OPEN LETTER

Global research and learning agenda for building evidence on contraceptive-induced menstrual changes for research, product development, policies, and programs [version 1; peer review: 2 approved]

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Abstract

Background: Contraceptive-induced menstrual changes (CIMCs) can

affect family planning (FP) users' lives in both positive and negative ways, resulting in both opportunities and consequences. Despite this, and despite the important links between FP and menstrual health (MH), neither field adequately addresses CIMCs, including in research, product development, policies, and programs globally.
Methods: In November 2020, a convening of both MH and FP experts reviewed the existing evidence on CIMCs and identified significant gaps in key areas.
Results: These gaps led to the establishment of a CIMC Task Force in April 2021 and the development of the *Global Research and Learning Agenda: Building Evidence on Contraceptive-Induced Menstrual Changes in Research, Product Development, Policies, and Programs Globally* (the CIMC RLA)**,** which 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.
Conclusions: Guided by the CIMC RLA, researchers, product developers, health care providers, program implementers, advocates, policymakers, and funders are urged to conduct research and implement strategies to address the beneficial and negative effects of CIMCs and support the integration of FP and MH. CIMCs need to be addressed to improve the health and well-being of women, girls, and other people who menstruate and use contraceptives globally.
***Disclaimer**: The views expressed in this article are those of the authors. Publication in Gates Open Research does not imply endorsement by the Gates Foundation.*

Keywords
family planning, contraceptive, menstrual health, contraceptive-induced menstrual change, CIMC, menstrual change, research agenda, research and learning agenda

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Introduction

Contraceptive-induced menstrual changes (CIMCs) affect contraceptive users' lives in both positive and negative ways. These include consequences such as dissatisfaction with and discontinuation of contraceptives, as well as opportunities[1], such as improved quality of life and potential treatment of menstrual disorders[2]. Despite the important links between family planning (FP) and menstrual health (MH),[a] neither field adequately addresses CIMCs, including in research, product development, policies, and programs globally.

Contraceptive-induced menstrual changes

CIMCs encompass all changes to a users' menstrual cycle caused by using contraception, including:

- Changes in bleeding duration, volume, frequency, and/or regularity/predictability
- 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[b]
- Changes over time with continued contraceptive method use
- Short-term changes to the menstrual cycle after contraceptive discontinuation

Some individuals dislike CIMCs, which can contribute to dissatisfaction or discontinuation or non-use of contraception[1,3–5]. These negative reactions are the result of the varied and real impacts of CIMCs on users' lives and their beliefs surrounding menstruation. CIMCs, particularly heavier, longer, irregular, or painful bleeding, may exacerbate difficulties in managing menstruation, including changes in the quantity or type of menstrual materials needed, increased need for analgesics, and an increase in the need for safe, private, accessible water, sanitation, and hygiene (WASH) facilities[6,7]. In addition, CIMCs can have significant effects on users' abilities to participate in regular activities like school, work, sex, and social and religious activities[4,8]. For example, in some contexts, social norms inhibit users from participating in religious practices or household work like cooking when they are menstruating[10]. CIMCs can also be associated with psychosocial impacts caused by the stress of managing these changes and worry related to hiding CIMCs among those trying to use their contraceptive method discreetly[11]. CIMCs can also negatively affect sexual satisfaction and well-being[12]. In addition, beliefs about CIMCs can reduce individuals' motivation to begin or continue using contraception, and can influence the attitudes and behaviors of providers[13]. Some contraceptive users fear that CIMCs indicate, or can lead to, negative health consequences, especially bleeding that is heavier in volume or longer in duration. On the other hand, some users may fear that contraceptive-induced amenorrhea—or paused bleeding—means there is a buildup of "dirty" or "bad" blood in their bodies that might indicate or lead to major health issues including infertility, although these are not clinically documented health effects of contraceptive-induced amenorrhea[4,14–16].

CIMCs can also have advantages that motivate individuals to begin and/or continue contraceptive use. Reduced menstrual bleeding, pain, or cramping, as well as paused bleeding can offer increased freedom to engage in regular activities, improved convenience, improved sexual satisfaction, decreased stress and worry, and reduced spending if fewer menstrual materials are needed[2,17]. Some individuals choose to use contraception primarily, or at least in part, for the resulting beneficial menstrual changes, including the management of menstrual and gynecologic disorders and symptoms, such as heavy menstrual bleeding, which affects approximately 30 percent of those who menstruate[18], and endometriosis, which affects an estimated 10% of menstruators worldwide[19]. Contraceptives that reduce bleeding may also prevent or improve other health conditions, including iron deficiency and iron deficiency anemia, which can be caused by heavy menstrual bleeding and affects about a third of women of reproductive age globally[20]. 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[21].

Evidence and knowledge gaps

In November 2020, a convening of both MH and FP experts reviewed the existing evidence on CIMCs and identified significant gaps in key areas[22]. Critically, not enough is known about the biological mechanisms that underlie CIMCs; therefore, therapies for preventing undesired CIMCs and for prolonging desired CIMCs lack a robust mechanistic foundation[23]. This lack of mechanistic knowledge impacts the potential for research and development (R&D) to lead to new and innovative contraceptives that might also be treatments for menstrual and gynecologic disorders and symptoms[24]. While evidence exists around the preferences of contraceptive users related to CIMCs, not enough is known about the social and relational influences that shape these preferences and existing evidence is from a limited population that lacks diversity. More research is needed to understand the full impact of CIMCs on contraceptive use, menstrual health, and quality of life[4,25]. There is also a substantial evidence gap in understanding the most effective programs and interventions to address CIMCs, including ideal approaches for counseling and the potential impact of

[a] The terminology used to describe the needs of people who menstruate 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.*,[9]

[b] 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).

integrating FP services and MH services[c 26,27]. Finally, a lack of standardized and validated measures for different aspects of CIMCs and harmonization across the measurement of biological mechanisms, user preferences, social influences, impacts, and programs compounds the evidence gap[22].

These gaps led to the establishment of a CIMC Task Force in April 2021 and the development of the ***Global Research and Learning Agenda: Building Evidence on Contraceptive-Induced Menstrual Changes in Research, Product Development, Policies, and Programs Globally,*** referred to below as the "CIMC RLA"[28].

The contraceptive-induced menstrual changes global research and learning agenda

The CIMC RLA includes four research agendas focused on: (1) measurement, (2) contraceptive research and development (R&D) and biomedical research, (3) social-behavioral and user preferences research, and (4) programmatic research. It was developed to provide guidance to researchers, product developers, health care providers, program implementers, advocates, policymakers, and funders interested in expanding understanding of CIMCs. For all four agendas, it is essential that research is conducted with diverse populations across different locations, races and ethnicities, socio-economic status, ages, abilities/disabilities, sexual orientations, and gender identities, and that researchers recognize the complexity and intersection of identities that play a role in people's perceptions, experiences, and behavior. In addition, groups who have been historically systematically marginalized or underserved should be involved to the extent possible in this research, including 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.

Measurement research agenda

Across research efforts, the measurements used shape what is learned. For CIMCs, an integrated and interdisciplinary approach is needed to ensure essential concepts are identified and measured appropriately. Figure 1 provides the full measurement research agenda. Future CIMC research and programs should be

[c] MH services include provision of menstrual materials such as pads, tampon, cups, cloth, underwear, and soap; comprehensive MH education and information; access to pain medicine and treatment for menstrual and gynecologic disorders and symptoms; and access to safe, private, accessible WASH facilities[9].

Recommended Research Questions for Measurement

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

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 validation of 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, using, and developing measures and indicators?
c) What are the best ways to measure equity in experiences of and care for CIMCs?

Figure 1. Measurement Research Agenda for Contraceptive-Induced Menstrual Changes.

informed by a 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 (Figure 2). As a priority, those working in CIMC research should review the indicators and tools being used across disciplines to identify opportunities for standardization and gaps to be addressed.

Contraceptive R&D and biomedical research agenda

The full agenda for contraceptive R&D and biomedical research is provided in Figure 3. Research in this area should focus on: (1) understanding the biological mechanisms that lead to CIMCs and factors that affect these mechanisms; (2) developing evidence-based 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. This work should integrate users' preferences and needs related to CIMCs into product development. As a priority, researchers should work to streamline and improve research definitions, measurement, methodologies, and analyses.

Social behavioral and user preferences research agenda

Figure 4 provides the agenda for better understanding users' perceptions, attitudes, and experiences related to CIMCs. Future social-behavioral research should seek to understand: (1) the nuance and diversity of perceptions, attitudes, and practices related to all types of CIMCs; (2) the factors that influence CIMC perceptions, attitudes, and practices, including at the individual, interpersonal, and wider socio-ecological levels and across the life course; and (3) the impacts of CIMCs on users' lives, including their FP and MH practices and decision-making. As a priority, socio-behavioral researchers should assess the state and strength of the existing evidence related to CIMC perceptions.

Programmatic research agenda

When designing and testing ways to address CIMCs through education, counseling, and provision of services, it is important to monitor progress, evaluate impact on a wide variety of measures related to CIMCs, MH, FP, and other areas of sexual and reproductive health and rights (SRHR), and assess the cost-effectiveness of various approaches as well as equity in access. 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 in Figure 5. Future programmatic research should prioritize identifying, defining, and designing how FP and MH can be effectively integrated, including to address CIMCs.

Cross-cutting considerations and foundations

The CIMC RLA is grounded in the socioecological model[29] and a life course approach[30]. Therefore, we call for research related to CIMCs to: (1) consider the impact of different levels of socio-ecological influence; (2) consider the changing experiences and preferences of users across the reproductive life course, from menarche to menopause; (3) integrate equity using a rights-based framework including considerations for social and environmental determinants of health; and (4) consider and incorporate equity, choice, gender, and self-care.

Conclusion

Guided by the CIMC RLA, researchers, product developers, health care providers, program implementers, advocates, policymakers, and funders are urged to conduct research and implement strategies to address the beneficial and negative effects of CIMCs and support the integration of FP and MH. Due consideration of CIMCs will help to avoid missed opportunities to integrate MH into sexual and reproductive health and vice versa. Moving forward, CIMCs need to be addressed to improve the health and well-being of women, girls, and other people who menstruate and use contraceptives globally.

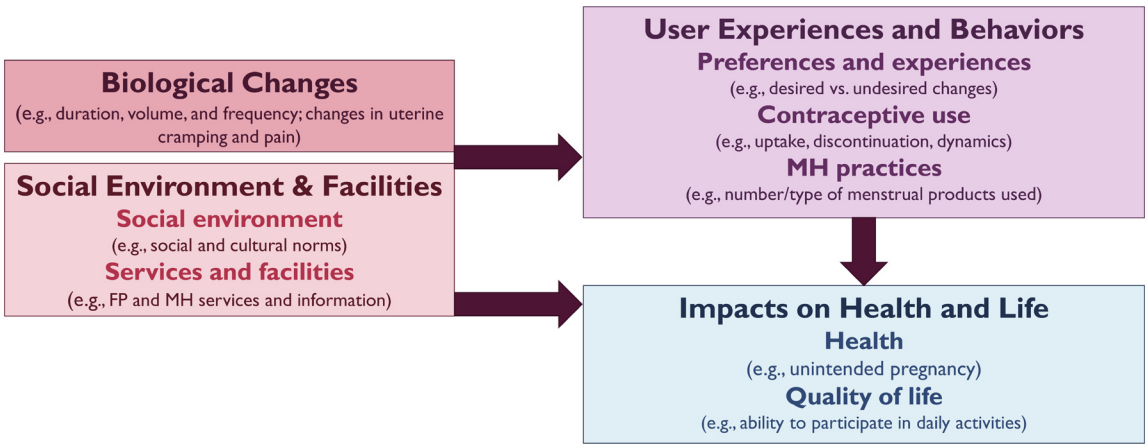

Figure 2. Contraceptive-Induced Menstrual Changes Measurement Framework.

Recommended Research Questions for Contraceptive R&D and Biomedical Research

1) Improving understanding of biological mechanisms CIMCs for current methods and methods under development

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 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?
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?

Figure 3. Contraceptive R&D and Biomedical Research Agenda for Contraceptive-Induced Menstrual Changes.

Recommended Research Questions for Social Behavioral and User 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?

Figure 4. Social Behavioral and User Preferences Research Agenda for Contraceptive-Induced Menstrual Changes.

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 CMICs?
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?

Figure 5. Programmatic Research Agenda for Contraceptive-Induced Menstrual Changes.

Data availability

No data are associated with this article.

Acknowledgements

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Version 1

Reviewer Report 17 May 2022

https://doi.org/10.21956/gatesopenres.14882.r31980

✔ **Alison B. Edelman**
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This publication outlines the existing research, research gaps, and strategic planning processes around outcomes, terminology, and future research in the arena of contraceptive-induced menstrual changes. CMIC research needs core outcomes and an updated shared agenda in order to ensure studies both report on clinically relevant outcomes, and meta-analyses can be performed to give more robust health evidence which may result in a definite answer or again, help to better identify the next research steps. The inclusion of patient input regarding these outcomes is also essential to ensuring the research addresses the need of the end user.

This paper describes the process of how to get there and provides an organized path forward. As a frequent peer reviewer, I can honestly say it was a pleasure reading this manuscript – it was easy to read, well-written and thoughtful. It will add significantly to the literature and it will be an incredibly useful reference for those in the field. I have no minor or major edits.

Is the rationale for the Open Letter provided in sufficient detail?
Yes

Does the article adequately reference differing views and opinions?
Yes

Are all factual statements correct, and are statements and arguments made adequately supported by citations?
Yes

Is the Open Letter written in accessible language?
Yes

Where applicable, are recommendations and next steps explained clearly for others to

follow?
Yes

Competing Interests: I was one of the researchers that participated in part of this process that the authors are reporting on. I confirm that this potential conflict of interest did not affect my ability to write an objective and unbiased review of the article.

Reviewer Expertise: Routine and complex family planning, contraceptive induced menstrual changes, menstrual health, emergency and post-coital contraception, contraceptive development, contraceptive pharmacodynamics

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 16 May 2022

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Peter Bundi Gichangi
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The topic being addressed is quite important with significant impact on the health of the individuals as well as uptake and discontinuation of family planning/contraceptives (FP/C). This is a topic which has not been addressed adequately in literature.

The framework proposed to ensure there is research which is guided by identified research questions is likely to result in coherent research output.

The question I am not sure is addressed adequately is the role of comprehensive counselling as measured using method plus index in Performance Monitoring for Action (PMA) or DHS. This should be considered.

Is the rationale for the Open Letter provided in sufficient detail?
Yes

Does the article adequately reference differing views and opinions?
Yes

Are all factual statements correct, and are statements and arguments made adequately

supported by citations?
Yes

Is the Open Letter written in accessible language?
Yes

Where applicable, are recommendations and next steps explained clearly for others to follow?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Sexual and Reproductive Health, Family Planning, gender based violence, cervical cancer.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.