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Gendered Logics of Biomedical Research: Women in U.S. Phase I Clinical Trials

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Abstract

Despite the importance of including diverse populations in biomedical research, women remain underrepresented as healthy volunteers in the testing of investigational drugs in Phase I trials. Contributing significantly to this are restrictions that pharmaceutical companies place on the participation of women of so-called childbearing potential. These restrictions have far-reaching effects on biomedical science and the public health of women. Using 191 interviews collected over 3 years, this article explores the experiences of 47 women who navigate restrictions on their participation in U.S. Phase I trials. Women in this context face a number of contradictory criteria when trying to enroll, which can curtail their participation, justify additional surveillance, and deny pregnant women reproductive agency. The pharmaceutical industry's putative protections for hypothetical fetuses exacerbate inequalities and attenuate a thorough investigation of the safety of their drugs for public consumption. We use the framework of "anticipatory motherhood" within a gendered organizations approach to make sense of women's experiences in this context.

Keywords

biomedical research; women's health; anticipatory motherhood; gendered organizations; clinical trials

Clinical trials are the testing ground for developing pharmaceuticals aimed at a range of therapeutic needs. From sexual dysfunction to cancer treatments, they are the mechanism through which pharmaceutical companies demonstrate the safety and efficacy of their products before receiving approval from the Food and Drug Administration (FDA) in the U.S. (Carpenter 2010). While necessary for the advancement of biomedical science and the commercialization of drugs, clinical trials have historically excluded women, particularly women of "childbearing potential" (Institute of Medicine 1999).¹ The U.S. National Institutes of Health (NIH) now requires the inclusion of women in research they fund, arguing that failing to include women compromises the validity and clinical significance

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¹Regarding our terminology, we often use the word "women" when describing the inclusion of females in biomedical research. Whereas sex is the more accurate descriptor than gender in this context, federal policies and the biomedical literature use the terms "women" and "women of childbearing potential." We reproduce this terminology to mirror these common usages, but we recognize that we are actually referring to cisgendered women.

of trial results (Epstein 2007). As a result, women are now more equally represented in NIH-funded clinical trials, but the low representation of women persists in clinical trials funded by the pharmaceutical industry, particularly trials that require healthy volunteers for Phase I testing. Women make up between 29 and 34 percent of participants in this early stage of drug testing (Chen et al. 2018).

Phase I clinical trials are designed to test the safety and tolerability of investigational drugs, and they largely use healthy individuals who are easier to recruit and are less vulnerable to drug effects than are patients with an underlying disease (Pasqualetti et al. 2010). To incentivize their enrollment, healthy participants are compensated several thousand dollars for their time, which typically includes an in-patient “confinement” period in a research clinic (Edelblute and Fisher 2015). While framed as healthy “volunteers,” Phase I research participants often think of themselves as workers, and generally rely on income from trials to support themselves and their families (Cottingham and Fisher 2016; Edelblute and Fisher 2015; Elliott and Abadie 2008). In this sense, healthy individuals who participate in clinical trials are engaged in “clinical labor” (Cooper and Waldby 2014), supplying their time, compliance, and bodies to advance scientific knowledge for a financial pay-off.

To be eligible, individuals not only have to be healthy, but they also have to be relatively young, with most trials excluding participants older than 55 and many using 45 as the cut-off point (Authors 2020). For women, this time frame overlaps significantly with their reproductive years, so women’s so-called childbearing potential often comes to bear in decisions about who should be eligible for or excluded from Phase I trials (Corrigan 2002). Because clinical trials on humans can commence while nonhuman animal testing is still underway, there is often limited data prior to Phase I testing about the reproductive toxicity and potential for teratogenic effects on fetal development (Parkinson, Thomas, and Lumley 1997). Women’s exclusion from pharmaceutical clinical trials, however, can lead to more frequent and serious adverse drug reactions in women after a product is available on the market (Parekh et al. 2011). Thus, similar to contemporary and historical framings of fetal life in the U.S. (Linders 1998), women’s health can suffer as a result of policies and practices designed to protect hypothetical fetuses.

Given that the negative effects of excluding women from early drug testing are known and that national policy calls for the equitable inclusion of both sexes in research, what are the mechanisms that maintain women’s underrepresentation? More specifically, how might the policies and practices of clinical research organizations, as experienced by women, contribute to their underrepresentation? We build on prior conceptual frameworks on “anticipatory motherhood” in health policy (Waggoner 2013, 2017) and on gendered organizations theory (Acker 1990; Britton and Logan 2008; Martin 2003) to examine the underlying sex-based assumptions of clinical research organizations and how women experience restrictions on their Phase I trial participation. The experiences of women who are eager and active clinical trial participants can shed light on the potential double standards and added demands that women confront, explaining partially why reaching representative levels in early testing continues to be elusive.

We draw upon 191 interviews conducted with 47 racially diverse women over a period of three years to better understand how they experience and confront underlying assumptions that seem to privilege men as the ideal research subject. Marked by their alleged childbearing ability, women deviate from the male ideal and face a number of contradictory criteria to participation. We explore how women react to the restrictions they face, including their perceptions of the reproductive risks, as they attempt to earn income through clinical trials. We find that the pharmaceutical industry's putative protections for hypothetical fetuses exacerbate sex and gender inequalities and attenuate a thorough investigation of the safety of their drugs for public consumption.

Anticipatory Motherhood in Healthcare

While biomedicine now emphasizes the importance of including diverse populations in clinical trials, parallel concerns have developed in the United States regarding women's "preconception" health and its effects on the health of future children (Waggoner 2017). On one hand, since the late 1990s, the NIH has demanded that researchers incorporate more women into biomedical research, and on the other, new health policies during the same time period have emphasized that women should engage in health-promoting behaviors that essentially presume that "all women are pregnant unless proven otherwise" (Junod 2003:56). These two frameworks are in conflict given that the latter brings the risks to potential fetuses to the foreground while minimizing the individual health needs of women. In this climate, the potential benefits of sex-based scientific research for its subsequent higher validity to women as medical consumers can be overshadowed by looming concerns for future children. Certainly, past medical practices have led to detrimental outcomes for babies, as was the case with the anti-nausea drug thalidomide that was used in the 1950s and 1960s with devastating effects on fetal development (Kim and Scialli 2011). The thalidomide tragedy directly resulted in a climate of paternalistic and protectionist agendas regarding women's role in clinical trials (Corrigan, 2002).

Outside of medical research, women's health has been reframed to focus on the "zero trimester"—the time prior to conception when women (regardless of their desire to become pregnant) should maximize their health through a balanced diet and vitamin consumption; achieving and/or maintaining a normal body-mass index; and avoiding alcohol, tobacco, and illicit drugs (Waggoner, 2017). These suggestions aim to improve birth outcomes in the U.S., recognizing prenatal care's failure to do so on its own (Waggoner 2017). To capture the cultural significance of this approach to women's health, Waggoner develops the concept of "anticipatory motherhood," which she defines as "a framework that positions *all* women of childbearing age as 'prepregnant' and exhorts them to minimize health risks to phantom fetuses and future pregnancies" (2013: 347). Viewing women as "prepregnant," however, conflates "women's health and maternal health" and "exalts women as mothers and not women qua women" (Waggoner 2013:346). In other words, during their reproductive years or roughly four decades of their lives, women's health concerns are subordinated to or in the service of potential future pregnancies. This framework responsabilizes women for any negative birth outcomes despite limited evidence indicating how women's behavior prior to pregnancy actually affects a fetus and the child it might become. It also erases any contribution men's sperm might make to adverse birth outcomes (Daniels 1997).

Notions of the “zero trimester” and “anticipatory motherhood” are also useful for understanding how women are positioned within biomedical research. As Cooper and Waldby (2014) explain, “While women are considered naturally suited to the biological labor of gestation and reproductive gift giving, since the mid-1970s they have been routinely excluded from Phase I clinical trials for the very same reasons” (121). Indeed, women of childbearing potential were explicitly barred by the FDA from Phase I trials until 1993 (Corrigan 2002), and their inclusion today is largely at the discretion of the pharmaceutical company sponsoring the Phase I trial. Corrigan (2002) writes, “this paternalistic and protectionist framework needs to be understood in the context of prevailing anxiety about the dangers of giving drugs to pregnant women, as well as concern over the abuse of subjects in biomedical research more generally” (43). Unlike the larger framework of informed consent in which prospective research participants are given detailed information about a clinical trial in order to make an autonomous decision based on risks and benefits, women of childbearing potential are often not given the choice to enroll in a trial that could adversely affect a fetus, even when those women have no plans to become pregnant in the near-term.

Within the U.S. regulatory system, there is no right to participate in research, merely the right to decline (Faden and Beauchamp 1986). Anticipatory motherhood assumes that “women are mothers-in-waiting and that it is the job of public health and medicine to control women’s bodies for the sake of the greater good” (Waggoner 2017:7). Yet, it is important to highlight the notable racial differences in how would-be mothers are perceived and how they might be controlled. Advances in reproductive technology, for example, have largely increased the reproductive options of affluent white women, whereas the fertility of poor women of color is stereotyped as irresponsible and a sign of poor self-control (Roberts 2009). While cast differently, both groups, in Roberts’ view, have been responsabilized for their own health and reproductive outcomes. The “greater good” might be the production of many healthy children in the case of affluent white women, but as few children as possible in the case of poor or Black and Latina women (Roberts, 2009).

In the context of biomedicine, women’s commodification of their bodies—as paid research participants (Authors 2019) or egg donors (Almeling 2011)—can be perceived as at odds with cultural norms regarding women’s “role” as mothers. Yet, this paternalistic approach effectively constructs the “greater good” as protecting or preventing hypothetical fetuses in lieu of having better representation of women in biomedical research and improving the safety of pharmaceuticals for women. Numerous studies show that women have been harmed because men alone were used as test subjects, most notably in heart and other cardiovascular diseases (Healy 1991; Merkatz 1993). Additionally, after twenty years on the market, the popular insomnia drug Ambien® (zolpidem) underwent relabeling that instructs physicians to prescribe a lower dose to their female patients based on clear evidence of harm to women, such as higher rates of vehicular accidents resulting from the drug clearing more slowly out of their systems (Roth 2018). Thus, there are real effects on women’s health when they are excluded from clinical trials on the basis that they have the potential to become pregnant as well as the guiding assumption that any pregnancies that occur will not be terminated (Waggoner 2017).

Gendered Organizations Theory

Though the pharmaceutical industry is adamant to classify individuals who are paid to participate in clinical trials as volunteers rather than workers (Elliott and Abadie 2008; Lemmens and Elliott 1999), their experiences often mirror that of an employee, albeit of a precarious nature. Participants must be physically present at the clinic where the research takes place and follow the rules and policies set forth by the pharmaceutical sponsor and the research clinic. They must observe health behavior requirements, such as fasting, prior to checking into the study, and undergo a number of procedures both as a part of screening to enroll in a study and as a part of data collection. Cooperating with staff during blood draws, drug administration, and other possible procedures like ECGs, MRI scans, biopsies, and even lumbar punctures is required for them to receive the promised financial compensation.

In light of this contractual relationship between clinic and subject, we turn to the scholarship on gender and organizations/occupations as a way of understanding women's experiences in this understudied aspect of clinical labor (Cooper and Waldby 2014). Acker's (1990) gendered organizations approach can shed further light on how Phase I trial protocols, as experienced by women themselves, appear to privilege "men's bodies, sexuality, and relationships to procreation and paid work" (139). Acker's work provides a theoretical apparatus that links individual experiences with organizational logics and explains how occupations and organizations can be sites for the reproduction of gendered assumptions despite tacit claims of gender neutrality.

According to a gendered organizations approach, gender shapes occupations and organizations in a number of ways. At the cultural level, occupations are seen as gendered by virtue of the gendered meanings associated with particular jobs. For example, nursing has historically been and continues to be framed as a feminine profession (Cottingham 2014; Williams 1992), whereas construction work is seen as masculine (Denissen and Saguy 2014). Scholarship on work and organizations has increasingly emphasized the importance of examining how gender—as well as race, class, and sexuality—are categorically reproduced through a number of social mechanisms (Acker 1990; Britton 2000; Britton and Logan 2008; Williams 1992; Williams, Muller, and Kilanski 2012). These mechanisms include organizational policies, logics, and assumptions that tend to hold the "ideal worker" as one free from family responsibilities and whose career-trajectory is uninterrupted by children. Thus, the "ideal worker," according to these and other assumptions, is often a man who is also heterosexual and married, and in the context of professional work, is assumed to be white and middle-class (Britton and Logan 2008).

In the context of Phase I clinical trials, however, low-income, minority men are overrepresented (Fisher and Kalbaugh 2011). Due to profound social and economic inequalities in the U.S. (Thernstrom and Thernstrom 2009; Wilson 2010), they often have few other opportunities to earn comparable sums of money through other paid work (Cottingham and Fisher 2016). While Phase I trials are often a hidden world and the public arguably holds limited knowledge of clinical trial participants and their expected sociodemographic characteristics, media representations of healthy research participants tend to portray them as desperate men willing to harm themselves for monetary

compensation (Fisher and Cottingham 2017). High-risk professions are often assumed to be men's work as well as more suitable for those with backgrounds of lower income and lower educational attainment (Paap 2006; Ribas 2015). Phase I trials are no different, and minority men who can be incentivized to consent to a long-term confinement in a research clinic are directly recruited for studies and perceived by the industry as ideal participants (Author 2018). Yet there is a long and sordid history of racial and ethnic minorities being exploited and harmed by biomedical researchers (Briggs 2002; Reverby 2009; Savitt 1982; Skloot 2010), and the economic context of unstable and precarious work in the U.S. allows this trend to continue (Cooper and Waldby 2014). The prominence of men in Phase I trials might also be due, in part, to the initial history of healthy volunteer trials being conducted in men's prisons (Hornblum 1998).

Elsewhere (Jain, Cottingham, and Fisher Forthcoming) we have described women's vulnerability in Phase I trials because men outnumber them in the clinic space and the discouragement women receive from husbands or partners. This article further investigates the assumptions that women confront as they seek to enroll and participate in clinical research and the role that these organizational assumptions and practices might play in limiting women's participation. Framing these experiences within gendered organizations theory allows us to connect their individual experiences to the organizational context of clinical research and explore the relevance of "anticipatory motherhood" as an underlying assumption within biomedical research.

Methods

Prior work on gendered organizations and the ideal subjects that comprise them has used a variety of methods for empirical investigation, including interview-based studies of individual experiences within organizations (Britton and Logan 2008; Pierce 1995). The current article uses interview data collected between July 2013 and December 2016 as part of a longitudinal study of individuals who participate in U.S. Phase I clinical trials. We met participants in one of seven research clinics. Three clinics were located on the East Coast, two in the Midwest, and two on the West Coast. Participants were approached by a member of the research team at the clinic facility and asked to participate in a 3-year research study on the decisions and experiences of healthy volunteers. They were compensated with a \$20 gift card for their first "baseline" interview; a \$50 check for the second interview, which took place 6-months later via phone; a \$100 check for the third and fourth interviews, which took place via phone one year and two years from enrollment; and \$200 for the fifth interview, which took place via phone three years from enrollment and concluded their participation in our study. In order to control for any unintended effects that inclusion in our study might have had on individuals' participation in or perceptions of clinical trials, we randomly assigned participants to either the "full-participation" group (~80%) or the control group (~20%). Individuals assigned to the full-participation group completed all five interviews, while those in the control group completed only the baseline interview and a final interview three years later. Additionally, participants in the full-participation group reported via a survey all the Phase I trials that they screened for or enrolled in during our three-year study (see Edelblute and Fisher 2015). All participants provided written informed

consent, and this study was reviewed and approved by the institutional review board at the University of North Carolina – Chapel Hill.

Sample

Our total study sample included 178 men and women, but we focus here on the women we enrolled. Our sample of 47 women was racially diverse, with blacks and Hispanics making up over 50 percent of the total number of women. Participants included 21 non-Hispanic white women and 26 women of color. Participants' race/ethnicity, age, employment status, fertility status, and other demographic variables are displayed in Table 1.

Data and Analysis

We conducted a total of 191 interviews with the 47 women in our study. This includes 47 baseline interviews; 33 6-month interviews, 33 1-year interviews, and 33 2-year interviews with the women randomized to our full participation group; and 45 3-year (final) interviews with women in both the full-participation and control groups. We retained 96% of the women in our study, with one woman choosing to discontinue her participation and another lost to follow-up.

Interviews covered a range of topics, including background information on each participant's employment, education, and family life, along with detailed questions about the studies she had enrolled in and her experiences and motivations for participating in clinical trials. Across all interviewing waves, the average interview length was approximately one hour. All interviews were transcribed by a transcription company and verified and corrected for accuracy before being coded by the research team.

Our coding structure included both *a priori* codes developed from the literature on clinical trials and preliminary research on healthy volunteers as well as *emergent* codes relevant to the particular experiences of women (Timmermans and Tavory 2012). In the first wave of analysis, we used qualitative analysis software (Dedoose) to excerpt and code relevant passages based on any and all reference to barriers to enrolling in clinical trials that were specific to women as well as experiences within clinical trials that might be unique to women. In a second round of analysis, we created more nuanced categories to represent how women described their experiences, and these select excerpts were scrutinized further to analyze how different groups of women compared. We use pseudonyms below to protect our participants' confidentiality.

Anticipatory Motherhood and the Experiences of Women in Phase I Trials

To earn income through Phase I trials, healthy individuals must first find studies for which they qualify. This is not as easy for women as it is for men, which means that they often must work harder to find clinical trials and encounter more obstacles to enrolling. Women in our study seemed acutely aware of the fact that they are not ideal research participants in the eyes of clinics and regulatory bodies. As Tina, a white woman in her 40s who had participated in more than 30 studies over a twenty-year timespan, reflected,

“[W]hen I first started doing studies, the FDA was very-, you know, your ideal participant was a young, healthy, non-smoking male, you know, [chuckles] which is not what we all are!”

While Tina has seen more inclusion of women in clinical trials over time, her experiences as well as those of other women in our sample point to a labyrinth of inclusion-exclusion criteria and surveillance practices that often reduce women to their childbearing status. As with other studies of biomedical encounters (e.g. Timmermans & Buchbinder, 2010), we have structured our findings to loosely follow the chronology that women experience, from enrolling, to participating in, and reacting to clinical trial policies. We begin by describing the lengths to which women must go to meet the inclusion criteria of various studies, as well as the surveillance experiences they undergo to “prove” that they have not become pregnant during a clinical trial. Finally, we analyze women’s diverse reactions to reproductive-based study criteria and surveillance.

Overcoming Anticipatory Motherhood to Enroll in Trials

Past research on the inclusion of women in clinical trials has noted the number of barriers that women confront as they seek to enroll in clinical trials—including an agenda of paternalism and protectionism as well as scientific preferences for homogenous populations (Cotton 1990; Institute of Medicine 1999; Mazure and Jones 2015). Not surprisingly, such barriers in Phase I trials are often tied to women’s reproductive status, leading to a catch-22: Phase I trials seek young, healthy adults as participants, typically those between 18 and 45 years old, but in the case of women these are prime years of “childbearing potential.” Thus, to include women at all means to accept older women who are postmenopausal, younger women who are surgically sterile, or find alternative ways to define who might be at risk of getting pregnant. Women experienced this dilemma directly. Becca, a white woman in her 30s, noted:

Mostly now, the reasons I don’t get into studies is because of my age. I’m at a really funny age. I’m not young enough for some studies, and I’m not old enough for others because I’m still able to have children.

Becca had participated in nine clinical trials at baseline—less than one per year since she had begun pursuing studies to supplement her income from a part-time job. Becca spent a fair amount of time searching for new studies, including signing up for online services that would “match” her to available studies for healthy women in her metropolitan area. Nonetheless, she could not find a single study in which to enroll during our study’s three-year follow-up period.

When we met Joan, a white woman in her 40s, she was in her first clinical trial, but she had quit her job at a grocery store and was unemployed “by choice” to try to earn income through trials. Her motivation to do so was seeing her boyfriend of three years make large sums through his participation. To ready herself, she lost 80 pounds, but soon found out her fertility status made it much harder for her to qualify for studies than what she had expected based on her boyfriend’s experience. She reflected, “So it’s not as easy as it is for a 44-year old male, but I’m working on it. ... A lot of study places want you to be basically just like no childbearing risk at all.” Three years after that first clinical trial, she had participated in

only four more studies, blaming her childbearing status for the lack of opportunities she had had:

I'm in menopause, and I'm not *post*-menopausal that I'm still technically childbearing, that that's actually kept me out of studies. ... At this point, yeah, either I have to go through menopause, which isn't something that I can really-. I go like four to six months between periods, but I'm not-, you know, I can't really rush it. [laughs] ... And I don't really want to, you know, go get my tubes tied 'cause it seems unnecessary at this particular point.

For Joan and other women in their 40s, the hope is that becoming postmenopausal will create more study opportunities, even if they are older than 45 by the time they have not menstruated for more than 12 months. Nonetheless, Becca's and Joan's cases illustrate why many "childbearing" women, despite their efforts and desire, might be unable to participate in trials.

Women who pursue clinical trials as full-time work appear to have two options: travel farther for studies or change their childbearing status. Bree, a black woman in her late 30s and self-proclaimed "professional lab rat," was the highest earning woman in our study (i.e., ~\$60,000 from ten studies in three years²), and she adopted both strategies. Bree lived in the Northeast, but she traveled to Texas and other Midwestern Phase I clinics to participate. She had also undergone a tubal occlusion after having her three children. Despite this, Bree lamented,

Men can easily-, if you don't make it into one study [as a man], you can easily go somewhere else and get into another, ... but as a woman, ... you have to look at the birth [control] options: are you childbearing [or] are you nonchildbearing? If you're nonchildbearing, what type of procedure did you have? What are they looking for exactly? If you are childbearing, then have you taken the appropriate type of birth control because if you're not taking anything, they might not want that. You might not have had sex for years, but so what, you know? [laughs] They still won't want you because there is always that assumption that you could get pregnant.

While Bree had participated in more than 40 clinical trials and could earn a relatively decent income from it, she had to put in much more effort than most healthy volunteers—women *and* men—ever would. Her reflection here also highlights the implicit assumption in biomedicine that women screening for trials are heterosexual and sexually active.

To cope with the always-present assumption that women are "mothers-in-waiting," at least two women in our study expressly underwent permanent sterilization to qualify for more Phase I trials. One of these women was Tammy, a white woman in her 40s who had participated in 13 trials at baseline:

²Bree's \$60,000 in clinical trial compensation over three years can be compared to the \$104,100 earned by the top earning male participant in the study. The 47 women in our study averaged \$11,712 in earnings compared to the 131 men who earned \$18,975 across the same three-year period. Thus, our data suggest a wage gap between men and women who participate in Phase I clinical trials.

This is kinda embarrassing to admit. Nobody knows this, not one person in my life, not my family or friends, but I got a procedure called Essure, E-s-s-u-r-e. There were so many good paying studies coming up for women who were surgically sterile or postmenopausal and I was never qualifying for them. ... So, then I became a surgically sterile category and I could get into quite a few of these better paying studies. Like the \$6,000 one [I did] was for women who are surgically sterile.

Tammy gave herself an advantage (while taking on a risky procedure that is now deemed unsafe³) by undergoing Essure. Her experience illustrates the lengths to which women must go in order to be able to earn money from clinical trials.

However, even when women modify their bodies for Phase I trials, their generic potential for pregnancy *as women* can remain more compelling to clinics than their actual anatomy or sexual practices. Studies varied from liberal inclusion criteria in which women could claim abstinence as their primary method of birth control to studies that considered women who had tubal ligations or tubal occlusions to still be of childbearing potential. For Renee, who had also undergone permanent sterilization to increase her eligibility, this inconsistency in what counts as sterile and childbearing was particularly disheartening. A multiracial woman in her 30s, Renee had quit her full-time job in a large corporation's HR department in order to participate in clinical trials full-time and simultaneously pursue more creative endeavors. She was chagrined to discover that her tubal occlusion procedure was insufficient to make her count as nonchildbearing for all trials:

I went ahead and got my tubes tied in December, and it's still the same thing [I'm excluded from studies]. A lot of places like [Northeast Clinic], most of their studies are for postmeno women, and I'm like, "I can't have kids. You know, what's the big deal?"

Phase I clinics are also not always clear about the eligibility requirements for a particular study. Based on a phone screening process, women can be under the impression that their tubal ligation or occlusion is sufficient to allow enrollment. They might make an appointment to screen in person at the clinic only to find out the study demanded a hysterectomy or postmenopausal status. This was a complaint we heard from Penny, a black woman in her 40s who had participated in six studies at baseline:

My tubes are tied, but I still have all my female parts. ... They [the clinic staff] called me and they told me, "Oh, well, you're not completely sterile [so you can't participate]." And I had already went through all the screening and everything. ... They were looking for women that were completely sterile, and that was a mistake on their part [to let me screen]. ... But I mean, that's not the first time that's happened. It happened a couple times, I guess, where I come to the screening and they told me I didn't qualify because I didn't have a hysterectomy.

³Essure is no longer available for sale or distribution in the United States due to serious risks, including perforation of the uterus and fallopian tubes and allergic reactions. See <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/default.htm> (last accessed December 18, 2019).

The money trial participants spend traveling to clinics is not reimbursed, so for women who travel far from home to screen, these expenses are considerable when not counterbalanced by study compensation. Thus, the wide variation across studies as well as the lack of detailed and accurate information provided in advance of screening can prove costly, disempowering, and ultimately devalue women's contributions to clinical labor.

Surveillance Experiences while Participating in Trials

After enrolling, women must also consent to ongoing surveillance during a Phase I study. Here too we see the assumption of anticipatory motherhood underlying women's experiences in clinics. Regardless of their individual childbearing potential, women routinely experienced additional procedures, such as blood draws and urine collection, to test for pregnancy. Bree flagged the discrepancy in blood draws for men and women: "For this study, it has 42 [blood draws], but for me, I get 45. ... Because every time I check in, they're checking to see if I'm pregnant, so I get three extras." In contrast, men are merely instructed to use two methods of birth control during a clinical trial and for 90 days after their last dose of an investigational drug. Women's bodies require additional documentation about their childbearing status while also being actively monitored.

For those women who have gone through sterilization procedures, they must supply their medical records or submit to additional testing, such as sonography, to confirm that they have had a tubal ligation or other procedure. Ultimately, as Penny declared, the burden of proof is on women when it comes to their childbearing status: "And, you have to bring proof. You can't just be like, 'Oh yeah, I'm using a condom. Oh yeah, I'm on birth control.' You have to bring the proof." None of the 131 men in our study discussed the need to "prove" that they use condoms to trial administrators. In this way, women encounter the logics of anticipatory motherhood that pervade Phase I research. Consenting to the risks to themselves or potential future fetuses is not seen as sufficient in the informed consent process, and instead their agency here is subordinated to the clinic and pharmaceutical company's authority—a practice also seen in certain patient populations, such as trans patients, whose agency in informed consent processes is routinely subordinated to medical authority (shuster 2019).

When women are excluded from Phase I trials, it is not only because of their biological sex; it is also because of assumptions about sexual activity. While abstinence can be an authorized form of birth control in some studies, the informed consent process largely assumes all participants to be sexually active. Using standardized consent forms, which include details about the study risks, inclusion-exclusion criteria, and proscribed behaviors during the study, sex within Phase I trial parameters is always presumed to be a heterosexual and procreative activity that can result in a pregnancy, regardless of a woman's age, medical history, sexuality, or other factors (Cottingham and Fisher 2015). From the perspective of participants, this can be perplexing and annoying. For instance, Helen, a white woman in her 40s, commented,

But see, I had a tubal ligation, so there's nothing else happening here [referencing her torso], you know? [laughs] ... I'm like, "I don't know why I have to take a

pregnancy test. You know my stuff's sterile." But it's still required. I said, "It's a waste of money [for the clinic], but I'll do it."

Helen's quote here suggests that even when conception is implausible, women can be subjected to surveillance practices similar to those detailed by Bree. Underlying these practices is a framing of women as always potentially pregnant regardless of her actual fertility status along with the assumption that even if she were to become pregnant, other choices such as abortion would not be an option for her. This relies on a limited view of women's reproductive agency.

In another example, Jackie, a multiracial Hispanic woman in her 40s, noted how even postmenopausal women are subjected to frequent pregnancy tests:

A lot of ladies in the study [with me], they're like 60 and something like that, and they have me cracking up. They're like, "Oh my God, I don't even have a period anymore. ... I'm not gonna get pregnant. ... I don't wanna have to pee in a cup all the time every time I come. I haven't had a menstrual cycle in like 12 years, so I don't know why they're worried." [laughs] ... Yeah, they get a little upset.

While the postmenopausal women in Jackie's study might have been frustrated by the additional procedures, Jackie's mirth signals the absurdity of the situation. Even if postmenopausal or surgically sterile, women are still required to be under surveillance, suggesting that all women are seen through the eyes of clinic policy as pre-pregnant.

The need for heightened surveillance of women after they enroll in Phase I trials might be affirmed by the occasional pregnancies that do occur. Two of the women in our study told us they became pregnant during a clinical trial and chose to have an abortion. One was Celeste, a black woman in her mid-20s who participated in clinical trials full-time and was completely financially dependent on trial earnings. Celeste claimed either abstinence or spermicidal condoms as her primary method of birth control, which restricted her access to many clinical trials, but by traveling throughout more than half of the U.S., she was nevertheless able to find studies that allowed her to enroll. When discussing her birth control method, she initially confided in us,

As far as the birth control method, I don't [follow trial restrictions]. ... I've been with one person for three years, so it's just, we're not gonna be using that [i.e., condoms]. ... So I don't follow that. ... As long as I don't get pregnant, I'm good.

The interviewer followed up to ask, "But you're not trying to get pregnant?" To which, Celeste responded, "No, I don't want kids." Three years later, during our final interview, Celeste recounted how her pregnancy was detected at an outpatient visit after she had already been dosed with the investigational drug and completed the confinement portion of the study:

I wound up getting pregnant, but I didn't know I was pregnant. The study doctor called me and told me I was pregnant. And I wound up getting banned [from enrolling in studies at that clinic], so yeah. I wound up getting an abortion. ... That happens to a lot of women. A lot of women get pregnant and then get banned.

Celeste was notably bothered by being banned by one of the best paying clinics in the country. She understood that the ban was because she had lied about her birth control method, but she asserted, “They’re [the male participants] not supposed to get anybody pregnant either, but I’m quite sure they do, you know?” Although Celeste did not develop this line of thought further, the implication, based on her experience, is that women are held to a different standard because their bodies are the ones subjected to pregnancy surveillance. The partners of heterosexual men who participate in clinical trials are seen as beyond the reach of Phase I clinics’ surveillance practices. The tools of the clinic, and the logics by which they are used, mean that men can never be similarly penalized for breaking the rules or misrepresenting their contraceptive methods.⁴

Celeste’s experience illustrates another critical piece of how anticipatory motherhood shapes Phase I trial participation and forms part of the gendered logics of clinical research organizations. Abortions are legal in the U.S., but unknown and putative fetal risks are framed as the inevitable outcome of an unplanned pregnancy as opposed to a new decision point at which a woman might weigh her options to carry a pregnancy to term or opt for an abortion. Surveillance practices in the clinic and inclusion-exclusion criteria that require varying types of sterilization or postmenopausal status focus on preventing a pregnancy altogether rather than recognizing abortion as an option. Such practices appear at odds with ones that would uphold women’s autonomy to make reproductive decisions. Despite these heightened efforts to avoid pregnancy, women still become pregnant, which might confirm for the industry the need to treat women’s involvement in clinical trials with all the more caution.

Women must navigate a more intricate screening process and additional surveillance compared to their male counterparts, highlighting the gendered assumptions embedded in clinical trial protocols. In turn, these restrictions might encourage women to manipulate the truth to gain access to Phase I trials and the income they offer. Men may be equally dishonest about their sexual practices (see footnote 4), but they are less likely to be caught and banned from clinics as a result of any nonadherence to contraceptive requirements. By stripping women of childbearing potential of their agency—both medical *and* reproductive—through the always-present assumption of anticipatory motherhood, women are hampered in earning a living through clinical trial participation.

Women’s Reactions to Trial Practices

The women in our study had mixed views about the restrictions Phase I trials impose. It is important not to treat the category of woman as monolithic, so we examined our data to determine if these reactions varied across race, ethnicity, or dependence on clinical trial income. Women of childbearing potential from all racial and ethnic groups described the barriers they—and other women like them—had faced when trying to enroll in clinical trials.

⁴It is difficult to determine for certain if Celeste’s hunch here is correct. From our longitudinal follow-up with the 131 men in the study, we identified 5 instances in which they likely did have a pregnant partner in violation of clinic policy. In one of the five cases, the pregnancy was terminated. But the total number of terminated pregnancies among both men and women in our sample is impossible to determine.

However, our data suggest that white women tended to approach these restrictions with greater trust in the clinics and a sense that clinic protocols are intended to protect them.

For those women who framed women's study restrictions as positive rather than negative, they often accepted the logic that women and fetuses must be protected from clinical trial risks. With her long history of clinical trial participation, Tina largely trusted the clinics to keep women safe. In describing how she explained studies to a female friend, she said,

I told her the good thing about females doing studies is you usually don't qualify for the really risky ones, especially since she still has childbearing potential. ... Some clinics are very nervous about women doing things with childbearing potential. They're not gonna let you do any of the risky things, you know?

In another example, Jackie noted that due to the research clinic's warnings, she modified her sexual activity with her husband, even though he had a vasectomy:

Because they did say in the study, "We're not sure like if someone did become pregnant how it would affect the fetus," or something like that. So, I'm like, "Okay, how about I just don't do anything [i.e., have sex] until ... the study ends. And so, I'm like, "Okay. I'd rather be safe than sorry."

Some women explicitly wanted to avoid deleterious effects on their childbearing potential, and they trusted the clinics because they perceived that, as commercial enterprises, the clinics have an economic incentive not to harm women. Jennifer, a white woman in her 20s who was enrolled in her first Phase I trial at baseline, stated,

For a lot of [studies], you could not be a woman of childbearing potential, so that made things kinda difficult [to find a new study]. ... I think they probably do it because they don't want to get sued—which I totally understand—just in case it makes you barren or something. So depending on the type of drug that they're testing, I think that would be pretty fair [to exclude women]. They're just looking out for their own asses and, you know, try not to hurt people in a way that would last.

In these three cases, women did not critique the paternalism embedded in study protocols, seemingly feeling personally safer as healthy volunteers due to these restrictions.

Concerns about the risks to women of childbearing potential were particularly poignant for Becca, as in many respects she embodied anticipatory motherhood in her orientation to her clinical trial participation. When we met Becca, she was engaged, and over the next three years, she got married and planned to have children. Even though her childbearing status regularly prevented her from enrolling in a new trial, Becca's desire for future children was a critical part of her perceptions of those restrictions on her participation:

I guess it's just a safety precaution. ... If it's [the study drug] really like something that could possibly have long-term effects on you and you still plan on having kids, and ... I guess that if they have to put that protocol [to exclude childbearing women] in there, it's necessary. You know?

Rather than critique the assumptions underlying this policy, however, Becca also emphasized her trust in the doctors:

It kind of sucks for me because, you know, I can't do as many studies as I'd like to. But, I mean, overall, I think they're probably doing it for the best, you know. They're the doctors; they know what's going on, so you got to trust them in that aspect.

Becca never explicitly questioned that restrictions on her trial participation were anything but reasonable. Over the final two years of her participation in our study, Becca suffered two miscarriages. Reflecting on the inclusion of women of childbearing potential in Phase I studies, she confided,

I guess I really started thinking more about how it affects you later on in your life, with all the medical issues I've been having now [i.e., both miscarriages]. ... Before, I didn't really think about how it would affect my future. ... I hate to think negatively about it, but I mean, there's always the possibility that one of these trials affected me carrying a child. But I prefer not to think about it.

Becca will likely never know whether her clinical trial participation played any role in her miscarriages, but if anything, it would confirm for her that women of childbearing potential ought to be considered a population in need of special protection in clinical trials. For her and some of the other women in our study, these concerns outweighed their frustration at not being able to earn as much income enrolling in Phase I trials as men typically can.

In contrast to a reaction of trust, a second group of women in our sample took a less charitable stance toward the restrictions on women of childbearing potential that were in place. These individuals perceived the restrictions as unfair, particularly for those who have had sterilization procedures done. For example, as someone who had no intentions of having another child, Renee had concerns not about the potential risks of her clinical trial participation to a future pregnancy but to her livelihood, especially since she relied fully on studies to support her two daughters and herself. When she learned that her tubal occlusion was insufficient to qualify her for a high-paying study that was seeking men and postmenopausal women, she reflected on the "rough" financial situation she was experiencing: "So, once again, [laughs] once again, I felt like I was screwed." In another example, Joan noted that it was completely unfair that women were excluded from many Phase I trials. She felt that if women use a reliable form of birth control, there should be no issue with them participating. She even went further and connected such exclusion to population health, noting both the importance of knowing how women react to medications and the absence of that information based on how studies are currently designed.

The "unfairness" of the exclusion of women from clinical trials often focused on women's need to take care of the children they have, and the lack of clinical trial opportunities impeded the income they could earn for their families. Rachel, a black woman in her 30s who had participated in two studies at baseline, simply stated, "I'm just an average person, a mother who was looking for a way to feed my family and keep my head above water until I was able to find a stable job again." Evonne, a black woman in her 30s, had tried to enroll in dozens of studies but kept getting denied because of her childbearing status, which she

contrasted to her brother's ability to enroll whenever he desired. Acknowledging that there could be risk to a future fetus, Evonne shared,

I'm not pushing to have any kids right now or anything like that. ... I would be concerned if I did have another child because I would be concerned that I've done these studies and if it would be defected or if I had any, you know, issues with my child's birth. ... But even if you're not doing any studies, you never know. You never know what kind of kids you're going to get. And I just look at life like that. Things come your way and just take them as it goes. You make decisions in life and you just have to live off of them, and that's kind of how I see it.

This quote from Evonne highlights the ambivalence that the majority of women expressed when it comes to the risk of trials. More important than risk to a future fetus, however, was Evonne's unstable financial situation. Putting her present child in the frame, she explained, "I've just been kind of preparing myself for the worst-case scenario and just, you know, give myself a [financial] booster any way possible, or just helping with my daughter." In this sense, Evonne saw her current situation as necessitating some level of risk that she was prepared to accept. Doing so meant prioritizing her role as actual mother to her daughter over the possibility of harm to future, hypothetical children. Yet, the policies and practices embedded in clinical research organizations curtail her ability to make such choices or weigh these risks herself and instead deny her access to certain clinical trials outright.

Conclusion

Examining Phase I trials as a gendered organization (Acker 1990) highlights the logics and assumptions that underlie policies and practices that women experience while trying to enroll and participate in Phase I clinical trials. We found that women, as potential research subjects, confront their childbearing status as one of the key barriers to enrollment—though the definition of this status and the criteria used to include or exclude women varied across clinical trials and research clinics. As "clinical laborers," female healthy volunteers must continuously prove through heightened surveillance that they are not (yet) pregnant, a risk which is constructed as so great that it can defy the odds and occur even in postmenopausal and surgically sterile women.

Our findings further demonstrate not simply the barriers, varying criteria, and experiences of surveillance that women confronted, but also their diverse reactions to these policies. Some women accept paternalistic policies as a sign of protection and accept the logics of "anticipatory motherhood." Such women rarely questioned, despite scientific evidence to the contrary, that women should be treated differently than men when it comes to (presumed) fetal risk, accepting that women hold full responsibility for future adverse fetal outcomes (Daniels 1997). Yet, other women in our sample did not perceive the exclusion of women of childbearing potential as wholly benevolent and might instead point to their need to provide for existing children, not phantom fetuses. In this sense, women as a group see clinical practices along a continuum between "care" and "control" similar to that described by surveillance scholars (Lyon 2001; Monahan 2011). Although not absolute, white women were more likely to interpret policies of exclusion and surveillance as a form of care, while black women focused on these policies' effect as gatekeeping mechanisms that limit their

access to the financial benefits of trial participation. Certainly, the specter of medical abuse and unethical practices that exploited racial and ethnic minorities in the past could be at play here (Briggs 2002; Reverby 2009; Skloot 2010), but minority women did not articulate *distrust* in researchers. Indeed, they wanted more access to the financial benefits of enrolling in Phase I trials. This suggests that low-income women of color may feel these practices of exclusion more acutely and be disproportionately harmed by a lack of financial alternatives.

Anticipatory motherhood marks all women as potential carriers of financial and legal risks to pharmaceutical sponsors and research clinics. Through their attempts to meet inconsistent inclusion criteria and repeated surveillance in pregnancy testing, even the most motivated women in our sample can have difficulty finding studies in which to enroll. The logic of the female body as a source of risk and always potentially pregnant then occludes the real harms that can occur when women are routinely excluded from biomedical research. This practice seems to devalue women as clinical laborers, but also as patients. All women might be harmed further downstream if they become consumers of pharmaceuticals whose safety has been insufficiently vetted for their bodies. Framing clinical research organizations as gendered (Martin 2003) draws our attention to the tacitly circulating assumptions and practices that create added demands for women. The logic of anticipatory motherhood is clear in this context, and future research on gender and organizations should continue to examine it directly as a possible mechanism of exclusion in other contexts. Yet our findings also suggest that the logic of anticipatory motherhood may have disproportionate effects based on social class and race, eliciting diverse reactions and varying degrees of harm depending on one's access to alternative work opportunities.

The practices and policies of pharmaceutical companies and research clinics that we identify here are avoidable. In this quasi-healthcare context, just another blood draw, medical record, or urine test seems like the most obvious solution to concerns about hypothetical fetuses and corporate liability. But we can easily imagine other practices that do not reinforce a logic of anticipatory motherhood in which all women (and only women) are reduced to their childbearing status and subjected to added surveillance. For example, free birth control, including condoms for men, abortion care, or checks on sperm count and vitality for male participants could be implemented into these organizational practices. Rather than distrust and scrutinize women, policies could instead facilitate the medical and reproductive agency of all participants.

The organizational logics of Phase I clinical trials, parallel to logics in other contexts (Waggoner 2017), assume that women are “pregnant until proven otherwise,” painting women to be actively and irresponsibly heterosexual. The gendered meaning of this is that the female body and its connection with motherhood is at odds with earning money through clinical trials, which supposedly engender risks to future children for base and selfish reasons (Cf. Almeling 2011; Waggoner 2017). Moreover, within this frame, the assumption is that any pregnancies that occur will be carried to term and with negative fetal outcomes. Our findings show that some women are willing to seek abortions, yet terminating a pregnancy is never spoken of as an option when restricting women's clinical trial participation. These policies disadvantage working-class and minority women by denying them equitable access to clinical-trial work and revoking their ability to assess risk for

themselves. Thus, rather than helping women by affirming their reproductive choices, the anticipatory motherhood logics inscribed in clinical trial organizations constrict vulnerable women individually and further a biomedical reality in which women's health depends on therapies tested primarily on male bodies.

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Table 1.

Demographics of Women Study Participants (N = 47)

	n	%
Arm of Study		
Full-Participation	35	74.5%
Control	12	25.5%
Clinical Trial Experience		
1 study	11	23.4%
2–4 studies	19	40.4%
5–10 studies	10	21.3%
11–45 studies	7	14.9%
Race / ethnicity		
Non-Hispanic white	21	44.7%
Black	15	31.9%
American Indian	1	2.1%
Asian	1	2.1%
More than one race	2	4.3%
Hispanic ¹	9	19.1%
Age		
18–21	1	2.1%
22–29	8	17.0%
30–39	11	23.4%
40–49	16	34.0%
50+	11	23.4%
Marital Status		
Single, never been married	13	27.7%
Married (or marriage-like, long-term relationship)	15	31.9%
Separated or divorced	16	34.0%
Widowed	3	6.4%
Number of Children		
0	13	27.7%
1–2	18	38.3%
3–4	13	27.7%
5–6	3	6.4%
Fertility Status at Baseline		
Childbearing potential	24	51.1%
Post-menopausal	6	12.8%
Sterile	14	29.8%
Unknown/missing data	3	6.4%

	n	%
Educational Attainment		
Less than high school	2	4.3%
High school or GED	5	10.6%
Some college	16	34.0%
Trade/Technical/Vocational training	4	8.5%
Associates degree	9	19.1%
Bachelor degree	10	21.3%
Graduate degree	1	2.1%
Employment Status ²		
Full-time/Business owner (self-employed)	18	38.3%
Part-time/Independent or Irregular Contractor	8	17.0%
Unemployed/Retired	21	44.7%
Household Income		
Less than \$10,000	10	21.3%
\$10,000 to \$24,999	13	27.7%
\$25,000 to \$49,999	17	36.2%
\$50,000 to \$74,999	5	10.6%
\$75,000 to \$99,999	1	2.1%
\$100,000 or more	1	2.1%

¹The category Hispanic includes all racial groups, of which we had participants in our sample who identified as white, more than one race, and American Indian.

²These data are based on consolidated definitions of each employment category that we used to standardize self-reported data from participants.