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"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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24 Abstract

25 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 26 27 more from side-effects remains unknown. Through inductive analysis of in-depth interviews 28 and focus groups discussions with 40 contraceptive users and 3 key informants in Central 29 Oromia, Ethiopia, we explored women's rationales for variation in side-effect experiences. 30 The data first reveal the wide diversity in type and severity of side-effect experiences 31 reported by users of contraception. Second, we found that women's rationales for why some 32 individuals suffer more side-effects from contraception invoke economic and physical 33 hardship (food insecurity and heavy workloads), as well as interindividual differences in 34 biology (one's blood must 'fit' with contraception). Finally, the analysis revealed the tension 35 many women face in trying to negotiate the trade-off between the consequences of these side-36 effects with those of an unwanted pregnancy. The results show the value of using a biosocial 37 approach, which centres women's voices and experiences, for informing the measurement of 38 contraceptive side-effects within population health surveys and clinical trials and for gaining 39 a greater understanding of how an individual's social, biological, and cultural contexts drive 40 variation in when and why different side-effects manifest.

41

43 Introduction

44 Side-effects are consistently cited as a leading reason why women have an unmet need for 45 contraception (Sedgh, Ashford, and Hussain 2016). Many women, who want to use 46 contraception to avoid pregnancy, choose not to use it or stop using it because of side-effects, 47 or, any unwanted bodily changes or symptoms associated with contraceptive use. The 48 proportion of women with unmet needs increases further if we include women who are 49 currently using contraception, but are dissatisfied with their current method due to sideeffects (Rominski and Stephenson 2019). Despite the importance of side-effect experiences 50 51 to contraceptive decision making, there continues to be significant methodological barriers to 52 understanding, measuring, and potentially reducing the contribution of negative side-effect 53 experiences to unmet need. These barriers include (1) a reliance on researcher-driven 54 measurement categories, (2) a lack of research on variation in side-effects, and (3) omission 55 of women's priorities in guiding research and technology development. A biosocial approach 56 utilising qualitative evidence can help address these gaps by revealing the lived experiences 57 of women across different cultural and ecological contexts. This knowledge can be leveraged 58 to inform future research outcome measures and to guide the development of comprehensive 59 measurement instruments.

60

(1) A reliance on researcher-driven measurement categories in studies about contraceptive use means that side-effect measurement tools, if employed at all, often don't 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 non-specific side-effects are lacking enough in
evidence 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).

75

76 Given this backdrop, it is perhaps unsurprising that detailed side-effects experiences are 77 rarely measured in population-based surveys, such as the Demographic and Health Survey 78 (DHS), which instead ambiguously asks past users of contraception whether they stopped 79 'due to fear of side-effects or health concerns.' This category has been critiqued as too broad 80 and non-specific (Jain et al. 2021; Rominski and Stephenson 2019), lumping all side-effect 81 experiences and fears together, and also failing to measure the occurrence of any side-effects 82 experiences among current users. Several recent studies have set out to measure side-effects 83 directly (Odwe et al. 2020; Rothschild et al. 2021; Keogh et al. 2021; Jain et al. 2021; 84 Zimmerman et al. 2021) and collect data on a broad range of specific symptoms to 85 understand their impact on contraceptive use decisions. Amongst others, these symptoms 86 include bleeding changes, weight changes, libido changes, headaches, dizziness, and delays 87 in return to fertility post-use. However, there is a huge range in the number and types of side-88 effects recorded (from 6 to 29 categories of side-effect symptoms collected), with only two 89 studies justifying which side-effects they chose to measure (based on literature reviews 90 (Keogh et al. 2021; Zimmerman et al. 2021) and prior qualitative studies (Zimmerman et al. 91 2021)). Several of these studies discuss limitations in current side-effect measurement 92 approaches and call for "further methodological research to identify how best to accurately

93 identify and quantify the experience of side-effects in large-scale, population-based surveys"
94 (Zimmerman et al. 2021). If we are to understand the true prevalence and diversity of
95 symptoms experienced, comprehensive measurement instruments would include user-driven
96 side-effect categories based on women's accounts of their experiences across different
97 contexts.

98

99 (2) There is a lack of research on variation in side-effects between women and across socio-100 cultural contexts, meaning that little is known about what causes certain women to suffer 101 more than others. Past qualitative studies have noted the presence of a perception among 102 users that some groups of women, particularly those living in poverty or with poor diets, 103 suffer a greater burden of side-effects than others (Burke and Ambasa-Shisanya 2011; 104 Alvergne, Stevens, and Gurmu 2017). For instance, a study among women using 105 contraception in Morocco documented the perception that only "the rich who can afford a 106 balanced diet" should use hormonal contraceptives (Mernissi 1975). Despite this, no study to 107 our knowledge has set out to uncover the drivers of variation in side-effect prevalence and 108 understand which groups of women experience the greatest burden of side-effects. This is 109 partly because most clinical trials and public health studies ascribe to the biomedical logic of 110 a global standardised body (Lock and Nguyen 2018). This logic assumes that all women will 111 respond similarly to the same intervention, with variation seen as a pathological deviation 112 from a morally charged physiological 'norm' (Cullin, Vitzthum, and Wiley 2021). The 113 archetype of this standardised human body is Euro-American, meaning that much of 114 medicine does not account for non-pathological biological differentiation in other bodies 115 (Hamdy 2013). This concept has allowed for the testing and global exportation of 116 contraception, with the assumption that it will be equally as effective and acceptable in all 117 women.

118

119 Thus, contraceptive technology development research typically only captures a limited 120 proportion of the diversity in women's biologies and their reactions to using contraception, 121 due to the assumption that inclusion criteria will provide a representative picture for 122 extrapolating to all women. In actuality, trial conditions and participants are often far from 123 typical compared to most of the worlds' potential contraceptive users (A. Hardon 1992; 124 Bertotti, Mann, and Miner 2020), and in terms of geographies, African countries have been 125 particularly under-represented (Bick et al. 2021; Taylor-Robinson, Spearman, and Suliman 126 2021). Thus, if we are to meet the contraceptive needs of all women, research on side-effect 127 experiences is needed among participants more representative of the range of contraceptive 128 users. This follows the decolonising global health movement which exposes how coloniality 129 - hierarchies stemming from European imperialism that relate to economic wealth, power, 130 being, and knowledge production – underpins discourse and interventions to address any 131 health issue (Newman 2023). Calls have already been made to decolonise the development 132 and distribution of contraception (Sowemimo 2018; Bhatia et al. 2019) and to place critical 133 focus the language used to describe experiences of suffering among individuals across 134 different contexts (Hommes et al. 2021). However as it stands, dubious framings of sideeffect reports from women across the world persist, and there has been relatively little 135 136 investment made into contraceptive technology development to reduce side-effects (Callahan 137 et al. 2020a). This can be considered a form of structural violence given the concentration of 138 negative impacts among those already most marginalised (McLean and Panter-Brick 2018). 139 140 (3) The omission of women's broader priorities in guiding contraceptive research and 141

technology development has resulted in a focus on the impact of contraceptives on

142 suppressing fertility and has left out other outcomes which matter to women (Bertotti, Mann,

143 and Miner 2020). Many of the most commonly used contraceptive methods today were 144 created during the population control movement (Hartmann 1995) when efficacy and 145 continued use were prioritised by policy makers and providers over other qualities typically 146 more important to women themselves, such as acceptability and safety (A. P. Hardon 1992; 147 Bertotti, Mann, and Miner 2020). Thus, there has been a lack of focus on measuring 148 outcomes beyond continued use of contraception, which has persisted in some contemporary 149 family planning policies (Hendrixson 2019) and recent clinical trials (Inoue, Barratt, and 150 Richters 2015). Further, population-based surveys which do measure side-effects directly 151 alongside other metrics predominantly do so to understand their impact on discontinuation or 152 non-use. One study in Kenya, did look more broadly and investigated associations between 153 side-effect experiences and contraceptive satisfaction among current users, found that 154 bleeding and non-bleeding side-effects were both associated with reduced method 155 satisfaction, particularly when experienced together (Odwe et al. 2020). Nevertheless, there is 156 still a lack of quantitative research that seeks to measure the impact of side-effects on 157 women's wider lives, despite the large body of evidence from qualitative studies that side-158 effects can be severe and matter greatly to women, particularly when understood within an 159 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 160 161 priorities of avoiding unwanted pregnancy whilst trying to maintain their health and quality 162 of life.

163

164 This paper aims to provide a biosocial perspective on the extent and drivers of side-effect 165 variation in Ethiopia using a qualitative approach. A biosocial perspective conceptualizes the 166 biological and social as mutually constituting, enabling the of models and methods from the 167 biomedical and social sciences to explain patterns in side-effect experiences and impacts

168 (Harris and McDade 2018). By using a qualitative approach, the research aims to capture a 169 wider range of side-effect experiences, their impacts on women's lives, and individual 170 rationales for why some women suffer more side-effects than others. To that end, we 171 conducted in-depth interviews and focus group discussions with users of the injectable and 172 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 173 174 understanding of side-effects, rather than merely considering their role in driving 175 discontinuation.

177 **Research context**

178 This research is situated in Ethiopia because the country has a well-established government-179 funded family planning through its Health Extension Program (Assefa et al. 2019), meaning 180 that cost and access barriers to contraception are typically less prevalent than side-effect 181 related concerns. For instance, 52% of Ethiopian women who discontinued their method 182 whilst still in need of contraception in 2016 did so due to side-effects and health concerns, 183 compared to only 11% who gave lack of access as a reason (CSA Ethiopia 2016). Despite 184 these concerns, modern contraceptive prevalence in Ethiopia has risen from 4.7% in 2000 to 185 28.1% in 2019 (EPHI 2021). This can predominantly be attributed to the uptake of two main 186 methods: the 3-month progestin injectable contraceptive, and increasingly 3-year progestin 187 implant, which according to the most recent DHS made up 67% and 21% of modern 188 contraceptive use respectively in 2019 (Ethiopian Public Health Institute (EPHI) and ICF 189 2021). The injectable, or 'depo' as it is known locally, has maintained long-term popularity 190 through provision in government health services, its ease of use, and the secrecy it affords. 191 The use of implant, known locally as 'the buried one', has been increased recently through 192 the Implant Access Program, a Western-funded private-public partnership seeking to expand 193 lower income countries' access to long-acting contraceptives through a cost-reduction 194 scheme for bulk purchases, criticised for leading to targets for implant distribution 195 (Hendrixson 2019). Indeed, qualitative studies from Ethiopia and other sub-Saharan African 196 contexts have now documented instances of reluctance or even resistance among health care 197 providers among women seeking removals or to switch from the implant (Senderowicz 2019; 198 Yirgu et al. 2020), which was also a concern among our study participants. Our study sites in 199 Central Oromia, in and around the urban centres of Adama and Bishoftu, were chosen based 200 on previous research identifying side-effects as a significant barrier to contraceptive use and 201 quality of life in the area (Alvergne, Stevens, and Gurmu 2017). Additionally, despite high

- 202 levels of urban growth in both, there remains remote rural locations in close proximity, with
- 203 significant rural-urban variation in lifestyle allowing the experiences of women living across
- a range of social and ecological contexts to be captured.

206 Methods

207 Study design

208 We conducted fifteen in-depth interviews (IDIs) and five focus group discussions (FGDs) 209 between January and March 2020 with women, aged 18-35, who had used either the 210 injectable or implant contraceptives in the last 5 years, allowing us to document the accounts 211 of both current and past contraceptive users. As contraceptive use is most common within 212 marriage in Ethiopia, all but one of the recruited informants were married. We also undertook 213 three key informant interviews (KIIs), two with health workers and one with a husband of 214 one of the participants. In total, we interviewed 15 women in IDIs, 2 health extension 215 workers (HEWs) and 1 husband in KIIs, and 25 women in 5 FGDs with 4-6 women per FGD 216 (total N = 43).

217

218 IDIs were the best suited to explore in detail women's personal lived experiences, whereas 219 FGDs were useful for understanding consensus or divergence in opinion between women. 220 KIIs improved our understanding of the wider environment of women's contraceptive use. 221 Due to the COVID-19 crisis, it was not possible to attain the number of interviews initially 222 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 223 224 and Lincoln 2017). Due to these limited numbers, our findings from KIIs with health workers 225 and husbands are unlikely to cover a significant breadth of husband and health worker views 226 on side-effect experiences, but the findings were maintained in the analysis as they provided 227 useful depth and alternative perspectives to explain our findings.

229 **Recruitment of study informants**

Health extension workers (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, 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).

235

236 Data collection

237 After a referral was made by the HEWs, participants were then invited to a health post or 238 visited in their homes, depending on their preference. Study aims and procedures were explained to participants, and participants were asked for their informed consent before 239 240 recruitment to the study. If consent was given, interviews and discussions were conducted in 241 Amharic or Afan Oromo by a qualified Ethiopian female research assistant (the third author) 242 with a master's degree in Reproductive Health and several years' experience working within 243 the local health system. The first author, a British female doctoral student, was present for all 244 interviews, but otherwise interviews were conducted in private, away from HEWs and other 245 household members. Basic sociodemographic data on age, education, religion, parity, and 246 occupation was obtained at the beginning of the interview. Individuals were provided with a 247 kilo of coffee as a gift in kind for taking part. This was considered suitable compensation 248 after much discussion with local stakeholders, as it is a culturally valued commodity that 249 would be received with gratitude without any risk of coercion to take part.

250

Interviews and discussions were carried out using semi-structured guides, developed with feedback from Ethiopian stakeholders, including academics, policy makers, and health professionals. This feedback was obtained through a stakeholder workshop in Addis Ababa

254 prior to data collection, where study aims and methodology were presented and opportunities 255 to ask questions and give feedback, both via a group discussion and evaluation forms, were 256 provided. Guides were translated by an independent source initially, checked separately by 257 authors fluent in local languages, and pretested prior to data collection. Guides were 258 repeatedly re-evaluated in an iterative process to obtain in-depth information and cover the 259 breadth of experience. Semi-structured guides allowed for a more open and non-leading style 260 of interview that gave priority to women's voices and allowed them to use their own words 261 (Pope and Mays 1995). Participants were asked about the occurrence, breadth, and severity of 262 side-effect experiences, why they perceived some women to suffer more than others, and how 263 women negotiate the social, physical, and economic costs of these side-effects within their 264 wider lives. Women were given time to tell their own narratives of side-effect experiences 265 and interviewers were committed to not conveying any judgement as to valid or invalid side-266 effects by using open-ended side-effect questions and listening to any experiences that arose 267 in discussion. All discussions were tape recorded, transcribed, and then translated into 268 English by the interviewer. Discussions focused on understanding reasons for contraceptive 269 use, the types of side-effects women experience, their frequency and severity, variation 270 between women, and the impacts of side-effects on day-to-day life. Each interview lasted 271 around 20-30 minutes and each FGD between 40 minutes to 1 hour.

272

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 to create initial codes for
organising the data, noting repeated or emerging issues upon which themes were developed.

279 A bottom-up data driven approach to thematic analysis was employed, using constructivist 280 principles and with particular attention to the types of side-effects mentioned and women's 281 logics of what drove their occurrence (Braun and Clarke 2006). Developing themes were 282 discussed throughout between authors, with particular focus on the literal and cultural 283 meanings underpinning the words used to describe side-effects experiences and 284 vulnerabilities. Meetings took place weekly between the first author and the interviewer as 285 transcripts were being translated and reviewed for the first time in order to discuss any arising 286 translation issues and initial reflections on the emerging themes. These discussions 287 contributed to reducing cultural and confirmation bias in interpretation by checking that both 288 authors perceived the meanings of respondents similarly. Meetings with the whole authorship 289 team additionally took place every few weeks as analysis progressed to gather further 290 expertise and challenge any unexpected results. Based on these discussions, themes were 291 iteratively revised until a narrative picture of the results arose, which is portrayed visually in 292 a conceptual representation (see Figure 1 in Results section). 293

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296

298 **Results**

299 **Descriptive summary of sample**

300 Descriptive characteristics of our sample demographics are shown in Table 1. As women in 301 the local area typically choose to use contraception for birth spacing, often after the birth of 302 their first child, all women in our sample had been married and had children, and there was a 303 slight skew towards women 30 years or older. Whilst there was a range of cultural, religious, 304 and administrative types of marriage among our participants, all described themselves as 305 formally married rather than in informal marriages, characterised by cohabitation without a 306 formal union. Nearly two thirds of women described themselves as being a housewife, 307 typically implying that they do not engage in paid economic activities but look after children 308 and carry out informal agricultural and economic activities. Others were students, manual 309 labourers, or government administrative employees. Protestants are overrepresented in our 310 sample compared to their proportion in the general local population, which is only around 311 10%, suggesting some selection bias in our recruitment. One of our rural sites had a large 312 Protestant missionary presence, which may explain the high proportion of Protestants there. 313 The two female health workers interviewed were a nurse and a health extension worker, 38 314 and 28 respectively, one Muslim and one Protestant, both married and with their own 315 children. The husband interviewed was aged 34, degree educated with 2 children, and worked 316 in the government offices.

317 Side-effect experiences encompassed a wide range of symptoms and

318 severity

319 Despite contraception being seen as a necessary and useful tool, many women were not 320 satisfied with their experiences while using it. Across both urban and rural areas, women 321 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.

325

326 Side-effects relating to **bleeding and blood flow**, such as not bleeding at all, bleeding too 327 much, bleeding too irregularly, or bleeding with too much pain, were commonly reported. 328 Women highly valued seeing their monthly bleed and cited "feeling like a man" or worrying 329 about infertility if they did not see it. Several women even reported that after long periods of 330 injectable-induced amenorrhea, they would switch to the pill for a month just to see their 331 monthly bleed. Irregular, increased, or painful bleeding during contraceptive use was 332 reported as highly problematic: "Depo! Oh my God! My menses was irregular, coming every 333 2-3 months. When it comes it has aching type of pain, bleeds heavily..." (Housewife in urban 334 Adama, 34, 5 children, Diploma, Protestant) or "I can't tolerate the side effect of the 335 injection. Like the bleeding didn't stop, there was too much bleeding" (Housewife in Rural 336 Adama, 35, 3 children, Grade 6, Protestant). Wider public health and medical literature often 337 refer to irregular bleeding as a 'nuisance' or 'minor' side-effect (Grimes and Schulz 2011) 338 and the injectable patient information leaflet describes irregular bleeding as "normal and 339 nothing to worry about" (Pfizer 2024). However, these experiences were seen as common 340 and very serious to users, given the disruption they can cause to a woman's wider domestic, 341 work, school, social, or religious life. They took a toll on marital relationships: "When he [a 342 husband] has sexual desire, he asks how can you always say I'm on menstruation. It is 343 difficult to say it has minor side effects. There is a lot of hassle in our house" (Focus Group 344 in rural Adama). Even basic activities, such as taking public transport were made difficult, 345 impacting women's abilities to achieve their wider goals: "Yes, since I bleed heavily, I even 346 feel difficulties in attending class, and even staying on transportation to reach my school,

347 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.

351

352 Weight changes were commonly cited as side-effects and whilst some women did report 353 weight changes as being a positive effect of taking contraception, in general they were seen 354 as a negative: "Yes, it has a psychological effect; becoming too fat or too thin without any 355 reason is stressful" (Focus Group in rural Adama). Some women reported that this weight 356 gain impacted their appearance in a way they were not happy with and this was enough to 357 cause them to stop their method. Despite a lack of high quality evidence, these reports are 358 congruent with published reviews showing injectable or implant use to be associated with 359 weight gain (Dianat et al. 2019; Moray et al. 2021). There seemed to be variation in these 360 experiences with other participants reporting weight loss, often along with a suite of other 361 negative symptoms: "When I was using implanon after I gave birth I had prolonged heavy 362 menses, dysmenorrhea, weight loss and in general I was suffering" (Focus Group in urban 363 *Bishoftu*). Bleeding and weight changes often were reported together in our discussions, with 364 heavy bleeding particularly associated with weight loss and implant use and amenorrhea 365 associated with weight gain and injectable use. Others appreciated weight gain as a positive 366 side-effect and saw contraception as a way to counteract being too thin, described as being "" or "like a stick": "I am using the injectable [...] I am happy with it. Also, I prefer it, 367 368 wishing to gain weight. As you see, I am dry" (Focus Group in rural Adama).

369

370 Delays in return to fertility and potential infertility were cited by many women as side371 effects that they had experienced or worried about. A scoping review of fears about infertility

372 in Africa identifies a body of literature which predominantly frames women as 'believing 373 myths' if they worry about infertility associated with contraception (Boivin et al. 2020). 374 However, several women in our discussions reported direct experiences of struggling to 375 become pregnant for a while after stopping contraception. They perceived this to be due to 376 their contraceptive use and some worried it might have made them infertile more long-term: 377 "I am using the injectable and it is comfortable to me, but my menses didn't come, when I 378 want to be pregnant, I couldn't conceive quickly and it was delayed for one year" (Focus 379 Group in urban Adama). These fears may not be unfounded given a recent analysis of DHS 380 data from 47 countries which shows that women do experience delays in return to fecundity 381 after using many contraceptives, particularly injectables and implants (Gemmill, Bradley, et 382 al. 2023). Additionally, a recent trial of the lower-dose Sayana press injectable contraceptive 383 found that the patient leaflet, which claims that 80% of women desiring pregnancy will 384 conceive within one year after stopping use, is likely a significant overestimate, with one 385 study suggesting that women should expect to wait at least a year or more to return to fertility 386 after repeat dosing of the injectable (Taylor et al. 2022).

387

Being without a child in Ethiopia can have serious consequences for marital and social 388 389 relationships and health workers in our discussions reported that women faced difficulty if 390 they could not conceive: "Women who experience that they couldn't conceive by the time 391 they want find it causes conflict in the house with their husband. It has great impact on their 392 *life"* (Nurse in urban Adama, 38, 3 children, Orthodox). As timing a child was reported to be 393 a delicate balance of economic factors in this context, women valued the ability, once they 394 have the correct conditions, to become pregnant easily and if they could not, it had a negative 395 impact on their lives: "It is obvious people take it seriously, missing a child. You know after 396 they have good and full living conditions, not being able to have a child is very hard"

397 (*Housewife in rural Adama, 34, 2 children, Grade 10, Orthodox*). These findings support
398 other studies of fertility decision making among women in more uncertain circumstances,
399 which shows that the ability to flexibly time one's fertility to prevailing conditions is a strong
400 priority (Johnson-Hanks 2015; Trinitapoli and Yeatman 2018).

401

402 Women also experienced headaches, nausea, and feeling light and dizzy: "I switched to the

403 three years one and my bleeding stopped, but it makes me severely ill. I was feeling like my

404 *head was becoming light and dizzy" (Housewife in rural Adama, 35, 3 children, Grade 6,*

405 *Protestant*). These changes often came with other mental health changes of lower mood,

406 greater irritability, disappointment, and lowered libido: "While using the injection before,

407 I don't know, I used to be irritable and complain, headache, increase in my body weight and

408 *I was feeling disappointed [...] I was experiencing severe headache and I was whiny*"

409 (Housewife in urban Adama, 30, 3 children, Protestant). Published reviews show that there is

410 some quantitative evidence for the association of injectable and implant use with these

411 symptoms (Moray et al. 2021; Dianat et al. 2019), but the quality of evidence is mixed as

412 these symptoms often go unmeasured in clinical trials or dubbed as non-serious adverse

413 events. However, many of these mental health and mood changes were reported frequently in

414 our sample as serious issues that caused concern or conflict in a woman's household. For

415 instance, many women were troubled by their drop in libido: "I have also a problem related

416 to decrease in sexual feeling, so I have conflicts with my husband most of the

417 *time*"(Housewife in urban Adama, 27, 1 child, Grade 9, Orthodox).

418

419 Many other types of bodily **pain** were reported. There were joint pains, reported in the hands,
420 back, and legs, sometimes leading to difficultly standing, tender breasts, pain at the injection

421 or insertion sites, and stomach pains: "All of them complain like me, like back pain, joint

422 pain, muscle pain. [...] I think all the above effects I mention are true, they speak what they 423 experience" (Housewife in rural Adama, 35, 3 children, Grade 6, Protestant). A Cochrane 424 review on hormonal contraception and bone fractures states that the injectable contraceptive 425 is associated with a loss of bone mineral density and there is some evidence for increasing 426 risk of fracture and osteoporosis with its continued use (Lopez et al. 2015). Based on this 427 risk, for women using the injectable contraceptive in the United Kingdom, a review is 428 recommended every two years in order to assess their individual situations and discuss its 429 risks and benefits (Faculty of Sexual & Reproductive Healthcare 2020). For many Ethiopian 430 women in our discussions, who had taxing physical lives of manual and agricultural labour, 431 particularly in rural sites, increased pain, or inability to use parts of their body that hurt could 432 have huge impacts on their day-to-day lives: "I experience pain in my hand. I can't wash 433 clothes, even I can't lift my hand" (Housewife in rural Adama, 34, 2 children, Grade 10, 434 *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 435 436 instance, the husband interviewed, married to one woman who had experienced such pain, 437 was very concerned for his wife and often had to help her: "Yeah, she had too much pain 438 while she was using the injectable, even when she wanted to do something, she just stopped 439 since she felt pain, so that me and other family members helped her" (Husband in urban 440 Adama, Government employee, 34, 2 children, degree, Protestant).

441

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 a 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

447 changed to the one inserted in the arm - again it made me lose weight and I developed skin 448 lesions on my face" (Focus Group in urban Adama). This effect also jeopardised women's 449 ability to use contraception discretely and in some cases, prompted others to advise them to 450 stop in fear for their health: "You can see my face, it's the effect of contraception. All people 451 know that I am using contraception, and they advise me to stop" (Focus Group in urban 452 Bishoftu). This was referenced heavily in interviews and fits with a biological explanation. 453 We know that high levels of progesterone, as experienced in pregnancy, create increased skin 454 sun sensitivity (Filoni, Mariano, and Cameli 2019), and similar effects have been observed in 455 oral contraceptive users in Brazil, particularly those with greater skin pigmentation capacity 456 and greater sun exposure (Handel et al. 2014). However, to the best of our knowledge this 457 effect is not measured quantitatively in any side-effects measure and is hardly mentioned on 458 the patient information for the injectable or the implant, which document an "uncommon 459 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 documents fear of 460 461 melasma among women in Cambodia and South Africa who reported worrying about 462 unwanted changes in skin pigmentation and increased sun sensitivity (Snow et al. 1997). 463

464 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*

472 get hurt" (Focus Group in urban Adama). These factors were considered to be related to 473 socioeconomic status: "People are different in their economic status, but all might use the 474 injection. In those who don't get balanced diets, due to low economic status, the side effects 475 will be severe" (Graduate student in rural Adama, 22, no children, Degree, Orthodox). 476 Women applied this rationale to explaining their own experiences: "Since I was experiencing 477 the side effects, I know very well if you don't get enough food, you will have effects. Now 478 even, I think that I am malnourished" (Focus Group Urban Bishoftu). Sometimes, women 479 reported that particular dietary components were even recommended by health workers as 480 remedies to side-effect experiences, despite the fact that these foods were often well out of 481 reach of women's budgets: "Yeah, the health professionals also advise me to take a protein 482 diet like egg, meat and milk after frequently complaining about my experiences, but you may 483 not get those foods easily" (Focus Group in urban Bishoftu). The importance of being able to 484 obtain a good diet also factored practically into women's contraceptive choices: "*Women*] 485 mostly want injectable because if it causes complications it's easy to act on it, so that they 486 want the short term one, also because they say implanon needs diversified food" (Health 487 extension worker in Urban Adama, 28, 1 child, Diploma, Muslim).

488

489 Whether a woman would have a "simple" versus "serious" burden of side-effects was often 490 discussed in terms of whether a particular method was a good fit to her body and her life. If a 491 contraceptive caused a woman to have side-effects, she would commonly report that 'lene 492 altesmamagnm' – meaning 'it does not fit with me' in Amharic: "I was using the three year 493 one, but it did not fit with me. I used to have abdominal cramps, back pain, headache, feeling 494 dizzy, bleeding that didn't stop..." (Focus Group in urban Bishoftu). A key driver of fit was 495 typically conceptualised in terms of "blood compatibility", "blood type", or whether a 496 contraceptive "fit with a woman's blood". For instance, when asked why a woman might get 497 side-effects, one woman answered: "Maybe if their blood is not fit with it, because some say

498 the injection is not good for me, I think this comes as result of the injection and the blood of 499 the individual being incompatible" (Cafeteria worker in urban Adama, 33, 4 children, Grade 500 5, Muslim). Literal translations of the terms used to describe fit in our findings ranged from; 501 did it 'fit' with her, was it 'compatible' or 'suited' to her or her blood, was it 'the same as', 502 'selected for' or 'comparable' to her blood, did it 'interact well' with her blood or even 'did 503 it make her look good'.

504

505 Despite their perceived knowledge of which women were most 'at risk', many lamented the 506 difficulty in knowing whether they would get side-effects from a specific method. They were 507 frustrated with the burden of having to try out several methods, potentially enduring negative 508 symptoms whilst using each of them, to try to find one that was acceptable to them. Women 509 wanted guidance as to which contraceptive method was least likely to personally cause them 510 side-effects and would 'fit' well with them to start with. This was typically expressed as the 511 wish for a test to ascertain compatibility with an individual's blood: "I think different blood 512 types fit with different contraceptive methods, so for the future, I would prefer to use a 513 contraceptive method that fits with my blood after investigation" (Housewife in rural Adama, 514 35, 3 children, Grade 6, Protestant). Women suggested that a test should be developed to 515 help determine the method with the fewest side-effects: "For me, I prefer if contraception is 516 given after each woman has their blood examined by their doctors. Nowadays, everybody 517 simply gives contraception" (Focus Group in urban Bishoftu).

518

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

520 Many contraceptive users found themselves in a difficult position, trying to decide whether to

521 endure the contraceptive side-effects they experienced and prioritise continuing use, or give

522 up entirely and risk an unwanted or mistimed pregnancy. As documented in other sub-

523 Saharan African settings (Schwarz et al. 2019), choosing to use contraception and endure 524 side-effects was a hard decision based upon multiple contextual trade-offs, including how 525 many children they currently had, time since their last birth, and their social and economic 526 responsibilities. Some women, who couldn't tolerate the side-effects and the consequences on 527 their marriage or daily activities, decided to stop using contraception despite not wanting a 528 child at that time: "[Side-effects] become a hurdle to their plan, she couldn't achieve her 529 goals. If she wants to learn, she couldn't because of it. So, they will discontinue and they 530 prefer becoming pregnant than suffering" (Focus Group Rural Adama). Many of them only 531 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" 532 533 (Focus Group Urban Bishoftu).

534

535 Among women who participated in our discussions, the experience of going on to have an 536 unintended pregnancy after contraceptive discontinuation due to method dissatisfaction was 537 not uncommon, nor is it across many different low and middle income countries as shown 538 quantitatively byt a recent analysis of DHS data (Gemmill, Sarnak, et al. 2023). Women in 539 our discussions reported that these pregnancies impacted their economic, educational, and 540 career prospects, as well as their social and marital relationships. For instance, a woman in 541 urban Adama (34, 5 children, Diploma, Protestant, Housewife) had been using contraception 542 to avoid pregnancy after her fourth child, while she waited for her children to grow up, so 543 that she was able to return to studying to seek a better job and greater income. However, due 544 to side-effects, she stopped using contraception and gave birth to a fifth child, delaying her 545 ability to attend education, confining her to staying at home to look after her new child and 546 negatively impacting her family's financial circumstances.

547

548 Thus, many women considered the impacts of having a child too great to warrant stopping on 549 account of the side-effects: "In my opinion the benefit outweighs the side-effects. [...] People 550 simply complain about side-effects, but it is better to use it to prevent having too many 551 children, having no job outside the home, taking care of the children, and waiting until 552 they're grown up" (Farmer in rural Adama, 35, 4 children, no education, Orthodox). In 553 some cases, women decided that they must keep using family planning despite severe 554 negative effects and advice from others counselling them to stop: "It's difficult to live without 555 planning. This is why I am using it, even if I am in pain. [...] Yeah, I am feeling sick; my 556 abdomen, back pain, joint pain. I am simply using it even if people advising me to stop since 557 my life is not good" (Housewife in rural Adama, 35, 3 children, Grade 6, Protestant). 558 Women, particularly in rural areas, consistently stressed the need to use contraception to 559 avoid a pregnancy based on their current economic circumstances and situational precarity. 560 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 561 562 poverty" (Focus Group in rural Adama). In addition to being able to time fertility to their 563 economic circumstances, women in urban areas in particular discussed fertility control as 564 important for "the good of the country". There was a perception that it was their duty to limit 565 the number of children they had so that children could be well educated, self-sufficient 566 financially, and not become a "burden" on the state. These statements reflect rhetoric 567 promoted in some family planning discourse, which places the responsibility on individual 568 women to control their fertility to alleviate economic hardship, rather than placing the focus 569 on structural improvement of services and employment options (Sasser 2018). 570

571 Figure 1 shows a conceptual representation of how these different results fit together and572 shows the many factors that individuals must balance when making contraceptive decisions.

573 Firstly, it shows how socioecological factors, such as economic uncertainty, physical stress, 574 social and marital relationships, and gender norms impact both a woman's a) fertility desires 575 and the expectations placed upon her concerning childbearing, and b) her susceptibility to 576 suffering negative side-effect experiences. We represent the subsequent trade-off a woman 577 faces in her decision to continue, switch method, or stop using contraception all together as a 578 set of scales, representing the weighing up of the often-serious impacts of either side-effects 579 or pregnancy, be it desired, mistimed, or unwanted. It specifically uses words and concepts 580 employed by women in our discussions to utilise their understandings of what drives side-581 effects and centre their perspectives. 582 583

585 **Discussion**

586

587 In this study with injectable and implant users in Ethiopia, we used a biosocial approach to 588 investigate the breadth of side-effect experiences reported by women, causal rationales for 589 variation in side-effect burdens, and how women balanced competing priorities in their 590 contraceptive decisions. Women reported suffering from a wide range of side-effects, 591 including bleeding irregularities, weight changes, fertility delays, pain, and skin changes 592 (melasma). They perceived that contraceptive side-effects would be experienced more 593 severely by women who had poor diets and hard physical occupations. Women most "at risk" 594 were often those with the strongest motivation to control their fertility. Physical side-effects 595 had a negative impact on women's quality of life leading to impaired ability to work, attend 596 education, and perform daily chores as well as causing marital conflicts. Finally, participants 597 built on folk biology understandings and expressed their desire to access contraceptives that 598 would "fit" their body, i.e., that would minimise side-effects given their personal biology, a 599 finding that supports calls to develop a personalised medicine approach to contraception (Hill 600 and Mengelkoch 2023; Cella and Wagner 2015).

601

602 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

610 worrying experience among women living in precarious economic circumstances or under 611 social expectations to bear children, who are typically under great pressure to conceive in a 612 small window (Trinitapoli and Yeatman 2018). Increased sun sensitivity and the subsequent 613 development of dark marks or lesions on the face with contraceptive use, which is poorly 614 documented in other studies, was considered a serious issue, particularly given the presence 615 of other mediating risk factors in the local ecological context, such as high sun exposure. 616 These marks were an incredibly troubling side-effect in our sample, given their impact on 617 facial aesthetics, secrecy of contraceptive use, and incitement of concern among close 618 relations. Thus, which side-effects are considered serious, and how they are weighted against 619 other priorities around fertility and contraceptive use, cannot be understood without 620 understanding the context they are experienced within (Alvergne and Stevens 2021). These 621 findings highlight the importance of conceptualising contraceptive side-effects using a 622 biosocial lens, as bodily, biological experiences fundamentally mediated in their likelihood of 623 manifestation and impact by the social, environmental, and structural context within which 624 they are experienced.

625

626 What causes variation in contraceptive side-effects?

627 In our sample and around the world, women perceive that some women suffer more than 628 others with side-effects. Women in our sample assumed that there ought to be a way to 629 predict risk of side-effects and they wanted to know which contraceptive would 'fit' well 630 with them or be 'compatible with their blood' before they chose their method. These findings 631 echo other studies from sub-Saharan Africa about method fit and risk of side-effects. For 632 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 633 634 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.

640

641 Even without having a test to find out, participants in our study expressed various rationales 642 for which factors would drive good fit and which women were most likely to suffer from 643 side-effects. They perceived that women living in poverty, with harsh physical routines, poor 644 food security, and poor general health, were those who had the least resilience to 645 experiencing side-effects. Interestingly, many of these characteristics are also found to be 646 associated with low natural levels of endogenous reproductive hormone levels (Vitzthum 647 2009). Calls have been increasing to investigate how this variation in endogenous hormone levels may interact with external contraceptive hormone doses to impact chance of 648 649 experiencing side-effects (Vitzthum and Ringheim 2005; Alvergne and Stevens 2021), yet it 650 remains untested directly.

651

652 Women with characteristics perceived as leaving them most at risk of side-effects are 653 commonly excluded from the contraceptive development process. For instance, the dose 654 finding study for the new lower dose Sayana Press injectable contraceptive (DMPA-SC 655 104mg) excluded adolescents, those with irregular menstrual cycles, women not in 'good 656 general health', underweight, anaemic or breastfeeding women (FHI 360 2016). These 657 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 658 659 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).

664

665 Future studies investigating how the characteristics that women report as increasing the risk 666 of side-effects associate with a higher burden of symptoms are warranted. Such knowledge is key to guide inclusion criteria when estimating side-effect probabilities and during the 667 668 development of new contraceptive methods. This knowledge would also support precision 669 medicine approaches to contraception that aim to provide contraceptives that minimise risk of 670 side-effects given an individual's characteristics (Cella and Wagner 2015; Hill and 671 Mengelkoch 2023). For instance, recent innovations in personalised decision-making support 672 for choosing which contraceptive to use (Lazorwitz et al. 2021) are already going some way 673 to fulfil women's request for a test to help find the method that will likely work best for them. 674 These tools can be further improved with increased information on the risk of side-effects 675 among different women living in different contexts. These innovations follow calls from other avenues which advocate for more research into improved contraceptive technologies 676 677 (Callahan et al. 2020b), and fundamentally reject the idea that contraceptive side-effects are 678 just 'the price women pay' for preventing pregnancy (Schwarz et al. 2019; Rothschild et al. 679 2021).

680

681 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

685 pregnancy. They faced a dilemma: either continue to use contraception and tolerate a serious 686 burden of side-effects or stop use and handle some of the most serious consequences of 687 pregnancy - parenting as best they could within difficult circumstances. This can be 688 considered a form of structural violence (McLean and Panter-Brick 2018) when the only two 689 '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 690 691 symptom burdens would likely have most effect from an equity perspective if they were 692 centred on women whose lack of economic and physical capital gives them neither resistance 693 to side-effects nor the ability to handle an unplanned pregnancy This focus would utilise a 694 reproductive justice approach which 1) critiques the validity of the concept of choice when an 695 individual has only limited and unattractive options available to them and 2) which centres 696 the rights to choose when to have a child, when not to have a child, and the conditions to 697 parent a child as you wish (Ross and Solinger 2017b).

698

699 The value of a qualitative biosocial approach

700 By utilising qualitative methods within a biosocial approach, it is possible to gain a deeper 701 understanding of variation in contraceptive side-effect experiences and to inform the 702 development of methods for quantitative estimation of side-effects. By first asking about 703 lived experiences of side-effects in an open-ended way without pre-specified categories as to 704 the validity or importance of the reports provided, efforts to measure or alleviate side-effects 705 can be better centred on women's own experiences and priorities. An exploratory qualitative 706 approach can help identify symptoms which may otherwise go unmeasured or novel logics 707 for why some women may experience the worst burden of side-effects. It can also help reveal 708 where symptoms previously considered minor and dismissible may have salient impacts 709 given a certain cultural or ecological context. Whilst qualitative information may have

710 limited utility as direct evidence for the physiological causes of side-effects or to what extent 711 the reported symptoms are wholly attributable to contraceptive use, it still provides crucial 712 information about the perceived social, cultural, and biological factors influencing women's 713 experiences of side-effects and contraceptive decision making. With this knowledge, we may 714 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 715 716 and blanket categorise side-effect worries as myths and misconceptions. Centring satisfaction 717 and women's priorities beyond just continued use follows calls to broaden definitions of 718 unmet need (Rominski and Stephenson 2019; Senderowicz and Maloney 2022) by focusing 719 more on users' satisfaction and ability to regulate their fertility, free of experiences of 720 suffering or worry. It also follows calls from reproductive justice and decolonising global 721 health movements to consider whose words we choose to listen to, the words we use to 722 describe individuals' experiences of suffering, and the value of storytelling (Ross and 723 Solinger 2017a; Hommes et al. 2021).

724

725 Limitations

726 Our results are limited in their generalisability. Firstly, for comparisons within Ethiopia, our 727 sample was overwhelmingly women who were married and had children and therefore our 728 findings cannot necessarily be extrapolated to those using contraception before marriage or to 729 delay or avoid the birth of their first child. Additionally, protestants are overrepresented in 730 our sample, suggesting a selection bias meaning that the views captured may not be 731 representative of the local population. Nonetheless, our results may be likely to be more 732 representative of side-effect experiences across Ethiopia than many clinical trials that exclude 733 women who are underweight, in poor health, or anaemic amongst 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.

736

737

738 In conclusion, future population health and contraceptive development studies that seek to 739 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-740 741 effect symptoms while centring women's own voices and priorities. Measurement tools can 742 then be designed that better capture women's side-effect experiences and priorities, 743 particularly among those whose voices are commonly excluded from studies. With the 744 collection of high-quality data on variation in side-effect experiences between individuals and 745 contexts, we may finally be able to answer calls from precision medicine and women 746 themselves to personalise contraceptive prescription to minimise side-effects and better meet 747 women's contraceptive needs.

Tables

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Table 1: Descriptive characteristics of participants interviewed.

752 Figure legends

753 Figure 1: Conceptual representation of the perceived relationship between socioecological

context, side-effect susceptibility, fertility desires, and the trade-offs involved in contraceptive

decisions.

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759 Ethical Approval

760

- 761 Ethical approval was obtained from four bodies before data collection commenced: the
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- 763 Department of Microbiology Immunology and Parasitology, and the College of Health
- 764 Sciences at Addis Ababa University; and the Oromia Health Bureau. We obtained letters of
- permission from health offices at the zonal and woreda (county) levels and approached the
- administrating health centre in each kebele to obtain their support.

767 **Conflicts of Interest**

The authors have no conflicts of interest to declare.

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