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Women's Views about a Paternal Consent Requirement for Biomedical Research in Pregnancy

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Abstract

Clinical research to inform the evidence base to guide non-obstetrical care during pregnancy is critically important for the wellbeing of women and their future offspring. Conversations about regulations for such research, including whether paternal consent should ever be required, should be informed by the perspectives of those most affected, namely, pregnant women. We conducted in-depth interviews with 140 pregnant women living with or at risk of HIV - 70 in Malawi, 70 in the U.S. - exploring their views on requiring paternal consent for pregnant women's participation in trials offering the prospect of direct benefit solely to the fetus. The majority of women supported such a requirement; others raised concerns. A trio of themes – the father's or pregnant woman's rights, fetal protection, and gender/relationship dynamics – characterized views both supporting and against a paternal consent requirement, expanding the range of considerations that should inform approaches to paternal involvement in research with pregnant women.

Keywords

pregnancy; women's views; clinical trials; research ethics; paternal consent; qualitative methods; United States; Malawi

Introduction

The global burden of disease during pregnancy is extremely high, and there is growing recognition in the global research community that responsible research with pregnant women is an important priority (Sina, 2017). A number of organizations, including the Council of International Organizations for Medical Sciences (CIOMS) and the American College of Obstetricians and Gynecologists (ACOG) ("Ethical Considerations for Including Women as Research Participants - ACOG," 2015), now urge that one of the key pathways to adequately addressing the health needs of pregnant women – and the children they may bear – is increased research into safety and efficacy of treatments and preventives during pregnancy.

This increasing recognition has led to renewed conversation about updating guidelines, frameworks, and best practices for research with pregnant women. One persistent issue for these conversations is the role of the fetus's father in consent for research. In particular, there is an ongoing debate about whether paternal consent should ever be required, over and above the pregnant woman's own consent, for a pregnant woman to participate in clinical research. Advocates of requiring paternal consent have argued that doing so recognizes and respects the parental rights of fathers and protects the welfare of the fetus. Opponents argue that it fails to respect autonomy of the pregnant woman, fails to recognize the diversity of family structures, is difficult to apply given the intertwining of maternal and fetal health interests (ACOG, 2015), and may interfere with access to research that is potentially beneficial to the future child.

The debate can be seen in the different approaches of institutions and organizations guiding the research ethics community. US regulation governing research with pregnant women [45 *C.F.R. §46.204 (e)*] requires the addition of paternal consent in research that holds out the prospect of direct benefit to the fetus alone. That is, while consent of the fetus's father is not required if the research holds out any prospect of direct benefit to the woman, or again if the research carries no more than minimal risk to the fetus, it is required in cases of research that involve the prospect of direct benefit solely to the fetus, with exceptions if "[the father] is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest" (Subpart B, 2001). In contrast, CIOMS' December 2016 guidance explicitly rejects paternal consent requirements, endorsing a model in which fathers' engagement in the decision is supported but not required as a condition of pregnant women's participation in research (CIOMS, 2016). ACOG has similarly raised concerns that the requirement "may infringe upon and weaken maternal autonomy" (ACOG, 2015).

As the global research community deliberates on the role and guidelines for paternal consent, it is important that policy makers take into account the diverse array of perspectives of pregnant women as they shape evolving regulations and best practices (Lyerly & Faden,

2007). Although once “silent partners” in the research enterprise, research subjects’ views have been increasingly recognized as a critical component to adequate research ethics analysis and oversight (Dresser, 2016). While potential participants may not be knowledgeable about historical, institutional, or other factors that bear on policy options, they may well be aware of different, morally relevant considerations that policy makers and scholars might otherwise overlook. It is, thus, important to probe the perspectives and views of the population directly affected by the policy. Although researchers, clinicians, public health officials, religious authorities, and others have weighed in on the debate, we could identify no studies that portray the views of individuals who are most likely to experience the impact of these regulations – pregnant women. As a result, public discourse and policy debates have proceeded in the absence of an empirical understanding of their views and concerns.

To address this void, we conducted a qualitative study of pregnant women living with or at risk of HIV/AIDS to elicit their views on the topic of paternal consent. The context of HIV/AIDS research is particularly relevant for three reasons. First, considerable research has been conducted with pregnant women living with HIV/AIDS focusing on prevention of maternal-to-child transmission (PMTCT) of HIV, and requirements for paternal consent have repeatedly raised concern in this sphere (Minkoff & Moreno, 1993). Second, pregnant women living with or at risk of HIV/AIDS are disproportionately low-income and face a range of challenges regarding access and consent in health care settings; understanding particular challenges of low-and middle- income country (LMIC) contexts where HIV research is often conducted and to which findings will be most relevant is critical (Mystakidou, Honours, Nurse, Tsilika, & Parpa, 2009; Ssali et al., 2013; Ssali, Poland, & Seeley, 2016; Woodson & Karim, 2005). Third, given the international partnerships that characterize HIV/AIDS research, US regulations play an outsized role in determining parameters of research around the globe, highlighting the need for guidelines developed in the US to be sensitive to implications they may have for critical research in international settings. We therefore conducted a study of pregnant women in both the US and in Malawi, a country with a high prevalence of HIV/AIDS and a robust research infrastructure, in order to provide a diverse array of perspectives from contrasting cultural contexts.

Method

The data for this analysis was collected as part of a larger project, Pregnancy and HIV/AIDS: Seeking Equitable Study (PHASES), which aims to develop guidance for ethically acceptable research on HIV treatment and prevention during pregnancy. We conducted qualitative, in-depth interviews using a semi-structured guide. We employed qualitative research methods intended to surface themes, generate hypotheses, and provide rich descriptive information regarding a topic about which there is little information and novel understandings are desired (Strauss & Corbin, 1998). Our priority in choosing this methodology was to capture the range of considerations that might be relevant to potential research participants rather than to identify the relative importance or prevalence of views across a population. More specifically, the aim of this method is not to provide a representative picture of the views of pregnant women, either in Malawi or the United States, but to surface themes, issues, and concrete considerations salient to women that

regulators and the global research ethics community should be cognizant of when developing policy and best practices (Dresser, 2016).

Toward this end, the settings we identified provided an opportunity to capture a range of views from cultural settings with different gender norms. Malawian society has been described as largely patriarchal, (Kululanga, Sundby, Chirwa, Malata, A, & Maluwa, A, 2012; Manda-Taylor et al., 2017); marriage is nearly universal, with the median age for first marriage at 18 for women and 23 for men (National Statistical Office [Malawi] and ICF, 2017). In the US, gender power dynamics in couples vary more widely (Ruggles, 2015); and marriage rates are lower, with approximately a third of all births being to unmarried women (Lundberg, Pollak, & Stearns, 2016). Both sites however reflect settings where research with pregnant women would be likely to take place.

The interview guide was informed by a review of the literature on women's participation in research during pregnancy, interviews with investigators discussing challenges and opportunities in including pregnant women in HIV-related clinical trials (Krubiner et al., 2016), and consultations with US and Malawi based researchers and health care providers.

The data for this analysis pertains to women's opinions about requiring paternal consent for pregnant women's participation in trials offering the prospect of direct benefit to the fetus but not the woman. These data were collected between August 2016 and April 2017. Interviewers provided a description of such a regulation (see Box 1), and asked women to discuss what they thought of it, specifically probing about whether and why they thought the rule was good or bad, as well as if it would affect their personal ability or willingness to participate in a study. We deliberately described a paternal consent requirement without attributing it to any specific regulation or authority, and without detailing possible exceptions to the requirement such as those currently contained in the US regulation. Our intent was to surface women's own perceptions of a requirement for paternal consent, separate from their views about the authority of a particular government or institution, and surface their own views about when such a rule should or should not apply.

The interview guide was translated into Chichewa for use in Malawi by two researchers who are native Chichewa speakers and fluent in English. The guide was then reviewed by local interviewers, utilized in preliminary interviews, and adapted for clarity. Participants completed written informed consent prior to the interview and consented to being audio recorded. Interviews in Malawi were conducted in Chichewa by a native speaker; all interviews in the US were conducted in English. Women also answered demographic, pregnancy history, and HIV testing/treatment questions. The research was approved by the Institutional Review Boards at the University of North Carolina at Chapel Hill, Johns Hopkins University School of Public Health, and the National Health Science Research Committee of Malawi.

Participants

One hundred and forty interviews were conducted with pregnant or recently pregnant women living with or at risk for HIV; 70 were conducted at two sites in the Eastern US, the University of North Carolina (UNC) at Chapel Hill and Johns Hopkins University (JHU) in

Baltimore, MD, and 70 in Lilongwe, Malawi, in collaboration with UNC's Project Malawi. Eligibility criteria included women who were *either pregnant* or recently pregnant (within 2 years). Reflecting the broader purposes of the project to develop recommendations for the ethical inclusion of pregnant women in HIV prevention and treatment research, in both the US and Malawi, we collected the sample to equally represent women living with HIV and those at-risk.

Lilongwe is a study site for numerous US National Institute of Allergy and Infectious Diseases (NIAID) HIV/AIDS Clinical Trials Network studies where HIV-related research is conducted frequently among women of reproductive age. We were therefore able to purposively select nearly half of the sample (n=33) to be women who had previously participated in HIV-related biomedical research during pregnancy, or were denied enrollment in a study due to being pregnant; these participants did not have to meet the eligibility criteria of currently being pregnant or recently pregnant. The remainder of the women living with HIV in Malawi was a convenience sample from a local PMTCT clinic, and the balance of the HIV negative women were a convenience sample from an antenatal care clinic.

At both study sites in the US, women at-risk for HIV were recruited from university-affiliated antenatal clinics in jurisdictions with elevated incidence of HIV or AIDS among women aged 15 to 45 years. At UNC, women living with HIV were recruited from both an obstetrics clinic and an infectious disease clinic affiliated with the university. At JHU, women living with HIV were recruited from an urban obstetrics clinic affiliated with the university serving women living with HIV/AIDS.

Analysis

All interviews were audio recorded, transcribed verbatim, and reviewed for accuracy. Interviews conducted in Chichewa were then translated into English. The interviewer in Malawi then reviewed all translations for accuracy, reviewing the audio as needed. As interviews were completed, the interviewer wrote a summary of the interview and recorded her impressions. The analytic approach was informed by thematic analysis (Guest, Namey, & Mitchell, 2012). After the first 15 interviews were completed, interviewers began the process of codebook development. Codes were developed a priori from the interview guide and emergent themes identified from reviewing and discussing summaries and transcripts. Transcripts were coded using NVivo software (QSR, 2016). To ensure inter-coder reliability, twenty percent of the data (n=28) were double coded, with discrepancies discussed until consensus between the researchers was reached through recoding or revising our understanding of the codes. Coding was an iterative process with new codes added as needed and data re-coded as applicable.

Following our initial analysis, overarching themes emerged from making comparisons within and across individuals utilizing data display matrices, and identifying thematically and conceptually related categories. These themes were: 1) parental rights: maternal rights (including of bodily integrity) and paternal rights (inalienable or earned; partial or complete) 2) relationship/gender dynamics: avoiding conflict/violence or collaborating/strengthening union; and 3) promoting interests of fetus. Quotations representing each of the themes were

selected and are attributed by pseudonym, country of residence, age, race/ethnicity, HIV status, marital status, number of pregnancies (including current pregnancy, if applicable) and education level (Table 3). The demographics were self-reported by the participants, including marital status, which carries different connotations and social meanings in Malawian culture than in American culture. In Malawi, marriage is colloquially considered to be broader than the explicit legal definition, and includes many co-habiting couples who raise families together, corresponding to the combination of ‘married’ and ‘living with partner’ statuses in the American contexts.

Results

Participant demographics are presented in Table 1. Participants ranged in age from 18 to 50, with the largest proportion of women in both countries in the 25 – 34-year age group. All women in Malawi were Black Africans, and 70% of the US sample was Black/African-American. Twenty-three percent of the US sample were college graduates or higher, and 20% of the Malawi sample completed secondary school or higher. Thirty-six percent of U.S. participants were married, and 27% were cohabitating, whereas 90% from Malawi described themselves as married. In both countries, the majority of participants identified as Christians, and half of participants in each country were living with HIV.

The women we interviewed diverged in their views about the paternal consent requirement and they also offered different reasons for viewing the rule as ‘good’ or ‘bad’. Views in favor of the rule were more common among women in Malawi than in the US, though a majority of participants in both countries offered reasons in support of the paternal consent rule (Table 2). Those who were unsure generally supported the requirement in cases where the father was present/involved (US) or married to the woman (Malawi), but not where the father was uninvolved in the pregnancy or woman’s life. Many women, regardless of overall support for or opposition to the rule, articulated nuanced and multifaceted opinions on the rule, and the different contexts in which and reasons why they felt it to be appropriate or not.

Reasons in favor of a paternal consent requirement

Women offered varied reasons in favor of the paternal consent requirement. These reasons were grouped under three themes: parental (paternal) rights; relationship/gender dynamics; and protecting interests of the fetus (Table 3).

Paternal Rights

Many women discussed a shared sense of responsibility with the baby’s father for the fetus/child and a need to come to agreement before participating in research that may affect the fetus.

“I think I agree with it because the dad is just as much a parent as the mom and whatever consequences happen because of, even if they’re unforeseen, they have to live with as well... I think that we’re saying that men and women are equal and so I think it’s equally their child and we can’t say we want men to be involved in children’s lives and not give them some type of role in this.”

Wendy, US, 30, white, HIV-, married, 3 pregnancies,
graduate degree

“To me this rule is good. Because you cannot make decisions on your own whilst there are two of you in the family. You are pregnant and the one who made you pregnant is in the same house so you cannot just decide on your own to enroll without telling your partner.”

Fredah, Malawi, 25, Black African, HIV-, married, 2
pregnancies, some secondary school

Some women described that it’s “his baby too” and the father also has a right to give input to the research participation decision.

“I mean, I definitely think each party should have a say-so... Because regardless of the circumstances this is his child as well as yours, so it should be half and half.”

Kara, US, 28, white, HIV-, single, 5 pregnancies, some
college

Several participants supported the rule noting that it is appropriate given that for the studies to which it applies, the potential medical benefits are to the offspring, and not the woman. Interestingly, though this is presumably the rationale behind the US regulation, this reasoning was articulated less frequently than the other reasons to support paternal consent requirements.

“So because ... the focus is the baby, I would say that I’m okay with that.”

Wanda, US, 33, Black/African-American, HIV+, single,
2 pregnancies, bachelor’s degree

Some women, especially in Malawi, indicated that the man should have decisional authority, not necessarily in his capacity as father, but in his capacity as head of household.

“It is good because the head of the family is the husband”

Brenda, Malawi, 35, Black African, HIV+, married, one
pregnancy, some secondary school

Protecting the interests of the fetus

Several participants noted “if something happened to the mother”, the father should be informed of anything that could potentially affect the medical care or well-being of his potential offspring.

“It would be nice because whatever happens to the mother, the father will be left with the child so it will be nice for him to know what the child was exposed to or what benefits are there for him for a certain scenario.”

Tinesha, US, 38, Black/African-American, HIV+, living
with partner, 5 pregnancies, graduate degree.

One participant doubted pregnant women’s abilities to make rational choices for themselves and their fetuses if a financial incentive for participation is offered, and saw the fathers as a separate advocate for the fetus.

“Because some mothers, they – they don’t – they aren’t, like, thinking clearly sometimes, and they may be influenced by financial reasons. And he may be, um, may be able to provide some clarity for her. Um... and then he – his concern – some mothers, they aren’t concerned with the health of the baby because they’re thinking of themselves. But the father may be able to, you know, use his judgement for the child.”

Chanise, US, 23, Black/African-American, HIV-, single,
1 pregnancy, high school graduate/GED

Relationship/Gender Dynamics

A reason given by some married women in Malawi to support the paternal consent regulation was that, because he was informed, a husband would not have suspicions about his wife’s whereabouts when she was participating in the study, thereby avoiding conflict, breaking up the marriage, or paternal rejection of the baby. One woman explained that disallowing participation by the pregnant woman unless the husband consented would prevent problems that could occur for her if the rule weren’t in place and she disobeyed his wishes. For example, paternal consent prior to enrollment in a HIV prevention trial could allay partner fears of unfaithfulness or positive HIV status (and subsequent retribution) should a man find medication among his wife’s belongings.

“It is good because let’s say you have gone for the research and have come back late, then the man will not be surprised to say where were you and why are you late because he agreed for you to join the research.”

Cynthia, Malawi, 23, Black African, HIV+, married, two
pregnancies, completed secondary school

“It is somehow good... Because maybe you can do something on your own, maybe the husband has refused you but you cling onto it. It can cause you certain problems... Maybe the marriage breaks down. Maybe he even rejects the baby saying that it is not his.”

Tafadzwa, Malawi, 18, Black African, HIV+, married,
one pregnancy, some secondary school

Women acknowledged that to participate in trials that the husband explicitly refused would cause problems in explaining their whereabouts,

“(B)ut the husband has refused so where would you say you are going to, every time you leave the house? That would only bring about misunderstandings and quarrels in the marriage.”

Yvonne, Malawi, 37, Black African, HIV+, married, 4
pregnancies, completed secondary school

Additionally, some participants including those in the US viewed this regulation as protecting their interests because “if something happened” to the fetus, the blame wouldn’t rest solely on the mother for deciding to participate in research during pregnancy,

“But, if we are voluntarily trying to do this, then I think it should be something that both parents should agree on so tomorrow there will not be any blame on – like, where I’m from, when the child is bad, it is the mother’s child. When the child is good, it’s the father’s child. So the child grows up, one day the father will be like, ‘Yeah, your mother is the one that made you to be like this. I didn’t want this’ — so.”

Katrina, US, 37, Black/African-American, HIV+,
married, 6 pregnancies, high school graduate/GED

Reasons for opposing paternal consent requirement

Women offered several reasons for opposing the paternal consent requirement. These were grouped under a similar trio of themes: maternal rights; relationship/gender dynamics; and protecting fetal interests (Table 3).

Maternal Rights

A number of participants noted that because the woman is the one who is carrying the pregnancy, it is her body that would be involved in research and it should be her choice alone about whether to participate. In the US, some participants were offended at the suggestion the father would have an equal role to play in a decision that so directly affected their own bodies and saw it as a violation of bodily integrity.

“It’s my decision, it’s my body, at the end of the day I understand he’s the father, but I’m going to do more, I have to go through more. I don’t agree. I think that’s a bogus rule. That’s just ridiculous.”

Makayla, US, 26, Black/African-American, HIV+,
living with partner, 1 pregnancy, some college

Others similarly felt their physical involvement in the pregnancy gave them greater decision-making authority than the father in this realm, even when they acknowledged the legitimate interests of the father.

“I mean the father has a say so but it’s really the woman’s body and I understand the baby is theirs as well but at the end of the day, I feel like just like with breastfeeding. It’s the woman’s option. If the husband disagrees or the boyfriend disagrees ... it’s his business but it’s the woman’s choice because it’s her body being used...”

Monique, US, 19, Black/African-American, HIV-, living
with partner, 1 pregnancy, high school graduate/GED

A participant in Malawi noted the father’s disapproval would be a violation of her rights.

“It is not good because you want to enroll... but the husband is refusing. So it is not good because that is like violating one’s rights.”

Memory, Malawi, 25, Black African, HIV-, married, 2
pregnancies, some primary school

Some women described that they would discuss the research participation with an involved father regardless, but the ultimate decision should lie with the woman. Similarly, some women felt if the parents were in a relationship in which it would be discussed, the rule would be unnecessary, and if the parents were in a relationship in which communication was difficult or contentious, the rule would be inappropriate.

“No, I think it shouldn’t be a rule. It should be an individual decision. It should be, because if you’re in a relationship and the father’s involved, I feel that it’s a given to talk about it. Like with my husband, we have great communication. So I’m assuming that when there’s a baby involved and the father is known, I feel like if he’s in or not in it, whatever it is, at least he’s informed, but it’s the woman’s choice at the end.”

Selena, US, 36, Latina, HIV+, married, 1 pregnancy,
some college

Protecting interests of fetus

Participants noted that the mothers would want to act in the baby’s best interest, and if couples disagree, the fetus is the one who loses the potential benefit.

“Yeah, a bad rule because the father may not agree on such treatment when it would be beneficial to the baby, and he could be harming the child due to restraining this permission. Maybe he doesn’t have the understanding to save the life or want to save the life like the mom does, so it could go either way.”

Kendra, US, 36, Black/African-American, HIV+, single,
one pregnancy, some college

“I mean I don’t think it’s fair because what if one wants to do it but then the other one don’t want to do it and one don’t understand it could like help a whole lot in the long run. I don’t think that’s fair.”

Jessica, US, 24, white, HIV+, single, 2 pregnancies,
some high school

Relationship/Gender Dynamics

For some women, the dynamics of the relationship with the father figured prominently in their reflections on paternal consent requirements. One common theme was controlling and/or violent partners preventing participation.

“I don’t like that rule too much because my baby father ain’t letting me join... He gonna say no without no questions asked because he just – he’s kind of scared that something’s gonna happen to the baby. He won’t let me do anything.”

Alicia, US, 20, Black/African-American, HIV-, single, 4
pregnancies, some high school

Others discussed men’s aversion to research, their aversion to attending clinic appointments (especially in Malawi), and their controlling of women’s reproductive health choices.

“Most men refuse participation in research...So they (need to make) the rule in such a way that the woman can enroll individually and not depend on the husband’s consent. Most husbands even refuse for the the woman to use birth control methods, so the rule is not good.”

Martha, Malawi, 34, Black African, HIV-, married, 4 pregnancies, primary school

A Malawian woman who participated in a PMTCT trial noted some men left their wives after learning of their HIV positive status, and the refusal of some men to accompany their wives to the PMTCT clinic due to false beliefs about the medical procedures.

Participant: “So when approaching the women, target those who are married and can easily explain to their husbands because like at (PMTCT trial), they would say ‘You should come with your husbands,’ but it is only a few women who came with them...”

Interviewer: “Those women who did not come with their husbands, did you hear the reasons why they did not come with them?”

Participant: “Some said, ‘When I was found with the virus my husband left me; the marriage ended’, some would say, ‘My husband says he cannot come here [ob clinic], it is satanic,’ some would say ‘My husband says he cannot come here because they pump out blood.’...”

Sylvia, Malawi, 32, Black African, HIV+, married, 5 pregnancies, post-secondary school

One woman described the potential for violence as a result of seeking paternal consent for research participation both from the baby’s father and the mother’s new boyfriend.

“You talking about, you don't know, they coming out of abusive relationships, you don't know what kind of situations they were in, coming out of, going in—you don't know what kind of situation they're in now. So what if they're already in their abusive relationship and they can't even have no kind of contact with their, their baby's father. You understand what I'm saying? Because their new boyfriend or whomever they may be is beating, is beating them every time that he even thinks that she's going over there. So because you done sent them over there, because you want to consent you done caused a situation when that girl go home.”

Aleesa, US, 23, Black/African-American, HIV-, single, 2 pregnancies, some college

Some women made a distinction between involved and uninvolved fathers, suggesting it was appropriate to seek the permission of fathers who are/will be involved in pregnancy and/or the child’s life, but uninvolved fathers should not have input into the research participation decision of the mother.

“Like if you have somebody involved, then of course, that’s a good idea, but if you don’t, then you shouldn’t be forced because some people, you know, don’t have

good relationships with the father to their baby, so it's just like why I got to include him in something? He has nothing to do with it."

Sandra, US, 23, Black/African-American, HIV-, living with partner, 2 pregnancies, high school grad/GED

Women commonly expressed that uninvolved fathers, or fathers that were "out of the picture," should not have input, given that from their perspective, the woman shoulders the responsibility of caring for the child.

"Well, I don't think that that should be a rule because most fathers ain't really there. You could just be a baby daddy. We've just happened to got together and had a baby, and I barely talk to you, and then you got a decision in my baby's life that I have to take care of and you barely be around."

Whitney, US, 35, Black/African-American, HIV-, living with partner, 6 pregnancies, high school grad/GED

Some women also noted that they would support the rule in most cases, but not if the woman was pregnant from rape or if the father could not be located or was unknown. Although the US regulation allows exceptions to the paternal consent requirement for both situations, the extent to which the prospect of contacting an assailant might dissuade a woman from research is unknown.

"That's about women who get raped and don't know their assailant. Right? And, they have a baby. And they want to do this ... research. And, they can't because they need to go find a rapist who raped them! To have him sign so that you can do a study with this rapist's baby. No. It's not about to happen. No."

Aleesa, US, 23, Black/African-American, HIV-, single, 2 pregnancies, some college

In some cases, women reported that the circumstances of their relationship with the father of the fetus would make this rule particularly problematic for them. One woman discussed that her baby's father is married to another woman.

"(T)he house he stays I don't even know it...I just feel that if I should go and search for him, maybe the other woman there is strong and might beat me up."

Olivia, Malawi, 24, Black African, HIV+, married, 3 pregnancies, completed primary school

Another woman in Malawi believed the rule was good in situations where the parents were married, but that researchers should help women who are not married circumvent the rule by signing for them.

Participant: "This rule is a problem to someone who does not have a husband it is better you as medical people to intervene helping the person that if she really wants to take part you medical people you should take part to help her so that she can take part"

Interviewer: "How do you think the medical people can intervene in this issue?"

Participant: “Signing, helping to sign”

Interviewer: “They should be like the husband?”

Participant: “Yes.”

Leoni, Malawi, 34, Black African, HIV-, married, 6 pregnancies, some primary school

Another Malawian participant, who otherwise supported the rule, nonetheless imagined a scenario where the research involved HIV treatment, and described that this rule would prevent her participation because she had not disclosed her status to her partner.

“Interviewer: So is the rule encouraging you or discouraging you to participate in study?

Participant: It is discouraging but still it is a good rule.

Interviewer: Can you explain why it is discouraging?

Participant: Because there are some people they say, some people are in a situation where by the woman knows she is infected and she is taking medicine but the man/father does not know therefore such people cannot accept to inform the father. So because they don’t want the father to know they will just decide not to join the research.”

Ellen, Malawi, 26, Black African, HIV+, married, 3 pregnancies, completed primary school

In sum, while some women opposed the rule independently of their relationship with the father, because they felt it violated their individual rights and bodily autonomy in general, others opposed the rule specifically because it would interfere with a woman’s autonomy or well-being within a relationship, and might have an adverse health effect for the fetus.

Discussion

Our study is the first of our knowledge to describe women’s views about a paternal consent requirement for research involving pregnant women. In this qualitative study of 140 women in two countries, the majority of women offered support for a paternal consent requirement when the potential benefits of the study are solely to the fetus, while some women opposed the rule and others were unsure. A trio of themes – the father’s or pregnant woman’s rights, fetal protection, and gender/relationship dynamics – characterized views both in favor of and against a paternal consent requirement, adding depth to and expanding the range of considerations that should inform approaches to and policy about paternal involvement in research with pregnant women.

Not surprisingly, one set of considerations raised among both US and Malawian participants centered around the issue of who should have authority to decide about whether the fetus should be exposed to research. Notably, our data reflect an important distinction in how women understand the justification for the pregnant woman’s or man’s authority,

respectively. For a number of respondents, the authority of pregnant women to decide about participating in fetal benefit research stemmed from the fact that her body would be involved; while many respondents understood the authority of the father to stem from his responsibility to ensure the well-being of his offspring, or his authority as head of the household. Several women in the US also indicated a view that decision-making should be shared and collaborative. In both US and Malawian contexts, the father's role in the consent process was linked to his equal or specific responsibilities as a parent-to-be, or his place in the social structure with regard to decision-making. Interestingly, support for such a requirement stands in contrast to policies around clinical medical care during pregnancy in both the US and Malawi, where consent of the father is not required for any intervention during pregnancy, including those (*e.g., cesareans done for fetal indications; fetal blood transfusions; maternal vaccination to prevent neonatal disease*) aimed solely at fetal benefit.

Another set of considerations raised pertained to the relevance of paternal consent to the best interests of the fetus. Here, too, women differed about how they viewed the father's role in this regard. Among women opposed to a paternal consent requirement, the concern was that the father of the baby might prevent access to potentially beneficial research. These concerns are consonant with US regulations surrounding pediatric research: when research carries the prospect of direct benefit for the child, the consent of only one parent is required, in part to reduce the barriers to the child's access to that potential benefit (Subpart D, 1983). While we are not aware of any data describing why fathers decline consent to research with pregnant women, the pediatric literature indicates that parents who consent to research for their children had a greater understanding of the research than those who did not consent (Tait, Voepel-Lewis, & Malviya, 2003). Interestingly, among those in favor of a paternal consent requirement in pregnancy, only one woman offered that the father might play a role in protecting the fetus from the risks of research. Instead, women tended to focus on the father's involvement as an extension of his responsibility for the well-being of the child over the long term.

The third set of considerations suggests a relatively unexplored area important to discussions of paternal consent. Women raised issues of power dynamics both in support of and against a requirement for paternal consent – articulating the ways that the requirement could lead to disharmony or violence and the ways that it might prevent the same against women who wish to participate. While these considerations were raised among both US and Malawian women, our data suggest that power dynamics related to social structures (*e.g., men as head of the household in Malawi*) may intensify the concerns raised around paternal involvement in research. The prevalence of these concerns among women in both countries stands in stark contrast to their role in past discussions about or justifications for paternal consent requirements. In the US regulations, the relationship between the pregnant woman and the father is raised as relevant only where it is characterized by violation or absence: rape, incest, or unavailability of the father. In contrast, most of the relationship-based concerns of requirements for paternal consent raised by the women we interviewed relate instead to problems internal to *ongoing* relationships, especially where gendered norms entail power differentials.

Included in these considerations are potential harms that may result from a requirement for paternal consent, including violence to the pregnant woman, that does not provide an exception for women in extant relationships but for whom consent of the father could constitute a threat to her well-being. Providing exceptions only for rape, incest, and unavailability of the father puts these women in the difficult situation of deciding whether to participate in research that might benefit their fetus but result in harm to them; or decline to participate at all.

Finally, some comments raised concern that requesting the father's consent may indeed inhibit pregnant women's willingness to participate in research. This has been seen historically in HIV/AIDS research. In PMTCT studies in the 1990s, paternal consent was required in accordance with regulations at the time, which required informed consent from the father for research with pregnant women, unless the purpose of the research was to meet the health needs of the mother, or unless the father was not reasonably available or the pregnancy was due to rape. Because of the stigma of HIV/AIDS, many women did not disclose their status to their partners, and avoided participation in studies that would entail such disclosure (Kolata, 1991).

Moving from specific considerations to overall views, a majority of the women interviewed expressed overall support for the requirement of parental consent. A significant minority of women either opposed or voiced ambivalence about the appropriateness of paternal consent for research, with some suggesting that the requirement may present problems for a substantial proportion of pregnant research participants. While concerns about requiring paternal consent were more common among US respondents, approximately one in three women in Malawi were opposed or unsure. Theorists have underscored the importance of paying attention to difference and context – including implications for marginalized groups – of policies that may seem appropriate or acceptable (Young, 1990).

Notably, while the three major domains were common to US and Malawian respondents, some themes varied across country and context (Table 3). For instance, while women in both countries raised the concern that fathers might be reluctant to allow study participation, details about why fathers might resist agreeing to research varied by country and context. In Malawi, men's aversion to attending clinic appointments and false beliefs about medical procedures were commonly noted, whereas several women in the US discussed men's strong protectionist attitudes towards the fetus, which would result in their automatic refusal of consent. In addition, a few themes were country-specific: in Malawi, the institution of marriage was raised as an important consideration both among those in favor of and against the rule, whereas women in the US considered paternal "involvement" to be of relevance – *potentially reflecting cultural trends around marriage*. In addition, fear of disclosing HIV status to partners and fathers' mistrust of the clinic was raised only among women from Malawi.

Our data also suggest a possible role for culturally embedded gender dynamics in views about or experiences of paternal consent requirements. For instance, wider support for paternal consent in Malawi may reflect that men are often viewed as the primary decision makers in families, including decisions about their partner's reproductive health (Kululanga,

Sundby, Chirwa, Malata, A, & Maluwa, A, 2012; Manda-Taylor et al., 2017); whereas in the US gender dynamics in couples vary more widely (Ruggles, 2015); and ideas about reproductive autonomy and rights may be more familiar to participants in the U.S. and may have shaped their responses.

Our study has several limitations. It is important to note that we did not ask women to consider alternatives to a paternal consent requirement. ACOG, and CIOMS had benefit of extensive discussion and analysis of the pros and cons, not only of a paternal consent rule, but also of different formulations of possible alternatives, including a model that provides for a robust opportunity for participation by fathers, rather than one that requires paternal consent. The idea of proactively providing support for paternal participation in decisions is one that is well known in HIV/AIDS clinical settings. In recent years, the HIV community has increasingly recognized the importance of attending thoughtfully to relationships in advancing research and clinical care, especially in voluntary couple HIV testing and counseling (CHTC). Karney (2010) has argued for a dyadic approach to HIV prevention that attends in particular to the range of relationships and the ways in which they affect health behaviors (Karney et al., 2010). Such an approach aims at encouraging shared responsibility and decision-making where the familial circumstances allow it, but places the control in the hands of the woman herself to make that determination. It is an open question what our findings would have been had our participants been asked to respond not only to the paternal consent rule but also to alternatives to this rule, such as a rule that the non-gestational partner's consent be solicited if the woman wishes, though some women brought up the latter as a preferable approach.

Additionally, while the paternal consent question referenced research generally, rather than specifying a particular health condition, respondents were primed to respond to HIV-related research with interview questions that preceded this one; their answers may have been influenced by these prior references.

Finally, interviews were intended to identify and explore women's opinions on research rules rather than measure the prevalence of such views among women. Our sample is not representative of all women at risk for or living with HIV in the US and Malawi, or pregnant women more generally, and results cannot be generalized to the population of women who might be eligible for research participation. The methodology was designed instead to surface themes and concrete considerations that policy makers should be cognizant of when determining regulations and best practices.

In sum, this study yielded a diversity of views of pregnant women about the appropriateness of paternal consent for research during pregnancy that holds out the prospect of direct benefit for the fetus alone. While a majority supported the rule, others raised concerns, raising questions about whether involvement of fathers in the informed consent process should be mandated by regulations or instead supported in other ways. Our findings underscore the importance of crafting a rule that respects the autonomy of pregnant women, values fathers' interests and engagement while also appreciating the diverse nature of families and contexts, and respects the importance of reducing barriers to access research that may be in the best interests of future children.

Best Practices

US regulations require paternal consent in addition to the pregnant woman's for research involving the prospect of benefit solely to the fetus alone. The women we interviewed diverged about whether involvement of the father in the informed consent process was appropriate, and raised nuanced considerations on both sides of the debate having to do with both paternal and pregnant women's rights, the interests of the future child, and gender roles and relationship. Although our findings cannot be generalized to all pregnant women, the views expressed by participants provide an important set of considerations to inform discussions about how to appropriately involve fathers in the informed consent process for research during pregnancy. Quantitative trends should not be used alone to justify consent practices, but should be interpreted with attention to the range and particularity of views reflected in our qualitative findings. Given the divergence of opinion, the reasons women provided in favor of and against paternal consent should be considered in developing policies and practices around paternal consent. These policies and practices should take into account the potential problematic implications of requiring paternal consent and the possible advantages of developing a model that robustly supports paternal involvement where the pregnant woman deems it helpful or otherwise appropriate.

Research Agenda

The voices of pregnant women have been largely missing in discussions of policies and best practices for their ethical inclusion in clinical research, though they are both potential research participants and bear the clinical risks associated with the resulting evidence gaps. Greater research attention to exploring the diversity of perspectives they bring regarding paternal consent requirements will provide needed understanding and insight into the issues of concern for this population. Further data are needed on women's perspectives regarding the appropriate role for fathers in the consent process for fetal benefit research during pregnancy in diverse health research and cultural contexts. As described, our participants were primed to consider paternal consent requirements within the context of HIV-related clinical research, which may have importantly influenced responses. Further cross-cultural studies could be helpful in identifying a possible relationship between gender norms and views about paternal consent, including but not limited to further exploration of how financial incentives for research might operate in these circumstances. In addition, studies that explore women's experiences of participating in studies where paternal consent is required are needed to better understand how paternal consent requirements – and exceptions to them (in particular, unavailability) – are interpreted and implemented, to complement important work that has been done in the pediatrics research context (Nelson et al., 2013).

Second, studies that ask women to also consider alternatives to a paternal consent requirement are needed, as the process of comparison can allow for the identification of the rule features most salient and important to women. Third, fathers and other family members represent other important and underexplored voices in this policy debate that may also bring underappreciated issues to light; further research should therefore explore fathers' and family members' views on paternal consent for fetal benefit research during pregnancy.

Educational Implications

Investigators, policy makers and bioethicists who are shaping the practices and policies around research with pregnant women should consider the perspectives of women who might participate in or be affected by research. Understanding their nuanced and divergent views, including how gender dynamics can affect women's experiences where paternal consent may be required, will allow for more informed discussion and development of research regulations that are responsive to their interests. Investigators and ethical review boards should be made aware of the issues facing pregnant women in fetal benefit studies where paternal consent is required so that they can ensure protocols are designed to effectively support this process and minimize risk to the women. Pregnant women being recruited for clinical research studies, both in trials requiring paternal consent and those that do not, need information and support in communicating with fathers about research participation where appropriate.

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Box 1. Paternal consent regulation description used in study interviews.

“This first rule has to do with getting approval from the father of the baby. When people think about whether research is okay, they think about risks and possible benefits to the pregnant woman, and risks and possible benefits to the baby. Right now, government rules say that if a study offers no benefit to the pregnant woman but possible benefit to the baby, then, the father and mother must both agree before the mother can participate. In other words, both the pregnant woman and the baby’s father must agree to the research; the woman cannot decide on her own. If either the pregnant woman or father does not agree, then the pregnant woman cannot join the study.”

Table 1.**Demographic Characteristics of Women Participating in PHASES**

Characteristic	U.S. (<i>n</i> = 70)		Malawi (<i>n</i> = 70)		TOTAL (<i>n</i> = 140)	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Age						
18-24	18	26%	17	24%	35	25%
25-34	31	44%	39	56%	70	50%
35-44	20	29%	12	17%	32	23%
45+	1	1%	2	3%	3	2%
Race/Ethnicity						
Black/African American/Not Hispanic	49	70%	70	100%	119	85%
White/Not Hispanic	12	17%			12	9%
Hispanic/Latina	7	10%			7	5%
Asian/Other	2	3%			2	1%
Education						
US:						
Some HS	12	17%				
HS Grad/GED	19	27%				
Some College/Assoc Degree	23	33%				
College Graduate	6	9%				
Post Graduate Degree	10	14%				
Malawi:						
None			9	13%		
Primary: Some to Completed			32	46%		
Some secondary			15	21%		
Completed secondary			11	16%		
Post-Secondary			3	4%		
Marital Status						
Single	24	34%	3	4%	27	19%
Married	25	36%	63	90%	88	63%
Living with Partner	19	27%	--		19	14%
Divorced or Separated	2	3%	3	4%	5	4%
Widowed	--		1	1%	1	0%
Number of pregnancies						
1	17	24%	7	10%	24	17%
2-3	26	37%	30	43%	56	40%
4+	27	39%	33	47%	60	43%

Characteristic	U.S. (<i>n</i> = 70)		Malawi (<i>n</i> = 70)		TOTAL (<i>n</i> = 140)	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
HIV positive	35	50%	35	50%	70	50%
Religion						
Christian						
Catholic	8	11%	14	20%	22	16%
Protestant	39	56%	48	69%	87	62%
Jewish	--		1	1%	1	0%
Muslim	--		6	9%	6	4%
None	21	30%	--		21	15%
Other/Not Reported	2	3%	1	1%	3	2%

Table 2.

Participants' Overall Views on Paternal Consent Regulation by Country

Paternal Consent Opinion	US n (%)	Malawi n (%)
Support	36 (52%)	45 (66%)
Oppose	25 (36%)	13 (19 %)
Unsure/it depends	8 (11 %)	10 (14%)
Total	69 [*] (100)	68 [*] (100)

^{*} 1 US participant and 2 Malawi participants did not provide overall opinions

Table 3.

Themes Emergent Across Participants' Reasoning for Supporting and Opposing Paternal Consent Requirements

Domain	Reasons for supporting the rule	Country	Reasons for opposing the rule	Country
Parental rights	<u>Paternal rights</u>		<u>Maternal rights</u>	
	Paternity confers right to protect welfare of the fetus.	US & Malawi	Women's right to bodily integrity.	US & Malawi
	Father is head of household / rightful decision maker / authority figure.	US & Malawi	Women seek input from father of the fetus while retaining autonomy.	US & Malawi
	Conditional support; paternal rights to fetus must be earned through involvement.	US		
Protecting interests of fetus	Conditional support; paternal rights to fetus through marriage.	Malawi		
	Informs father's care of potential offspring	US	Woman will act in baby's best interest.	US & Malawi
	Father may protect baby's best interest	US	Fetus loses prospect of direct benefit if father does not consent.	US & Malawi
Relationship/gender dynamics	Fear of conflict/violence if participate without father's consent.	Malawi	Fear of conflict/violence with father of the fetus.	US
	Shared blame if the fetus is harmed from study participation.	US	Fear of conflict/violence if the father is married to another woman.	Malawi
	Shared responsibility for parenting or partnership between parents.	US & Malawi	Controlling partners will automatically refuse.	US
			Men avoid ob clinic (where consent would occur) due to rumors and beliefs.	Malawi
			Father is uninvolved, and has, therefore, abdicated parental rights.	US
			Father is unknown/can't locate or pregnant from rape.	US & Malawi
			Women who fear disclosing HIV status to father of the fetus will not participate.	Malawi