In Search of Success: The Politics of Care and Responsibility in a PrEP Demonstration Project among Sex Workers in India

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Abstract

Pre-exposure prophylaxis (PrEP), which contains a combination of tenofovir and emtricitabine, has emerged as a new biomedical HIV prevention option. Multilateral groups and health policy makers have called for demonstration projects to better understand PrEP’s everyday use and effectiveness. Funded by the Bill & Melinda Gates Foundation and in partnership with the University of Manitoba, Ashodaya Samithi, a sex worker collective, initiated a PrEP demonstration project in Mysore and Mandya, Karnataka State, South India. Drawing on qualitative ethnographic methods, a study of the PrEP demonstration project took place between January 2015 and April 2018 and included field visits, participant observation, and in-depth interviews with demonstration project participants and the implementation team. Community researchers and I conducted 167 interviews over the course of the study. Following a community validation and contextualization (or “member checking”) session, I coded the data for key themes and emergent categories. According to the biomedical indicators of retention and adherence, the demonstration project proved immensely successful, with 640/647 participants retained for the 16-month project and participants reporting high adherence confirmed by blood-level tenofovir testing. Attempting to more fully account for how this “success” arrived, however, I go beyond these biomedical interpretations of retention and adherence, pointing instead toward Ashodaya’s history of collectivization around sexual health—a history of community action that has given rise to forms of health citizenship and new spaces of belonging for sex workers. In what I call the “search for success”, a particular attention is placed on the role that care plays among Ashodaya sex workers over the life course of the demonstration project. This care is tied not only to the community of sex workers Ashodaya seeks to serve, but also to
the careful production of evidence that demonstrates accountability to funders, which is, furthermore, tied to caring for the very survival and future of the organization.
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<th>Full Form</th>
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<tbody>
<tr>
<td>ART</td>
<td>Antiretroviral Therapy</td>
</tr>
<tr>
<td>AVAC</td>
<td>AIDS Vaccine Advocacy Coalition</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>CMC</td>
<td>Clinic Management Committee</td>
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<tr>
<td>DMSC</td>
<td>Durbar Mahila Samanwaya Committee</td>
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<tr>
<td>HMSC</td>
<td>Health Ministry Steering Committee</td>
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<tr>
<td>IBBA</td>
<td>Integrated Behavioural and Biological Assessment</td>
</tr>
<tr>
<td>IEC</td>
<td>Institutional Ethics Committee</td>
</tr>
<tr>
<td>IERB</td>
<td>Institutional Ethics Review Board</td>
</tr>
<tr>
<td>ICTC</td>
<td>Integrated Counselling and Testing Centre</td>
</tr>
<tr>
<td>NACO</td>
<td>National AIDS Control Organization</td>
</tr>
<tr>
<td>NGO</td>
<td>Non-governmental Organization</td>
</tr>
<tr>
<td>NSWP</td>
<td>Global Network of Sex Work Projects</td>
</tr>
<tr>
<td>PrEP</td>
<td>Pre-exposure Prophylaxis</td>
</tr>
<tr>
<td>RDS</td>
<td>Respondent Driven Sampling</td>
</tr>
<tr>
<td>STI</td>
<td>Sexually Transmitted Infection</td>
</tr>
<tr>
<td>SCM</td>
<td>Syndromic Case Management</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<td>-----------</td>
</tr>
<tr>
<td>TI</td>
<td>Targeted Interventions</td>
</tr>
<tr>
<td>UNAIDS</td>
<td>The Joint United Nations Programme on HIV/AIDS</td>
</tr>
<tr>
<td>USD</td>
<td>United States Dollar</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>Wits RHI</td>
<td>Wits Reproductive Health and HIV Institute</td>
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Chapter 1. Introduction

BACKGROUND

India has the third largest HIV epidemic in the world, despite a low overall prevalence of 0.22% (National AIDS Control Organization & ICMR-National Institute of Medical Statistics, 2018). An estimated 2.14 million people currently live with HIV in the country, with an estimated 87,580 new infections in 2017 (National AIDS Control Organization & ICMR-National Institute of Medical Statistics, 2018). India has what public health researchers and policy makers working in the field of HIV term a concentrated epidemic among “key populations”,1 such as sex workers, men who have sex with men, and people who inject drugs. While national HIV prevalence has decreased among sex workers from 10.33% in 2003 to 1.56% in 2017, prevalence rates are higher in certain states such as Karnataka, where prevalence remains above the national average at 3.33% (National AIDS Control Organization, 2017).

Targeted interventions in India, led by the National AIDS Control Organization (NACO) and the Bill & Melinda Gates Foundation’s Avahan Initiative, have helped lead to these sharp declines in HIV incidence over the last decade. These “targeted interventions”, as epidemiologists refer to them, have largely focused on promoting consistent condom use among

1 Terms such as “key populations”, “high risk groups”, and “at-risk” have widely been used in the field of HIV research. While these terms seek to highlight the needs of populations who may experience higher HIV prevalence, they can also be stigmatizing and mask structural factors that can contribute to HIV risk, while focusing attention to individual-level behaviors.
sex workers and their clients, with 90% of sex workers reporting using condoms with new clients (Mitchell et al., 2016; Reza-Paul et al., 2008). However, condom use continues to remain low with regular partners, such as husbands and boyfriends (Deering et al., 2011; Fehrenbacher et al., 2018; Isac et al., 2016). Global health scientists remain particularly preoccupied with trying to further reduce HIV incidence among women who sell sex. For this reason, many leading figures in global health have touted pre-exposure prophylaxis (PrEP) as an exciting new HIV prevention strategy that involves the use of antiretroviral medications to reduce the risk of HIV infection (CDC, 2014). Accordingly, protocols developed by clinical scientists outline PrEP usage as the intake of a daily pill (the combination of the antiretroviral therapies tenofovir disoproxil fumarate (TDF or tenofovir) and emtricitabine (FTC)) among people who do not have HIV to keep the virus from establishing a permanent infection (CDC, 2014). PrEP is not intended to replace existing HIV prevention technologies and strategies, such as consistent condom use and behavioural change. Rather it is intended to be implemented in combination with them.

Various clinical trials throughout the world (such as in Brazil, Ecuador, Kenya, Peru, South Africa, Thailand, Uganda, and the United States) have shown high clinical efficacy of PrEP (see for example: Baeten et al., 2012; Choopanya et al., 2013; Grant et al., 2010; Haberer et al., 2015; Martin, Vanichseni, et al., 2015; McCormack et al., 2015; Ndase et al., 2014; Thigpen et al., 2012). However, public health program planners are faced with the challenge of how to roll out PrEP as part of their existing HIV services, without undermining or conflicting with existing condom promotion programs which not only protect from HIV infection, but other sexually transmitted infections (STIs). Based on these program concerns, the World Health Organization (WHO) has recommended that countries undertake PrEP demonstration projects to ascertain its “real world effectiveness” (World Health Organization, 2012). Although less
scientifically stringent than a randomized control trial, lacking a control group, PrEP demonstration projects nevertheless are conducted under technically-regulated conditions to produce standardized forms of knowledge, based on rigid measures that track retention, adherence, risk behaviours, and clinical markers. One could argue that these demonstration projects—where participants are enrolled in a study, provided PrEP free of cost, and closely monitored through ongoing clinical visits, survey participation, and blood-level monitoring of the drug—still more closely resemble clinical trials rather than “real world” conditions. At the same time, these demonstration projects provide important opportunities for frontline health workers and local program planners to better understand how new prevention technologies are accepted or refused and utilized within the communities to which they regularly provide health services.

Building on a feasibility study that assessed the acceptance of PrEP among sex workers (Reza-Paul et al., 2016), the Gates Foundation approached two world-renowned sex worker-led organizations in India to test the effectiveness of PrEP when rolled out as a program through a 16-month demonstration project. The two organizations, Durbar Mahila Samanwaya Committee (DMSC) in Kolkata, West Bengal and Ashodaya Samithi in Mysore-Mandya, Karnataka, were chosen as both are known for their leadership in sex worker-led mobilization and innovations in community-based sexual health interventions that have led to high rates of condom use, reductions in HIV and STIs, and a strong sense of community ties. While Ashodaya Samithi was inspired and mentored by DMSC, as part of the Avahan initiative, they cultivated a particular set of skills around evidence production and research that facilitated their lead in conducting the PrEP demonstration project. From a global public health perspective, according to indicators around retention and adherence, public health scientists have found the results in both sites to be
tremendously “successful”, with findings celebrated at international AIDS conferences (see for example, Cairns, 2018).

My ethnographic study raises a number of critical questions about this often-unquestioned notion of success. The attempt is not to query the numbers, per se, but to contextualize the social processes that underlie the making and remaking of success while also illuminating how “success” is problematically conceptualized in global health sciences. Focusing on the life story of the PrEP project in one of the two sites, Ashodaya Samithi in Mysore-Mandya, I argue that the “tremendous success” declared in terms of the project outcomes must be understood beyond narrow public health notions of retention and adherence—which are based on universalistic notions of human bodies and ahistorical notions of behaviours. To more fully contextualize the striking health outcomes of this project I consider, instead, the lively forms of sociality and politics that emerge around HIV prevention projects that engage sex worker groups. More broadly, this thesis aims to disrupt and move beyond the global HIV policy distinction continually redrawn between biomedical and social interventions (see for example Adam, 2011; Adams, Craig, & Samen, 2015; Guta, Strike, Flicker, Murray, Upshar, & Myers, 2014; Lorway & Khan, 2014; Nguyen, O’Malley, & Pirkle, 2011). As noted by sociologist Barry Adam (2011, p. 5), “all biomedical prevention technologies are also social interventions”; for they must account for, respond to, and navigate an array of social realities—including those socialities that they usher into being.
**LITERATURE REVIEW**

**Theoretical Framework**

This thesis draws upon medical anthropological theories of health citizenship, which move beyond the notion of citizenship as a natural legal status bestowed upon the “rights-bearing” individuals within a defined geographic territory or nation-state (Marshall, 1950). Health citizenship explores how the dynamics of health and disease can influence the formation of individual and collective identities, relations of responsibility, and strategies for protection to create new kinds of societies (Guta et al., 2014; Khan et al., 2017; Lorway & Khan, 2014; Nguyen et al., 2011; Petryna, 2004). This study explored how the introduction of PrEP produces new forms of “biosociality” (Gibbons & Novas, 2007; Hacking, 2006; Rabinow, 1992), where a newly introduced biomedical technology can create discourses of social inclusion or exclusion within sex worker communities. Although the concept of biosociality has been applied to research on HIV (see for example, Marsland, 2012; Valle, 2015) in the context of PrEP, little is known about how these types of projects stir up politics and usher in new forms of sociality in postcolonial contexts such as India.

**Citizenship and Social Class**

To begin to unpack conceptual questions that pertain to health citizenship, I begin with British sociologist Thomas Humphrey Marshall’s (1950) foundational work. Although my study is concerned with India, I take this foundational text as my theoretical entry point for two reasons: firstly, many of these notions of citizenship were first introduced by Marshall’s work in post-war Britain, and second, since independence, India took up a rather western model of the
nation-state and citizenship, as I later discuss in relation to Chatterjee (2004, 2011) and Sharma (2006, 2008) and the growing neoliberalization of India’s political and economic landscapes.

According to Marshall (1950), citizenship is a “status bestowed on all those who are full members of a community” (p. 28).\footnote{While Marshall (1950) himself admits that his discourse on citizenship relates to the experiences of men, scholars such as Wendy Sarvasy (1997) have re-addressed social citizenship through a feminist lens to rethink citizenship beyond capitalism towards a “vision of politics as centrally concerned with the nurturing of human life” (p. 55). Savarsy argues that a feminist notion of citizenship would encompass new modes of citizen activities, such as “social service” and “social service participatory politics” (p. 55), to account for women’s work in community service and expand spaces for feminist citizenship.} In his classic exploration of *Citizenship and Social Class* (1950) in Britain, Marshall outlines the expansion of civil rights afforded to citizens in the 18th century, which included such rights as freedom of speech and religion, individual liberty, property ownership, and justice. Political citizenship of the 19th century encompassed the rights to participate in the exercise of political power, in parliament or government. The 20th century saw these rights expanded to the social realm, with a focus on rights that allowed citizens to “live the life of a civilized being according to the standards prevailing in the society” (Marshall, 1950, p. 11). Social citizenship was aimed at “raising the basement” so that all members of a society have basic rights, however, in practice, it can be seen more as raising the basic standard of living just enough to ensure a productive society and productive work force, rather than addressing the root causes of inequality (Marshall, 1950). As Marshall put it, “[t]he duty to improve and civilize oneself is therefore a social duty, and not merely a personal one, because the social health of a society depends upon the civilization of its members” (1950, p. 26). Those who failed to contribute meaningfully to society and required social supports lost their rights to citizenship. In
this way, protections were provided to women and children, who were not seen as full citizens (Marshall, 1950).

It cannot be overlooked that with the rise in the rights of social citizenship, so too rose the growth of capitalism, a system steeped in inequality and class division. Social protections ensured a productive working class, with poverty seen as failure through a moral lens (Marshall, 1950). Importantly, Marshall explains that “[d]ifferential status, associated with class, function, and family, was replaced by the single uniform status of citizenship, which provided the foundation of equality on which the structure of inequality could be built” (1950, p. 34). Here we see the formation of the responsibilized citizen, one who must be a productive and contributing member of society in order to earn the social comforts available to him as a citizen (Marshall, 1950). Despite a growing interest in equality, citizenship rights did little to reduce social inequality, with capitalism posing limits to social and economic equality, despite the creation of certain safety nets like guaranteed minimum incomes, old age pensions, insurance benefits, and family allowances. Nevertheless, the expansion of citizenship into social rights was seen as enriching “civilized life” and leading to:

a general reduction of risk and insecurity, an equalization between the more and the less fortunate at all levels between the healthy and the sick, the employed and the unemployed, the old and the active, the bachelor and the father of a large family. Equalization is not so much between classes as between individuals within a population which is now treated for this purpose as though it were one class. Equality of status is more important than equality of income (Marshall, 1950, p. 56).

In this way of thinking, the rights of citizens are the rights to equality of opportunity. However, we understand that whereas citizenship takes on a rights-based approach, and affords certain
basic benefits to its members, status remains tied to social class. Through citizenship, subjects are meant to be “responsibilized” into moral citizens who are expected to perform in a specific way—that is, as productive and contributing members of a capitalist society.

Rose (2000) continues to build on Marshall’s analysis of citizenship in an exploration of community and citizenship in the “Third Way” political era in the United Kingdom, the United States, and parts of Europe, tied to the centrism of the 1990s ushered in by Tony Blair’s New Labour. Rose asserts, “what is most significant is the emergence of a new politics of conduct that seeks to reconstruct citizens as moral subjects of responsible communities” (2000, p. 1395). The Third Way claims a mutual responsibility and a belief in a common purpose among citizens. It internalizes the concept of “society” within its citizens, creating a “framework of belief” (Rose, 2000, p. 1396). Rather than being a tangible political program, the Third Way creates a set of moral principles that work to legitimize the responsibilities of citizens and somehow manage to instil a set of collective responsibility within an individualized society.

Human beings are now considered to be, at root, ethical creatures. The problems that human societies are undergoing are increasingly made intelligible as ethical problems, and new ways are emerging for governing the behavior of individuals through acting on this dimension of ethics (Rose, 2000, p. 1398).

The Third Way creates a new “ethical citizenship” and a responsibilized community, one that is removed from the state (Rose, 2000, p. 1398). Citizenship, according to Rose, can be

3 In sociology and anthropology, “community” has been multiply defined in relation to space, shared values, ideologies, histories, identities, and legal constructs. In this study, I am most interested in understanding how people come to think and feel about themselves as communities in and through global
viewed as occurring at the community-level, with the formation of associations through
eighbourhoods, regions, and subcultures. According to Rose, the state is no longer required to
answer to all of society’s needs for order, security, health, and productivity. Individuals,
organizations, and neighbourhoods would now be responsible for taking on portions of these
responsibilities. These emergent communities are formed around a shared set of “values, norms
and meaning, and a shared history and identity—in short, to a particular culture” (Etzioni, 1997, p.
127). The Third Way also creates a push to move conventional safety and support programs
towards community-led approaches, with an emphasis on volunteerism, self-help, and support
groups (Giddens, 1998; Rose, 2000).

Under these new conditions of citizenship, “the community”, as a shared set of values,
ethics, and experiences, is no longer bound by geographical territory or space. Clarke (2005), in
exploring what he calls New Labour’s “distinctive enthusiasm for citizenship” in Britain in the
1990s, uses the terms “activated”, “empowered”, “responsibilized”, and “abandoned” to discuss
this shift towards governance through community (p. 447). “Active” citizens are transformed
from passive recipients of state assistance into active self-sustaining individuals, such as
promoted in programs that link welfare to work. “Empowered” citizens are empowered to make
choices and have a voice through consultation and participation, expanding “consumer culture”
values to how public services are accessed. “Responsibilized” citizens are expected to make
prudent choices, to manage their health and well-being and contribute meaningfully to society.4

public health interventions. For example, sex workers in Mysore did not always see themselves as part of
a community until Avahan deployed community mobilization schemes.

4 These concepts are similarly explored by Petersen and Lupton (1996) in what they term the
“new public health” in which they explore concepts of the body and citizenship. In the new public health,
risk surveillance and governance strategies seen in health promotion place responsibility for managing
Citizens here are expected to avoid unhealthy habits such as binge drinking or over-eating, and must make “reasonable choices” when consuming public services to not overburden the system. “Abandoned citizens” are those abandoned by the dismantling of state safety nets – and abandonment is often masked by discourses surrounding activation, empowerment, and responsibilization (Clarke, 2005).

Citizenship in India

How responsibilization came to be manifested through modalities of citizenship in the West in many ways parallels the contemporary role of neoliberalism in India. Having undergone vast economic growth since the 1990s and 2000s, India’s upper and middle classes live vastly different lives from the country’s poorer citizens. India, like other neoliberal democracies, has rolled back or “streamlined” the welfare state by shifting attention towards individual responsibility.5 While poor and marginalized communities remain on the “margins of the state” (see Das & Pool, 2004), Indian anthropologist and political scientist Partha Chatterjee (2011) asserts that they also develop skills in pressuring state agencies to deliver benefits. This has led to an actively engaged population frequently protesting to demand rights and services and lay risk “throughout the social body” while also creating “new possibilities for intervention into private lives” (Petersen, 1997, p. 194). At the same time, the new public health broadens its focus to the “environment”, thus creating infinite sites for interventions aimed at addressing “risk”.

5 This is particularly true since the election of the conservative Bharatiya Janata Party government in 2014, which brought with it a rise in Hindu Nationalism, and a further rolling back of the welfare state, including a merging of the National AIDS Control Organization with the Ministry of Health and Family Welfare (NACO, 2014). Now mired in state bureaucratic procedures, such as those described by anthropologist Akil Gupta (2012), community-based organizations leading HIV programs throughout India, like Ashodaya, are forced to contend with punitive funding delays on the part of the state governments when viewed as failing to meet numerical-based program targets (Lorway, 2016).
claims on the state (Chatterjee, 2011). According to Chatterjee, the response by government is to break up “benefit-seekers” into smaller groups, defined by specific demographic or social characteristics, in order to divide opposition.

Development organizations, including non-governmental organizations (NGOs) and government agencies, now implement “empowerment” programs at the grassroots level focused largely on helping women (and other marginalized communities) in meeting their own needs, rather than relying on governmental assistance schemes. Anthropologist Aradhana Sharma (2008) points out how India’s focus on “empowerment-style self-development” in its gender and development policies implements empowerment as “technologies of citizenship”, which Cruickshank (1999) defines as “discourses, programs, and other tactics aimed at making individuals politically active and capable of self-government” (p. 1). Technologies of citizenship aim at inspiring the marginalized to become active, political, and responsibilized citizens. Much like Foucault’s (1991) concept of governmentality, technologies of citizenship aim to guide, shape, and compel, rather than force, the actions of others (Cruickshank, 1999). In empowerment terms, they are a way of “helping people to help themselves” (Cruickshank, 1999, p. 4).

However, under such empowerment schemes, experts inspire and direct the course of the disenfranchised towards their “emancipation”, thereby setting up new relations of power that simultaneously liberate and subjugate people. This exemplifies what Foucault (1982) describes as a productive mode of power that operates by deeply embedding the goals, intentions, and interests of larger institutions (in this case, global humanitarian organizations and multilateral groups) ever more deeply into social life by compelling “the marginalized”, “the subjugated”, and “the oppressed” to take up moral projects of health, self-improvement, and social betterment (Li, 2007). In other words, power here does not operate solely through a coercive means—that is,
by imposing the will of “the dominant” over “the subaltern”; instead it operates through desire by rousing, inspiring, and thereby increasingly entangling a diverse range of social actors in the project of governance itself (Rose, 2001). Empowerment, in this sense, is an ironic movement of power that subjugates people by stirring up visions of their emancipation and better futures.6

Drawing upon Foucault’s (1982, p. 231) notion that “not everything is bad but dangerous”, Sharma (2008, p. xix) stresses the inadvertent consequences of development and empowerment projects, which carry both predictable and unforeseen outcomes. When working with “imperfect subjects”, empowerment can sometimes have unpredictable effects, resulting from the “messy interplay between depoliticization and repoliticization, surveillance and subversion, and regulation and unruliness in the context of governance in India today” (Sharma, 2008, p. xx).

Chatterjee (2004) uses the term “political society” to discuss how development programs target poor and marginalized groups in India (p. 23). Perhaps counterintuitively, techniques of development, although feeding into governmental objectives, also foster unexpected political positions (Chatterjee, 2004; Sharma, 2008; also see Li, 2007 with respect to Indonesia). Sharma (2008) uses the example of women’s empowerment groups in India, such as Mahila Samakhya in Uttar Pradesh, to explore the types of subjects produced through membership in these groups. She notes that women engaged in these empowerment programs come to understand structural inequalities and learn the language of the state, which they then use to demand accountability

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6 At the same time, I would insist, as do Sharma (2008) and Chatterjee (2004), that communities of disenfranchised people become increasingly literate in the workings of power over time and are able to rework, subvert, and reprioritize these projects to serve their own political interests.
In this way, government-implemented empowerment becomes redefined through women’s enactments and lived experiences.

In discussing postcolonial India, Rajeswari Sundar Rajan (2003) notes that women have often been excluded from discussions on citizenship. So-called “women’s issues” have been relegated to the goals of developmental agendas of postcolonial nations, with the health and status of women seen as indicators of development (Rajan, 2003, p. 3). Whereas interest in these markers under British colonial rule were related to creating a “civilized” society, in a postcolonial era they are more linked to international accountability mechanisms emanating from development goals. Citizenship, most often defined by the right to vote, may have been relatively easily won by women in India according to Rajan (2003), however struggles for freedom and socioeconomic equality continue to be a battle in what remains a patriarchal society. With a clear gendering of citizenship, Indian states construct women as different than men, and draft policies to “protect” women. Furthermore, women are differentiated from each other, as the “good housewife” or the “bad prostitute”; with international development projects largely focused on “poor” and “marginalized” women (Rajan, 2003).

Focusing on the intimate world of home, family, and kinship relations, both Khan et al. (2017) and Das and Addlakha (2001) highlight the influential makings of female citizenship across a number of “dispersed sites” in the domestic sphere (Khan et al., 2017, p. 5). For example, when discussing the Devadasi in Northern Karnataka, India, young women who are dedicated to Hindu temples and referred to as traditional sex workers, Khan et al. (2017) point to how family and kinship groups remain influential in determining women’s “duty” in a patriarchal context, with female citizenship enacted as a sense of obligation and responsibility to family and nation.
Biosociality and Biological Citizenship

Drawing upon these discourses of citizenship, I also appeal to notions of biosociality and biological citizenship to analyze how communities mobilize around their biological, genetic, and health identities. Biosociality, as a concept, was first conceived by Paul Rabinow (1992) to help think through the forms of sociality (and citizenship) that emerge as new “truths” are produced about humans in the field of genetics that shape identities while opening up new opportunities for activism. Biosociality is rooted in “…exploring the implications of genetic knowledge for how individuals understand themselves or relate to others, and how persons affected by genetic conditions, through organizing themselves into groups, shape the production of knowledge about their conditions” (Gibbons & Novas, 2007, p. 2). Biosociality lies in the attempt to identify new forms of identities and socialites shaped around new genetic knowledge and its related power situated in industrial, academic, and medical fields (Gibbons & Novas, 2007; Rabinow, 1992). New information about genetics has resulted in individuals identifying themselves in relation to illness and forming groups with others who are similarly affected. This is deeply linked to how humans understand their experiences of health and illness in relation to their self and others, and how local, national, and global economies are being reorganized around health (Rose, 2001). Here, Kaushik Sundar Rajan (2006), in his studies of biotechnology in India, makes the argument for “staying attentive to the multiple, layered causations that lead to emergences of certain social worlds instead of others” (p. 145).

Rose and Novas (2004) built on this conversation of biosociality to explore a new kind of biological citizenship taking shape within the field of biomedicine and biotechnology. Biological citizenship is centred around contemporary norms and shared experiences of health, and can thus embody a demand for protections, for the enactment or cessation of particular policies or actions,
or, access to special resources. It forms a new type of social welfare based on medical, scientific, and legal criteria that acknowledges and compensates for biological injury (Rose & Novas, 2004; Petryna, 2004). Citizenship in the age of biomedicine gives rise to identity claims, forms of collectivization, demands for recognition, access to knowledge, and claims to expertise that centre around emerging spheres of scientific discovery and experimentation (Heath, Rapp, & Taussig, 2002).

Petryna (2004) perhaps most notably grounds the concept of biological citizenship through her ethnography among individuals affected by Ukraine’s Chernobyl disaster. Petryna explores how Chernobyl exemplifies a moment where new forms of citizenship and entitlements emerged, with images of suffering becoming increasingly objectified in legal, economic, and political discourse. In a deeply economically depressed post-Chernobyl setting, termed a “technogenic catastrophe”, people fought for disability status (Petryna, 2004, p. 254). The ability to construct one’s body in terms of injury and damage—that is, to possess knowledge about biological risk—was crucial for gaining access to resources, including compensation, denied more widely to Ukrainian citizens. A “political economy of Chernobyl-related illnesses” with new kinds of social categories and hierarchies of entitlement was formed” (Petryna, 2004, p. 255). These new formations of citizenship created new opportunities and inequalities. According to Petryna (2004), “…social forces and processes come to be embodied as biological events… illness and health are engendered and made sense of within the technical and political domain in which they come to be addressed” (p. 257).

Alongside these new categories of citizenship, come a need for enumeration and epidemiological methods of data collection (Petryna, 2004). As individuals come to make claims of their biological identity, the state comes to require ways to evaluate and legitimize these
claims. These new identity groups allowed for social and moral contracts to be formed between community and state, guaranteeing the right to medical care and education for these new formations of citizens.

**Health Citizenship: Pharmaceutical, Therapeutic, and Community-based**

Kaushik Sundar Rajan (2006, p. 102) links the notion of biological citizenship to how people in India get reconstructed as “experimental subjects” within clinical trial settings. In what I will more broadly term health citizenship, other social scientists have explored biological citizenship through its relationship to treatment (Ecks, 2005; Nguyen, Ako, Niamba, Sylla, & Tiendrébéogo, 2007) and community-based interventions (Lorway, 2016; Lorway & Khan, 2014).

Ecks (2005) focuses his discussion on citizenship around links to biomedicine and biotechnology, with what he calls pharmaceutical citizenship. In his ethnographic work on the marketing of antidepressants in Kolkata, India, Ecks proclaims that pharmaceutical citizenship is concerned with “demarginalization”. According to Ecks, under the dominant biomedical model, health care providers see the provision of medicine as the best way to remove “marginality”. In the example of depression, providers see antidepressants as bringing individuals “back into society” (p. 242). Pharmaceutical citizenship is therefore concerned with who has the right to medicines and what impact taking medicines has on citizenship status. Notably, Ecks describes how pharmaceuticals not only transform health, but transform social relations (Ecks, 2003; Whyte, Van der Geest, & Hardon, 2002).

Nguyen et al. (2007) employ the term therapeutic citizenship when talking about adherence to antiretroviral therapy (ART) for treating HIV in Cote d’Ivoire, West Africa. With
with respect to the emergence of groups of men who have sex with men, Nguyen and colleagues link “exceptional” treatment adherence in African countries to HIV programs focused on empowerment, community support groups, and testimonials of treatment success. Within the context of these programs, new forms of kinship solidarity networks emerged, addressing both social and biological vulnerability (Nguyen et al., 2007). By belonging to these networks, HIV status could be used to claim both emotional and material support. This therapeutic citizenship also created a moral economy where its members became effective HIV advocates, by bartering HIV self-disclosure testimonials to gain access to vital health services, including ART. In other words, HIV treatment access was mediated through various self-help confessional groups, which translated self-disclosure practices into a set of rights and responsibilities among its members. In this way, HIV treatment programs can be said to be both voluntary and coercive, as they demand certain responsibilized behaviours from their participants, such as high levels of treatment adherence as demonstrated in Nguyen’s example.

Lorway and Khan (2014) have explored citizenship from the perspective of communities engaged in global health interventions in Karnataka, South India. Through their participation in community-based research projects, men who have sex with men “re-assembled” epidemiological terms of reference, such as space, time, disease, and risk, to purify and maintain the boundaries of “the community”. By participating in mapping and other research exercises, as well as prevention and health interventions, epidemiological evidence led to “new relations of responsibility, strategies of protection, spaces of affinity, and zones of exclusion” (Lorway & Khan, 2014, p. 60). In this example, men who have sex with men re-assembled epidemiological
knowledge to define in-group inclusion, inform their health promotion and protection strategies, and find ways to self-govern that minimized their risks of HIV exposure.7


Building on the previous theoretical discussions of citizenship, I use these concepts to explore the role of health citizenship and responsibilization in the context of global PrEP trials. In recent years, there has been what some social scientists have termed a “remedicalization” of the HIV epidemic (Nguyen, O’Malley, Pirkle, 2011). With this remedicalization, comes the scale up of pre-exposure prophylaxis, otherwise known as PrEP, a prevention strategy that involves the use of antiretroviral medications to reduce the risk of HIV infection. Physicians prescribe PrEP, as a daily pill, to people who do not have HIV to keep the HIV virus from establishing a permanent infection (World Health Organization, 2012). Researchers have conducted a number of clinical trials that have demonstrated the clinical efficacy of PrEP (see for example, Okwundu, Uthman & Okoromah, 2012) and the WHO has since called for PrEP to be offered to individuals at “substantial risk” of HIV infection as an option in comprehensive HIV prevention services (World Health Organization, 2015). However, despite PrEP’s demonstrated clinical efficacy, PrEP trials globally have suffered from much controversy. Some early PrEP trials were cancelled before they started due to concerns about a lack of community involvement, drug safety, and

7 Lorway (2016, p. 117) terms this “seeing like an epidemiologist”, drawing from Biruk’s (2012) term “seeing like a research project” (p. 351).
confusion over the right to treatment, especially in instances of HIV infection during study participation (Haire, 2011; Ukpong & Peterson, 2009).8

**Resisting PrEP**

Participants enter clinical trials for a number of reasons. Petryna (2009) has critically reflected on “experimentality” in terms of the globalization of clinical trials, where clinical trials have been “offshored” to so-called developing countries where participant recruitment is facilitated by a lack of access to health care and treatment and where local research partners depend on the income generated from these trial partnerships (see also Rottenburg, 2009). Research funding now typically calls for these transnational partnerships (Moi Okwaro and Geissler, 2015) and many universities and teaching hospitals have developed their own NGOs to facilitate this work (Nguyen, 2009). This has especially been seen in the wake of PEPFAR, the U.S. President’s Emergency Plan for AIDS Relief, where universities became responsible for entire country-level treatment programs (Rottenburg, 2009; Sastry & Dutta, 2012).

Postcolonial science studies scholar, Richard Rottenburg (2009) describes the most striking feature of these interventions as their level of urgency and “exceptionality”. Under these descriptors, there is no time to wait for tested treatments and proven solutions or to address systematic issues. Rather, there is a need for immediate intervention, with the interventions themselves functioning as experiments (Rottenburg, 2009). Rottenburg (2009) expands on Nguyen’s concept of therapeutic citizenship by linking it back to the state as a form of

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8 In this way, PrEP builds on the legacy of community activism in early HIV research, where people living with HIV demanded a say in the shaping of clinical trials and access to early treatment. Affected communities embraced a biomedical response to what was at the time an unknown disease and actively worked at becoming experts in therapeutic regimes (see for example, Epstein, 1996).
“therapeutic domination”. Therapeutic domination is linked to postcolonial discourses where the "Global North" carries out interventions in the "Global South". Rottenburg (2009), like Petryna (2009), notes that clinical trials depend on finding “inexpensive trial populations” (p. 424). Furthermore, under the therapeutic domination model, humanitarian crises, such as the HIV pandemic, are used to declare states of emergency to justify the launch of new forms of “experimentality” that mainly benefit those in developed countries (Seth, 2009). Scientific and technology projects aimed at “modernizing” developing countries through transfers of expertise continue to unequally benefit the “Global North” through the extraction of natural, human, and economic resources back to these countries (Harding, 2008). Rottenburg (2009) describes how in the case of international humanitarian interventions, governmentality transgresses the boundaries of the state and targets populations not on the basis of national citizenship but rather on the basis of universal human rights, linking therapeutic citizenship to a form of global citizenship. The same can be said to hold true in international clinical trials. In postcolonial terms, these interventions may be seen as linking local and global identities, while challenging the distinction between global and local (Anderson, 2002). These interventions are seen as a “novel form of legitimate domination. It presupposes a state of emergency in humanitarian terms that legitimizes exceptional interventions and calls for urgent measures to save lives”, blurring the lines between biomedical experimentation and global health governance (Rottenburg, 2009, p. 427).

Sastry and Dutta (2012) highlight how postcolonial analysis disrupts one-dimensional constructions of health campaigns as inherently altruistic in order to create spaces for alternative interpretations. They point out how there has been a shift in “globalizing” and “medicalizing” public health discourse, with multilateral organizations such as the WHO transforming health programs from national to global realities. King (2002), in examining American discourses on
“emerging diseases” (p. 764), uses these notions of public health, national security, and commerce to illustrate how infections and diseases outside of the nation-state are seen as threatening sovereignty. According to King, contemporary public health draws on earlier “colonial logics” of security to control and monitor emerging diseases (p. 782). Addressing HIV is therefore framed as a security issue, rather than merely a public health one (Sastry & Dutta, 2012).

Clinical trials are part of a social and political landscape that link numerous actors, including, researchers, participants, health workers, and pharmaceutical companies in the production of benefits, profits, and risks (Petryna, 2009). In the case of the cancelled PrEP trials, potential participants pushed back against scientific regulatory regimes, asserting that the risks were not worth the benefits that they stood to gain. PrEP trials in Cameroon, Nigeria, Malawi, and Cambodia among sex workers and in Thailand among people who inject drug captured international media attention for concerns over ethical violations in research practices (Haire, 2011; Ukpong & Peterson, 2009). Organized community action shut down the Cambodian and African trials and brought up significant concerns about the Thai trial, which ultimately proceeded. All of the trials aimed to investigate the safety and efficacy of PrEP in preventing HIV infection. The rationale for the large number of international trials was the need to explore the intervention in a variety of settings, with different populations (see for example, Page-Shaffer et al., 2005). Allegations were made against each of these trials that they were unethical on the grounds of not collaborating sufficiently with communities, providing selective information about potential adverse effects, and being unwilling to provide comprehensive health insurance for participants (Haire, 2011; Ukpong & Peterson, 2009).
In each case of a cancelled, protested, or halted PrEP trial, “activated” and “empowered” citizens, to borrow Clarke’s (2005) words, mobilized around a shared identity: either as a sex worker or a person who uses drugs, to advocate for more equitable trial practices, leading to the ultimate shut down or discreditation of the trials. In Cambodia, the Women’s Network for Unity sex worker group created a short film to express concerns over potential harms of participation. In the African trials, ACT UP Paris led protests over concerns about who would treat seroconverted participants. Despite continuing, the Thai Drug Users’ Network and the Thai AIDS Treatment Action group raised awareness around scientists’ failure to provide participants with sterile injecting equipment, a lack of meaningful community consultation, and a lack of commitment to ensure participant safety (Haire, 2011; Ukpong & Peterson, 2009).

The collective demands of these activists within the contexts of the tenofovir trials displayed empowered community voices where citizens demanded more ethical research practices. Haire (2011) notes how this activism was met with disapproval from some of the wider community of people conducting HIV research. For example, Joep Lange, the co-chair of the 2004 International AIDS Conference in Thailand, which was disrupted by PrEP protesters, argued that the failed trials disrupted the need for new biomedical HIV prevention strategies, that the researchers in the Cambodia trial did consult with at least some community groups, and, in his opinion, the protests originated from outside groups, such as ACT UP, rather than the participants themselves (in Haire, 2011; see also Lange, 2005). From the perspective of Lange and other researchers, it would appear that these citizens were not taking the “proper” steps to “self-govern” their risks and were not acting as “responsibilized citizens” in contributing to the benefits of society as a whole. According to Haire (2011), activist groups demanding access to ongoing health care, especially in the case of seroconversions resulting from study participation,
highlight the need for equitable health care access for all, including study participants, regardless of where they live. As seen in Petryna’s (2004) account of biological citizenship in Chernobyl, these PrEP trials show that even very vulnerable populations have an expectation that if they undertake risks, they earn an entitlement to benefits that should offset those risks and should be consulted with in the determination of those benefits (Haire, 2011). It also cannot be ignored that this remedicalization of prevention strategies centres HIV risk and responsibility on the individual, while avoiding attention to the structural determinants of HIV risk (Clarke, 2005; Haire, 2011). Whereas access to biomedical prevention treatment might work to minimize some experiences of marginality (Ecks, 2005), communities increasingly assert their awareness of risks in the contexts of HIV prevention trials. In the cases of cancelled trials, active and empowered citizenship groups were able to push back to demand more equitable trial conditions.

**Demanding PrEP**

In light of sex worker-led protests, in 2005, the International AIDS Society and the Gates Foundation held a stakeholder meeting with researchers, government officials, and community members to find a way forward with biomedical prevention research (Peterson and Folayan, 2017). These consultations led to the development of new *Good participatory practice: Guidelines for biomedical HIV prevention trials* aimed at providing systematic guidance on how to effectively engage all stakeholders in HIV prevention trials (see Peterson and Folayan, 2017; UNAIDS 2007a, 2011). These guidelines build on the importance of the Greater and

9 The most recent version of the guidelines are available for download at: https://www.avac.org/sites/default/files/resource-files/Good%20Participatory%20Practice%20guidelines_June_2011.pdf
Meaningful Involvement of People Living with HIV (GIPA/MIPA) in HIV research (see for example, UNAIDS 1999, 2007b) and were globally circulated to researchers, activists, and policy makers for critical feedback. The published version of the report aims to provide a way forward towards the meaningful engagement of communities in HIV prevention research, creating new possibilities for communities to negotiate with health scientists in this rapidly emerging field. At the same time, there was a push among policy makers and funders to move forward with demonstration projects, with sex workers such as those belonging to Ashodaya Samithi, interested in guiding the course of PrEP projects while demanding access to these new experimental technologies and treatment (Figure 1).

Figure 1 – Image of PrEP provided for the Ashodaya PrEP Demonstration Project. Photo taken by author (Lazarus, 2017).

This thesis draws on an extensive qualitative ethnographic study that occurred alongside the Ashodaya PrEP Demonstration project and explores the experiences of sex workers, community leaders, and project staff throughout the 16-month PrEP trial. The thesis follows a
manuscript-based style.\textsuperscript{10} with each manuscript exploring the project from a different angle. In this thesis, I attempt to make sense of the extraordinary project results found in this community-driven PrEP intervention by contextualizing the findings within the larger life history of the organization. Going beyond biomedical understandings of retention and adherence, I point instead towards Ashodaya’s history of collectivization around sexual health—a history of community action that has given rise to forms of health citizenship and new spaces of belonging for sex workers, as well as desires and anxieties about the future, in what Biehl and Locke (2010) call the “transformative potential of becoming” (p. 317). As Lock and Biehl (2017) note, people inhabit “multiple temporalities”. Becoming is about transformation, and is occupied by the past, present, and a “possible or impossible future” (p. 32).

The demonstration project began enrolment in March 2016. Participants were provided with daily oral tenofovir/emtricitibine and followed up quarterly for 16 months. The first manuscript overviews the project findings following a biomedical narrative, based on the quantitative data collected during the clinical enrolment and follow up questionnaires. Here we see that the demonstration project showed exceptionally high retention, with 640 of the 647 participants retained for the 16-month project duration. High adherence was confirmed by self-reported pill intake and by tenofovir blood-levels (>40ng/mL, consistent with steady state dosing) at three and six months among a subset of participants (n=85 and 84, respectively). These findings are contrasted with data beginning to emerge from other demonstration project sites among sex workers globally and lay the foundation of “evidence” unpacked in the

\textsuperscript{10} As this thesis is manuscript-based, there is some repetition of background and contextual information throughout the chapters.
subsequent papers in order to locate the significance of these health outcomes within larger
global public health discourse.

The second manuscript explores the circumstances around the feasibility study that launched the project. Whereas early efficacy trials of tenofovir were mired in controversy for not including nor responding to community needs, scientists and community leaders working on the PrEP feasibility study paid careful attention to opportunities for sex workers to interrogate PrEP. The feasibility study here served to both inform their community of this new prevention technology and gauge interest in exploring PrEP use among sex workers in the Mysore-Mandya region. Initially some members of the research team were sceptical about this new technology; however their attitudes changed as they entered into dialogue with sex workers, who expressed an intense interest in PrEP and raised numerous critical questions. Particularly appealing to the sex workers that the research team spoke with was the notion of “double safety” in taking PrEP in combination with condom use, a possibility that addressed their anxieties associated with instances of unprotected sex. Throughout the feasibility study, sex workers excitedly interrogated and questioned PrEP, with their questioning expressed in terms of public health discourses surrounding risk.

The next manuscript explores the community-driven processes employed during the demonstration project. These community-led strategies included: 1) the participation of community leaders as the first to take PrEP, who shared their experiences through testimonials to their peers, as well as the endorsement of PrEP among community leaders living with HIV, to avoid social divisions around HIV status; and 2) ongoing community-level support from outreach workers that went beyond simply administering PrEP to address the various needs of the community. At a time when global and national funding for HIV prevention among sex
workers was in decline, the effect of which began to erode community solidarity networks, Ashodaya seized upon the resources furnished by the PrEP project to build a renewed position of relevance in the sex worker community. In addition to assuming responsibility for delivering a new HIV prevention technology, the demonstration project recuperated a sense of collective belonging among community members. This community-led approach to PrEP roll out demonstrates that communities themselves can play lead roles in delivering clinical interventions and should be key partners in planning, implementation, and monitoring when considering new prevention and treatment technologies.

In the final paper, in trying to understand how notions of success, anxieties, and desires live out in the social unfolding of interventions, I argue that the project must be analyzed within the more intimate sphere of care, affected by the past, future, and of becoming. In other words, instead of emphasizing adherence—the fulfillment of a public health imperative—I demonstrate how “success” is imminent within a highly-charged milieu of “responsibilization” and in a continual state of becoming. Drawing upon anthropological discussions of care, this paper therefore looks at how the PrEP demonstration project was made a success, and how success hinged on highly affecting notions of temporality. The search for success here draws a particular attention to the role of care played by Ashodaya sex workers. This care is tied not only to the community of sex workers Ashodaya seeks to serve, but to the careful production of evidence that demonstrate accountability to funders, which is further tied to caring for the very survival and future of the organization. As I show in the previous chapter, the PrEP demonstration project came at a moment where the organization was at risk of dissolving due to inconsistent funding flows, government deprioritization and stricter reporting and accounting requirements. PrEP carried with it not only the possibility of recapturing the golden age of HIV interventions (2003-
2010) ushered in by the Gates Foundation under the Avahan program (Lorway, Khan, Doshi, Sundararam, & Reza-Paul, 2018), but also a renewed hope for the future. In this sense, the search for success animated through the PrEP demonstration project was also highly successfully in acting on the hopes and imaginations of sex workers.
Chapter 2. Methods

This journey started ten years ago, in April 2009, when I made my very first trip to India. As part of my Masters of Public Health requirements, I spent three months at Ashodaya Samithi in Mysore, Karnataka. Going into this placement, I knew little about India, sex work, public health, or research, having recently moved into this field from social work. Here, by working alongside sex workers, I would gain invaluable knowledge on community-based research and activism that I would later apply in my future work.

I remember my first visit to Ashodaya Samithi, in the spring of 2009. At that time, organizational activities took place in a drop-in centre space where sex workers would gather to organize, socialize, and rest. The three-story building, located at the corner of a busy intersection, was near the city bus stand, a main transportation hub for the city, where many of the sex workers solicited clients at the time. It was also a five minute walk from the Mysore Palace, close to the main shopping streets, and the Deveraja Market, a historic market dating back to the 18th century and selling fresh flowers, fruits, vegetables, and colourful powders for pujas (Hindu prayer rituals). The building provided three main areas: a drop-in space for the male sex worker wing, Adarsha; a main meeting floor for outreach workers and community leaders; and a drop-in centre space for sex workers.

Adarsha, a separate wing of Ashodaya for male sex workers took up residence in the basement of the building, which was accessible through its own external entrance. In the open space, the men would hang out or nap on mats. On the main floor, community outreach workers
would meet for debrief and planning meetings. Around the open space would be a number of
desks and a few computers, where outreach workers and community leaders would fill out paper-
based ledgers tracking their fieldwork and other activities. I would often use one of these desks
while visiting, both to have a place to work and make sure that I was close to the action. The top
floor served as the most informal space, where sex workers would nap, freshen up before
meeting clients, watch TV, or simply hang out. Often, a group would practice dancing, which I
would be called upon to watch. The community clinic also had their office on this third floor,
taking an office space closest to the community it served.

Next to the drop in centre, members of Ashodaya also opened a restaurant where many of
the members worked to prepare the meals. The restaurant was supported through a World Bank
Marketplace Development grant to support community-led businesses. It received media
attention for its innovative method of not only generating income, but addressing sex work
stigma in the community by having sex workers run a successful restaurant (see for example,
World Bank, 2010). I would often eat lunch at the restaurant with members of the community,
enjoying plates of lemon rice. A second office, known as the Disha office, was located an auto
rickshaw drive away and served to house the technical support team, who would travel back and
forth between sites.

Meetings in the drop-in centre would take place in the mornings and the afternoons.
Community outreach workers would sit in a circle, filling up the large drop-in space, to discuss
their work and any challenges that they faced during outreach in the field with their peers.
Outreach focused not only on distributing condoms, but also on offering emotional support to the
network of sex workers in Mysore and its neighbouring districts. Efforts focused on sensitizing
police, government, health care workers, and local businesses to the rights of sex workers in an
effort to reduce stigma, discrimination, and violence and create what the organization called an “enabling environment”. Not infrequently, these meetings would erupt into heated debates, with members passionately trying to solve community issues. At times throughout the day, members of the community would show up distressed, looking for support from Ashodaya leaders, because of issues with boyfriends, the police, or colleagues. Leaders would step in to mediate disputes. While I could not follow all of the discussions, which occurred in Kannada, the local language, the intense emotion that sex work leaders, outreach workers, and health promotion staff invested in serving the community was palpable.

Fast forward to a subsequent visit to Ashodaya at the beginning of 2015 and I was shocked to hear that their drop-in centre was recently closed due to funding cuts and wondered what had happened to that bustling activity, and where all the outreach workers had gone? I learned that this was the second hit that members of the organization had faced, having recently experienced a devastating fire at the same location. While Ashodaya had managed to reopen following the electrical fire that destroyed much of their top floor and community clinic records, the reopening was short-lived, as the organization was faced with no longer being able to afford their rent due to cuts in project funding from the government. The restaurant had also been closed down. While the main community leaders had shifted over to the Disha office, which had previously been used mostly by the non-sex work staff and the technical support team, it was clear that the space was not being utilized in the same way. The three-story office still provided a space for community, however was located an inconvenient distance from the neighbourhoods where most sex workers worked, making it a less accessible space to gather or take a short work break. It is under this current system of government funding and delayed financial transfers that the PrEP demonstration project unfolded.
SITE SETTING: THE CITIES OF MYSORE AND MANDYA, KARNATAKA

According to anthropologist Smriti Srinivas (2001) in her exploration of *Urban Memory* centred around Bangalore, in the 1980s less than a third of India’s gross domestic product was produced in cities, with this figure rising to nearly 60% by the early 2000s. Similarly, in the beginning of the twentieth century, India's urban population was less than 11% of its total population, growing to around 35% by the year 2001. By 2001, India had roughly forty cities with a population of one million or more. As Srinivas (2001) states,

The issue for many cities is not so much whether the scale and the flow of persons, media commodities, and capital have accelerated in recent decades, but whether there are cultural aesthetics and ethics related to movements, migrations, and other protocols that can be adequately theorized (p. xxxi).

Bangalore, often referred to as the "Silicon Valley" of India, is the capital city of the southwest state of Karnataka. In her study of the city, Srinivas (2001) notes that while textiles, public sector industries, and government constitute the majority of employment opportunities for its citizens, the growing information industry plays a significant role in Bangalore. By the 1980s, local software industries, such as Infosys Consultants and Informatics, took hold of the city (Srinivas, 2001). Multinational software industries also began to set up residence. Accompanying this rise in technology, liberalization and an opening up of the economy has led to a growth in consumerism of both local and international goods for a growing middle and upper class since the 1990s (Srinivas, 2001).

An approximate three-hour drive southwest from the Bangalore airport is the nearby city of Mysore, known as the “City of Palaces” for its rich architectural history. Located at the
bottom of the Chamundi Hills, about 150 kilometers from Bangalore, Mysore shares a spill-over from the IT sector that is reflected in a rapidly expanding urban context, which increasingly reflects Bangalore’s cosmopolitan culture (Sudhira, Ramachandra, & Subrahmanya, 2007). Famous for its temples and palaces, Mysore draws a steady flow of national and international tourists. The head of the Kingdom of Mysore still takes his official residence in the Mysore Palace, located in the heart of the city. Mysore is also known for its festivals, such as the annual Hindu Dasara festival, a 10-day festival celebrating the victory of good over evil that takes place in September or October. As Srinivas (2001) describes, the annual Dasara procession is attended by ministers of the state and portrays various “folk” traditions through dance, music, and floats. While considered a mid-size city, Mysore is considerably calmer than Bangalore. It is also known for its silk sarees, sandalwood oil and soaps, and coffee (Mudde, 2017).

Mandya, located between these two rapidly urbanizing locations, has a distinctive working class urban culture that is tied to the sugarcane manufacturing sector (Rotti, 2017). Compared to Mysore, people are more tightly interconnected through kinship networks that can be traced to the surrounding villages and talukas (sub-districts). (Figure 2 and Figure 3).
Figure 2 – Map of India.
Image retrieved from Google Maps (Google Maps, n.d.a).
THE LIFE HISTORY OF A SEX WORKER ORGANIZATION

To try to understand how the Ashodaya intervention emerged, here I provide a brief reconstruction of the history of the organization based on observations and the many conversation that I have had with Ashodaya sex workers, the program team, public health researchers, and people accessing the services over the years.

11 In 2014, the Government of India officially renamed Mysore to Mysuru, as seen in Figure 3. However, Mysore is still commonly used to refer to the city. I have used Mysore throughout this thesis, as that is how the city has been named throughout the feasibility and demonstration project.
Located in the city of Mysore, Ashodaya Samithi was the first organization funded under the Gates Foundation’s Avahan Initiative. Avahan sought to address the HIV epidemic in six high prevalence states across India, including Karnataka (Ramakrishnan, & Alexander, 2006; Rao, 2010). In January 2004, a team of four public health professionals conducted a five-day exploratory field visit to understand the socio-cultural and organizational contexts surrounding sex work in Mysore. This team encountered a vibrant and thriving street-based sex work economy. At the time, female and male sex workers solicited on the streets and entertained clients in lodges, with transactions clustering around specific locations throughout the city. The team initially connected with three male sex workers through a sexual minority rights NGO working with men who have sex with men. These men then introduced the team to other female and male sex workers who were part of their sexual network.

The team characterized the sex workers as having very little sense of community or shared identity. Although both male and female sex workers reported regular harassment from police, goondas (gangs of men who harass sex workers, loosely translated to “thugs”), and boyfriends in the form of monetary extortion, physical beatings, and rape, no community organizations had yet emerged. Furthermore, at this time, sex workers shared that they were highly unlikely to access health services for fear of discrimination.

Despite the claim of representatives from the few organizations working on HIV prevention, condom distribution was found to be minimal. The team confirmed this during visits to the lodges and after talking with sex workers, none of whom were carrying or using condoms 12

12 Sex work has since moved to home-based settings in Mysore, which is further discussed in Chapter 4.
during their work. Moreover, the team found condom availability to be exceedingly limited. Few shops carried them and those that did often carried expired condoms.

Two weeks following the exploratory field visit, the team returned to initiate the HIV prevention program. An NGO working for the “rehabilitation” of sex workers strongly opposed the efforts of the team to mobilize the women for the intervention, even to the extent of coordinating frequent raids in the lodges and other locations where sex work was known to take place. Also posing a barrier were rumours suggesting that the proposed intervention would lead to the sale of sex workers’ organs. Yet, the team was able to readily build trust with male sex workers who were considerably more open about their sexual practices, including selling sex, and who had a greater awareness of the HIV epidemic after participating in local sexual minority rights HIV-related programs. To overcome the difficulties in contacting the women, the team built on the organic social relationship that existed between male and female sex workers, who shared clients and workspaces, by requesting that the men contact the women to inform them about the intervention.

During field visits, the team learned and began to address the immediate needs of sex workers, which included reducing police harassment, providing a safe space, and dedicated sexual health services. The team also responded to various crisis situations. For example, they negotiated the release of sex workers following police arrests, accompanied them to health facilities during health emergencies, and responded to partner and goonda violence.

Toward providing a safe space, the team consulted with the female sex workers and began searching for a suitable place for a drop-in centre that matched the criteria highlighted by sex workers. Based on the women’s advice, the team chose a location that was close to most of the major solicitation points in Mysore. By the end of the third week, the space was established
and sex workers began frequenting its premises. Initially, the drop-in centre operated as an unregulated space, with no conditions of use attached to it. The program team did not try to persuade participants to become involved in any of the programs or activities of the intervention. At the request of the community, the team provided sex workers with affordable lunches, mats for rest, a television, games for entertainment, and a place to wash before meeting with clients. Seemingly free from any encroaching procedures or techniques that sought to govern the conduct of sex workers, this space proved vital for ushering in a significant phase of collectivization.

Frequenting the space on a daily basis, sex workers began to interact with each other and soon recognized that they shared common problems and experiences. As noted by Kerrigan et al. (2015), providing a safe space where women can share their experiences and problem-solve is a necessary first step towards community empowerment. The drop-in centre provided such a space for the community to both collectivize and problem solve. According to sex workers and the public health practitioners, the safe space afforded by the drop-in centre quickly moved from a “problem sharing” to a “problem solving” space. Although the program team initially engaged in crisis management work, their role as the primary problem solvers gradually retreated as sex workers began to hold more formalized meetings to strategize solutions to their problems.

During the earliest phase of the project, the social bonds that had begun to form between sex workers began to translate into protective practices, as they began developing and implementing their own strategies to handle difficult situations in their everyday lives. For example, sex workers taught each other how to negotiate with clients at the beginning of their transactions to ensure a safe location for having sex. To further ensure safety within the sex worker community, regular attendees developed a system where community guides regularly patrolled the locations in Mysore where sex work was most concentrated. Thus, the subjectivities
of attendees during this phase not only emerged out of the identification and recruitment procedures launched by the initial public health team, they also developed as intimacies and resonances formed between the women and men who began to inhabit a common safe space.

A unique feature of the project from the onset was that female, male, and transgender sex workers started working together to protect “the community” in the field. An environment that was previously competitive, dangerous and isolating—a place where the fear of being identified as a sex worker prevailed—began to transform into one of solidarity, protection, and interdependence. What also helped to establish the public presence and collective identity of these sex workers was the formal establishment of the collective. In 2006, Ashodaya Samithi, which translates to Dawn of Hope, but most commonly referred to simply as Ashodaya, was officially registered as a community-based organization. To ensure that the organization remained by and for the community of sex workers, a board of governance was formed from elected representatives from the sex worker community. The public health team along with representatives from the DMSC in Kolkata helped Ashodaya set up the organization. Based on a philosophy of building community capacity, sex workers were paired with project managers, who were mostly trained social workers, to learn their roles, with the expectation of taking over the operations of the organization. At the end of its first year, Ashodaya opened a project office in the neighbouring city of Mysore that similarly included a drop-in centre space for sex workers to hang out and rest, and its own clinic space so that women would not have to travel the hour distance to be seen by the physician in Mysore, who would instead come to them.

While Ashodaya began to grow in visibility as an organization taking a lead in the fight against the HIV epidemic in Mysore, sex workers together with their public health allies began shifting the balance of power within the community. Perhaps most relevant for understanding the
PrEP Demonstration Project is Ashodaya’s role in setting up a community clinic. The community played a major part in the planning of the clinic and selection of health care providers, significantly shifting the usual power dynamics that exist in health care settings. Dixon et al. (2012) chronicle how through innovative strategies, ownership and management of health services increased dramatically among members. At the start of the intervention, HIV prevalence among sex workers in Mysore was 26%, along with high rates of STIs, and little knowledge or use of condoms (Reza-Paul et al., 2008). Fear of stigma, discrimination, confidentiality breaches, and cost posed major barriers to accessing care at government or private health facilities (Dixon et al., 2012).

The sex workers brought together through the intervention expressed a desire for their own clinic in the drop-in centre space, which was also centrally located to their work. A community clinic was opened within the first six weeks and quickly served to establish new norms around health seeking behaviour among Ashodaya members. As Dixon et al. (2012) note, by acknowledging sex work as a legitimate profession, project staff demonstrated respect for sex workers, working to reduce stigma and shame previously experienced when accessing care. Sex workers began to see their health as an important part of their occupation, with “good health” seen as “good for business” (Dixon et al., 2012, p. 784). Through collectivization, individual health also became important for community health (Dixon et al., 2012). Furthermore, health was seen as a right, something to engage with proactively, rather than waiting to fall sick. To further distinguish the community clinic from other health services, sex workers and program staff worked together to plan community services that met the needs of its members. For example, the clinic was opened in the drop-in centre space in order to be near where sex workers worked, such as the nearby bus stands and commercial centre, and was opened from 1-4pm,
when business was quiet and most sex workers took a break (Dixon et al., 2012). A second clinic was added to the city bus stand, operating in the evenings, with additional clinics opened in the surrounding areas of the city and nearby villages based on requests by the community.

Dramatically working to shift the usual power imbalances between those providing and accessing care, the clinic staff were selected and trained by community members, and a Clinic Management Committee (CMC) was formed in 2006, with members of the team responsible for monitoring and supervising the performance of the clinic doctor and staff (Dixon et al., 2012). Not only was the CMC intended to monitor services, but they were also empowered to enact change based on feedback provided by the community. The opening of the clinic started a new norm of health care seeking among the community, with almost 75% of the community accessing clinic services by the end of its first year. Program data has shown a decrease in HIV prevalence among sex workers in Mysore to 10.9% by 2009.

Ashodaya has continued to grow over the years, with organizational activities expanded to include program implementation, outreach and advocacy (at the district, state, and national level), social and economic empowerment, addressing sexual and gender-based violence, provision of non-discriminatory clinical services (including sexual and reproductive health services), and community-based research. Ashodaya’s governance structure remains grounded in democratic processes, with community needs at the forefront of its agenda. Drawn from a highly experienced cadre of long-time sex worker activists, the Board of Directors ensures that Ashodaya remains driven by the priorities of the communities of sex workers it serves. As a result of their expertise in community-led interventions, Ashodaya has been internationally recognized as an Asia Pacific Learning Site by the World Bank, and a learning academy by UNAIDS to provide curriculum to local institutions and training in intervention design and
implementation to community-based organizations in fourteen countries across the Asia Pacific and five countries in Africa. Ashodaya’s current membership base is currently estimated to be 8000 sex workers across the state of Karnataka.

Ashodaya was the first organization funded by the Gates Foundation Avahan Initiative. Under “The Avahan Business Model” (Ramakrishnan & Alexander, 2006, see also Lorway & Khan, 2014), interventions prioritized business logics, such as creativity and innovation, with communities at the centre of program delivery. The model was meant to bring “private sector efficiency to a public health programme” (Rao, 2010, p. i7). Avahan was intended to complement the government’s own program to control AIDS and was envisioned as a short-term initiative to be fully transferred over to the government. Under Avahan, full community ownership of the programs was the promoted goal. However, the initiative was heavily criticized for initiating transfer to government early, before this vision was fully realized, and for incredibly high program costs (see Rao, 2010). The transfer took place between 2010-2013, and many of the community-based organizations were deemed unready by proxy of government reporting standards and folded. Furthermore, questions arose as to how the government could support the system developed under Avahan, which has been said to have “lavishly over-funded” community programs with a budget of more than $330 million USD (Lorway, 2016, p. 93). While Ashodaya survived the transition, restrictive national program policies along with an avalanche of reporting requirements inhibited community leadership in HIV service delivery across much of the country (Lorway, 2017).

Although Ashodaya in many ways can be viewed as a community that was initially “made up” or “invented” by public health practices and interventions (Hacking, 1986), over the years I have witnessed the profoundly vital forms of solidarity and political mobilization that
emerged through sex workers’ as they engaged in these programs in Mysore. Lorway (2016) has described how these programs have “produced specific dimensions of sociality—subjectivities; social connections, affinities and tensions; organizational allegiances and oppositions, and cultural politics” (p. 91). Having partnered with Ashodaya for nearly ten years on a number of different projects, I have witnessed the organization evolve and change, from periods of consistent and multiply-funded projects under Avahan, to moments of program insecurity and uncertainty following the transition to the public system, a funding shift that led to punitive funding delays when state governments viewed sex worker organizations as failing to meet numerical-based program targets.

Returning to the project at the centre of this thesis, my work on the Ashodaya PrEP Demonstration Project began in January 2015 during the feasibility study, an awareness-raising phase prior to the demonstration project (see Reza-Paul et al., 2016 and Chapter 4 of this thesis), whose timing occurred post transition from the Gates Foundation’s Avahan to government funding, with the organization facing significant budget cuts. During the feasibility phase, community leaders and researchers held meetings to inform Ashodaya members about PrEP and raise questions about interests to move forward with a PrEP trial. I had been closely following the debates around PrEP and had my own reservations as to whether this type of biomedical prevention intervention was in the best interest of the community. Unlike in the earlier tenofovir trials, the feasibility study provided an opportunity to check in with the community. These consultations provided the community with the chance to help shape the roll out of the subsequent study, and perhaps most importantly, provided the community with the chance to reject the study outright. Had the feasibility study not shown high levels of interest in moving
forward, sex work leaders and members of the research team have indicated to me that they would have halted the subsequent demonstration project.

**STUDY DESIGN**

The findings in this thesis are based on fieldwork that took place between January 2015 and April 2018 (Geertz, 1998; Spradley, 1980). Throughout this time, I made six trips to the Ashodaya office in Mysore (in January 2015; June and September/October 2016; April and November/December 2017; and April 2018). However, the analysis is based on nearly 10 years of research collaboration with the organization. I first became involved with Ashodaya during my masters practicum in 2009, where I conducted an assessment of a new peer support program for the organizational wing for people living with HIV, known as Ashraya (see Lazarus et al., 2012; also see Chevrier, Khan, Reza-Paul, & Lorway, 2016). Over the years, the organization has invited me back to work on numerous projects. In 2015, Ashodaya representatives invited me to conduct the qualitative analysis portion of a feasibility study that pre-dated the PrEP Demonstration Project (see Reza-Paul et al., 2016 and Chapter 4 of this thesis). Following that work, I took on a study of the demonstration project, drawing on qualitative ethnographic methods as my PhD research. This thesis is based on participation observation, field notes, conversations with interlocutors, as well as in-depth interviews with project staff, academic researchers, and study participants.

In order to capture a range of experiences with the PrEP Demonstration Project, I developed an extensive interview plan, with the intent of capturing the perspectives of the
research and implementation team, as well as the experiences of the Ashodaya community members who were both taking and not taking PrEP over the course of the project.

I conducted interviews with project staff, which include sex work leaders, community outreach workers, and the technical team (made up of the doctor, nurse, counsellors, and non-sex work program managers), in September/October 2016 and November/December 2017 to capture the demonstration project processes towards the start and end of the study. I invited all core members of the Ashodaya project team to participate in an interview. I included community outreach workers in the project team interviews, as they played key roles in the demonstration project, as the most frequent contacts with participants. In consultation with the community leaders and technical team, we purposively recruited community outreach workers as research participants who represented women working across different networks in different geographical areas of the city. Everyone that I asked to participate in the study consented to the first round of interviews, and in total 21 interviews were done. I conducted all interviews in English or in Kannada with simultaneous translation performed by one of the technical team members who played a significant role in facilitating all aspects of the qualitative study. During the second round of interviews in November and December 2017, three members of the technical team and three of the community outreach workers had left the project and were not available for follow up. The three technical team members had left the organization. The three community outreach workers had simply left their role on the demonstration project, but remained connected to Ashodaya. I and other members of the Ashodaya team attempted to arrange interviews with these outreach workers, and while agreeing to meet, interviews kept getting rescheduled and did not end up happening. One additional outreach worker was invited to participate in the follow up round of interviews to ensure that the experiences of outreach workers were included. In total, I
conducted 16 interviews during the second round (consent forms can be found in appendices A-C; the interview guides for project staff interviews can be found in appendix D).

I also conducted seven one-time interviews with all members of the Indian and Canadian academic research team between December 2017 and April 2018. Similar to project staff interviews, discussions with the research team focused on the implementation procedures they followed to roll out the demonstration project, and what they considered to be the successes, failures, and challenges encountered along the way. Project staff and researcher interviews lasted between 30 minutes and 2 hours (appendix D).

To capture the experiences of women taking PrEP, I invited sex workers enrolled in the demonstration project to participate in a longitudinal cohort that involved three rounds of in-depth interviews in September/October 2016, April 2017, and November/December 2017. These participant interviews drew on community-based participatory research methods (Israel, Schulz, Parker, & Becker, 2001; Minkler, 2000). As a community-led organization, Ashodaya Samithi has participated in numerous research studies and many community leaders have received previous training in both quantitative and qualitative research processes from researchers working in collaboration with the organization. Over the duration of the qualitative study, eight community researchers conducted the participant interviews. Although all community researchers had experience in working on previous studies, they participated in four days of training prior to each round of interviews. The training provided refreshers on research ethics, confidentiality, and interviewing techniques. During these trainings, we also reviewed the interview guides and revised them based on community input and piloting.

The technical team and community outreach workers assisted in purposively sampling participants for the interviews, to ensure representation of women of different ages, belonging to
different networks, who practiced sex work in different contexts (such as home-based versus street-based), and who had been connected to the organization for varying lengths of time. We invited forty participants to take part in the first round of interviews in September/October 2016. Community researchers and outreach workers attempted to reach all participants for the second round of interviews, with thirty of the women returning to participate in the second round. Additionally, community researchers interviewed two extra participants who they believed to be part of the original cohort and we collectively decided to include these interviews. While none of the original participants explicitly refused to be re-interviewed, reasons for not taking part included being out of town, difficulty scheduling an appointment, and difficulty tracking down some of the participants due to original community outreach worker having left the project. During the second round of interviews, one woman came to the interview heavily under the influence of alcohol and we therefore decided not to move forward with her interview at that time.

Community researchers interviewed thirty-six women in the final round of interviews in November/December 2017. As in the previous round of interviews, we included one new participant in the cohort. At the time of the final interview, the research team informed me that one of the participants had passed away.\(^\text{13}\) Participant interviews lasted from fifteen minutes to one hour and took place at both the Mysore and Mandya project offices during each round of interviews. The questions I posed in the last round of interviews explored experiences taking PrEP, as well as participants’ experiences as a member of Ashodaya (appendix E).

\(^\text{13}\) Two participants in the larger PrEP Demonstration Project passed away over the course of the study, however neither death was related to their PrEP use or involvement in the study.
To capture the experiences of Ashodaya community members not enrolled in the demonstration project, the research team decided to conduct short questionnaire-style interviews with both ineligible participants (appendix F) and with those who refused to participate in the study (appendix G). The community researchers conducted fifteen short interviews with participants who had been approached to participate in the study, undergone the clinical screening and lab testing, and were ineligible to take PrEP based on testing positive for HIV or showing clinical signs of acute HIV infection; testing positive for Hepatitis B; having a creatinine clearance ≥ 60ml/min (Cockcroft-Gault formula) upon screening; or testing positive for pregnancy (urine test). These interviews took place in October 2016 and lasted from three to fifteen minutes.

Although attempts were made to interview individuals who refused to participate in the demonstration project, no one agreed to participate in these interviews. It was generally quite difficult to come up with a potential list of participants who refused to participate, as such a large number of Ashodaya members were enrolled in the study. Furthermore, recruitment for the main PrEP demonstration project largely took place through outreach workers in the field and refusals rates were not monitored, with those who refused PrEP less likely to be connected to the organization. Table 1 provides an overview of the completed interviews.
Table 1 – Overview of interviews.

<table>
<thead>
<tr>
<th>Interviews</th>
<th>Rounds of Interviews</th>
<th>Interview Period</th>
<th>Number of Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Staff</td>
<td>2</td>
<td>September/October 2016</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td></td>
<td>November/December 2017</td>
<td>16</td>
</tr>
<tr>
<td>Academic Researchers</td>
<td>1</td>
<td>December 2017-April 2018</td>
<td>7</td>
</tr>
<tr>
<td>Participants¹⁴</td>
<td>3</td>
<td>September/October 2016</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>April 2017</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td></td>
<td>November/December 2017</td>
<td>36</td>
</tr>
<tr>
<td>Ineligible Participants</td>
<td>1</td>
<td>October 2016</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>167</td>
</tr>
</tbody>
</table>

During my visits to the Ashodaya office, I took field notes, mostly as jottings that I made in notebooks and later typed up and fleshed out (Emerson, Fretz, & Shaw, 2011; Spradley, 1980). These notes captured observations of my time in the project office and clinic space, conversations with interlocutors, and summaries and thoughts of meetings I attended during my field visits. While the findings presented in this thesis are largely drawn from the interviews with the project team and participants, all collected data informed the analysis and helped contextualize the interview transcripts.

Recognizing the importance of meaningful community-involvement in all phases of the research process, community-based research principles greatly informed my ethnographic work (Allman, Myers, & Cockerill, 1997; Israel et al. 2001; Minkler, 2000; Schnarch, 2010). As

¹⁴ Demographics for participants taking PrEP at baseline are presented in appendix H. Details are not provided for staff or academic interviews in order to protect anonymity and confidentiality. Pseudonyms are used throughout the thesis for all quotes.
explored by Moyi Okwaro and Geissler (2015), this project drew on a collaborative framework to support all research activities. Collaboration here indicates a desire to detach current structures and practices from the legacy of colonial power relations (Crane, 2010) and to avoid reproducing them through the invocation of an ethic of collaboration, which should entail a more balanced vision of control and responsibility (Moyi Okwaro and Geissler, 2015, p. 494).

Accordingly, in my ethnographic practice I have attempted to pay close attention to the power relations that underlie contemporary global projects and other forms of transnational research by reflecting on who benefits from partnerships, while recognizing the reality that explorations around collaboration can at times burden busy researchers—especially community researchers who often balance multiple responsibilities—or threaten pre-existing relationships (Moyi Okwaro and Geissler, 2015).

**Analysis**

All of the interviews were audio recorded with a digital recorder and then uploaded onto my password-protected laptop. As I conducted the project team and researcher interviews in either English or with simultaneous translation, they were sent to a professional transcription company in Canada that specializes in research transcription. A transcriptionist who has a long history of working with the organization and knowledge of sex work and the local context transcribed participant and ineligible interviews done in Kannada directly into English. I

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15 Due to the large volume of interviews, I made the decision to not undertake transcription myself.
reviewed transcripts after each round of interviews in order to help guide the development of the interview guide for the next rounds of interviews. Reviewing of the transcripts also helped guide the trainings for the community researchers and highlighted questions that required further probing in subsequent rounds.

Following the final round of interviews and transcriptions, I organized a community analysis workshop in April 2018 with the community researchers. I began the workshop with training on how to conduct qualitative analysis, as none of the researchers had previously been involved in this process. Following the analysis training, I shared interview segments from the third round of interviews with the group for interpretation and contextualization, also known as “member checking” (Creswell & Miller, 2000). Discussions helped to interpret quotes and ensure that themes reflected local experiences. Next, we collaboratively developed a coding list of main themes (Figure 4). The contextualization session around selected quotes and themes helped to guide my analysis process. Following the session, I used NVivo 11 software for thematic analysis (Boyatziz, 1998), paying special attention to the list of themes co-developed with the community researchers, as well as coding for emerging themes. I present additional details on the analysis process and theoretical frameworks utilized in the subsequent manuscripts.
Ethics

Nested within the larger PrEP Demonstration Project, the University of Manitoba Institutional Ethics Review Board (IERB) reviewed and approved my ethnographic study. Local and community approval for the PrEP Demonstration Project was obtained from the Institutional Ethics Committee (IEC) at Durbar Mahila Samanwaya Committee (DMSC), a sex worker organization that operates the Sonagachi project, an HIV prevention program in Kolkata, West
Bengal, which was also the other PrEP demonstration project site in India. Interviewers obtained written informed consent prior to all interviews, including follow up interviews.
Preface to Chapter 3

This first paper presents the quantitative findings in straightforward epidemiological and biomedical terms, drawing on the questionnaire data collected during the baseline enrolment and follow up visits of the PrEP demonstration project. Although unproblematised, this paper sets the stage for the subsequent manuscripts that follow, which attempt to “make sense” of the project outcomes in more contextualized ethnographic terms. I conducted the literature review and wrote the first draft of the paper. Dr. Raviprakash Maiya and Dr. Sushena Reza-Paul were responsible for the quantitative data analysis and tables presented in this chapter. The paper is adapted from a previously submitted project report to UNAIDS and is intended to be submitted to a peer-reviewed journal for publication.

Report details:

Chapter 3. A Community-led PrEP Demonstration Project among Sex Workers in India: Findings from the Ashodaya PrEP Study

INTRODUCTION

The World Health Organization, following the release of clinical trials findings, soon began to recommend PrEP to individuals at “substantial risk” of HIV to prevent infection (World Health Organization, 2015). Efficacy indeed has been well established in clinical trial research; however, results have varied among participant groups. Trials such as the iPrex Study have shown efficacy among men who have sex with men and transgender women in eleven global sites in Peru, Ecuador, South Africa, Brazil, Thailand, and the United States (Grant et al., 2010; Liu et al., 2014). The Bangkok Tenofovir Study showed a reduced risk of HIV infection among people who inject drugs in Thailand (Choopanya et al., 2013). The Partners Study in Kenya and Uganda has also found PrEP to be efficacious among serodiscordant couples (Baetan et al., 2012). However, two trials among women were terminated due to inefficacy resulting from low adherence. PrEP use among women in the FEM-PrEP Trial in Kenya, South Africa, and Tanzania did not significantly reduce the rate of HIV infection (Van Damme et al., 2012). Similarly, the VOICE trial, which provided PrEP to women in South Africa, Uganda, and Zimbabwe, did not reduce the risk of HIV due to low PrEP use (Marrazzo et al., 2015). Qualitative research with participants from both the FEM-PrEP and VOICE trials described a number of challenges to adherence including stigma, risk perception, and difficulty with clinic attendance (Corneli et al., 2016; van der Straten et al., 2014). Research has also pointed to lower
“forgiveness” of missed doses in women due to relatively lower concentrations of PrEP in vaginal tissue, compared to rectal tissue, with women requiring a “near perfect” adherence to reach protective therapeutic levels (Cottrell et al., 2016).

In 2012, based on the results from these clinical trials, the World Health Organization (WHO) issued a recommendation for PrEP use among serodiscordant couples and men and transgender women who have sex with men and called for demonstration projects to answer questions surrounding implementation (World Health Organization, 2012). In 2014, the WHO went on to release a strong recommendation for governments to consider adding PrEP to their combination prevention strategies for men who have sex with men (World Health Organization, 2014). As of 2015, recommendations were expanded to promote offering PrEP to all individuals at “substantial risk” of HIV infection as an option in comprehensive HIV prevention services (World Health Organization, 2015). However, low adherence levels in clinical trials highlight the need for more research regarding PrEP use among women, including sex workers who were excluded from those studies (Caceres et al., 2015; Shannon et al., 2018).

Under the recommendations of the WHO and global health funders such as the Bill & Melinda Gates Foundation, demonstration projects are taking place globally, with the stated aim of offering insights into the delivery and scale up of PrEP to governments and health care providers. PrEPWatch, a website repository of PrEP research and policy run by the AIDS Vaccine Advocacy Coalition (AVAC), displays a count of over a hundred demonstration and implementation projects as of December 2018 (AVAC, 2018a; 2018b). Whereas sex workers were notably left out of clinical trials (see Chapter 1 or Chapter 5 for more details), they have been a key group in demonstration projects. According to PrEPWatch, there are eighteen
ongoing or completed projects with sex workers, fifteen of which include female sex workers\textsuperscript{16} (AVAC, 2018b). While results from these demonstration projects are only beginning to be published in scholarly journals, initial findings from some of these studies have shown low levels of participant retention over the course of the project. For example, the TAPS Demonstration Project was an observational cohort study that offered early antiretroviral therapy (ART) or PrEP to female sex workers in South Africa (Eakle et al., 2017). Wits Reproductive Health and HIV Institute (Wits RHI), a prominent research institute in South Africa, led the TAPS project through their existing sex work program, which is run by nurses, community health workers, and peer outreach workers at two urban clinic sites providing primary health care services. The study found a PrEP uptake of 98%, with only 22% of participants remaining on PrEP at 12 months (Eakle et al., 2017).

SAPPH-Ire was a cluster-randomized trial that offered combination HIV prevention and treatment within the existing national sex work program in Zimbabwe (Cowan et al., 2018). Cluster areas surrounding sex work clinics were enrolled in matched pairs to receive usual care (sexual health services supported by peer outreach workers, including HIV testing, referral for ART, and health education) or an intervention that supported additional regular HIV testing, on-site initiation of ART or PrEP, and intensified community mobilization. PrEP uptake was 38% among women who tested negative for HIV. Retention was found to be low, with women taking PrEP for an average of just over four months. The SAPPH-Ire researchers state that the evidence for the effectiveness of PrEP in women was less known at the time of the roll out of the study.

\textsuperscript{16} The term female sex worker is used throughout this thesis, as the Ashodaya PrEP Demonstration Project’s inclusion criteria was limited to enrolling only sex workers who were assigned female at birth.
and that the numbers of peer outreach workers supporting communities were low in both arms of the trial, which they conclude points to the need for effective adherence support strategies (Cowan et al., 2018).

In India, the renowned sex worker organizations, the Durbar Mahila Samanwaya Committee (DMSC) in Kolkata, West Bengal (Ghose, Swendemen, George, & Chowdhury, 2008; Jana, Basu, Rotheram-Borus, & Newman, 2004; Jana & Singh, 1995) and Ashodaya Samithi in Mysore-Mandya, Karnataka (Argento et al., 2011; Reza-Paul et al., 2008; Reza-Paul et al., 2012), have recently completed demonstration projects. Targeted HIV prevention interventions in India, led by the National AIDS Control Organization (NACO) and the Gates Foundation’s Avahan Initiative, and largely implemented by sex worker community-based organizations, have led to sharp declines in HIV prevalence over the last decade, with national HIV prevalence estimates among sex workers decreasing from 10.33% in 2003 to 1.56% in 2017 (National AIDS Control Organization, 2017). These interventions have largely focused on promoting consistent condom use among sex workers and their clients, with 90% of sex workers in Karnataka reporting using condoms with new clients (Mitchell et al., 2016; Reza-Paul et al., 2008). However, research in both Karnataka (Deering et al., 2011; Isac et al., 2016) and West Bengal (Fehrenbacher et al., 2018) have shown that condom use continues to remain low with regular partners, such as husbands and boyfriends. The results from various surveys in Mysore show that while condom use is high in the last sex act with occasional clients, consistent condom use with all clients and partners continues to be a challenge (Reza-Paul et al., 2008). Following on this, HIV prevalence among sex workers in Karnataka remains higher than the national average, at an estimated 3.33% (National AIDS Control Organization, 2017).
There has been much excitement over PrEP among global health care providers, policy makers, and funders as a potential addition in the HIV prevention toolkit (Mayer, Chandhiok, & Thomas, 2016). Mathematical modeling parameterized to the HIV epidemic in Bangalore found that providing PrEP to female sex workers or high risk men who have sex with men could substantially reduce HIV incidence among the prioritized group, with the greatest population-level impact seen when sex workers were prioritized (Mitchell et al., 2016). In qualitative research exploring the willingness to implement PrEP, policy makers and health care professionals in India expressed that they felt that current HIV prevention efforts were insufficient, but that local data was needed to make the case for allocating funding towards PrEP (Wheelock, Eisingerich, Gomez, Grey, Dybul, & Piot, 2012).

Much has been written about community empowerment approaches to HIV prevention among sex workers globally (see for example, Kerrigan et al., 2015). Communities, however, have typically not played key roles in clinical and biomedical interventions. The two demonstration project sites in India were selected by the Gates Foundation especially due to their expertise in community-led interventions. In this paper, I present the findings from the Ashodaya PrEP Project on behalf of the project team, which provide a novel example of a community-led approach to providing PrEP though a well-established sex worker-led organization. The findings presented here provide important details on the demonstration project process, as well as the project findings that are unpacked in the subsequent chapters.
METHODS

Site Setting: Mysore and Mandya, Karnataka (Ashodaya Samithi)

In 2004, Mysore was the first intervention site supported through the Gates Foundation’s Avahan Initiative, aimed at addressing high rates of HIV/AIDS in six states across India, including Karnataka. Within their first year, Ashodaya opened a second program office in the neighbouring town of Mandya. Ashodaya’s membership base grew, and now stands at over 8000 female, male, and transgender sex workers, covering four districts across the state of Karnataka with community-led health outreach programs and clinical services such as condom promotion, screening and treatment for HIV and other STIs, and reproductive health services. These interventions rely on the knowledge and expertise of community leaders and outreach workers who play lead roles in connecting sex workers to Ashodaya’s services. As Dixon et al. (2012) note, Ashodaya sex work leaders even assumed decision-making roles on clinic management committees, so that the clinical staff working within their spaces would be made accountable to the community.

Ashodaya also boasts a wealth of community-based research resources, working closely with researchers from the University of Manitoba who offered numerous research training sessions in order to both impart skills and ensure that any research knowledge produced on the community is owned, understood, and utilized by the organization and the local sex worker community. Indeed, members of Ashodaya continually drew upon these prior experiences of running programs, delivering health services, and research studies to execute the PrEP demonstration study.
Study Design for the Demonstration Project

Following a commitment to community-led principles, Ashodaya leaders played a pivotal role in all aspects of the design and roll out of the PrEP demonstration project. Under Ashodaya’s existing targeted interventions, community outreach workers make daily contact with members of their sex work networks in the field to distribute condoms, answer questions, or make service referrals, with clinic visits for STI testing occurring once per three months. As the demonstration project was integrated alongside the existing targeted interventions,\textsuperscript{17} it took advantage of this system of community outreach workers to provide: (1) information about PrEP and referral to the project site for enrolment into the demonstration project while conducting outreach in the field; (2) home-based delivery of PrEP for those who desired this delivery mechanism; and continued support and monitoring for adherence, side effects, adverse events, and condom provision; (3) the use of Ashodaya’s own community clinic with physicians, counsellors, and auxiliary nursing midwives; and (4) the use of Ashodaya’s community-based laboratory for pregnancy, HIV, and syphilis screening.

Community outreach workers identified potential participants during their field visits and upon agreement, accompanied them to the Ashodaya clinic. After a discussion with the community counsellor, if they agreed to participate, participants were referred to the clinic counsellor who obtained informed consent. Next, the onsite physician conducted a physical examination, and then referred the participants to the lab for screening. Once the lab sent the

\textsuperscript{17} When implementing research-funded interventions, Ashodaya often refers to these as TI+, as a means of emphasizing that these new programs are being offered in addition to the existing package of targeted interventions (TI), rather than in parallel to them. In this sense, participants enrolled into the PrEP Demonstration Project are also connected to the array of previously available services offered through Ashodaya’s targeted intervention.
results to the physician, the team shared them with the potential participant, who was provided with another chance to withdraw from the study. If the participant again provided consent, the counsellor would then complete the baseline questionnaire.

**Inclusion Criteria**

In order to be eligible for the study, at enrolment, participants had to: self-identify as a sex worker and currently be engaged in sex work; be 18 years or older; express an interest in and willingness to take PrEP; test negative for HIV; show no clinical signs of acute HIV infection; test negative for Hepatitis B; have a creatinine clearance \( \geq 60\text{ml/min} \) (Cockcroft-Gault formula)\(^{18}\) upon screening; test negative for pregnancy (urine test); live within the operational area of the project site with no plans to move in the next 16 months (so either in the Mysore or Mandya areas); and express a willingness to avoid pregnancy during the 16-month study period.\(^{19}\)

**Follow Up Process**

Along with delivering PrEP, community outreach workers reminded participants about their follow up visits. According to the PrEP Demonstration Project protocol, the research team scheduled clinic visits at month: 1, 3, 6, 9, 12, and 15 (Figure 5). At each follow up visit, the

\(^{18}\) Creatinine clearance testing was undertaken to determine kidney functioning, as is typically required with PrEP use. As per the study protocol, participants required a creatinine clearance \( \geq 60\text{ml/min} \) (see also Molina et al., 2015).

\(^{19}\) At the time of enrolment, it was unclear whether PrEP use during pregnancy was safe and therefore, women in our study who were or became pregnant were not eligible to take PrEP under the study protocol. However, newer research suggests that PrEP use during pregnancy may be safe and provide an important prevention option during a period of increased risk (Heffron et al., 2018; Seidman et al., 2017). The WHO has since suggested that PrEP can be offered during pregnancy to women at high risk of HIV exposure (Seidman et al., 2018; World Health Organization, 2017).
clinic team saw participants for clinical tests for HIV, pregnancy, and creatinine. The counsellor then met with them to complete a follow up questionnaire on their PrEP experience. Participants who missed their follow up visit date could visit later as an “unscheduled visit” and therefore were still able to complete their testing and questionnaire. In addition to the routine tests during the follow up visits, study staff selected 85 participants for tenofovir blood-level testing during their third month visit, with 84 of the participants returning for repeat testing during their sixth month.²⁰

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²⁰ Staff selected participants for tenofovir blood-level testing by inviting the next 85 participants due for follow up to provide blood samples. The same participants were tested at month six.

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Figure 5 – Flowchart of study visits  
Image provided by Ashodaya Samithi (Ashodaya Samithi, 2018).
Integral to the follow up process was the network of community outreach workers who regularly followed up with their contacts to promote PrEP adherence. Although the network of outreach workers pre-existed the PrEP demonstration project, they received extensive additional training about PrEP and were assigned specific participants to follow. As detailed by the project team, the follow up plan entailed daily contact for the first 4-6 weeks, and then streamlined to alternate days, twice weekly, once a week, and finally once every other week. Follow up included a mix of daily visits and/or phone call reminders, depending on the needs, preferences, and relationships between the participants and their community outreach workers. Outreach workers recorded daily adherence on an Adherence Monitoring Card: a check mark indicated that PrEP was taken that day; an X meant that the dose was missed; and a question mark was used if the outreach worker was unable to reach the participant to confirm adherence (Figure 6). These cards provided outreach workers with a record of their follow up, as well as reminders of which participants might need additional support. Along with the adherence monitoring cards, project staff posted a follow up spreadsheet to the clinic door so that outreach workers could keep track of which participants were due for either their PrEP refills or clinic tests. Community outreach workers initially distributed PrEP refills once every seven days for the first month, then shifted generally to once in fifteen days. However, if participants were traveling out of the region, outreach workers might provide them with more pills to cover the travel period (usually not more than a one-month supply).

21 Although the plan called for a phased out follow up process, through discussions with community outreach workers and the project team, more extensive follow up processes were detailed at different phases of the project to meet the needs of participants, as explored in Chapters 5 and 6.
Data Entry and Analysis

Members of the project team collected all data from the questionnaires and clinic forms from all visits into individual paper-based participant files. Members of the team hired specifically for data entry purposes then entered the data into Epidata software. Program data, which included screening, enrolment, follow up visits, lab test results, and pill distribution details for each participant, was entered into MS Access. Four trained data entry operators (sex worker and non-sex worker staff alike) completed the data entry. Throughout the project, due to the
volume of data collected, data entry occurred daily. The team then stored the case files in the
Ashodaya central office in secured cabinets. The data management team checked all data entered
for consistency and correctness, then exported all data to Stata11 for data analysis.

**Ethics**

The study received approval from the University of Manitoba, Ethics Review Board in
Winnipeg Canada, the Health Ministry Steering Committee (HMSC) in India, and the
Institutional Ethics Review Board from DMSC, Kolkata, India.

**Results**

In total, 707 participants from Mysore and Mandya underwent the screening process
between March and November 2016. Among them, the study staff found 55 participants to be
ineligible to participate due to: high serum creatinine (n=40, 5.66%), testing positive for HIV
(n=9, 1.27%), testing positive for Hepatitis B (n = 3, 0.42%), or not meeting other eligibility
criteria (n=3, 0.42%). Five additional participants refused to take part in the study after the

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22 During my visits to the project office, I witnessed the clinic staff dedicating countless hours to
completing the participant files. Towards the end of each day, and sometimes throughout the day, they
would sit at the round table in the clinic space and update stacks of files following participant visits.
These paper files would then be inputted into the electronic database by the data entry staff.

23 Throughout the screening process, the office was bustling, with the project team working seven
days a week to accommodate enrolment of the large sample size. Negotiations occurred with the private
lab used for the enrolment screening. In order to minimize loss to follow up of participants who presented
for the study, outreach workers accompanied participants to the lab on the same day and provided PrEP to
participants following the screening process. Lab results were also reported back to the project team on
the same day, with a member of the team then informing the participant that they could start taking PrEP.
Similarly, a deliberately slow enrolment process took place, where a smaller sample of community
leaders were the first to be enrolled into the study to build confidence in the project among the wider
community. An initial shortage of PrEP pills also further initially delayed enrolment.
screening process. Of the 647 (91.51%) participants enrolled in the project, 7 exited from the study after enrolment for the following reasons: pregnancy (n=4), death (n=2), and health issues (n=1). It is important to note that withdrawal for health reasons or death were unrelated to PrEP use. 640 (98.92%) participants completed their 16-month follow up.

**Socio-demographic Characteristics**

At the time of enrolment, the median age of participants was 35 years. The study team found that the majority of participants (58.58%; n=379) reported to being illiterate. Most participants (51.47%; n=333) were married. The median income during the last month was Rs.5400 (approx. $72.90USD) (Table 2).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (all participants)</td>
<td>647</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>Median (Range)</td>
<td>35 (18-48)</td>
</tr>
<tr>
<td>&lt;=20</td>
<td>5 (0.77)</td>
</tr>
<tr>
<td>21-25</td>
<td>43 (6.65)</td>
</tr>
<tr>
<td>26-30</td>
<td>150 (23.18)</td>
</tr>
<tr>
<td>31-35</td>
<td>151 (23.34)</td>
</tr>
<tr>
<td>&gt;35</td>
<td>298 (46.06)</td>
</tr>
<tr>
<td><strong>Age at first commercial sex (years)</strong></td>
<td></td>
</tr>
<tr>
<td>Median (Range)</td>
<td>28 (15-44)</td>
</tr>
<tr>
<td>&lt;=20</td>
<td>73 (11.28)</td>
</tr>
<tr>
<td>Characteristic</td>
<td>n(%)</td>
</tr>
<tr>
<td>---------------</td>
<td>------</td>
</tr>
<tr>
<td>21-25</td>
<td>162 (25.04)</td>
</tr>
<tr>
<td>26-30</td>
<td>195 (30.14)</td>
</tr>
<tr>
<td>31-35</td>
<td>131 (20.25)</td>
</tr>
<tr>
<td>&gt;35</td>
<td>86 (13.29)</td>
</tr>
</tbody>
</table>

**Number of years in sex work**

- Median (Range): 6 (1-30)
- <=5: 309 (47.76)
- 6-10: 242 (37.4)
- 11-15: 61 (9.43)
- >15: 35 (5.41)

**Education**

- Illiterate: 379 (58.58)
- Literate: 268 (41.42)

**Marital status**

- Never married: 15 (2.32)
- Married: 333 (51.47)
- Widow/divorced/separated: 299 (46.21)

**Income during last month (in rupees)**

- Median (Range): 5400 (2000-30000)
- <=5000: 322 (49.77)
- >5000: 325 (50.23)
### Characteristic

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Living children</strong></td>
<td></td>
</tr>
<tr>
<td>Median (Range)</td>
<td>2 (0-6)</td>
</tr>
<tr>
<td>0 child</td>
<td>43 (6.65)</td>
</tr>
<tr>
<td>1-2 children</td>
<td>491 (75.89)</td>
</tr>
<tr>
<td>&gt;2 children</td>
<td>113 (17.47)</td>
</tr>
</tbody>
</table>

### Partner’s HIV Status

Of the 647 participants, 86.40% (n=559) reported having regular partners. Of those with regular partners, 23.97% (n=134) of participants knew the HIV status of their partners, with eight partners (5.97%) reportedly living with HIV. Four of the partners (50%) living with HIV were on ART.

### Condom Use

Ashodaya’s condom promotion had been very high since 2008 (see Reza-Paul et al., 2008) and was a benchmark of Ashodaya’s targeted interventions. Risk compensation is an often-cited concern among health care providers when rolling out PrEP (see for example, Wheelock et al., 2012); however in this context, messaging in the PrEP project by the project team and outreach workers stressed the importance of PrEP and condom use. Self-reported condom use with clients and partners remained high throughout the study and is almost consistent during all visits (Table 3).
Table 3 – Condom use during last sex with clients and partners during last week.

<table>
<thead>
<tr>
<th>Visit</th>
<th>Condom use with occasional clients (%)</th>
<th>Condom use with repeat clients (%)</th>
<th>Condom use with regular partners (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>97.99</td>
<td>95.44</td>
<td>62.97</td>
</tr>
<tr>
<td>End of 1st month</td>
<td>99.22</td>
<td>89.56</td>
<td>63.70</td>
</tr>
<tr>
<td>End of 3rd month</td>
<td>98.91</td>
<td>86.50</td>
<td>62.70</td>
</tr>
<tr>
<td>End of 6th month</td>
<td>98.91</td>
<td>87.14</td>
<td>62.57</td>
</tr>
<tr>
<td>End of 9th month</td>
<td>99.22</td>
<td>95.91</td>
<td>62.57</td>
</tr>
<tr>
<td>End of 12th month</td>
<td>99.22</td>
<td>94.97</td>
<td>62.50</td>
</tr>
<tr>
<td>End of 15th month (exit visit)</td>
<td>98.44</td>
<td>92.19</td>
<td>62.50</td>
</tr>
</tbody>
</table>

**Clinical Tests at Follow up Visits**

STI screening using enhanced syndromic case management (SCM)\(^{24}\) identified one case at the end of the 1st month follow up, five cases at the end of 3rd month follow up, and two cases at the end of 5th month follow up. All cases were treated using the SCM approach. Three participants became pregnant during the duration of the study and exited the project (Table 4).

---

\(^{24}\) Syndromic case management involves both symptomatic and speculum exam. Based on the findings (syndromes), treatment is provided.
**Table 4 – Clinical tests at follow up visits.**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>End of 1st month</th>
<th>End of 3rd month</th>
<th>End of 6th month</th>
<th>End of 9th month</th>
<th>End of 12th month</th>
<th>End of 15th month (exit visit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>STI screening</td>
<td>N: 637, n(%) 1 (0.16)</td>
<td>N: 642, n(%) 5 (0.78)</td>
<td>N: 641, n(%) 2 (0.31)</td>
<td>N: 641, n(%) 0 (0)</td>
<td>N: 640, n(%) 0 (0)</td>
<td>N: 640, n(%) 0 (0)</td>
</tr>
<tr>
<td>HIV test-positive</td>
<td>N: 637, n(%) 0 (0)</td>
<td>N: 642, n(%) 0 (0)</td>
<td>N: 641, n(%) 0 (0)</td>
<td>N: 641, n(%) 0 (0)</td>
<td>N: 640, n(%) 0 (0)</td>
<td>N: 640, n(%) 0 (0)</td>
</tr>
<tr>
<td>Pregnancy Test-positive</td>
<td>N: 637, n(%) 0 (0)</td>
<td>N: 642, n(%) 2 (0.31)</td>
<td>N: 641, n(%) 0 (0)</td>
<td>N: 641, n(%) 1 (0.16)</td>
<td>N: 640, n(%) 0 (0)</td>
<td>N: 640, n(%) 0 (0)</td>
</tr>
<tr>
<td>Syphilis-reactive*</td>
<td>N: 637, NA</td>
<td>N: 642, NA</td>
<td>N: 641, n(%) 0 (0)</td>
<td>N: 641, NA</td>
<td>N: 640, n(%) 0 (0)</td>
<td>N: 640, NA</td>
</tr>
<tr>
<td>Cervical cancer screening-reactive*</td>
<td>N: 637, NA</td>
<td>N: 642, NA</td>
<td>N: 641, n(%) 0 (0)</td>
<td>N: 641, NA</td>
<td>N: 640, n(%) 0 (0)</td>
<td>N: 640, NA</td>
</tr>
<tr>
<td>Kidney function (high serum creatinine)</td>
<td>N: 637, n(%) 0 (0)</td>
<td>N: 642, n(%) 0 (0)</td>
<td>N: 641, n(%) 0 (0)</td>
<td>N: 641, n(%) 0 (0)</td>
<td>N: 640, n(%) 0 (0)</td>
<td>N: 640, n(%) 0 (0)</td>
</tr>
</tbody>
</table>

*Syphilis and cervical cancer screening were done every six months.*
**Side Effects**

194 (30.46%) participants reported experiencing side effects such as vomiting, nausea, and headaches during their 1st month follow up visit. Reported side effects reduced over the following months. All side effects reported by participants were minor and resolved by the clinic doctor (Table 5).

Table 5 – Reported side effect during follow up visits.

<table>
<thead>
<tr>
<th>Follow up visit</th>
<th>Number of participants visited for follow up (N)</th>
<th>Number of participants experienced side effect (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>End of 1st month</td>
<td>637</td>
<td>194 (30.46)</td>
</tr>
<tr>
<td>End of 3rd month</td>
<td>642</td>
<td>68 (10.59)</td>
</tr>
<tr>
<td>End of 6th month</td>
<td>641</td>
<td>38 (5.93)</td>
</tr>
<tr>
<td>End of 9th month</td>
<td>641</td>
<td>11 (1.72)</td>
</tr>
<tr>
<td>End of 12th month</td>
<td>640</td>
<td>0 (0)</td>
</tr>
<tr>
<td>End of 15th month (exit visit)</td>
<td>640</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

**Self-reported Adherence**

Self-reported adherence was initially lower during the first three months of the study and was >96% during the last two follow up visits. The longest stretch of non-adherence (more than

25 Community leaders living with HIV who were taking ART provided additional adherence support to participants. Through their experiences taking ART, these community leaders acted as “testimonial ambassadors” and were able to normalize initial side effects, support continued adherence throughout the initial period of adjusting to taking PrEP, and provide tips on how to manage side effects. The clinic doctor also made himself available at all hours to respond to and treat side effects during the early stages of the project.
7 days) reported by participants was observed during the first three months of the project. By the end of the project, reported adherence by participants increased to 97.97% (n=627) for pill taken every day during the last month and to 98.28% (n=629) for pill taken every day during the last 7 days (Table 6).
Table 6 – Self-reported adherence.

<table>
<thead>
<tr>
<th></th>
<th>End of 1st month</th>
<th>End of 3rd month</th>
<th>End of 6th month</th>
<th>End of 9th month</th>
<th>End of 12th month</th>
<th>End of 15th month (exit visit)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>n(%)</td>
<td>N</td>
<td>n(%)</td>
<td>N</td>
<td>n(%)</td>
</tr>
<tr>
<td>Pill taken every day during last month</td>
<td>637</td>
<td>480 (75.35)</td>
<td>642</td>
<td>447 (69.63)</td>
<td>641</td>
<td>575 (89.70)</td>
</tr>
<tr>
<td>Pill taken every day during last 7 days</td>
<td>637</td>
<td>573 (89.95)</td>
<td>642</td>
<td>568 (88.47)</td>
<td>641</td>
<td>578 (90.17)</td>
</tr>
<tr>
<td>Longest stretch of non-adherence in the last month (&gt; = 7 days)</td>
<td>637</td>
<td>53 (8.32)</td>
<td>642</td>
<td>65 (10.12)</td>
<td>641</td>
<td>2 (0.31)</td>
</tr>
</tbody>
</table>
**Tenofovir Blood-Level Testing**

The project team selected a subset of participants to undergo tenofovir blood-level testing twice during the 16 months, at three and six months. They used a tenofovir blood-level concentration of 40 ng/mL as a marker for daily pill consumption in the last seven days, as this has been used as a marker of daily adherence according to the literature (see Donnell et al., 2014). 80% (n=68) of the participants in round 1 and 90.48% (n=76) of the participants in round 2 had a tenofovir blood-level concentration of more than 40 ng/dL (Table 7).

Table 7 – Round 1 and round 2 comparisons for tenofovir concentration.

<table>
<thead>
<tr>
<th>Tenofovir Concentration (ng/mL)</th>
<th>Round 1</th>
<th>Round 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>No peak</td>
<td>5 (5.88)</td>
<td>3 (3.57)</td>
</tr>
<tr>
<td>Below 40</td>
<td>12 (14.12)</td>
<td>5 (5.95)</td>
</tr>
<tr>
<td>40 or above</td>
<td>68 (80)</td>
<td>76 (90.48)</td>
</tr>
<tr>
<td>Total</td>
<td>85</td>
<td>84</td>
</tr>
</tbody>
</table>

Note: All participants were the same in round 1 and round 2.

**DISCUSSION**

The Ashodaya PrEP Demonstration Project holds important insights for providing PrEP. Our retention and adherence rates are significantly higher than those reported in other demonstration project findings, pointing to the potential benefits of a community-led approach. Since Ashodaya, an established community-based organization led the study implementation and offered PrEP alongside their existing package of services, community leaders and outreach workers were able to successfully inform their community about PrEP, recruit a large number of
participants into the study (N=647), and provide adherence support which led to high retention (99%) and high levels of reported adherence (≥97%) among participants. 80% of the participants in round 1 and 90.48% of the participants in round 2 had a tenofovir blood-level concentration of 40 or more ng/dL. Condom use remained consistent throughout the duration of the study.

Adherence was extremely high in our study, with variations at the start of the project. As in other demonstration projects with sex workers (Eakle et al., 2017), Ashodaya also prioritized continued engagement over perfect adherence. This allowed for periods of variable adherence, especially during the earlier months of the study where people were getting used to taking PrEP. Health care providers and researchers often flag risk compensation as a concern when discussing PrEP, however, as seen in our study, condom use remained consistent. This reflects findings in other studies, where PrEP clinical trials did not show substantial risk compensation (Marcus et al., 2013; Mugwanya et al., 2013). As stated by Mugo and colleagues (2016) in a review of recent PrEP findings, evidence shows that PrEP uptake and adherence in demonstration projects seems to be driven by risk, that is that those who perceive themselves to be at risk are more likely to initiate PrEP. Similarly, Eakle et al. (2017), reported little change in condom use over time in their TAPS Demonstration Project among sex workers in South Africa, noting that women in PrEP studies may instead improve their attention to prevention strategies. Mathematical modeling looking at PrEP use among sex workers in South Africa has also shown that PrEP is likely to be of benefit in reducing HIV risk, even if reductions in condom use do occur (Grant et al., 2017). We also saw very few STIs in our study, again pointing to the likelihood of continued consistent condom use. Side effects were not a major issue in our study, which is consistent with reports that PrEP is well tolerated (Eakle et al., 2017; Mayer & Ramjee, 2015; Mugo et al., 2016; Venter, 2018).
While our study took place within the context of a well-established community-led organizations, similar models of community mobilization and support can be adopted to other environments. The Princess PrEP Program (Phanuphak et al., 2018) is another example of a community-led project among men who have sex with men and transgender women in Thailand, where community health workers who were already trained to provide peer-led HIV testing and counselling received additional training to provide same-day PrEP in community health centre settings. Community health workers provided visit reminders and continued adherence counselling that sought to address any challenges with adherence. While overall retention in the Princess Program was low (43.9% at 12 months), self-reported adherence was near perfect at 99.5% (Phanuphak et al., 2018).

Global roll out of PrEP has generally been slow, partly due to restricting delivery models to health facilities, as well as requirements around HIV testing and toxicity monitoring (Venter, 2018). Venter (2018), while addressing the challenges of scaling up PrEP, suggests that expanding access through specialized health services could be seen as an additional model for PrEP delivery. Shannon et al. (2018) echo that investments are needed in community and structural interventions for sex workers to benefit from PrEP. Our demonstration project provides important evidence that sex worker organizations can effectively deliver PrEP to their communities with extremely high levels of retention and adherence.

Findings from some demonstration projects have led to PrEP being included in national HIV plans (see for example, Eakle et al., 2017). According to PrEPWatch, Botswana, Kenya, Lesotho, Nigeria, South Africa, Uganda, the United Kingdom, the United States, Zambia, Zimbabwe, and some Canadian provinces have published PrEP guidelines (AVAC, 2018a). PrEP is not yet available through India’s National AIDS Control Organization’s HIV prevention
programs. Ashodaya, as an important community voice among sex workers, has a long history of advocating for policy change and sex workers’ rights. Dissemination and advocacy is planned at the national level. Our findings fit within calls by researchers to answer questions about the roll out of community-led approaches to PrEP implementation and calls to increase community and sex worker-led involvement within biomedical interventions (Shannon et al., 2018).

**Limitations**

Our study took place within a well-established community-led sex worker organization. Participants were recruited by community outreach workers through their existing networks, which may have led to both higher retention and adherence throughout the study. Responses to surveys were self-reported, which could be influenced by social desirability bias, however, results from the tenofovir blood-level testing support the high self-reported adherence. We believe that the community-led models developed here hold lessons about community-led PrEP interventions that can be applied in other settings, by tapping into and trusting the knowledge held by community organizations to expand upon their existing package of HIV prevention services towards also providing biomedical interventions.

**Conclusion**

The Ashodaya PrEP Demonstration Project holds important insights for rolling out PrEP and highlights the importance of community-led programs in promoting high levels of PrEP adherence, which is a critical component for ensuring its efficacy in HIV prevention. Following the demonstration project, Ashodaya is currently in the process of advocating for continued access to PrEP through inclusion of PrEP in India’s national HIV prevention guidelines.
This paper is adapted from a publication that presents the findings of the feasibility study that launched the Ashodaya PrEP Demonstration Project. Whereas early efficacy trials of tenofovir were mired in controversy for not including nor responding to community needs, scientists and community leaders working on the Ashodaya Feasibility Study paid careful attention to furnish opportunities for sex workers to interrogate PrEP. The feasibility study here served to both inform their community about this new prevention technology and gauge interest in exploring PrEP use among sex workers in the Mysore-Mandya region. I conducted the qualitative data analysis and took the lead on the first draft of the manuscript, with support from Dr. Robert Lorway and Dr. Sushena Reza-Paul. The quantitative analysis and tables presented in this chapter were done by Dr. Raviprakash Maiya and Dr. Sushena Reza-Paul. All authors provided input into the published version of the manuscript, which has been published in PLOS ONE.

Publication details:

Chapter 4. Prioritizing Risk in Preparation for a Demonstration Project: A Mixed Methods Feasibility Study of Oral Pre-Exposure Prophylaxis (PrEP) among Female Sex Workers in South India

BACKGROUND

Much is known about the clinical efficacy of PrEP, with trials beginning in 2005 (see for example, Okwundu et al., 2012), however guidance and practices around its implementation and scale up in India remain unclear. For this reason, we planned a demonstration project in two sites in India: the Durbar Mahila Samanwaya Committee (DMSC) at Sonagachi in Kolkata (see Jana et al., 2004) and Ashodaya Samithi (Ashodaya) in Mysore (see Reza-Paul et al., 2008) to test its effectiveness if rolled out as part of an actual program. Prior to moving forward with a demonstration project, the research team considered it essential to consult with the communities who they expected would participate in the study.

Despite PrEP’s demonstrated clinical efficacy as a new prevention technology, some early oral tenofovir trials among sex workers in Cameroon, Nigeria, Malawi, and Cambodia were embroiled in controversy. Between 2004-2005, sex work and activist protests culminated in the halting or cancelation of these trials amid concerns around a lack of community consultation and involvement, questions around the safety of tenofovir use as a prevention drug, and the failure of researchers to ensure the provision of treatment in cases of HIV infection during study
participation (Haire, 2011; Ukpong & Peterson, 2009). The Cambodia trial never occurred due to activists’ concerns over the lack of treatment and loss of employment in cases of seroconversion (Cáceres et al., 2015). In Cameroon and Nigeria, trials were cancelled due to questions over inappropriate research standards (Cáceres et al., 2015). In Malawi, ethics approval was withdrawn due to fears over drug resistance (Cáceres et al., 2015). The collectivized power of activist networks through these protests demonstrated the global influence of this emergent form of transnational citizenship and demands for more ethical research practices.

Paralleling Adriana Petryna’s (2004) ethnographic account of biological citizenship in Chernobyl, these PrEP trials show that even very vulnerable populations have an expectation that if they undertake risks, they earn an entitlement to benefits that should offset those risks. In other words, participants sought assurances that should PrEP not prove efficacious, HIV treatment and income support would be provided. Or as Stefan Ecks (2005) writes in his research on antidepressant use in India, while access to biomedical prevention treatment might work to minimize some experiences of marginality, there is an expectation that it should not create new vulnerabilities. In the cases of these cancelled PrEP trials, activists pushed back to demand more equitable trial conditions.

Following these highly publicized protests, in May 2005, the International AIDS Society and the Gates Foundation held a stakeholder consultation to find a way forward with biomedical prevention research (Peterson and Folayan, 2017). UNAIDS also organized regional consultations. The outcome of these meetings resulted in the preparation of the Good Participatory Practice Guidelines by UNAIDS and AVAC. These guidelines were meant to provide systematic guidance on how to effectively engage all stakeholders in HIV prevention
trials (see Peterson and Folayan, 2017; UNAIDS 2007a, 2011). The document points to the need for community engagement, however, in the words of Peterson and Folayan (2017):

> Community engagement was not imagined to extend to independent assessments that evaluate whether the trial and its objectives are actually beneficial to trial participants. In other words, ‘saying no’ to a clinical trial, as was done in Malawi and Nigeria, is not imagined to be part of an independent scrutinizing process because such a response disrupts ‘effective partnerships’ (p. 29).

Clinical trials continued to roll out between 2007-2013, however sex workers have largely been left out of these clinical trials (Shannon et al., 2018) and research among women has shown low efficacy due to low rates of adherence, such as in the FEM-PrEP trial in Kenya, South Africa, and Tanzania (Van Damme et al., 2012) and the VOICE trial in South Africa, Uganda and Zimbabwe (Marrazzo et al., 2015).

Feasibility studies can help ascertain whether or not an intervention is appropriate for further testing, and they can help inform the acceptability, demand, practicality, and implementation of proposed research projects (Bowen et al., 2009). Unlike in the case of the cancelled or halted clinical trials, our feasibility study served to check in with the community of Ashodaya sex workers to assess their interests in moving forward with the demonstration project, as well as seek their guidance on important planning issues, such as determining inclusion criteria. Whereas Peterson and Folayan’s (2017) interpretation of the *Good Participatory Practice Guidelines* highlight the guide’s purpose as finding a way to move forward with research, our feasibility study was also meant to provide the community with the opportunity to say no to the demonstration project. With this in mind, the University of Manitoba’s Centre for Global Public Health, in partnership with Ashodaya Samithi, conducted a feasibility study to
assess the acceptance of a PrEP demonstration project, willingness to use PrEP, and recommendations for project roll out among female sex workers in Mysore and Mandya, Karnataka, India.

**METHODS**

The Ashodaya program team and trained community researchers conducted the feasibility study in both Mysore and Mandya between January and April 2015. The study followed a sequential mixed methods approach (Johnson, Onwuegbuzie, & Turner, 2007; Morse, 1991), drawing on both qualitative and quantitative research methodologies. Participants for the feasibility study included female sex workers who were 18 years of age or older and currently practiced sex work in Mysore and Mandya.

The project team and community researchers conducted the study in the urban centres of these cities, and surrounding villages and talukas. Posing a challenge at the time of the study was a shift from street-based to home-based sex work. Sex work in the early days of Ashodaya largely occurred at the city’s bus stations, railway station, and commercial centres, in what the project staff and community referred to as zones A, B, or C. Beginning in 2007-2008, sex work in Mysore began to shift from street and lodge-based (hourly room rentals) settings towards solicitation through cell phone and home-based sex work (O’Brien, Reza-Paul, & Lorway, 2011). Renovations of the bus stands in 2008, as well as massive closings of lodges in the same year pushed sex workers to start working in home settings. At the same time clients also began requesting to meet in homes to avoid police raids and arrests (O’Brien, Reza-Paul, & Lorway, 2011). While lodges began re-opening in 2010-2011 and invited sex workers to return (see
O’Brien, Reza-Paul, & Lorway, 2011), sex work remains predominantly home-based in the city. The proliferation and affordability of cell phones also made it significantly easier to book clients, rather than spending hours on the street. It should be noted that cell phones also facilitated outreach activities and communication, as work moved indoors (O’Brien, Reza-Paul, & Lorway, 2011). Therefore, while previous studies, such as the cross-sectional integrated behavioural and biological assessments (IBBA) surveys used to examine the impact of the program, were able to recruit participants from these hotspot zones (see for example, Reza-Paul, 2008), shifts in patterns of sex work posed new challenges for reaching women on the part of the organization, which meant that Ashodaya had to engage sex workers in the feasibility study through networks of home-based sex work locations. A home-based sampling strategy was developed by the organization to help facilitate recruitment into the feasibility study (Figure 7).

While I was not initially involved in the feasibility study, I joined the team in January 2015 to conduct the qualitative data analysis and draft the study report, from which the published version of the manuscript was later developed. During this time, I visited the project office in both Mysore and Mandya. It was in Mandya that I sat in on a community meeting where both male and transgender sex workers passionately pleaded that they too needed PrEP because they too experienced risk during their work. Although the inclusion criteria for the demonstration project was set by funders and limited to include only sex workers who were assigned female at birth, Ashodaya has always worked as an inclusive space, open to all genders and identities.

26 The map depicted here is not highly specific to protect the privacy and anonymity of the location of the homes.
While Ashodaya spent much time explaining the parameters of the study protocol to its members, it was clear that the transgender community also desired access to PrEP.

**Awareness Campaigns**

As a new HIV prevention strategy, PrEP has yet to be implemented in India and knowledge around it remains quite limited. The initial community consultations revealed very low or no knowledge around PrEP. Therefore, in order to ensure informed decision making by the community around the feasibility of PrEP implementation, raising awareness around PrEP became critical. Ashodaya prepared a PrEP fact sheet based on the Centers for Disease Control and Prevention (CDC), AIDS Vaccine Advocacy Coalition (AVAC), and Global Network of Sex Work Projects (NSWP) guidelines and simplified in a language that could be easily understood by the community. Approximately thirty PrEP-related group discussions took place in Mysore and Mandya with members of the Ashodaya community; each discussion had 25-30 participants. Awareness campaigns lasted for almost nine months. Following this, a feasibility study was undertaken.

**Focus Group Discussions**

A team of trained community and non-community researchers conducted focus group discussions in small groups of 6-8 female sex workers. The researchers kept these groups as homogenous as possible using criteria such as socio-economic status, education level, or social networks. The research team used purposive sampling to identify participants by using peer outreach workers’ contact lists. Focus group facilitators obtained informed consent from each participant before the start of the discussion. Discussions focused on exploring (a) knowledge, interests, and concerns around PrEP; (b) the acceptability and willingness for PrEP uptake,
including perceptions of HIV risk, as well as barriers and facilitators to uptake and adherence; and (c) inclusion/exclusion criteria for participant enrolment into the demonstration project.

**In-depth Interviews**

Trained community and non-community researchers conducted semi-structured in-depth interviews among female sex workers. Researchers identified participants through purposive sampling procedures, being mindful to include community leaders as participants. Participants in the in-depth interviews had not participated in the focus group discussions. In addition to the questions explored in the focus groups, the semi-structured interviews also addressed possible delivery mechanisms for PrEP roll out in Mysore and Mandya.

**Qualitative Data Collection and Analysis**

Members of the Ashodaya program team translated the focus group and in-depth interview guides from English to Kannada and conducted the interviews in Kannada, the local language. Interviews were audio-recorded. A transcriptionist who had a long history of working with Ashodaya and knew the local context was responsible for transcribing the Kannada recordings directly into an English translation. I coded all transcripts for key themes and emergent categories, followed by thematic and content analysis (Boyatzis, 1998). The research team drew on the key findings from the qualitative research to inform the phrasing of the quantitative questionnaire to ensure that questions were worded in a way that resonated with participants and that survey response options were exhaustive.
Cross-sectional Survey

Community researchers administered a questionnaire to female sex workers in Mysore and Mandya. The research team developed the questionnaire in English, translated it into Kannada, and then back-translated it into English to ensure completeness. The team employed respondent driven sampling (RDS) to facilitate inclusion of and to capture the perspectives of sex workers who belong to different networks. To ensure representativeness in the sample, the team selected the initial seeds from diverse social networks. Community researchers introduced eligible candidates to the study procedures, obtained informed consent, and administered the questionnaire. Interviewers then asked the seeds to recruit their peers who met the study inclusion criteria. The study coordinator was responsible for screening the referrals for inclusion/exclusion criteria, while project supervisors were responsible for ensuring that the entire protocol (from issuing the coupon to administration of the consent and interview) was adhered to. The supervisors and the study coordinator were also responsible for quality checks of the data.

An initial eight seeds were given five coupons to distribute to five potential participants. Based on previous studies, it was understood that three waves are optimal for the sex work context in Mysore and Mandya. After the initial seeds, participants from waves 1 and 2 were given three coupons each to distribute to potential participants. To avoid duplication of intake, all participants were given a unique participant ID, and this information was recorded and tracked for duplication. The questionnaire was designed to collect information on demographic characteristics; knowledge, interest, perceptions, beliefs, and concerns around PrEP; acceptability and willingness for PrEP uptake; HIV-related risk and vulnerability (including HIV knowledge, misconceptions, behaviour, and HIV testing practices); barriers to PrEP uptake and
adherence; facilitators to PrEP uptake and adherence; inclusion and exclusion criteria for enrolment into the demonstration project; and delivery mechanisms for PrEP roll out and scale up.

**Statistical Analysis**

The statistical team used SPSS (IBM, Version 22) to analyse both continuous and categorical data, then conducted univariate descriptive analysis to summarise the data and present frequency distributions and means.

**Ethical Considerations**

Following approval from the World Health Organization, the research protocol was approved by the University of Manitoba’s Institutional Ethics Review Board (IERB) and the Institutional Ethics Committee (IEC) at Durbar Mahila Samanwaya Committee (DMSC), Kolkata, a sex worker organization that operates the Sonagachi project. All participants provided their written consent to participate in the study and the consent process was approved by both Research Boards.

**RESULTS**

**Participant Socio-demographic Characteristics**

From January to April 2015, community researchers conducted 35 in-depth interviews and 6 focus group discussions with female sex workers. Participants in the in-depth interviews were on average 34 years old (age range=25-45 years) and they had been practicing sex work for an average of 11 years (range=1-20 years). Thirty-eight women participated in the six focus
group discussions. The average age of focus group participants was 35 years (age range=23-47 years) and they had been practicing sex work for an average of 9 years (range=2-25 years).

A total of 427 female sex workers (including 8 seeds) participated in the cross-sectional survey. The eight seeds recruited 419 participants. The mean age of survey participants was 33 years (range=19-49 years). The majority (95%) of participants reported using multiple means for solicitation of clients (such as, cell phone, public places, homes, through brokers). We present the socio-demographic and sex work related characteristics of survey participants in Table 8 and Table 9.
Table 8 – Socio-demographic characteristics of the participants in the feasibility study.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>32.72 (5.5)</td>
<td></td>
</tr>
<tr>
<td>&lt;=25</td>
<td>56</td>
<td>13.1</td>
</tr>
<tr>
<td>26-35</td>
<td>226</td>
<td>52.9</td>
</tr>
<tr>
<td>36-45</td>
<td>143</td>
<td>33.5</td>
</tr>
<tr>
<td>&gt;45</td>
<td>2</td>
<td>0.5</td>
</tr>
<tr>
<td><strong>Place of Residence</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>193</td>
<td>45.2</td>
</tr>
<tr>
<td>Urban</td>
<td>234</td>
<td>54.8</td>
</tr>
<tr>
<td><strong>Able to read and write</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>256</td>
<td>60.0</td>
</tr>
<tr>
<td>No</td>
<td>171</td>
<td>40.1</td>
</tr>
<tr>
<td><strong>Highest level of education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No formal schooling</td>
<td>174</td>
<td>40.8</td>
</tr>
<tr>
<td>Primary school (1-4)</td>
<td>58</td>
<td>13.6</td>
</tr>
<tr>
<td>Higher primary school (5-7)</td>
<td>83</td>
<td>19.4</td>
</tr>
<tr>
<td>High school (8-10)</td>
<td>88</td>
<td>20.6</td>
</tr>
<tr>
<td>PUC (11-12)</td>
<td>19</td>
<td>4.5</td>
</tr>
<tr>
<td>Higher education Undergraduate degree completed</td>
<td>4</td>
<td>0.9</td>
</tr>
<tr>
<td>Technical/Vocational School</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>Current marital status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Divorced/separated/Unmarried - Living alone</td>
<td>19</td>
<td>4.5</td>
</tr>
<tr>
<td>Characteristic</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>-----</td>
<td>------</td>
</tr>
<tr>
<td>Divorced/separated/Unmarried/Married - Living with husband</td>
<td>170</td>
<td>39.8</td>
</tr>
<tr>
<td>Married (live with partner other than husband)</td>
<td>99</td>
<td>23.2</td>
</tr>
<tr>
<td>Married - living alone</td>
<td>72</td>
<td>16.9</td>
</tr>
<tr>
<td>Widowed - live alone</td>
<td>45</td>
<td>10.5</td>
</tr>
<tr>
<td>Widowed - live with partner</td>
<td>22</td>
<td>5.2</td>
</tr>
</tbody>
</table>

**Age at first sex**

- **Mean (SD)**: 17.12 (2.9)
- **<18**: 228, 53.4%
- **18-20**: 166, 38.9%
- **>20**: 31, 7.3%
- **Don’t know/Can’t remember**: 2, 0.5%

**Age at first sex for money or gift**

- **Mean (SD)**: 23.41 (4.34)
- **<18**: 17, 4.0%
- **18-25**: 291, 68.2%
- **>25**: 119, 27.9%

**Duration of practicing sex work-years**

- **Mean (SD)**: 9.31 (5.3)
- **1-5**: 118, 27.6%
- **6-10**: 162, 37.9%
- **>10**: 147, 34.4%

**Place of solicitation**
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(N=427)</td>
<td></td>
</tr>
<tr>
<td>Rented home or friends' home</td>
<td>187</td>
<td>43.8</td>
</tr>
<tr>
<td>Through cell phone</td>
<td>330</td>
<td>77.3</td>
</tr>
<tr>
<td>Own home</td>
<td>36</td>
<td>8.4</td>
</tr>
<tr>
<td>Through a broker/pimp</td>
<td>153</td>
<td>35.8</td>
</tr>
<tr>
<td>Public places</td>
<td>195</td>
<td>45.7</td>
</tr>
<tr>
<td>Lodge, hotel, motel or bar</td>
<td>73</td>
<td>17.1</td>
</tr>
<tr>
<td>Dhaba (roadside restaurant)</td>
<td>26</td>
<td>6.1</td>
</tr>
<tr>
<td>Highway</td>
<td>115</td>
<td>26.9</td>
</tr>
<tr>
<td>Other</td>
<td>23</td>
<td>5.4</td>
</tr>
</tbody>
</table>

**Place where clients are entertained**

<table>
<thead>
<tr>
<th>Place</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Own home</td>
<td>85</td>
<td>19.9</td>
</tr>
<tr>
<td>Rented home or friend's home</td>
<td>388</td>
<td>90.9</td>
</tr>
<tr>
<td>Client's home</td>
<td>216</td>
<td>50.6</td>
</tr>
<tr>
<td>Public places</td>
<td>26</td>
<td>6.1</td>
</tr>
<tr>
<td>Lodge, hotel or motel</td>
<td>222</td>
<td>52.0</td>
</tr>
<tr>
<td>Dhaba</td>
<td>32</td>
<td>7.5</td>
</tr>
<tr>
<td>Client's vehicle</td>
<td>123</td>
<td>28.8</td>
</tr>
<tr>
<td>Other</td>
<td>37</td>
<td>8.67</td>
</tr>
</tbody>
</table>

**Number of clients entertained in a day**

<table>
<thead>
<tr>
<th>Number</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD)</td>
<td>3</td>
<td>(1.3)</td>
</tr>
<tr>
<td>2 – 5 clients</td>
<td>400</td>
<td>93.7</td>
</tr>
<tr>
<td>&gt;5</td>
<td>27</td>
<td>6.3</td>
</tr>
</tbody>
</table>
### Experience of a condom breaking in the past month

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (N=427)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>79</td>
<td>18.5</td>
</tr>
<tr>
<td>No</td>
<td>344</td>
<td>80.6</td>
</tr>
</tbody>
</table>

Table 9 – Sex work and income.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (N=427)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amount of money (in rupees) received per sex act in past one month</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>509.79 (212.07)</td>
<td></td>
</tr>
<tr>
<td>&lt;500 (&lt;$7.50 USD)</td>
<td>156</td>
<td>36.5</td>
</tr>
<tr>
<td>500 (&lt;$7.50 USD)</td>
<td>161</td>
<td>37.7</td>
</tr>
<tr>
<td>&gt;500 (&gt; $7.50 USD)</td>
<td>110</td>
<td>25.8</td>
</tr>
<tr>
<td>Amount of money (in rupees) received for overnight stay</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>1596.62 (984.79)</td>
<td></td>
</tr>
<tr>
<td>&lt;=1000 (&lt;=$15 USD)</td>
<td>137</td>
<td>32.1</td>
</tr>
<tr>
<td>1001-2000 ($15-30 USD)</td>
<td>179</td>
<td>41.9</td>
</tr>
<tr>
<td>&gt;2000 (&gt; $30 USD)</td>
<td>39</td>
<td>9.1</td>
</tr>
<tr>
<td>No overnight stay</td>
<td>72</td>
<td>16.9</td>
</tr>
<tr>
<td>Average monthly income in the past month (in rupees)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>13309.86 (5521.42)</td>
<td></td>
</tr>
<tr>
<td>500-5000 ($7.50-75 USD)</td>
<td>31</td>
<td>7.3</td>
</tr>
<tr>
<td>6000-10000 ($90-149.50 USD)</td>
<td>131</td>
<td>30.7</td>
</tr>
<tr>
<td>11000-15000 ($164.50-224 USD)</td>
<td>158</td>
<td>37.0</td>
</tr>
</tbody>
</table>
To help Ashodaya interpret the data for the purpose of deciding whether to move forward with the demonstration project, the research team (including myself as the qualitative analyst) broke down the findings (from the quantitative survey, in-depth interviews, and focus group discussions) into the following main themes: (1) community interest and the need for PrEP; (2) prioritizing risk in participant selection for the PrEP demonstration project; and (3) the importance of experience and trust in addressing barriers to uptake and adherence. I detail the findings for each theme below.

**Community Interest and the Need for PrEP**

Following the PrEP awareness campaigns, participants demonstrated a good knowledge and understanding of PrEP. Geeta and Darsha, two of the participants in the in-depth interviews, shared their thoughts on PrEP following their interactions with Ashodaya:

Some of them who are working in Ashodaya. They met me and told me about PrEP as a tablet and it will prevent HIV infection, but we also need to use condom…. She told me that PrEP is a tablet that can be given only to those who are negative and not HIV positive, but along with the tablet women should also use a condom. She also said we will be provided training on it. (Geeta, in-depth interview)

It is for my own safety. For myself. Something new is coming through the tablet and I feel excited about it. If there is something new that is good for our health, I feel I should take it. (Darsha, in-depth interview)
Participants expressed high levels of interest in PrEP and strongly associated its need to their experiences of risk. Almost all participants surveyed (95%, n=406) expressed an interest in taking PrEP and among those, 89% stated that they would be willing to take PrEP every day. In her interview, Gina described how participants saw PrEP as an exciting new tool in HIV prevention, one that would place control into her own hands:

We can prevent ourselves from getting infected by HIV. We see many people suffering because of HIV. So to take prior precaution we can take PrEP, which will prevent us from HIV. I was convinced about this medicine. (Gina, in-depth interview)

In the focus group discussions, women portrayed PrEP as a prevention strategy that could potentially ease the stress and fear associated with instances where condom use was not possible, providing peace of mind to women in the knowledge that they are protected from contracting HIV.

Yes. We want that tablet because it will prevent us from HIV. We used to be afraid that we will get HIV when some clients would have sex without condoms and sometimes when the condom gets torn. But if we take these tablets we need not worry about HIV. We can’t trust the clients to have safe sex. Our partners and boyfriends also refuse to wear condoms. This tablet will be useful for us to be fear free when we have sex with them even without condoms. (Focus group discussion #5, Mysore)

Furthermore, participants, such as Inu and Darsha, expressed that PrEP will allow them to maintain their health, thus protecting their earning potential and ability to support themselves, as well as their dependents. Many of the women interviewed had families for whom they were financially responsible. Participants viewed their earning potential as directly impacted by their health and they viewed taking PrEP as good for business.
Yes. Most of the community wants to earn money, and they know they need to be healthy to do so. So, they want PrEP to stay healthy. They want it and after knowing how it can prevent HIV infections, they will also demand it…. (Inu, in-depth interview)

I have the responsibility of earning and looking after my children and family. Many women are taking care of their children and aged people at home. Not all have a man providing for them. By taking these tablets I feel I will not get infected and so can earn and take care of my family. If I do not take it and I die of HIV then my children will face hardships. (Darsha, in-depth interview)

As PrEP in this setting is being recommended as a combination prevention strategy, alongside consistent condom use to prevent other STIs, it is important to gain an understanding of the perceived value of PrEP in the context of consistent condom use. Despite community norms of widespread condom use, Kaira expressed how there was still a feeling among community members that condoms alone are not enough.

Now if I take this PrEP tablet, I will be safe even if someone forces me for sex [or] without a condom or even when the condom breaks. I will not have the fear because I know I have taken the precautionary tablet… (Kaira, in-depth interview)

Participants reported far too common experiences of forced sex and violence, making condom use impossible at times. One-quarter of the participants surveyed had experienced violence in the past twelve months and 8% reported experiencing forced sex during that time frame. Among the thirty-six participants surveyed who had experienced forced sex, condoms were known to be used only 42% of the time. In sharing her experience, Rathi explained how PrEP would help her in cases of forced sex:
Many times, apart from clients, lodge [motel] owners also have sex with us. They do not pay us, but have sex without condoms. Then they threaten that they will inform the police, or will not give a room to a client, etc. So I have sex without a condom so that they will continue to give rooms. Also if there is a raid and the police catch me, they take away all my money and also have free sex with me without a condom. So there are so many such occasions that I cannot avoid. Having PrEP tablets will help me greatly. (Rathi, in-depth interview)

According to some participants, when clients use condoms, some intentionally remove or break them, placing women at risk of infection. Over one-third of surveyed participants reported experiencing condom breakage in the last year and 19% of all participants experienced breakage in the last month.

I need it. Maybe once in a week while having sex, the condom may break and I may be exposed to risk of infection, so I need the tablet. (Rathi, in-depth interview)

Despite high rates of condom use with clients, sex without condoms with husbands, partners, and lovers is still common. Nearly all participants (97%) surveyed reported that they use a condom every time they have sex with occasional clients. Condom use with regular clients was slightly less consistent, with 85% of participants reporting that they used a condom every time with regular clients. However, condom use with regular partners is less common. Of the 303 participants (71%) surveyed who reported having a regular non-paying sexual partner, only 29% of respondents used a condom consistently, and 48% of them reported using a condom at the time of last sex. PrEP could play an important role in providing protection in these instances of unprotected sex. Nalini, in her interview, described the challenges of using condoms with regular
partners, acknowledging that while she uses condoms with clients, it is sex with her partner that may put her at risk of HIV infection.

I have a lover from the past two years…. This person is now having sex with me without condoms from the past two years. He doesn’t know that I do sex work. I do it without his notice. He questions me if I insist that he use condoms. I may not have any health problems. But how can I trust him that he doesn’t have any problems? So, I will use condoms outside with other clients. But I have sex without condoms at home. So I will take the tablets that you are giving me so that I will be safe. It may so happen that I will get the infection from my lover. What will I do in such situations? (Nalini, in-depth interview)

According to Neha and Rathi, PrEP and condoms used in combination would provide a “double safety”. In the event that a condom breaks or a woman is pressured into sex without a condom, PrEP would provide an extra layer of protection against HIV transmission and some assurance.

I don’t completely rely on condoms because due to its wear and tear there might be chances of STI or HIV infection. So for double safety I would prefer taking this tablet as well as use condoms. (Neha, in-depth interview)

To continue to be in good health. It is kind of double protection for me, using condoms as well as PrEP tablets. Sometimes while I am returning home from a client the auto driver also has sex with me. He doesn’t use a condom. So I need PrEP tablets to protect me from all such instances. (Rathi, in-depth interview)

Although participants expressed a need for PrEP, it is important to note that not all participants were open to using both PrEP and condoms. Some participants, such as Sakshi and Bhanu, questioned the need for PrEP at all, as they have managed to effectively protect themselves from infections through other HIV prevention strategies. Both women stated
scepticism over whether women would agree to take tablets, expressing challenges to taking pills even in cases of illness.

PrEP prevents us only from HIV but condoms will prevent us from infecting STIs. If I don’t use condoms I will get different kinds of STIs. So we should use condoms even if we take PrEP. But I don’t think our community women will agree to use both. (Sakshi, in-depth interview)

As a community leader when I was educating our community about PrEP many asked me as to why they should take both PrEP and use condoms. Why can’t we use either of them? Many said they don’t take tablets even when they have fever but prefer some home remedies, they ask why should they take this tablet. (Bhanu, in-depth interview)

Some participants also expressed concern that PrEP use may undermine the community norm of condom use.

I feel when we started talking about condoms, we stressed on its use saying we will not get HIV infection. Now if the tablets do the same, we will all feel that why use condoms when we are taking the tablets? Just like it is important to eat food regularly, we feel using condoms regularly is equally critical. But with the tablets, I feel people will lose interest in using condoms. (Darsha, in-depth interview)

In contrast, many survey participants reported that condom use would remain unchanged while taking PrEP (Table 10). Of participants surveyed, 99% reported that they would continue to use condoms while taking PrEP and 99% also claimed that they would use them as much or more than they do now.
Table 10 – Condom use among women who are willing to take PrEP.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Continue to use condoms while taking PrEP (N=424)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>420</td>
<td>99.1</td>
</tr>
<tr>
<td>No</td>
<td>3</td>
<td>0.7</td>
</tr>
<tr>
<td>Refused</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>Frequency of condom usage while taking PrEP (N=420)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>More than you do now</td>
<td>20</td>
<td>4.8</td>
</tr>
<tr>
<td>Same as you do now</td>
<td>396</td>
<td>94.3</td>
</tr>
<tr>
<td>Less than you do now</td>
<td>3</td>
<td>0.7</td>
</tr>
<tr>
<td>Refused</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>Frequency of condom use with clients while taking PrEP (N=420)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>More condom use</td>
<td>18</td>
<td>4.3</td>
</tr>
<tr>
<td>Same condom use</td>
<td>389</td>
<td>92.1</td>
</tr>
<tr>
<td>Less condom use</td>
<td>14</td>
<td>3.3</td>
</tr>
<tr>
<td>Refused</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>Frequency of condom use with regular partner while taking PrEP (N=420)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>More condom use</td>
<td>7</td>
<td>1.7</td>
</tr>
<tr>
<td>Same condom use</td>
<td>248</td>
<td>59.1</td>
</tr>
<tr>
<td>Less condom use</td>
<td>16</td>
<td>3.8</td>
</tr>
<tr>
<td>I don't have a regular partner</td>
<td>123</td>
<td>29.3</td>
</tr>
</tbody>
</table>
Prioritizing Risk in Participant Selection

An important goal of the feasibility study was to explore the inclusion criteria for participants in the demonstration project.\(^2^7\) Although there was an overall feeling that all sex workers would benefit from PrEP, there was clear consensus among participants that women who experienced more risk should be given priority for inclusion. According to participants such as Chetana, this often meant younger sex workers, who attracted more clients, and also might be less knowledgeable about safer sex practices, less experienced with condom use, and less empowered to negotiate condom use.

Like I have some friends who are [around] 25 years of age and they have a huge client load. They might use condoms with some of their clients and may not with some. As mentioned earlier they might have carried 4 or 5 condoms and unexpectedly they might go with much more clients where getting a condom would be impossible. In such cases these are the people under high risk and these are the people who should have PrEP tablets. (Chetana, in-depth interview)

\(^{27}\) The need to consult the community on inclusion criteria was incredibly important in order to attempt to minimize rifts in the community between those who would get PrEP and those who would not. While a risk scale was initially conceived as part of the screening process for the demonstration project, this was ultimately scraped, as it was decided that anyone who thought that they would benefit from PrEP should be given the opportunity to participate in the demonstration project. However, discussing inclusion criteria early on certainly helped inform Ashodaya members that not everyone would have access to PrEP through the demonstration project.
As a means of judging “client load”, and thus risk, participants in the focus group discussions suggested looking at how many condoms community members picked up. They also viewed younger and newer sex workers to be less experienced with proper condom use.

Women who take more condoms means that they get more clients, irrespective of their age and so they must be given preference…. Young women [sometimes] do not know how to put a condom onto a man, and if they don’t do it correctly it may break… So they will be at high risk to HIV infections and so preference must be given to them. Women like me who take 3 clients a month may be left out and given only if the tablets are available. (Focus group discussion #1, Mysore)

Participants also stressed that attempts should be made to reach women who work in home-based settings, who may be less likely to access services, and may practice sex work in secret. Bhanu explained how women who work in home-based environments may experience higher risk, as they may not come to the office and mingle with other sex workers. She suggests that these women stand to benefit from PrEP as they may be reluctant to come to the clinic to access services.

Those doing this work at home or their brokers will not come forward to the office and mingling with our community will be comparatively less. As they basically prefer maintaining their work as secret. But those community [members] among the street will interact with other community [members] and information about this tablet will thereby pass on to one community to other. The ones who maintain secrecy about their work will hesitate to come forward and collect information on this tablet. For such people, PrEP is very useful and necessary. (Bhanu, in-depth interview)

As women are increasingly working in home-based settings, participants suggested that it would be important that the demonstration project also reaches these women.
The Importance of Experience and Trust in Addressing Barriers to Uptake and Adherence

Despite high levels of interest in PrEP, participants cited numerous potential barriers for consideration prior to rolling out PrEP (Table 11).

Table 11 – Challenges in taking PrEP every day.

<table>
<thead>
<tr>
<th>Challenges in taking PrEP every day</th>
<th>n (N=424)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>I might experience side effects</td>
<td>262</td>
<td>61.8</td>
</tr>
<tr>
<td>I might have difficulty taking PrEP as I consume alcohol</td>
<td>96</td>
<td>22.6</td>
</tr>
<tr>
<td>Others might see me take PrEP/ask questions about PrEP</td>
<td>200</td>
<td>47.2</td>
</tr>
<tr>
<td>My boyfriend/partner/lover might not give me permission to take PrEP</td>
<td>167</td>
<td>39.4</td>
</tr>
<tr>
<td>It is difficult to take tablets everyday</td>
<td>140</td>
<td>33</td>
</tr>
<tr>
<td>I live far, it will be difficult to travel to the office to collect tablets/for regular check-ups</td>
<td>110</td>
<td>25.9</td>
</tr>
<tr>
<td>I cannot afford to pay for my travel to the office</td>
<td>127</td>
<td>30</td>
</tr>
<tr>
<td>It will be difficult to take tablets when I am away on contract work</td>
<td>42</td>
<td>9.9</td>
</tr>
<tr>
<td>People might suspect that I have HIV</td>
<td>159</td>
<td>37.5</td>
</tr>
<tr>
<td>I might have difficulty in paying for PrEP medicine</td>
<td>43</td>
<td>10.1</td>
</tr>
</tbody>
</table>

Participants expressed major concern around dosing and the need to take PrEP daily. The biggest obstacle facing PrEP may be the need for daily intake. One hundred and forty participants (33%) surveyed expressed daily intake as a challenge to PrEP use and pointed to frequent travel and unpredictable work schedules as obstacles towards adherence. A desire for a
weekly or monthly dosage, was often expressed. Darsha shared her concerns over daily adherence:

> If you make it compulsory that we have to take it every day, it is difficult. We forget so many things that we have to do every day. Similarly we may forget taking the tablet also. Many times we are away for days together, we cannot carry the tablets with us wherever we go. Then we may miss it. That’s why I say if there are tablets that we can take once a week, then it is fine…. (Darsha, in-depth interview)

The need for long-term adherence was also of concern. Participants, such as Bhanu, pointed to challenges with medication compliance as an example of the difficulties that people have in finishing their course of treatment, once symptoms subside. She warns that these difficulties with long-term compliance are also to be expected when medication is prescribed for prevention purposes, such as is the case with PrEP.

> For example, I was suffering from severe fever I went to hospital and the doctor gave me some antibiotics and told me to take it for 5 days, I got those tablets but by then there was no fever or body pain. So I thought I will not take it as I was relieved from fever and rather decided to store it for the fever next time. Even though I know antibiotics have to be taken as this has been given for fever but still when I was relieved from fever, I thought it is not necessary to take antibiotics as they create drowsiness. With such attitude I think I might miss out the tablets. (Bhanu, in-depth interview)

Notably, Aisha and other interview participants often referenced Ashodaya’s trusted legacy of past work in health programs, such as condom promotion, screening and treatment for STIs, and reproductive health services, as a key way of tackling these challenges.

> If we take time to talk to the community and make them understand that this is for their health and to keep them from getting HIV, then they will listen and
take the tablets. In the beginning we did not use condoms, then, when Ashodaya came they taught about STIs, condoms, and encouraged us to go to ICTC [Integrated Counselling and Testing Centre] for HIV testing. Community understood it and followed. Similar methods must be used to convince them to take PrEP tablets. (Aisha, in-depth interview)

Privacy also becomes a major concern with daily intake, as participants expressed concern over challenges they might face in trying to hide PrEP use over an indefinite period of time from family and partners. Two hundred (47%) participants surveyed named people seeing/questioning their PrEP use as a potential challenge. Participants anticipated facing questions from partners, family members, brokers, and clients. Some expected that partners would not allow women to take PrEP (39%). Some participants were concerned that others may suspect that they had HIV (38%), placing them at risk of violence, abandonment, and loss of income, as also explained by Darsha in an interview.

Some clients may be close to us and open our purse. They may see the tablets within and ask us what they are and why we are taking it. They may suspect we are infected and so are on medication. People at home also open our purse and if they see tablets they also may get suspicious. Once when I had some tablets for my gas problem, a client saw it and ran away thinking I have some disease. So carrying them with us is also a problem. (Darsha, in-depth interview)

Many women in focus groups recommended strategies for addressing questions about daily intake based on their involvement in other health interventions. For instance, participants emphasized the need to extend information sessions to broader networks, including brokers and boyfriends, a process that had been undertaken in past education campaigns.

There are possibilities that the brokers will not get clients for those women if they come to know that they are taking tablets. So we should first counsel the
brokers and madams about the benefit of these tablets, so that they will know why women are taking the tablets. (Focus group discussion #4, Mandya)

Participant: There may be problems especially at home because we have our family members around who would observe us. Same will be the case with boyfriends.

Interviewer: How do we address that?

Participant: We should conduct a meeting like we did initially about using condoms. We have to sensitize them and educate them about the tablets. We should conduct stakeholders meetings so that they will not create problems to women. (Focus group discussion #5, Mysore)

To address hesitations about new medications, Gina and Aarushi, as senior members of Ashodaya, suggested that the demonstration project should start by enrolling respected community leaders such as themselves in order to build interest and trust in PrEP.

We [community leaders] are the ones who are engaged in having sex with multiple partners. So we should be more conscious about our health and if we take these tablets we can ensure good health. First, we have to start using [PrEP] and once we know that it helps us, then we can spread that message to other community members who would in turn tell other women also. In this way all the community members will agree to take this tablet. (Gina, in-depth interview)

See what happens is, women are smart. If I tell them to start the tablets, they will say you take them first for three months and get tested. Show us the reports after three months and if we are convinced no infection is there, then we will also start on the tablets. So we [community leaders] need to demonstrate and show them that the tablets work. (Aarushi, in-depth interview)
Once women are selected for the demonstration project, it will be important that special consideration is paid to pairing participants with outreach workers (based on their individual preference) who will play a key role in promoting adherence. Pairings will be important, as most participants named specific individuals from whom they wanted to access PrEP. Surveyed participants interested in taking PrEP preferred to collect it from peer educators/community leaders (69%), the Ashodaya Clinic/Drop-In Centre (13%), delivered to their home (9%), or collected from a friend (8%). Confidentiality, privacy, and trust were the most important factors in choosing this person, as expressed in the focus group discussions.

We would like to take it from the women we know well like outreach workers, whom we meet regularly. We will like to take it from those whom we believe and trust. We can take from those women who work in Ashodaya. We trust all of them. (Focus group discussion #4, Mandya)

Other participants, such as Chandni, relayed a preference in accessing PrEP directly from Ashodaya’s doctor, as it was thought that the doctor would be able to respond to medical questions and side effects about treatment.

I would like to take it from the doctor because he will examine me properly and then give the tablet. I will come to Ashodaya, meet the doctor and take it. I trust the doctor in Ashodaya. If I go elsewhere they may ask me pointed questions on what is wrong and what I did and so on. If I tell them I am a sex worker, I will be discriminated against. Here, the doctor knows I am a sex worker and I can tell my problems like white discharge or stomachache, etc., and I will be treated well… (Chandni, in-depth interview)

Ashodaya, according to feasibility study participants, should also be mindful of supports for those traveling far distances to access PrEP. PrEP availability should be individualized based on each participant’s preferences. Some women prefer to take a month’s supply, as they are not
able to regularly come to the office, either because they live far away or because frequent visits may cause suspicion at home. Other women prefer to come daily or weekly, due to concerns that someone may find their tablets in the house and question them. Nearly half of participants (47%) surveyed wished to collect PrEP weekly, while about one-quarter preferred either daily or monthly pick-up. Darsha and Sakshi described the different preferences women may have in accessing PrEP:

I live close by and so I can frequently take it. I cannot take it in bulk and stock at home. So I can take small dosages and keep coming back for more…. In some houses the husbands do not know what work we are doing. So if they come across the tablets they may get suspicious and find out about the tablet and questions will be asked why we are taking it. We cannot keep it in the house of relatives either. So we can keep it in our close friend’s house. If not, then I have to come every day to the office and take it. I am willing to do so. (Darsha, in-depth interview)

I don’t have any problem in coming to the clinic. But in community members there are few of them who come from faraway places… It becomes difficult to follow up such people on their clinic visits and check-ups. Women who live in Mysore or nearby places would come to Mysore city for soliciting. It will not be a problem to those women but it will be tough for those who come from other places. We should think about them…. (Sakshi, in-depth interview)

As women are already working with outreach workers to access condoms and regular health screenings, PrEP pick-up can be negotiated to best meet the needs of individual participants based on existing routines.

Finally, participants raised questions about what will happen following the 16-month demonstration project period. Some have concerns about health consequences related to stopping PrEP after the trial. If PrEP were to remain free of cost (as it will be throughout the project), 86%
of surveyed participants would be willing to take PrEP as long as required. Although 80% of surveyed women indicated that they would be willing to pay for PrEP out of pocket after the demonstration project, it was also clear that adherence might falter if women were expected to assume the cost. Table 12 shows the amount women are willing to pay for PrEP after the demonstration project ends. Transition planning following the 16-month project period will be crucial if continued PrEP use is desired among the community.

<table>
<thead>
<tr>
<th>Willingness to pay in Indian rupees per day</th>
<th>n (N=424)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not willing to pay (0)</td>
<td>79</td>
<td>18.6</td>
</tr>
<tr>
<td>1-25 ($0.01-0.37 USD)</td>
<td>219</td>
<td>51.7</td>
</tr>
<tr>
<td>26-50 ($0.38-0.75 USD)</td>
<td>63</td>
<td>14.9</td>
</tr>
<tr>
<td>51-75 ($0.76-1.12 USD)</td>
<td>3</td>
<td>0.7</td>
</tr>
<tr>
<td>76-100 ($1.13-1.49 USD)</td>
<td>36</td>
<td>8.5</td>
</tr>
<tr>
<td>&gt; 100 ($1.50)</td>
<td>20</td>
<td>4.7</td>
</tr>
<tr>
<td>Refused</td>
<td>4</td>
<td>0.9</td>
</tr>
<tr>
<td>Total</td>
<td>424</td>
<td>100</td>
</tr>
</tbody>
</table>

**DISCUSSION**

Some early PrEP studies among sex workers in parts of Asia and Africa were cancelled before they started due to a lack of community consultation and concerns about study protocols (Cáceres et al., 2015; Haire, 2011; Ukpong and Peterson, 2009; Syvertsen, Bazzi, Scheibe, Adebajo, Strathdee, & Wechsberg, 2014). The feasibility study discussed in this manuscript was
an important step in assessing interest and acceptance of PrEP before moving forward with a large-scale demonstration project in Mysore and Mandya districts, in Karnataka state, southern India. The study itself served to open spaces in which the community could critically interrogate PrEP. It was an opportunity to obtain community consent for the upcoming project, and a means of gathering community insights regarding participant inclusion criteria and PrEP delivery mechanisms.

Participants in our study belonged to a well-established community organization, and their familiarity and involvement with the organization shaped their understanding of risk and prevention programs, as well as their interest in participating in the demonstration project. Participants expressed their responses related to participant selection in terms of public health discourse surrounding risk, prioritizing women who may experience more HIV risk in their occupational environments for enrolment into the study, such as younger sex workers and those who do not use condoms regularly. These findings align with previous research that uncovered how collectivization surrounding interventions shape community identities and collective security strategies (see for example, Lorway & Khan, 2014 in discussing the same context). Furthermore, qualitative research on PrEP use in Sub-Sahara Africa found that women placed a high level of importance on contributing to the well-being of their community (Amico et al., 2017). Our findings point to the importance of situating PrEP roll out within the trusted spaces of community-based organizations as a means of supporting PrEP uptake and adherence.

High interest in PrEP was linked to ongoing risks encountered by some sex workers that often create barriers to consistent condom use. PrEP offers an HIV prevention strategy that places control into the hands of its users, specifically sex workers themselves in our context.
These findings are similar to reviews of studies that have found that PrEP use increases a feeling of safety and empowerment during sex (Grant & Koester, 2016).

The data from the feasibility study shows the readiness, willingness, and strong desire for a PrEP demonstration project. Despite high levels of interest in PrEP, participants expressed concerns regarding the potential stigma associated with being recognized as someone who takes pills every day; privacy around the administration of PrEP; the possibility of being identified as being HIV positive; potential adverse effects of a new medication; and challenges with daily drug adherence. These barriers mirrored those discussed in other acceptability studies in Kenya and Nairobi (Mack, Odhiambo, Wong, Agot, 2014; Van der Elst et al., 2013). Within a clinical trial setting, men who have sex with men and female sex workers identified counselling as an important component to supporting adherence (Van der Elst et al., 2013). Researchers noted, however, that adherence was likely to suffer without the extra support systems present within a study setting. In a separate acceptability study, also in Kenya, community consultation with district stakeholders from the Ministry of Health, faith- and community-based organizations, health facilities, and community groups identified the importance of trained adherence facilitators to address specific population needs when rolling out PrEP to priority populations, including sex workers (Mack et al., 2014). The findings from these studies point to the need for targeted PrEP interventions that are tailored to best meet community needs. In our study setting, Ashodaya’s extensive experience in rolling out community-based health interventions will enable tailor-made approaches to PrEP delivery and adherence support, based on each individual participant’s needs and preferences. These adherence supports are especially important in the context of well-documented challenges to long-term medication adherence (Amico et al., 2014; Mack et al., 2014). Wider community consultations with other networks that govern sex work,
such as boyfriends and brokers, will also be undertaken to address concerns over the stigma and discrimination that women may face while on PrEP.

There are several potential limitations to our study. As survey questions relied on self-reporting, it is possible that findings are subject to social desirability bias (Catania, Gibson, Chitwood, & Coates, 1990). Furthermore, as focus group discussions, in-depth interviews, and surveys were conducted by community leaders, it is also possible that participants were more likely to feel pressure to speak favourably about PrEP. However, research has shown that the involvement of community researchers can facilitate the disclosure of sensitive information and improve the quality of data (Coupland et al., 2005; Schnarch, 2004). As participants expressed both interest and concerns about PrEP, it is likely that they felt comfortable disclosing their views during interview. Finally, as this research occurred within the context of a well-established sex worker collective, the findings of this study may not be generalizable to other settings where sex work occurs.

**Conclusion**

As this paper helps to illustrate, community-organizations working with sex workers may be best-positioned to implement demonstration projects due to their capacity, connections, and trust to reach those members who stand to benefit the most from access to PrEP. In our unique study setting, Ashodaya was able to draw on its past experience in HIV prevention and treatment programs to offer effective strategies to address community concerns surrounding uptake and adherence, including reaching out to broader social networks. It is imperative that if PrEP is to be introduced to sex worker communities, it should only be done after adequate capacity building,
awareness raising, and demand creation. Situating PrEP delivery within the trusted spaces of community-based organizations should be considered as a means of supporting PrEP roll out.
Preface to Chapter 5

This chapter explores the community-driven processes, which were informed by the suggestions from the feasibility study participants as discussed in the previous chapter, that the study team employed during the demonstration project that contributed to its success. These community-led strategies included: 1) the participation of community leaders as the first to take PrEP, who shared their experiences through testimonials to their peers, as well as the endorsement of PrEP among community leaders living with HIV, to avoid social divisions around HIV status; and 2) ongoing community-level support from outreach workers that went beyond simply administering PrEP to address the various needs of the community. These community-led strategies were developed to minimize tensions and challenges in the demonstration project. I was responsible for the study design, data collection, analysis, and writing of the manuscript. Syed Hafeez Ur Rahman assisted with all aspects of the qualitative data collection. Theoretical concepts were developed through discussions with Dr. Sushena Reza-Paul and Dr. Robert Lorway. These findings have been presented in part at the 2018 Canadian Anthropology Society (CASCA) Annual Meeting, 2018 Association for the Social Sciences and Humanities in HIV (ASSHH) Conference, and 2018 Canadian Association of HIV Research (CAHR) Conference.

Conference citations:


Chapter 5. Beyond Remedicalization: A Community-led PrEP Demonstration Project among Sex Workers in India

BACKGROUND

In recent years, there has been what some medical anthropologists have termed a “remedicalization” of the HIV epidemic, with remedicalization ushering in a shift away from HIV activism and “a return to the early 1980s view of the epidemic as a medical problem best addressed by purely technical, biomedical solutions whose management should be left to biomedical professionals and scientists” (Nguyen, O’Malley, Pirkle, 2011, p. 291). Playing into this remedicalization process are attempts to scale up PrEP, a prevention strategy that administers antiretroviral medications to reduce HIV infection to individuals who do not have HIV (World Health Organization, 2012). These individuals, considered to be “at-risk”, take a daily pill to prevent acquiring the virus. The clinical efficacy of PrEP has been well documented through numerous randomized control trials among a number of populations (see for example, Okwundu et al., 2012). In 2015, the World Health Organization called for PrEP to be offered to individuals at “substantial risk” of HIV infection as an option in comprehensive HIV prevention services (World Health Organization, 2015).

According to global health policy, we have now entered a period of exploring how people actually use PrEP in their everyday lives. To better understand these questions of effectiveness, the Bill & Melinda Gates Foundation have funded a number of PrEP demonstration projects with
both serodiscordant couples and sex workers (see AVACb for a full list of projects).28

Demonstration projects are often described as providing “real life” evidence, as a bridge between the stringent guidelines of clinical trials and full availability of a drug (see for example, World Health Organization, 2013). One could argue, however, that demonstration projects, where participants are enrolled in a study, provided drugs free of cost, and closely monitored through ongoing clinical visits, survey participation, and blood-level drug monitoring still more closely resemble clinical trials, rather than “real world” conditions. At the same time, these demonstration projects provide important opportunities for frontline health workers and local program planners to better understand how the communities they regularly provide health services to actually accept or refuse new prevention technologies.

In reflecting on the third decade of HIV, Mykhalovskliy and Rosengarten (2009) call for a “revival of the sort of scholarly innovation that characterized the early years of the HIV epidemic” where multidisciplinary theoretical approaches “emphasized the ‘social’ for understanding the significance of AIDS and opened up new avenues for critiquing and reimagining scientific, cultural and social responses to infectious disease” (p. 187). Similarly, sociologist Barry Adam (2011), states that “all biomedical prevention technologies are also social interventions” (p. 5); for they must account for, respond to, and navigate an array of social and political realities. This paradigm is perhaps best exemplified in the case study of one of the Gates-funded demonstration project sites that took up residence in Ashodaya Samithi, a sex

28 I have also been involved in a multi-sited paper looking at the community processes employed across a group of seven sites funded by the Gates Foundation. These sites include projects with serodiscordant couples in Kenya, Uganda, and Nigeria and with sex workers in India, South Africa, Benin, Senegal, Nairobi, and Kenya.
worker-led organization based in the South Indian city of Mysore. The Gates Foundation chose Ashodaya as one of only two sites in India, the other being Durbar Mahila Samanwaya Committee (DMSC) in Kolkata, as both are home to organizations that are internationally renowned sex worker collectives, known for their leadership in sex worker-led mobilization and innovations in community-based sexual health interventions that have led to high rates of condom use, reductions in HIV and STIs, and a strong sense of community ties (see for example, Jana et al., 2004; Reza-Paul et al., 2008).

Moving beyond the distinction often assumed between biomedical and social interventions, I refer to my ethnographic findings of the Ashodaya PrEP Demonstration Project to explore the role of community participation within the context of biomedical trials. The PrEP project is one chapter in a broader history of community mobilization, activism, research, and support. Like Catherine Campbell (2003), whose ethnographic work sought to understand how the Summertown Project failed to effectively address the HIV epidemic affecting a small mining town in South Africa, I too am concerned with the social processes that lead to program success (p. 9). Drawing on Ashodaya’s history of collectivization around sexual health—a history of community action that has given rise to forms of health citizenship and new spaces of belonging for sex workers, this paper highlight’s Ashodaya’s community-led approaches to anticipating and addressing challenges in a PrEP demonstration project.
SITE SETTING AND METHODS

Ashodaya Samithi

Beginning in 2004, the Gates Foundation funded Ashodaya Samithi as the first organization supported under their Avahan initiative, which strived to address the HIV epidemic in six high prevalence states across India (Ramakrishnan, & Alexander, 2006; Rao, 2010). Ashodaya began through the attempts of public health researchers to understand the local sex work context in Mysore, with an initial goal of setting up clinical services to test and treat STIs and HIV. During visits to Mysore by the researchers, it was clear that while many sex workers operated in the city, little sense of community existed. Despite initial resistance from NGOs working to rehabilitate sex workers and rumours from the community that the researchers were in the business of selling organs, the research team worked to build trust, initially among male sex workers who then helped provide a link to the women with whom they shared networks.

Priorities shifted from a biomedical focus on testing and treating STIs, towards first addressing the needs of sex workers. A drop-in centre was opened in a location chosen as convenient by sex workers that provided them with a safe space to spend time between clients. This space provided an informal place for the women to gather, leading them to share their experiences with each other, thus beginning to cultivate bonds of solidarity. These relationships soon spilled out to the street, with the women working more collaboratively to ensure their physical and health protection. Sex workers also shared their experiences of violence at the hands of police, clients, and boyfriends with the public health staff, and told of avoiding health services due to fears of discrimination. The team began to address these immediate needs of sex workers, by speaking with police to curb harassment and arrests, responding to client and partner violence, and providing accompaniment to health care visits (see Reza-Paul et al., 2012). The drop-in centre
provided a space for the community to both collectivize and problem solve. Uniquely, men, women, and transgender sex workers all came together to form the Ashodaya community. Within the drop-in centre site, Ashodaya opened a community-based clinic in the first year of the organization, with the community playing a key role in designing the clinic and selecting health care providers (Dixon et al., 2012). By the end of that year, according to the team, almost 75% of the estimated sex worker population had begun to access services at the clinic, creating new norms around community-based health care.

By 2006, Ashodaya was officially registered as a community-based organization. Sex work leaders established a board of governance comprised of elected representatives from the sex worker community. Based on a philosophy of building community capacity, sex workers were paired with project managers to learn their roles, with the expectation of taking over the operations of the organization. Sex workers played key roles in all organization activities, which over the years were expanded to include outreach and advocacy, sexual and reproductive health services, cooperative banking, addressing sexual and gender-based violence, and community-based research. Since its start, sex workers have been at the centre of all of Ashodaya’s operational activities. Beginning in 2010, Avahan began transferring funding responsibility over to the government (Rao, 2010), which has led to significant funding delays and a scale back in activities. Within this context of funding cuts, the PrEP demonstration project unfolded.

**STUDY DESIGN AND ANALYSIS**

The findings in this paper are based on an ethnography (Geertz, 1998; Spradley, 1980) of the PrEP Demonstration Project, with fieldwork taking place between January 2015 and April
2018. As part of the research, I invited project staff and participants to take part in in-depth interviews. I conducted interviews with project staff, which includes sex work leaders, community outreach workers, and the technical team, towards the start of the project in September/October 2016 and closer to the project end in November/December 2017. I conducted the staff interviews in English, or in Kannada with simultaneous translation done by one of the program officers who played a significant role in the qualitative study. Trained community researchers were responsible for conducting the participant interviews in Kannada. Participants were invited to participate in three rounds of in-depth interviews in September/October 2016, April 2017, and November/December 2017. Over the duration of the study, I conducted 37 staff interviews; community researchers conducted 108 participant interviews.

Interviewers obtained written consent prior to each interview and all interviews were audio recorded. Project staff interviews were sent to a transcription company. A transcriptionist, who had a long history of working with the organization and knows the local sex work context, translated and transcribed the participant interviews directly into English. I coded all interviews for emergent themes and thematic analysis (Braun and Clarke 2006) using NVivo 11 software. While coding, I paid special attention to themes related to the community-based processes employed in the rolling out of the demonstration project.

The University of Manitoba Research Ethics Board and the Institutional Ethics Committee (IEC) at Durbar Mahila Samanwaya Committee (DMSC) granted ethics approval for the larger PrEP demonstration project. I obtained secondary ethics approval through the University of Manitoba Research Ethics Board for the work presented in this thesis.
LESSONS FROM A SEX WORKER-DRIVEN PrEP DEMONSTRATION PROJECT

The PrEP Demonstration Project began in March 2016 and proved immensely successful by public health indicators. The study team enrolled 647 women into the project. Community outreach workers provided ongoing support for PrEP, which the women received free of cost for 16-months. The clinic team screened participants quarterly for any health complications. The study protocol is described elsewhere (see Chapter 3 of this thesis). By project end, 640 women completed their follow up and high self-reported adherence was confirmed by tenofovir blood-level testing. These findings differ significantly, particularly in terms of retention, from other demonstration project sites among sex workers (see Cowan et al., 2018; Eakle et al., 2017) and beg the question as to what processes led to these high retention rates? To understand these findings, I point to the community-led strategies and careful roll out of the project. Ashodaya’s experience in community-based outreach, research, and support has formed a wealth of knowledge from which to anticipate challenges and formulate strategies to confront problems in the project. These community-led strategies included: 1) the participation of community leaders as the first to take PrEP, who shared their experiences through testimonials to their peers, as well as the endorsement of PrEP among community leaders living with HIV, to avoid social divisions around HIV status; and 2) ongoing community-level support from outreach workers that went beyond simply administering PrEP to address the various needs of the community, as described in the following sections.
Going Slow: The Role of Testimonials in Obtaining Community Consent

The demonstration project itself posed a new challenge for the team—made up of both community and non-community staff, as the first biomedical trial undertaken by the organization. Although not a clinical trial per se, the demonstration project shared many of the same characteristics, in terms of recruitment targets, continued medical screenings, and extensive adherence monitoring. Despite the scope of the project, Ashodaya was able to draw on their expertise in community-based health care delivery, support, and research, particularly drawing on their experience in condom distribution and other HIV and STI prevention interventions in order to minimize potential risks and challenges when rolling out the project.

As PrEP was a completely new intervention, Ashodaya had a deliberately slow recruitment plan, first enrolling senior community leaders into the project, who could then share their experiences with their networks. Over the years, community mobilization programs have, in the words of Lorway (2016), “produce specific dimensions of sociality—subjectivities; social connections, affinities and tensions; organizational allegiances and oppositions; and cultural politics” (p. 91). It is within this context of shared socialities that testimonials become highly influential means of recruitment and retention. Nguyen et al., (2007) have linked “exceptional” treatment adherence in Cote d’Ivoire, West Africa to HIV programs that mediate treatment access through various self-help confessional groups, where HIV self-disclosures are exchanged for access to ART. Boellstorff (2009) has written about the power of testimony in his ethnography of an HIV organization working with gay and transgender men in Indonesia. According to Boellstorff, testimony, unlike confessionals, “emphasize form over content”, and call to the dynamics of belonging (p. 351). Whereas the confessionals that Nguyen and colleagues discuss are much more personal, testimony, in Boellstorff’s words, aims “to compel
listeners to constitute themselves as persons “at risk” and thus as persons who would take action to prevent becoming infected with HIV” (p. 359). This is mirrored in the testimonial examples at Ashodaya, where testimony draws on experiences of shared risk and normalizes the pill-taking process through the role-modeling done by trusted and respected community leaders. Saumya, a community outreach worker who has been with the organization since its start, describes the testimonial process:

So the community is already ready for this because we had done a lot of group works and other thing. And simultaneously when this PrEP enrolment started, the screening and other thing, we have not done with the community first. We identified leaders of the community. They first took the tablets and they went through the testing and they started taking [PrEP] and they had given the testimonial by saying that, “Okay, first we went through this. This is useful for us. See nothing has happened to us.” They [the community] started watching them and based on that community has come so that we have not faced much difficulties in mobilizing them. (Saumya, community outreach worker, October 2016)

As described in the above quote, enrolment was deliberately slow and began with senior community leaders as the first to take PrEP, so that other community members could take a “wait-and-see” approach to deciding whether to be a part of the study. Deepa, a participant enrolled in the study, explains how she watched community leaders take PrEP, before deciding to take it herself.

They said this tablet is good for you and will keep you healthy. Then I asked them to take it and show it to me that they are also taking it. In front of me they took the tablet and so I also started taking the tablet. Then they followed up with me to see if I am taking it regularly. I was taking it regularly. (Deepa, participant, November 2017)
Starting with trusted community leaders served to build trust and confidence in the process.

Furthermore, as more women began to take PrEP, they too started to provide testimonials to their friend networks. Mishka, another participant, explains how she decided to take PrEP herself, in order to be able to encourage other women to also take it.

I did not know about PrEP, then they told me about it. Then I thought if I take it then I can tell others also. If I take it and I am fine then I can tell other women also to take it. I can tell them to take it and they will not get any diseases, they will not get HIV, STIs or any such thing. So I am taking it and so are the other women….

They did all tests on me and then told me about PrEP. I decided to take it because unless I take it I cannot tell other women. So I started taking it. Initially when I started taking it I thought why should I take it daily but now I realize it is good for me and so am taking it. (Mishka, participant, December 2017)

Ashodaya was sensitive about creating tensions among members left out of the demonstration project. Research projects by their very nature create groups of exclusion (see for example, Montgomery & Pool, 2017). As an organization led by women, men, the transgender community, and people living with HIV, the demonstration project left out significant portions of Ashodaya’s membership by only involving sex workers who were assigned female at birth. During the community awareness and feasibility phase that launched the demonstration project, I witnessed push back by the transgender community about their exclusion from the study. This concern was echoed to me by some of the staff, who questioned whether they would be causing feelings of rejection and potentially increasing HIV-related risks among non-eligible community members by not providing them with PrEP. In order to maintain unity, Jayesh, a member of the technical team, and Prisha, a long-term community leader living with HIV, explain how leaders
living with HIV also offered testimonials, linking PrEP to the benefits that they experience from antiretroviral therapy and offering their endorsement of the project.

And what we have done is for recruiting from beginning, during even the feasibility also, we used the positive sex workers [sex workers living with HIV] as the major testimonial. They are the good will ambassadors. They are the ones who had started campaigning for PrEP by giving their own testimonial. What opportunity they missed, what is coming to the other sex workers that, “You are getting an opportunity today. Because of that you can safeguard yourself. If we might have got this opportunity, we will also not get into this infection like that.” That is big this one actually. We had used not only for… I mean they had participated in this whole process and not only like just observers, they had become like proactive. They started giving their own testimonial and with regard to the adherence and everything, many of the ART person, those who are on ART continuing, they started giving their testimonial. “Okay how much it is important and how to manage this adherence and everything, daily taking a tablet and other things like that.”… (Jayesh, project staff, September 2016)

I have trust that okay all are continuing and all had a tablet every day without failing. I will give my own testimonial to many of them by saying that, “Okay you guys are lucky ones because you are getting at least PrEP tablet and you are able to prevent yourself from getting infected but we unfortunately got infection. Now as you can see my life. We had got infected. If we might have got the PrEP we also [might have been] safe.” So like that also I will mobilize many of them and motivate others… (Prisha, community outreach worker, October 2016)

The reason these testimonials proved so effective is due to the longstanding relationships and trust among community leaders and members of the organization. Communal experiences of loss of friends and fellow sex workers to AIDS produced a shared sociality where members of the organization came together to support and deliver PrEP, regardless of their HIV status or desire to individually take PrEP. A shared sense of citizenship and an understanding of risk pointed to
the benefits of PrEP as an option for those interested. An early endorsement from community-members living with HIV served to mediate some of the tensions that these exclusions could have caused.

That is not to say that the study did not cause some feelings of being left out among those not taking PrEP. Saanvi, a senior outreach worker, shares pushback she received from some Ashodaya members who did not get PrEP:

Those who are a little bit elderly age persons they are saying that, “This is not right that you are giving only [to some] people. You have to give this tablet to all others also, whoever are present sex workers who are doing sex work. We are also entertaining the clients. We are also under risk. We may also fall under infections and other things. Why you are not providing the tablet to all other sex workers also? Why are you limited to this particular one?” These kinds of questions are coming because [Ashodaya] until now has served for everybody. It has not served for a particular community or particular sect or that, so many of them are demanding, “You know how important PrEP is but you are not giving it for everybody after knowing this?” These kinds of questions are also coming. (Saanvi, community outreach worker, December 2017)

In such situations, the project team shared that they would emphasize the research nature of the intervention, explaining that they could only recruit so many people into the demonstration project, but that hopefully the study would lead to PrEP being available in the future. Although the demonstration project by its very nature creates divides within a close-knit community, as expressed in the above quote, overall Ashodaya, through its intimate knowledge of its membership, was able to mitigate this risk through testimonials and the endorsement of the project by senior community leaders, as well as drawing on the community’s research knowledge to explain enrolment restrictions.
Revitalization: Reconnecting to Community

As community leaders and other project team members expected that a biomedical intervention, such as PrEP, could create frictions between members by differentiating between those taking and not taking the drug, Ashodaya also used the study as an opportunity for its members to come together and reconnect to the organization. The team made strategic efforts to ensure that all members, regardless of PrEP-taking status, were linked to Ashodaya’s array of services. Ashodaya handled this by re-emphasizing the services and support programs that they offer to all sex workers, regardless of PrEP enrolment. In other words, Ashodaya approached PrEP as one of a number of services that people could take advantage of through their organization.\(^2^9\) Furthermore, as the project protocol called for intense follow up for the purpose of distributing and monitoring PrEP over a 16-month period, the demonstration project provided an opportunity to reconnect to the community. Ishaan, a senior community leader, shares how calling participants to check on adherence led to conversations beyond PrEP:

> When I came back actually I started thinking about my community. The community is very much interested to take this tablet. After that when we came back and we started the process, first we thought that one month trial we will do with those who are taking it. We will do the very close watch with them for a month, like every three days we’ll do personally visiting and every day we are calling and getting information, collecting information and details from them like that. Then I realized that I started calling them every day just to

\(^2^9\) This concept is quite similar to what Rhodes, Egede, Grenfell, Paparini, and Duff (2018) have termed “care beyond the virus” when discussing HIV care, where “care of the virus” is transformed into “care beyond the virus”, “constituting care as more-than biomedical” and responding to “vital concerns” beyond simply treating HIV (p.18). Rhodes et al.’s work is further described in the next chapter.
know, “You started taking the tablet. How are you feeling? What is going on?” Like that. So definitely when we’ll start a conversation, we will not only talk about PrEP but a lot of things we will discuss about their personal life and other things also. So what happened is slowly, slowly this conversation after second week or third week, I started realizing that they’re waiting for my call.... (Ishaan, community leader, December 2017)

In order to understand the full scope of the project, it is necessary to situate PrEP within the intervention life of the organization. The demonstration project itself went far beyond a clinical intervention. The project came at a time of stretched funding, when government transfers to support community-based programs had been facing significant delays over the past years and Ashodaya had been forced by budget cuts to pare down their previous outreach activities. The demonstration project provided an influx of funding and purpose to the organization. Moving beyond simply delivering a drug, Ashodaya was able to use the project as a catalyst to reconnect to its members and provide services beyond PrEP. While adherence support and health screenings required community leaders and outreach workers to maintain frequent contact with their peer networks, conversations extended beyond PrEP and led to opportunities to reconnect its memberships to social, health, and financial support programs available through Ashodaya. Ramesh, a member of the technical team and Zara, a long-term outreach worker, both describe how PrEP provided community with an opportunity to connect to other services and other members.

Because of new community members. Mobilizers [outreach workers] are old members but some community members are new community members. They are also getting information about [Ashodaya]. Once they came not only to get PrEP, they came and they can get the other services also. They link with the cooperative [bank], they link with some social and treatment programs, they link with [Ashodaya] programs… (Ramesh, project staff, September 2016)
One more thing that happened is whenever they used to come they used to meet a lot of new people and others here. So they started developing the friendship with them and it has become something like a close-knit…. Even we felt happy that no one needed reminding, many of them, only just a phone call will make them come here and appear… (Zara, community outreach worker, November 2017)

In the excerpt below, Jayesh, goes on to further describe how Ashodaya, through the PrEP project, underwent a revitalization with a renewed sense of purpose.

So then what happened is I mean the stratification is not only happened on a program management level but it has gone up to the ground level and like we lost that net. So that somehow actually PrEP has come, since we went to the field, we realized one thing that, “Okay somewhere the spirit of coming together it is not PrEP or it is not DIFFER [a sexual and reproductive health study] or it is not something like a project. The major coming back is [Ashodaya]. We came mainly because of sex workers, being a sex worker, a good life and getting a quality of this one. Because of that we came here, not because of a project or because of some TI [targeted intervention] or something like that. That we lost.” So now once we went back to the field, we are able to break that one. Again peoples are coming back, not for the sake of PrEP actually. Somewhere actually this spirit of [Ashodaya] is coming. Slowly, slowly it is getting connected. (Jayesh, project staff, September 2016)

PrEP, in this case, was the catalyst needed to push community and leaders back out into the field at a time when funding had cut program activities. The demonstration project created an excitement and a new hope for the organization, with a flurry of new activity. The project office was now bustling with daily activity as previously disengaged members came in for their PrEP screening and follow up. As the months progressed, outreach workers proudly shared that they no longer needed to remind their networks about picking up pills or follow up appointments, with ownership of the study gradually passing down to the participants. Saanvi explains how the
follow up process brought her network closer together, leading to much stronger ties between the community and Ashodaya:

Actually the community has come very close to the organization because of this project. Until now there is no other way of getting prevented from HIV. Only one device is there that is called condom, but there is no medicine…. This particular tablet has given that this is a shield between the virus and the community, so many of them think that this is a good opportunity for many of them who are in a risk. Along with that during this time actually our attention level, not “our,” [our] means everybody, whoever is working in our organization also started showing extra concern towards the community members and we are always ready for serving them at any moment of time. We are addressing all their needs and other things. This is not happening in the beginning, so because of that also community started thinking that, “Whatever we are expecting and whatever our requirements and our issues we are getting all kind of services from [Ashodaya].” Because this procedure is so that they need to visit frequently and it has developed as a habit that whenever they feel like anything, they will walk directly to the office and they started consulting us even when they have any doubts or anything like that. Not necessary that they need to come for a particular health reason…. So this has definitely given us good bondage between the community and the organization because of this project. (Saanvi, community outreach worker, December 2017)

**The Marriage Between Community and Science**

The Ashodaya PrEP Demonstration Project holds important insights for moving biomedical research outside of clinical and into community-led spaces, demonstrating that communities can be supported by researchers and clinicians to play vital roles in collaboratively leading biomedical interventions. PrEP here builds on a legacy of AIDS activism where, in the words of Stephen Epstein (1996), “lay experts” conducted their own community-based trials in the early days of HIV treatment and learned new languages to be able to advocate for their right to access innovative therapies. These lay experts shaped the design and roll out of clinical trials,
and we see how this tradition continues on in the case of the Ashodaya project. In the words of Vijay, a member of the technical team, blending community engagement and science is what leads to project success.

Yeah definitely. When these two are coming together then definitely it’s going to be a success because if you go only with the community agenda and not following the science and not following the methodology, not following this one then there will be no success. And if you go only with the scientific research and not keeping the community interest and community together then there will be no results out of that. So we need to marry both and we need to keep them together always and we have to be very cautious that should not leave in between and always go together then we can see the success of that. (Vijay, project staff, October 2016)

Although community empowerment and mobilization have been recognized as leading approaches in HIV prevention work among sex workers (see for example, UNAIDS, 2012; Vijayakumar, 2018), community knowledge and wisdom still continues to be left out of more biomedically-oriented research. Ashodaya provides a novel example of a community-led PrEP intervention, where sex workers were able to guide and shape the program. Ishaan and Saanvi describe the pride that they felt in the active roles they played in rolling out a community-led PrEP project.

So I feel very proud because I gained a lot of knowledge and gained a lot of skills about this one. I know the loop and corners about this particular project. I can say with my gut feeling what is the screening processes and what is happening in screening and why it is essential and how the tablet needs to be preserved and how they need to distribute it and how they need to keep a track record and other things. I know about all that. I have become a master trainer now. I can train on PrEP about this here. In that way I feel very much proud. One more thing that makes me proud is I’m HIV positive and during this project and particularly from last one year this one, I have contributed many of them to get prevented from HIV. That I feel like somewhere I’m being HIV
positive, I feel very proud that through me this particular work has happened. (Ishaan, community leader, December 2017)

As I’m working here for the last 13 years, so I used to attend a lot of district level meetings and other NGO meetings…. When onwards PrEP has started, I am very proud that no other person has any information, any clue about PrEP and I’m talking about PrEP that, “Okay this is a tablet, this is what is going to be happening and we are giving it for so many people and we had done this, this time. We had done so many follow ups like that.” By presenting these things I feel really proud in front of other organizations because they don’t know damn about this particular PrEP and I am the one who is talking about this. So I felt really very proud. (Saanvi, community outreach worker, December 2017)

In both quotes, Ishaan and Saanvi point particularly to their intimate knowledge of the project, describing themselves as PrEP experts, demonstrating that “lay experts” can continue to play important rolls in new waves of biomedical HIV prevention.

**Discussion**

In this era of remedicalization, the Ashodaya PrEP Demonstration Project has provided a novel model of a community-led biomedical intervention, that is not unlike Epstein’s (1996) depiction of gay activists leading clinical trials in the United States during the early years of the HIV epidemic. However, while Epstein depicts the scientific entanglements of activism and science of mostly white gay men who possessed considerable social, intellectual, and economic capital and political influence; Ashodaya’s leadership during the PrEP project stands apart, impressively, as a community-driven force in the global South—a force driven by a working class community, from a much lower social economic status, and having much less direct access to political power and prestige. Ashodaya’s expertise demonstrated in the PrEP project came
from fourteen years of leading structural HIV interventions, which formed the foundation of knowledge and experience from which they were able to anticipate challenges and formulate strategies to confront problems in the project before they arose.

The project started with a deliberately slow roll out, to build acceptance and trust in the project. Community leaders, as the first to take PrEP, used testimonials as an important tool to constitute a shared experience of risk and motivate others to take PrEP. This testimonial sharing spread through the community as more members began taking the prophylaxis and shared their experiences. Participants professed an interest in PrEP due to their communal experiences of loss of friends and fellow sex workers to AIDS (Reza-Paul et al., 2016). Their shared sociality created a shared experience of risk and trauma.

Attention was also paid to whether the project would lead to the creation of excluded groups. Clinical trials, and by extension demonstration projects, by definition, create divisions by actively differentiating between members who are eligible for inclusion in the study from those who are not (Biehl, 2004; Epstein 1997; Montgomery & Pool, 2017). In the Ashodaya PrEP Demonstration Project, only female sex workers were eligible to participate, despite the trial occurring in partnership with an organization comprised of female, male, and transgender sex workers. The communities of and around clinical trials are reshaped by the power dynamics of inclusion and exclusion and subjected to multiple forms of sociality and citizenship (Montgomery & Pool, 2017). Montgomery and Pool (2017) illustrate this in their case study of an HIV prevention microbicide trial in Zambia among women. Excluding men from the trial threatened power dynamics, with women holding all of the information on the trial and positioned as “agential scientific citizens”, which subsequently lead to rumours from men about Satanism and mistrust, and at times leading men to act violently and controllingly (Montgomery
& Pool, 2017, p. 56-57). Here we see the tensions caused by top-down funding decisions that target specific groups, rather than take into consideration the complex relationships of communities on the ground who share spaces and solidarities. Ashodaya, in recognizing these relationships beyond “key population” demarcations, was able to confront these tensions due to their longstanding relationships with the communities that have assembled to make up Ashodaya. Through their intimate knowledge of community dynamics, Ashodaya pre-emptively employed strategies, such as testimonials of peer leaders and members living with HIV, to minimize tensions that could have disrupted community solidarity throughout the project. While dissidence was expressed by the transgender community members left out of the study protocol, an understanding of research and scientific rationalities among sex workers, what Lorway (2019) has termed “evidentiary politics”, ultimately led to support for the project to move on, with the expectation that project “success” would lead to PrEP availability for all of Ashodaya’s members.

At a time when public funding for HIV prevention was in decline, the effect of which began to erode community solidarity networks, Ashodaya seized upon the resources furnished by the PrEP Demonstration Project to build a renewed position of relevance in the sex worker community. Along with delivering PrEP, Ashodaya outreach workers re-engaged with their networks to provide other services and supports. In this way, the demonstration project revitalized a sense of collective belonging among community members. In Campbell’s (2003) ethnography of the Summertown Project, she points to the challenge of key global health stakeholders and decision makers’ greater interest in biomedical approaches to STI control over community mobilization. She concludes that:
There was too little acknowledgement of the need to supplement biomedical
STI control and traditional health education with efforts to create community
and social contexts which would enable and support increased condom use,
and increased use of potentially vital STI clinics and services (p.189).

By contrast, Ashodaya, in their project, managed to blend funders’ interest in biomedical
HIV prevention with community mobilization strategies that go beyond remedicalization to
consider the complexity of community politics (further discussed in the next chapter), in order to
provide services in a manner that best meets the needs of their community. While, as Campbell
puts it, donor funding is increasingly being conceptualized in terms of biomedical approaches,
rather than social ones, with no clear funding dedicated to training, organizational infrastructure,
and community building, instead earmarked for the provision of tests and drugs, Ashodaya has
capitalized on these resources to reach their community members. Furthermore, this community-
led approach to PrEP roll out demonstrates that communities themselves can play lead roles in
delivering clinical interventions and should be key partners in planning, implementing, and
monitoring when considering new prevention and treatment technologies.
Preface to Chapter 6

This final chapter attempts to “make sense” of the findings presented in previous chapters. Here I discuss how the search for success was driven by care for the community and for the organization as a whole. To understand this care, the success of the project must be understood within the contextual terms of the life history of Ashodaya. The care enacted throughout the project is tied not only to the community of sex workers Ashodaya seeks to serve, but to the careful production of evidence that demonstrates accountability to funders, which is further tied to caring for the very survival and future of the organization. I took the lead in the analysis and writing of the first draft of the manuscript, with theoretical and critical input from Dr. Robert Lorway. This manuscript is part of a special journal issue exploring “Intervention Life” intended for Medical Anthropology Quarterly and will also include papers by Elsabe du Plessis (University of Manitoba), Claudyne Chevrier (University of Manitoba), Danya Fast (University of British Columbia), Emma Varley (University of Brandon), Eileen Moyer (University of Amsterdam), and Robert Lorway (University of Manitoba) (Editors Lorway & Fast). This work was partially developed during two special workshops held in Winnipeg (in January and September 2018).

Suggested citation:

Chapter 6. In Search of Success: The Politics of Care and Responsibility in a PrEP Demonstration Project among Sex Workers in India

The present is governed, at almost every scale, as if the future is what matters most. Anticipatory modes enable the production of possible futures that are lived and felt as inevitable in the present, rendering hope and fear as important political vectors. (Adams, Murphy, & Clarke, 2009, p. 248).

Notions of “success” (and failure) are a recurring theme in global health, often bound by a priori project “timelines”, “indicators”, and “outputs” circumscribed by funders. In this paper, I attempt to unravel the complexities surrounding the redeployment of the notion of success by analyzing its life history during what became a highly celebrated global public health intervention. Departing from reigning evidentiary interpretations of success, I illustrate, instead, how the notion of success has a lively existence in the social unfolding of a PrEP demonstration project led by a renowned sex worker organization named Ashodaya Samithi, based in Mysore, South India. More than yielding extraordinary health outcomes, I argue, the futurity of success, as a driving social force, bears significant weight throughout the project. Furthermore, I contend that the momentum of the project roll out, as driven by the pursuit of success, not only constitutes new forms of sociality itself, but the very notions of temporality it infuses in the life world of the project draws particular attention to the multiple overlapping and, at times, contradictory roles of care played by Ashodaya sex workers themselves.
Rather than emphasize the more standardized indicators of “retention” and “adherence” employed to evaluate success in PrEP demonstration projects globally, I argue that the project must be analyzed within the more intimate sphere of care, affected by the past, future, and of becoming, to borrow notions from the French philosopher and critical literary theorist Gilles Deleuze (Biehl & Locke, 2010). In other words, instead of emphasizing adherence—the fulfillment of a public health imperative—I demonstrate how “success” is imminent within a highly-charged milieu of “responsibilization” and in a continual state of becoming. As Biehl and Locke (2017) write, people inhabit “multiple temporalities” (p. 6). Becoming is about transformation, and is occupied by the past, present, and a “possible or impossible future” (p. 32). Drawing upon anthropological discussions of care, this paper therefore looks at how the PrEP demonstration project was made a success, and how success hinged on highly affecting notions of temporality.

**Re-temporalizing Success**

Reconstructing a genealogy of the notion of “success” in global health, public health historian Anne-Emanuelle Birn (2009) claims “meanings of success are neither uniform over time nor steadily progressing but, rather, are framed within the political, economic, social and medical contexts of particular eras” (p. 51). In her historical retelling, she details how global health interventions have evolved from a focus in 1851 on minimizing the spread of epidemics across country and colony lines to the reign of the WHO’s “Health for All” approach beginning in 1946 to the current era of private sector investments that prioritize business-style accountability over broader assessments of health and well-being. She argues that successes (or failures) are not solely bound by project timelines but exist across longer periods, bleeding from
one era into the next. However, project success within contemporary global health arenas tend to be confined to goals that are based on “anticipated success” within narrowly-set time limits (Birn, 2009, p. 51). In other words, goals are created, in advance, so that success can be performed within the very timelines set by funders. The infusion of private sector rationalities, management-style performance measures, and the narrow delivery of new technologies greatly facilitate this performativity of success (Birn, 2009).

Such themes of temporality speak to more recent discussions in the anthropology of HIV, and how forms of social life re-arrange themselves around “adherence time” and “project time” (Benton, Sangaramoorthy, & Kolofonos, 2017). In their comparative ethnographic fieldwork conducted in Mozambique, the United States, and Sierra Leone, Benton and colleagues (2017) explore how time and temporality come into play in global health interventions aimed at shaping “positive living” among people living with HIV. Positive living here is defined as being encouraged to follow “healthier and more fulfilling lives through a set of moral, physical, and social practices” (Benton et al., 2017, p. 454). More specifically, they point to how “temporal rationalities”, shape communities’ responses and interpretations of positive living. In positive living, “temporal logic entails synchronizing the rhythms of everyday life with HIV/AIDS treatment” (Benton et al., 2017, p. 456). Furthermore, HIV programs, like most global health initiatives, unfold within timelines defined by donors, in what Benton and colleagues call “project time”. Whereas public health interventions often focus attention towards individuals and behaviours, it is project time, they argue, that can disrupt health processes such as taking medications. Furthermore, a “logic of scarcity” over the future of programs, or medication availability in the case of HIV treatment, beholds patients to the priorities of donors, and underlies fears of the future availability of medicines, forcing the “synchronizing of everyday
life” to the life of interventions (Benton et al., 2017). Scarcity leads to the need to demonstrate patient responsibility and show project success.

Conceptualizing success in more ontological terms, I build on Birn (2009) and Benton et al. (2017), by showing the work that “success” does in making up new forms of sociality and in ushering in relations of responsibility. I argue that to more fully understand how positive health outcomes arrive in the PrEP demonstration project, we must carefully account for the lively and dynamic life history of the very notion of success itself. What I attempt to reveal is how “success” assembles various contradictory affects—of hope, excitement, fear, despair—as it comes to inhabit various moments of the project. Secondly, I argue that the ontology of success, as it lives (and haunts) the project, is heavily implicated in the various forms of care that are realized and enacted—forms that go beyond a preoccupation with epidemic prevention.

**Care and the Exigencies of Success**

Annamarie Mol (2008), in her ethnography of hospital-based diabetes management in the Netherlands, criticizes a neoliberal consumerist rationality that pervades modern health care delivery, embodied in the “logic of choice”, by reframing it as a “logic of care”, arguing that “good care” does not view patients as autonomous and rational, but as collaborative partners, requiring tailored approaches to care that respond to their specific needs and unique experiences. She provides the example of a nurse following up on the reasons why someone might have challenges using an at-home blood monitoring system or might continue to indulge in unhealthy foods, rather than simply labeling the person as incompliant. Under “good care”, according to Mol, health care professionals accept that everyone sometimes needs help and thus refuse to give
up on people. Care does not blame or punish, but rather often demands support, and, at the same
time may conflict with what the patient wants. It is a tense, uneasy, and precarious space created
between those delivering and receiving care, where disagreements and conflicts may arise.
Similar to discourses on becoming, the logic of care is nonlinear, folding together temporalities
(Mol, 2008, p. 62), as it acts towards an imagined future while being continually influenced by
the past.

Beckman (2013) and Rhodes, Egede, Grenfell, Paparini, and Duff (2018) have applied
principles of care to HIV treatment. In her ethnographic work with people living with HIV in
Tanzania and Zanzibar, Beckman (2013) argues that the pharmaceuticalization of HIV has
placed “responsibility for the success of the heavily funded programmes onto the shoulders of
the patients” (p. 161). Beckman points out how HIV programs, through scientific rationality and
Western neoliberal notions of responsibility, often prioritize biomedical self-care over all other
responsibilities. She argues that people living with HIV negotiate “responsible behaviour” by
taking into account social environments, as well as HIV status. “Responsible behaviour”,
therefore, cannot be interpreted simply by looking at adherence, but instead needs to be viewed
through the lens of social responsibilities to understand complex choices surrounding HIV care
(Beckman, 2013). Beckman argues that:

Good care means providing emotional support in the context of uncertainty and
anxiety and disentangling the practicalities the patient has to deal with in
finding ways to make life more bearable. Rather than moralising and judging
the patient, the logic of care aims to mutually adjust technology, everyday
habits and constraints, people’s skills and propensities, and their social
In their study of people living with HIV in London, Rhodes and colleagues (2018) examine how care practices relate to the “cascade of HIV care”, a public health notion that asserts a linear temporal spectrum, for people living with HIV utilizing health services. They ground care “beyond the virus” by locating it in social relations and networks and new socialites derived from membership in community organizations and HIV clinics. HIV care, in this sense, is attuned to social life. Rather than narrowing in on the care cascade, care actors must respond to “care that matters” to those they treat, giving rise to multiple practices of care, what science and technology scholar Maria Puig de la Bellacasa (2011) has termed “thinking with care” (in Rhodes et al., 2018, p. 5). As Rhodes et al. (2018) argue, rather than antiretroviral therapy (or in our case PrEP) “acting on” people, “care transformations and potentials are produced by entangled interactions between the multiple bodies of an assemblage (people, technologies, organisations, discourses)”, what he calls transforming “‘care of the virus’ into ‘care beyond the virus’”, which is more linked to the concerns of daily life (p. 6).

Drawing upon de la Bellacasa’s (2011) theories of care as an “affective state, a material vital doing, and an ethico-political obligation” (p. 90), Martin, Myers, and Viseu (2015) further articulate the notion of care as inherently political, as continually embroiled in “complex politics”, while warning against an overly romanticized notion of care:

Practices of care are always shot through with asymmetrical power relations: who has the power to care? Who has the power to define what counts as care and how it should be administered? Care can render a receiver powerless or otherwise limit their power. It can set up conditions of indebtedness or

30 The cascade of HIV care is a stepwise framework for engaging people in HIV care. It provides metrics for the number of people living with HIV, tested, diagnosed, on treatment, and virally suppressed (Rhodes et al., 2018, see also MacCarthy et al., 2015).
obligation. It can also sediment these asymmetries by putting recipients in situations where they cannot reciprocate. Care organizes, classifies, and disciplines bodies. Colonial regimes show us precisely how care can become a means of governance. It is in this sense that care makes palpable how justice for some can easily become injustice for others (Martin, Myers, & Viseu, 2015, p. 627).

This idea of care as inherently political is also reiterated in Aradhana Sharma’s (2006, 2008) ethnographic work of women’s empowerment programs in Uttar Pradesh, India. Drawing on Michel Foucault’s (1991) concept of “governmentality”, Sharma describes how empowerment programs pursue a goal of promoting responsibility among its members, resonating with neoliberal shifts away from the state and towards self-rule and self-care. These empowerment programs, according to Sharma, are seen as embodying feminine characteristics of charitable work and care. Whereas empowerment programs have been criticized by some critical scholars for their role in creating compliant participants who make the “right” health choices (Finn & Sarangi, 2006), Sharma (2006, 2008) contends that while these programs can produce disciplined state subjects, they can equally produce active political actors who come to better understand the structural inequalities that they face through their membership in these programs and then go on to make demands on the state (Chatterjee, 2004, 2011; Sharma, 2006, 2008). In all its iterations, whether fuelled by “warm feelings of love, affection, or nurture” or “anxiety, injury, injustice, indignation, or frustration” care is active, it involves doing (and not doing), and is a practice (see for example, de la Bellacasa, 2011; Martin, Myers, & Viseu, 2015; Mol, 2008). Furthermore, de la Bellacasa (2011) states that we need to ask “how to care” in each unique situation (p. 96).

Alongside notions of temporality in the PrEP demonstration project, I draw on these concepts of care to tease out the wider implications of claims of success made in global public
health, which tend to be under-examined by anthropological and critical theorists. Whereas “the logics of care” have been applied by Beckman (2013) and Rhodes et al. (2018) to HIV care and administering antiretroviral therapy, I argue that the pharmaceuticalization of prevention, as exemplified by PrEP, unsettles the conceptual and practical public health distinctions upheld between HIV prevention and HIV care. Through PrEP and the expectations of daily adherence, prevention now requires much of the same biomedical supports previously reserved for treatment.

A PrEP Demonstration Project in India

PrEP, as a new pharmaceutical option for HIV prevention in India, emerged amid a climate of dwindling and uncertain funding. Touted as a ground-breaking advance in HIV prevention science, multilateral organizations like the World Health Organization (WHO) recommended the global undertaking of PrEP demonstration projects in multiple countries to ascertain its effectiveness in different settings among different populations (World Health Organization, 2012). This recommendation followed on the success declared in clinical trial efficacy studies (see for example, Okwundu et al., 2012).

The Bill & Melinda Gates Foundation selected Ashodaya Samithi as one of only two sex worker-led organizations in India as the ideal sites to demonstrate the effectiveness of PrEP when rolled out as a 16-month program.31 Both sites are renowned for their mobilization of sex worker organizing and their community-based leadership models.

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31 The other PrEP demonstration project site is the Durbar Mahila Samanwaya Committee (DMSC) in Kolkata. While Ashodaya was inspired by DMSC and benefitted from their mentorship, Ashodaya has since grown to cultivate their own community-based leadership and fostered the
workers and are well represented in the literature (see for example, Argento et al., 2011; Dixon et al., 2012; Ghose et al., 2008; Jana et al., 2004; Jana & Singh, 1995; Lazarus et al., 2012; Lorway et al., 2014; Reza Paul et al., 2008, 2012).

My ethnographic study focuses on the PrEP demonstration project delivered by Ashodaya Samithi. Although less scientifically stringent than a randomized control trial, lacking a control group, PrEP demonstration projects nevertheless are conducted under technically-regulated conditions to produce standardized forms of knowledge, based on rigid measures that track retention, adherence, risk behaviours, and clinical markers. In other words, participants are enrolled in a study, provided PrEP free of cost, and closely monitored through ongoing clinical visits, survey participation, and blood-level monitoring of the drug.

According to the standardized indicators of “retention” and “adherence”, public health scientists characterize the PrEP demonstration project results in Mysore as tremendously “successful”, with findings celebrated at international AIDS conferences.32 Ashodaya’s PrEP Demonstration Project began in March 2016 and enrolled 647 female sex workers into the 16-month study. Throughout the duration of the project, participants underwent quarterly health screenings, including HIV and STI testing, and participated in bio-behavioural surveys. Ashodaya’s Demonstration Project showed exceptionally high retention, with 640/647 (98.92%) participants retained for the 16-month project duration. Moreover, participants reported high rates of adherence, which was confirmed by blood sampling that detected a therapeutic level of

devlopment of other sex worker organizations across the Asia-Pacific region through their Learning Academy.

32 The findings have been presented at a special session at the 2018 International AIDS Conference in Amsterdam (Reza-Paul, 2018; see also Cairns, 2018 for media reporting of the presentation).
tenofovir (>40ng/mL, consistent with steady state dosing, see Donnell et al., 2014) among 80% (n=68) of the participants in the first round of testing at month 3 and 90.48% (n=76) of the participants in the second round of testing at month 6.

**Study Setting**

In the city of Mysore, southern Karnataka, the sex worker-led organization known as Ashodaya Samithi has established a vital presence in the local HIV response. Named by a diverse grouping of sex workers who formed the organization, Ashodaya Samithi means Dawn of Hope, a sentiment that speaks to many of the aspirations expressed by the women, men, and transgender people who congregate there on a daily basis.

Ashodaya was the first organization funded by the Bill & Melinda Gates-funded Avahan HIV Initiative in India. Under “The Avahan Business Model” (Ramakrishnan & Alexander, 2006; see also Lorway & Khan, 2014), organizations like Ashodaya were expected to prioritize their intervention activities in accordance with particular business logics, such as creativity and innovation, in their efforts to connect highly marginalized groups of sex workers to health services. Although Avahan engaged a broad sector of technical resources at the global, national, and state level, the mitigation of the HIV epidemic hinged on the participation of sex workers, bringing with it hopes for a better future that transcended epidemic prevention. Ashodaya community leaders discussed how they wanted to be seen as caring for their community beyond simply HIV prevention.

Although the Gates Foundation planned Avahan as a temporary measure to control the epidemic, with the aim of handing the intervention back to the public system, the “lavish” resources poured into it brought Avahan under criticism as creating programs that would be
unsustainable in the public system (Lorway, 2016, p. 93). Moreover, the initiative drew criticism for initiating the “transfer” to the government too early (Rao, 2010).

The transition of Avahan to the public system took place between 2010-2013, and many of the previously funded community-based organizations shut down, after receiving poor performance ratings with respect to meeting predefined program targets. Ashodaya, by contrast, was appraised by national and international evaluation teams as highly successful in mitigating curable STIs—a success statistically tied to “community-led” empowerment strategies (Reza-Paul et al., 2008). Garnering the reputation as a centre for excellence in community-based HIV prevention, the central governments granted permission to the sex workers running Ashodaya Samithi to lead HIV programs in ten districts in southern Karnataka.

Within the global public health literature, indeed much has been written about the successes of Ashodaya’s community-led strategies with respect to fostering ownership over health services (Dixon et al., 2012), responding to and reducing violence (Reza-Paul et al., 2012), and bringing down HIV prevalence among women sex workers from 26.1% in 2004 to 10.9% in 2009 (Reza-Paul et al., 2008). Although Ashodaya in many ways can be viewed as a community “made up” or invented by public health practices and intervention techniques (Hacking, 1986), over the years I have witnessed the profoundly vital political stirrings and

33 As a result of its expertise in community-led interventions, Ashodaya has been internationally recognized as an Asia Pacific Learning Site by the World Bank, and a learning academy by UNAIDS to provide curriculum to local institutions and training in intervention design and implementation to community-based organizations in fourteen countries across the Asia Pacific region and in five countries in Africa.

34 Due to continued program cuts, this has since been scaled back to include four districts across Karnataka.
forms of solidarity that emerged among sex workers’ as they engaged in these programs in Mysore.

Having conducted extensive applied public health and qualitative ethnographic research with Ashodaya over a ten-year period, I have witnessed how the organization has evolved and changed, from periods of multiply-funded projects under Avahan, to moments of program insecurity, following the transition to the public system. Although branded a success at the beginning of the transition in 2010, the funding landscape radically shifted for sex worker organizations in India, especially with the election of the conservative Bharatiya Janata Party government in 2014 and the merging of the National AIDS Control Organization with the Ministry of Health and Family Welfare (NACO, 2014). Now mired in state bureaucratic procedures, community-based organizations leading HIV programs throughout India, like Ashodaya, are forced to contend with punitive funding delays on the part of the state governments when sex worker organizations are viewed as failing to meet numerical-based program targets (Lorway, 2016).

The findings in this paper are based on fieldwork that I conducted between January 2015 and April 2018. Throughout this time, I made six trips to the Ashodaya office in Mysore (in January 2015; June and September/October 2016; April and November/December 2017; and April 2018). However, my analysis is based on nearly ten years of research collaboration with the organization, dating back to 2009. In 2015, I was asked to conduct the qualitative analysis portion of a feasibility study that pre-dated the PrEP demonstration project (see Reza-Paul et al., 2016). I had been closely following the debates around PrEP and had my own reservations as to whether this type of biomedical prevention intervention was in the best interest of the community. However, following my visit in 2015, and meeting with community members, it
became clear that there was an excitement for a new form of HIV prevention and a demand to get started with the project. Following the feasibility work, I took on a study of the PrEP demonstration project, drawing on qualitative and ethnographic methods as my PhD research.

This paper is based on participant observation, field notes, conversations with interlocutors, as well as in-depth interviews with study staff and participants. In total, over 150 interviews were done at three time points over the course of the study (in September/October 2016, April 2017, and November/December 2017). I invited all full-time staff members (which includes both sex workers and non-community staff) to participate in an interview in September/October 2016 and November/December 2017. Community outreach workers were included in these interviews and purposively selected to represent women working in different environments. I conducted all interviews either in English, if the interlocutor was fluent, or in Kannada, the local language, with on-the-spot translation by a local team member who played a key role in all aspects of this project. Trained peer researchers conducted the participant interviews in Kannada, which occurred at all three time points, with sex workers taking PrEP purposively sampled to ensure representation across different ages, locations, and networks. All interviews were audio recorded and transcribed directly into English.

I coded all data for key themes and emergent categories. Thematic analysis initially focused on the PrEP project processes, and women’s experiences in taking PrEP. At the start of the project, I was originally interested in concepts of governmentality and responsibilization (Cruikshank, 1999). A community contextualization session took place with peer researchers in April 2018, where selected interview segments were discussed and a coding scheme was collaboratively developed based on group analysis. Multiple and complex notions of care (Mol, 2008) began to emerge during this community contextualization session and eventually became
the theoretical framework of this paper. Transcripts were re-read and analyzed to capture the many ways in which care was enacted throughout the course of the PrEP Demonstration Project, building on Mol’s call to apply the “logic of care” in other contexts and settings. While working through the analysis on care, notions of temporality (Adams et al., 2009; Benton et al., 2017) became equally important to understanding care enactments and both theories have framed the analysis I present.

**Findings**

The findings presented below provide portraits of different moments in the life history of the project and attempt to illustrate how the search for success gives rise to particular tensions, alliances, connections, frustrations, and anxieties—that is, affective dispositions that are underscored by various overlapping temporal registers, particularly the early stages of supporting adherence, project fatigue and mid-point tenofovir testing, and excitement and disappointment of anticipating what comes next for the organization at the end of the project.

**Supporting Early Adherence: Care for Community**

Senior members of Ashodaya tell how their organization was founded—based on the goal of caring for women who had fallen on hard times, a sentiment vividly embodied in their organizational logo, which appears as a prominent statue in the main office and on their program stationary (Figure 8). The promise of PrEP, as a life-saving technology, further engaged this logic of care, and soon fuelled a demand for access within this community of sex workers (Reza-Paul et al., 2016). While Ashodaya staff had worked tirelessly to established norms around condom use among their peers before the arrival of PrEP, it became clear during the feasibility
study phase that there were still numerous instances where women were simply unable to use condoms. Although knowing the women for many years, this was the first time many of them candidly articulated the many circumstances in which condom use was occluded: when new clients took them to locations where they could not access condoms; when clients deliberately removed condoms during sex; during sexual assaults or forced sex; during encounters with police and lodge owners who demanded “free sex” (sex without money and without condoms); and with intimate partners. In other words, the introduction of PrEP at the feasibility study phase opened up an abundance of new discussions of scenarios in which sex workers could receive greater care from Ashodaya.

Figure 8 – Ashodaya’s organization logo.

Photo taken by Syed Hafeez Ur Rahman (Rahman, 2019).
As they recounted their past tales of condom failure during the feasibility study phase, the women expressed considerable anxiety over their past safer sex struggles, an emotional response that helped frame the futurity of PrEP as a promising new option for health protection. Much to the surprise of some of the authors who shared an initial scepticism of PrEP, Ashodaya sex workers expressed an intense interest in the prophylaxis, and asked Ashodaya staff and members of our team a litany of questions such as: “Can you take PrEP if you have had a hysterectomy?”, “Will it cause problems for people taking diabetes medication?”, “What about drinking; many of our community are regularly taking alcohol—can we still take it?”, and so on. Although initial discussions of PrEP among Ashodaya sex workers generated, at times, heated critical interrogations of the new technology, much excitement also permeated the discussions, which was evident in the optimistic smiling and hopeful expressions that reflected an imagined future that was safer for their community.

Despite much initial enthusiasm for the new technology during the feasibility phase, discussions of PrEP still gave rise to doubts, rumours, and mistrust when the actual medications were distributed. Women began to describe various reasons for being sceptical of PrEP at the beginning – it was new, unknown, the pill was big, there were expected side effects, and there was pressure from friends and partners to both take it and not take it. However, these fears were eventually mitigated by a deep sense of trust in Ashodaya’s care for their well-being.

To ensure that relations of trust were sustained throughout the demonstration project, Ashodaya developed an extensive community-outreach strategy to follow and encourage their members in taking PrEP on a daily basis. This strategy involved a network of community
outreach workers\textsuperscript{35} regularly communicating with PrEP study participants through a mix of phone calls, daily visits, and sometimes even direct observations of people as they took the pill.

Prisha, who served as a community outreach worker since the organization was founded in 2006, was highly experienced in doing health promotion work among women in her network who she characterized as being “difficult” to engage in Ashodaya’s health programs, working especially with women who work in street-based settings\textsuperscript{36} and wrestled with heavy drinking. In my second interview with her, Prisha describes how she conducted her daily visits with these women at the beginning of the demonstration project, when participants were still unsure and adjusting to taking PrEP. Although direct observation of the women taking PrEP was not included in the support strategy that Ashodaya developed, Prisha took it upon herself to have the women swallow the pill in front of her, as she discussed during one of my interviews with her.

\begin{quote}
Prisha: Actually four or five girls have created a problem. One thing is that they are very high risk. They are so much busy so the problem is I used to hand over the tablet. After that, they will not remember that. Wherever they are sitting they will keep it [PrEP] there only and move.
\end{quote}

Interviewer: Okay, so they’ll leave the tablets behind.

\begin{quote}
Prisha: Yes. So I used to give and I used to follow them, “You should not miss.” At the same time, I’ll just call them in the evening and find out, “Have you taken your tablet to your home?” Like that. That is a little bit difficult
\end{quote}

\textsuperscript{35} The system of community outreach workers pre-dated the PrEP study, with outreach workers playing a critical role in Ashodaya’s targeted HIV interventions, such as condom distribution. However, during the PrEP project, outreach workers received additional training on PrEP and were assigned participants to follow for whom they were responsible for delivering PrEP, providing adherence support, and reminders for scheduled clinic visits.

\textsuperscript{36} Although much of sex work has moved to indoor settings in Mysore, the women that Prisha work with still predominantly solicit clients in outdoor street spaces.
because they missed out sometimes…. they [the PrEP pills] are left there only…

Interviewer: Yeah. In your impression do you think that was because they weren’t interested in taking the tablets or do you think it’s just because they were busy and forgetting?

Prisha: No actually most of them used to forget because of the business. They are busy… and few of them purposefully they had done because they don’t want to tell [us] directly that, “I don’t want the tablet.” They will just take it from me and just put it somewhere and go like that. Then actually I came to know after a few days who are all these kind [those not taking PrEP], so I used to always shadow them and I personally used to put the tablet in their mouth and every day I used to give water to them. “Okay now you will take the tablet from me only like that.” I started doing like that. I discussed with them because they will also respect me. (Prisha, community outreach worker, December 2017)

Growing frustrated with the women not consistently taking their pills, Prisha eventually arranged for a group meeting to reinforce the “many benefits” of PrEP, as she put it, and provide people with the opportunity to opt out of the project, rather than feel like they had to pretend to take it. Prisha goes on to explain, “We are not pushing anybody for extra this one. If nobody is interested they can express in front of us directly and instead of doing all this kind of this one, it’s not good that you guys [the participants] are trying to hide from us…”. Following the group meeting, two of the women, according to Prisha, admitted to being concerned that PrEP would negatively affect their health. After the information session, however, they appeared convinced of PrEP’s benefits and expressed their desire to commit to taking it daily. Prisha describes her own persistence in wanting to convince her peers to take PrEP as an act of care, for she wanted to ensure that her community would derive advantage from PrEP. She especially did not want to leave “trouble-makers”, as she called them, behind.
I have confidence that okay I will overcome these challenges because they are our own community. I know about them. Yes they are troublemakers. From the beginning they are troublemakers. They will do that but the thing is what is important for us is their health and their life. That we need to safeguard. That we will do. We will bring into their concern, we will make them that their anger is different and fighting is different and issues are different but the thing is when it comes to their life, their health and other areas that is our concern also. I feel that somewhere actually we will organize group discussions and group meetings and do counselling sessions and other thing and we’ll try to make them understand. (Prisha, community outreach worker, December 2017)

Speaking with some of Prisha’s participants, I learned that they too had initial misgivings in taking the medications. However, over time, and through their consistent interactions with community outreach workers, they increasingly came to express an appreciation of the added security of taking the prophylaxis. Prisha and other outreach workers worked tirelessly to overcome perceptual barriers by closely following participants during this initial adjustment period in the demonstration project.

The following narratives of these participants illustrate how mistrust and confusion exist when people confront new interventions, especially those that involve unfamiliar medications.

Interviewer: You said that few women would throw the PrEP tablets. What was the reason for throwing them?

Anu: They had a fear that these tablets [PrEP] are given to kill us because we are doing this work so that slowly we will die.

Interviewer: Who brought that kind of fear in them?

Anu: All that was by women in groups who would talk [gossip]. We would sit together and talk. There were many women who would do this in public, we would talk among ourselves that they want to get rid of us, and want to kill us,
we had fear that we will die. Now I have no fear. I am saved from that disease.
(Anu, participant, December 2017)

Anu, who has been a member of Ashodaya for eight years and works in mostly street-based settings, discusses her becoming convinced about PrEP. With ongoing and regular contact from Prisha and other outreach workers, these continual negotiations over time transform PrEP from a new and unknown threat, to a medication that is familiar and possessing life saving properties.

Building on this premise of care, outreach workers would go to great lengths to reach their community for PrEP distribution and follow up. Although described as “tedious” at times, by some of the outreach workers, they also believed that PrEP was of great importance to their community and therefore put tremendous effort into reaching their peers at times and locations most convenient to the participants, rather than merely requesting them to come to the office to pick up PrEP refills. In the excerpt below, Raina, a participant in the demonstration project and an Ashodaya member for eleven years, discusses the lengths to which she would make outreach workers go in delivering PrEP to her, amid the unpredictability of client flows.

Raina: Yes, when they [community outreach workers] come to give [PrEP], sometimes I would get angry with them. They will say they brought the tablets and I would say go away, why are you disturbing me, I haven’t taken a single client yet and you are interfering in my workplace. I would get angry with them, but they will be patient and tell me this is for my safety and I should take it. They try to placate me. I tell them once in a week or fortnight you keep coming with the tablets, I don’t want it now, and then I will say come tomorrow morning and I will take it.

Interviewer: Why do you say I don’t want it?
Raina: It is time for the clients to come and this aunty has come with the tablets. I haven’t made any money so far and I don’t wish to be disturbed at that time. So in that frame of mind I would tell them.

Interviewer: But for that you don’t have any issues…

Raina: No, in fact I ask for the tablets and take it.

Interviewer: It is because you hadn’t got a single client until then….

Raina: Yes, since I am waiting for a client and this aunty comes with the tablet, I get irritated. But later I call and ask for the tablets.

Interviewer: What would they say for that?

Raina: They will say no problem, I am in office and I will come and give it. (Raina, participant, November 2017)

Despite Raina’s own admission of wanting to take PrEP and requesting the tablets, there is an expectation that community outreach workers will adapt to her sex work schedule. In this case, “project time” (Benton et al., 2017) is expected to bend to work time. Ashodaya, as an organization made up of sex workers, prioritized these demands, recognizing the irregular and unpredictable work schedules facing sex workers. Permitting flexibility in daily fieldwork schedules by adapting project time to meet participants’ work priorities becomes an important way of both striving to achieve “success” and enacting care. Indeed, outreach workers expressed a willingness to accommodate demands on the basis that they too encountered such irregular work times.
Similarly, Saanvi, another community outreach worker, describes how some of her participants made her wait outside for extended periods of time, which she accommodated in order to ensure that the women benefited from PrEP.

There actually the women’s group will work there. We call it [name of group], that microfinancing group. So they used to tell me that every time, “You need to come there to hand over the tablet to me and you will wait until my meeting will finish and we will come out like that.” I used to go there because they had given an instruction that, “Don’t talk in front of everybody like that.” So that I used to sit aside or else I’ll wait outside. So many times they observed me that I am waiting from last half hour to one hour and many times beyond that also. I’ll wait until they will make themselves free. Three of them are there then I’ll hand over [PrEP]. So they started asking me one thing that, “Are you not feeling bad that we are asking you to wait for such a long time and other? Why are you showing so much of this? What is the profit for you?” Then I explained to them that, “Okay it is not a profit for me. It is a profit for you…. I’m ready to wait for another hour together like that for you because if you are safe, my biggest priority is that, our concern, because we are working for your life. So that is my job, so I can wait for you. It is not a problem like that.” They turned emotional after some this one and then onwards they started inviting me to their home. (Saanvi, community outreach worker, December 2017)

Saanvi describes the emotional transactions that are part of fieldwork, and the recurring moral economic exchanges between outreach workers and participants. This approach to practising care here disrupts conventional biomedical practices where patients are required to wait for clinical staff before receiving services. In the Ashodaya Demonstration Project, by contrast, community outreach workers are asked to wait by their peers. Furthermore, initial shows of resistance are ways in which participants test the commitment of the outreach workers and the extent to which they care. Once satisfied that the fieldworkers “passed the test” by showing their willingness to accommodate unpredictable schedules, participants quickly agreed to the regular follow up and daily pill consumption.
While wanting the community to benefit from PrEP’s prevention properties, it was often expressed by outreach workers, the project team, and participants alike that “forcing” women to take PrEP is not a viable solution and would neither lead to long-term adherence nor project “success”. Ashodaya, possessing an intimate knowledge of their community, was able to effectively disrupt the traditional boundaries maintained between health care providers and service users (also see Dixon et al., 2012). There was a firm understanding among community leaders responsible for rolling out the project that participants had to “choose” to take PrEP. At the same time, an intimate understanding of the community informed the need to develop follow up procedures to give space to participants to grow accustomed with PrEP-taking. Care in this context is, therefore, ever moving, occurring within the continual re-negotiations between the participant choice and the encouragement to adhere to maximize the benefits of medication.

“Becoming Compliant”\textsuperscript{38}: From Self-Care to Collective Care

There was no PrEP in those days. I have been coming to Ashodaya for 15 years now and PrEP started only 16 months back. If it had come earlier, then many more women would have benefited from it… others would come to the field and give me tablets. Some clients would notice and ask me what it is for. I would tell them we have our own organisation and they take care of us and they are giving this tablet so that nothing wrong happens to us and we are healthy. (Deepa, participant, November 2017)

\textsuperscript{37} Dixon et al. (2012) explore how Ashodaya, in their creation of a community clinic, has established new norms of health care seeking and ownership over health care delivery among sex workers in this context.

\textsuperscript{38} The term “becoming compliant” is borrowed here from Mykhalovskiy, McCoy, and Bresalier (2004).
In an interview with a long time member of Ashodaya, Deepa recounts a time before PrEP, when she first joined Ashodaya. Recalling a past when PrEP did not exist and her friends’ missed opportunities to benefit from the protective effect of PrEP drives Deepa’s decision to become a vital advocate and defendant of PrEP for Ashodaya. Her loss of friends in the past motivates the pursuit of a better future, one in which her peers become safer and avoid becoming infected with HIV. PrEP itself becomes the tangible entity that carries the meaning of care with it, extending its reach beyond the clinic, to the field through the ongoing follow up and support on the part of the outreach workers. Indeed, for Deepa, PrEP availability itself embodies cares.

Kyra, another participant in the demonstration project, who also follows up and delivers PrEP to members in her network, recounts how adherence support, over time, led participants to evolve from questioning PrEP to taking a lead in monitoring their own refill schedule. This unfolding of time, which allows for the fieldworkers to ease apprehensions through ongoing support, not only fostered a particular way of “becoming compliant” among participants but also compelled their demand for PrEP.

They said that they feel good after taking the tablets; it is good for them and they said that they will tell others also. Initially they would ask me why they should take tablets, then later they started asking me for the tablets, and now they ask me before the tablets are over, if I don’t go for a day or two, they ask me about where the tablets are and why I did not go to meet them, because they also know that they should be healthy, then I get the tablets from the office and give it to them. There is no problem from PrEP tablets. (Kyra, participant, November 2017)

Taking PrEP not only became a form of self-care, but the women also began to assume the responsibility of sharing the benefits of PrEP with other members of their community, further promoting the medication within their peer circles, as described by Meera.
We got our full health check-up done in Mysore, I shared this with my friends, and they shared to their friends, like this we informed more than 100 people, when we shared about good things that happened to us after taking tablets, they too started the tablets and those who had health issues got cured because of these tablets, people from our office would come and ask us every time when they meet us in the office or in the field, they would ask us if we are taking tablets regularly, if we are going for health check-up. We started to go regularly for check-up, take tablets regularly, go to district hospitals for check-up, and also started to ask other community members if they are taking tablets regularly, if they are undergoing health check-up, using condoms and other things. Ashodaya people take a lot of care and similarly all the community women also take good care of each other and are supportive. (Meera, participant, November 2017)

This care for others further manifested in wanting to reach peers who had opted out of taking PrEP. Some of the women taking PrEP reasoned that those who had decided not to take the pills likely did so due to a lack of information or misunderstandings about the drug, and they began to express a deep sense of responsibility in trying to ensure that everyone could benefit from PrEP, as Pihu, a newer member of Ashodaya, explains.

We have to make women understand it is good for them. It is not just us, all should get the benefit. There are fears and negativity about the tablet and we should convert it to positive and tell women we are taking this tablet for so long and we are alive and fine, so they can also start taking it. (Pihu, participant, November 2017)

Here caring for others is closely intertwined with discourses of collective responsibility, thus moving to fulfill a kind of “redemptive citizenship” (Chevrier, 2016) in which participants themselves assume the obligation to ensure that any woman “left behind” is granted a second chance to receive what they have come to see as the life protecting benefits afforded by taking PrEP.
Project Fatigue and Tenofovir Testing: Caring for the Evidence

As anthropologist Aradhana Sharma (2008) notes, people who work in community-based settings often do so through a sense of moral and political “devotion” to the work, one that may differ from those working in governmental and other sectors (p. 101). The PrEP Demonstration Project differed significantly from previous socio-political empowerment work undertaken by the organization, posing a considerable challenge for the team in running their first biomedically-oriented prevention project. The way the study differed most from other projects they ran related to the need for daily adherence monitoring, which required the entire staff of the organization to make tremendous time investments. During my early visits, I witnessed the toll that the long working hours took, with the team initially working seven days a week to try to best figure out the complex research procedures in a way that aligned with their community-centric model of health service delivery.

The intense effort to maintain regular follow up with participants, although related to their commitment toward delivering quality of care, was also tied up with the desire for the project to succeed, as the PrEP study had arrived at a time of diminished funding. The sustainability of Ashodaya, like many community-driven health programs globally, rests on the ability to secure grants and there is a pressure and pride in living up to the expectations of funders placed on the organization. In this way, care and success are mutually reinforcing—co-evolving throughout the life course of the project.

Built into the study protocol were two rounds of tenofovir blood-level testing for a subset of the participants, conducted at three and six months, for 85 and 84 participants, respectively. During the first round of testing, 80% of the participants showed a tenofovir blood-level concentration of 40 ng/mL, which has been considered to reflect daily adherence (see for
example, Donell et al., 2014). Although scientists would generally consider these readings as showing tremendously high adherence for a new prevention drug, the implementation team was clearly disappointed by the results, as recounted in my interview with Aman, one of the long-term program technical support staff, who, like Prisha, has been working for the organization since its inception.

Aman: Yeah, seems good. In the clinic also nobody was finding any problems. We are not even finding any STI symptoms so we thought, “Okay, everything is going smoothly.” So then after this first round [of tenofovir testing] results, oh we got a real shock. We were under the impression of [adherence being] very good.

Interviewer: I still thought the numbers were good from the first round. They were still high, right?

Aman: Still high but our expectation was a hundred percent. (Aman, project staff, December 2017)

While daily monitoring had been the norm at the start of the project, things had relaxed once it appeared that rumours had subsided and women had grown more comfortable taking PrEP. The tenofovir blood-level testing results sent a shock to the study staff who expected to see higher levels of adherence. Following these first round testing results, Aman explains, efforts were made to understand the challenges that participants were facing in achieving “a hundred percent” adherence.

Aman: After the results from the first round [of tenofovir testing], we went to them [the participants], “What is the problem? Where is the problem? Why are some of the people not taking the medicines?” …. They’re taking the medicines but they are missing the doses. What is the problem? Where do you find the problems?
Interviewer: And what was the answer to that?

Aman: They said that, “Sir, no sir, sometimes we will be going out sir, so sometimes we’ll be having booze also. That is the reason we’re not able to take the medicines and sometimes when we are not going to the field for sex work, so why should I take the medicine? That is the reason we could not take the medicines, sir.” Such kind of answers they started giving. “Then at least what is the commitment we have made? When you are on the PrEP program, you should not stop the medicine in between. So if you stop the medicine in between as we clearly said, if you stop today then the medicine content [will be lowered] in your body.”

While participants justify skipping doses because of drinking or breaks in sex work, Aman and the study team, in response, stress to them the importance of high levels of adherence to prevent HIV infection, warning against a false sense of protection.

It will take a minimum of 15 to 20 days, so in between something happens, we don’t know. Something happens, you will be going somewhere or you will get some client, you will not be having a condom at that time or if you’re having a condom, condom may burst. So something goes wrong, what will happen?.... You will be thinking that, “I am taking the medicine, then I’m on the medicine so medicine will be saving [me].” But you’re already not on the medicine for 15 days, so just imagine what will happen. And many people are dying to take the medicine but you are not. We selected you that you will be going to continue the medicine for 16 months until the project ends. So you stop the medicine, what are you saying now?” Then they started crying, “Oh sorry sir, because of us your project will not get affected and [Ashodaya] should not get bad name…” “See, we’re not saying that [Ashodaya] will get the bad name but you will suffer if something goes wrong”.

An emotional exchange takes place here, where Aman calls on participants to act responsibly and take PrEP, asserting that they were fortunate enough to be enrolled in the project, while others are left behind and “dying to take the medicine”. He invokes adherence as a moral
responsibility. While the participants, in Aman’s words, express a sense of duty to not let the project fail, thereby giving Ashodaya a “bad name”, Aman reframes this responsibility as one of caring for the participants’ own health, and not wanting them to “suffer” should they become infected with HIV. The tenofovir blood-level testing results were taken as a signal that continued adherence monitoring and support were necessary for the project to succeed and maintain adherence levels. Following the results from the first round of testing, monitoring efforts were scaled up once again. An enhanced monitoring plan also worked to re-engage the community in the project and demonstrate care and concern on the part of the staff implementing the project. In the second round of testing, adherence did in fact increase to 90.48%.

The scarcity in funding and an uncertainty over the future availability of PrEP also fuelled the need to demonstrate project success. As expressed by Arjun and Vihaan, two long-term staff members, success is needed to show community interest in PrEP and advocate for continued access at the national level, so that others can similarly benefit from PrEP.

Overall the result is good that we’re able to provide medicine to the community members because it’s the first time in India that we are providing to the sex workers and it should not look like the community is not interested in taking the medicine. But our result shows that communities are willing to take the medicines and if we provide correct and consistent information and awareness to the community member, definitely they’ll take this one. (Arjun, project staff, November 2017)

So it shows that participants are really interested in taking the tablets, so it’s not for compulsions or from the external pressure or something like that… There’s a chance that they can take the tablets and they can throw it away or something like that but the data is showing that they’re getting the tablets. (Vihaan, project staff, November 2017)
Tremendous effort went into achieving these high levels of adherence, driven by notions of care for the community, a trust in the product “doing good”, and underlined by a belief in people’s choice to participate. But what does success mean for the longer-term outcomes and future of Ashodaya? As the project drew to a close, demand for continued access to PrEP remained high with no sign of a national plan from the central government.

The Temporality of Success and Hopes for the Future: Care for the Organization

Questions of “success” unfurled in the project from its infancy. Since the first round of interviews, participants and staff alike approached me with concerns over the availability of PrEP “post-demonstration”. As a long time partner of Ashodaya, demands were made on me to “do my part” in advocating for PrEP. I had been in Mandya, the neighbouring district to Mysore, towards the end of the project, in December 2017, with the community researchers who had been conducting interviews with participants taking PrEP. We were exiting the office, getting ready to make the hour-long drive back to Mysore. As I put on my shoes and said my goodbyes, knowing that this would be my last visit to Mandya for quite some time, I was stopped by one of the outreach workers, named Bhavya. I had not met Bhavya before, but had noticed her throughout the day, as she had been in and out of the office a number of times, and had been arguing with one of our community researchers earlier. She had come to pick up a supply of PrEP to distribute to her network, but had to leave suddenly when she received a call from a client. She was now back to collect the pills, and stopped me just as we were leaving. Holding a stack of white envelopes containing PrEP, she demanded to know what the plans were post-project. She explained to me that all of the participants that she had been tasked with following had been asking her about what will happen after the study ends. As their main link to the project, she
wanted answers for them, and for herself. She wanted these answers from me. I had been faced with this question during each of my previous visits to Ashodaya. I too was struck by the sense of urgency as the project quickly approached its end. I too wondered what was next. Her voice added to a growing chorus of community leaders and participants alike who had expressed concerns about PrEP availability and demanded action.

While the project was a tremendous “success” in terms of public health notions of “retention” and “adherence”, as well as reported participant satisfaction, questions of “what’s next” haunted the project, from start to finish. The excitement over the renewed community spirit and sense of organizational purpose was heavily burdened by previous experiences with short-term projects and interrupted funding. Therefore, I argue that in order to better understand how “high adherence” arrived in this project, it is necessary to re-envision “success” within the affective terrain spiralling within the project itself—animating around the multiple, conflicting, and intertwining temporal registers convergent in the demonstration project. In the end, community outreach workers faced the brunt of questioning from their peer networks. They shared their troubles over what might happen if the state did not grant access to PrEP post-study. As two senior community leaders, Saanvi and Zara, put it:

Along with that my worry is actually if we’ll not give them this tablet and we’ll not continue, they should not feel that they had utilized it for a particular purpose, after that they’re left over. And maybe some people will get infected out of this one and other thing and possibly we will lose the trust of the community members also like, “They had brought it [PrEP] for a short-term and after that they are not thinking at all about [us]. Only whenever they’ll feel like they want this one they will show attention, otherwise they will not show it.” Those kinds of things are also going on, so those things also we need to keep it in our consideration. (Saanvi, community outreach worker, December 2017)
…from the last 15 months continuously we are in touch with them, we are meeting them, we are talking to them…. They followed us, we won their trust. Whatever we had told them they just trusted us and blindly followed and many of them are using condom, now they are using the tablet also. They have prevented HIV and most of them had not had any single symptom of STIs. So my difficulty is now also they are calling and asking that, “What about my next due date of the tablet…” I don’t know how to tell them that, “We are not going to give tablets to you next.” It is very difficult actually. I don’t know how I will face them if I need to tell them that, “We are going to stop this.” (Zara, community outreach worker, November 2017)

What are the implications in these narratives for measuring and understanding success in global public health projects? In terms of funding, PrEP provided much needed resources, and led to a revitalization and a remobilization of community. At a time when public funding for HIV prevention was in decline, the effect of which began to erode community solidarity networks, Ashodaya seized upon the resources furnished by the PrEP project to build a renewed position of relevance in the sex worker community around health. In addition to assuming responsibility for delivering a new HIV prevention technology, the demonstration project revitalized a sense of collective belonging among community members. However, feelings of dread and anxieties over the fate of PrEP delivery post-study, de-temporalizes the project endpoints, thus leaving us with larger questions about what happens next for Ashodaya and for the many members they have served for more than fourteen years.

Much of the concern over next steps expressed by community leaders and the project team is tied to neither wanting to lose the re-established bonds cultivated over the course of the demonstration project nor disappoint the community. Community participants too have voiced their expectations that Ashodaya will find a way to continue providing PrEP, as they have previously managed to integrate other research project activities into their care services post-
study period. While participants were expected to act as responsibilized citizens and take PrEP, Ashodaya is similarly expected to find a way to meet the community’s demand for continued access to PrEP. This pressure has been clearly felt since the start of the project through to its end, as expressed by senior community outreach worker, Saanvi and long-term staff member, Jayesh, who both reflect on the need to find ways to maintain community engagement.

Actually even I’m thinking that this whole process of community gathering and showing so much of this one [attention] and regular health check-up, I feel that somewhere we should not stop this. I don’t know. I’m feeling very bad that this project is going to end and maybe we’ll lose this thread. What are we going to [do]? Slowly, slowly this bondage will also become weaker and weaker because if we will not show the same concern and frequency… automatically those things will definitely affect our relationship with the community members also. My worry is actually that many of them should not fall on risk and they should not get some kind of infections… That is also my major concern but somehow I wish that somewhere we’ll get some resources or we can be able to continue this for many others also to save their lives at least. (Saanvi, community outreach worker, December 2017)

Even we don’t have much stronger cause and we don’t have a stronger reason for meeting every day, but still I feel that is also a reason for continuing it. We have to continue. We should not compromise on that. It is not only from the ground level team I’m saying, even including us also. We have to keep these visits continuing, always in touch, and we need to creatively think of how we can keep them engaged and how we can artificially create something that could make people come together again with some purpose or something like that. We can use this particular bondage for developing some good things and we’ll come out creatively with some new project or new thing like that. (Jayesh, project staff, December 2017)

The question remains whether this level of involvement can be maintained without continued funding or a specific project driving contact. In fact, staff restructuring began before the end of the demonstration project, with some of our PrEP community researchers affected by the
reshuffling and losing their positions in the organization due to the upcoming cuts to operational funding following the end of the project. Kashvi, a long time community leader and outreach worker on the project, described the team’s low morale as the project wrapped.

So if you could just go through, I think it’s nearly two and a half years by now. So you can involve more than 24 months and it does feel a bit kind of low to know that the project is coming to an end because we were kind of involved and trying to do our best. Now that it’s coming to an end I think we have mixed kind of feelings. Though we feel, yes, we’ve done something to the community but again, just because this is coming to an end, now what next? (Kashvi, community outreach worker, December 2017)

Whereas Ashodaya holds much experience in advocating for policy change at the national level, at the end of the project there were no plans from the government to scale up PrEP. Despite that, nearly all participants stressed their desire for continued access to PrEP, and their anxiety over the loss of this prevention option. Anu, who earlier discussed her fear of PrEP, now describes the fear associated with not taking it. She was adamant that she needed to find a way to continue taking it, even if that meant purchasing it herself.

Yes, that is what they are saying that they are going to stop providing them [PrEP tablets]. We are thinking now. We should get the tablets on our own and use them. We can’t stop these tablets. It will increase the fear that we have. We will be in more trouble. Now at least we know that we are taking tablets and so we are fearless. But afterwards, we have thought of buying it on our own and using them. (Anu, participant, December 2017)

Similarly, Aadhya stressed that participants did not want to see the project end.

All are saying they need it. Every one of them that I spoke to said this should be continued. No one has said it should be stopped. Yes, in the beginning some
said it can be stopped, but now they all feel, oh, they may stop it soon, we need them to continue. (Aadhya, participant, November 2017)

Returning to Prisha, the outreach worker who recounted her adherence support strategies at the start of the project, she now calls for the need to disseminate findings to health authorities, demanding support from myself and the other “scientific researchers” to share the message of “success”.

If earlier HIV is something like a big this one, nowadays actually whoever is an HIV-infected person, also we’ll say that, “Now if you’ll get HIV, there is a tablet. There is a medicine that can [keep you] stable…” In the same way, whoever is doing sex work, they are having their own fears…. So we can give the tablet to them by saying that, “You can keep yourself safe.” Is it not right that we can give the tablet to them also? Actually we need to talk to the higher authorities and others. We need to make them understand that [Ashodaya] has done this project and it is successful. We need to share that there and we tell them that [Ashodaya] recommends that, we feel that you need to give it to everybody, and it is not only [Ashodaya] will talk, it will happen. Everybody needs to talk, persons like you who know scientific this one and other things. You guys can take a lead in this one and make them understand how it is working so then at least they’ll get convinced. (Prisha, community outreach worker, December 2017)

Prisha’s call for action is repeated by Sana, a project participant, who calls for her demand for continued PrEP access to be shared with the “big people”, so that more women like her can benefit from PrEP.

PrEP is as important as condoms. This should continue and more women should get it. I wish that it is continued and it should not be stopped. We will be able to look after our family better if this continues. So please tell the big people [donors] and ensure that this is not stopped at all (Sana, participant, November 2017).
It is clear from the above narratives that concerns abound over future directions for the organization, which once again finds itself in flux at the end of a “successful” project, without any guarantees about continued support. Furthermore, this overriding sense of precarity makes them acutely aware of their unequal positioning in relation to their reliance on international donors who hold the power to make projects live or let them die.

**DISCUSSION**

Anticipation is not just betting on the future; it is a moral economy in which the future sets the conditions of possibility for action in the present, in which the future is inhabited in the present (Adams et al., 2009, p. 249).

The PrEP demonstration project came at a moment when Ashodaya faced inconsistent funding flows, government deprioritization of community-led HIV programs, and stricter reporting and accounting requirements. The PrEP study carried with it not only the possibility of recapturing the golden age of Avahan funding for HIV interventions of the early 2000s, but also a renewed sense of hope for the future, what Biehl and Locke (2010) call the “transformative potential of becoming” (p. 317). In this sense, the search for success animated through the PrEP demonstration project acts on the contemporaneous desires and imaginations of sex workers. By situating PrEP within the longer and more complex life history of Ashodaya, we see how the demonstration project generated desires and anxieties about the future.

The search for success was driven by both care for the community and for the organization as a whole. By measuring the demonstration project in the conventional terms of health outcomes around “retention” and “adherence”, we are able to call the project an overwhelming success, especially when compared to outcomes from PrEP demonstration
projects among sex workers emerging from other settings (see for example, Cowan et al., 2018; Eakle et al., 2017). However, by reckoning with the importance of temporality, we are forced to question what comes of the hopes and anxieties of project staff and community members once a project ends and they again find themselves in a moment of uncertainty. We see here how temporary programs, such as the PrEP demonstration project, can bring influxes of funding and create excitement, but, as is the case with all research projects, is bound by the timeline of the study. Here we see success (or failure) as artificial project endpoints that must be understood in contextual terms of the life histories of interventions, and the broader histories of organizations leading them. Success is not a simple project outcome, but rather a generative social force.

What is revealed in my ethnographic account of success and care is how study staff, organizational members, community leaders, and participants alike attempt to manage and control success by attending to the fears, anxieties, excitements, and anticipations produced by the demonstration project. As noted by Benton et al. (2017) in her ethnographic fieldwork on HIV care, demands for “adherence time” draw community into relationships with organizations that are marked by the uncertainty of future resources. By taking PrEP, participants are receiving a benefit not afforded to those who came before them in an era of HIV prevention that pre-dated PrEP. Research participants are often left with an acute awareness of their reliance on international donors, and through adherence, show their indebtedness (and care) to donors and previous generations of community members alike (Benton et al., 2017).

In his work on compliance and adherence among people living with HIV, Mykhalovskiy et al. (2004) describes what they call “becoming compliant” as an accomplishment, linked to feelings of empowerment, satisfaction, and pride (p. 327). Mykhalovskiy et al. (2004) link this to the meaning that people assign to medications. In this sense, non-adherence can only be fully
understood when viewed through the lens of participants’ lives. Furthermore, adherence must be explored through the “complex and creative interplay between biomedical and other ways of knowing” (Mykhalovskiy et al., p. 326). In moving classic discourses on compliance beyond control and domination, adherence is framed as a “site where multiple forms of power–biomedical authority, population-based forms of risk governance, and liberal techniques of the self–intersect in relations of tension, negotiation, and support” (Mykhalovskiy et al., 2004, p. 318). In this way, we can link Mykhalovskiy and colleagues’ framing of adherence as a form of empowerment to the success and care that we see in the PrEP Demonstration Project.

Felder, Felt, and Penkler (2016), in their ethnography of pre- and post-care for a bariatric surgery program located in a research centre in Vienna, note how research protocols can open up (or close down) spaces for care. As in our demonstration project, the bariatric surgery program wove clinical research and care into one intervention. Felder and colleagues (2016) note how the research aimed not just at gathering data, but at providing extended care, something that was previously lacking. They illustrate how research moments, such as collecting data, create spaces to come into contact with participants and provide opportunities for care outside of research protocols. Furthermore, they note how this frequent contact worked to promote adherence and compliance to the medical intervention (in their case strict dietary regimes post-surgery, in our case daily PrEP adherence). These interventions therefore create spaces for care that extend beyond the clinical research interaction into the everyday habits and lives of participants.

Returning to Adams, Murphy, and Clarke’s (2009) notion of temporality in global public health, in their work, they states that “[a]nticipation is the palpable sense that things could be (all) right if we leverage new spaces of opportunity, reconfiguring ‘the possible’” (p. 246). This idea find resonance in Elsa Fan’s (2014) ethnography of outsourcing HIV testing to community-
based organizations for men who have sex with men in China, where she links the scaling up of HIV testing to new forms of surveillance and citizenship, but also to the survival of organizations who are struggling due to global shifts in funding priorities. Like in India, China saw a flood of funding for HIV-related initiatives in the 2000s that has since dried up, leaving organizations in need of new directions. In China, a focus on testing served to provide some sustainability. For Ashodaya, PrEP showed a similar promise that did not materialize post-demonstration project.

Although PrEP has not yet been taken up in the government program in India, in the words of Chatterjee (2004, 2011), governmental programs (or in our case research projects) do not simply produce bureaucratized and passive subjects. In postcolonial contexts, programs are generative in that they can create active, and sometimes dissident political actors who go on to make claims on the state, in what Sharma (2008) refers to as the “surprising forms of empowerment” that take shape under neoliberalism. The question that remains then, is what happens next for Ashodaya? In the anticipated state of becoming, what does it mean when people invest in a future that does not arrive, as is the case with the promise of PrEP? A future, that as Sundar Rajan (2003, p. 91) notes is “desperately in need of the services…that only the state can provide in the [quantity] and at the cost that can answer to such massive (and as yet unrecognized and unmet) demand” (in Sharma, 2008, p. 192).

Despite the celebration of Ashodaya’s PrEP Demonstration Project in global scientific circles, at the end of the 16-month study, there was no national commitment or plan to scale up PrEP in India, even though there has been a swell of demand for continued access among sex workers. Furthermore, access to PrEP has dried up for project participants, leaving Ashodaya with questions of what success means when larger global health policy spheres fail to shift into alignment. In order to “make sense” of care and success in these contexts, there is a need to look
at the echoes of past projects and how funding scarcity influence the rolling out of global health interventions. As the current PrEP intervention draws to a close, Ashodaya finds itself at yet another period of transition, and must once again make new collective demands on the state to ensure their survival.
Chapter 7. Discussion, Limitations, and Conclusion

In this thesis, I reconsidered the extraordinary project results, as defined in global health terms of “outcome indicators”, that appeared in a community-driven PrEP intervention by contextualizing the findings within the larger life history of a sex worker organization known as Ashodaya Samithi. The attempt was not to query the numbers, per se, but to illuminate the social processes that made “success” and understand how these processes unfolded across the rolling out of a biomedical intervention. In other words, my interest lies in the socialities ushered into being by the pursuit of success, and the productive force of these socialities that underlie the numbers. Going beyond biomedical universalistic logics of retention and adherence as markers of success, my ethnographic study pointed, instead, towards Ashodaya’s history of collectivization around sexual health that gave rise to new forms of health citizenship and new spaces of belonging for sex workers. While my starting point on this research was grounded in anthropological discourses of health citizenship and responsibilization, through my observations, conversations, and interviews with Ashodaya members, my theorizing eventually moved towards notions of care and temporality, which speak to how the participants and staff alike framed their involvement in the intervention and efforts to roll out PrEP and promote adherence.

My methodological approach attempts to shed light on the hidden processes that are often overlooked when presenting traditional public health metrics (see Adams, 2016). Evans and Lambert (2008), in asking the question: “Why do some community-based HIV prevention
projects succeed whereas others falter?” point to the importance of ethnographic research in uncovering the “complex and inter-dependent dynamics of context, practice, agency and power that are specific to a project and shape the course of intervention implementation in ways that may be ‘hidden’ in conventional techniques of project reporting” (p. 467). In exploring the work of the DMSC, they point towards the “private contexts of practice” that help make “success”. Similarly, I draw on ethnographic methods to reconceptualize success and bring attention to what typically gets overlooked in global health. Ethnography, as a methodological approach, helps reveal the life worlds that go unrecognized in the final reporting of "health outcomes", and yet are crucial in producing what gets quickly and uncritically recognized as success.

By highlighting community-based knowledge and processes, I aim to push beyond current discussions on “participation” and “engagement” in HIV biomedical research by revealing communities as possessing key insights for the on-the-ground making of scientific knowledge itself. While documents such as the Good participatory practice: Guidelines for biomedical HIV prevention trials (UNAIDS, 2011) provide “systematic guidance on how to effectively engage” (p. 5) with all stakeholders, “effective engagement” is often deployed in order to move public health research forward, as Peterson and Folayan (2017) state in their critique of the guidelines. But how does this version of engagement articulate with community exigencies and priorities? Alliances, such as the Global Network of Sex Work Projects (NSWP, 2016) have released their own recommendations for moving forward with PrEP, calling for the engagement of sex workers in all levels of PrEP policy and program discussions, including in the design, implementation, and monitoring of programs, stressing that the demand for PrEP must come from sex workers themselves, rather than pressure or force from governments, researchers, or funders. Sex workers and sex worker organizations must be called upon to formulate context-
specific community priorities for PrEP access and help lead these interventions. Ultimately, I argue that the extraordinary success of the Ashodaya PrEP Demonstration Project, which is tied to community innovations, laborious time investments, and careful attention to producing successful results, highlights the importance of further democratizing the role that communities can play in biomedical research.

In the first manuscript (Chapter 3), I overview the findings from the PrEP demonstration project using the conventional public health indicators of success of retention and adherence. The exceptionally high retention, in particular, is contrasted against data beginning to emerge from other PrEP research sites among sex workers globally. Ashodaya community leaders and outreach workers informed their community about PrEP, recruited a large number of participants into the study, and provided adherence support which led to high retention, with participants also reporting high adherence. This overview of findings lays the foundation of my argument that I critically interrogate in the subsequent papers in order to locate the significance of these health outcomes within larger global public health discourse.

The second manuscript (Chapter 4) explored the feasibility study that served as the first step towards undertaking the demonstration project. Learning from the infamous fallout from the early clinical trials among sex workers, demonstration projects moved forward with community involvement as an important tenant (UNAIDS, 2011). Ashodaya Samithi, as a community-led organization and a globally recognized community learning site, not only took time to inform their members about this new intervention, but perhaps most importantly, used the feasibility study as a sort of referendum to decide whether to move forward with the project. Despite critical questions about this completely unknown intervention, sex workers expressed
considerable excitement about an innovative new option in HIV prevention that spoke to community concerns about HIV risk and infection.

The next manuscript (Chapter 5) delved into the community-led processes of the demonstration project. As this paper helped to illustrate, community-organizations working with sex workers may be best positioned to implement these projects due to their capacity, connections, and trust to reach those members who stand to benefit the most from access to PrEP. In our unique study setting, Ashodaya was able to draw on their past experience in HIV prevention and treatment programs to develop a tailored roll out plan for the project, anticipating conflicts and challenges before they arose. The paper also shows how in an era of remedicalization (Nguyen et al., 2011), community organizations seize upon opportunities for funding based on donor priorities and use these resources not only to deliver agreed upon interventions, but to find ways to meaningful reengage with their members and rebuild solidarity networks. Even as donor priorities continue to shift away from community empowerment and mobilization schemes, and towards biomedical prevention interventions (Campbell, 2003), community knowledge and expertise must still be called upon in shaping and delivering interventions. Although community involvement in delivering biomedical interventions with the degree of engagement demonstrated by Ashodaya is rare, our study shows that communities, with technical support, can play leading roles in delivering clinical services and should be regarded as vital partners in planning, implementation, and monitoring when considering new prevention and treatment technologies.

In the final paper (Chapter 6), in trying to understand how notions of success, anxieties, and desires lived out in the social unfolding of the PrEP intervention, I argued that the project must be analyzed within the more intimate sphere of care, affected by the life history of
Ashodaya. In other words, instead of emphasizing adherence, I highlighted the particular role of care played by Ashodaya sex workers and the project team. This care was tied not only to the community of sex workers who make up Ashodaya, but to the careful production of evidence in the demonstration project, and care for the very survival and future of the organization. PrEP carried with it not only the possibility of recapturing the golden age of HIV interventions under Avahan’s funding, but also a renewed hope for the future of the organization. In this sense, the search for success animated through the PrEP demonstration project acted on sex workers’ hopes and imaginations of the future.

So where does that leave us now? The demonstration project officially ended in May 2018 and PrEP is not yet available through the National AIDS Control Organization’s national HIV prevention programs, with, to the best of my knowledge, no current plans to roll out PrEP. A National Strategic Plan was released in December 2017, and although stepping up prevention efforts is cited as a priority, PrEP is barely mentioned in the seven-year plan, only referenced in an annexe listing priorities for evidence generation (NACO, 2017). Ashodaya itself managed to continue to provide PrEP to 266 members through August 2018, however the overstock of PrEP that allowed that has since run out. Despite this, participants have expressed a demand for continued access to PrEP. India, at the time of writing this thesis in April 2019, is currently undergoing “the world’s largest election” considered to be a referendum on Modi’s Bharatiya Janata Party (Schmall, 2019).39 Time will tell what the outcome of this election means for the future of funding for community-based organizations and HIV prevention and treatment in India.

39 Hassan Minaj also recently dedicated an episode of his Netflix show The Patriot Act to covering the upcoming Indian election (Minaj, 2019).
In the meantime, what are the responsibilities of funders and researchers in global health? While certainly not a new question in global health research, or all research for that matter, it begs the question of what promises are made to participants who provide the “evidence” needed to inform policy and programs? Here I turn the question back to notions of responsibilization and care. While participants were expected to take PrEP, they in turn expected Ashodaya to find a way to continue providing PrEP, with Ashodaya turning to funders and research partners as sharing that responsibility to advocate at the national level. Certainly, the sex workers of Ashodaya made it clear that I needed to do my part in advocating for PrEP. That expectation was clearly and persuasively expressed to me throughout every stage of my involvement and I continue to hold that responsibility, as conversations unfold over the next steps. While funders like the Gates Foundation are eager to provide funding to test new technical and easily measurable “magic bullet” solutions to prevention and treatment (Storeng, 2014, p. 871), they often fail to take the steps necessary to negotiate with the state to advocate for access to these interventions when the data proves “successful”. However, it becomes difficult for organizations and researchers to criticize the “Gates approach”, as many remain dependent on their funding (Storeng, 2014, p. 875).

Ashodaya, as an important community voice among sex workers, has a long history of advocating for policy change and sex workers’ rights. The project has been featured in local media coverage both in Kannada and English news outlets (see for example, City Today, 2018; Star of Mysore, n.d.; The New Indian Express, 2017). Ashodaya and the demonstration project were featured prominently in the 2017 UNAIDS World AIDS Day Report, Right to Health (UNAIDS, 2017). Members of the research team have also been involved in conversations taking place at the national level. As an ally and collaborator of Ashodaya over the last decade, I
continue to reflect on my role of care and responsibility in supporting the organization both in terms of PrEP and beyond. According to Ida Susser (2010), anthropology calls for an activist approach, with engagement and partnership the foundation for most anthropologists working in the field of HIV. This is a stance that I have long adopted in my work, since my social work days, and I continue to follow this approach within all of my research activities. In her words, “[e]thnography and the method of participant observation requires personal face-to-face relations and the establishment of trust and ongoing human responsibilities” (p. S232).

Returning to the remedicalization of HIV, or what Biehl (2007) has termed the “pharmaceuticalization of public health” (p. 1100), at a time when PrEP is growing in popularity, communities globally have an important roll to play in ensuring that the HIV prevention and other health services needs of their members are met. And yet, communities are often left out of the design and delivery of biomedical interventions. In the findings from this demonstration project, we see how community knowledge can help inform strategies to predict and respond to potential challenges in rolling out new pharmaceutical interventions. At the same time, these findings move past articulations of health and therapeutic citizenship (Nguyen et al., 2007) as purely strategies of governance, by also calling on the logics of care (Mol, 2008; Rhodes et al., 2018). As Rhodes et al. (2018) state, “HIV care is transformed from a biomedical order of governance to a practice of vital care that far exceeds the virus to encompass social relationships that express new modes of sociality…” (p. 20). He goes on to warn that “[u]ndoing care beyond the virus also risks disabling how social care supports biomedical care. As we have seen, care beyond the virus is at once a more-than biomedical care that also secures biomedical care engagement” (p.21). I would argue that communities themselves are best able to “transform” biomedical care into forms of social care.
Limitations

There are several potential limitations to the work I present in this thesis. First, the work presented only includes interviews with people connected to the organization, either as participants taking PrEP or as project staff and community leaders involved in running the project. Although I attempted to interview individuals who refused to participate in the demonstration project, no one agreed to participate in these interviews. It was difficult to come up with a potential list of participants who refused to participate, as such a large number of Ashodaya members were enrolled in the study. Furthermore, outreach workers largely recruited participants for the main PrEP demonstration project in the field, with those who refused PrEP less likely to be connected to the organization. Community researchers did conduct interviews with ineligible participants—those who underwent screening but could not participate for health reasons. While those findings are not presented in this thesis, they generally showed that most participants understood why they could not participate, had received follow up care from Ashodaya, and although disappointed at not receiving PrEP, continued to engage with the organization and other members.

Second, it is important to note that although the involvement of community members as researchers has the potential to create concerns surrounding privacy and confidentiality, past research in this setting has found that participants are generally more comfortable speaking with a trusted community insider (see Lazarus et al., 2012; Lorway et al., 2014). Furthermore, research has shown that the involvement of community researchers can facilitate the disclosure of sensitive information and improve the quality of data (Coupland et al., 2005; Schnarch, 2004). As participants spoke both about positive and negative experiences surrounding PrEP, it is likely that they felt comfortable disclosing their views during interviews. The same can be said in
regards to my interviews with staff members and community leaders, including those done with the assistance of a team member for the purpose of translation. Throughout my visits, the project team appeared happy to meet for interviews, which sometimes lasted hours. Some participants would come find me again after the interview to add a detail that they felt they had forgotten to address, indicating that they took their participation in the research extremely seriously.

Finally, participants in our study were drawn from members of a well-established community organization, and their connection to the organization shaped their understanding of HIV risk and prevention (Lorway & Khan, 2014), as well as their interest in participating in the demonstration project. As this research occurred within the context of a well-established sex worker collective, the findings of this study may not be generalizable to other settings where sex work occurs, however, important insights about the role of community in biomedical research interventions can be taken up in ways that make sense in other contexts.

**Conclusion**

While HIV prevention strategies have undergone a shift towards the biomedical, the papers in this thesis illustrate how communities can and should play a role in designing and implementing these clinical interventions. Instead of forgetting the success of past community mobilization interventions, these very same organizations hold valuable wisdom and community know-how to help build awareness and support their members in accessing these new biomedical prevention options. The Ashodaya PrEP Demonstration Project, through their community-led strategy, demonstrated vastly different results than those seen in other settings among sex workers, setting an imperative for the involvement of community. As the project has officially ended, demand for PrEP continues to be high. Despite continued interest in PrEP, availability
remains limited in the Indian context and the government has yet to integrate PrEP into its existing HIV prevention packages. Based on Ashodaya’s connections and past successes in informing health policies at the national level, it is hopeful that the findings from this project will help inform the development of national PrEP guidelines. We see here how temporary programs, such as the PrEP Demonstration Project, can bring influxes of funding and create excitement, but, as is the case with all research projects, are bound by the timeline of the study. As the current PrEP intervention draws to a close, we will again see what comes next for Ashodaya, as the organization again finds itself in a period of transition and must once again make new collective demands on the state.
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Appendix A: Consent Form for Project Staff and Academic Researchers

Ashodaya Samithi, Mysore

and

University of Manitoba, Winnipeg, Canada

The Life Cycle of a PrEP Demonstration Project among Female Sex Workers in India: An Ethnographic Exploration of a Global Health Intervention

Consent Form for Key Informant Interviews

Place IDI held ____________________________________________________________

Interviewer Name ________________________________________________________

Date of interview: DAY MONTH YEAR

Principal Investigator:

Lisa Lazarus, PhD Candidate, University of Manitoba

Namaskar. My name is …………………. I am requesting you to participate in a research study. Please take your time to review this consent form. You may ask any questions that you have. You may take your time to make your decision about participating in this study, and you may discuss it with your friends or family before you make your decision. This consent form may contain words that you do not understand. Please ask me to explain any words or information that you do not clearly understand.

Purpose of study

The purpose of the PrEP study, which is a demonstration project, is to provide a better understanding of a new HIV prevention method called pre-exposure prophylaxis (PrEP). PrEP involves individuals who do not have HIV taking tablets each day which contain drugs that are
effective against HIV. Therefore, if they are exposed to HIV through sexual contact, they will have less chance of becoming infected with HIV. This demonstration project will provide information on how to provide PrEP effectively within existing HIV preventive intervention programs for female sex workers in India, and will potentially have a significant impact on similar efforts for sex workers globally.

Alongside the larger demonstration project, we are conducting qualitative interviews with project researchers and staff to better understand the demonstration project. We hope that by speaking to you about the successes and challenges of implementing this type of project, as well as its effects on the community, that we can better inform recommendations for the implementation of PrEP among female sex workers in India.

**Study procedures**

We will be interviewing some of the core staff, community mobilizers, researchers, and project implementers to better understand the demonstration project. If you take part in this part of the study, the following will occur:

- You will be asked some questions about your ideas and feelings regarding the project, your role in the project, any challenges that you faced and how you overcame them, and how the project is impacting the community.
- In this interview you can feel free to express your ideas and thoughts regarding the topics mentioned above.
- If you agree, the interview will be tape (audio) recorded for the purpose of transcription. If not, we will make notes.
- The interview will take approximately 45 minutes to 1 hour.
- The study will maintain complete anonymity of the information shared by you. All the materials which are used to document the information provided by you, including tape recordings, will be kept confidential and destroyed after the completion of the study, within 5 years.

**Risks and Discomforts**

There is a possibility that answering questions about your opinions on the project and your work could make you feel uncomfortable or stressed.

**Benefits**

There may or may not be direct benefit to you from participating in this study. We hope that the information learned from this study will benefit people at risk for HIV infection in the future.
Costs

There will be no cost to you for participating in the study.

Payment for participation

There is no compensation for participating in the study.

Confidentiality

Information gathered in this research study may be published or presented in public fora. However your name and other identifying information will not be used or revealed. We will completely maintain your anonymity by not recording on the interview guide any information which can later be used to identify you. Upon participation in the study, the names and other identifiers of all respondents will be deleted from any log of study participants that might have been prepared for the recruitment process.

The Research Ethics Board of the University of Manitoba and the research ethics boards in Kolkata may review tapes and/or transcripts related to the study for quality assurance purposes.

Voluntary Participation/Withdrawal from the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect you in any way, including your work.

Questions

You are free to ask any questions that you may have about your treatment and your rights as a research participant. If any questions come up during or after the study contact

Lisa Lazarus through Dr. Sushena Reza-Paul in Mysore, telephone XXXXXXXXXXXXXX

For questions about your rights as a research participant, you may contact [redacted] of the Institutional Ethical Review Board at DMSC in Kolkata, telephone XXXXXXXXXXXXXX. You will be reimbursed for any telephone costs incurred.

Please do not give consent for the interview unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.
Statement of Consent

I have read/been read this consent form. I have had the opportunity to discuss this research study with the study staff. I have had my questions answered by them in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential. I authorize review of any audio tapes or transcripts that relate to this study by the Research Ethics Board of University of Manitoba and the ethics boards in Kolkata for quality assurance purposes.

By signing this consent form, I am not waiving any of my legal rights as a participant in this study, nor releasing the investigators or the sponsor from their legal and professional responsibilities.

Participant agrees to participate in this research study and to answer the questions asked.

Yes ☐ No ☐

Participant agrees to have the interview tape-recorded.

Yes ☐ No ☐

I, the undersigned, have witnessed the consent process for the participant and believe that the participant has understood and has knowingly given consent to be interviewed.

Signature of the witness: ___________________ Name of witness: _______________________

I, the undersigned, have fully explained the relevant details of this research study to the participant and believe that the participant has understood and has knowingly given her/his consent to be interviewed.

Printed Name: _________________________ Date _________________

Signature of the interviewer that participant agrees to participate: ______________________
Appendix B: Consent Form for Participants

Ashodaya Samithi, Mysore

and

University of Manitoba, Winnipeg, Canada

The Life Cycle of a PrEP Demonstration Project among Female Sex Workers in India: An Ethnographic Exploration of a Global Health Intervention

Consent Form for Participants Interviews

District name ________________________________________________
Village/urban block ____________________________________________
Taluka ______________________________________________________
Place IDI held ________________________________________________
Interviewer Name ______________________________________________

Date of interview:        DAY        MONTH        YEAR

To be administered in a Kannada

Principal Investigator:

Lisa Lazarus, PhD Candidate, University of Manitoba
Namaskar. My name is ………………… I am requesting you to participate in a research study. Please take your time to review this consent form. You may ask any questions that you have. You may take your time to make your decision about participating in this study, and you may discuss it with your friends or family before you make your decision. This consent form may contain words that you do not understand. Please ask me to explain any words or information that you do not clearly understand.

Purpose of study

The purpose of the PrEP study, which is a demonstration project, is to provide a better understanding of a new HIV prevention method called pre-exposure prophylaxis (PrEP). PrEP involves individuals who do not have HIV taking tablets each day which contain drugs that are effective against HIV. Therefore, if they are exposed to HIV through sexual contact, they will have less chance of becoming infected with HIV. This demonstration project will provide information on how to provide PrEP effectively within existing HIV preventive intervention programs for female sex workers in India, and will potentially have a significant impact on similar efforts for sex workers globally.

Alongside the larger demonstration project, we are conducting qualitative interviews with participants taking PrEP to better understand their experiences with PrEP. We hope that by speaking to you about your decision to participate in the demonstration project and your experiences with PrEP that we can better inform recommendations for the implementation of PrEP among female sex workers in India.

Study procedures

Approximately 40 female sex workers will be invited to participate in individual in-depth interviews. If you take part in this part of the study, the following will occur:

- You will be asked some questions about your decision to take PrEP, and your experiences taking PrEP throughout the demonstration project. We will ask you about any challenges and benefits you’ve experienced while taking PrEP. We will also ask you about how taking PrEP has impacted any of your relationships, either personal or professional and what affects PrEP has had on the community.
- In this interview you can feel free to express your ideas and thoughts regarding the topics mentioned above.
- If you agree, the interview will be tape (audio) recorded for the purpose of transcription. If not, we will make notes.
- The interview will take approximately 30-45 minutes.
• The study will maintain complete anonymity of the information shared by you. All the materials which are used to document the information provided by you, including tape recordings, will be kept confidential and destroyed after the completion of the study, within 5 years.

**Risks and Discomforts**

There is a possibility that answering personal questions about sexual activity and your personal habits could make you feel uncomfortable, embarrassed or stressed.

**Benefits**

There may or may not be direct benefit to you from participating in this study. We hope that the information learned from this study will benefit people at risk for HIV infection in the future.

**Costs**

There will be no cost to you for participating in the study.

**Payment for participation**

We will compensate you for your travel costs (approximately 200inr).

**Confidentiality**

Information gathered in this research study may be published or presented in public fora. However your name and other identifying information will not be used or revealed. We will completely maintain your anonymity by not recording on the interview guide any information which can later be used to identify you. Upon participation in the study, the names and other identifiers of all respondents will be deleted from any log of study participants that might have been prepared for the recruitment process.

The Research Ethics Board of the University of Manitoba and the research ethics boards in Kolkata may review tapes and/or transcripts related to the study for quality assurance purposes.
Voluntary Participation/Withdrawal from the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect you in any way, including your access to health care.

Questions

You are free to ask any questions that you may have about your treatment and your rights as a research participant. If any questions come up during or after the study contact Lisa Lazarus through Dr. Sushena Reza-Paul in Mysore, telephone XXXXXXXXXXXXXX

For questions about your rights as a research participant, you may contact [redacted] of the Institutional Ethical Review Board at DMSC in Kolkata, telephone XXXXXXXXXXXXXX. You will be reimbursed for any telephone costs incurred.

Please do not give consent for the interview unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.
Statement of Consent

I have read/been read this consent form. I have had the opportunity to discuss this research study with the study staff. I have had my questions answered by them in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential. I authorize review of any audio tapes or transcripts that relate to this study by the Research Ethics Board of University of Manitoba and the ethics boards in Kolkata for quality assurance purposes.

By signing this consent form, I am not waiving any of my legal rights as a participant in this study, nor releasing the investigators or the sponsor from their legal and professional responsibilities.

Participant agrees to participate in this research study and to answer the questions asked.

Yes ☐ No ☐

Participant agrees to have the interview tape-recorded.

Yes ☐ No ☐

I, the undersigned, have witnessed the consent process for the participant and believe that the participant has understood and has knowingly given consent to be interviewed.

Signature of the witness: ____________________ Name of witness: ____________________

I, the undersigned, have fully explained the relevant details of this research study to the participant and believe that the participant has understood and has knowingly given her/his consent to be interviewed.

Printed Name: ____________________ Date _________________

Signature of the interviewer that participant agrees to participate: ____________________
Appendix C: Consent Form for Ineligible/Refused Participants

Ashodaya Samithi, Mysore

and

University of Manitoba, Winnipeg, Canada

The Life Cycle of a PrEP Demonstration Project among Female Sex Workers in India: An Ethnographic Exploration of a Global Health Intervention

Consent Form for Ineligible/Refused Interviews

To be administered in a Kannada

Principal Investigator:
Lisa Lazarus, PhD Candidate, University of Manitoba
Namaskar. My name is ………………… I am requesting you to participate in a research study. Please take your time to review this consent form. You may ask any questions that you have. You may take your time to make your decision about participating in this study, and you may discuss it with your friends or family before you make your decision. This consent form may contain words that you do not understand. Please ask me to explain any words or information that you do not clearly understand.

**Purpose of study**

The purpose of the PrEP study, which is a demonstration project, is to provide a better understanding of a new HIV prevention method called pre-exposure prophylaxis (PrEP). PrEP involves individuals who do not have HIV taking tablets each day which contain drugs that are effective against HIV. Therefore, if they are exposed to HIV through sexual contact, they will have less chance of becoming infected with HIV. This demonstration project will provide information on how to provide PrEP effectively within existing HIV preventive intervention programs for female sex workers in India, and will potentially have a significant impact on similar efforts for sex workers globally.

Alongside the larger demonstration project, we are conducting qualitative interviews with some female sex workers who are not taking PrEP. We hope that by speaking to you about your interactions with the project that we can better inform recommendations for the implementation of PrEP among female sex workers in India.

**Study procedures**

Female sex workers who have decided not to participate in the PrEP Demonstration Project are being asked to participate in brief individual interviews. If you take part in this part of the study, the following will occur:

- You will be asked some questions about your interactions with the PrEP demonstration project and the reasons why you are not participating in the study.
- In this interview you can feel free to express your ideas and thoughts regarding the topics mentioned above.
- If you agree, the interview will be tape (audio) recorded for the purpose of transcription. If not, we will make notes.
- The interview will take approximately 5-15 minutes.
- The study will maintain complete anonymity of the information shared by you. All the materials which are used to document the information provided by you, including tape recordings, will be kept confidential and destroyed after the completion of the study, within 5 years.
Risks and Discomforts

There is a possibility that answering personal questions about sexual activity and your personal habits could make you feel uncomfortable, embarrassed or stressed.

Benefits

There may or may not be direct benefit to you from participating in this study. We hope that the information learned from this study will benefit people at risk for HIV infection in the future.

Costs

There will be no cost to you for participating in the study.

Payment for participation

We will compensate you for your travel costs (approximately 200INR).

Confidentiality

Information gathered in this research study may be published or presented in public fora. However your name and other identifying information will not be used or revealed. We will completely maintain your anonymity by not recording on the interview guide any information which can later be used to identify you. Upon participation in the study, the names and other identifiers of all respondents will be deleted from any log of study participants that might have been prepared for the recruitment process.

The Research Ethics Board of the University of Manitoba and the research ethics boards in Kolkata may review tapes and/or transcripts related to the study for quality assurance purposes.

Voluntary Participation/Withdrawal from the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time. Your decision not to participate or to withdraw from the study will not affect you in any way, including your access to health care.
**Questions**

You are free to ask any questions that you may have about your treatment and your rights as a research participant. If any questions come up during or after the study contact

Lisa Lazarus through Dr. Sushena Reza-Paul in Mysore, telephone XXXXXXXXXXXXXXX

For questions about your rights as a research participant, you may contact [redacted] of the Institutional Ethical Review Board at DMSC in Kolkata, telephone XXXXXXXXXXXXXXX. You will be reimbursed for any telephone costs incurred.

Please do not give consent for the interview unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.
Statement of Consent

I have read/been read this consent form. I have had the opportunity to discuss this research study with the study staff. I have had my questions answered by them in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will be kept confidential. I authorize review of any audio tapes or transcripts that relate to this study by the Research Ethics Board of University of Manitoba and the ethics boards in Kolkata for quality assurance purposes.

By signing this consent form, I am not waiving any of my legal rights as a participant in this study, nor releasing the investigators or the sponsor from their legal and professional responsibilities.

Participant agrees to participate in this research study and to answer the questions asked.

Yes ☐ No ☐

Participant agrees to have the interview tape-recorded.

Yes ☐ No ☐

I, the undersigned, have witnessed the consent process for the participant and believe that the participant has understood and has knowingly given consent to be interviewed.

Signature of the witness: _______________________ Name of witness: ___________________

I, the undersigned, have fully explained the relevant details of this research study to the participant and believe that the participant has understood and has knowingly given her/his consent to be interviewed.

Printed Name: _____________________________ Date _____________________

Signature of the interviewer that participant agrees to participate: _______________________
Appendix D: Project Staff Interview Guide

Key Informants: Demonstration Project Staff (Project implementers, managers and coordinators; community mobilizers; clinicians, counsellors, and referral health providers)

Name: _______________________
Participant ID: __________________
Role at Ashodaya: __________________
Number of years with Ashodaya: __________________

Script: Thank you for agreeing to talk with me today. We are interested in learning more about your experiences and challenges working on the PrEP demonstration project and how you were able to overcome them.

1. Can you tell me about the different steps of the PrEP project and where you are involved?

2. What kind of challenges did you and your team encounter during:
   a) the initial planning and set up of the demonstration, and
   b) the recruitment and enrolment phase (including lab testing and confirmation)

   [*INTERVIEWER MAKES A LIST]

3. How did you and the team respond to these challenges?
   [*INTERVIEW PROBES AROUND EACH LIST ITEM]

4. How has this project differed from other projects? What have you learned?

5. In your opinion, how has this projected affected community dynamics?
Appendix E: Participant Interview Guide

Date: ____________________
Site: ____________________ Participant unique ID number: __________________

TI number: __(1: FSW1 TI, Mysore, 2: FSW2 TI, Mysore, 3: Rural CC TI, Mysore, 4: FSW TI, Mandya)

Name and designation of person completing this form: ____________________

Script: You have been selected as one of 750 people to participate in the PrEP demonstration study. We are interviewing some of the participants to find out more about their experiences with taking a daily pill known as PrEP. The questions that I am going to ask you don’t have right or wrong answers. You can skip any questions that you don’t want to answer.

1. Can you please tell me about why you decided to take PrEP as part of this project?
   - What influenced your decision to take PrEP?
   - Did you feel any pressure to take/not take PrEP?

2. Who knows that you are taking PrEP?
   - What do others think about you taking PrEP (probe for friends, other community members, clients, partners/boyfriends/husbands, project staff, health care workers)

3. How do you access PrEP?
   - Can you tell me why you chose this delivery method?

4. Please describe any difficulties/benefits while taking PrEP.
   [PROBE SEPERATELY FOR DIFFICULTIES AND BENEFITS]
   - How has PrEP impacted your professional life (i.e., work, interactions with other community, brokers, clients)?
   - How has PrEP impacted your personal life (i.e., with partners, boyfriends, husbands, family)?
   - How was PrEP influenced your use of other HIV prevention strategies (i.e., condoms)?

5. Please describe how you fit taking PrEP into your daily routine.
   - Do you have any difficulties taking PrEP every day?

6. Up until this point, do you have any worries about taking PrEP as part of this project?
   *Probe: Cost, effectiveness, clinic visits, side effects, access to the medication, storing medication, stigma, etc.*
7. In your opinion, how do you think PrEP has affected the whole community?

8. What else would you like to say about your experiences with PrEP? Is there anything else that you would like me to know?
Appendix F: Ineligible Interview Guide

Date: __________________________

Site: __________________________ Participant unique ID number: __________________

TI number: (1: FSW1 TI, Mysore, 2: FSW2 TI, Mysore, 3: Rural CC TI, Mysore, 4: FSW TI, Mandya)

Name and designation of person completing this form: ________________________________

Script: A number of people who have been screened are not able to continue with the study. We hope that we can ask you a few questions to understand how not being selected for this study at this time has affected you?

<table>
<thead>
<tr>
<th>#</th>
<th>Topic</th>
<th>Question</th>
<th>Answer choices</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Age</td>
<td>How old are you?</td>
<td>Years ________</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Years in sex work</td>
<td>How many years have you been in sex work?</td>
<td>Number ______</td>
<td>Put 0 if less than 1 year</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>97. Refused</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Age started sex work</td>
<td>How old were you when you first started selling sex?</td>
<td>Number ______</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>97. Refused</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Registration</td>
<td>How many years have you been registered with DMSC/Ashodaya?</td>
<td>Number ______</td>
<td>Put 0 if less than 1 year</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>97. Refused</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Sex work location</td>
<td>Where do you usually practice sex work?</td>
<td>______City/town/village/neighborhood</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix F

**Mobility**
In the past month, did you spend more than 10 days away from your main city/town of residence?
1. Yes
2. No
97. Refused

**Marital status**
What is your current marital status?
1. Never Married,
2. Married,
3. Widow / Widower,
4. Divorced,
5. Separated,
97. Refused.

**Clinic visit**
In the past 3 months, have you been seen at the Ashodaya/DMSC clinic (other than for PrEP)?
1. Yes
2. No
97. Refused

1. How did you learn that you were not able to continue in this study? What happened? How do you feel about this?

2. Was Ashodaya staff able to provide the health information (like diet) or link you to the health services that you required? If not, were you able to access the services that you needed on your own?

3. How has not being able to continue in the project affected your relationship with Ashodaya staff and other community members?
   - Has not being able to continue in the project affected your access to other health services?

4. [For those who are HIV-] If your health improves, would you be interested in participating in the PrEP project?

5. In the future, would you ever be interested in participating in other Ashodaya activities that test medications?

That is the end of our interview today. Thank you so much for your time. Do you have any questions for me? 

[Answer any questions.]
Appendix G: Refused Interview Guide

Date: ________________

Site: ________________ Participant unique ID number: ________________

TI number: (1: FSW1 TI, Mysore, 2: FSW2 TI, Mysore, 3: Rural CC TI, Mysore, 4: FSW TI, Mandya)

Name and designation of person completing this form: ______________________________

Script: A number of people have decided that they do not want to participate in the study and we respect people’s rights to not participate. For our future learning, we would like to understand some of the reasons why some people want to participate and some people don’t. Can we ask you a few questions about why you decided not to take PrEP as part of this project?

<table>
<thead>
<tr>
<th>#</th>
<th>Topic</th>
<th>Question</th>
<th>Answer choices</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Age</td>
<td>How old are you?</td>
<td>Years ____</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Years in sex work</td>
<td>How many years have you been in sex work?</td>
<td>Number ____</td>
<td>Put 0 if less than 1 year</td>
</tr>
<tr>
<td></td>
<td></td>
<td>97. Refused</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Age started sex work</td>
<td>How old were you when you first started selling sex?</td>
<td>Number ____</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>97. Refused</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Registration</td>
<td>How many years have you been registered with DMSC/Ashodaya?</td>
<td>Number ____</td>
<td>Put 0 if less than 1 year</td>
</tr>
<tr>
<td></td>
<td></td>
<td>97. Refused</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Sex work location</td>
<td>Where do you usually practice sex work?</td>
<td>____ City/town/village/neighborhood</td>
<td></td>
</tr>
</tbody>
</table>
1. What were your thoughts and feelings when you were first approached about this study?

2. Can you tell me why you felt that you were unable to participate in the study?
   - What influenced your decision?
   - Is there any information that you were given during the recruitment process that influenced your decision?
   - Did you feel pressure from anyone to take or not take PrEP (boyfriend, partner, mother-in-law)? If so, can you please explain?

   **Probe:** What would have to be different (e.g., relationship status, HIV risk, daily pill vs. injection, etc.)? What would you want to know that you don’t know now?

4. In the future, would you ever be interested in participating in other Ashodaya research projects that test medications?

That is the end of our interview today. Thank you so much for your time. Do you have any questions for me? 

Answer any questions.
### Appendix H: Demographics of Interview Participants Taking PrEP at Baseline

Table 13 – Socio-demographic characteristics of qualitative study participants at baseline.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n  (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (all participants)</td>
<td>40</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>Median (Range)</td>
<td>31 (22-47)</td>
</tr>
<tr>
<td>&lt;=20</td>
<td>0 (0)</td>
</tr>
<tr>
<td>21-25</td>
<td>6 (15)</td>
</tr>
<tr>
<td>26-30</td>
<td>13 (32.5)</td>
</tr>
<tr>
<td>31-35</td>
<td>5 (12.5)</td>
</tr>
<tr>
<td>&gt;35</td>
<td>16 (40)</td>
</tr>
<tr>
<td><strong>Number of years registered with Ashodaya</strong></td>
<td></td>
</tr>
<tr>
<td>Median (Range)</td>
<td>5 (1-11)</td>
</tr>
<tr>
<td>&lt;=5</td>
<td>21 (52.5)</td>
</tr>
<tr>
<td>6-10</td>
<td>15 (37.5)</td>
</tr>
<tr>
<td>11-15</td>
<td>4 (10)</td>
</tr>
<tr>
<td><strong>Number of years in sex work</strong></td>
<td></td>
</tr>
<tr>
<td>Median (Range)</td>
<td>8 (1-20)</td>
</tr>
<tr>
<td>&lt;=5</td>
<td>18 (45)</td>
</tr>
<tr>
<td>Characteristic</td>
<td>n (%)</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>6-10</td>
<td>13 (32.5)</td>
</tr>
<tr>
<td>11-15</td>
<td>4 (10)</td>
</tr>
<tr>
<td>&gt;15</td>
<td>5 (12.5)</td>
</tr>
</tbody>
</table>

**Education**

<table>
<thead>
<tr>
<th>Education</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Illiterate</td>
<td>21 (52.5)</td>
</tr>
<tr>
<td>Literate</td>
<td>19 (47.5)</td>
</tr>
</tbody>
</table>

**Marital status**

<table>
<thead>
<tr>
<th>Marital status</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never married</td>
<td>1 (2.5)</td>
</tr>
<tr>
<td>Married</td>
<td>18 (45)</td>
</tr>
<tr>
<td>Widow/divorced/separated</td>
<td>21 (52.5)</td>
</tr>
</tbody>
</table>