps and digital platforms
<ul style="list-style-type: none"> Knowledge, attitudes toward, and practice related to MH, FP, and CIMCs (for users, partners, providers, and communities) 	
<ul style="list-style-type: none"> Reasons (e.g., why is “X” considered undesirable?) and links with stages in the life course and household and community environments 	
<ul style="list-style-type: none"> Common experiences and practices managing CIMCs 	
<ul style="list-style-type: none"> Individual and normative views on normal vs. abnormal changes over the life course (according to users, partners, providers, and communities) 	
<ul style="list-style-type: none"> Societal and cultural norms that shape FP and MH perceptions and practice 	
<ul style="list-style-type: none"> Perceptions and normalization of menstrual dysfunction and pain 	
Services and Facilities	
<ul style="list-style-type: none"> FP and MH information 	
<ul style="list-style-type: none"> FP and MH services 	
<ul style="list-style-type: none"> FP-MH service integration and referrals 	
<ul style="list-style-type: none"> CIMC treatment approaches and options 	
<ul style="list-style-type: none"> Infrastructure and facilities for menstrual management 	
<ul style="list-style-type: none"> Provider training and knowledge of MH, FP, and CIMCs 	
<ul style="list-style-type: none"> Training and capability of health care providers 	
User Experiences and Behaviors	
Indicator Categories	Measurement Tools
Preferences and Experiences	<ul style="list-style-type: none"> Quantitative tools Qualitative methods (in-depth interviews, focus group discussions, ranking activities, etc.) Questionnaires (Menstrual Practices Questionnaire & Menstrual Practices Needs Scale [Hennegan et al., 2020], etc.) Health Management Information Systems (HMIS) National/cross-national surveys Health apps and digital platforms
<ul style="list-style-type: none"> Desirable vs. undesirable changes 	
<ul style="list-style-type: none"> Experiences with contraception and satisfaction 	
<ul style="list-style-type: none"> Risk/Benefit analysis and tolerance 	
<ul style="list-style-type: none"> Self-care for CIMCs 	
Contraceptive Use	
<ul style="list-style-type: none"> Contraceptive non-use 	
<ul style="list-style-type: none"> Contraceptive choice 	
<ul style="list-style-type: none"> Contraceptive self-care 	
<ul style="list-style-type: none"> Contraceptive discontinuation 	
<ul style="list-style-type: none"> Contraceptive switching 	
Menstrual Health	

<ul style="list-style-type: none"> Menstrual health experiences and practices 	
Impacts on Health and Life	
Indicator Categories	Measurement Tools
Health	<ul style="list-style-type: none"> Qualitative methods (in-depth interviews, focus group discussions, ranking activities, etc.) Questionnaires (Quality of Life Scale, Mood scales, etc.) Clinic records National/cross-national surveys
<ul style="list-style-type: none"> Unintended pregnancy 	
<ul style="list-style-type: none"> Symptom management for menstrual and gynecologic disorders 	
<ul style="list-style-type: none"> Anemia/iron deficiency 	
Quality of Life	
<ul style="list-style-type: none"> Overall quality of life 	
<ul style="list-style-type: none"> Psychosocial well-being 	
<ul style="list-style-type: none"> Sexual well-being 	
<ul style="list-style-type: none"> Gender affirmation 	
<ul style="list-style-type: none"> Quality of relationships 	
<ul style="list-style-type: none"> Financial well-being 	
<ul style="list-style-type: none"> Ability to participate in daily activities 	
← Integrated Measurement Tools and Methods →	

Building on what is depicted in Figure 4 and Table 1, the research agenda below calls for expanding on and adding to this initial measurement framework and indicator categorization. As is reflected in the organization of this measurement agenda below, work related to CIMCs needs to happen in a stepwise manner in which researchers and implementors: (1) understand the frameworks and indicators that already exist, (2) assess the usefulness of what exists and identify any gaps, and (3) develop and test new tools to fill those gaps.

1) Recommended Areas of Measurement Research and Corresponding Research Questions	PRIORITY (Time frame)²		
	Short-term	Mid-term	Long-term
1) Identifying current measurement frameworks and indicators			
a) What indicators are currently being used to measure CIMCs in national and global monitoring, and by whom are these being used?			
b) What indicators from the FP and MH fields, relevant to the framework for measuring CIMCs, are currently being used for national and global monitoring of CIMCs?			
c) What validated measures are being used for biomedical and social research related to CIMCs?			
2) Assessing the usefulness of existing indicators and measures and identifying gaps			

² These categories do not indicate a distinct amount of time; rather, they are meant to provide guidance about the sequence and priority of the research.

a) What standardized indicators should be measured routinely through large-scale national and cross-national surveys (e.g., DHS, PMA, other)?			
b) What indicators and validated measures can be used across biomedical research, clinical trials, and social research on user preferences and experiences, social-behavioral influences, and impacts related to CIMCs?			
c) What new indicators and measures are needed for biomedical and social research and large-scale monitoring?			
3) Developing, testing, and validating necessary measures to address measurement gaps			
a) What is the usefulness and performance (validity and reliability) of new measures developed for CIMC research and monitoring, including both quantitative and qualitative measures for biological changes, social-behavioral influences, user preferences and experiences, and impacts of CIMCs?			
4) Translational research: Integrating research across domains and disciplines			
a) How can we encourage and support interdisciplinary and integrated approaches to measuring CIMCs, including both the consequences and benefits of CIMCs?			
b) How can we ensure that all dimensions of CIMCs are considered and that they align with the socio-ecological model, a life course approach, and a rights-based framework during the process of identifying, developing, and using measures and indicators?			
c) What are the best ways to measure equity in experiences of and care for CIMCs?			

ADDITIONAL CONSIDERATIONS: EQUITY IN MEASUREMENT

This measurement framework is rooted in important principles for measuring needs and progress related to equity that, if done well, will create a baseline understanding of the social determinants influencing FP and MH outcomes (UNCESCR, 2016). Building in equity also requires the use of “rights-reflective” indicators specific to CIMCs such as: agency in decision-making and choice, to what degree contraceptive use is voluntary, effects of stigma on menstrual experiences, and the reliability of available FP and MH resources and services (UNFPA, 2020).

2) Contraceptive R&D and Biomedical Research Agenda

➤ **Key Recommendation:** Future contraceptive R&D and biomedical research should focus on: (1) understanding the biological mechanisms that lead to CIMCs and factors that affect them; (2) developing improved prevention and treatment options for undesired CIMCs and options to accelerate and maintain desired CIMCs; and (3) understanding the use of existing and new contraceptive methods to treat menstrual and gynecologic disorders and symptoms. Future contraceptive

R&D should integrate users' preferences and needs related to CIMCs into new method development.

Due to the diversity of user preferences related to CIMCs, a wide variety of contraceptive methods are needed that offer a range of CIMC profiles, including some methods that cause no menstrual changes. Biomedical research for existing and new methods will first require a greater understanding of the biological mechanisms that underly CIMCs and the factors (biological, genetic, microbiome, lifestyle, etc.) that lead to CIMCs. Ideally, there would be ways to accurately predict the CIMCs a user would experience for any method, and this could be an important aid in decision-making about contraceptive method use. In addition, research should focus on developing interventions that prevent, reduce, or treat undesirable CIMCs, as well as interventions that accelerate and maintain desirable CIMCs. Related, biomedical research should include treatment options for menstrual and gynecologic disorders and symptoms, including bleeding and other cycle-related effects. The following research agenda can be used to inform, guide, and unify biomedical research and contraceptive R&D related to CIMCs for current methods and methods under development.

2) Recommended Areas of Biomedical Research and Corresponding Research Questions	PRIORITY (Time frame) ³		
	Short-term	Mid-term	Long-term
1) Improving understanding of biological mechanisms of CIMCs for current methods and methods under development			
a) What percentage of contraceptive users experience CIMCs?			
b) What are the biological mechanisms that lead to CIMCs?			
c) What characterizes a healthy vaginal microenvironment when experiencing different CIMCs? How does this vary based on age, race or ethnicity, diet, weight, location, sexual and menstrual practices, etc.?			
d) What biological factors, including genetic, hemostatic, immune, inflammation, microbiome, and mycobiome affect which users experience which CIMCs?			
e) What behavioral and environmental factors (e.g., diet, exposures, exercise, drug-drug interactions, etc.) impact CIMCs?			
2) Advancing prevention and treatment of undesired CIMCs and acceleration of desired CIMCs for current methods and methods under development			
a) What is the strength of the evidence on existing interventions for treating undesirable CIMCs? ⁴			
b) What is the strength of the evidence on existing interventions for preventing undesirable CIMCs? ⁴			

³ These categories do not indicate a distinct amount of time; rather, they are meant to provide guidance about the sequence and priority of the research.

⁴ Systematic and/or scoping reviews are needed to answer questions about the current "strength of the evidence."

c) What are the best study designs and methodologies for measuring the impact of new CIMC treatment and prevention interventions?			
d) What are new possibilities for treating or preventing undesirable CIMCs?			
e) What existing and new interventions might be effective at accelerating the onset of and maintaining desirable CIMCs?			
f) What role do multipurpose technologies play in treating CIMCs and menstrual and gynecologic disorders? (i.e., pain management and contraception, menstrual management and contraception, etc.)			
3) Improving and standardizing methodologies			
a) How can diagnostics and methods for measuring biological changes be improved and made less invasive (e.g., ex vivo, new animal models, tissue/organ chips, blood and effluent collection, etc.)?			
b) How can big data approaches and existing sample repositories or databases be used to help answer these research questions? (e.g., using machine learning, artificial intelligence, etc.)			
c) What standardizations should be implemented for sample and data collection for high-quality analysis, including for clinical trials?			
4) Exploring the prediction and personalization of CIMCs for current methods and methods under development			
a) What are the possible strategies for developing methods to predict CIMCs for contraceptive users?			
b) What are the possible strategies for developing “personalized” contraceptives based on biological attributes and needs?			
5) Advancing treatment and management of menstrual and gynecologic disorders			
a) What is the strength of the evidence of existing contraceptive interventions for treating and managing menstrual and gynecologic disorders and symptoms? ⁴			
b) Which underserved populations could benefit from currently available contraceptive methods for treatment and management of different menstrual and gynecologic disorders and symptoms?			
c) What contraceptive methods could potentially be used to treat or manage menstrual and gynecologic disorders and symptoms?			
d) What additional treatment options could benefit populations choosing contraception for CIMC-related benefits?			
6) Translational considerations: Integrating research across domains and disciplines			
a) How can researchers across biological sciences (bioengineering, bioinformatics, genetics, etc.) collaborate to improved CIMC research?			
b) How can contraceptive R&D and biomedical research better define and measure CIMCs to collect, analyze, and report data that aligns with user experiences?			
c) How can research on user preferences about CIMCs, as well as perspectives at other levels of the socio-ecological model (e.g., partners, providers, community norms), be integrated into all phases of contraceptive R&D?			
d) How can contraceptive R&D better define and measure CIMCs to align with programmatic and service delivery requirements for product introduction?			

e) How can biomedical research and contraceptive development related to CIMCs increase diversity, equity, and inclusion throughout the R&D process?			
f) What other aspects of sexual and reproductive health are associated with and impacted by CIMCs (e.g., satisfaction, wellness and pleasure, HIV and other STIs, other reproductive tract infections, gender-based violence), and how can integration be better achieved at these intersections?			
g) What additional biomedical research is needed to differentiate between CIMCs and similar symptoms caused by more serious conditions (e.g., HIV, cancers) among contraceptive users to not delay diagnosis and treatment?			

3) Social-Behavioral and User Preferences Research Agenda

➤ **Key Recommendation:** Future social-behavioral research should take an integrated approach to understanding; (1) the nuance and diversity of perceptions, attitudes, and practices related to all types of CIMCs; (2) factors that influence CIMC perceptions, attitudes, and practices, including at the individual, relationship, and wider socio-ecological levels and across the life course; and (3) the impacts of CIMCs on users’ lives and their FP and MH decision-making.

Understanding the diversity, nuance, and complexity of users’ perceptions, attitudes, and experiences related to CIMCs is one of the greatest challenges faced by FP and MH researchers interested in this issue. In addition to the challenge of understanding a wide range of user perspectives, research must also consider these within the larger social, cultural, and ecological context and across a user’s life course. There may also be unique considerations for populations who have been marginalized and underserved, such as youth, perimenopausal people, people with disabilities, people living with HIV, postpartum people, refugees, migrants or other mobile populations, sex workers, people in the LGBTQ community, survivors of abuse and violence, and prisoners, among others. In addition, these questions should be taken with intentional attention to the context, lived experience, and diversity of the populations or geographies engaged in research. The following questions are priorities to address in future research to better understand users’ experiences and preferences and community norms. The questions have been developed based on the existing literature and are rooted in the theoretical basis described above.

3) Recommended Areas of Social-Behavioral and User Preferences Research and Corresponding Research Questions	PRIORITY (Time frame) ⁵		
	Short-term	Mid-term	Long-term
1) Understanding varied experiences of and perceptions and attitudes toward CIMCs			
a) How do users perceive and understand the concept of CIMCs? Do they view bleeding during contraceptive use as menstruation?			
b) How do users experience and describe different types of CIMCs?			
c) Which types of CIMCs do users generally consider to be desirable? Which types of CIMCs do users generally consider to be undesirable?			
d) What are the primary drivers for users finding different types of CIMCs desirable and/or undesirable?			
e) What are the diverse characteristics of users who view different types of CIMCs as desirable and/or undesirable? Do these views change across the life course?			
f) How do race and ethnicity, socioeconomic status, age, disability, sexual orientation, gender identity, location (e.g., urban/rural) and other social factors and identities impact users' perceptions of and experiences with CIMCs across the life course?			
g) How do partners, families, providers, and communities perceive different types of CIMCs? How does this change when considering gender?			
h) What is the strength of the evidence ⁶ on experiences of and perceptions and attitudes toward CIMCs?			
2) Understanding what influences perceptions and preferences around CIMCs			
a) How does a user's existing understanding of and experiences with menstruation, menstrual and gynecologic disorders, fertility, family planning, and other reproductive health issues impact user preferences related to CIMCs?			
b) How do experiences and perceptions of CIMCs relate to broader sociocultural norms around gender, menstruation, fertility, childbearing, and sexuality?			
c) How do perceptions of partners impact user preferences related to CIMCs?			
d) How do perceptions of other family members, peers, teachers, community leaders, as well as community norms, impact user preferences related to CIMCs?			
e) How do provider's perceptions of CIMCs impact how they counsel clients on FP methods that induce menstrual changes and what methods they provide?			
f) How do knowledge and perceptions of providers influence users' preferences around CIMCs, and in contraceptive selection or non-use?			

⁵ These categories do not indicate a distinct amount of time; rather, they are meant to provide guidance about the sequence and priority of the research.

⁶ Systematic and/or scoping reviews are needed to answer questions about the current "strength of the evidence."

g) What other sources of information on CIMCs, beyond providers, contribute to users' sense of self-efficacy related to understanding and managing CIMCs?			
h) How do digital tools and information contribute to users' self-efficacy related to understanding and managing CIMCs?			
i) How does self-efficacy at the individual, interpersonal, and community levels influence user preferences for CIMCs?			
3) Identifying and measuring the impacts of CIMCs			
a) How do CIMCs impact users' quality of life (i.e., psychosocial well-being, sexual well-being, gender affirmation, relationship dynamics, finances, and daily life, including work, religion, schooling, and household responsibilities)?			
b) How do CIMCs affect users' contraceptive satisfaction and reproductive autonomy, including opportunities for self-care?			
c) How do perceptions and experiences of different types of CIMCs affect contraceptive use dynamics (e.g., uptake, continuation/discontinuation, method switching, and non-use) over the life course?			
d) How do CIMCs impact users' menstrual cycle experiences and menstrual practices (e.g., choice and use of different menstrual products) across the life course?			
e) How do users manage CIMCs, and where and how do they access the materials and information to do so?			
f) How do CIMCs impact users' contraceptive choice across the life course, including their willingness to tolerate CIMCs in exchange for other method characteristics (e.g., method efficacy)?			
4) Understanding the relationship between CIMCs, MH, FP, and other reproductive outcomes⁷			
a) How do users of contraception manage CIMCs within the context of larger community and societal norms related to menstruation and menstrual health?			
b) How does knowledge of and/or experience with the use of hormonal methods for management of menstrual and gynecologic disorders and symptoms affect contraceptive satisfaction, contraceptive use dynamics, and menstrual cycle experiences?			
c) How do CIMCs affect a contraceptive user's ability to detect and understand reproductive events, such as pregnancy, miscarriage, and menopause, and make subsequent pregnancy and/or reproductive decisions?			
5) Translational considerations: Integrating research across domains and disciplines			
a) How can formative and implementation research best communicate and integrate user preferences research findings into other research, as well as into policies and programs for both FP and MH?			
b) What are the possible strategies for developing "personalized" contraceptives that integrate both biological attributes and user preferences?			

⁷ Including, but not limited to: contraceptive-induced amenorrhea, impact of irregular bleeding on timing of pregnancy recognition, and subsequent reproductive options

4) Programmatic Research Agenda

- **Key Recommendation:** Future programmatic research should aim to identify and scale up cost-effective approaches to addressing CIMCs, including through FP and MH programs and as part of self-care.

It is critical to address CIMCs in policy and programs and facilitate stronger linkages between FP and MH to address CIMCs, including through integrated service delivery models. Integrated approaches can include:

- Information about CIMCs as part of both FP and MH education and programming (e.g., for younger and older adolescents)
- Integrating MH information, referrals, and/or products into FP service delivery platforms, including to facilitate self-care
- Integrating FP method provision and/or referrals into MH platforms, including to facilitate self-care.⁸

When addressing CIMCs through education, counseling, and provision of services, it is important to monitor progress, evaluate impact, and assess the cost-effectiveness of various approaches. It is also critical to document successes and failures, adjust services accordingly, and disseminate findings to key stakeholders. Key evaluation questions that can be included in implementation science and routine or enhanced monitoring and evaluation are outlined below.

4) Recommended Areas of Programmatic Research and Corresponding Research Questions	PRIORITY (Time frame) ⁹		
	Short-term	Mid-term	Long-term
1) Developing effective models to address CIMCs and improve health outcomes			
a) What are existing opportunities and barriers to address CIMCs in both FP and MH programs?			
b) Where do users currently learn about menstruation, menstrual health, family planning, and CIMCs?			
c) How can interventions be designed to address CIMCs to improve contraceptive satisfaction and use?			
d) How can interventions be designed to improve users' menstrual cycle experiences and menstrual practices, including early diagnosis and treatment of menstrual and gynecologic disorders?			
e) How do existing FP and MH interventions affect attitudes and beliefs related to CIMCs?			

⁸ This agenda uses the WHO's definition of self-care: "the ability of individuals, families, and communities to promote health, prevent disease, maintain health, and to cope with illness and disability with or without the support of a health care provider" (WHO, 2019a).

⁹ These categories do not indicate a distinct amount of time; rather, they are meant to provide guidance about the sequence and priority of the research.

f) How do existing FP and MH interventions affect behaviors and practices related to FP, MH, and CIMCs?			
2) Addressing CIMCs through integrated FP-MH service delivery			
a) How can interventions be designed to increase access to FP and MH products and services, including to address CIMCs?			
b) What type of training/guidelines/protocols do providers currently receive and use for FP and MH, including CIMCs, and how can these be improved?			
c) What types of providers are best positioned to provide CIMC information and services?			
d) How does the availability, accessibility, and affordability of MH products and facilities influence contraceptive choice?			
e) Do integrated FP-MH interventions improve client-centered care for CIMCs and other key outcomes (e.g., FP satisfaction, uptake, continuation)?			
3) Understanding CIMC self-care and user education			
a) How can FP and MH interventions be designed to improve self-care for managing CIMCs?			
b) How can interventions be designed to improve counseling and education on FP, MH, and CIMCs?			
c) How can educational tools and resources be designed to improve access to information, products, and services to address CIMCs?			
d) What messaging and education is needed to help users differentiate between CIMCs and similar symptoms caused by more serious conditions (e.g., HIV, cancers)?			
e) How do self-care interventions change how community members support one another regarding FP, MH, and CIMCs?			
f) How do self-care interventions affect behaviors and practices related to FP, MH, and CIMCs?			
4) Developing digital tools and resources for FP-MH integration			
a) How can digital tools and resources be designed to improve access to information, products, and services to address CIMCs?			
b) How do digital tools that integrate information, products, and services about CIMCs enhance knowledge or change attitudes?			
c) How do digital tools that integrate information, products, and services about CIMCs improve FP and/or MH behaviors/practices?			
5) Understanding FP-MH integration and equity			
a) How should integrated programs be designed/modified to address the unique needs of populations who have been marginalized and underserved?			
b) Which populations who have been marginalized and underserved are not currently reached by MH and FP policies and/or programs?			
c) Is the potential for provider bias toward populations who have been marginalized and underserved affected when integrating FP and MH?			
6) Examining cost-savings and efficiencies			
a) What are the main cost drivers for integrated approaches?			

b) How might improvements in self-care for CIMCs lead to fewer resource requirements for the health care system (e.g., fewer visits with a facility-based provider)?			
c) What service delivery models are most cost-effective at integrating FP and MH, including to address CIMCs?			
7) Understanding CIMCs and social context			
a) How can interventions be designed and adapted to address social norms related to FP, MH, CIMCs, and gender, among different populations and in different contexts across the life course?			
b) Are interventions that address CIMCs effective at changing social norms in different contexts and among different populations?			
8) Translational considerations: Integration into policy and practice			
a) What policies and guidelines already exist or can be leveraged to address CIMCs and FP-MH integration?			
b) What new policies or guidelines are required to address CIMCs?			
c) How are national and international policies and guidelines implemented at the institutional, facility, and community levels, and who is responsible for implementation at each level? Where is technical support needed to address CIMCs?			
d) How can CIMC information and services be integrated into other health areas (i.e., water, sanitation, and hygiene (WASH); maternal health; HIV; environmental health)?			

Next Steps

Moving forward, CIMCs need to be addressed to improve the health and well-being of FP users globally and to avoid missed opportunities to integrate MH into sexual and reproductive health. Guided by this Global RLA, researchers, product developers, health care providers, program implementors, advocates, policymakers, and funders are encouraged to take immediate action to conduct research and implement strategies to address the issue of CIMCs and support the integration of FP and MH. To make this work equitable and more impactful, stakeholders are encouraged to involve a wide range of perspectives across a variety of contexts and conduct research with diverse populations. As is evident from the CIMC Global RLA, a substantial amount of work has yet to be accomplished. This work should take prioritization into account and begin with assessment of the existing evidence surrounding CIMCs to gain a baseline understanding of the many dimensions of CIMCs, including the following concrete next steps:

- **MEASUREMENT:** Compile and review the current indicators and tools being used across disciplines to measure CIMCs at all levels (including FP and MH indicators that can be used and/or adapted) and identify gaps and areas for opportunity and standardization.

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- **CONTRACEPTIVE R&D AND BIOMEDICAL RESEARCH**: Streamline and improve research definitions, measurement, and processes to facilitate future contraceptive R&D and biomedical CIMC research with a focus on elucidating the biological mechanisms underlying CIMCs, their individual variations, and the factors affecting their manifestation and intensity.
 - **SOCIAL-BEHAVIORAL RESEARCH**: Understand and contextualize contraceptive users' experiences, perceptions, and attitudes toward CIMCs, including assessing the state and strength of the existing evidence related to CIMC perceptions.
 - **PROGRAMMATIC RESEARCH**: Identify, define, and design how FP and MH can be effectively integrated, including to address CIMCs.
 - **CROSS-CUTTING ACTIVITIES**: Ensure that interdisciplinary and integrated approaches are supported and used to measure and research all dimensions of CIMCs and that informed choice and equity are considered and embedded within these processes.

CONTACT US

The CIMC Task Force strongly encourages you to share your experiences implementing the CIMC Global Research & Learning Agenda including adaptations, evidence generated, or programs and policies implemented. Please report these experiences and direct all inquiries about this document to Emily Hoppes, Senior Technical Officer, Product Development and Introduction at FHI 360, ehoppes@fhi360.org.

Appendix

A. Consolidated CIMC Research Agenda

This table is a consolidated version of all of the research questions above for easy reference.

Recommended Research Questions for Measurement
<p>1) Identifying current measurement frameworks and indicators</p> <ul style="list-style-type: none">a) What indicators are currently being used to measure CIMCs in national and global monitoring and by whom are these being used?b) What indicators from the FP and MH fields, relevant to the framework for measuring CIMCs, are currently being used for national and global monitoring of CIMCs?c) What validated measures are being used for biomedical and social research related to CIMCs?
<p>2) Assessing the usefulness of existing indicators and measures and identifying gaps</p> <ul style="list-style-type: none">a) What standardized indicators should be measured routinely through large-scale national and cross-national surveys (e.g., DHS, PMA, other)?b) What indicators and validated measures can be used across biomedical research, clinical trials, and social research on user preferences and experiences, social-behavioral influences, and impacts related to CIMCs?c) What new indicators and measures are needed for biomedical and social research and large-scale monitoring?
<p>3) Developing, testing, and validation of necessary measures to address measurement gaps</p> <ul style="list-style-type: none">a) What is the usefulness and performance (validity and reliability) of new measures developed for CIMC research and monitoring, including both quantitative and qualitative measures for biological changes, social-behavioral influences, user preferences and experiences, and impacts of CIMCs?
<p>4) Translational research: Integrating research across domains and disciplines</p> <ul style="list-style-type: none">a) How can we encourage and support interdisciplinary and integrated approaches to measuring CIMCs, including both the consequences and benefits of CIMCs?b) How can we ensure that all dimensions of CIMCs are considered and that they align with the socio-ecological model, a life course approach, and a rights-based framework during the process of identifying, using, and developing measures and indicators?c) What are the best ways to measure equity in experiences of and care for CIMCs?
Recommended Research Questions for Contraceptive R&D and Biomedical Research
<p>1) Improving understanding of biological mechanisms CIMCs for current methods and methods under development</p> <ul style="list-style-type: none">a) What percent of contraceptive users experience CIMCs?b) What are the biological mechanisms that lead to CIMCs?

- c) What characterizes a healthy vaginal microenvironment when experiencing different CIMCs? How does this vary based on age, race or ethnicity, diet, weight, location, sexual and menstrual practices, etc.?
- d) What biological factors, including genetic, hemostatic, immune, inflammation, microbiome, and mycobiome affect which users experience which CIMCs?
- e) What behavioral and environmental factors (e.g., diet, exposures, exercise, drug-drug interactions, etc.) impact CIMCs?

2) Advancing prevention and treatment of undesired CIMCs and acceleration of desired CIMCs for current methods and methods under development

- a) What is the strength of the evidence on existing interventions for treating undesirable CIMCs?
- b) What is the strength of the evidence on existing interventions for preventing undesirable CIMCs?
- c) What are the best study designs and methodologies for measuring the impact of new CIMC treatment and prevention interventions?
- d) What are new possibilities for treating or preventing undesirable CIMCs?
- e) What existing and new interventions might be effective at accelerating the onset of and maintaining desirable CIMCs?
- f) What role do multipurpose technologies play in treating CIMCs and menstrual and gynecologic disorders? (i.e., pain management and contraception, menstrual management and contraception, etc.)

3) Improving and standardizing methodologies

- a) How can diagnostics and methods for measuring biological changes be improved and made less invasive (e.g., ex vivo, new animal models, tissue/organ chips, blood and effluent collection, etc.)?
- b) How can big data approaches and existing sample repositories or databases be used to help answer these research questions? (e.g., using machine learning, artificial intelligence, etc.)
- c) What standardizations should be implemented for sample and data collection for high-quality analysis, including for clinical trials?

4) Exploring predicting and personalizing CIMCs for current methods and methods under development

- a) What is the strength of the evidence of existing contraceptive interventions for treating and managing menstrual and gynecologic disorders and symptoms?
- b) Which underserved populations could benefit from currently available contraceptive methods for treatment and management of different menstrual and gynecologic disorders and symptoms?
- c) What contraceptive methods could potentially be used to treat or manage menstrual and gynecologic disorders and symptoms?
- d) What additional treatment options could benefit populations choosing contraception for CIMC-related benefits?

5) Advancing treatment and management of menstrual and gynecologic disorders

- a) What is the strength of the evidence of existing contraceptive interventions for treating and managing menstrual and gynecologic disorders and symptoms?

- b) Which underserved populations could benefit from currently available contraceptive methods for treatment and management of different menstrual and gynecologic disorders and symptoms?
- c) What contraceptive methods could potentially be used to treat or manage menstrual and gynecologic disorders and symptoms?
- d) What additional treatment options could benefit populations choosing contraception for CIMC-related benefits?

6) Translation considerations: Integrating research across domains and disciplines

- a) How can researchers across biological sciences (bioengineering, bioinformatics, genetics, etc.) collaborate to improved CIMC research?
- b) How can contraceptive R&D and biomedical research better define and measure CIMCs to collect, analyze, and report data that aligns with user experiences?
- c) How can research on user preferences about CIMCs, as well as perspectives at other levels of the socio-ecological model (e.g., partners, providers, community norms), be integrated into all phases of contraceptive R&D?
- d) How can contraceptive R&D better define and measure CIMCs to align with programmatic and service delivery requirements for product introduction?
- e) How can biomedical research and contraceptive development related to CIMCs increase diversity, equity, and inclusion throughout the R&D process?
- f) What other aspects of sexual and reproductive health are associated with and impacted by CIMCs (e.g., satisfaction, wellness and pleasure, HIV and other STIs, other reproductive tract infections, GBV) and how can integration be better achieved at these intersections?
- g) What additional biomedical research is needed to differentiate between CIMCs and similar symptoms caused by more serious conditions (e.g., HIV, cancers) among contraceptive users to not delay diagnosis and treatment?

Recommended Research Questions for Social-Behavioral User and Preferences Research

1) Understanding experiences of and perceptions and attitudes towards CIMCs

- a) How do users perceive and understand the concept of CIMCs? Do they view bleeding during contraceptive use as menstruation?
- b) How do users experience and describe different types of CIMCs?
- c) Which types of CIMCs do users generally consider to be desirable? Which types of CIMCs do users generally consider to be undesirable?
- d) What are the primary drivers for users finding different types of CIMCs desirable and/or undesirable?
- e) What are the diverse characteristics of users who view different types of CIMCs as desirable and/or undesirable? Do these views change across the life course?
- f) How does race and ethnicity, socioeconomic status, age, disability, sexual orientation, gender identity, location (e.g., urban/rural) and other social factors and identities impact users' perceptions of and experiences with CIMCs across the life course?
- g) How do partners, families, providers, and communities perceive different types of CIMCs? How does this change when considering gender?
- h) What is the strength of the evidence on experiences of and perceptions and attitudes towards CIMCs?

2) Understanding what influences perceptions and preferences around CIMCs

- a) How does a user's existing understanding of and experiences with menstruation, menstrual & gynecologic disorders, fertility, family planning and other reproductive health issues impact user preferences related to CIMCs?
- b) How do experiences and perceptions of CIMCs relate to broader sociocultural norms around gender, menstruation, fertility, childbearing, and sexuality?
- c) How do perceptions of partners impact user preferences related to CIMCs?
- d) How do perceptions of other family members, peers, teachers, community leaders, as well as community norms, impact user preferences related to CIMCs?
- e) How do provider's perceptions of CIMCs impact how they counsel clients on FP methods that induce menstrual changes and what methods they provide?
- f) How do knowledge and perceptions of providers influence users' preferences around CIMCs, and in contraceptive selection or non-use?
- g) What other sources of information on CIMCs, beyond providers, contribute to user's sense of self-efficacy related to understanding and managing CIMCs?
- h) How do digital tools and information contribute to user's self-efficacy related to understanding and managing CIMCs?
- i) How does self-efficacy at the individual, interpersonal, and community levels influence user preferences for CIMCs?

3) Identifying and measuring the impacts of CIMCs

- a) How do CIMCs impact users' quality of life (i.e., psychosocial well-being, sexual well-being, gender affirmation, relationship dynamics, finances, and daily life, including work, religion, schooling, and household responsibilities)?
- b) How do CIMCs affect users' contraceptive satisfaction and reproductive autonomy, including opportunities for self-care?
- c) How do perceptions and experiences of different types of CIMCs affect contraceptive use dynamics (e.g., uptake, continuation/discontinuation, method switching, and nonuse) over the life course?
- d) How do CIMCs impact users' menstrual cycle experiences and menstrual practices (e.g., choice and use of different menstrual products) across the life course?
- e) How do users manage CIMCs and where and how do they access the materials and information to do so?
- f) How do CIMCs impact users' contraceptive choice across the life course, including their willingness to tolerate CIMCs in exchange for other method characteristics (e.g., method efficacy)

4) Understanding the relationship between CIMCs, MH, FP, and other reproductive outcomes

- a) How do users of contraception manage CIMCs within the context of larger community and societal norms related to menstruation and menstrual health?
- b) How does knowledge of and/or experience with the use of hormonal methods for management of menstrual and gynecologic disorders and symptoms affect contraceptive satisfaction, contraceptive use dynamics, and menstrual cycle experiences?
- c) How do CIMCs impact a contraceptive user's ability to detect and understand reproductive events, such as pregnancy, miscarriage, and menopause, and make subsequent pregnancy and/or reproductive decisions?

5) Translation considerations: Integrating research across domains and disciplines

- a) How can formative and implementation research best communicate and integrate user preferences research findings into other research, as well as into policies and programs for both FP and MH?
- b) What are the possible strategies for developing “personalized” contraceptives that integrate both biological attributes and user preferences?

Recommended Research Questions for Programmatic Research

1) Developing effective models to address CIMCs and improve health outcomes

- a) What are existing opportunities and barriers to address CIMCs in both FP and MH programs?
- b) Where do users currently learn about menstruation, menstrual health, family planning, and CIMCs?
- c) How can interventions be designed to address CIMCs to improve contraceptive satisfaction and use?
- d) How can interventions be designed to improve users’ menstrual cycle experiences and menstrual practices, including early diagnosis and treatment of menstrual and gynecologic disorders?
- e) How do existing FP and MH interventions affect attitudes and beliefs related to CIMCs?
- f) How do existing FP and MH interventions affect behaviors and practices related to FP, MH, and CIMCs?

2) Addressing CIMCs through integrated FP-MH service delivery

- a) How can interventions be designed to increase access to FP and MH products and services, including to address CIMCs?
- b) What type of training/guidelines/protocols do providers currently receive and use about FP and MH, including CIMCs, and how can these be improved upon?
- c) What types of providers are best positioned to provide CIMC information and services?
- d) How does the availability, accessibility, and affordability of MH products and facilities influence contraceptive choice?
- e) Do integrated FP-MH interventions improve client-centered care for CIMCs and other key outcomes (e.g., FP satisfaction, uptake, continuation)?

3) Understanding CIMC self-care and user education

- a) How can FP and MH interventions be designed to improve self-care for managing CIMCs?
- b) How can interventions be designed to improve counseling and education on FP, MH, and CIMCs?
- c) How can educational tools and resources be designed to improve access to information, products, and services to address CIMCs?
- d) What messaging and education is needed to help users differentiate between CIMCs and similar symptoms caused by more serious conditions (e.g., HIV, cancers)?
- e) How do self-care interventions change how community members support one another regarding FP, MH, and CIMCs?
- f) How do self-care interventions affect behaviors and practices related to FP, MH, and CIMCs?

4) Developing digital tools and resources for FP-MH integration

- a) How can digital tools and resources be designed to improve access to information, products, and services to address CIMCs?
- b) How do digital tools that integrate information, products, and services about CIMCs enhance knowledge or change attitudes?
- c) How do digital tools that integrate information, products, and services about CIMCs improve FP and/or MH behaviors/practices?

5) Understanding FP-MH integration and equity

- a) How should integrated programs be designed/modified to address the unique needs of populations who have been marginalized and underserved?
- b) Which populations who have been marginalized and underserved are not currently reached by MH and FP policies and/or programs?
- c) Is the potential for provider bias towards populations who have been marginalized and underserved impacted when integrating FP and MH?

6) Examining FP-MH cost-savings and efficiencies

- a) What are the main cost drivers for integrated approaches?
- b) How might improvements in self-care for CIMCs lead to fewer resource requirements for the health care system (e.g., fewer visits with a facility-based provider)?
- c) What service delivery models are most cost-effective at integrating FP and MH including to address CIMCs?

7) Understanding CIMCs and social context

- a) How can interventions be designed and adapted to address social norms related to FP, MH, CIMCs, and gender, among different populations and in different contexts across the life course?
- b) Are interventions that address CIMCs effective at changing social norms in different contexts and among different populations?

8) Translational considerations: Integration into policy and practice

- a) What policies and guidelines already exist or can be leveraged to address CIMCs and FP-MH integration?
- b) What new policies or guidelines are required to address CIMCs?
- c) How are national and international policies and guidelines implemented at the institutional, facility, and community levels, and who is responsible for implementation at each level? Where is technical support needed to address CIMCs?

B. Additional FP and MH Linkages

FP and MH are closely related fields that are often not effectively linked and integrated, which may result in missed opportunities to improve SRHR services (Hennegan et al., 2019; Wilson et al., 2021). This disconnect can be addressed by strategically identifying key areas for integration. In addition to addressing CIMCs, other priority areas include:

- 
- **Expanding education and awareness:** A lack of information, stigma, and myths and misperceptions impact both the FP and MH fields and can be addressed through inclusive educational outreach and dissemination of correct and accessible information. This includes context-specific puberty education, with information about the menstrual cycle and how it relates to pregnancy and fertility, delivered using evidence-based curricula and teaching methods, such as comprehensive sexuality education (CSE). There is a growing body of evidence that suggests providing young people with age-appropriate puberty and SRHR education improves their ability to communicate about SRHR and more easily access services such as FP later in life (UNESCO, 2018; IRH et al., 2015; HIPs, 2015). Puberty and SRHR education for young men also creates gender supportive environments for FP use (UNESCO, 2018). Additionally, puberty education, CSE, and other SRHR education and awareness interventions should aim to be as inclusive as possible and more regularly include information about gender identity and sexuality, which will help to address the unique needs of all menstruators and FP users
 - **Reducing medical barriers to FP access:** Providers often rely on the presence of menses as an indicator that an individual seeking FP is not pregnant before providing contraceptive methods; this can create a barrier if a client comes to the clinic on a day they are not menstruating. The pregnancy checklist addresses this by using a series of questions to rule out pregnancy based on criteria endorsed by the World Health Organization (WHO, 2004). Evaluations of the pregnancy checklist have demonstrated that the tool can be effective in ruling out pregnancy for over 85% of clients (Stanback et al., 2005). Further studies have shown that use of the pregnancy checklist by FP providers significantly reduced the proportion of clients being turned away due to menstrual status and improved access to same-day contraceptive services (Stanback et al, 2013). Research also shows that increasing the availability of simple, low-cost pregnancy tests in FP programs can reduce barriers to access among individuals seeking FP services on a day they are not menstruating (Stanback et al., 2017).
 - **Offering a full contraceptive method mix including Fertility Awareness Based Methods (FABMs) and Lactational Amenorrhea Method (LAM):** FABMs and LAM are important FP options for those who cannot use hormonal methods due to personal or medical reasons. LAM is a highly effective modern method that can be used up to 6 months postpartum for those exclusively breastfeeding while amenorrhea persists. FABMs include both calendar-based methods, in which the menstrual cycle is carefully tracked, and symptoms-based methods, which depends on observing physical signs of fertility. Some FABMs, including the TwoDay Method and Standard Days Method, are more effective than others, and there are a number of resources and job aids available to support use. Both FABMs and LAM are enhanced by an environment of open

communication and familiarity with the concepts of menstruation and fertility (Urrutia et al., 2018, Van der Wijden et al., 2003).

Below is a diagrammatic representation of these and other linkages between FP and MH.

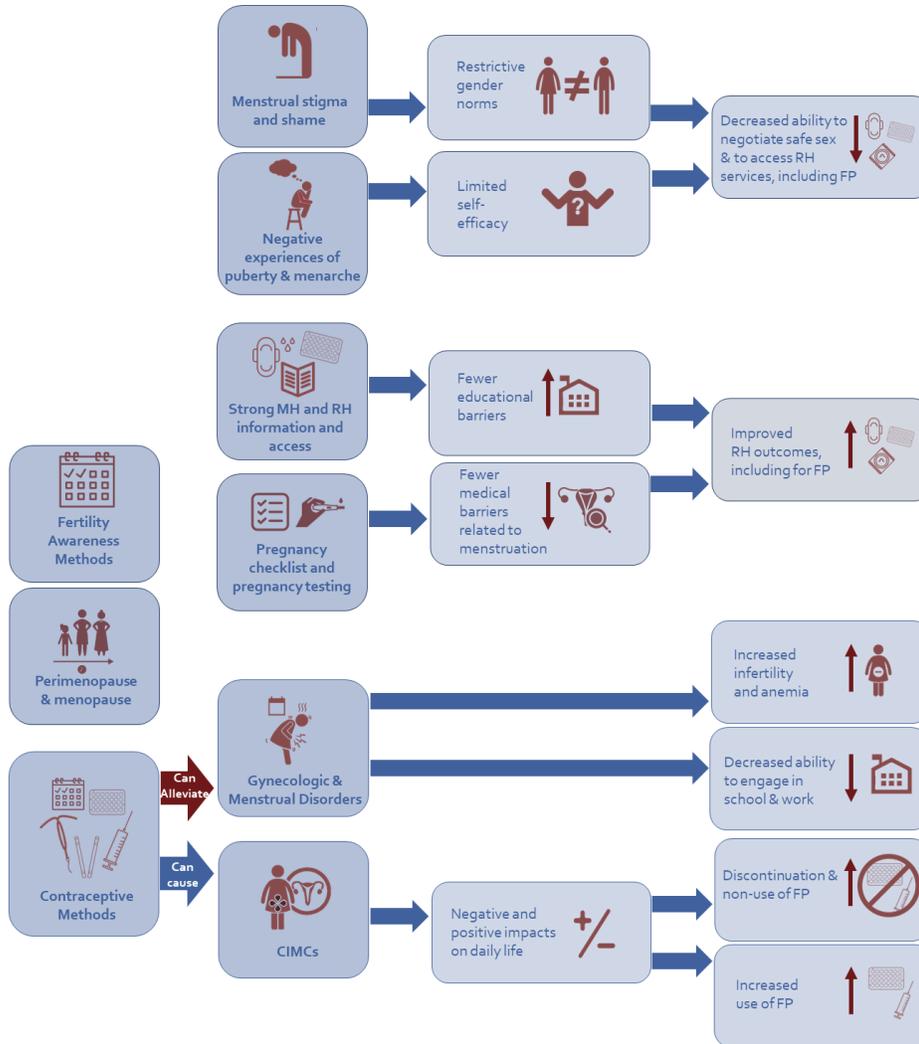


Figure 5. Linkages between FP and MH (Source: Rising Outcomes)

Unless indicated otherwise, “→” in this figure means “may lead to” or “associated with.”

C. CIMC Meeting Materials

MEETING GOAL:

Identify research, product development, policy, and program priorities

OVERALL MEETING OBJECTIVES:

By the end of the two-day meeting, we hope the group will:

- Gain an overview of the existing evidence and identify key gaps;
- Contribute to the development of a research agenda and a wider “call to action”;

- Facilitate new and increased connections between the FP and MH fields; identify additional key stakeholders to engage; and
- Provide input on appropriate global and country forums to advance these agendas.

DAILY MEETING OBJECTIVES:

DAY 1

- Define common CIMCs and associated consequences and opportunities;
- Identify synergies between family planning and menstrual health;
- Review evidence regarding users' perspectives and experiences with CIMCs;
- Discuss types of programmatic interventions, including recent evidence.

DAY 2

- Review measurement approaches and indicators for CIMCs;
- Review existing and potential biomedical interventions;
- Discuss new product development and implications for menstrual experiences;
- Contribute to the development of draft research agenda and wider "call to action."

PARTICIPATING ORGANIZATIONS:

Abt Associates, Accountability Lab Nigeria, AFRIPads, ANSSP/MS, Anuflo Industries Limited, APHRC, ARFH, Avenir Health, Bill & Melinda Gates Foundation, Boston University, Burnet Institute, CAMI Health, Camris, Centre for Health Agriculture Development Research and Consulting, CHAI, CIFF, CILSIDA, Clinton Health Access Initiative, Clue, Columbia University, Community Health Information Education Forum (CHIEF), CONRAD, CREHPA, Days For Girls International, Deloitte, DesireLine, Development Solutions Inc, DKT WomanCare, Driscoll Consultancy, Duke University, Eastern Virginia Medical School, Eco Femme, Edu Platforms, Escola Paulista Medicina – UNIFESP, FCDO, Federal Medical Centre Abeokuta, Femme International, FHI 360, Gender mobile initiative, Gold Hormones, Grand Challenges Canada, Guttmacher Institute, Huru, Immi health, International Planned Parenthood Federation, International youth alliance for family planning, IntraHealth International, Ipas, ISON BPO, IYAFP, Jhpiego, Johns Hopkins University, Johnson & Johnson, Just a Cup Europe, Khadijat Memorial Hospital, KIT Royal Tropical Institute, Levy Mwanawasa University; Live Healthy Initiatives, Lobatse DHMT, London School of Hygiene and Tropical Medicine, Makerere University, Marie Stopes International, Matchboxology, Medicines360, Menstrual Matters, Minia University, Ministry of Health – Kenya, Mombasa Catholic, MRU, National Defence College – Abuja, NHSSP, NICHD, OCON, One Voice Initiative For Women and Children Emancipation, ONG Sainte Philomène, l'Espérance (OSPE), Oregon Health & Science University, Ottawa Hospital Research Institute, Palladium, PATH, Pathfinder, PERIOD Movement, Population Council, PRB, PSI, Purdue University, Real Relief, RHSC, RHU, Rising

Outcomes, Routes2Results, S G Consulting, Save the Children, Swedish International Development Cooperation Agency (Sida), The Case For Her, The Manoff Group, The Menstrual Health Hub, The Tru Company, Tufts University, UNAIDS, UNFPA, UNHCR, UNICAMP, UNICEF, University of Alabama – Birmingham, University of Edinburgh, University of Ghana, University of Ibadan, University of Massachusetts – Boston, University of Michigan, University of New Mexico, University of São Paulo, University of Zambia, Upstream, USAID, WoMena, WoMena Uganda, YCDA, and ZanaAfrica.

MEETING AGENDA:

DAY 1 AGENDA: NOVEMBER 17, 2020 - 9AM-11AM EST		
9:00-9:15	Welcome & Introduction • Greeting • Review of meeting objectives and cross-cutting themes	Speakers: Tabitha Srikipatana, USAID Laneta Dorflinger, FHI 360
9:15-9:25	Rapid review of contraceptive-induced menstrual changes (CIMCs): Types and CIMCs and potential impact	Dr. Marsden Solomon, Chief of Party, Afya Uzazi project, FHI 360/Kenya
9:25-9:40	•Seekingsynergies: What are the linkages between family planning and menstrual health? What connections are currently overlooked or inadequately addressed? • Q&A	Marni Sommer, Columbia University Lucy Wilson, Rising Outcomes
9:40-10:20	User experiences and perceptions: What do we know about how users perceive and experience different types of CIMCs and what users want and need? How do these relate to contextual meanings and practices around menstruation? What are key considerations for special populations and across the reproductive life course? • Q&A	Facilitator: Funmi OlaOlorun, EVIHDAF Speakers: Chelsea Polis, Guttmacher Institute Amelia Mackenzie, FHI 360 Simon Kibira, Makerere University
10:20-10:55	Panel: Programmatic interventions – existing knowledge & evidence gaps • Review of evidence about programmatic interventions including data on what women's and providers' perceptions and experiences • Q&A	Facilitator: Eva Lathrop, PSI Speakers: Kate Rademacher, FHI 360 Francia Rasoanirina, EECO - PSI/Madagascar Sofia Córdova, PSI Central America Roopal Thaker, ZanAfrica
10:55-11:00	Closing • Summary; review of agenda and goals for Day 2 • Logistics for Day 2	Linda Sussman, USAID Kate Rademacher, FHI 360

DAY 2 AGENDA: NOVEMBER 18, 2020 - 9AM-11:30AM EST		
9:00-9:05	Welcome & Introduction • Greeting, Re-cap of Day 1; review of meeting objectives for Day 2	Speakers: Mihira Karra, USAID Trinity Zan, R4S, FHI 360
9:05-9:20	Measurement & indicators • Developing and using better, more consistent measures • Q&A	Facilitator: Emily Hoppes, FHI 360 Julie Hennegan, Burnet Institute Aurélië Brunie, FHI 360
9:20-9:50	Biomedical interventions and CIMCs • Non-contraceptive benefits: Treatments for menstrual disorders • Research on preventing undesirable & accelerating desirable CIMCs	Facilitator: Lisa Haddad, Population Council Jackie Maybin, U. of Edinburgh Kavita Nanda, FHI 360
9:50-10:20	Panel: Product Development - Forward-looking innovations • The panel will discuss new products and biomedical interventions being developed and how to incorporate user preferences at all phases of development and introduction. • Q&A	Facilitator: Amelia Mackenzie, FHI 360 Gustavo Doncel, CONRAD Kirsten Vogelsong, BMGF Diana Blithe, NICHD Laneta Dorflinger, FHI 360
10:20-10:25	Development of learning agenda and “call to action”	Kate Rademacher, FHI 360
10:25-10:30	BREAK	All
10:30-11:00	Breakout rooms 1: Measurement, indicators, and data sources 2: Social-behavioral and user experience research 3: Biomedical research and contraceptive R&D 4: Service delivery guidelines 5: Considerations for special populations and equity	All
11:00-11:20	• Report out in plenary + discussion about format(s) to move forward	All
11:20-11:30	• Summary and next steps; Closing	Tabitha Srikipatana, USAID

D. Expanded Version: Theoretical Basis

NOTE: This is an expanded version of the theoretical basis section provided in the above.

The concept of CIMCs naturally lends itself to focusing on the individual at a single point in time: What does a current or potential FP user want and need? How are they thinking through their decisions about menstruation and contraception? At the same time, FP users do not experience and make judgments about CIMCs in a vacuum. Experiences and preferences regarding CIMCs affect and are affected by relationships, organizations, communities, and societies. Additionally, CIMCs will affect users differently depending on their age, and more specifically during important life stages such as during and just after menarche, before and after childbearing (should users choose to have children), and during perimenopause. In order to understand the breadth and depth of issues surrounding CIMCs, it is best to frame them within two important socio-behavioral theories: the socio-ecological model and the life course approach (shown in Figures 2 and 3). Additionally, these theories enable and prompt considerations regarding equity in the development of CIMC research, product development, policies, and programs.

1) SOCIO-ECOLOGICAL MODEL

As is shown in Figure 2, the socio-ecological model is a framework that places health within multiple levels of influence: individual, relational, organizational, communal, and societal (Sallis et al., 2015). In the case of CIMCs, a user's experience with menstrual changes could be shaped by individual sense of self-efficacy; the opinions of partners and friends; the availability of FP and MH products and related services; the type of organizations and health care providers through which products and services are accessed; community beliefs and practices around menstruation; national and international policies and guidance; and societal meta-norms related to gender, sexuality, menstruation and reproduction. For example, an individual may live in a community where menstruation is stigmatized and considered "dirty" while at the same time have a friend group that views having a menstrual cycle as an important sign of fertility and topic of discussion. That same individual might face challenges navigating sexual intercourse during menstruation with their partner and may also be impacted by a lack of policy guidelines and programs in the community that support healthy menstrual practices, especially during FP use. As is illustrated by this example, all these influences happen concurrently and often interact with one another; therefore, research on CIMCs needs to consider all of these levels. This complexity is reflected in the research Global RLA above.

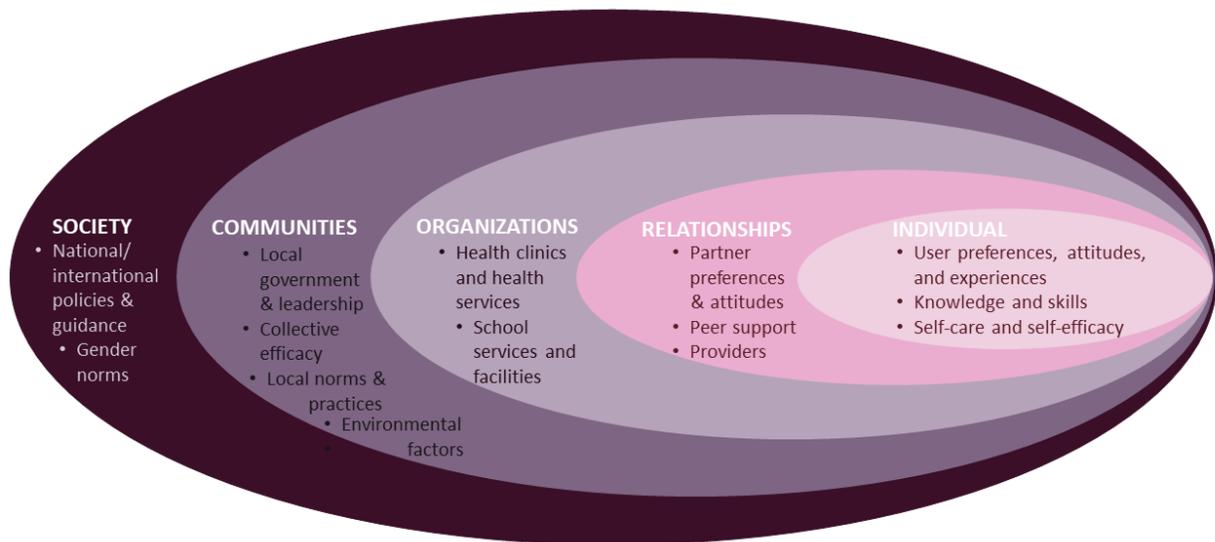


Figure 2. The socio-ecological model and CIMCs
(image adapted to fit the issue of CIMCs from Caprio et al., 2008 and HC3, 2017)

2) LIFE COURSE APPROACH

The life course approach is also important to consider in discussions around MH, FP, and wider considerations related to SRHR, including CIMCs. According to the widely utilized life course theory detailed by Elder et al. (2003), experiences and behaviors early in life impact health and behaviors later in life. For example, learning about puberty and menstruation in early adolescence can lead to healthier reproductive choices as one gets older (IRH/Pathfinder, 2015). Also important to the life course theory is the concept of critical periods, which suggests that impacts on health are more significant during certain development or transition stages such as adolescence and puberty (Elder et al., 2003). Some of these critical periods are shown in Figure 3.

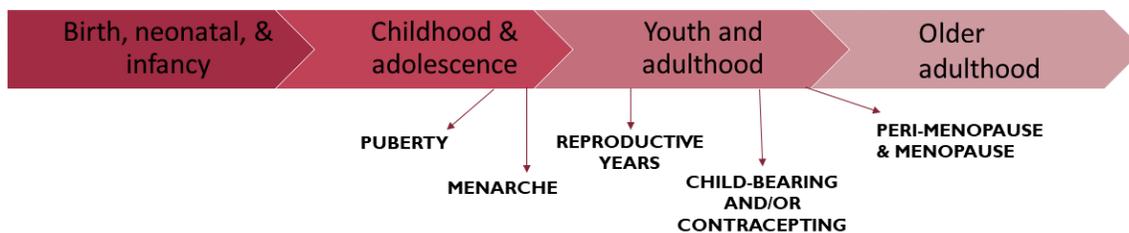


Figure 3. Life course and CIMCs *(image adapted from life stages content in Elder et al., 2003)*

A life course approach is particularly important when addressing CIMCs because the MH sector often focuses on young adolescents, which can exclude a large population of menstruators from the focus of programmatic interventions, including FP service provision. On the other

hand, much of the FP sector is focused on the needs of adult users, although there are important youth engagement efforts. In order to address CIMCs effectively, researchers, clinicians, and policymakers need to consider the changing experiences and preferences of users in all stages of life, from menarche to menopause. A life course approach is integrated into the frameworks and learning agenda described below.

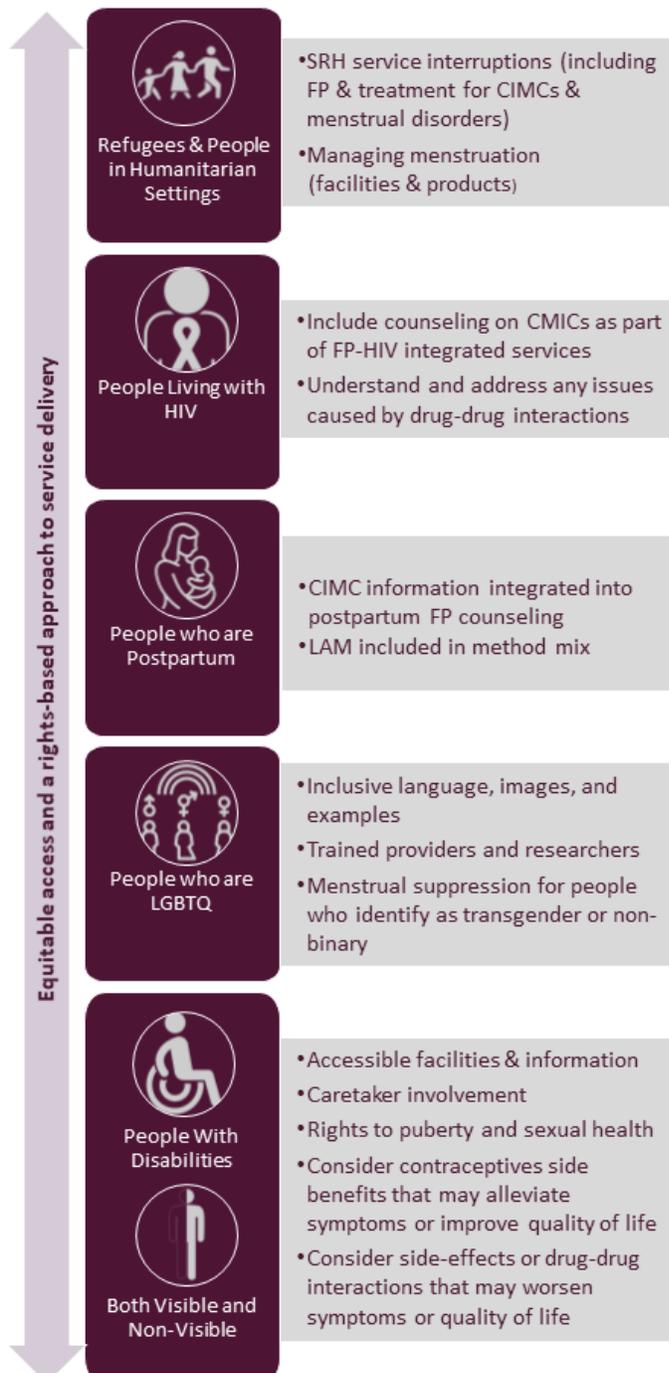


Figure 6. Examples of marginalized and underserved populations who may have unique CIMC needs

3) EQUITY

Socio-behavioral theories and approaches, especially the socio-ecological model, offer mechanisms through which researchers and implementors can identify gaps, needs, and actionable opportunities for equity work at all levels. At its core, equity is about access to and availability of resources including economic or material resources, education, knowledge, skills, social capital, quality of care, and information and services (Hardee, 2019). Barriers to access can occur at any level of the socio-ecological model and will vary based not only on economic factors, but social and environmental determinants and how each intersects with one another. These determinants can be shaped by social norms related to gender and identity as well as by environmental factors like geographic location, humanitarian issues, and geographically degradation.

Identifying root causes of inequities requires direct collaboration with populations who have been systemically marginalized or



underserved (Figure 6) in the design and implementation of policies, programs, clinical practices, and research (Gillespie et al., 2007). This necessitates collaborative understanding of both where and to what extent marginalization persists and how groups who have been systematically marginalized or underserved define themselves. There may be unique considerations for populations who have been marginalized and underserved, such as youth, perimenopausal people, people with disabilities, people living with HIV, postpartum people, refugees, migrants or other mobile populations, sex workers, people in the LGBTQ community, survivors of abuse and violence, and prisoners, among others. A crucial first step is to define and use inclusive language, imagery, and examples that are specified and vetted by marginalized communities. This is just the start—in order to comprehensively understand and address the type(s) and extent of inequity, a multi-level approach is encouraged, recognizing the unique, context-specific needs of certain populations.

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