1	Title: Women's perspectives on, and experiences of using postpartum intrauterine device in
2	Tanzania
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11	
12	Abstract
13	Despite numerous attractive features of the immediate postpartum copper intrauterine
14	device (PPIUD), it is underutilized in many resource-constrained settings, including Tanzania. We
15	conducted in-depth interviews with 20 pregnant women after receiving contraceptive counseling and
16	27 postpartum women who had PPIUD inserted to understand reasons for use versus non-use and
17	continuation versus discontinuation. The majority of women who received counseling planned to
18	use PPIUD after delivery, primarily motivated by perceived lack of side-effects, convenience, and
19	trust in information received during counseling. Barriers to PPIUD use included fear of method-
20	specific side-effects, perceived lack of adequate information, and preference for alternative methods.
21	We will report themes related to PPIUD continuation at the conclusion of data analysis. Postpartum
22	contraceptive counseling may be more effective if fears associated with PPIUD are addressed more
23	thoroughly and counselors focus on rapport-building. Our study will highlight important barriers to
	thoroughly and courselors rocus on rapport bundling. Our study with ingringht important barriers to

25	Background
26	Despite many postpartum women's desire to delay their next pregnancy, few use
27	contraception (Ross & Winfrey, 2001). Short birth intervals, defined as pregnancies conceived less
28	than 18 months following a prior birth, are associated with increased risk of adverse perinatal
29	outcomes, such as preterm birth, low birthweight, and small size for gestational age (Conde-
30	Agudelo, Rosas-Bermúdez, & Kafury-Goeta, 2006). In low- and middle-income countries (LMICs),
31	birth intervals less than 36 months may result in increased risk of neonatal and infant mortality and
32	undernutrition (Rutstein, 2005). Postpartum contraceptive use may improve health outcomes
33	through longer birth spacing (Cleland, Conde-Agudelo, Peterson, Ross, & Tsui, 2012; Yeakey et al.,
34	2009). Improving access to contraception following a birth is critical to avoiding unintended
35	pregnancy and improving the health and wellbeing of women and their children.
36	The copper intrauterine device (IUD) is well-suited for use in the postpartum period. The
37	immediate postpartum copper intrauterine device (PPIUD) is highly-effective, long-lasting,
38	reversible, and requires little maintenance (Kapp & Curtis, 2009; Polis et al., 2016). PPIUD does not
39	interfere with breastfeeding and is safe for use by the vast majority of women, including those with
40	asymptomatic or mild HIV (Lopez, Bernholc, Hubacher, Stuart, & Van Vliet, 2015; World Health
41	Organization, 2015) and is associated with less discomfort than insertion outside of the immediate
42	postpartum period (Lopez et al., 2015). In low-resource settings, where many women experience
43	access-related barriers to postnatal care (Vernon, 2009), PPIUD offers a cost-effective and
44	convenient option for postpartum women wanting to avoid another pregnancy (Foreit, Foreit,
45	Lagos, & Guzman, 1993). Moreover, in some African settings, women have reported high levels of
46	satisfaction with PPIUD (Blumenthal et al., 2016; Bryant et al., 2013). Despite numerous benefits of
47	PPIUD, insertion rates remain low in LMICs (Pfitzer et al., 2015).
48	Within LMICs, barriers and facilitators of PPIUD use and continuation are underexplored in
49	the literature. This is surprising, given the potential benefits to women in resource-constrained
50	settings, and the renewed interest in postpartum contraception over the last decade among
51	researchers and practitioners (Cleland et al., 2012). Only a handful of studies have explored barriers
52	to PPIUD use in LMICs. For example, fear of insertion (Bryant et al., 2015; Vansjaliya, Prajapati,
53	Shah, & Parmar, 2017), fear of side effects and infertility (Bryant et al., 2015; Robinson, Moshabela,
54	Owusu-Ansah, Kapungu, & Geller, 2016; Vansjaliya et al., 2017), and preference for interval IUD or
55	another method (Mohamed, Kamel, Shaaban, & Salem, 2003; Vansjaliya et al., 2017) have been

56 documented as barriers to PPIUD uptake in Malawi, Egypt, Ghana, and India. Existing literature on

57 the facilitators of PPIUD use is even more sparse. A prospective observational study of PPIUD users in Zambia suggests that long-term protection against pregnancy was the most important 58 59 motivator for PPIUD uptake (Blumenthal et al., 2016). A qualitative study of Malawian PPIUD 60 users, discontinuers, and nonusers and their male partners revealed three primary facilitators of PPIUD use were trusting the information given by health providers, involvement of male partners in 61 62 decision-making, and past experience of side-effects while using short-term hormonal methods (Bryant, Hamela, Gotter, Stuart, & Kamanga, 2015). A more nuanced understanding of what 63 motivates postpartum women's decisions to use or not use the PPIUD, as well as reasons for 64 65 dis/continuation, is needed to improve family planning programs and postpartum services.

66 Most women do not use contraception in the postpartum period in Tanzania. Within six 67 months of delivery, only 23 percent of women use any method of family planning to avoid 68 pregnancy (Winfrey & Rakesh, 2014). Among women who do use contraception within 12 months 69 after delivery, most rely on lactational amenorrhea method (LAM) (26%) or injectables (23%), while 70 almost no women use the IUD (Winfrey & Rakesh, 2014). Due to low contraceptive prevalence, 71 short birth intervals are common: one in five births occurs within 24 months of the previous birth 72 (Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) 73 [Tanzania Mainland], Ministry of Health (MoH) [Zanzibar], National Bureau of Statistics (NBS), 74 Office of the Chief Government Statistician (OCGS), and ICF, 2016). 75 The aims of this study were to 1) explore currently pregnant women's attitudes towards the

PPIUD, highlighting reasons for planned use or non-use, and 2) understand the rationale for
contraceptive decisions, including reasons for continuation or discontinuation of use among women
who had PPIUD inserted. We use data from 20 in-depth interviews with currently pregnant women
conducted after facility-based antenatal and postpartum contraceptive counseling, and from 27 indepth interviews with postpartum women who had PPIUD inserted 9 months prior to the interview.

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Methods

83 Program Description and Parent Study

The International Federation of Gynecology and Obstetrics (FIGO), in collaboration with its national societies, launched an initiative in 2013 to institutionalize PPIUD services as a routine part of antenatal counselling and delivery room services in six LMICs: Tanzania, Nepal, Sri Lanka, India, Kenya, and Bangladesh. The initiative trained community midwives, nurses, doctors, and delivery unit staff on the provision of counselling and postpartum contraceptive services and aimed

89 to institutionalize the provision of counselling and postpartum contraceptive services in selected 90 urban health facilities. The intervention primarily focused on changing provider knowledge and 91 behavior by training providers on postpartum family planning, with an emphasis on PPIUD 92 counseling and insertion techniques as a newly added service. Providers were expected to improve 93 patient knowledge and assist with informed choice through counseling delivered during antenatal 94 care services. During these counseling sessions, clients were provided information about family 95 planning methods, including how methods work, duration of use, effectiveness, and side effects. 96 Furthermore, clients were shown how the PPIUD was inserted through counselling aids, such as 97 visual aids, informational brochures, and anatomical models. Women who were counselled on 98 PPIUD during antenatal care were able to consent to PPIUD insertion after delivery, and their 99 medical charts were marked with their stated decision. Women who consented before delivery were 100 also asked to provide consent a second time before PPIUD insertion to confirm their decision.

101 The Postpartum Intrauterine Device (PPIUD) Study was undertaken to evaluate the causal 102 effect of the initiative on the uptake and subsequent continued use of PPIUD in Tanzania, Nepal, 103 and Sri Lanka. In Tanzania, the study was conducted in five urban cities: Dodoma, Mbeya, Dar es 104 Salaam, Arusha, and Pwani. A teaching hospital and its satellite clinics were selected in each area to provide national geographic coverage. The FIGO intervention in satellite clinics focused on 105 106 postpartum contraceptive counseling during ANC so that women delivering in the teaching 107 hospitals could be counseled and make a decision on postpartum contraceptive use prior to delivery. Canning et al. (2016) provides detailed information about study procedures. 108

109 Study Design and Data Collection Procedures

110 This qualitative investigation was nested within the PPIUD Study in Tanzania. To assess the performance of the initiative, in-depth interviews were conducted with 20 women who had had at 111 least two antenatal care visits and had not yet delivered (conducted between June 2016 and February 112 2017), hereafter known as baseline interviews, and a separate sample of 27 women who received a 113 114 PPIUD after delivery (conducted between April and August 2018), hereafter known as follow-up interviews. Baseline interviews were conducted following an antenatal care visit. Follow-up 115 116 interviews were conducted approximately 12 to 18 months postpartum. We determined that a 117 sample size of 20 and 27 women for baseline and follow-up interviews, respectively, would be sufficient to achieve saturation in themes and to achieve study aims (Corbin & Strauss, 2008). 118 119 We developed semi-structured interview guides in English and translated the guides into 120 Kiswahili. Tanzanian colleagues verified translations and back-translated the guides to ensure

content and semantic equivalence of each question (Brislin, 1970). In addition, we pre-tested the
interview guides to assess question phrasing, sequencing, and overall comprehension. The interview
guides were modified on the basis of the pre-testing.

124 Women were eligible to complete a baseline in-depth interview if they received at least two antenatal care sessions in a teaching hospital or satellite clinic receiving the FIGO intervention. Four 125 126 women were purposively sampled from each urban area on the basis of their socio-demographic characteristics (higher and lower income, and young women under age 25 and women age 25 or 127 128 older). A trained female data collector worked with facility staff to identify women who met the 129 eligibility and selection criteria. Women were purposively selected for follow-up interviews on the 130 basis of PPIUD outcomes (i.e., continuer, discontinuer due to expulsion, intentional discontinuer). 131 Hospital staff called women to inform them about the interviews, briefly explained the purpose of 132 the interviews, and requested participation. Hospital staff scheduled times for women to come to the 133 hospital for interviews.

Before each interview, trained Tanzanian researchers gave participants a choice of providing 134 135 oral or written consent to take part in the study, depending on their literacy and ability to sign their 136 names. Participants who were unable to sign their names provided a thumbprint signature with a 137 witness' signature. No identifying information was collected from participants. Trained Tanzanian 138 researchers conducted the one-on-one interviews in a private space on-site at the facilities and in the 139 Kiswahili language. Open-ended interview questions solicited information about participant 140 demographic characteristics, reproductive health and family planning behaviors, and perceptions of 141 and experiences with PPIUD. Interviews were audio-recorded with the woman's permission, and 142 subsequently transcribed and translated to English for analysis. On average, interviews lasted 60 to 143 90 minutes.

144 Analytical Strategy

We used ATLAS.ti (Version 8.0, Scientific Software Development, Berlin) for data 145 146 management, coding, and analysis. We approached data analysis from a narrative approach and 147 thematic inquiry (Padgett, 2008). The analysis involved four stages in order to develop the 148 codebooks and identify key themes. In the first stage, the second author prepared an initial list of 149 codes and definitions applicable to the baseline interviews, informed by the existing literature on 150 postpartum contraception and aims of the study. Two analysts independently reviewed baseline 151 transcripts line-by-line to apply codes and develop the final codebook. Second, the 20 baseline interviews were divided between the first, second, and third authors and thematically analyzed and 152

153 coded using the finalized codebook. In addition, the lead author reviewed the general context of 154 every transcript and tabulated sociodemographic characteristics and contraceptive behaviors. Next, 155 the first author developed a preliminary codebook applicable to the follow-up interviews. The first 156 author modified the baseline codebook after reviewing ten follow-up transcripts and developed a 157 final codebook. Lastly, the 27 follow-up interviews were again divided between the first, second, and 158 third authors. Analysis of the follow-up interviews is on-going and will be completed by October 1, 2018.

160 Ethical approval

161 Ethical approval as exempt was granted by the Harvard T.H. Chan School of Public Health
162 Office of Human Research Administration. The study received approval from the National Institute
163 for Medical Research in Tanzania.

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Results

165 **Participant Characteristics**

Baseline Interviews. Overall, half of women were in their mid- to late-twenties and half
had completed secondary education (Table 1). The majority of women were married (75%), and
most were employed (60%). Almost one-third of women had no previous children. For many other
women, they had only one previous child (40%).

Follow-up Interviews. Upon completion of analysis, we will report the participant
demographics and PPIUD behaviors of women who participated in follow-up interviews.

172 Baseline Interviews

173 Facilitators of PPIUD Intended use. More than half of women reported that they had 174 consented or planned to consent to placement of PPIUD. Among these women, all mentioned multiple benefits of PPIUD which included the following: minimal side-effects, no impact on 175 176 breastfeeding, and that PPIUD is a convenient, long-lasting, and highly effective method. Women 177 frequently mentioned the lack of hormones in PPIUD as a positive feature of the method, which 178 they associated with fewer side-effects and less disruption to regular, monthly menstruation. One 179 respondent, who became pregnant as a result of method failure while using oral contraception, 180 expressed these sentiments:

"I heard about the injection... People tell you that once you use injection, you won't bleed for a
long time. [The nurse] was saying if you use loop (IUD), you will get normal menstrual periods.
So I wish to see that. I don't want to miss my period without knowing where that blood goes
every month. As a woman, I wish to get my monthly period as usual, and if a person tells me to

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use injection and I won't bleed, I become hesitant; where does that blood go? For me, I think loop (IUD) is good." (Planned user, age 33, married)

187 Overall, the convenience of immediate insertion following delivery highly motivated women
188 to consent to PPIUD. Several women mentioned that returning to a health facility during the
189 postpartum period is burdensome, given the competing demands in their daily lives.

190 "When [the nurse] told me that this [PPIUD] is inserted after you give birth, that was so good to

hear. As you know, after giving birth one feels tired and lazy going back to the dispensary astime goes on." (Planned user, age 27, married)

193 Women also expressed that methods that require resupply (e.g., condoms, oral

194 contraceptives, injectables) are onerous for the same reason; thus, PPIUD was considered a

195 convenient option among women who did not want to worry about resupply:

"… I have decided that am going to use [PPIUD] instead of calendar method… With [PPIUD]
you become more confident; not like other methods, for example, pills which needs someone to
have a good memory so that you have to take it every day and if you have a poor memory, it

becomes a loss. So [PPIUD] is better. With [PPIUD], even if you come home drunk, there is no
problem because you are confident it is there." (Planned user, age 25, married)

Perceived effectiveness and length of pregnancy protection of PPIUD were also valued 201 202 characteristics among women who planned to use the method. Women's preference for extended 203 protection against pregnancy was the most salient factor influencing their intention to use PPIUD over other long-acting methods, such as the implant. Several women also appreciated that PPIUD 204 205 could be removed at any time and would not affect fertility. For example, one woman who was planning to use PPIUD said, "... If you decide to get pregnant you can remove it or if you decide to 206 stay 12 years without delivering a baby, it's fine." Another woman stated, "I will use [PPIUD]... 207 208 You may consider removing it at any time when you want to have another pregnancy, even before 209 the ten to twelve years. Any time you feel like having another pregnancy you can simply take it off?" 210 Additionally, the counseling influenced women to adopt PPIUD over permanent methods:

"Most of the time I was thinking of that tubal ligation. I didn't even have any information on
how that PPIUD can last for how long and so on. So when I came here I got counselled and
[received] the information on PPIUD, if I use this and I can stay for those 13 years by that
time I will be older so even the [side] effects that people say about tubal ligation won't be
there because I won't be any younger." (Planned user, age 39, married)

Among women who planned to use PPIUD, health care providers were considered a valued
source of information and motivation to adopt PPIUD. Women's fears and misperceptions about
PPIUD were often mitigated by the PPIUD counseling, especially when counseling involved
teaching aids, and when providers took the time to address all of their concerns. For example, a
planned user said, "... I have obtained clarification, before I was scared but now I have clarification,
I think [PPIUD] safe... I will use [PPIUD]."

Barriers to PPIUD use. While most women displayed awareness of several modern 222 223 contraceptive methods (e.g., pills, injections, condoms), few had extensive IUD-specific knowledge, 224 contributing to delayed decision-making or stated preference to not use PPIUD. This lack of 225 knowledge was present even though participants had received counseling from a provider 226 immediately prior to the in-depth interviews. Further, a few women's narratives suggest that despite 227 prior awareness of the IUD, they misunderstood the information presented about its use in the 228 postpartum period or believed PPIUD to be a new contraceptive method (i.e., distinct from the 229 IUD). For example, a planned nonuser from Muhimbili (age 25, married) stated:

"There is something that I haven't understood. That's why I have not provided the answer
[about using the PPIUD], because they told me [PPIUD] is also a loop (IUD), only that it is
different in terms of insertion time. If I realize [PPIUD] is loop (IUD) and the only difference is
insertion time, I will use it... I will ask [about this]. If I find that I haven't obtained a satisfactory
response, I might leave and [will use loop], which I know is [inserted] after forty-eight days and not
immediately after delivery."

236 Women's limited knowledge of PPIUD may have stemmed from incomplete or low-quality 237 contraceptive counseling. A handful of women reported that they were not able to ask questions during counseling, and we infer from the interviews that some misinformation was provided to 238 239 women with, perhaps, the motivation to provide counseling quickly. For instance, many women 240 mentioned that they were told PPIUD does not have any side effects or that it is the "best" method 241 to use. One woman mentioned that if there was not enough time in the counseling session and 242 patients did not understand the information, then patients were instructed to read the informational 243 posters in the clinic to have their questions answered.

Fear of side effects and incomplete information were common themes that influenced women's decisions to not use PPIUD. While some common side-effects were mentioned (e.g., body pains, weight fluctuation), many women expressed very specific concerns related to PPIUD use, including increased risk of cervical cancer and fears related to sexual intercourse. This 248 misinformation was largely spread through informal social networks, such as peers, relatives, and 249 "people on the streets." Fears regarding sexual compatibility and the influence of PPIUD on sexual encounters were the most commonly expressed health concerns by women, highlighting the 250 251 importance of sexual acceptability (i.e., the influence of contraception on sexual experiences) of 252 contraceptive methods. The following women who were not planning to use PPIUD expressed this: 253 "[My friend who has loop] only talked about the good side of it; that it is good. But there is something she mentioned, that it requires being a husband and wife in terms of the size of 254 penis. If it happens that you have a bigger penis size, it pushes the device; something like 255 that, so the size has to be the same always... If you go to a person with a different body 256 257 physique from your husband, he might push it inside and cause problems... She told me 258 something like that even when you go for insertion you have to go with your husband." 259 (Planned nonuser, age 25, unmarried/cohabitating) "...I heard that once you insert [PPIUD], you can't make love to your husband. One may 260 tell you that if a man has a long penis, he pushes it and you feel pain; they also claim that you 261 262 can get back and stomach pains." (Planned nonuser, age 29, married) 263 For the above mentioned reasons, some women expressed disapproval of PPIUD use by unmarried women or women who have multiple sexual partners. Furthermore, women expressed 264 265 fear about pain during intercourse, for themselves and their partners, while using the PPIUD, possibly an indication of incorrect knowledge about PPIUD placement. 266 267 Women who were undecided or chose not to use the PPIUD tended to prefer other 268 contraceptive methods, including methods they had used in the past. For these women, the fear of 269 side effects and lack of complete information about PPIUD outweighed any perceived benefits of 270 the method. The conversation below highlights this thought pattern: 271 Respondent: "I have decided to use the same implant [as I was using before]." Interviewer: "Why the implant and not the PPIUD which you were taught about?" 272 273 Respondent: "Because it is something new to me and it's a method that I just heard today, so 274 I can't make the decision to use it or not, just now. I don't know its side effects. As some 275 women say when you insert PPIUD, you should then have intercourse with only one man. Also, I don't know how will it be like during sexual intercourse, if it may be painful or not." 276 (Planned nonuser, age 28, married) 277

278 Women's male partners and husbands' preferences for specific methods may have

influenced women's PPIUD decision-making. One woman mentioned that she will use the calendarmethod after delivery, because it is the method her husband is familiar with and prefers.

281 Respondent: "As you know, such things you need to share with your husband. You may say

you are going for family planning and perhaps he asks you that who told you that I can't

count the days. You may find that other men are good at counting the days in a calendar."

Interviewer: "But you have gone for counselling two to three times, but you haven't spokenabout it?"

286 Respondent: "He advises me to use the calendar, because he is good at counting it."

287 Interviewer: "So, that is the method he knows?"

288 Respondent: "Yes." (Planned nonuser, age 29, married)

289 Facilitators and Barriers to PPIUD Continuation

Results from the analysis of 13 in-depth interviews with women who discontinued use of PPIUD and 14 with women who continued use of PPIUD will be presented upon completion of analysis (anticipated October 1, 2018). The purpose of this analysis is to explore women's contraception decisions post-PPIUD placement. By understanding women's reasons for continuation and discontinuation, we aim to inform the development of strategies to support and meet women's contraceptive needs in the postpartum period.

296

Discussion

Overall, over half of the pregnant women interviewed in this study were interested in using 297 298 the PPIUD to prevent pregnancy after delivery. Most women were motivated to use the PPIUD due 299 to its perceived effectiveness, convenience, and duration of protection against pregnancy. However, 300 the most salient facilitator of PPIUD intended use was that it does not release hormones, and is 301 therefore thought to cause fewer side effects compared to alternative methods. In contrast to 302 planned PPIUD users, women who did not intend to use it described method-specific side-effects as 303 primary deterrents. These findings support previous research demonstrating that women's 304 perceptions about the presence or absence of side-effects, the types of side-effects, and the 305 magnitude or severity of side-effects are key decision-making components in contraceptive 306 behaviors (Campbell, Sahin-Hodoglugil, & Potts, 2006; Williamson, Parkes, Wight, Petticrew, & 307 Hart, 2009; Wulifan, Brenner, Jahn, & De Allegri, 2016). 308 Family planning programs should ensure that counsellors address women's individual needs

and fears, local beliefs and misinformation, and address side-effects explicitly. However, a "one size

fits all" approach may be inappropriate. Women in this study were concerned about the potential impact of PPIUD on sexual compatibility and experiences, and the influence on their partner's sexual experience. In other LMICs, women have expressed fears about contraception directly related to sexual pleasure, performance, and libido (Bisika, 2008; John, Babalola, & Chipeta, 2015). Despite this body of work, the effects of contraception on sexual function and experience is not frequently discussed with women during counseling.

316 Our study had several limitations. First, since participants were recruited from six hospitals 317 participating in a study of PPIUD provider training and patient counseling, our sample likely has a 318 large representation from women who have access to health care. Thus, we cannot transfer findings 319 to women who may have poorer access, such as those in rural settings. Second, as in any interview 320 study, social desirability bias was a risk. We had highly trained Tanzanian researchers, with similar 321 ethnic backgrounds, conduct interviews in private settings in the local language to help minimize 322 perceived power dynamics between researcher and participant. Additionally, interviews were 323 conducted at the facility where services were received, which may have also contributed to social 324 desirability bias. On the other hand, the strength of this design is that women were interviewed on 325 the same day of the counseling, so we were able to capture their initial reactions.

326 Postpartum family planning programs may be more effective in their promotion efforts if 327 they recognize and address women and their partners' nuanced perceptions of specific contraceptive 328 methods. With respect to PPIUD, contraceptive interventions that highlight the non-hormonal 329 features of the method and address sexual acceptability of the method may be valuable. Counseling 330 may be more effective if women trust the information they receive from providers; thus, attention 331 should be paid to client-provider interactions and long-term relationship building, rather than one-332 time counseling sessions. To improve PPIUD uptake in Tanzania, we recommend improving 333 postpartum contraceptive counseling that addresses women's concerns, clarifies misinformation, and 334 emphasizes the benefits that women value most.

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421

	Baseline I	Baseline Interviews	
Characteristic	n	%	
Location			
Mbeya	3	15	
Mt. Meru	6	30	
Dodoma	2 5	10	
Muhimbili	5	25	
Tumbi	4	20	
Age			
17 – 23	4	20	
24 - 29	10	50	
30 - 39	5	25	
Missing	1	5	
Education			
Some Primary	1	5	
Completed Primary	3	15	
Some Secondary	3	15	
Completed Secondary	10	50	
More than Secondary	2	10	
Missing	2	10	
Marital Status			
Married	15	75	
Single, not living together	2	10	
Single, living together	1	5	
Missing	2	10	
Occupation	-	10	
Unemployed	5	25	
Homemaker	1	5	
Business owner	5	25	
Teacher		10	
Other (e.g., nurse, tailor,	2 5	25	
secretary, salonist)	J	20	
Missing	2	10	
Religion	_	10	
Christian	15	75	
Muslim	3	15	
Missing	2	10	
Total No. of Children (alive or	4	10	
deceased)			
0	6	30	
1	8	30 40	
2	8 2	40 10	
3 or more	23	10	
	5 1	15 5	
Missing	1	5	
Consented/Planned to use PPIUD	10	(0	
Yes	12	60	

422 Table 1. Participant's characteristics

No