

Closing the Information Gap: Chronic Disease, Pregnancy, and Breastfeeding

2024



for Women with Chronic Diseases
Before, During and After Pregnancy



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Letter from the BRIDGE Co-Chairs

When women* living with a chronic disease**, such as diabetes, epilepsy or autoimmune conditions, decide to start a family, they face more than the ordinary anxieties. *“Can I get pregnant? Will my disease hurt my baby? Will my condition flare and how will I control it? Should I stop taking my medication when I’m trying to conceive or during my pregnancy? Will my medication hurt my baby? Will I be able to breastfeed my baby?”*

In many cases, there are no easy answers, leaving women and their families to make difficult decisions—often without a clear understanding of the benefits and risks of continuing or stopping their medications.

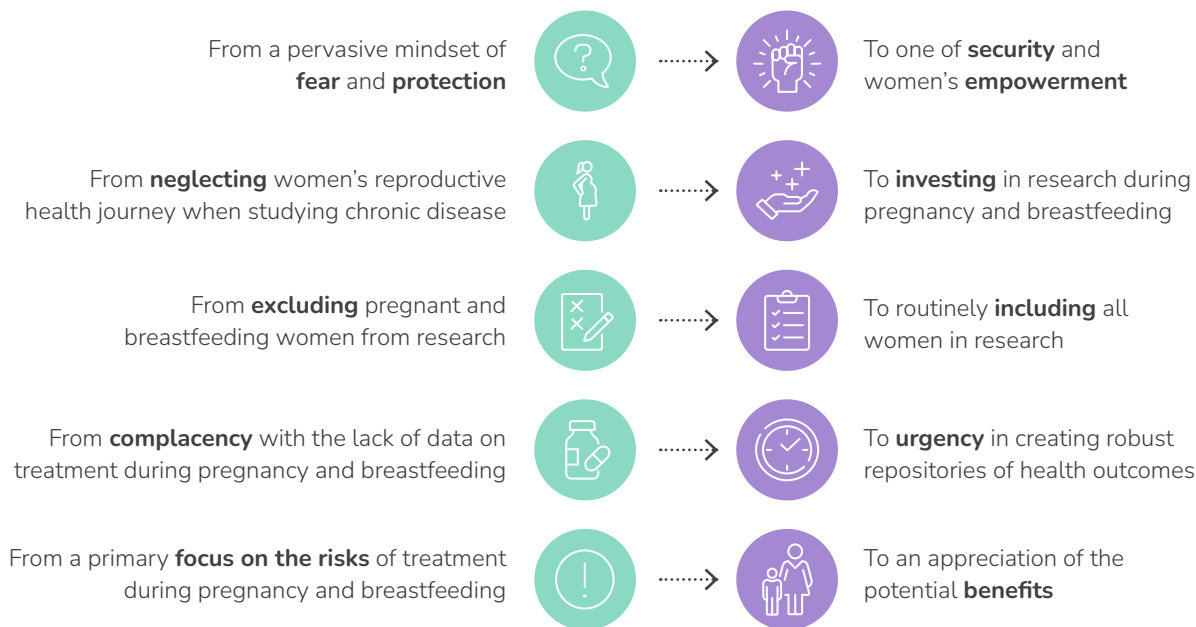
There should be no such uncertainty. **Women deserve to have clear, evidence-based guidance on managing chronic conditions while they are pregnant or breastfeeding to optimize their health and the health of their babies.**

For years there has been insufficient research to address these questions. This is deeply troubling. We see an urgent need for high-quality data that women can rely on to make informed decisions about their treatment. No woman should be forced to make decisions without the trustworthy information she needs.

That is why we are calling for a paradigm shift in the pregnancy and breastfeeding journey for women living with chronic disease. We demand a world where women are equipped with the information that matters most to them. A world where women’s care – and their experiences of care – respects their choices about their health.

Paradigm shift to improve women’s health

Prioritizing the inclusion of pregnant and breastfeeding women in research is long overdue. The status quo, in which women are routinely excluded from biomedical research, can no longer be tolerated. The change we seek will require fundamental shifts:



* We use a variety of terms throughout this report, including mother and pregnant women. We recognize gender is a spectrum and individuals may identify as birthing parents or use other gender nonconforming terms. We also acknowledge there are many different ways in which gender identity intersects with the issues and topics in this report.

** We also recognize that chronic illnesses include a wide range of visible and invisible conditions, and that experiences of chronic disease are unique to each individual.

BRIDGE (Better Research, Information and Data Generation for Empowerment) is a multidisciplinary group of experts in the field of pregnancy and breastfeeding. We are physicians, researchers, patients, and women's health advocates who came together because of a common goal: **All women living with a chronic disease should have access to reliable, high-quality data to help them understand the benefits and risks of disease management – from the point of diagnosis through the reproductive journey.**

Representing different countries and health systems, this team met voluntarily in working sessions over the past year to consider this challenge and potential solutions in a different light. We set out to change the prevailing sentiment of fear around treatment and pregnancy by redefining recommendations from the point of view of a woman living with a chronic illness during her childbearing years.

BRIDGE was formed to seek ways to elevate women as the guardians of their own health in partnership with their health care team. We established three core principles to guide this report and its recommendations:



Women living with chronic illnesses should be at the forefront of decision-making about their health.



Access to relevant and reliable information is every woman's fundamental right.



Decision-making must be individualized to each woman's needs and preferences.

We have identified practical solutions that respond to the needs and preferences of women living with one or more chronic diseases. These measures are intended to guide a wide range of stakeholders - health systems, health professionals and medical associations, women living with chronic diseases, patient advocacy groups, policymakers, the media, regulatory agencies, researchers, research funders, the pharmaceutical industry, medical and nursing schools, and others with an interest in improving the lives of women living with chronic conditions - in the quest to address fundamental knowledge gaps and make sure that women are at the center of their care.

These recommendations underscore the broader imperative of ensuring that women – regardless of where they live, their circumstances, or their health – have the tools to make informed decisions about their well-being. This report is organized into two main sections that delve into changing the paradigm about chronic disease and pregnancy:



What it will take to generate the data that women and their health care team need.



How to make sure that data are available, interpreted in a balanced and individualized way, and communicated clearly.

The report examines a woman's journey for information, starting with an overview that outlines her hurdles to informed decision making. This is followed by our blueprint for a better future, the collective action needed to realize this vision, and specific recommendations for each part of the health ecosystem to achieve profound and enduring change to improve women's health. Together these elements provide a framework for a rights-based approach to transforming the care of women living with chronic diseases.

We are not alone in our efforts to close persistent information gaps and empower women living with chronic diseases to take control of their reproductive lives. While we have resolved to prioritize the perspective of patients and devise practical solutions reflecting our bedrock principles, other groups share our concerns and are working in complementary ways to tackle this critical issue and transform care. Now is the time to bring greater clarity to decision-making so that women living with chronic illnesses can face this momentous chapter of life with confidence.

We wish to thank the members of the BRIDGE Commission and the patients who contributed their feedback for their dedication to this vital goal. Without your invaluable contributions, this report would not have been possible.

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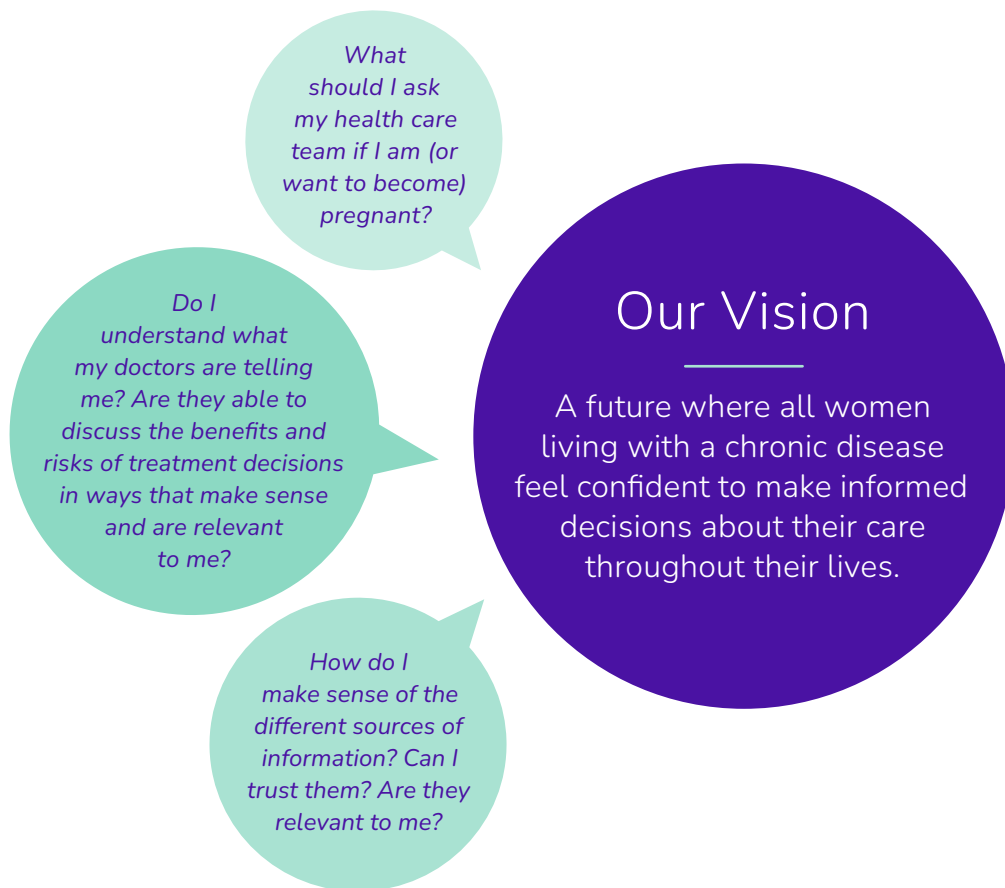
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The Challenges Women Face



The Challenges Women Face



The scarcity of high-quality data on chronic disease and pregnancy has far-reaching consequences.

Women in every corner of the globe suffer from limited information about how their treatment for a chronic illness may affect a current or future pregnancy, or breastfeeding. The burden may be compounded if a woman has more than one chronic condition. Because conception is often unplanned, these are concerns that have an impact on women throughout their reproductive lives.

As a result, critical decisions—whether to become pregnant, whether to breastfeed, and whether to stop, start, or modify treatment to manage their chronic disease—are difficult.

Many women living with a chronic disease are left to wonder and worry. Likewise, without good data, health providers are at a loss in terms of advising their patients on the best course of action. These statistics put the problem into perspective:



200m

Globally, 200 million women become pregnant each year.¹



>1/3

More than a third of pregnancies in the U.S.² and nearly half of all pregnancies globally³ are unintended.



1 in 5

Some studies have shown that one in five women is living with at least one chronic disease.^{4,5}



70%

About 70% of pregnant women in the U.S. take at least one prescription drug during pregnancy.⁶



5%

Only about 5% of medications in the E.U. have been properly monitored, tested, and labelled for use before, during, or after pregnancy.⁷

History of exclusion

The glaring knowledge gaps have a long history. Women have been excluded from research, with the justification of “protecting” the fetus from harm. The health of the mother takes a second seat. And when research does include pregnant and breastfeeding women, these women are rarely asked for their input on the design, potentially omitting what is important to them. Moreover, such studies in pregnancy tend to be oriented toward whether a treatment is safe for the fetus, without due regard for its impact on the pregnant woman.

This legacy has persisted, affecting women in different places and contexts around the world. For instance, pregnant women were initially excluded from drug and vaccine studies during the Ebola outbreak and COVID pandemic, even though these infections pose a serious threat to the lives of women as well as their babies.^{8,9}

Prioritizing women’s health

Decisions on how to treat a chronic condition when a woman could become pregnant or is pregnant or breastfeeding must begin to consider her health. Indeed, promoting the health of pregnant women is key to ensuring the health of their babies.

Research highlighting the benefits as well as the risks of studied treatments is a critical piece of the puzzle. Just as the effects of stopping or changing the dose of a needed medication are not fully known, neither are the positive effects of untested medications. The data are simply not there to make the best decision – with potentially dire consequences for women and their babies.

Growing momentum

Fortunately, there is growing recognition that access to information is a woman’s right. In addition to BRIDGE, several governmental and non-governmental organizations are spearheading efforts to better understand and address this complex issue. These include, but are not limited to, ConcePTION (an Innovative Medicines Initiative public-private partnership that is partially funded by the European Commission), International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, United Kingdom Medicines and Healthcare Products Regulatory Agency, and the United States Food and Drug Administration and National Institutes of Health (including PRGLAC and other initiatives).

It is encouraging that women’s health is receiving more attention, including addressing the gaps in research. In 2023, the United States government launched a new initiative on [Women’s Health Research](#) that will recommend changes to how the country funds women’s health research to close research gaps and improve women’s health. At its 2024 meeting in Davos, the World Economic Forum published the report, [Closing the Women’s Health Gap: A \\$1 Trillion Opportunity to Improve Lives and Economies](#), and launched the [Global Alliance for Women’s Health](#), a multi-sector platform to prioritize, protect, and promote the health of women.

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“In any other scenario, we trust that when we go to the doctor, they have the knowledge, they have the right information, they’re telling us the right thing. [But when it comes to pregnancy] it’s up to you if you want to keep taking that medication. It’s one area that is still very grey. And it’s very scary for any woman with a health condition.”

Mary living with acute ulcerative colitis and endometriosis (UK)





Data
Generation

The Catch-22 of Generating Data: Pregnant and Breastfeeding Women's Participation in Research

Women should be able to actively participate in research studies in order to have the information they need to make decisions about their health.

Barriers to participating in research

In current medical research, women who are pregnant or breastfeeding are rarely recruited for clinical trials evaluating new treatments for chronic diseases. The reasons for this exclusion are multifold, starting with the longstanding taboo against enrolling pregnant women in studies. In general, researchers and research protocols require female study participants to take pregnancy tests and use contraception. If they become pregnant during a study, they are usually removed from the clinical trial and asked to discontinue medication.

Women also lack opportunities to participate in research during pregnancy and breastfeeding. Many women are unaware of such trials or mistrust the institutions conducting them and may not believe that such studies will provide long-term benefits to them and their babies. The lack of a centralized repository of information about studies and inadequate data regarding the risks and benefits of interventions present health providers with a profound ethical dilemma about whether research participation is in their patients' best interests. As a result, they tend to avoid broaching the topic, neither advising women about whether to enroll in a trial nor dissuading them from joining one.

The resulting data gap prevents providers from helping women weigh the risks of continuing or stopping medication, which in turn impedes women's ability to make informed decisions about treatment during their childbearing years. This creates a vicious cycle, further limiting information on the effect of chronic disease treatments on pregnancy and breastfeeding.



"There's a notion that pregnant women or breastfeeding moms should not undergo clinical trials, but neglecting the condition might lead to worse effect and hinder the mother more than help her"

Hellen living with psoriasis (Kenya)

Data Generation Challenges:

- **Data is not generated early enough** to support women throughout their reproductive journey
- **Medical management** of women living with a chronic disease who are pregnant or breastfeeding is not standardized.
- Few research studies follow a woman on treatment through **each phase of her pregnancy and postpartum.**
- There is a **lack of standardized methodologies** for generating data.
- Data from clinical trials and registries are affected by **limited participation and poor representation** of all patient populations.
- Real-world data and other studies **may not reflect the diversity of women living with one or more chronic diseases.**

Our Vision

All women living with a chronic disease – including those of reproductive age and women who are currently pregnant or breastfeeding – **are aware of and have access to clinical research studies, understand the value of their participation, and are offered the choice to enroll.**

New drugs with the potential to manage a chronic disease are carefully tested in **women who are pregnant and breastfeeding** (as appropriate), and international standards guide the collection of data from this population, providing a comprehensive and continually updated data set.

Recommendations

Invest in research that focuses specifically on the particular issues that women confront in managing chronic disease throughout their reproductive journey. Promote and facilitate women's participation in clinical trials, registries, and other studies to generate the data needed to make strong, evidence-based, and individualized recommendations about the impact of chronic disease treatment on pregnancy and breastfeeding.

Research & Development



Research Funders

Support clinical research studies on chronic disease management during women's reproductive journey.

- Require **a-priori inclusion** of pregnant and breastfeeding women in clinical research and rationale for exclusion.
- **Invest in long-term data collection** to strengthen the evidence base for women living with chronic diseases and their children.
- Prioritize the **inclusion of pregnant women in funding clinical research** and require the collection of pregnancy-specific data in all studies that include women of reproductive age.
- Emphasize the need to collect data on the **benefits of disease management** for a woman and her child, not just the risks of treatments.
- Establish and apply diversity criteria, such as requiring trials to **include women from underserved populations**, in awarding research funding to make sure research is representative.
- Ensure research has **world wide impact**. Allocate funding for research in low resource regions and countries.
- Make robust **research dissemination** a central criterion in grant applications to ensure that findings will have widespread impact.



Industry and Academic Researchers

Involve and engage women throughout the research process, including contributing to research priorities, questions, outcome measures, research design and management, to ensure that studies include the data that women want and need, particularly analyses of the benefits of treatments as well as the risks.

- Understand and address ethical and other obstacles to **conducting research** involving women who are pregnant or breastfeeding.
- Expand enrollment in studies of **chronic illness** to include breastfeeding women and pregnant women, regardless of stage of pregnancy.
- Engage women living with a chronic disease to develop, co-produce, and **contribute to research information summaries** to make sure they are understandable.
- Set and meet **diversity targets in clinical trial participation** to reflect patient populations.
- Incorporate **questions on pregnancy and trimester status** into current and future data collection tools and registries, and integrate data sets.
- Create a **central repository** to report on medication use in pregnancy and breastfeeding.
- Expand the **collection of pharmacokinetic data** to include information on pregnant and lactating individuals.



Policymakers

Require research studies to evaluate the potential impact on pregnant and breastfeeding women for every drug in development. Ensure the collection of pharmacokinetic data to improve the benefit/risk analysis.

- Invest in the resources needed to regularly **update clinical guidelines** to ensure they reflect the latest evidence.



Regulators

Centralize information on pregnant or breastfeeding women's participation in clinical trials to promote easy access to enrollment data.

Health Care Delivery



Health systems

Develop protocols to provide continuously updated, evidence-based approaches to manage the care of women of childbearing age who are living with a chronic disease. Develop tools to consistently capture relevant data to build the evidence base, including the benefits of treatment for pregnant women and their babies.

- Create systems for women and their health providers to easily **share information on women's experiences** on treatment while pregnant or breastfeeding as part of the goal of generating real-world data.
- **Leverage electronic health systems** to prompt physicians to log, monitor, and report patient information specific to pregnancy and breastfeeding.
- **Provide and fund opportunities for researching** the impact of treatment on women who are pregnant or breastfeeding.
- **Invest in the resources** needed to regularly update clinical guidelines and health curriculums, ensuring they reflect the latest evidence and incorporate considerations for women living with chronic conditions during pregnancy.



Health care teams

Discuss pregnancy and breastfeeding as part of early conversations with women about chronic disease treatment and management at the point of diagnosis. Highlight the importance of research and clinical trials to women living with a chronic disease who may become pregnant and alert them to opportunities to enroll in a trial during pregnancy. Emphasize the potential benefits—such as enhanced care, close monitoring, and the opportunity to receive an effective new treatment—as well as risks.

- **Invite patients to have open discussions with primary care physicians, obstetricians and gynecologists, and specialist physicians** (e.g., rheumatologists, neurologists) about their concerns and questions regarding participation in clinical trials.
- Keep track of and make women aware of specific **opportunities to participate in clinical trials**.

Patients

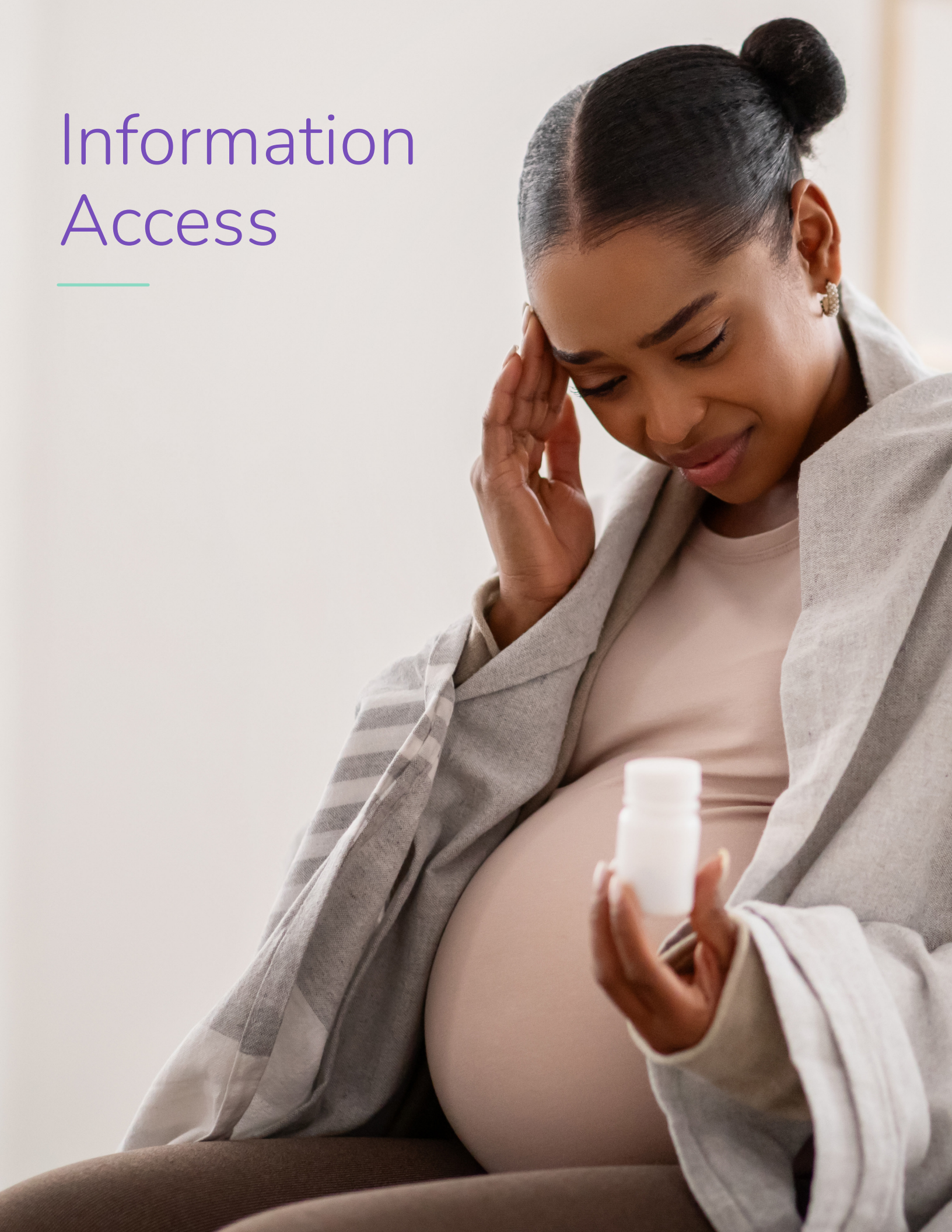


Patient Advocacy Groups

Elevate awareness of the troubling data gaps that leave women at a loss for guidance during pregnancy and breastfeeding and promote participation in research - including enrollment in clinical trials and disease registries. Advocate for using real-world data to advance understanding of how treatments affect women who are pregnant or breastfeeding.

- **Involve women with lived experience** in efforts to communicate and elevate the need for greater access to research and communicate the value of participation.
- **Expand efforts to promote participation in research**, including clinical trials and registries, to women's health organizations, birthing support groups, and other entities that are working to improve women's experiences during pregnancy, childbirth, and the postpartum period.
- **Advocate for women's participation** in national panels, commissions, medical society meetings, and other forums where deliberative bodies are considering issues that could be relevant to chronic disease and pregnancy and breastfeeding.

Information Access



Unleashing the power of data:

Availability, interpretation, and communication

Women should have access to timely and relevant information, be aware of the benefits as well as the risks of their choices, and understand how the data pertains to them specifically in order to make informed decisions about their health.

Making an informed choice is only possible with accurate and robust information. Yet research studies are rarely designed to include women living with a chronic disease who may be pregnant. As a result, women do not have high-quality data to differentiate between the impact of their disease on their pregnancy and the potential effects of treatment during pregnancy and breastfeeding.

Data women can rely on

Given the rampant spread of health misinformation on social media, it is even more critical to ensure that women have access to evidence-based information from **trustworthy sources**. However, a centralized database containing up-to-date and accurate information that women and providers can turn to for guidance does not exist.

Conflicting information-and misinformation-creates misperceptions and expands fear among patients and providers alike. While the lack of data to interpret can lead to a false sense of security, it can also cause pregnant women to decline a medication or stop a treatment that is keeping their disease under control.

Data Availability, Interpretation, and Communication Challenges:

- Healthcare systems are often **not designed to support shared decision-making** between providers and patients.
- Health providers **may not have the skills, tools, or information** to discuss the medical needs of women living with chronic diseases who want to get pregnant, are pregnant, or are breastfeeding.
- **Product labels are not updated in a timely manner** to reflect new research findings that may affect benefit-risk analyses.
- **Medication labeling is hard for patients to interpret.**
- **Adverse reactions and risks are often emphasized** over beneficial therapeutic outcomes.



Access to reliable data

When strong data are generated, the relevant findings do not always reach a wide audience. Editors of consumer publications may perceive the health of pregnant women living with a chronic disease as a niche topic, less likely to attract reader interest. Thus, the data are rarely reported in magazines or on websites.

When reliable and trustworthy information does reach the public, the interpretations can be misleading. The bias is to overstate the risks of exposure and not adequately consider the benefits of treatment. Often this bias is reflected in the titles of medical journal publications and press releases about these studies, which media tend to follow closely. As a result, news articles may convey information without important context or caveats about a study's limitations, even though these are noted in the study.

At the same time, inconsistent advice from doctors and other providers often leaves women in limbo and distress. Even when information is available about a medication's safety, women may encounter providers who are reluctant to prescribe and pharmacists who are unwilling to dispense to prevent imagined harm to the fetus.¹² This fear-based paradigm benefits no one. What is needed is a health-based paradigm where health care teams help women stay healthy during pregnancy and breastfeeding, giving women power and agency over their bodies.

Unfortunately, women often feel do not feel equipped to ask their doctors questions in a way that will lead to fact-based decisions and doctors feel unprepared to answer these questions. Women may not feel actively included in conversations about chronic disease treatment throughout their pregnancy journey. Compounding the problem is the increasing pressure on providers to limit their time with individual patients, which prevents thoughtful deliberations that promote better outcomes and patient satisfaction.

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“The compassion that the doctors have is very important because that really determines how we feel about our decisions and how we feel about our situations. I, myself, have had an experience where I left the consultation room feeling helpless instead of feeling like I got help”

Chiara living with psoriasis and Transverse Myelitis (Indonesian residing in Estonia)

“It's important to train doctors to ask their patients about their plans for a family. Many doctors don't ask that question at all and decide on a medical treatment without knowing what plans the woman has for a family.”

Karina living with psoriasis (Peruvian residing in Spain)

Our Vision

All women living with a chronic condition have the information they need to collaborate with their health providers and play an active, central role in all decisions related to their disease management – whether or not a pregnancy is planned, and during pregnancy, postpartum, and breastfeeding.

Up-to-date, accurate, and relevant data on how chronic disease treatment affects women who are pregnant or breastfeeding are captured in a systematic and consistent manner, facilitating unbiased interpretation and clear communication with patients before they become pregnant.

Recommendations

Make sure that women have access to relevant, contextualized information about chronic disease treatment and pregnancy and breastfeeding, and that health providers communicate this information in an understandable, supportive, and individualized way to patients before they become pregnant.

Research & Development



Industry and Academic Researchers

Report all findings - as well as an absence of findings - in a timely manner to avoid skewing perceptions of a treatment's risks over its benefits. Where potential risks are identified, use language that does not overstate causation or clinical relevance.

- **Report study results to participants** in an understandable way, enabling women to amplify the findings and clearly communicate them to other women living with a chronic disease.
- **Devise dissemination strategies** that help to convey findings to women, clinicians, policymakers, and the public at large.
- **Disseminate study findings widely** so they are accessible to women and health care professionals around the world.



Medical Journals and Consumer Media

Place the risks of treatment in context, convey benefit/risk considerations using visual graphics and comparisons to promote full understanding, and avoid misleading study titles and sensationalized headlines that emphasize only adverse findings.

- **Improve the accessibility of published data** for lay audiences through press releases and special reports for general media.
- **Make content comprehensible to patients**, apply health literacy principles, use inclusive language, and translate articles into more languages.



Research Funders

Disseminate research findings that focus on the impact of both chronic disease management and untreated disease on pregnancy and breastfeeding.



Regulators

Make sure that medication labelling reflect the most up-to-date and comprehensive information on appropriate use and side effects and give equal weight to a treatment's benefits and risks.

Health Care Delivery



Health Systems

Provide physicians and other health professionals (particularly pharmacists, nurses, and midwives) with up-to-date, culturally relevant information about chronic disease and pregnancy. Permit health professionals the time they need to have meaningful conversations with their patients about treatment plans during pregnancy and breastfeeding.

- Make high-quality, relevant, clearly interpreted data on the effects of chronic disease treatment during pregnancy and breastfeeding available to women **through a centralized platform that is owned and managed by a trusted, independent, authoritative source.**
- **Incentivize health providers to discuss pregnancy-related issues** with their patients throughout their reproductive journey by adding a billable code enabling reimbursement for this crucial service.
- **Incorporate simulation and role-playing into the training of medical students** and the continuing education of providers to ensure confident and appropriate communication with women of reproductive age about the benefits and risks of treatments during pregnancy or breastfeeding.



Health Care Teams

Prepare for respectful, potentially difficult conversations with women about their pregnancy journey and offer clear, evidence-based rationale for treatment recommendations and decisions — including acknowledging when the data are limited.

- **Participate in simulations, training and role playing as part of medical school and in-service training** to support confident and appropriate communications with patients about the benefits and risks of treatments.
- **Leverage telehealth to increase access to medical experts** who can give women targeted and time sensitive information to make informed decisions about their treatment and disease management.

Patients



Patient Advocacy Groups

Enable and encourage women to have informed, productive conversations about how their chronic disease may affect pregnancy and breastfeeding, such as the dilemmas they face in determining whether and when to become pregnant, how to make decisions about staying on treatment, what to discuss with their provider, and what they wish they still knew.

- **Provide resources that will help women ask the appropriate and relevant questions** of their health providers and participate in shared decision-making.
- **Connect women considering pregnancy with mothers who have the same chronic condition** to share their lived experiences and lessons from navigating treatment during pregnancy and breastfeeding.
- Disseminate information – including personal stories – that **addresses women's key questions and concerns.**
- Ensure advocacy efforts are tailored to specific cultural contexts and **consider the beliefs, family dynamics, biases, and misinformation about pregnancy and chronic disease that influence women's decision-making.**

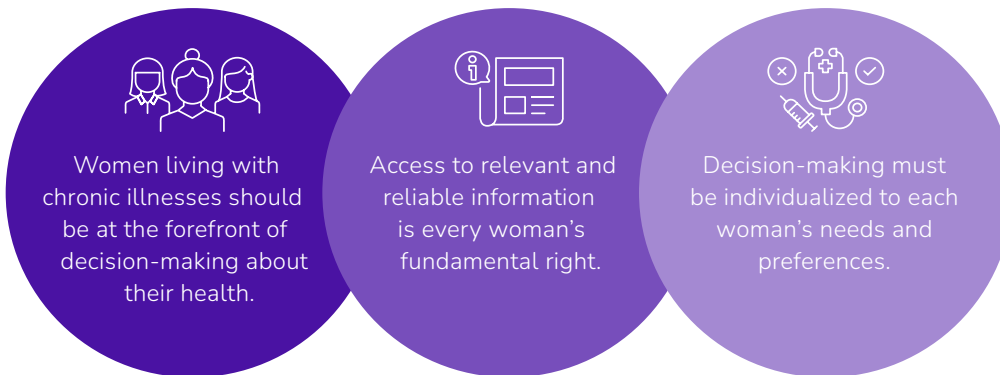
Conclusion



Our vision for women everywhere

The dearth of investment in research involving pregnant women living with chronic diseases has come with a steep cost to women, children, medicine, and society. It is clear that studies centered around the experiences and needs of this population are crucial to correcting the course and opening the door to new insights about managing illness when pregnancy occurs. The health and wellness of countless women and their children is at stake.

Our core principles bear repeating:



With our recommendations to various stakeholders, **we join with others to demand a change in the status quo.** Now is the time to create a culture of support and inclusion for women living with chronic diseases who become pregnant or want to breastfeed.

In an ideal world, these women would be the starting point for major research initiatives and an integral part of the drug development process, from beginning to end. The benefits and risks of treatments would be evident, every clinician would have clear guidance for caring for women during pregnancy, and the options for effective interventions would expand, improving the lives of all mothers and babies. **Most important, women living with chronic diseases would anticipate motherhood with more joy and less trepidation.**

By elevating women's voices and maintaining a focus on their rights, needs, and values, we can reach this pivotal and essential milestone.

Acknowledgments

We thank the following women - as well as the many others we spoke with, all of whom have personal experience managing a chronic disease throughout their reproductive journey - for sharing their insights and stories:

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- Natalie Whyte
- Rhiannon Scott
- Sally Darby

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We also thank Rabin Martin for their support of BRIDGE and for developing this report.

“

My wish for every woman living with a chronic disease is...

“To be empowered to have the information that they need, and to be able to ask questions. We're told to trust in the words of the healthcare professional. I think we need access to more [information], we deserve more. We deserve someone to advocate for us.”

Kathryn living with epilepsy (UK)

“That the right information is shared with any woman who is pregnant, breastfeeding, or looking to get pregnant in the future.”

Hellen living with psoriasis (Kenya)

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USA

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Former Clinical Advisor at FDA, Developmental Toxicology



BEL

Marie Teil

Head of Women of Childbearing Age Program at UCB BioPharma

Glossary of Terms

Adverse drug reactions

Harmful, unintended reactions to medicines that occur at doses normally used for treatment ([World Health Organization](#))

Clinical trial

A type of research that studies new tests and treatments and evaluates their effects on human health outcomes; clinical trials are carefully designed, reviewed and completed, and need to be approved before they can start ([World Health Organization](#))

Chronic disease

Conditions that last one year or more and require ongoing medical attention or limit activities of daily living or both ([U.S. CDC](#))

Real world evidence

Clinical evidence about the usage and potential benefits or risks of a product as informed by real-world data analysis. This is data relating to patient health status and the delivery of care that is collected from sources including electronic health records, product or disease registries, or other information sources ([U.S. FDA](#))

Registry

Prospective observational studies specifically designed to collect clinically relevant data and provide information for treating or counseling not only to women who are pregnant but also women of childbearing potential ([NIH NCBI](#))

Shared decision-making

A model of patient-centered care that enables and encourages people to play a role in the medical decisions that affect their health ([Agency for Healthcare Research and Quality](#))

Side effects

Any unintended effect of a pharmaceutical product occurring at doses normally used by a patient which is related to the pharmacological properties of the drug ([World Health Organization](#))

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