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RESEARCH ARTICLE

# ‘They will be like a person with a disease’: a qualitative investigation of variation in contraceptive side-effect experiences in Central Oromia, Ethiopia

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## Abstract

Contraceptive side effects are consistently given as the main reason why women are dissatisfied with contraception or choose not to use it. However, why some women suffer more from side effects remains unknown. Through inductive analysis of in-depth interviews and focus group discussions with 40 contraceptive users and 3 key informants in Central Oromia, Ethiopia, we explored women’s rationales for variation in side-effect experiences. The data first reveal the wide diversity in type and severity of side-effect experiences reported by users of contraception. Second, we found that women’s rationales for why some individuals suffer more side effects from contraception invoke economic and physical hardship (food insecurity and heavy workloads), as well as interindividual differences in biology (one’s blood must ‘fit’ with contraception). Finally, the analysis revealed the tension many women face in trying to negotiate the trade-off between the consequences of these side effects and those of an unwanted pregnancy. The results show the value of using a biosocial approach, which centres women’s voices and experiences, for informing the measurement of contraceptive side effects within population health surveys and clinical trials. Additionally, the findings help gain an understanding of how an individual’s social, biological, and cultural contexts drive variation in when and why different side effects manifest.

**Keywords:** Family planning and contraception; human ecology; demography

## Introduction

Side effects are consistently cited as a leading reason why women have an unmet need for contraception (Sedgh, Ashford, and Hussain, 2016). Many women, who want to use contraception to avoid pregnancy, choose not to use it or stop using it because of side effects or any unwanted bodily changes or symptoms associated with contraceptive use. The proportion of women with unmet needs increases further if we include women who are currently using contraception but are dissatisfied with their current method due to side effects (Rominski and Stephenson, 2019). Despite the importance of side-effect experiences to contraceptive decision-making, there continue to be significant methodological barriers to understanding, measuring, and potentially reducing the contribution of negative side-effect experiences to unmet needs. These barriers include (1) a reliance on researcher-driven measurement categories, (2) a lack of research on variation in side effects, and (3) omission of women’s priorities in guiding research and technology development. A biosocial approach utilising qualitative evidence can help address these gaps by

revealing the lived experiences of women across different cultural and ecological contexts. This knowledge can be leveraged to inform future research outcome measures and guide the development of comprehensive measurement instruments.

(1) A reliance on researcher-driven measurement categories in studies about contraceptive use means that side-effect measurement tools, if employed at all, often do not capture the full breadth of side-effect symptoms and can leave lesser-known or 'low priority' side effects unmeasured. These measurement gaps are perhaps unsurprising given that in much of the medical and global health literature, most side effects are still framed as either minor symptoms, worth enduring for the sake of pregnancy prevention, or as misconceptions and rumours, lacking in clinical evidence (Stevens *et al.*, 2023). For instance, one commentary published in *Contraception* posits that evidence for non-specific contraceptive side effects is lacking enough that including these symptoms 'in package labelling is unwarranted and probably unethical' (Grimes and Schulz, 2011). This paternalistic view of side-effect experiences as exaggerated or not real is not uncommon for women's health issues or expressions of female pain (Doyal, 1995). This dismissal of women's pain intersects with other attitudes towards race and class, leaving reports of pain or adverse effects among poor, marginalised women of colour rarely listened to (Whittle and Inhorn, 2001).

Given this backdrop, it is perhaps unsurprising that detailed side-effect experiences are rarely measured in population-based surveys, such as the Demographic and Health Survey (DHS), which instead ambiguously asks past users of contraception whether they stopped 'due to fear of side effects or health concerns'. This category has been critiqued as too broad and non-specific (Jain *et al.*, 2021; Rominski and Stephenson, 2019), lumping all side-effect experiences and fears together, and also failing to measure the occurrence of any side-effect experiences among current users. Several recent studies have set out to measure side effects directly (Odwe *et al.*, 2020; Rothschild *et al.*, 2021; Keogh *et al.*, 2021; Jain *et al.*, 2021; Zimmerman *et al.*, 2021) and collect data on a broad range of specific symptoms to understand their impact on contraceptive use decisions. Amongst others, these symptoms include bleeding changes, weight changes, libido changes, headaches, dizziness, and delays in return to fertility post-use. However, there is a huge range in the number and types of side effects recorded (from 6 to 29 categories of side-effect symptoms collected), with only 2 studies justifying which side effects they chose to measure (based on literature reviews [Keogh *et al.*, 2021; Zimmerman *et al.*, 2021] and prior qualitative studies [Zimmerman *et al.*, 2021]). Several of these studies discuss limitations in current side-effect measurement approaches and call for 'further methodological research to identify how best to accurately identify and quantify the experience of side-effects in large-scale, population-based surveys' (Zimmerman *et al.*, 2021). If we are to understand the true prevalence and diversity of symptoms experienced, comprehensive measurement instruments would include user-driven side-effect categories based on women's accounts of their experiences across different contexts.

(2) There is a lack of research on variation in side effects between women and across socio-cultural contexts, meaning that little is known about what causes certain women to suffer more than others. Past qualitative studies have noted the presence of a perception among users that some groups of women, particularly, those living in poverty or with poor diets, suffer a greater burden of side effects than others (Burke and Ambasa-Shisanya, 2011; Alvergne, Stevens, and Gurmu, 2017). For instance, a study among women using contraception in Morocco documented the perception that only 'the rich who can afford a balanced diet' should use hormonal contraceptives (Mernissi, 1975). Despite this, no study to our knowledge has set out to uncover the drivers of variation in side-effect prevalence and understand which groups of women experience the greatest burden of side effects. This is partly because most clinical trials and public health studies ascribe to the biomedical logic of a global standardised body (Lock and Nguyen, 2018). This logic assumes that all women will respond similarly to the same intervention, with variation seen as a pathological deviation from a morally charged physiological 'norm' (Cullin, Vitzthum, and Wiley, 2021). The archetype of this standardised human body is Euro-American, meaning that much of medicine does not account for non-pathological biological differentiation in other

bodies (Hamdy, 2013). This concept has allowed for the testing and global exportation of contraception, with the assumption that it will be equally as effective and acceptable in all women.

Thus, contraceptive technology development research typically only captures a limited proportion of the diversity in women's biologies and their reactions to using contraception, due to the assumption that inclusion criteria will provide a representative picture for extrapolating to all women. In actuality, trial conditions and participants are often far from typical compared to most of the world's potential contraceptive users (A. Hardon, 1992; Bertotti, Mann and Miner, 2020), and in terms of geographies, African countries have been particularly under-represented (Bick *et al.*, 2021; Taylor-Robinson, Spearman and Suliman, 2021). Thus, if we are to meet the contraceptive needs of all women, research on side-effect experiences is needed among participants more representative of the range of contraceptive users. This follows the decolonising global health movement which exposes how coloniality – hierarchies stemming from European imperialism that relate to economic wealth, power, and knowledge production – underpins discourse and interventions to address any health issue (Newman, 2023). Calls have already been made to decolonise the development and distribution of contraception (Sowemimo, 2018; Bhatia *et al.*, 2019) and to place critical focus on the language used to describe experiences of suffering among individuals across different contexts (Hommes *et al.*, 2021). However as it stands, dubious framings of side-effect reports from women across the world persist, and there has been relatively little investment made into contraceptive technology development to reduce side effects (Callahan *et al.*, 2020a). This can be considered a form of structural violence given the concentration of negative impacts among those already most marginalised (McLean and Panter-Brick, 2018).

(3) The omission of women's broader priorities in guiding contraceptive research and technology development has resulted in a focus on the impact of contraceptives on suppressing fertility and has left out other outcomes that matter to women (Bertotti, Mann, and Miner, 2020). Many of the most commonly used contraceptive methods today were created during the population control movement (Hartmann, 1995) when efficacy and continued use were prioritised by policymakers and providers over other qualities typically more important to women themselves, such as acceptability and safety (A. P. Hardon, 1992; Bertotti, Mann, and Miner, 2020). Thus, there has been a lack of focus on measuring outcomes beyond the continued use of contraception, which has persisted in some contemporary family planning policies (Hendrixson, 2019) and recent clinical trials (Inoue, Barratt, and Richters, 2015). Further, population-based surveys which do measure side effects directly alongside other metrics predominantly do so to understand their impact on discontinuation or non-use. One study in Kenya, which did look more broadly and investigated associations between side-effect experiences and contraceptive satisfaction among current users, found that bleeding and non-bleeding side effects were both associated with reduced method satisfaction, particularly when experienced together (Odwe *et al.*, 2020). Nevertheless, there is still a lack of quantitative research that seeks to measure the impact of side effects on women's wider lives, despite the large body of evidence from qualitative studies that side effects can be severe and matter greatly to women, particularly when understood within an individual's cultural context (Jain *et al.*, 2017; Schwarz *et al.*, 2019). As a result, we have little idea of how much weight women give to side effects when negotiating the competing priorities of avoiding unwanted pregnancy while trying to maintain their health and quality of life.

This paper aims to provide a biosocial perspective on the extent and drivers of side-effect variation in Ethiopia using a qualitative approach. A biosocial perspective conceptualises the biological and social as mutually constituting, enabling the models and methods from the biomedical and social sciences to be used to explain patterns in side-effect experiences and impacts (Harris and McDade, 2018). By using a qualitative approach, the research aims to capture a wider range of side-effect experiences, their impacts on women's lives, and individual rationales for why some women suffer more side effects than others. To that end, we conducted in-depth interviews (IDIs) and focus group discussions (FGDs) with users of injectable and implant contraception, and several other key informants, in and around the cities of Adama and Bishoftu in Central

Oromia, Ethiopia. The research aims specifically to gain a deeper understanding of side effects rather than merely considering their role in driving discontinuation.

## Research context

This research is situated in Ethiopia because the country has a well-established government-funded family planning through its Health Extension Program (Assefa *et al.*, 2019), meaning that cost and access barriers to contraception are typically less prevalent than sideeffect-related concerns. For instance, 52% of Ethiopian women who discontinued their method while still in need of contraception in 2016 did so due to side effects and health concerns, compared to only 11% who gave lack of access as a reason (CSA Ethiopia, 2016). Despite these concerns, modern contraceptive prevalence in Ethiopia has risen from 4.7% in 2000 to 28.1% in 2019 (EPHI, 2021). This can predominantly be attributed to the uptake of two main methods: the 3-month progestin injectable contraceptive and increasingly the 3-year progestin implant, which according to the most recent DHS made up 67% and 21% of modern contraceptive use respectively in 2019 (Ethiopian Public Health Institute (EPHI) and ICF, 2021). The injectable, or ‘depo’ as it is known locally, has maintained long-term popularity through its provision in government health services, its ease of use, and the secrecy it affords. The use of implant, known locally as ‘the buried one’, has been increased recently through the Implant Access Program, a Western-funded private–public partnership seeking to expand lower-income countries’ access to long-acting contraceptives through a cost-reduction scheme for bulk purchases, criticised for leading to targets for implant distribution (Hendrixson, 2019). Indeed, qualitative studies from Ethiopia and other sub-Saharan African contexts have now documented instances of reluctance or even resistance among healthcare providers among women seeking removals or to switch from the implant (Senderowicz, 2019; Yirgu *et al.*, 2020), which was also a concern among our study participants. Our study sites in Central Oromia, in and around the urban centres of Adama and Bishoftu, were chosen based on previous research identifying side effects as a significant barrier to contraceptive use and quality of life in the area (Alvergne, Stevens, and Gurmu, 2017). Additionally, despite high levels of urban growth in both, there remain remote rural locations in close proximity, with significant rural–urban variation in lifestyle allowing the experiences of women living across a range of social and ecological contexts to be captured.

## Methods

### Study design

We conducted 15 IDIs and 5 FGDs between January and March 2020 with women, aged 18–35 years, who had used either the injectable or implant contraceptives in the last 5 years, allowing us to document the accounts of both current and past contraceptive users. As contraceptive use is most common within marriage in Ethiopia, all but one of the recruited informants were married. We also undertook three key informant interviews (KIIs), two with health workers and one with the husband of one of the participants. In total, we interviewed 15 women in IDIs, 2 health extension workers (HEWs) and 1 husband in KIIs, and 25 women in 5 FGDs with 4–6 women per FGD (total  $N = 43$ ).

IDIs were the best suited to explore in detail women’s personal lived experiences, whereas FGDs were useful for understanding consensus or divergence in opinion between women. KIIs improved our understanding of the wider environment of women’s contraceptive use. Due to the COVID-19 crisis, it was not possible to attain the number of interviews initially planned, and we were limited in our ability to attain thematic saturation, though fewer new observations were recorded in the later interviews, suggesting saturation was neared (Denzin and Lincoln, 2017). Due to these limited numbers, our findings from KIIs with health workers and husbands are

unlikely to cover a significant breadth of husband and health worker views on side-effect experiences, but the findings were maintained in the analysis as they provided useful depth and alternative perspectives to explain our findings.

### **Recruitment of study informants**

HEWs in the selected kebeles (lowest administrative unit in Ethiopia) were approached to assist with identifying women that fit the inclusion criteria (aged 18–35 years, had used injectable or implant in last 5 years) and helping to purposively select information-rich cases to increase the breadth of experiences documented (Palinkas *et al.*, 2015).

### **Data collection**

After a referral was made by the HEWs, participants were then invited to a health post or visited in their homes, depending on their preference. The study aims and procedures were explained to participants, and participants were asked for their informed consent before recruitment to the study. If consent was given, interviews and discussions were conducted in Amharic or Afan Oromo by a qualified Ethiopian female research assistant (the third author) with a master's degree in Reproductive Health and several years of experience working within the local health system. The first author, a British female doctoral student, was present for all interviews, but otherwise, interviews were conducted in private, away from HEWs and other household members. Basic sociodemographic data on age, education, religion, parity, and occupation were obtained at the beginning of the interview. Individuals were provided with a kilo of coffee as a gift in kind for taking part. This was considered suitable compensation after much discussion with local stakeholders, as it is a culturally valued commodity that would be received with gratitude without any risk of coercion to take part.

Interviews and discussions were carried out using semi-structured guides, developed with feedback from Ethiopian stakeholders, including academics, policymakers, and health professionals. This feedback was obtained through a stakeholder workshop in Addis Ababa prior to data collection, where study aims and methodology were presented and opportunities to ask questions and give feedback, both via a group discussion and evaluation forms, were provided. Guides were translated by an independent source initially, checked separately by authors fluent in local languages, and pretested prior to data collection. Guides were repeatedly re-evaluated in an iterative process to obtain in-depth information and to cover the breadth of experience. Semi-structured guides allowed for a more open and non-leading style of interview that gave priority to women's voices and allowed them to use their own words (Pope and Mays, 1995). Participants were asked about the occurrence, breadth, and severity of side-effect experiences, why they perceived some women to suffer more than others, and how women negotiate the social, physical, and economic costs of these side effects within their wider lives. Women were given time to tell their own narratives of side-effect experiences and interviewers were committed to not conveying any judgement as to valid or invalid side effects by using open-ended side-effect questions and listening to any experiences that arose in discussion. All discussions were tape-recorded, transcribed, and then translated into English by the interviewer. Discussions focused on understanding reasons for contraceptive use, the types of side effects women experience, their frequency and severity, variation between women, and the impacts of side effects on day-to-day life. Each interview lasted around 20–30 minutes and each FGD between 40 minutes and 1 hour.

### **Data analysis**

Data analysis began as data collection was underway, with frequent conversations between the interviewer and other authors to iteratively mould the guides and discuss arising themes.

Interviews were analysed by the first author using NVivo software. Transcripts were read several times to get an overall impression of the data and create initial codes for organising the data, noting repeated or emerging issues upon which themes were developed. A bottom-up data-driven approach to thematic analysis was employed, using constructivist principles and with particular attention to the types of side effects mentioned and women's logics of what drove their occurrence (Braun and Clarke, 2006). Developing themes were discussed throughout between authors, with a particular focus on the literal and cultural meanings underpinning the words used to describe side-effect experiences and vulnerabilities. Meetings took place weekly between the first author and the interviewer as transcripts were being translated and reviewed for the first time in order to discuss any arising translation issues and initial reflections on the emerging themes. These discussions contributed to reducing cultural and confirmation bias in interpretation by checking that both authors perceived the meanings of respondents similarly. Meetings with the whole authorship team additionally took place every few weeks as analysis progressed to gather further expertise and challenge any unexpected results. Based on these discussions, themes were iteratively revised until a narrative picture of the results arose, which is portrayed visually in a conceptual representation (see Figure 1 in Results section).

## Results

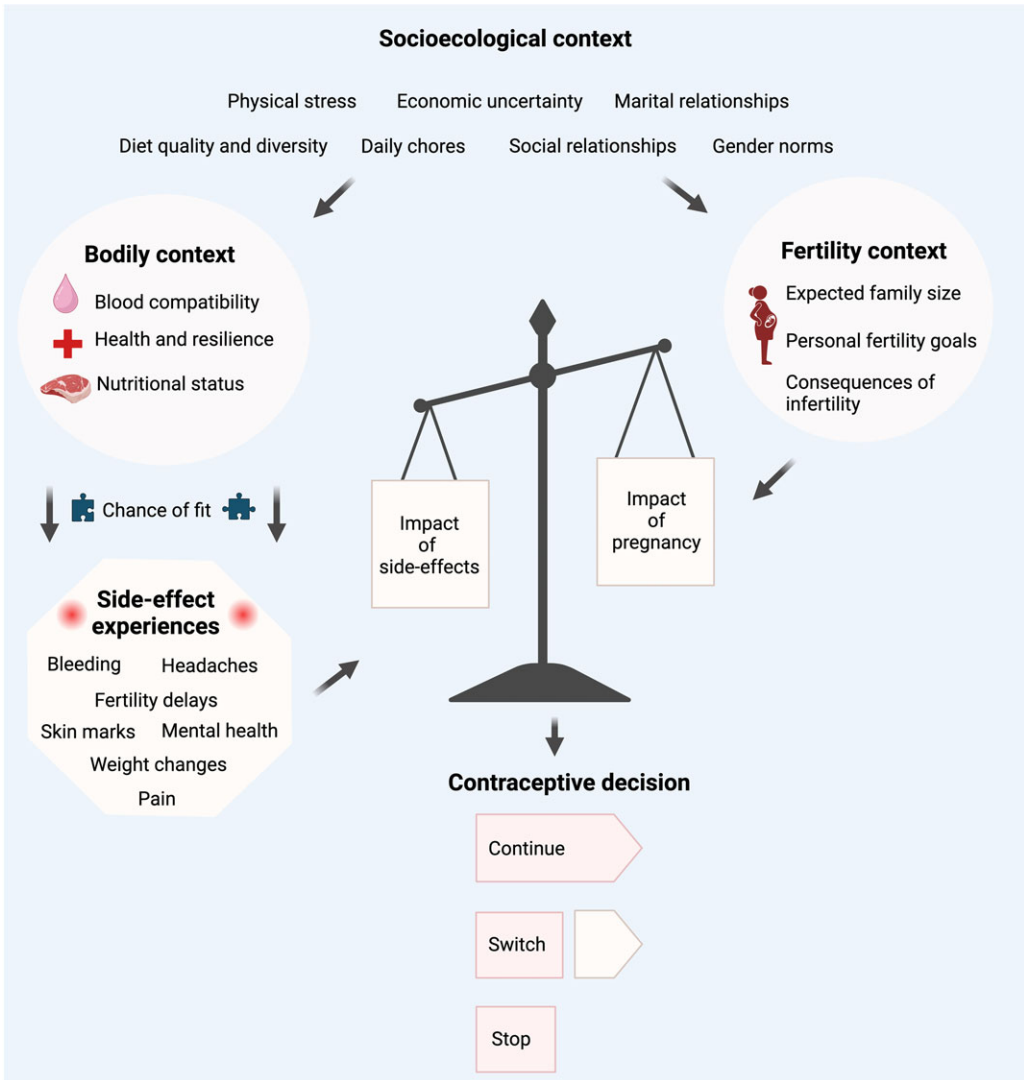
### *Descriptive summary of sample*

Descriptive characteristics of our sample demographics are shown in Table 1. As women in the local area typically choose to use contraception for birth spacing, often after the birth of their first child, all women in our sample had been married and had children, and there was a slight skew towards women 30 years or older. While there was a range of cultural, religious, and administrative types of marriage among our participants, all described themselves as formally married, rather than in informal marriages characterised by cohabitation without a formal union. Nearly two-thirds of women described themselves as being a housewife, typically implying that they do not engage in paid economic activities but look after children and carry out informal agricultural and economic activities. Others were students, manual labourers, or government administrative employees. Protestants are overrepresented in our sample compared to their proportion in the general local population, which is only around 10%, suggesting some selection bias in our recruitment. One of our rural sites had a large Protestant missionary presence, which may explain the high proportion of Protestants there. The two female health workers interviewed were a nurse and an HEW, aged 38 and 28 years, respectively, one Muslim and one Protestant, both married, and with their own children. The husband interviewed was aged 34 years, degree-educated with two children, and worked in the government offices.

### *Side-effect experiences encompassed a wide range of symptoms and severity*

Despite contraception being seen as a necessary and useful tool, many women were not satisfied with their experiences while using it. Across both urban and rural areas, women reported a wide variety of side effects in both frequency and severity, comprising a whole host of physiological bodily symptoms detailed below. Many of these symptoms have been documented during clinical trials, carried out during contraceptive development, and in broader qualitative studies, while others are more novel.

Side effects relating to **bleeding and blood flow**, such as not bleeding at all, bleeding too much, bleeding too irregularly, or bleeding with too much pain, were commonly reported. Women highly valued seeing their monthly bleed and cited '*feeling like a man*' or worrying about infertility if they did not see it. Several women even reported that after long periods of injectable-induced amenorrhoea, they would switch to the pill for a month just to see their monthly bleed. Irregular,



**Figure 1.** Conceptual representation of the perceived relationship between socioecological context, side-effect susceptibility, fertility desires, and the trade-offs involved in contraceptive decisions.

increased, or painful bleeding during contraceptive use was reported as highly problematic: ‘*Depo! Oh my God! My menses was irregular, coming every 2–3 months. When it comes, it has aching type of pain, bleeds heavily . . .*’ (Housewife in urban Adama, 34, 5 children, diploma, Protestant) or ‘*I can’t tolerate the side effect of the injection. Like the bleeding didn’t stop, there was too much bleeding*’ (Housewife in rural Adama, 35, 3 children, grade 6, Protestant). Wider public health and medical literature often refer to irregular bleeding as a ‘nuisance’ or ‘minor’ side effect (Grimes and Schulz, 2011) and the injectable patient information leaflet describes irregular bleeding as ‘normal and nothing to worry about’ (Pfizer, 2024). However, these experiences were seen as common and very serious to users, given the disruption they can cause to a woman’s wider domestic, work, school, social, or religious life. They took a toll on marital relationships: ‘*When he [a husband] has sexual desire, he asks how can you always say I’m on menstruation. It is difficult to say it has minor side effects. There is a lot of hassle in our house*’ (Focus group in rural Adama).



**Table 1.** Descriptive Characteristics of Participants Interviewed

Characteristic	Individual interviews, N = 15	Focus group participants, N = 25	Health workers, N = 2	Husband, N = 1
Age	32 (28, 34)	30 (27, 32)	33 (30, 36)	34 (34, 34)
Marital status				
Married	14 (93%)	25 (100%)	2 (100%)	1 (100%)
Widowed	1 (6.7%)	0 (0%)	0 (0%)	0 (0%)
Number of living children				
0	2 (13%)	0 (0%)	0 (0%)	0 (0%)
1	2 (13%)	6 (24%)	1 (50%)	0 (0%)
2	4 (27%)	7 (28%)	0 (0%)	1 (100%)
3	3 (20%)	7 (28%)	1 (50%)	0 (0%)
4	3 (20%)	4 (16%)	0 (0%)	0 (0%)
5	1 (6.7%)	1 (4.0%)	0 (0%)	0 (0%)
Highest education level				
None/primary	4 (33%)	7 (54%)	0 (0%)	0 (0%)
Secondary	4 (33%)	5 (38%)	0 (0%)	0 (0%)
Higher education	4 (33%)	1 (7.7%)	1 (100%)	1 (100%)
Missing	3	12	1	0
Religion				
Muslim	2 (13%)	2 (18%)	1 (50%)	0 (0%)
Orthodox	7 (47%)	3 (27%)	1 (50%)	0 (0%)
Protestant	6 (40%)	6 (55%)	0 (0%)	1 (100%)
Missing	0	14	0	0

Numerical: median (interquartile range (IQR)); Categories: *n* (%). 'Missing' indicates where women were unwilling to give a response or where this information was not recorded.

Even basic activities, such as taking public transport were made difficult, impacting women's abilities to achieve their wider goals: 'Yes, since I bleed heavily, I even feel difficulties in attending class, and even staying on transportation to reach my school, which was far from here' (Graduate student in rural Adama, 22, no children, degree, Orthodox). Thus, while much biomedical literature considers bleeding changes as minor and clinically safe, many women experiencing or afraid of these experiences are unlikely to be reassured by medical advice telling them not to worry.

**Weight changes** were commonly cited as side effects and, while some women did report weight changes as being a positive effect of taking contraception, in general they were seen as a negative: 'Yes, it has a psychological effect; becoming too fat or too thin without any reason is stressful' (Focus group in rural Adama). Some women reported that this weight gain impacted their appearance in a way they were not happy with and this was enough to cause them to stop their method. Despite a lack of high-quality evidence, these reports are congruent with published reviews showing injectable or implant use to be associated with weight gain (Dianat *et al.*, 2019; Moray *et al.*, 2021). There seemed to be variation in these experiences with other participants reporting weight loss, often along with a suite of other negative symptoms: 'When I was using implanon after I gave birth

*I had prolonged heavy menses, dysmenorrhea, weight loss and in general I was suffering'* (Focus group in urban Bishoftu). Bleeding and weight changes often were reported together in our discussions, with heavy bleeding particularly associated with weight loss and implant use, and amenorrhoea associated with weight gain and injectable use. Others appreciated weight gain as a positive side effect and saw contraception as a way to counteract being too thin, described as being 'dry' or 'like a stick': *'I am using the injectable [ . . . ] I am happy with it. Also, I prefer it, wishing to gain weight. As you see, I am dry'* (Focus group in rural Adama).

**Delays in return to fertility** and potential infertility were cited by many women as side effects that they had experienced or worried about. A scoping review of fears about infertility in Africa identifies a body of literature that predominantly frames women as 'believing myths' if they worry about infertility associated with contraception (Boivin *et al.*, 2020). However, several women in our discussions reported direct experiences of struggling to become pregnant for a while after stopping contraception. They perceived this to be due to their contraceptive use and some worried it might have caused them long-term infertility: *'I am using the injectable and it is comfortable to me, but my menses didn't come, when I want to be pregnant, I couldn't conceive quickly and it was delayed for one year'* (Focus group in urban Adama). These fears may not be unfounded given a recent analysis of DHS data from 47 countries, which shows that women do experience delays in return to fecundity after using many contraceptives, particularly injectables and implants (Gemmill, Bradley, *et al.*, 2023). Additionally, a recent trial of the lower dose Sayana press injectable contraceptive found that the patient leaflet, which claims that 80% of women desiring pregnancy will conceive within one year after stopping use, is likely a significant overestimate, with one study suggesting that women should expect to wait at least a year or more to return to fertility after repeat dosing of the injectable (Taylor *et al.*, 2022).

Being without a child in Ethiopia can have serious consequences for marital and social relationships, and health workers in our discussions reported that women faced difficulty if they could not conceive: *'Women who experience that they couldn't conceive by the time they want find it causes conflict in the house with their husband. It has great impact on their life'* (Nurse in urban Adama, 38, 3 children, Orthodox). As timing a child was reported to be a delicate balance of economic factors in this context, women valued the ability, once they have the correct conditions, to become pregnant easily and if they could not, it had a negative impact on their lives: *'It is obvious people take it seriously, missing a child. You know after they have good and full living conditions, not being able to have a child is very hard'* (Housewife in rural Adama, 34, 2 children, grade 10, Orthodox). These findings support other studies of fertility decision-making among women in more uncertain circumstances, which shows that the ability to flexibly time one's fertility to prevailing conditions is a strong priority (Johnson-Hanks, 2015; Trinitapoli and Yeatman, 2018).

Women also experienced **headaches, nausea, and feeling light and dizzy**: *'I switched to the three years one and my bleeding stopped, but it makes me severely ill. I was feeling like my head was becoming light and dizzy'* (Housewife in rural Adama, 35, 3 children, grade 6, Protestant). These changes often came with other mental health changes of **lower mood, greater irritability, disappointment, and lowered libido**: *'While using the injection before, I don't know, I used to be irritable and complain, headache, increase in my body weight and I was feeling disappointed [ . . . ] I was experiencing severe headache and I was whiny'* (Housewife in urban Adama, 30, 3 children, Protestant). Published reviews show that there is some quantitative evidence for the association of injectable and implant use with these symptoms (Moray *et al.*, 2021; Dianat *et al.*, 2019), but the quality of evidence is mixed as these symptoms often go unmeasured in clinical trials or dubbed as non-serious adverse events. However, many of these mental health and mood changes were reported frequently in our sample as serious issues that caused concern or conflict in a woman's household. For instance, many women were troubled by their drop in libido: *'I have also a problem related to decrease in sexual feeling, so I have conflicts with my husband most of the time'* (Housewife in urban Adama, 27, 1 child, grade 9, Orthodox).

Many other types of bodily **pain** were reported. There were joint pains, reported in the hands, back, and legs, sometimes leading to difficulty standing, tender breasts, pain at the injection or insertion sites, and stomach pains: *'All of them complain like me, like back pain, joint pain, muscle pain. [...] I think all the above effects I mention are true, they speak what they experience'* (Housewife in rural Adama, 35, 3 children, grade 6, Protestant). A Cochrane review on hormonal contraception and bone fractures states that the injectable contraceptive is associated with a loss of bone mineral density and there is some evidence for increasing risk of fracture and osteoporosis with its continued use (Lopez *et al.*, 2015). Based on this risk, for women using injectable contraceptives in the United Kingdom, a review is recommended every 2 years in order to assess their individual situations and discuss its risks and benefits (Faculty of Sexual & Reproductive Healthcare, 2020). For many Ethiopian women in our discussions, who had taxing physical lives of manual and agricultural labour, particularly in rural sites, increased pain, or inability to use parts of their body that hurt could have huge impacts on their day-to-day lives: *'I experience pain in my hand. I can't wash clothes, even I can't lift my hand'* (Housewife in rural Adama, 34, 2 children, grade 10, Orthodox). These negative experiences and inability to carry out normal tasks caused worry among women's social networks and left a void where others had to step in to support. For instance, the husband interviewed, married to one woman who had experienced such pain, was very concerned for his wife and often had to help her: *'Yeah, she had too much pain while she was using the injectable, even when she wanted to do something, she just stopped since she felt pain, so that me and other family members helped her'* (Husband in urban Adama, government employee, 34, 2 children, degree, Protestant).

Women also noticed **changes to their skin**. An effect, called melasma (Ogbechie-Godec and Elbuluk, 2017), in Amharic *'mediyat'*, refers to the darkened patchy lesions or colouring of the skin, often on the cheeks. Some describe it as their *'face was burned out'* and it was generally reported with high levels of distress: *'I am using the 3 years [implant] and it's going to end. It ruined my face and I got thin. I am so worried about my face'* and *'I changed to the one inserted in the arm – again it made me lose weight and I developed skin lesions on my face'* (Focus group in urban Adama). This effect also jeopardised women's ability to use contraception discretely and in some cases, prompted others to advise them to stop in fear for their health: *'You can see my face, it's the effect of contraception. All people know that I am using contraception, and they advise me to stop'* (Focus group in urban Bishoftu). This was referenced heavily in interviews and fits with a biological explanation. We know that high levels of progesterone, as experienced in pregnancy, create increased skin sun sensitivity (Filoni, Mariano and Cameli, 2019), and similar effects have been observed in oral contraceptive users in Brazil, particularly, those with greater skin pigmentation capacity and greater sun exposure (Handel *et al.*, 2014). However, to the best of our knowledge, this effect is not measured quantitatively in any side-effect measure and is hardly mentioned in the patient information for the injectable or the implant, which documents an 'uncommon risk' of 'temporary brown patches' for the injectable and 'rash' for the implant (Pfizer, 2024; Organon, 2023). Other qualitative studies on contraceptive side effects also document fear of melasma among women in Cambodia and South Africa who reported worrying about unwanted changes in skin pigmentation and increased sun sensitivity (Snow *et al.*, 1997).

### **Who suffers the most?**

Women with poorer diets and higher physical workloads were perceived to be those who suffered the worst side effects when using contraception: *'I think the injectable needs good food, I think women with no resistance will be hurt so much. If they have a work burden and if they don't get an adequate diet, it will be hard to use it and they will be hurt badly. They will be like a person with a disease'* (Housewife in urban Adama, 32, 4 children, diploma, Muslim). Another said: *'In those with a high work burden and who don't eat appropriately, it [using contraception] is difficult [...] Women who get whatever food they want, they don't get hurt'* (Focus group in urban Adama).

These factors were considered to be related to socioeconomic status: *'People are different in their economic status, but all might use the injection. In those who don't get balanced diets, due to low economic status, the side effects will be severe'* (Graduate student in rural Adama, 22, no children, degree, Orthodox). Women applied this rationale to explain their own experiences: *'Since I was experiencing the side effects, I know very well if you don't get enough food, you will have effects. Now even, I think that I am malnourished'* (Focus group in urban Bishoftu). Sometimes, women reported that particular dietary components were even recommended by health workers as remedies to side-effect experiences, despite the fact that these foods were often well out of reach of women's budgets: *'Yeah, the health professionals also advise me to take a protein diet like egg, meat and milk after frequently complaining about my experiences, but you may not get those foods easily'* (Focus group in urban Bishoftu). The importance of being able to obtain a good diet also factored practically into women's contraceptive choices: *'[Women] mostly want injectable because if it causes complications it's easy to act on it, so that they want the short term one, also because they say implanon needs diversified food'* (Health extension worker in urban Adama, 28, 1 child, diploma, Muslim).

Whether a woman would have a 'simple' versus 'serious' burden of side effects was often discussed in terms of whether a particular method was a good fit for her body and her life. If a contraceptive caused a woman to have side effects, she would commonly report that *'lene altesmamagnm'* – meaning *'it does not fit with me'* in Amharic: *'I was using the three year one, but it did not fit with me. I used to have abdominal cramps, back pain, headache, feeling dizzy, bleeding that didn't stop...'* (Focus group in urban Bishoftu). A key driver of fit was typically conceptualised in terms of *'blood compatibility'*, *'blood type'*, or whether a contraceptive *'fit with a woman's blood'*. For instance, when asked why a woman might get side effects, one woman answered: *'Maybe if their blood is not fit with it, because some say the injection is not good for me, I think this comes as result of the injection and the blood of the individual being incompatible'* (Cafeteria worker in urban Adama, 33, 4 children, grade 5, Muslim). Literal translations of the terms used to describe fit in our findings ranged from; did it *'fit'* with her, was it *'compatible'* or *'suited'* to her or her blood, was it *'the same as'*, *'selected for'* or *'comparable'* to her blood, did it *'interact well'* with her blood, or even *'did it make her look good'*.

Despite their perceived knowledge of which women were most 'at risk', many lamented the difficulty in knowing whether they would get side effects from a specific method. They were frustrated with the burden of having to try out several methods, potentially enduring negative symptoms while using each of them, to try to find one that was acceptable to them. Women wanted guidance as to which contraceptive method was least likely to personally cause them side effects and would *'fit'* well with them to start with. This was typically expressed as the wish for a test to ascertain compatibility with an individual's blood: *'I think different blood types fit with different contraceptive methods, so for the future, I would prefer to use a contraceptive method that fits with my blood after investigation'* (Housewife in rural Adama, 35, 3 children, grade 6, Protestant). Women suggested that a test should be developed to help determine the method with the fewest side effects: *'For me, I prefer if contraception is given after each woman has their blood examined by their doctors. Nowadays, everybody simply gives contraception'* (Focus group in urban Bishoftu).

### **Whether to endure side effects is a context-dependent trade-off**

Many contraceptive users found themselves in a difficult position, trying to decide whether to endure the contraceptive side effects they experienced and prioritise continuing use or give up entirely and risk an unwanted or mistimed pregnancy. As documented in other sub-Saharan African settings (Schwarz *et al.*, 2019), choosing to use contraception and endure side effects was a hard decision based upon multiple contextual trade-offs, including how many children they currently had, the time since their last birth, and their social and economic responsibilities. Some

women, who could not tolerate the side effects and the consequences on their marriage or daily activities, decided to stop using contraception despite not wanting a child at that time: *'[Side-effects] become a hurdle to their plan, she couldn't achieve her goals. If she wants to learn, she couldn't because of it. So, they will discontinue and they prefer becoming pregnant than suffering'* (Focus group in rural Adama). Many of them only stopped after having tried switching between several contraceptive methods and finding that none fit: *'I used to try to switch but nothing fit with me, so I discontinued and gave birth'* (Focus group in urban Bishoftu).

Among women who participated in our discussions, the experience of going on to have an unintended pregnancy after contraceptive discontinuation due to method dissatisfaction was not uncommon, nor is it across many different low- and middle-income countries as shown quantitatively by a recent analysis of DHS data (Gemmill, Sarnak, *et al.*, 2023). Women in our discussions reported that these pregnancies impacted their economic, educational, and career prospects, as well as their social and marital relationships. For instance, a woman in urban Adama (34, 5 children, diploma, Protestant, housewife) had been using contraception to avoid pregnancy after her fourth child, while she waited for her children to grow up, so that she was able to return to studying to seek a better job and greater income. However, due to side effects, she stopped using contraception and gave birth to a fifth child, delaying her ability to attend education, confining her to staying at home to look after her new child and negatively impacting her family's financial circumstances.

Thus, many women considered the impacts of having a child too great to warrant stopping on account of the side effects: *'In my opinion the benefit outweighs the side-effects. [...] People simply complain about side-effects, but it is better to use it to prevent having too many children, having no job outside the home, taking care of the children, and waiting until they're grown up'* (Farmer in rural Adama, 35, 4 children, no education, Orthodox). In some cases, women decided that they must keep using family planning despite severe negative effects and advice from others counselling them to stop: *'It's difficult to live without planning. This is why I am using it, even if I am in pain. [...] Yeah, I am feeling sick; my abdomen, back pain, joint pain. I am simply using it even if people advising me to stop since my life is not good'* (Housewife in rural Adama, 35, 3 children, grade 6, Protestant). Women, particularly in rural areas, consistently stressed the need to use contraception to avoid a pregnancy based on their current economic circumstances and situational precarity. Many women expressed sadness about the difficulty of affording to raise children and wished it was possible to have more: *'No one hates having more children, except because of poverty'* (Focus group in rural Adama). In addition to being able to time fertility to their economic circumstances, women in urban areas in particular discussed fertility control as important for *'the good of the country'*. There was a perception that it was their duty to limit the number of children they had so that children could be well educated, self-sufficient financially, and not become a *'burden'* on the state. These statements reflect rhetoric promoted in some family planning discourse, which places the responsibility on individual women to control their fertility to alleviate economic hardship rather than placing the focus on structural improvement of services and employment options (Sasser, 2018).

Figure 1 shows a conceptual representation of how these different results fit together and shows the many factors that individuals must balance when making contraceptive decisions. Firstly, it shows how socioecological factors, such as economic uncertainty, physical stress, social and marital relationships, and gender norms impact both a woman's (a) fertility desires and the expectations placed upon her concerning childbearing, and (b) her susceptibility to suffering negative side-effect experiences. We represent the subsequent trade-off a woman faces in her decision to continue, switch method, or stop using contraception all together as a set of scales, representing the weighing up of the often-serious impacts of either side effects or pregnancy, be it desired, mistimed, or unwanted. It specifically uses words and concepts employed by women in our discussions to utilise their understanding of what drives side effects and centre their perspectives.

## Discussion

In this study with injectable and implant users in Ethiopia, we used a biosocial approach to investigate the breadth of side-effect experiences reported by women, causal rationales for variation in side-effect burdens, and how women balanced competing priorities in their contraceptive decisions. Women reported suffering from a wide range of side effects, including bleeding irregularities, weight changes, fertility delays, pain, and skin changes (melasma). They perceived that contraceptive side effects would be experienced more severely by women who had poor diets and hard physical occupations. Women most 'at risk' of side effects were often those with the strongest motivation to control their fertility. Physical side effects had a negative impact on women's quality of life leading to impaired ability to work, attend education, and perform daily chores as well as causing marital conflicts. Finally, participants built on folk biology understandings and expressed their desire to access contraceptives that would 'fit' their body, that is, that would minimise side effects given their personal biology, a finding that supports calls to develop a personalised medicine approach to contraception (Hill and Mengelkoch, 2023; Cella and Wagner, 2015).

### *Side effects and their impacts vary in how seriously they manifest*

Our results support findings from other studies (Schwarz *et al.*, 2019; Jain *et al.*, 2017; Polis, Hussain and Berry, 2018) that the cultural, social, and biological contexts within which contraception is taken are central to the experience of side effects, which symptoms manifest, and which are considered serious. For instance, continuous bleeding manifested as a serious issue among women whose marriages required their continued sexual availability or whose daily routines required them to be sat on public transport for long periods. Lack of bleeding and a slow return to menstruating after contraceptive use was an emotionally painful and worrying experience among women living in precarious economic circumstances or under social expectations to bear children, who are typically under great pressure to conceive in a small window (Trinitapoli and Yeatman, 2018). Increased sun sensitivity and the subsequent development of dark marks or lesions on the face with contraceptive use, which is poorly documented in other studies, was considered a serious issue, particularly, given the presence of other mediating risk factors in the local ecological context, such as high sun exposure. These marks were an incredibly troubling side effect in our sample, given their impact on facial aesthetics, secrecy of contraceptive use, and incitement of concern among close relations. Thus, which side effects are considered serious, and how they are weighted against other priorities around fertility and contraceptive use, cannot be understood without understanding the context they are experienced within (Alvergne and Stevens, 2021). These findings highlight the importance of conceptualising contraceptive side effects using a biosocial lens, as bodily, biological experiences fundamentally mediated in their likelihood of manifestation and impact by the social, environmental, and structural context within which they are experienced.

### *What causes variation in contraceptive side effects?*

In our sample and around the world, women perceive that some women suffer more than others with side effects. Women in our sample assumed that there ought to be a way to predict the risk of side effects and they wanted to know which contraceptive would 'fit' well with them or be 'compatible with their blood' before they chose their method. These findings echo other studies from Sub-Saharan Africa about method fit and risk of side effects. For instance, to avoid side effects, women in the Democratic Republic of Congo (DRC) and Burundi describe wanting the contraceptive best 'suited' to them (Schwarz *et al.*, 2019). In Nigeria, women wanted methods 'compatible' with their 'body system' or 'body chemistry' (Schwandt *et al.*, 2016). In Kenya, women said they needed methods that 'rhymed' with their bodies (Rutenberg and Watkins, 1997). Among

our participants and in Kenya, Ghana, and the DRC (Hindin, McGough, and Adanu, 2014; Schwarz *et al.*, 2019; Rutenberg and Watkins, 1997), women express a desire for a blood test to determine this compatibility and whether a method would cause side effects.

Even without having a test to find out, participants in our study expressed various rationales for which factors would drive a good fit and which women were most likely to suffer from side effects. They perceived that women living in poverty, with harsh physical routines, poor food security, and poor general health, were those who had the least resilience to experiencing side effects. Interestingly, many of these characteristics are also found to be associated with low natural levels of endogenous reproductive hormone levels (Vitzthum, 2009). Calls have been increasing to investigate how this variation in endogenous hormone levels may interact with external contraceptive hormone doses to impact the chance of experiencing side effects (Vitzthum and Ringheim, 2005; Alvergne and Stevens, 2021), yet it remains untested directly.

Women with characteristics perceived as leaving them most at risk of side effects are commonly excluded from the contraceptive development process. For instance, the dose-finding study for the new lower dose Sayana press injectable contraceptive (subcutaneous Depo-Medroxyprogesterone Acetate (DMPA-SC 104mg)) excluded adolescents, those with irregular menstrual cycles, women not in 'good general health', underweight, anaemic, or breastfeeding women (FHI 360, 2016). These criteria are understandable given cost considerations and statistical limitations but may limit the ability of trials to capture the experiences of much of the world's population and those with potentially high side-effect burdens. For instance, in the 2016 Ethiopian DHS, the prevalence of adult women with a BMI under 18.5 is 22.4% or with anaemia is 23.6% (CSA Ethiopia, 2016). Our previous analysis of this dataset found anaemic women to be twice as likely as non-anaemic women to discontinue the injectable contraceptive due to side effects (Stevens *et al.*, 2022).

Future studies investigating how the characteristics that women report as increasing the risk of side effects associated with a higher burden of symptoms are warranted. Such knowledge is key to guide inclusion criteria when estimating side-effect probabilities and during the development of new contraceptive methods. This knowledge would also support precision medicine approaches to contraception that aim to provide contraceptives that minimise the risk of side effects given an individual's characteristics (Cella and Wagner, 2015; Hill and Mengelkoch, 2023). For instance, recent innovations in personalised decision-making support for choosing which contraceptive to use (Lazorwitz *et al.*, 2021) are already going some way to fulfil women's requests for a test to help find the method that will likely work best for them. These tools can be further improved with increased information on the risk of side effects among different women living in different contexts. These innovations follow calls from other avenues that advocate for more research into improved contraceptive technologies (Callahan *et al.*, 2020b) and fundamentally reject the idea that contraceptive side effects are just 'the price women pay' for preventing pregnancy (Schwarz *et al.*, 2019; Rothschild *et al.*, 2021).

### ***Navigating 'the perfect storm'***

Our discussions also highlighted the existence of a particular group of women, typically living in already difficult conditions and not wanting to conceive, who faced a perfect storm when it came to navigating the trade-off between contraceptive side effects and unwanted pregnancy. They faced a dilemma: either continue to use contraception and tolerate a serious burden of side effects or stop use and handle some of the most serious consequences of pregnancy – parenting as best they could within difficult circumstances. This can be considered a form of structural violence (McLean and Panter-Brick, 2018) when the only two 'choices' presented to a group through the structures around them both seriously negatively affect their quality of life. Going forward, efforts to measure side effects and reduce symptom burdens would likely have the most effect from an equity perspective if they were centred on women whose lack of economic and physical capital

gives them neither resistance to side effects nor the ability to handle an unplanned pregnancy. This focus would utilise a reproductive justice approach which (1) critiques the validity of the concept of choice when an individual has only limited and unattractive options available to them, and (2) which centres the rights to choose when to have a child, when not to have a child, and the conditions to parent a child as you wish (Ross and Solinger, 2017b).

### **The value of a qualitative biosocial approach**

By utilising qualitative methods within a biosocial approach, it is possible to gain a deeper understanding of variation in contraceptive side-effect experiences and to inform the development of methods for quantitative estimation of side effects. By first asking about lived experiences of side effects in an open-ended way without pre-specified categories as to the validity or importance of the reports provided, efforts to measure or alleviate side effects can be better centred on women's own experiences and priorities. An exploratory qualitative approach can help identify symptoms that may otherwise go unmeasured or novel logic for why some women may experience the worst burden of side effects. It can also help reveal where symptoms previously considered minor and dismissible may have salient impacts given a certain cultural or ecological context. While qualitative information may have limited utility as direct evidence for the physiological causes of side effects or to what extent the reported symptoms are wholly attributable to contraceptive use, it still provides crucial information about the perceived social, cultural, and biological factors influencing women's experiences of side effects and contraceptive decision-making. With this knowledge, we may be able to improve upon current measurement efforts, which either only measure side effects chosen by researchers for their perceived clinical validity or measure no side effects at all, and blanket categorise side-effect worries as myths and misconceptions. Centring satisfaction and women's priorities beyond just continued use follows calls to broaden definitions of unmet needs (Rominski and Stephenson, 2019; Senderowicz and Maloney, 2022) by focusing more on users' satisfaction and ability to regulate their fertility, free of experiences of suffering or worry. It also follows calls from reproductive justice and decolonising global health movements to consider whose words we choose to listen to, the words we use to describe individuals' experiences of suffering, and the value of storytelling (Ross and Solinger, 2017a; Hommes *et al.*, 2021).

### **Limitations**

Our results are limited in their generalisability. First, for comparisons within Ethiopia, our sample was overwhelmingly women who were married and had children, and therefore, our findings cannot necessarily be extrapolated to those using contraception before marriage or to delay or avoid the birth of a first child. Additionally, protestants are overrepresented in our sample, suggesting a selection bias meaning that the views captured may not be representative of the local population. Nonetheless, our results may be likely to be more representative of side-effect experiences across Ethiopia than many clinical trials that exclude women who are underweight, in poor health, or anaemic among other factors and are likely relevant to other sub-Saharan African contexts where there are high levels of agricultural labour and food insecurity and similar contraceptive method mixes.

In conclusion, future population health and contraceptive development studies that seek to measure contraceptive side effects may gain from starting with biosocial grounding, such as that provided in this paper, which qualitatively documents context-specific variation in side-effect symptoms while centring women's own voices and priorities. Measurement tools can then be designed to better capture women's side-effect experiences and priorities, particularly among those whose voices are commonly excluded from studies. With the collection of high-quality data on variation in side-effect experiences between individuals and contexts, we may finally be able to



answer calls from precision medicine and women themselves to personalise contraceptive prescription to minimise side effects and better meet women's contraceptive needs.

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