Aligning Business and Public Health Needs: Assessing the Customer Value Proposition of an HIV Pre-Exposure Prophylaxis Adherence Startup

ALIGNING BUSINESS AND PUBLIC HEALTH NEEDS: ASSESSING THE CUSTOMER VALUE PROPOSITION OF AN HIV PRE-EXPOSURE PROPHYLAXIS ADHERENCE STARTUP

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ABSTRACT

Entrepreneurship plays a major role in developing innovative medical technologies that contribute to better public health; however, most entrepreneurs fail to scale their innovations. One of the most commonly cited reasons for startup failure is the lack of customer need. Therefore, during the early stages of the startup lifecycle, entrepreneurs must focus on achieving product-market fit by developing robust value propositions that will enable early market success.

The goal of this Doctor of Public Health (DrPH) thesis is to assess the challenges and opportunities associated with a host organization's value proposition for its product offering. The host organization for this project, UrSure, Inc., is an early-stage startup established at the Harvard Innovation Labs seeking to improve adherence to HIV pre-exposure prophylaxis (PrEP) medications through the use of a novel diagnostic test. As part of this doctoral project, I took a full-time position as Director of Business Development at UrSure from June 2018 to March 2019. This experiential learning, combined with an interdisciplinary review of entrepreneurship and public health literature, informed the development of a qualitative research protocol to understand the needs, opportunities, and purchasing behaviors of customers in a key market segment, 340B clinics. I interviewed thirteen health care providers at 340B clinics that

offer PrEP services and used thematic analysis to uncover three global themes that provide insight on UrSure's customer value proposition.

From the global themes, I distilled implications for practice in the form of three strategic recommendations to help UrSure improve its chances of achieving entrepreneurial success. The first recommendation is to conduct ongoing customer discovery research. The second recommendation is to consider reframing the value proposition to more aptly meet the unmet needs of potential customers. The third recommendation is to continue generating evidence on the efficacy and utility of PrEP adherence testing. This thesis also presents important lessons learned that can inform customer development strategies at other health care startups to increase the likelihood of successfully commercializing impactful public health interventions.

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DEDICATION

I dedicate this thesis to my loving parents, Nayyar Shaheen Bahalim and Abdul Naeem Bahalim, who gave me the freedom to explore the world and whose sacrifices enabled me to pursue a better life through education.

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INTRODUCTION

Entrepreneurship plays a major role in developing innovative medical technologies that contribute to better public health (Productivity Commission, 2005). Nevertheless, translating scientific research into realized applications and commercializing them for public health impact is a challenging endeavor (Burns, 2005). This is compounded by the fact that the vast majority of entrepreneurs fail to scale their innovations, most frequently citing a lack of customer need as the primary reason for startup failure (CB Insights, 2019). The high prevalence of entrepreneurial failure highlights inefficiencies in developing critical health care technologies that have the potential for significant, positive public health impact.

While many barriers exist in the process of commercializing health care technologies, this Doctor of Public Health (DrPH) thesis focuses on the customer development challenges faced by UrSure, Inc., an early-stage health care startup with a novel public health intervention to improve adherence to medication that prevents HIV. As part of this doctoral project, I took a full-time position as Director of Business Development at UrSure for nine months (June 2018-March 2019). Through this practical experience, and combined with my interdisciplinary research and reflections, I aim to highlight the challenges and opportunities of UrSure's customer value proposition for its adherence test among a key customer segment. A compelling value proposition is critical for obtaining paying customers; and without whom, a startup idea is just that, an unrealized idea—or a lost opportunity to positively impact society (Kander, 2014).

The motivation for this project comes from the fact that HIV continues to be a worldwide public health crisis despite the availability of tools, resources, and technologies to reverse the trends of this epidemic. There are over 37 million people currently living with HIV/AIDS globally (World Health Organization, 2018a). In the U.S. alone, there are an estimated 1.1 million people living with HIV, and many of them do not know they are infected; moreover, in 2018, more than 38,000 Americans became newly infected with HIV (U.S. Department of Health & Human Services, 2020). Anti-retroviral therapies (ARTs) have been developed to treat patients living with the virus, and a specific combination of these medications can be used to prevent the transmission of the virus to uninfected people (i.e., those with an HIV-negative status). This type of prevention is known as pre-exposure prophylaxis (PrEP), and in 2012, the U.S. Food and Drug Administration (FDA) approved Truvada®, a combination of two HIV medicines (tenofovir and emtricitabine) produced by Gilead, as PrEP medication for adults (U.S. Food & Drug Administration, 2012). Since September 2015, the World Health Organization (WHO) has been recommending PrEP for people at substantial risk of HIV infection as part of comprehensive prevention programs (World Health Organization, 2018b).

PrEP has been shown in studies to reduce the risk of acquiring HIV in men and women by over 90% (Grant et al., 2010). The medication comes as a once-daily dose and must be taken consistently in order to be effective. Evidence also shows that lower adherence is associated with low or no protection (PrEPWatch, 2015). In order to address non-adherence, health care providers must determine which patients are taking their

medications and which are not. Until recently, the only lab tests available to measure adherence were lengthy and complicated blood or hair tests, considered unappealing to most patients (Hicks, 2018).

There are also major cost implications for using a drug like Truvada. In 2017, the cost of this drug in the U.S. was approximately $12,600 per patient per year (Adamson et al., 2019). An estimated 225,000 individuals were on PrEP in 2018 in the U.S. (Pebody, 2018), but there were 1.1 million individuals estimated as being at risk of contracting HIV and recommended to be on the medication in the U.S. in 2015 (Smith et al., 2018). Based on these estimates, the total annual cost of administering this drug, in the U.S. alone, could range from an estimated current cost of $2.8 billion ($12,600 x 225,000) for only existing users to a projected total of $13.9 billion ($12,600 x 1.1 million) for existing users and at-risk individuals combined. Such a high price tag calls for commensurate returns in the form of public health benefit through the medication's efficacy.

In 2014, the two clinician founders of UrSure sought out techniques to measure adherence to PrEP, and they developed a urine test that can be implemented in clinical practice. The company commercialized a laboratory-based urine drug test and is currently developing a point-of-care (POC) rapid test, anticipated to launch in 2020. Prior to the existence of this test, clinical care providers had no practical way of objectively measuring HIV/ PrEP medication adherence. They could survey patients, who typically provide inaccurate or incomplete recollections when self-reporting adherence (Kagee & Nel, 2012), or they could use a proxy measure like pharmacy prescription pickup data. Alternatively, in the case of clinical research, they could request one-off blood plasma or

dried blood spot tests to be analyzed in a research laboratory (Hicks, 2018; Lam & Fresco, 2015). By successfully scaling up the use of UrSure's new test at clinics offering PrEP, there may be a chance to improve the efficacy of PrEP in curbing the HIV epidemic while reducing overall costs to the health system.

The company remains in an early stage, without significant external investments (e.g., Series A funding) or substantial sales traction. Successful scale up of the UrSure test depends fundamentally on communicating a compelling customer value proposition. UrSure must ensure that its product helps clinics and health care providers solve some significant problem, creating sufficient value for them to induce the purchase of the offering. Once the company has identified early customers and the potential value created for them, it can move on to growing the customer base into a critical mass of adopters that will enable future growth.

The primary goal for this thesis was to assess the challenges and opportunities associated with UrSure's customer value proposition among a key customer segment in order to develop strategic recommendations for the company. To achieve this, I applied a combination of my experiential learning at the company, a review of extant literature, and a series of customer interviews to develop a deeper understanding of the needs, opportunities, and purchasing behaviors of core customers. This shaped my ability to assess the company's value proposition and provide recommendations to improve the likelihood of business success.

This thesis is organized into the following sections: Background, Experiential Learning, Literature Review, Methods, Analysis, Results, and Conclusion. The Background section provides the motivation for the research, an overview of the host organization, a description of my role, and other information relevant to the goals of this project. The Experiential Learning section presents the key takeaways from my experience of working full-time at the host organization. The Literature Review provides a summary of relevant literature on entrepreneurship and adoption of innovation in health care. The Methods section outlines the motivations for using qualitative research, how the interviews were developed, and the means for analyzing the results. The Analysis section describes the process of conducting the thematic analysis and the presents the emergent findings. The Results section discusses implications for practice, strategic recommendations for UrSure, reflections on the research methodology, and broader lessons for health care entrepreneurship. Lastly, the Conclusion section offers a summary of the project and considerations for future work.

BACKGROUND

This purpose of this section is to provide an overview of the project, pertinent information regarding HIV and PrEP, and background on the host organization. In the Project Overview section, I describe why I have undertaken this doctoral project and the central motivating framework used. I also introduce the intended project goals and strategy. In the Background on HIV and PrEP section, I provide a high-level summary of HIV as a public health problem and an overview of PrEP as a prevention tool. Finally, in the Host Organization section, I present a brief history of UrSure, an overview of my role, and descriptions of target customer segments.

Project Overview

Motivation for Research

The framework for change for this doctoral project parallels the mission of the Doctor of Public Health (DrPH) degree program. The DrPH program trains public health leaders to translate knowledge into public health impact. Keeping this idea in mind, I have focused this project on the commercialization of life sciences technology that can lead to public health impact, as I have illustrated in the schematic diagram in Figure 1. At one end of the continuum, there are life sciences innovations that are rooted in basic science research. At the other end, there is public health impact, which is rooted in fulfilling public health need. In order to go from innovation to addressing public health need, medical technologies typically follow the commercial innovation ecosystem

pathway, which is rooted in business. This project is concerned with the entrepreneurial model within this commercialization pathway, in which startups drive the development and implementation of new technologies.

As will be described in subsequent sections of this thesis, there are important business development challenges, such as identifying and aligning market need, that must be overcome in order to develop a new product or service that can impact public health. By synthesizing my experiential learning at the host organization, understanding of fundamental entrepreneurship concepts, and qualitative research, I hope to help a health care startup address business development challenges that make it so difficult for most entrepreneurs to succeed. This work is intended to support the venture in its mission to achieve public health impact, and it gives a data point for the application of entrepreneurial theories in a real world, practical public health context.

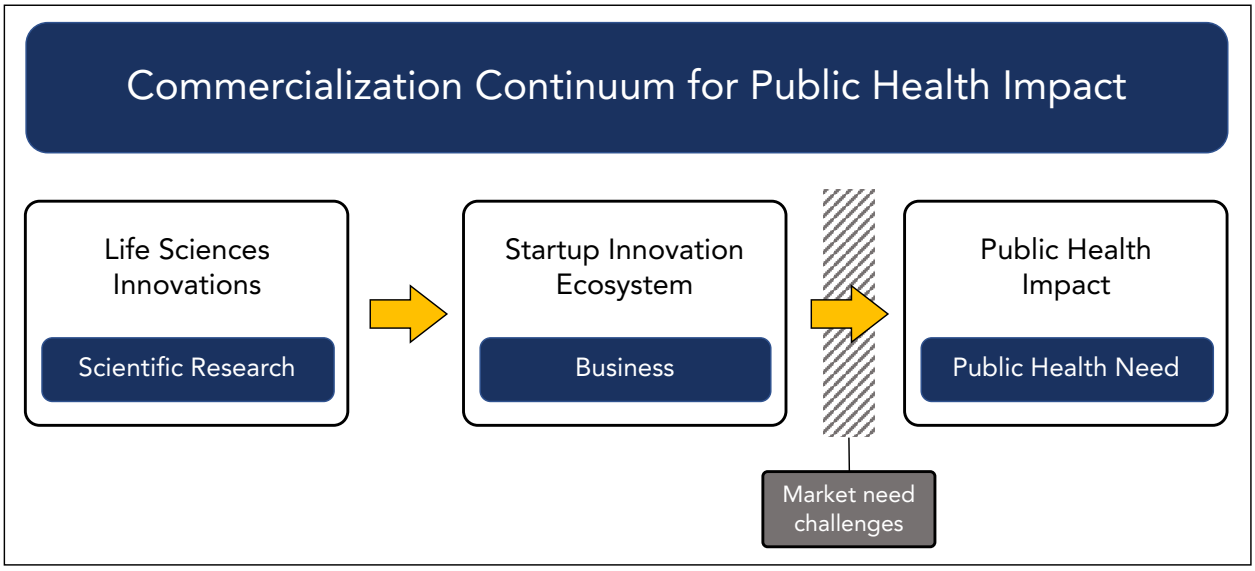

Figure 1: Conceptual pathway for commercializing life sciences technologies for public health impact.

Project Goals & Strategy

The strategic objective of this doctoral project is to provide recommendations that can help UrSure advance on its path to scale and realize public health impact. I have used the customer development model to better understand the venture's current stage of growth and identified that establishing a robust customer value proposition remains a critical step. Therefore, the operational goal of this project is to assess the challenges and opportunities associated with UrSure's customer value proposition within a key customer segment, 340B clinics. In order to accomplish this goal, I synthesize: my experiential learning from a nine-month stint as Director of Business Development at UrSure; an interdisciplinary literature review covering entrepreneurship and health care innovation; and a qualitative research study of potential UrSure customers in a key customer segment.

Background on HIV and PrEP

HIV remains a public health crisis, with more than 900,000 deaths globally in 2017 (Institute for Health Metrics and Evaluation, 2020). While there is still no cure for HIV, there have been several anti-retroviral therapies (ART) developed that suppress the virus and allow patients to live longer without developing AIDS. Most public efforts in the early 2000s and continuing today have focused on increasing access to these treatments for HIV-positive people while also promoting the use of condoms as the main strategy for prevention. However, prevention efforts have received more attention as the costs of the disease have become clearer. For instance, in the U.S., one study has estimated that

averting one HIV infection can save $229,800 in lifetime medical costs alone (Schackman et al., 2015).

Although ARTs allow individuals infected with HIV to manage the disease like a chronic condition, acquiring HIV is still a highly undesirable outcome. The virus increases the chances of risk of additional disease conditions, which may also increase the chances of death. Moreover, treatment protocols require lifelong clinic visits as well as medications that can have many unpleasant side effects (e.g., nausea, diarrhea, pain, etc.) (U.S. Centers for Disease Control and Prevention, 2020). Additionally, there are many social and psychological consequences that further exacerbate the negative impact on quality of life triggered by an HIV diagnosis (Chambers et al., 2015; Sowell et al., 1997). Therefore, prevention is critical, and it requires uninfected people who are at risk to ensure appropriate compliance with prevention tools.

As described in the introduction, pre-exposure prophylaxis (PrEP) refers to the use of HIV anti-retroviral medication to prevent HIV-negative people from becoming infected with the virus. Several studies show that PrEP is safe to use and effective at preventing HIV infections: both men and women who take PrEP consistently, once a day, reduce their risk of getting HIV by over 90% (Grant et al., 2010). The recommendation is one dose per day for everyone using PrEP, and adherence is essential. Lower adherence has been associated with low or no protection, and taking extra pills does not provide extra protection (PrEPWatch, 2015). Measuring adherence not only helps generate evidence on effectiveness of this drug, but when combined with counseling, it can also help improve adherence (Laufs et al., 2011).

PrEP is not a cure for HIV, nor is it a vaccine for HIV. Moreover, it does not provide protection against other sexually transmitted diseases (e.g., herpes, gonorrhea, and syphilis). While PrEP does not prevent pregnancy, it may be taken by pregnant and lactating women. Recent studies also show that PrEP does not reduce the effectiveness of birth control and does not affect the use of hormones taken by transgender people (Nanda et al., 2017; Radix, 2017). The drug can cause mild side effects, including stomach pain, diarrhea, and headache, but these tend to go away in the short term (PrEP REP project, 2018).

In order to obtain a prescription for PrEP, patients must be HIV-negative, have normal functioning kidneys, and commit to quarterly visits to their care providers that include laboratory screening for HIV and sexually transmitted infections (STIs) (PrEP REP project, 2018). Resistance to a PrEP drug can arise if a person with undiagnosed HIV starts using PrEP. It can also occur if someone takes PrEP inconsistently, or acquires HIV without knowing it, and continues taking PrEP. This is why providers require HIV testing before they refill PrEP prescriptions (AVAC, 2018). In case a person on PrEP becomes infected with a drug-resistant strain of HIV, alternative treatment regimens usually come with worse side effects and higher costs (Krentz et al., 2013). In practice, there is limited evidence of an association with low PrEP adherence and the development of drug resistance, as this has been reported as a rare outcome (Sidebottom et al., 2018).

Clinics offering PrEP services typically employ PrEP navigators, or PrEP coordinators, who guide patients through the care process. These roles are sometimes filled by licensed clinical social workers or public health practitioners. They may

communicate with patients on a regular basis through phone calls and text messages, and they are usually in charge of answering basic questions about PrEP, following up with patients about appointments, and encouraging patients to maintain adherence (NMAC Capacity Building Division, 2017).

Gilead's Truvada was the first drug to be approved by the FDA as a PrEP medication and the only one recommended by the WHO as such. In May 2018, the FDA also approved the use of Truvada to reduce the risk of sexually acquired HIV-1 in at-risk adolescents (U.S. Food & Drug Administration, 2012). The cost of this drug in the U.S. was approximately $12,600 per patient per year in 2017 (Adamson et al., 2019). Part of the reason for the high cost of the drug stems from Gilead's patent on Truvada, set to expire in 2021. However, Gilead has agreed to allow other manufacturers to produce generic formulations as early as September, 2020 (Gilead Sciences, Inc., 2019). Most recently, Gilead obtained approval from the FDA on Descovy, another one of the company's branded HIV drugs, as a PrEP medication in October, 2019 (U.S. Food & Drug Administration, 2020).

In order to stop the vicious cycle of HIV transmission, PrEP use and adherence must be scaled up, particularly among the groups most at risk of contracting the virus. These groups include gay men of all races, injecting drug users (IDUs), and transgender individuals. According to the U.S. Centers for Disease Control and Prevention (CDC), African Americans and Latinos are the most disproportionately affected, making up significantly higher proportions of new infections than any other population groups (U.S. Centers for Disease Control and Prevention, 2015). These same groups are also the ones

least exposed to PrEP and who have lower rates of adherence if they do take PrEP (AIDSVu, 2018; Khanna et al., 2016; Snowden et al., 2017).

Host Organization

Company background

My host organization, UrSure, Inc., is a for-profit start-up incorporated in 2015 and based at the Harvard Innovation Labs. UrSure is positioned as a therapeutic drug monitoring company with HIV PrEP adherence as its first target. The company commercialized a laboratory-based urine test (lab test) to measure adherence to HIV PrEP medication and is working to develop a point-of-care test (POC), anticipated for launch in 2020. Both types of tests measure drug concentrations of tenofovir, one of the two main components of PrEP, in the body.

This doctoral thesis focuses primarily on the lab test, which was available for commercial use during my time at the company. The lab test uses mass-spectrometry analysis to measure tenofovir concentrations in urine samples, which are collected from patients during the routine quarterly clinic visits that are required for obtaining PrEP prescription refills. Urine samples are collected in plastic containers from patients at clinics during routine PrEP exams, or quarterly clinic visits required to obtain new PrEP prescriptions. These samples are shipped to a partner laboratory facility that is contracted by UrSure to perform the mass-spectrometry test and determine the corresponding adherence levels. The results are then delivered to the ordering clinic within three days

of testing. The results indicate whether a patient has been recently adherent (PrEP taken within past 48 hours), inconsistently adherent (PrEP taken within past 7 days but not last 48 hours), or non-adherent (PrEP not taken in the last 7 days). The samples do not require refrigeration. Appendix 1 shows UrSure's Best Practices Document, which was used as a summary guidance document for potential customers.

The POC test was being developed as a lateral-flow immunoassay test, which is a dipstick similar to a pregnancy test, that can be used by a care provider to obtain a result within ten minutes. This test was under development, with commercialization anticipated by some point in 2020. The predicted costs of producing and using this test will likely be lower than the lab test, which will also likely be reflected in the pricing structure.

My role as Director of Business Development

When I joined in June 2018, I was the third full-time employee. By the time I left the company in March 2019, we had grown to 11 employees, with 4 members in the Business Development team, including myself. My role as Director of Business Development entailed generating sales traction for the lab-based test with the ultimate goal of creating a market for the point-of-care test. This involved pursuing potential customers and partners in a variety of domains for both establishing revenue streams and raising awareness of the products.

UrSure's potential customers and leads

UrSure's overall go-to-market strategy was to first introduce the lab test in the U.S. to begin generating demand for PrEP adherence testing. Concurrently, the company would continue research and development efforts with the goal of creating a POC version that could be a cheaper and faster alternative to the lab test. Once ready for market launch, the new POC test would take over and expand the market created by the lab test. After obtaining the appropriate regulatory approvals in the U.S., the POC test's lower price point and easier logistics would allow the company to potentially expand into the international market.

At the outset of this project, we imagined several different types of customers and partners for UrSure, from collaborating with manufacturers and global health aid agencies to selling directly to end consumers. Through a market segmentation exercise, we arrived at three early customer segments to target in the U.S.:

- Departments of Public Health (DPH) clinics administered by U.S. state and city departments of public health;
- Researchers/key opinion leaders involved in HIV/HIV prevention/HIV medication adherence studies; and,
- 340B-eligible clinics and affiliated pharmacies offering PrEP services.*

* The 340B Drug Pricing Program is a federal program that enables eligible covered entities, certain clinics and hospitals, to obtain outpatient prescription medication at significantly reduced prices from manufacturers. Entities can sell the medications for any price up to a list price and retain potential margins as programmatic revenue for providing specific services to patients.

The sections below provide some background on why we chose these segments and the implications of selling to each of them.

Customer segment: Departments of Public Health (DPHs)

At UrSure, we identified our first customer segment as sexually transmitted disease (STD) clinics offering PrEP services and run by municipal departments of public health (DPHs). Having DPHs become early adopters of UrSure's technology provided important marketing benefits despite some drawbacks. In the absence of clinical guidelines to encourage the use of adherence monitoring for PrEP programs, endorsement from DPHs provided much needed credibility to UrSure's test. For instance, the public health departments of major cities like New York and San Francisco tend to set the precedent for implementing public health interventions. Other public health departments, including those abroad, use these precedents to establish their own programs. If UrSure could get a few major DPHs piloting its test, its sales could snowball to many other DPHs.

The major drawback to selling to DPHs was the incredibly long sales cycles, both due to the burden of obtaining decision-maker signoffs and the procurement bureaucracy. In some cases, it took more than a year to go from first contact with a DPH representative to running the first UrSure lab test for that pilot, despite persistent communications with DPH focal points over many months.

Financing was also a concern with DPHs, but UrSure succeeded in finding public health agencies with innovation budgets to catalyze pilot programs. In the two DPH

pilots that we implemented while I was there, state-level innovation grants provided substantial funding. From the DPH perspective, the success of these UrSure pilots in the first year would determine whether additional funds would be set aside in future years. From UrSure's perspective, the pilot would help jumpstart the implementation process while buying time to determine alternative sources of funding that could make these programs financially sustainable.

The DPH segment would bring relatively smaller initial contracts (~$20,000-$50,000), but the marketing benefits of having them as early adopters was worthwhile. By the time I left the company, UrSure had implemented two DPH pilots.

Customer segment: Researchers

UrSure's second target segment consisted of researchers conducting studies on, or involving, PrEP/HIV treatment adherence. This segment included approximately 50-100 key academic opinion leaders working in clinical or public health research related to HIV treatment and prevention. We positioned ourselves to be able to support these researchers at any phase of their research, from study design to implementation and analysis. Prospectively, we could offer adherence monitoring through our lab or POC tests; retrospectively, we could offer testing of previously-collected frozen urine samples through our lab test. With respect to the POC tests, we could also use early prototypes labeled as *Research Use Only* tests, without undergoing full regulatory approvals for that test.

UrSure's opportunity with researchers was bigger than simply generating revenue. Ongoing and upcoming research studies provided credibility, generated important effectiveness data, and opened up additional sales channels through early adopters. Similar to our approach with DPHs, we believed that clinicians and public health researchers could help generate sufficient data showing improved clinical outcomes to compensate for the lack of a policy mandate to use adherence monitoring. Moreover, data from these same studies could be used as supportive evidence for the POC test's regulatory approvals process. Lastly, key opinion leaders would be talking about these latest findings, which could have a positive network effect to help drive future sales for UrSure.

UrSure had a strong value proposition to researchers. For researchers who were interested in medication adherence as a primary or secondary outcome, there were only a few ways to obtain an objective measure. Moreover, there did not seem to be any commercially available tests apart from UrSure's. Furthermore, UrSure's lab test was quantitative, meaning that it could distinguish a graduated level of adherence.

Some drawbacks to working with researchers included long sales cycles, funding constraints, and capped revenue streams. Despite the interest of the researchers in using our test, they were typically slowed down by the processes of designing or funding their studies. Besides, even after obtaining funding to include the UrSure test in a study, the total quantity of tests purchased would be capped based on the number of anticipated participants. On the plus side, this funding did not involve any insurance billing, which eliminated all uncertainty around reimbursement amounts.

Each researcher sale was anticipated to generate anywhere from $10,000-$40,000, and we had two research customers by the time I left UrSure.

Customer segment: 340B Clinics

The third segment UrSure focused on was 340B clinics. The 340B Drug Pricing Program is a federal program that enables eligible clinics and hospitals to obtain outpatient prescription medication at significantly reduced prices from manufacturers. The hospitals and clinics can then sell these medications to their patients for any price up to a suggested list price, which is paid by the patient out-of-pocket or covered in some portion by the patient's insurance. The health care facility can keep the 'profit' as programmatic revenue to fund either the approved program, such as the case for clinics designated as Sexually Transmitted Disease (STD) clinics, or for any program at a Federally Qualified Health Center (FQHC). In practice, this program allows many health care facilities to subsidize the costs of clinic visits, lab testing, and medications for patients on PrEP who are un- or under-insured.

The cost savings are typically shared by the clinic with a *contracted pharmacy*, from where the particular prescription was filled. Given the high cost of Truvada, eligible entities and their contracted pharmacies are able to receive a significant amount of money ($500-$900 per patient) for each Truvada fill or refill. While the distribution of incentive money between the clinic and the contracted pharmacy is not publicly available, we ascertained that only a small percentage, likely less than 20%, went to the pharmacy.

Many of the clinics offering HIV PrEP services in the U.S. qualify as 340B eligible entities, and they work with one or many contracted pharmacies to obtain the cost-savings incentives. Once we had a basic understanding of the 340B program and the substantial incentive payments, we realized that our primary claim to increase adherence and retention to Truvada could lead to a significant windfall of 340B revenue at clinics and their contracted pharmacies. Subsequently, we began targeting clinics and pharmacies that participated in this program as one of our main customer segments. Based on publicly available data, we estimated that there were at least several hundred of these types of clinics across the country (U.S. Health Resources & Services Administration, 2020).

Within the 340B clinic segment, we learned to focus on private instead of public clinics. While both public and private clinics participated in the 340B program, we discovered that they had different levels of autonomy over the 340B payments. For instance, we were not able to close a deal with any of the publicly administered 340B clinics, even though the primary decision maker may have wanted to implement the UrSure test at the clinic. Several of these decision makers told me that they had almost no control over the 340B incentive money, as it would be fed back to the DPH or other body administering the clinic. On the other hand, we discovered that many of the private 340B clinics were quick to move forward with UrSure as they saw the incentive payments affect their clinic's bottom line.

The sales cycles with 340B clinics were much shorter than those with DPHs. In one case, with UrSure's first major customer, it took less than 3 months to go from first contact

to running the first test. On average, the sales cycle was between 3-4 months. Working with shorter sales cycles made it easier for us to qualify our sales leads and to iteratively improve our sales processes.

Not only were private 340B clinics faster to work with, they were generally more motivated to try our novel testing approach to attract more patients. For instance, state policies in Florida gave rise to increasing accessibility of PrEP across the state, and PrEP clinics sought to differentiate themselves in an increasingly crowded marketplace. A couple of our 340B clinic sales leads in Florida wanted to publicize the use of UrSure's test in order to be perceived as innovative centers of care among potential patients seeking out PrEP. Riding this wave of interest from clinics allowed UrSure to also gain marketing momentum with other sales leads because we could point to the uptake of UrSure's test at competing clinics.

The 340B clinic segment was anticipated to be the largest revenue generating segment for UrSure's lab test, as each clinic customer could lead to sales between $50,000-$200,000 annually. By the time of my departure from UrSure, the company had three fully operational customers, and several others in a trial phase. The company's goal was to rapidly scale up to twenty to thirty additional 340B clinics in the year after my departure.

EXPERIENTIAL LEARNING

In this section, I outline the key takeaways from my experience of working full-time as Director of Business Development at UrSure. The first subsection describes the overarching strategy for the lab test. In the second subsection, I briefly discuss some aspects of the sales strategy and how we gathered information from potential customers. Lastly, in the third subsection, I present factors that we considered to be important in our sales execution and our understanding of the customer value proposition for the lab test within the 340B clinic segment.

Focused on Product, not Value Proposition

In UrSure's case, the company had already developed a product, the lab test, based on needs identified through the clinical experiences of the co-founders; subsequently, the venture's strategy during my tenure was driven more by a need to sell the product as opposed to further understanding its fit in the market. The goals of selling the lab test were to generate revenue, gather data on adherence outcomes, and prime the market for the launch of the point-of-care test. Additionally, the process of selling the lab test and implementing its use with customers was seen as a learning opportunity that would inform the development of the POC test. While the sales efforts could have been used to further investigate the basic elements of the value proposition for the lab test, we did not explicitly prioritize this in the business development role.

Validating Demand

Prior to my arrival at UrSure, the company's business development efforts led to several letters of intent from potential customers, mainly public health clinics and clinical researchers. The company had pitched the piloting of the lab test at various clinics and obtained positive written responses from these clinics. While non-binding, we believed these commitments would lead to potential trials and eventual contracts with those customers. During my tenure, our sales efforts included focusing on these leads and we were able to actualize the proposed pilots into implementing customers. These pilots served as market trials through which we could test various pricing/ reimbursement strategies, learn how clinics derived utility from the test, and gather data on outcomes.

Six months after I joined the company, we conducted our first customer visit. This was motivated by several of the new hires, including myself, wanting to better understand how a PrEP program at an HIV specialty clinic actually works. Our Director of Product Development, Manager of Business Development, and I went on this visit to a clinic in another city along the Northeast Corridor. We spent several hours meeting with PrEP navigators to understand how they engage with patients on PrEP, discussing workflow implementation with operations staff, answering questions from clinicians on the potential benefits of the test, and touring the facility to get a firsthand glimpse of potential logistics challenges. We learned that operational challenges, such as establishing clear guidance for shipping samples and delivering results electronically, were just as important as the challenges of convincing clinical leadership of the potential for improved adherence outcomes.

Assumptions at UrSure and the Customer Value Proposition

During my tenure at UrSure, we made certain assumptions about our customers and our value proposition that guided our sales efforts. These assumptions helped us develop our sales pitches to customers, partners, and potential investors. Many of the assumptions were grounded in evidence gathered by the company's co-founders, some were based on peer-reviewed studies, and others came from our preconceived notions of patient, provider, and payer behavior. In this subsection, I elaborate on these assumptions and categorize their implications into sales facilitators and sales barriers, as illustrated in Figure 2 below. Lastly, I describe the existing value propositions at UrSure that were developed iteratively with our sales efforts.

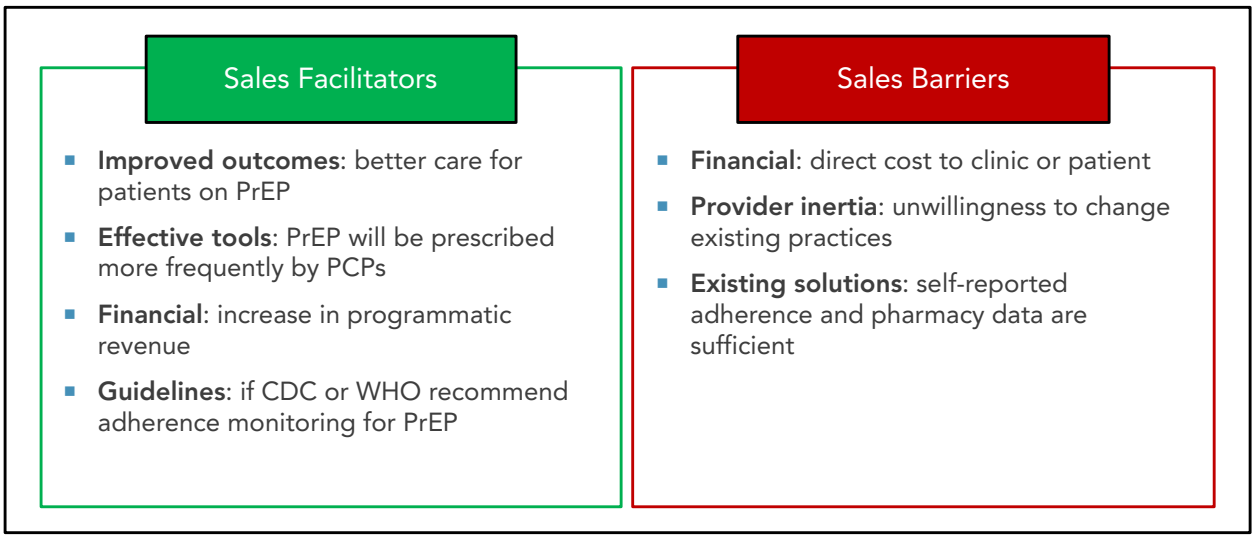

Figure 2: Summary of factors driving 340B clinic sales efforts at UrSure.

First and foremost, we believed that the use of our urine test would actually improve adherence and retention outcomes. Much of this came from the clinical use of the lab test in UrSure's co-founder's own PrEP clinic, and the substantial improvements

she was able to report among her patient population. The underlying assumption was that non-adherent patients could be identified more accurately and provided the appropriate resources (e.g., counseling, SMS reminders, engagement from PrEP navigator, etc.) to improve compliance. For already adherent patients, the test result could serve as a positive reinforcement tool to encourage sustained compliance. However, without any authoritative studies published on the impact of PrEP adherence monitoring on actual adherence, we were limited in the claims we could make during our sales pitches. Moreover, although we discussed the benefits of tracking adherence data across all customers to monitor population level outcomes and to evaluate the effectiveness of the urine test, most of those data were collected after my departure from the company in March 2019. Therefore, I cannot speak to whether internal data from the first few thousand tests validates the adherence outcomes we assumed.

We also believed that providers would be able to more easily have substantive conversations around adherence by using the urine test, and that the test could ease concerns among primary care providers (PCPs) to enable them to prescribe PrEP to more patients. The underlying assumption here was that the conversation around adherence during a PrEP visit is uncomfortable for both the patient and the care provider. Given that PrEP is still under-prescribed (Buchbinder, 2018), we theorized that adherence concerns may make PCPs feel reluctant to prescribe the medication. Therefore, UrSure's adherence test was at times pitched as an effective tool to increase the overall number of PrEP prescriptions.

Another major assumption about the market was the role of PrEP care guidelines from normative guidance bodies such as the CDC or WHO. We believed that guidelines recommending the use of adherence monitoring tests, such as urine tests, as part of routine PrEP or HIV care, would naturally give rise to a market for our test. The recommendation could be for all patients or certain types of patients. In either case, the guidelines could help drive the demand for UrSure's test through an imperative for its use. However, in the absence of such guidelines, we understood that the burden would be on our sales efforts to convey compelling benefits of the test.

Lastly, we believed that provider inertia, or the implementation of new procedures and practices at a clinic, was a significant barrier to customer adoption. Not only would this factor determine whether providers are even willing to consider using the UrSure test, it would also determine the duration of the sales cycle and necessary workflow adjustments. For larger health care facilities, like hospitals with networks of satellite clinics, there would be many hoops to jump through before a decision could be made on using the test and then a separate set of obstacles for actually implementing it. The opposite could be true for smaller facilities.

UrSure's general customer value proposition statement in November, 2018, was: "We help care providers deliver targeted adherence support to individuals on PrEP by giving them a practical, easy-to-use, and cost-effective tool to identify which patients need support." This value proposition contains both implicit and explicit links to the sales factors discussed above. For instance, "helping care providers deliver targeted adherence support" implies that the test would lead to appropriate resources for improving

adherence, ultimately leading to improved health outcomes, the biggest potential benefit of the test. On the other hand, calling out the ease-of-use and cost-effectiveness features of the test addresses potential concerns around financial and provider inertia barriers to sales. For the 340B clinic segment, UrSure had an additional value proposition: "We help 340B clinics increase programmatic revenues by increasing the number of PrEP prescription fills using a tool that improves patient adherence and retention outcomes." We believed this supplementary value proposition addressing financial benefits could be particularly compelling within the 340B clinic segment.

Working at UrSure informed my understanding of the sales context of the 340B clinic segment and guided my research approach, as described in subsequent sections. Some of the assumptions described above are investigated through this research but others are outside the scope of this project. For example, while I do not intend to test the underlying assumption that adherence testing improves adherence, I am able to focus on whether potential improved outcomes influence clinician decisions on adopting innovations. I am also able to investigate the merits of our assumptions regarding financial benefits (i.e., increased 340B incentive funding) being powerful sales facilitators. While the investigative approach in this project is not comprehensive, it can still reveal constructive insights for the company's business strategy.

LITERATURE REVIEW

This section is divided into two main subsections: Entrepreneurship Literature and Innovation in Health Care. The Entrepreneurship Literature section establishes the importance of the customer value proposition and relevance of the customer development model to this project. The Innovation in Health Care section outlines distinguishing features of the health care sector, including differences in value proposition and key factors that affect adoption of health care innovations.

Entrepreneurship Literature

What is a customer value proposition?

The customer value proposition is a crucial element of the business model, which is the foundation for how a business operates. Entrepreneurship theory suggests that a business model is "an integrated array of distinctive choices specifying a new venture's unique customer value proposition and how it will configure activities […] to deliver that value and earn substantial profits" (Eisenmann, 2014, p. 1), and there are four categories in which to group these choices:

- Customer Value Proposition: the value that a venture's offering creates and for whom
- Go-To-Market Plan: how a venture reaches potential customers

- Profit Formula: the variables associated with costs and revenue to determine how the venture generates cash flow
- Technology and Operations Management: the resources, activities, and infrastructure required to deliver the venture's offerings to customers

These business model choices influence how startups discover, drive, and scale up demand (Eisenmann, 2014; Payne et al., 2017).

While all four categories are important for fully developing a business, the customer value proposition provides the existential motivation for a business. A value proposition breaks down the customer, the problem, and the venture's solution in a way that clearly outlines why a customer would value the venture's solution. It establishes what value is created for a customer based on unmet need, which helps determine who the customers are, what they would be willing to pay, and what sort of complementary services are necessary to ensure realization of the proposed value (Eisenmann, 2014; Siegrist, 2014). Siegrist (2014) suggests that a value proposition "should be clear, concise and verifiable initially through conversations with potential customers and later through actual customer sales" (p. 1).

There are common elements across varying definitions of customer value proposition. For instance, Carlson presents value proposition as an "important customer and market **N**eed addressed by a unique, compelling, and defensible **A**pproach for the offering and business model that provides superior **B**enefits per costs when compared to the **C**ompetition and alternatives"(C. Carlson et al., 2019, p. 17; C. R. Carlson, 2006). Another approach comes from Blank's template: "We help **x**, do **y**, by doing **z**" (Blank,

2011), where **x** is the customer, **y** is value derived by the customer, and **z** is how the offering leads to creating the value. In both cases, the core elements are the customer, the value derived, and the approach.

Why is customer value proposition so important for startups?

Without a good customer value proposition, a new venture cannot achieve *product-market fit*, constraining any opportunity for future growth. Roberge's *Start-to-Scale* framework (see Figure 3 below) proposes the business activities of an early-stage company in three phases of growth. The first phase focuses on achieving *product-market fit*, a thorough validation of customer demand for a particular offering. During this first phase, the venture must understand who its customers are and decide what its offerings will be—essentially establishing a good customer value proposition. Failure in this phase prevents the venture from going on to the second phase or third phases of growth, which focus on achieving *go-to-market fit* and *revenue growth*, respectively (Roberge, 2018).

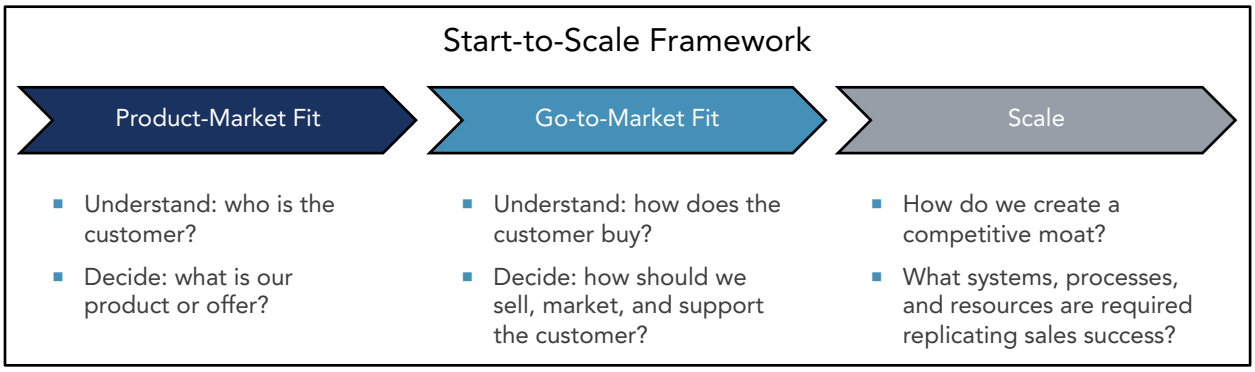

Figure 3: Start-to-Scale Framework for entrepreneurial growth adapted from Roberge, 2018.

How can new ventures develop and refine their value propositions?

Customer value proposition is core to Blank's *customer development* model. Based on his experience in many entrepreneurial ventures, Steve Blank proposed the four-step *customer development* model as a way for new ventures to develop products. Instead of focusing on isolated product development as companies had traditionally done in the 1990s and early 2000s, this model emphasizes a customer-centric way to iteratively develop products based on an improving understanding of customer needs. The approach provides practical guidance for entrepreneurs to create successful businesses. Moreover, given the need for startups to maximize efficiency based on resource constraints, it stresses relentless hypothesis testing on the most important aspects of a company's innovation and business model in order to arrive at a decision to persevere, pivot, or perish (Blank, 2013; Eisenmann et al., 2013).

Customer development consists of *customer discovery*, *customer validation*, *customer creation*, and *company building* (see Figure 4 below). Each of these is a recursive step that considers the unpredictable nature of finding markets, and they collectively assume built-in functions to adapt based on learning from hypothesis testing. The goal of customer discovery is to establish whether customers exist for a particular vision of innovation by actively engaging with potential customers to understand their needs. The goal of customer validation is to create a repeatable sales process that has proven success among early customers. Only when a company can replicate this success among different segments of the early buyers can it move on to scaling up. The customer creation stage is focused on generating consumer demand that can be pushed to the company's sales

channel. The company building stage is a major transition in which the startup shifts focus from learning and discovery to execution by establishing formal teams focused specifically on sales and marketing. By placing company building as the final stage, the process allows startups to minimize the risk of premature scaling that can occur during sales growth among the early market (Blank, 2013).

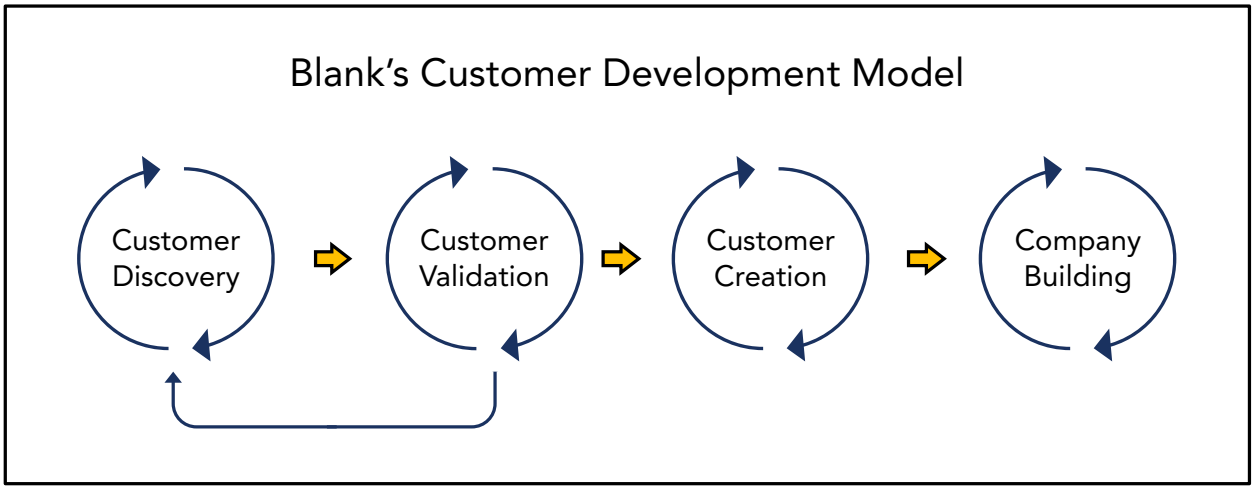

Figure 4: Customer development model adapted from Blank, 2013.

The focus of this thesis is on the customer discovery step, through which entrepreneurs can better understand the opportunities for creating value for customers. By engaging in customer discovery, entrepreneurs can more quickly address uncertainty around the target customers, customer needs, buyer journey, and product attributes, among others. There are several ways to execute customer discovery. Entrepreneurs can conduct one-on-one interviews or focus groups that bring together a small group of individuals from a set of relevant potential customers to understand attitudes toward customer challenges and potential solutions. They can also conduct customer surveys of current and potential customers to better understand factors such as purchasing

behavior, preferences, and satisfaction. At an even earlier stage, a venture can obtain letters of intent, which would be non-binding commitments from potential customers to purchase an offering once it has been developed. Lastly, a venture can conduct market trials among subsets of customers within certain geographies or among certain types of customers to obtain feedback that could help refine the offering before a full-scale market launch. When combined with the hypothesis-driven approach of the lean startup method, these activities can help entrepreneurs obtain some of the most critical information about customer demand to further improve the chances of establishing a profitable business (Cespedes, 2014; Cespedes et al., 2012; Roberge, 2018).

What makes for a compelling value proposition?

A venture must develop its customer value proposition around an unmet need, the root of customer demand. An unmet need is a customer problem that either does not have a satisfactory existing solution or could be solved in a cheaper, faster, or better way. There are several different scenarios that a venture could encounter when considering customers and unmet needs. A customer may or may not be aware of a problem. They may or may not have an existing solution. The existing solution may or may not be satisfying. In all cases, the venture's offering must create value for the customer. In other words, it must provide customers with benefits that exceed the costs of adopting the offering, while also outperforming alternative solutions (C. Carlson et al., 2019; Cindy Barnes et al., 2009; Lindič & Marques da Silva, 2011).

First, as a matter of framing, entrepreneurs must distinguish between a product and a problem. A venture sells the features of a product or service, but a customer buys a solution to a problem, satisfaction, or business outcome. While the features of a venture's offering describe its functional attributes, what matters are the benefits that a customer receives as a result of accepting that offering. Therefore, it is incumbent upon entrepreneurs to interact with potential customers to understand what difficult problems they face, what outcomes they need to gain more satisfaction than what existing solutions provide, and what sort of offering would be most relevant to addressing their problems (Cespedes, 2014).

Secondly, the benefits derived by the customer from the venture's offering must overcome those from existing solutions. Several studies in behavioral science indicate that people evaluate new offerings on perceived value relative to what they already possess as a potential solution, the *status quo*. The underlying theory is that *loss aversion*, valuing the magnitude of a perceived loss as being greater than that of a similar sized gain, leads to customers ascribing more value to what they already own relative to a new offering, known as the *status quo bias* (Cespedes, 2014).

According to Gourville, the mismatch between innovators' perceptions and buyers' perceptions is approximately a factor of nine. The *status quo bias* implies that customers will be more reluctant to buy, consume, or adopt a new offering, given that they will value their existing solutions more than the perceived benefits they will derive from the new offering. Empirical research has shown that the magnitude of perceived losses is valued at between two to four times that of perceived gains. Moreover, the same

behavioral principle applies to the innovators, who overvalue the benefits of their novel offering in a similar manner. Therefore, the combined differential, a product of the two factors, results in an approximate 9:1 mismatch between innovators and buyers; specifically, innovators perceive their creations as nine times more beneficial than do potential buyers (Cespedes, 2014; Gourville, 2006).

Understanding the status quo bias can help an entrepreneur adjust the variables of their value proposition to make it more compelling. For instance, the most straightforward approach is to aim for a 10x improvement by designing offerings that have perceived customer benefits of at least ten times greater than perceived losses from adoption. This would essentially neutralize the status quo bias. Another option is to minimize resistance by reducing the magnitude of behavior changes required to adopt a new offering. If prospective customers have smaller perceived losses, then the perceived benefits would be relatively greater, resulting in less resistance to change. A third option is to target customers who do not have or use an alternative solution, and therefore would not experience loss aversion. Lastly, the company could seek "believer" customers who naturally value the perceived benefits as much greater than perceived losses, which would make them more susceptible to adopting an innovative offering to existing alternatives (Cespedes, 2014; Gourville, 2006).

In summary, there are several key concepts that entrepreneurs must consider when seeking to establish a compelling value proposition. As illustrated in Figure 5 below, these include: identifying customers and unmet needs; products versus problems;

status quo bias; and, derived value. These concepts also help develop the basis for assessing UrSure's customer value proposition.

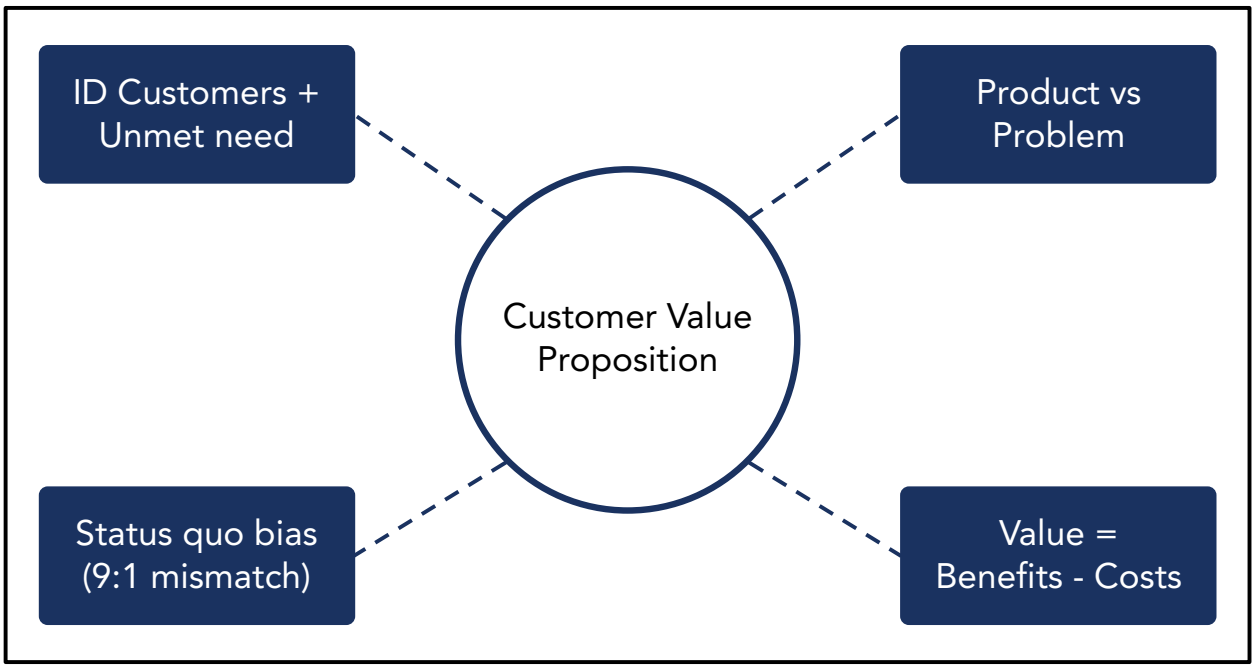

Figure 5: Important factors for a compelling customer value proposition.

Innovation in Health Care

The health care industry poses its own set of unique challenges for entrepreneurs hoping to introduce innovations. This section provides an overview of the factors relevant to customer value propositions in the health care sector. While much of the health care value proposition literature is on systemic factors, I found one practical tool that may provide further grounding for this thesis. In addition, this section also presents an overview of literature on adoption of health care innovations, which may shed light on other important factors for examining value propositions in health care.

Prescribers versus patients; customers versus consumers

Value proposition relates to the customer; however, in health care, there is a difference between the consumer and the customer since the entities procuring, using, and paying for a product or intervention are typically distinct. Usually, a clinical care provider will determine which product a patient needs as a medical necessity, and the patient will be the end consumer. The patient's health insurance, if applicable, will then pay for this product based on the relevant coverage policies. Even though the patient is the end user, or consumer, the decision-making process for purchasing the product is made by the care provider. The insurance company may be paying for most, if not all, of the cost of the product, but it may be excluded from the decision-making process (Cecere, 2014; Hixon, 2015; Leng, 2015; Pearl, 2015). The benefits may be realized by the patient directly in the form of improved outcomes, by the provider through efficiencies in clinical decision-making, or indirectly by the health system more broadly (Price & St John, 2014). Given this complexity, I will limit the scope of this thesis by defining customers as the clinics and associated clinicians involved in prescribing PrEP.

Factors relevant for healthcare-specific value propositions

The concept of the value proposition carries over in health care but requires additional considerations that are sector-specific. Price and St. John (2014) provide a practical tool for developing value propositions that promote the adoption of innovation in clinical laboratory testing. They mapped commercial value proposition elements to a checklist for value propositions in health care (see Figure 6 below), primarily for

laboratory medical science but broadly applicable across other areas. Their checklist can be used to sequentially develop a customer value proposition for a health care offering.

More importantly for the purposes of this thesis, their research collates the unique factors important for health care ventures. They identified six key sets of issues that must be addressed in order to develop useful value propositions for medical applications. The first set is identifying customers and unmet needs. The second set focuses on benefits, particularly the impact on health outcomes. The third incorporates the need for cost and clinical effectiveness evidence. The fourth highlights the expected changes to practices, processes, and resources from adopting the offering. The fifth set relates to the development of a strategy for implementing the offering at the health care facility. The sixth set deals with ensuring accountability of all relevant stakeholders in participating where required to use the innovation (Price & St John, 2014).

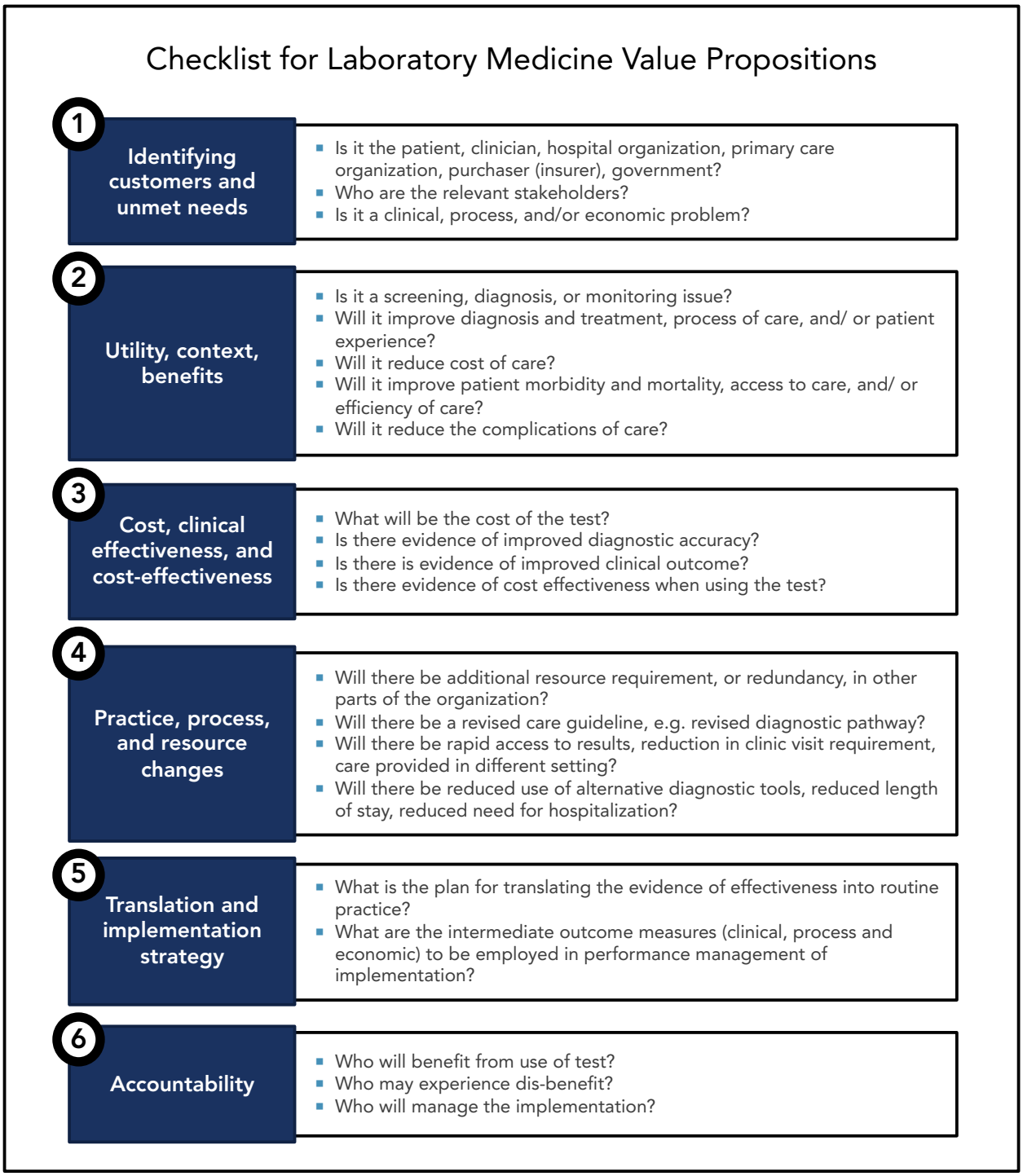

Figure 6: Health care value proposition checklist adapted from Price and St. John, 2014.

Factors influencing the adoption of health care innovations

In addition to the aforementioned literature that directly addresses the nuances of value propositions in health care, I found literature on adoption of health care innovations that gives a holistic view of other pertinent factors. Much of this literature is categorized as either barriers to adoption or criteria for adoption of health care innovations. In this subsection, I distill some of these barriers and criteria into factors relevant to assessing challenges and opportunities associated with a particular health care value proposition.

There is plenty of evidence to suggest that innovations are adopted slowly in the health care sector (Hresko & Haga, 2012; Lim & Anderson, 2016), and there are a variety of reasons for this. For instance, a systematic review of diffusion of innovations in health service organizations by Greenhalgh et al. (2007) found that innovation characteristics, adopter characteristics, internal organizational context, external context, and dissemination efforts are the main factors influencing the rate of adoption. Organizational context could include staff expectations, perceived need, and potential compatibility with existing routines, as found in a study among primary care units in Sweden (Siw et al., 2010). A separate systematic review of studies, conducted by Robert et al., found that the organizational context, stage of innovation, power and politics of the stakeholders involved, social influence, and other factors interact in a complex way that influences adoption decisions (Robert et al., 2010). In another paper, Austin suggests that safety and efficacy are the most important features of a new product, and their relative importance is an order of magnitude greater than other features, such as price. He also

suggests that psychological factors among physicians, such as attitudes toward existing practices and interpersonal relationships with patients, may be influential in innovation adoption (Austin, 2006).

Research provides criteria for considering the adoption of health care innovations. For instance, Poulin et al. (2013) developed a set of twelve criteria as part of a multi-criteria decision tool to help clinics determine whether to adopt a new technology. The criteria were: efficacy, population health, standard of care, safety, training, access, service coordination, sustainability, strategic fit, knowledge and research, cost, and economic analysis. They were grouped into five major domains (health gain, service delivery, strategic fit, innovation, and financial).

Summary of Literature Review and Experiential Learning

Entrepreneurship theory and health care innovation adoption literature provide useful concepts that inform the assessment of UrSure's customer value proposition. The former prepares the foundational underpinning of customer value proposition and the latter adds useful layers to help tailor the analysis to the health care startup context. The Entrepreneurship Literature section demonstrates the importance of customer value proposition to entrepreneurial growth and presents customer discovery as a practical tool to help develop a customer value proposition. Moreover, that section also outlines the key elements of a customer value proposition and vital concepts to strengthen it, as illustrated in Figure 5 above. The Innovation in Health Care section reinforces the importance of many of the customer value proposition concepts from entrepreneurship

theory (e.g., identifying customers, identifying unmet need, costs, benefits) and provides additional dimensions to consider.

I synthesize these concepts gathered from the literature review with my experiential learnings from working at UrSure, as illustrated in Figure 7 below. In the course of my work, I encountered sales barriers and facilitators, which have been reinforced by what I have learned through the literature review, as color-coded in the figure. The literature review has also helped uncover additional concepts that further shape how I evaluate the challenges and opportunities associated with UrSure's customer value proposition. Taken together, these ideas ultimately form the lens of my analysis.

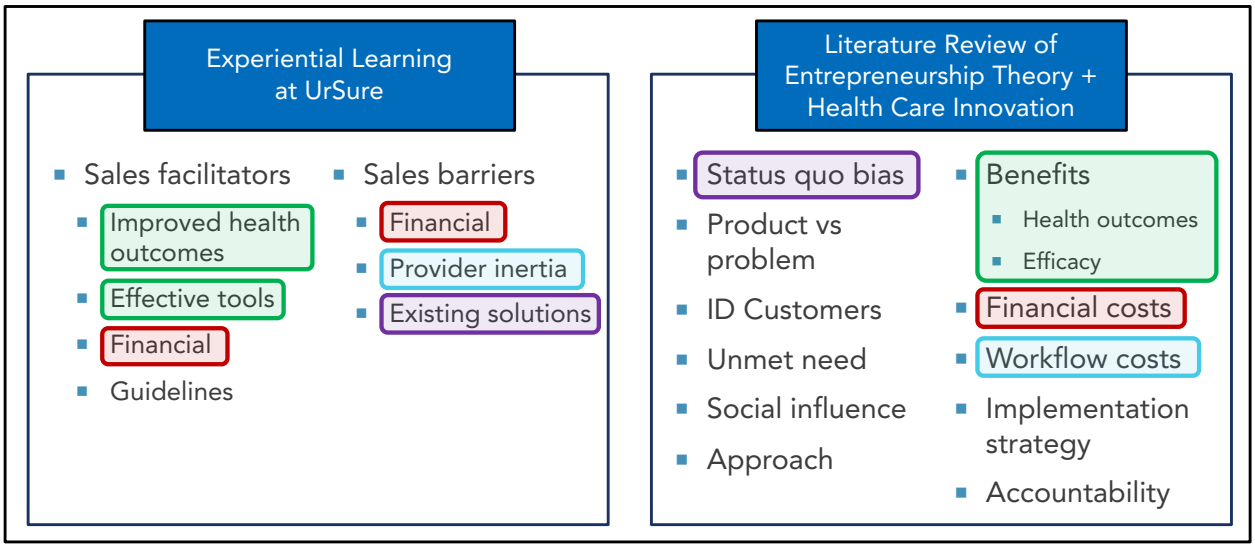

Figure 7: Summary of factors relevant to UrSure's customer value proposition gathered from experiential learning and literature. Concepts that overlap between theory and practice are represented by similar color shades.

METHODS

The purpose of this section is to describe why certain methods were chosen to answer the main research question (i.e., what are the challenges and opportunities associated with UrSure's customer value proposition within the 340B clinic segment?) and how I went about conducting the research. The customer development model serves as a grounding theory for the overarching research question in UrSure's context, and I used qualitative research, in the form of customer interviews, to distill relevant findings for the company. The following subsections provide details on the motivation for selecting the methods, the methods for conducting the interviews, and the approach used for interpretive analysis.

Motivation for Approach

The customer development model is the conceptual underpinning for understanding how a startup, like UrSure, can maximize its chances to build a successful business. This model is specific to startups and is the leading contemporary approach to entrepreneurship. In this thesis, I focus on the first step, customer discovery, which corresponds to UrSure's stage of entrepreneurial maturity during the timeframe of this project. I also chose to focus on customer discovery because it provides a method for critically analyzing the assumptions, challenges, and opportunities associated with UrSure's customer value proposition for its lab test within the 340B market segment. Customer discovery and validation calls for primary market research that helps entrepreneurs distill the core benefits associated with the customer value proposition.

Additionally, this helps identify unmet customer needs, understand existing solutions comprising the status quo bias, and reveal customer decision-making models for choosing solutions (Cespedes et al., 2012).

I limited the scope of this research to the 340B customer segment because it represented the most promising market opportunity for UrSure during my tenure at the company. There are several thousand health care facilities in the U.S. that are designated as 340B entities, and there are hundreds of these facilities that could be potential UrSure customers. Additionally, since the company had made a strategic decision to invest its sales efforts toward this segment, the findings from this research have the most potential to immediately impact business success.

While there are different modalities of conducting primary market research for customer discovery, including surveys, focus groups, and others, I chose to conduct one-on-one customer interviews. Interviews allow a deeper exploration of the "'what,' 'how,' and 'why'" of a particular subject of study as opposed to focusing on the underlying quantitative elements (Green, 2014). Moreover, just by conducting only a handful of interviews, either as focus groups or one-on-one sessions, entrepreneurs can identify the majority of needs among customers in a particular market segment (Griffin & Hauser, 1993; Roberge, 2018). Cespedes (2012) recommends that entrepreneurs should physically visit customers to gain an enriched understanding; however, given logistics and financial constraints of this project, phone interviews were the best alternative.

In terms of a methodological foundation for designing and executing the qualitative research in this project, I relied on the seven-step *customer visits* process, described by Cespedes (2012) (see Table 1 below), and thematic analysis for interpretive analysis. The customer visits process is relevant to this project because it integrates directly with the customer development model. This approach provides practical guidance on clarifying research objectives, sampling strategies, developing topic guides, roles for team members, debriefing, and following up with customers. In addition to its practicality, I also relied on this process because it serves as a useful foundation on which UrSure can conduct further customer discovery work in the future on additional customer segments. Although the debriefing step (Step 6) suggests performing a structured analysis iteratively after each interview, I focused my efforts on a deeper thematic analysis after the completion of all interviews—mainly due to the limited number of interviews conducted.

Table 1: Steps for customer visits adapted from Cespedes, 2012.

Process for Planning Customer Visits		
Step		Description
1	Set objectives	• Specify the kind of information you want to collect.
2	Select a sample	• Identify the types and required number of customers to be visited.
3	Assemble the visit team	• Identify the individual(s) who should participate in the visits.
4	Develop a discussion guide	• Generate the topics and questions to be covered in each visit. • Organize the topics and questions into a sequence and set priorities.
5	Conduct the interviews	• Specify roles for team members. • Consider factors of time, space, and things to avoid.
6	Debrief after each interview	• Begin a structured process of analysis. • Assess whether changes should be made to the interviews.
7	Follow up	• Provide closure for the customer and the team.

Interview Methodology

Over the course of two months from January–February 2020, I conducted thirteen semi-structured phone interviews with various health care providers at different types of 340B clinics offering PrEP services. Participants were sampled through a combination of internet searches for providers at 340B PrEP clinics, convenience sampling through personal contacts, and snowball referrals from interviewees. I recruited participants through cold calling and email requests. I contacted fifty health care providers, including physicians, nurse practitioners, physician assistants, and pharmacists, and fifteen of them expressed interest in participating. I excluded two of those interested respondents from the study, given that their clinics did not have any patients on PrEP. Temporal constraints

for this doctoral project limited sampling and recruitment. Each interview was audio-recorded, with prior consent, and audio recordings were transcribed manually.

I developed a topic guide (see Appendix 2) primarily informed by my experiential learning at UrSure and from the entrepreneurship literature. Most of the questions were intended to gather information related to the underlying sales facilitators and barriers described in Figure 2 above. Cespedes and Roberge recommend developing an interview guide with open-ended questions in advance, but there should be flexibility to explore opportunities as needed. They also suggest that interviewers should minimize the sharing of information about the venture and its offering, as it may bias the respondents' views. Good questions may include asking about how customers carry out tasks, what challenges they encounter, and where they seek information about new solutions. Interviewers may also ask about the respondent's responsibilities, their priorities, and the interactions they must have with others in their organization to authorize purchases of new solutions (Roberge, 2018).

The research protocol was reviewed by the Harvard T.H. Chan School of Public Health Institutional Review Board and given a human subjects exemption determination (IRB20-0075).

Analysis Methodology

I chose to use thematic analysis because it is a foundational method for qualitative research and enables researchers to systematically develop a rich understanding of

complex data. Braun and Clarke (2006) define thematic analysis as a "method for identifying, analyzing and reporting patterns (themes) within data" (p. 79). This method also provides flexibility in using both deductive and inductive approaches to analyzing data. In a deductive analysis, prior assumptions can serve as a framework for codes and themes. An inductive approach, such as grounded theory, relies on developing a thematic framework from the ground up, based on close reading and coding of the first few interview transcripts. The flexibility of this method allowed me to use prior assumptions to create an initial coding framework and then refine it inductively to arrive at higher-ordered themes.

Out of several variants of thematic analysis, I followed these five steps outlined in Braun and Clarke's (2006) approach:

1. Familiarization – review notes, transcribe audio recordings, and closely read transcriptions to become intimately familiar with the entirety of the dataset.
2. Generate initial codes – systematically and comprehensively assign codes that describe the basic features of each element of the dataset.
3. Search for themes – begin forming themes that consist of codes grouped together to capture repeating patterns or meaningful concepts and begin establishing lateral and hierarchical links between themes.
4. Review themes – analyze coded data within themes and links between themes to ensure coherence and validity.
5. Define and name themes – define each theme clearly and establish the story of the analysis.

ANALYSIS

Through interviews with clinicians at 340B health care facilities, I have uncovered a number of findings that shed light on challenges and opportunities associated with the customer value proposition of UrSure's PrEP adherence lab test. This section begins with a descriptive summary of the interviewees and then outlines the main findings of the thematic analysis.

Summary of Interviewees

Thirteen interviewees from nine different 340B clinics participated. Most of the participants were physicians, medical doctors (MDs) or doctors of osteopathic medicine (DOs), and the majority of them were infectious disease specialists. There was one nurse practitioner (NP) and two pharmacists. The types of health care facilities ranged from community-based STD clinics to academic medical centers and large health care systems. The number of patients on PrEP at each facility ranged from approximately 115 patients to 1,700 patients. Several clinicians had around 15-20 patients on PrEP under their care while a few were managing more than 70 patients each. Appendix 3 below provides a detailed list of the interview participants.

Identifying Themes

As mentioned in the Methods section, I conducted the thematic analysis using Braun and Clarke's approach. I began by transcribing audio-recordings and closely reading transcripts in order to become deeply familiar with the concepts discussed in

each interview. During this process, I also created domain summaries of the responses to specific questions across interviews to better understand the dataset. For the second step, I used these domain summaries to create an initial coding framework and coded all the transcripts. During the coding process, I incorporated new codes inductively and refined the framework continuously. In the third step, I constructed themes and sub-themes from the codes using a semantic approach which calls for identifying themes "within the explicit or surface meanings of the data" (Braun & Clarke, 2006, p. 84). I considered themes across the whole dataset as opposed to only considering specific aspects. For the remaining two steps, I iteratively reviewed, refined, and redefined themes until arriving at a set of interpretive global themes underpinned by sub-themes of the dataset.

Through this analysis, three global themes emerged, as outlined in Table 2 below. The first is that providers believe multiple factors influence patients' PrEP adherence outcomes, with sub-themes of barriers to care, engagement, risk perception, patient trust, and risk factors for HIV. The second theme is that providers trust their existing approaches to monitoring PrEP adherence concerns, with underlying sub-themes of evidence of efficacy, existing adherence tools, provider concerns, and provider trust. The third theme is that financial factors are important in how clinics run their PrEP programs, with sub-themes of organizational decision-making, resource constraints, and the importance of 340B revenue. The rest of this section describes each of the main themes and sub-themes.

Table 2: Summary of global themes and sub-themes.

Global Themes	Sub-Themes
1. Providers believe multiple factors influence patients' PrEP adherence outcomes.	• Patient barriers to care • Patient engagement • Patient risk perception • Patients' trust in providers and the health system • Risk factors for HIV
2. Providers trust their existing approaches to monitoring PrEP adherence but have continuing frustrations with patients dropping out of care.	• Evidence of efficacy or utilization guidelines • Existing adherence tools • Providers' trust in patients • Provider concerns
3. Financial and workflow factors are important in how clinics run their PrEP programs.	• Organizational decision-making • Resource constraints • Importance of 340B revenue

Global Theme 1: Providers believe multiple factors influence patients' PrEP adherence outcomes

Table 3: Global Theme 1 and its sub-themes.

Global Theme 1	Sub-Themes
Providers believe multiple factors influence patients' PrEP adherence outcomes.	• Patient barriers to care • Patient engagement • Patient risk perception • Patients' trust in providers and the health system • Risk factors for HIV

Patient barriers to care

All providers made some reference to the way in which financial, structural, and social barriers to care affect adherence to PrEP and retention in care. For instance, some participants emphasized the importance of flexibility in appointment hours for those patients who could not afford to miss time away from work. One interviewee summarized these issues well:

> *I mean, they're all interested in PrEP, but they work, and […] our labs don't operate afterhours. They have a hard time breaking away […] it's important to them but it's not as big of a priority as you know making money, and being able to afford their house, and things like that. And those are the same barriers often to taking PrEP every day, but there are so many important things going on in their life […] and their life is very chaotic because of their low socioeconomic status. They're just not as in control. And so, it's all folded in the same mechanism that leads to adherence issues.*

At several clinics, intake screening includes an assessment of whether the patient has the appropriate prescription drug benefits to cover the cost of PrEP and subsequent guidance in accessing appropriate financial prescription support programs through the government or Gilead (e.g., copay assistance cards) for those with limited coverage. For patients with limited transportation options, some providers offer to send prescriptions to closer pharmacies or home delivery programs. Multiple participants mentioned the presence of social workers at the clinic or clinic collaborations with community organizations to aid patients struggling with issues like housing, addiction, or gender discrimination.

Patient engagement: self-referred versus others

Higher levels of patient engagement are associated with patients being compliant with PrEP guidelines. Every provider made some reference to patient engagement, whether explicitly as engagement or through descriptions of patient motivation, how informed patients are, or patients' consistency in following up. Some providers even defined poor adherence not just as missed PrEP doses but as also encompassing missed appointments and prescription pick-ups. In some cases, providers used language expressing inherently different motivations of patients on PrEP as compared to other types of patients—that prevention is different from treatment. For example, one respondent said:

> *The patients on PrEP that I have, are the MOST responsible of ALL my patients in primary care. When you compare my patients on PrEP with people with hypertension, with cholesterol, with diabetes, my patients […] these are not irresponsible people who take PrEP so that they can do what they want and have sex with whomever they want […] This is about people who are so thoughtful and so responsible that they are willing to pay the copays, go through the parking, all to prevent a problem that they may never ever have.*

This idea of intentionality recurred frequently in the way many providers described self-referred patients (i.e., those who understand that they are at risk of contracting HIV and seek PrEP services) as proactive, well-informed, and engaged. Another clinician stated:

> *In my mind, I am assuming they are adherent because they have taken the initiative to be coming to these visits on a regular basis, understand their risks, and are taking the steps to take care of themselves.*

At the same time, most providers articulated concerns about poor adherence for patients who missed appointments, failed to pick up prescriptions on time, or seemed to be poorly-informed. Those patients are typically the ones who are counseled to initiate PrEP by providers based on their risk of HIV as opposed to taking the initiative themselves to seek out PrEP. For the patients who are counseled about PrEP, there are several different referral pathways for them to arrive at a clinician who initiates their PrEP prescription. These referral pathways include starting in emergency rooms at hospitals, community-based STI screening programs, and primary care facilities. While I did not find accurate estimates of the distribution of self-referred patients versus others across clinics, most interviewees indicated that most of their patients on PrEP were self-referred.

Information appears to play a key role as a determinant of adherence. For instance, most providers mentioned that they help set expectations by providing patients with information on the importance of adherence, especially during the initial PrEP visit. Self-referred patients, who come to the clinic asking for PrEP, have a clearer sense of what to expect as they have already encountered this information prior to the initial clinic visit. One respondent said:

> *They are seeking us for PrEP. And so, when it comes to explaining things to them, educating them and counseling them, they have a good idea and they understand what's going on.*

The availability and absorption of accurate information regarding PrEP makes these patients more engaged in care and thus more adherent. Perhaps the same factors that determine how informed a patient is also determine the likelihood of being self-referred.

Patient risk perception

Patients' awareness and understanding of their risk of contracting HIV affect their adherence to PrEP. A few clinicians described cases of patients who had become HIV positive, and in each of those cases the patient had a misperception of their risk. For instance, one doctor described a patient's attitude by saying:

> *She had this disconnect where she didn't believe she would ever get HIV.*

This doctor was describing a patient who was at high risk of contracting HIV. Although the risk was identified by the doctor, the patient had difficulty internalizing the reality until it was too late. Similarly, several other respondents described scenarios in which patients had stopped taking PrEP due to a change in risk factors, such as transitioning from a sexually active lifestyle with multiple partners to a single-partner; however, these patients misperceived their own risk given that their partners had continued engaging in risky practices.

Patients' trust in providers and the health system

Patients who have more trust in the health care system and in their providers tend to have better PrEP adherence outcomes. The concept of trust emerged in several different ways, including: trust between patients and the broader health care system; interpersonal trust between individual patients and providers; and, trust between groups of patients and providers. This sub-theme highlights trust from the patient perspective, whereas another sub-theme of Global Theme 2 examines the provider perspective.

The interviews revealed two well-defined types of patients: those who trust the health system and those who do not. Providers from clinics with 50% or more non-white patients often mentioned that minority populations, especially African American women, tend to exhibit higher levels of mistrust in the health care system and lower levels of PrEP adherence. Several respondents attributed this to the history of racism in the U.S. In one case, a provider described a *flipped perception* among certain patients who believe that taking PrEP leads to HIV:

> *Race. Racism. […] The perception of the system and providers, and that in providing something like PrEP we're trying to control people who are black. So, there's a lot of counseling we have to do around there, and we're trying to give them control rather than control them. And, um, it's just a lot of sort of flipped perception of PrEP's role in the community […] A lot of people think that PrEP is a way to give HIV to people […] like they can actually transmit HIV to people or they think that we're trying to kind of systematically give PrEP to people, who are minorities, in order to try to control them or you know […] This is something that a lot of people feel like if they're on a daily med, it controls them – that they're not in control but they have to take this […] We talk a lot about benefits and the ability to take control and write your own story. […] They come in with the opposite frame of mind in terms of its role, you know. And we have to then flip that in our first encounter, and teach them that this gives them control.*

In attempting to counter these flipped perceptions, providers must be sensitive to how care processes affect patient trust. For example, another provider expressed concern about these types of patients perceiving PrEP adherence monitoring negatively as an invasive mechanism for controlling patients.

In terms of patients who do trust the health care system, they are also the ones who have higher levels of interpersonal trust with their providers. Providers described

how comfort and patient trust also play a role in how forthcoming patients are about adherence issues. For instance, patients who feel comfortable discussing sexual health with their providers are also more likely to discuss when they struggle to keep up with taking their PrEP pills. Interpersonal trust was also linked to barriers to primary care providers in prescribing PrEP. Both primary care and infectious disease specialists emphasized the importance of creating environments of trust for the patients so they could feel more comfortable in discussing sexual health.

Risk factors for HIV

Demographic and epidemiological risk factors for HIV are connected with adherence to PrEP because they are directly linked to the sub-themes above. Out of the various groups most at risk of HIV infection, all interviewees indicated that men who have sex with men (MSM) make up the vast majority of patients on PrEP at their respective clinics. Interviewees mentioned that other at-risk groups (e.g., transgender women, injecting drug users, and heterosexual women with unknown or positive HIV status partners) comprise smaller percentages of the overall distribution of patients on PrEP. Furthermore, there was a clear distinction in the dataset between self-referred patients and patients identified by a health care provider as being at risk and counseled to initiate PrEP.

Most providers expressed that older, educated white MSM have higher engagement, lower barriers to accessing care, and better understanding of their risk. The providers also described most of these patients as being self-referred. These patients tend

to have the highest compliance, in terms of clinic appointment attendance, following up with lab work, picking up prescriptions on time, and remaining in care. The opposite can be said about younger, non-white, non-MSM patients. Those patients tend to mistrust the health care system, struggle with compliance, and drop out of care faster. One provider said:

> *Younger people, African Americans, heterosexual women, and transgender women are the first to drop out of care. The ones that stay in care are the educated, gay, white males with commercial insurance.*

The dataset gave strong signals for the idea that those patients who struggle with adherence are also the hardest to reach. For instance, another provider said:

> *Many of our patients who are the least adherent are the ones who we have to chase down for that […] we get a lot of adherence data from patients that are the most adherent and have to really work to get it from [non-adherent patients]. For example, you know, we've got six people right now that have not gone to get their labs, who have been due for over a month.*

Global Theme 2: Providers trust their existing approaches to monitoring PrEP adherence but have continuing frustrations with patients dropping out of care

Table 4: Global Theme 2 and its sub-themes.

Global Theme 2	Sub-Themes
Providers trust their existing approaches to monitoring PrEP adherence but have continuing frustrations with patients dropping out of care.	• Evidence of efficacy • Existing adherence tools • Providers' trust in patients • Provider concerns

Evidence of efficacy or utilization guidelines

Providers need more evidence of the efficacy of UrSure's approach to believe that their laboratory adherence test would improve PrEP adherence outcomes. Evidence can take the form of either research studies on the subject or guidelines from normative agencies like the CDC. Some providers mentioned that they do not currently use laboratory adherence measures because there are no guidelines recommending their use. Others said that they would require more information about the utility, cost-effectiveness, impact on clinic workflow, and patient perceptions in order to consider implementing adherence testing for their patients on PrEP. Moreover, there was a prevailing belief among interviewees that laboratory adherence measures were not needed for patients who are already adherent. One provider said:

> *So, objective measure of adherence, I'm eager to see data from clinical studies that it improves adherence among people that are non-adherent. People who are adherent don't need additional measures because they're adherent.*

Existing adherence tools

Providers appear satisfied with their existing approaches to measuring PrEP adherence and interventions for addressing adherence concerns. All providers interviewed confirmed that they rely on self-report data for adherence information from their patients as their primary measurement tool. Additionally, most participants cited using pharmacy fill data for some or all patients, from both on-site, integrated pharmacies as well as external pharmacies. Data from clinic-integrated pharmacies are typically easier to obtain and, in some cases, directly linked to the patient electronic medical

records. For external pharmacies, providers rely on an internal pharmacist or other staff member of the clinic to call the external pharmacy to obtain patient pickup information. The way providers feel about self-reported adherence measures depends on multiple factors, including trust and engagement, as one provider described:

> *Thus far, self-reported adherence has seemed to be sufficient in that the patients that I have tended to see in my own personal clinic for PrEP have been very engaged, very excited about it […] and they are just glowing about how PrEP has improved their sexual health care.*

With regards to interventions for poor adherence, some providers talked about counseling patients directly during the clinic visit, suggesting the use of pillboxes, and inviting patients to meet with a clinical pharmacist. In addition, a few providers praised the power of motivational interviewing† in helping patients recognize their original intentions for starting PrEP in the first place. One provider stated:

> *Understanding or establishing why the patient was interested or what brought them to PrEP in the first place. Like, why did you come here? What prompted you to start this process? And kind of getting back to that. Getting back to your why if you will. And realizing that PrEP is something that, you know, your why may change. Your why may not be what it once was. Maybe this is something that you just felt like you needed to continue doing even though the reason you came in the first place isn't the same or maybe it doesn't exist anymore.*

Most clinics also use PrEP navigators, or PrEP coordinators, who are non-clinician staff in charge of communicating with patients on a regular basis through phone calls and text

† Motivational interviewing refers to a technique in which providers survey patients about adherence and intervene directly in case of non-adherence by: 1. helping patients identify their resistance to change and 2. fostering behavior change through interviewing and advice.

messages. These navigators answer basic questions regarding PrEP, send reminders for appointments, and provide positive reinforcement messaging to keep patients engaged in care. Respondents praised the efforts of PrEP navigators, as one provider said here:

> *We have an extremely good coordinator, navigator person, who follows up with people. She does a really good job, you know, texting everyone following up their three-month follow up appointment. And to this point, everyone who has stayed in our care is negative. There have been people who have, you know, dropped out of care and we don't know about them. Hopefully they're negative but we don't know that. So, it's a difficult and ongoing issue to keep the people in, in care and if we did not have this person who you know, it is a full-time job to follow up, you know, text, call, assist facilitate, help them reapply for financial assistance, etc. If she wasn't doing that, you know, we'd have a lot more people falling out of care and maybe even, you know, seroconverting.*

Providers' trust in patients

As described in Global Theme 1 above, trust plays an important role in patient-provider interactions. Several dimensions of trust are important from the provider perspective that influence concerns about adherence. When they feel patients are engaged and consistent with clinic visits, providers tend to believe self-reported adherence and are less concerned about adherence. According to the interviewees in this dataset, most of their patients on PrEP are engaged and consistent with visits, which is reflective of risk factors, demographics, and other patient characteristics across the board. Several respondents expressed trust in self-reported adherence for both patients who voice positivity about being on PrEP and who are forthcoming about their struggles with adherence. A few providers also used language conveying the ease of a clinic visit as an

indicator of how much they trust the patient's self-reported adherence. For example, one provider said:

> *Very, very easy visits. I would say they're overall my most compliant patients. They come to every single appointment. Almost always, they're on schedule. We have very frank conversations about what they're doing, and I really just don't have a lot of concerns. They're the people who decided they needed it. They understand their risks. They own it. They appreciate what we're doing to protect themselves.*

On the other hand, providers were suspicious of self-reported adherence by patients who regularly miss appointments or prescription pickups, as well as when there are glaring discrepancies between appointment dates and prescription fill dates (e.g., patient returns for a follow-up visit six months after the last prescription fill which would have provided only three months of medication). Some providers stated that they do not corroborate self-reported adherence using pharmacy fill data unless they have suspicions about the self-report.

Provider concerns with patient retention

Providers acknowledge that adherence to PrEP is important given its efficacy in preventing HIV, but they are generally more concerned with patients who drop out of care completely. Many of the respondents explicitly cited retention in care as the biggest challenge in their clinic's PrEP program. Most providers reported that more than 30%-40% of patients dropped out of care. The main hypotheses were that patients were transferring care to a different clinic, had lifestyle changes leading to reduction in HIV risk, changes in insurance coverage, or struggles with costs of care and/or side effects.

While some proportion of the drop-outs are due to changing patient risk factors that obviate the need for PrEP, providers have no way of verifying this since patients do not communicate these changes after the last visit. One provider expressed interest in using technology, such as better-integrated electronic record systems, to improve how clinics track patients over time and predict who may be at risk of dropping out. Moreover, some providers are particularly concerned about vulnerable populations who drop out. For instance, one prescriber stated:

> *There have been people who have, you know, dropped out of care and we don't know about them. Hopefully they're negative, but we don't know that. So, it's a difficult and ongoing issue to keep the people in care […] So we saw a lot of younger women, minority women basically because those are the people who live around the hospital would come in, you know, to the ED. But the minority women would say they had chlamydia, gonorrhea, or something like that […] and they were all dropped out of care by at least six months. Many of them dropped out after the three months visit. They just did not follow up.*

Global Theme 3: Financial and workflow factors are important in how clinics run their PrEP programs

Table 5: Global Theme 3 and its sub-themes.

Global Theme 3	Sub-Themes
Financial and workflow factors are important in how clinics run their PrEP programs.	• Organizational decision-making • Resource constraints • Importance of 340B revenue

Organizational decision-making

The type of clinic influences how decisions are made for adopting medical innovations. Across the board, most respondents said that in their clinics, changes to care guidelines and protocols could take anywhere from several months to a year, with respondents from larger facilities suggesting longer time horizons. A medical director of a PrEP program at a large health care system mentioned that it would take approximately six months to obtain a decision from the senior clinic leadership on whether to adopt a new lab test. Another medical director at a smaller health care facility mentioned that implementing a new lab workflow could be done in as little as a week. Several respondents described similar processes in making changes to standard care guidelines that included: a proposal based on new research; discussions with various stakeholders, including clinical leadership; approvals from some governance bodies; and implementation processes.

Resource constraints

Many of these health care facilities are resource-constrained; therefore, the cost-effectiveness of interventions plays an important role in how they allocate resources. At certain clinics, the facility cannot bill for the clinical consultation for a PrEP visit. So, time constraints also become important. One provider said:

> *They're short visits, you know, consulting visits, and I think they probably get three cents on the dollar or something like that for our consulting visits. The meetings are really short, and I don't think the clinics earn a lot from it.*

Similarly, another provider at an infectious disease clinic specified that their PrEP program does not make money for their clinic. Instead, they rely on public and private grant funding to sustain the program. Some providers described insurance mix, or the distribution of insurance coverages of patients, as an important financial consideration at a clinic level. For example, private insurance reimbursements are higher than Medicaid reimbursements, which makes financial sustainability more feasible for a clinic with privately insured patients. Furthermore, when there are financial constraints, the PrEP program may not be a priority for a clinic. One provider described competing priorities at their facility:

> *Because finances are tough in an academic medical center, I'm not sure that's where they would put additional resources, when they are fighting for additional nursing, staffing, and other things that we need that benefit a larger population of the patients.*

Importance of 340B revenue

The 340B revenue can be critical to sustaining PrEP services at clinics. At some clinics, certain resources for the PrEP program – or even the entire program – were funded directly through 340B program revenue. For instance, one infectious disease clinic uses 340B funds to pay for a full-time clinical pharmacist. Additionally, this 340B revenue seems to be vital at clinics that have higher proportions of under-/ un-insured patients. One participant stated:

> *The 340B program is a lifesaver. That's how we pretty much stay alive, pretty much the FQHCs.*

Another participant stated that many of the clinic-wide services would be cut without 340B revenue. A third respondent, at a clinic where approximately 75% of patients are uninsured, indicated that their clinic offers free labs, free medications, and free visits, all enabled by revenue from 340B, stating:

> *We make no money on our own. We don't charge for anything. We offer free labs, free medications, and we don't charge for visits […] All of our revenue is 340B.*

RESULTS

This section discusses the implications for practice, in the form of implications from each of the three global themes followed by three strategic recommendations for UrSure. Later in the section, I present reflections on the methodology and limitations of the project.

Implications for Practice

This section summarizes the implications for UrSure derived from the global themes described in the Analysis. I extrapolated these implications by analyzing the themes through the lens of my experience at UrSure and the findings from the literature review. Specifically, I relied on key elements of customer value propositions in health care as outlined in Figure 7 in the Literature Review: identifying customers and unmet needs; perceived benefits, especially health outcomes; perceived costs, including status quo bias, financial costs, and workflow costs; implementation strategy; and approach. Where appropriate, I also highlight how my findings substantiate the importance of some of these factors. Throughout this process, I referred to the operational goal of this project, which is to assess challenges and opportunities associated with UrSure's customer value proposition.

I have identified implications for each of the three global themes. The implications for Global Theme 1 are presented as challenges for UrSure's approach and in identifying customers: 1.) UrSure's approach may not be addressing the underlying determinants of

poor PrEP adherence and 2.) additional customer discovery work may be required to find the right customer. The implications for Global Theme 2 are highlighted as challenges stemming from status quo bias and identifying unmet needs, as well as an opportunity to address customer needs around retention. The implications from Global Theme 3 are outlined as opportunities in customer identification through financial factors.

Implications from Global Theme 1

Table 6: Global Theme 1 and its sub-themes.

Global Theme 1	Sub-Themes
Providers believe multiple factors influence patients' PrEP adherence outcomes.	• Patient barriers to care • Patient engagement • Patient risk perception • Patients' trust in providers and the health system • Risk factors for HIV

There are two important implications of the first theme for UrSure's customer value proposition. First, the determinants of adherence to PrEP challenge UrSure's proposed innovation and its approach to delivering intended benefits to its customers. In many cases of poor adherence, UrSure's lab test might not be able to address the underlying factors. For instance, UrSure's test only works when patients actually show up for their clinic visits and submit samples for laboratory testing. Yet, for many patients who cannot or choose not to make it to their clinic appointments, there would be no way to identify them and address why they are not adherent. Moreover, while UrSure's test can in some cases help providers identify non-adherent patients and improve their risk

perceptions through counseling, those same patients may be susceptible to mistrusting the health system. The company must ensure that its test is not perceived by providers as a risk for exacerbating patient mistrust. One way to do this is by communicating the supportive aspects of the test both in sales calls and in implementation strategies.

The second implication of this theme relates to identifying customers. UrSure may need to conduct additional customer discovery work to better understand where its offering has the best fit within the 340B clinic segment. There may be clinics with certain patient populations, based on demographics, clinic type, and HIV risk factors, that could benefit more from UrSure's test than others. Through additional customer discovery research, the company can sharpen its value proposition by narrowing in on the most appropriate target customer. Moreover, from an operational point of view, these learnings can help develop the criteria for qualifying sales leads, a way of improving sales efficiency by targeting only potential customers with the highest likelihood of converting into actual customers.

Implications from Global Theme 2

Table 7: Global Theme 2 and its sub-themes.

Global Theme 2	Sub-Themes
Providers trust their existing approaches to monitoring PrEP adherence but have continuing frustrations with patients dropping out of care.	• Evidence of efficacy • Existing adherence tools • Providers' trust in patients • Provider concerns

The second global theme highlights major implications for UrSure in terms of the customer value calculus and unmet needs. The first implication is that status quo bias may be much worse than previously assumed by UrSure, magnifying the perceived costs in the value equation. Providers not only seem to trust that many of their PrEP patients are adherent, they also seem to have faith in their existing solutions for measuring adherence. Although studies on medication adherence among patients with chronic illnesses have shown that self-reported adherence is generally not the most reliable measure of adherence (Jerant et al., 2008; Lam & Fresco, 2015), many providers continue to depend on this tool for patients on PrEP. They perceive most patients on PrEP to be forthcoming with adherence issues during visits; furthermore, they seem content to rely on pharmacy fill data when adherence suspicions do arise, and therefore do not see the need for UrSure's test.

In terms of implications related to unmet need, there are both challenges and opportunities. Based on the interviews for this thesis, there may not be a substantial unmet need for adherence testing for patients on PrEP. Many providers are not concerned about adherence for most patients on PrEP, since they generally perceive them to be more engaged in care than other types of patients. Moreover, if providers believe that the same mechanisms that lead to poor adherence cannot be solved by objectively measuring adherence or that already adherent patients would not benefit from adherence testing, there is a considerable burden on UrSure to demonstrate otherwise.

On the other hand, there seems to be a clear unmet need related to patients on PrEP dropping out of care. This global theme corroborates the idea that providers are

concerned about improving patient health outcomes, and it highlights an unmet need for achieving improved outcomes. When patients drop out, they typically do not notify their care providers, which makes it almost impossible for providers to know for whom they should have adherence concerns. Providers would likely be relieved if there were some mechanism that helped distinguish whether patients drop out of care due to non-concerning reasons (e.g., going from high-risk behavior to low-risk) or concerning reasons (e.g., poor understanding of HIV risk). If UrSure's lab test can demonstrate improved outcomes for keeping patients in care, then the value proposition could be framed more around retention than adherence. Alternatively, the company could also work on developing complementary solutions that more directly address providers' concerns around retention.

Implications from Global Theme 3

Table 8: Global Theme 3 and its sub-themes.

Global Theme 3	Sub-Themes
Financial and workflow factors are important in how clinics run their PrEP programs.	• Organizational decision-making • Resource constraints • Importance of 340B revenue

The main implication emerging from the third global theme is that certain types of 340B clinics may be particularly interested in UrSure's lab test as they may gain substantial financial benefits from its use. This highlights the importance of financial benefits as a factor for a compelling value proposition. For instance, FQHCs and

community STD clinics that rely on the 340B funds to sustain their PrEP programs would likely be interested in increasing their programmatic revenue. So, the company could target these types of clinics and make a stronger financial case for using UrSure by providing evidence of improved outcomes. Given that finance, workflow, and cost-effectiveness are important factors in how clinics make decisions, the company should emphasize the financial and cost elements of its value proposition. In particular, UrSure could demonstrate how the clinic can generate a good return on investment from improved adherence outcomes, a win-win proposition. Something as simple as a spreadsheet-based 340B revenue calculator may help catch the attention of decision-makers interested in financial benefits.

Additionally, as I briefly described in the Background section, the sales efforts with 340B clinics uncovered differences in organizational context among different types of 340B clinics. For instance, 340B clinics administered by public health agencies expressed having limited autonomy in using 340B revenue, whereas privately-run clinics seemed more flexible with their funds. The privately-run clinics also tended to move faster in making decisions on whether to adopt new innovations. Perhaps UrSure could use these types of organizational context factors to further narrow the target list of potential 340B clinic customers.

Strategic Recommendations

In this section, I present three strategic recommendations for UrSure. In order to translate my research into relevant, practical, and actionable recommendations for

UrSure, I considered the implications discussed above collectively and drew upon my firsthand experience in the role of Director of Business Development. The first recommendation is for UrSure to conduct additional customer discovery research to verify customer needs. The second recommendation is to consider reframing the customer value proposition of the lab test. Finally, the last recommendation is to continue generating evidence that demonstrates the efficacy and utility of adherence testing among the company's existing customers. Although these recommendations were made specifically for UrSure, they may be relevant to many other early stage businesses in general.

Strategic Recommendation 1: Lean into Lean Startup: Conduct Additional Customer Discovery Research to Verify Unmet Customer Needs

My first recommendation to UrSure is to embrace the customer development model and conduct additional customer discovery research. The implications from Global Themes 1 and 2 demonstrate that UrSure has not achieved a clear product-market fit among the clinicians interviewed. Additionally, as I have learned from this project, the importance of customer discovery cannot be overstated. In fact, it is so important that the National Science Foundation's Innovation Corps (I-Corps) program, a customer discovery approach to commercializing life science, calls on aspiring entrepreneurs to conduct highly-disciplined interviews with 100 potential customers before even considering launching a venture (Robinson, 2012; Thamjamrassri et al., 2018; U.S. National Science Foundation, 2020; VentureWell, 2014). While I am not necessarily

suggesting the company should follow the regimented I-Corps model, I do believe some form of additional customer discovery must be undertaken by UrSure to resolve questions regarding unmet need.

During the latter half of my tenure at the company, we discussed applying lean startup principles into our work but fell short of fully implementing the approach. Since the lean startup philosophy emerged from the customer development model, I would encourage UrSure to revisit implementing the central concept of rapid and targeted hypothesis testing of customer demand. The company should repeatedly test hypotheses about potential customer segments and what problems are important to them until it finds a segment/ problem that clicks into place with its lab test. Through iterative customer discovery, the company can address the challenge of verifying unmet customer need, whether that means reimagining who the customer might be or gaining a better understanding of how they prioritize their problems.

In addition to improving the chances of achieving product-market fit for the lab test, customer discovery efforts will help optimize UrSure's sales processes. They will help develop enhanced criteria for qualifying sales leads. For instance, based on the findings of this thesis, I would now de-prioritize sales outreach at academic medical centers and instead focus on FQHCs in regions that serve vulnerable populations. Similarly, additional customer discovery research will reveal new customer characteristics that can turn into decision factors for whether to expend resources on certain leads.

This project offers UrSure a practical approach to conducting customer discovery research. Not only can this research be replicated by someone currently at UrSure, it can also be used as a foundation for deeper inquiry. For instance, in addition to the analysis presented in this thesis, I will also be sharing the domain summaries of my interviews with the CEO of UrSure. These domain summaries contain useful pieces of exploratory information that can inform new hypotheses.

Strategic Recommendation 2: Consider Reframing the Value Proposition of the PrEP Adherence Lab Test

My second recommendation to UrSure is to consider reframing its customer value proposition by communicating different aspects of its test or focusing on a radically different set of benefits. As outlined in the implications from Global Theme 2, the status quo bias is widespread and intense among most providers since they appear to value their existing adherence tools considerably. Therefore, UrSure must overcome this bias by demonstrating benefits that providers or clinics will perceive as substantially greater.

One approach could be to focus on providers' concerns around patients on PrEP dropping out of care, as discussed in the implications from Global Theme 2. UrSure could highlight how the test improves retention in care and, if available, provide strong evidence to back this up. Alternatively, UrSure could develop a separate, and perhaps complementary, product or service that tackles the drop-out problem. For example, there may be a digital health solution to predict the likelihood of a patient dropping out and provide interventions in advance.

Secondly, a rather radical approach could be to reposition UrSure's offerings as a PrEP advisory service for clinics. For instance, UrSure could help clinics set up new PrEP programs or optimize existing ones in the same way certain companies help setup 340B programs (e.g., Shields Health Solutions, which has helped clinics integrate specialty pharmacy programs in Massachusetts). Given UrSure's growing expertise in the PrEP adherence space, the company could offer best practices for clinical protocols related to PrEP, such as effective adherence counseling approaches. Moreover, the company currently produces clinic-level summaries that provide aggregated PrEP adherence measures to benchmark clinic performance, and it could highlight these as part of a suite of consulting offerings.

Lastly, the company could focus on HIV-positive patients enrolled in treatment programs instead of patients on PrEP, who are prevention focused. Since the lab test measures concentrations of tenofovir, it works for most HIV treatment regimens. While HIV treatment patients do not necessarily come for clinic visits as regularly or as frequently as patients on PrEP, it would be worth exploring the potential needs in this segment through further customer discovery.

Strategic Recommendation 3: Continue Generating Evidence to Demonstrate Utility and Efficacy of Prep Adherence Testing Among Existing Customers

My final recommendation to UrSure is to continue generating evidence on improved outcomes using data from existing customers. Global Theme 2 illustrates the need for evidence on efficacy as a formidable challenge to UrSure's value proposition.

Given the limited number of studies that have been done on ways to measure or improve adherence to PrEP in real-world settings, UrSure's unique data repository of longitudinal adherence outcomes across several different existing clinic customers is a tremendously valuable asset, both from public health and business perspectives. For example, this dataset can be used for clinic-level performance assessments, especially since UrSure has a growing set of reference values from other clinics as benchmarks. From a sales and marketing point of view, showing these types of performance summaries may help demonstrate the benefits in its value proposition among skeptical potential customers. This would not only apply to the 340B clinics customer segment but to all customers UrSure aims to reach. Alternatively, there could be a way to monetize these data with public health agencies, which may be willing to sponsor continued population-level analysis. Internally, the growing database could help the company validate customer development hypotheses on outcomes and cost-effectiveness. Therefore, UrSure should continue gathering what it can from existing customers and find ways to use that knowledge to strengthen its value proposition.

Project Limitations

There were several limitations to this project, including the sampling strategy, the total number of interviews, the rigidity of the topic guide, and the duration of the interviews. Additionally, this project focused on one type of customer, so the results may not generalize to other customer segments.

In terms of the interview sampling, I ended up relying on convenience sampling for several earlier interviews, which were mostly with infectious disease clinicians at academic medical centers. Although the original outreach was done across a broad range of clinic types and locations, there was less diversity than anticipated among the respondents who actually participated. For instance, out of the thirteen interviews, four providers were affiliated with the same hospital system. Furthermore, there were limitations in terms of clinic locations, since almost all participants were affiliated with urban health care centers.

The interview topic guide and duration of each interview were also limitations. Although I had intended the interviews to be semi-structured, the short duration of each interview (30-45 minutes) limited my ability to let interviewees diverge from the topic guide. Sometimes, these divergences can provide meaningful insights that may not have been initially considered in a topic guide. The shorter interviews were mainly due to time constraints on clinicians' schedules—it can be quite challenging to get a hold of clinicians during business hours.

The project could have also benefitted from more interviews, as the total number of interviews was limited by time constraints and low response rates to the initial outreach. A topic guide should be tested and refined through practice interviews, and perhaps even adjusted over the course of the first few interviews. I did not have the opportunity to trial my initial topic guide before the first interviews, and I recognized later on that certain questions did not trigger insightful responses. However, due to the limited number of total interviews, I decided to continue using the same questions. With

more interviews, I would have been able to evolve the topic guide over time. Moreover, given that conducting interviews in a standardized way can be a learning process for the interviewer, I know that my earlier interviews had more variations as I tried out different questions.

There were also limitations in the generalizability of my findings, as this project focused only on 340B clinics and clinicians. While many of the learnings can be generalized to many other types of clinics, there may not be much generalizability to other segments like DPHs or researchers. Also, there seem to be key distinctions within the 340B segment, so some of the results may not apply across all 340B clinics. Furthermore, since I did not interview non-clinician stakeholders, I may have missed useful insights from patients, PrEP navigators, and other individuals.

Broader Lessons in Entrepreneurship

Through this doctoral project, I have collected several lessons that may be useful for entrepreneurs across sectors. The first is a confirmation of the central thesis of the customer development model, that entrepreneurs should avoid developing products without identifying and validating market demand. Secondly, entrepreneurs should always be aware of competition, even when it seems that none exists. Lastly, startups can save precious resources by ensuring work activities correspond to their appropriate stage of growth.

Even the best-intentioned and best-designed offerings may fail to scale due to market demand issues. At UrSure, the offering was developed by clinicians attempting to address a real problem within their clinic. While the solution they developed seemed promising in their own setting, my experience and research illustrates that many questions around market demand remained unanswered. Reflecting back on this experience, it seems that we may have been in the proverbial *hammer-looking-for-a-nail* situation, where we had a product for which we were seeking a customer problem. Perhaps the company would have benefited from following the customer development model from the very beginning.

Secondly, entrepreneurs should be suspicious when there seems to be no competition. Part of this warning comes from what I have learned about the status quo bias, where customers may value existing solutions so much that they essentially create a substantial barrier to entry for alternative solutions. Customers always have alternative solutions for problems, including the option to do nothing. Surprisingly, doing nothing may have a strong status quo bias, especially in the health care sector due to provider inertia.

Lastly, entrepreneurs should ensure that they align their work appropriately to their startups stage of growth. Upon encountering the Start-to-Scale model (see Figure 3 above), I realized that the activities I carried out in my Director of Business Development role at UrSure were geared more to the go-to-market fit phase; yet, in reality, the company was still in the product-market fit phase. Instead of establishing sales processes and

trying to sell a product, my efforts should have been more focused on understanding our potential customers and their problems.

CONCLUSION

HIV continues to be a major public health crisis, with more than 1 million people infected and an additional 1 million people at risk in the United States. UrSure's PrEP adherence test has the potential to help address this crisis by improving the efficacy of prevention based on PrEP, which could lead to a reduction in the spread of the disease. In order to maximize its potential public health impact, UrSure must overcome barriers to entrepreneurial growth and successfully scale up its business.

This doctoral project accomplished both the strategic objective of providing recommendations to help UrSure on its path to scale and the operational goal of assessing challenges and opportunities associated with UrSure's customer value proposition within the 340B clinic customer segment. In this thesis, I synthesized my experiential learning from a nine-month stint as Director of Business Development at UrSure, an interdisciplinary literature review covering entrepreneurship & health care innovation, and a qualitative research study of potential UrSure customers within the 340B clinic market segment.

My experiential learning and literature review informed the design, execution, and analysis of a set of customer interviews. The experiential learning provided useful contextual understanding of the company, potential customer segments, and the facilitators & barriers to sales within the 340B clinic segment. The literature review of entrepreneurship theory and health care innovation helped anchor this project with the customer development model and establish the pertinent factors affecting customer value

proposition in health care. Together, these provided the evaluative lenses for assessing UrSure's value proposition.

Using thematic analysis on data collected during interviews with thirteen clinicians at 340B health care facilities, I interpreted the findings as three emergent global themes. The first is that providers believe multiple factors influence patients' PrEP adherence outcomes. The second theme is that providers trust their existing approaches to monitoring PrEP adherence concerns. The third theme is that financial factors are important in how clinics run their PrEP programs.

I distilled implications from each of the global themes as challenges and opportunities associated with UrSure's value proposition within the 340B customer segment. The implications for Global Theme 1 are challenges for UrSure's approach to delivering intended benefits to its customers: 1) UrSure's approach may not be addressing the underlying determinants of poor PrEP adherence and 2) additional customer discovery work may be required to find the right customer. The implications for Global Theme 2 include challenges stemming from status quo bias and identifying unmet needs, as well as an opportunity to address unmet customer needs around patients dropping out. The implications from Global Theme 3 are outlined as opportunities in customer identification through financial factors.

Considering the implications collectively, I translated my research into three relevant, practical, and actionable recommendations for UrSure. The first recommendation is for UrSure to conduct additional customer discovery research to

verify customer needs. The second recommendation is to consider reframing the customer value proposition of the lab test. Finally, the last recommendation is to continue generating evidence that demonstrates the efficacy and utility of adherence testing among the company's existing customers.

Future work could include several interesting topics, such as implementing the strategic recommendations from this project, conducting customer discovery research on UrSure's anticipated point of care test, or assessing the potential business impact of largescale changes in the HIV prevention space. For instance, the company could focus on developing strategies to deal with the scale-up of generic PrEP formulations in the U.S. or the introduction of Gilead's new branded PrEP formulation, Descovy. Finally, with the development of long-acting injectable PrEP or the discovery of an HIV vaccine, there may be broader implications to UrSure's long-term growth.

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APPENDICES

Appendix 1

UrSure Customer Best Practices Document (page 1 of 2)

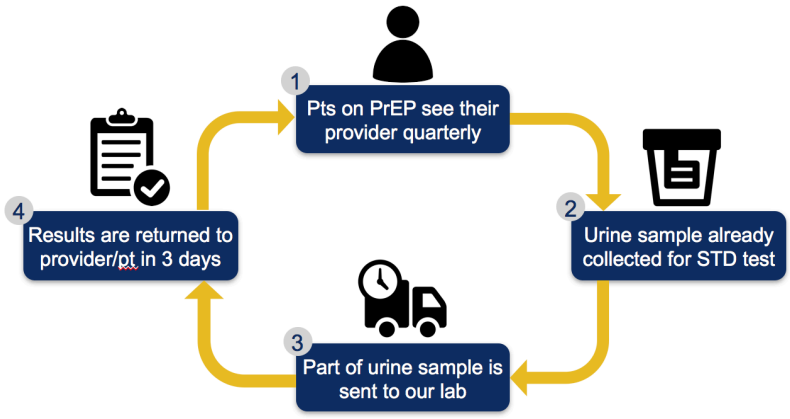
UrSure inc.
Diagnostics to Prevent HIV

Best Practices for Clinical Use of UrSure Tenofovir in Urine Test

This document is a guide to recommended best practices for using the UrSure Tenofovir Adherence test with patients taking PrEP. Recommendations are the result of clinical experience using the urine test in a number of settings for research and pilot work.

Logistics of using the urine test

We recommend using the urine test as part of the patient's standard quarterly testing schedule. When the patient comes in for their quarterly visit, a blood and urine sample are already collected. A portion of that urine sample should then be transferred to the UrSure urine cup, placed in a pre-labeled envelope along with an order form, and picked up by FedEx for shipping to UrSure's commercial lab. Results will be returned within three days to the provider through either an online portal or fax.



Introducing the test to patients

When framing the need for the urine test to patients, we have found it most helpful to discuss it as a tool to help better protect them from HIV. The test has two key benefits:

1. *For the individual on PrEP*: If adherent, the test shows you that the drug is in your system at a level consistent with recent adherence and therefore protection from HIV infection. We have found that when the patients have a way to actively visualize the benefit of PrEP, it seems to be a strong motivator to continue taking their medication adherently.

UrSure inc.
Diagnostics to Prevent HIV

2. *For the provider*: The test allows the provider to have an objective measure of adherence. This serves as a conversation starter around barriers the patient may be encountering to taking the medication adherently and how to overcome them.

While introducing the test to patients, we have found it helpful to share that we have also had to take daily medications, and we know how hard it can be to remember and remain adherent.

Interpreting the test results

The concentration of tenofovir is reported in ng/mL and will fall into one of three levels. The interpretation of those levels is described below.

TFV level (ng/mL)	<10	10 < X < 1,000	>1,000
Interpretation of results	Drug not taken in last 7 days	Drug taken in last 7 days but not last 48 hours	Drug taken in last 48 hours
Adherence level	Non-adherent	Inconsistently adherent	Recently adherent

Discussing results with patients

If the results show recent adherence (>1,000 ng/mL): A level above 1,000 ng/mL indicates the patient was recently adherent and has taken a dose of the drug in the last 48 hours. This information should be shared with the patient as evidence the drug is in their system at a level consistent with protection, and they should be encouraged to continue their adherence.

If the results show inconsistent adherence (Between 10 and 1,000 ng/mL): This range indicates the patient has access to the drug but is inconsistently taking it. For these patients, we share results, encourage them to share what their barriers to adherence are, and discuss ways to improve adherence. In this range, we often find that patients have the drug in their home but are forgetting to take it daily. Placing their pill bottle next to something they do on a daily basis like their toothbrush can be helpful to improve the consistency with which the patient takes their medication.

If the results show non-adherence (<10 ng/mL): With these patients, we also share results, encourage them to share what their barriers to adherence are, and discuss ways to improve adherence. For these patients, we often find that the issue is not being able to access the medication, and we allocate resources to help them afford or pick up their medication depending on the barrier.

Appendix 2

Topic Guide for 340B Clinic Interviews

Research question: What is the perceived value of adherence information in HIV PrEP programs at 340B and other clinics?

Introduction:

- Thank the interviewee for their time and willingness to participate
- Remind interviewee about the purpose of the study and the assignment
- Remind the interviewee that there are no right or wrong answers and that they can stop the interview at any point
- Remind the interviewee of prior consent via email/ phone, and request consent to audio record the interview
- Ask if they have any questions

----------TURN ON RECORDER----------

Interview questions:

- Can you start by telling me a little bit about the clinic and your role at the clinic?

Understanding needs and opportunities

- About how many patients at your clinic are on PrEP?
- Can you describe to me the workflow of a typical PrEP patient visit?
- Can you tell me about a time when one of your patients on PrEP seroconverted with HIV?
- Is obtaining PrEP adherence information important to you? Why or why not?
    - How do you obtain this information from patients?
    - What other sources of information help you determine adherence? / How do you validate adherence information?
    - How do you define poor, satisfactory, and excellent PrEP adherence? What do you do if a patient has poor adherence?
    - If you could improve anything with this process, what would it be?
- What percentage of your PrEP patients drop out of care annually? Why do you think that happens and how has your clinic addressed it?
- What are the typical demographics of your patient community? Why are you / are you not serving vulnerable populations? How important is increasing PrEP adoption among your patient population?
- How important is the PrEP program to the overall financial performance of the clinic?
- Does your clinic participate in the federal government's 340B program? How important is the 340B program to the overall financial performance of the clinic?
- How does your clinic differentiate itself from similar clinics in the region?

Understanding the purchasing process and buying center roles

- What is the process for making changes to your clinic's standard care protocols in general? Who are the people involved in that process?
- What are some examples of new guidelines, procedures, or interventions your clinic has adopted in the last 6 months?

Willingness to pay (yes/ no questions)

- Do you believe you could provide better individual care to your patients if you had an objective measure of their recent adherence to PrEP?
- Do you believe your clinic would benefit from PrEP adherence measures at a clinic-level?
- Do you think your clinic would be willing to pay for such information, at either the individual or clinic level?

----------TURN OFF RECORDER----------

Appendix 3

Table A-1: List of interviewees.

Respondent	Clinic	Clinic Type	Location (US Census Region)	Clinician Type	Clinician Specialty	# of Patients on PrEP at Clinic	# of Patients on PrEP in Clinician's Care	Patient Demographics / Health Literacy / Risk Factors
1	A	Academic / Infectious Disease	Northeast	MD	Infectious Disease	150-200	60-90	70% white; "80% very high health"
2	A	Academic / Infectious Disease	Northeast	MD	Infectious Disease/ Clinic Director	150-200	15-20	Mostly MSM; "well-engaged and fairly well-educated population"
3	A	Academic / Infectious Disease	Northeast	MD	Infectious Disease	150-200	~20	90% MSM; "health literate"
4	B	Community-based / STD	South	PharmD	Director of Pharmacy Services	120	-	50% Caucasian, 50% people of color/ African American; most aged under 40; "generally health literate"
5	C	Large Size Health System	Northeast	MD	Infectious Disease	300-400	~20	Virtually all MSM or transgender women
6	A	Academic / Infectious Disease	Northeast	MD	Infectious Disease	150-200	~15-20	Almost all white, MSM; 50% aged 18-30, 50% aged 45-55; "extremely health literate"
7	D	Large Size Health System	West	MD	Primary Care + HIV specialty	-	75-100	80% aged less than 40; >90% MSM, 5% transgender women
8	E	Academic / Infectious Disease	West	MD	Infectious Disease	~200	~70	Majority MSM; 50% people of color, 50% white; mostly aged 20-40; higher proportion of women and transgender women who do sex work than national average
9	F	Academic / Primary Care	Northeast	MD	Primary Care + HIV specialty	115	15	Vast majority MSM; age range 25-65; health literate
10	E	Academic / Infectious Disease	West	NP	Infectious Disease	200-300	75	~75% Caucasian MSM; Majority aged 25-40; Some sex workers
11	G	Community-based / FQHC	Midwest	PharmD	VP of Pharmacy Services	500-600	-	Mostly white MSM; Most patients aged 25-45; high health literacy
12	H	Medium Size Health System / FQHC	South	DO	Medical Director/ Primary Care	1700	-	Mostly MSM; majority aged 25-40; Mostly Hispanic; health literacy varies
13	I	Large Size Health System	South	MD	Primary Care	127	-	80% black/ African American; median age: 40, range 17-60s; mostly MSM or transgender women

MSM: men who have sex with men