

**Barriers and Facilitators to Long-Acting Injectable HIV PrEP Implementation in Primary Care Since Its Approval in the United States**

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## Abstract

**Background:** HIV pre-exposure prophylaxis (PrEP) is a highly effective method to mitigate the HIV epidemic, but uptake of PrEP has been slow and is associated with racial and gender disparities. Oral PrEP requires high levels of adherence to be effective, which may disadvantage certain high-risk groups. The first injectable HIV PrEP, a drug given every two months rather than as a daily pill, was approved by the FDA in December 2021.

**Setting:** A Family Medicine practice in a single health organization in the United States (November 2022 – February 2023)

**Methods:** We conducted interviews with patients and key stakeholders to characterize factors affecting LAI PrEP implementation. Data collection and analysis were guided by the Consolidated Framework for Implementation Research. Interviews were transcribed and analyzed using guided content analysis.

**Results:** Twenty-five patients (n=13) and practice stakeholders (n=12) were interviewed. Overall, stakeholders described a very low uptake of LAI PrEP. Barriers to LAI PrEP included a lack of awareness, insurance and access issues, a lack of streamlined workflow, and a trust in pills over injectables. Facilitators to LAI PrEP implementation included the absence of a pill burden, a culture of shared decision making, and pharmacy support.

**Conclusion:** While uptake has been slow, we have identified several promising strategies for improving rollout and implementation of LAI PrEP. Approaches that can bolster rollout of LAI PrEP include having an interdisciplinary care team that is supported by PrEP navigators and pharmacists and are informed by a patient-centered model of care to increase patient engagement and trust.

**Key Words:** Long-Acting Injectable, HIV Pre-Exposure Prophylaxis, Implementation, Primary Care

## Introduction

HIV pre-exposure prophylaxis (PrEP) is a highly effective method to mitigate the HIV epidemic in the US.<sup>1</sup> While PrEP use for HIV prevention has increased since its approval in 2012, only 30% of the 1.2 million people for whom PrEP is recommended were prescribed it in 2021.<sup>2</sup> Data demonstrate the feasibility, safety, and effectiveness of oral PrEP, but uptake has been slow in some settings. Given the gap in uptake and PrEP-associated racial and gender disparities, there is significant room for improvement.<sup>3</sup> Oral PrEP requires high levels of adherence to be effective, which may disadvantage certain risk groups.<sup>4,5</sup> The first injectable treatment for HIV PrEP, a drug that can be given every two months rather than as a daily pill, was approved by the FDA in December 2021.<sup>6</sup>

LAI PrEP can address some of the limitations of oral PrEP. Barriers to oral PrEP uptake include stigma, healthcare access, side effects, competing stressors, and low HIV risk perception.<sup>4,7</sup> LAI PrEP has some advantages that may alleviate oral PrEP-associated barriers as it does not require the user to store or remember a daily pill. However, LAI PrEP is not without challenges. Patients

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seeking LAI PrEP, who may not be accustomed to regular engagement with healthcare, are required to see a healthcare provider for an injection six times a year, which may also represent a challenge for patients. Additionally, ambulatory settings need to grapple with the development of new processes for insurance coverage, storage, staffing, scheduling, tracking, and follow-up. Providers need to shift counseling and outreach to incorporate new PrEP options to best support patient autonomy and shared decision-making.

Primary care providers (PCP) are in a unique position to make a significant impact by delivering LAI PrEP to a range of historically disadvantaged individuals. HIV specialists indicate that individuals at risk of HIV are more likely to seek and initiate PrEP care through their PCP, who are in an ideal position to screen for PrEP eligibility.<sup>8,9</sup> A recent analysis of 2018-2017 insurance claims data, indicates that PCPs were responsible for 79% of oral PrEP prescriptions in the US.<sup>10</sup> Given that the burden of PrEP care delivery falls on PCPs, it is imperative to evaluate rollout of injectable PrEP in the primary care setting.

While LAI PrEP was reported to be desirable and acceptable to patients in early studies<sup>11,12</sup>, little is known about patient preferences for LAI PrEP since FDA approval. To date, studies of LAI PrEP have been largely hypothetical and have not assessed the real-world challenges involved in the rollout and implementation of LAI PrEP. Using qualitative interviews guided by the Consolidated Framework for Implementation Research (CFIR 2.0)<sup>13, 14</sup>, this study sought to explore and characterize contextual factors affecting LAI PrEP implementation in a Family Medicine primary care setting from the patient and clinical stakeholder perspectives.

## Methods

The study was guided by the CFIR 2.0<sup>13,14</sup>, which provides a backdrop for assessing contextual factors relevant to developing, implementing, and evaluating preventative care interventions. In this study, the CFIR guided the development of the interview protocol, codebook generation, coding, and analysis. The study received ethical approval from the University of Pennsylvania Institutional Review Board.

Study participants were recruited from a Family Medicine practice at an academic medical center in Philadelphia. Participants included practice stakeholders and patients. Practice stakeholders were identified by program implementers and invited to participate by email. Implementers were individuals who were involved with the design, rollout, and implementation of LAI PrEP. During the interviews, practice stakeholders identified additional individuals who could provide important perspectives regarding rollout of LAI PrEP. In addition, patients prescribed LAI or oral PrEP were identified through the medical record and contacted by mail. Patients who did not respond following the initial letter were contacted by phone. Recruitment calls were made three times before researchers assumed patients did not want to participate. During recruitment calls, research staff confirmed patient eligibility, provided in-depth information about study processes, and scheduled an interview.

Patient and practice stakeholder interview guides were developed by an interdisciplinary team including HIV and infectious disease clinicians, primary care clinicians and qualitative researchers. Both patient and provider interviews were designed to elicit barriers and facilitators to LAI PrEP implementation in five CFIR domains: inner setting, outer setting, innovation characteristics, individuals, and implementation process. All interviews were conducted virtually

by trained qualitative researchers with a background in public health. The interviews lasted 20-60 minutes and were audio recorded and transcribed. Patients were given \$40 for participation.

Transcripts were cleaned by redacting identifying information and correcting typographical errors, then imported into NVivo qualitative software, version 14 (Lumivero). Before creating the codebook, researchers (S.K., S.T., and O.C.) coded three transcripts each (a total of 9 transcripts) to identify potential codes related to barriers and facilitators that impacted patient access to, uptake of, and adherence to injectable PrEP. After an initial round of coding, the research team met to develop a codebook based upon the codes identified by each coder. After group consensus of codes, coders then utilized the established codebook to code all the remaining transcripts. To assess coding agreement, 6 transcripts (24% of the sample) were double coded by 2 coders. Agreement was measured using a kappa coefficient, with a final mean kappa coefficient of 0.92 (range 0.35 – 1.00) and all discrepancies were resolved by consensus. Once all transcripts were coded, barriers and facilitators were organized into the five CFIR domains including inner setting, outer setting, innovation, individuals, and implementation process.

## Results

### Sample Description

Twenty-five participants were interviewed including 13 patients and 12 practice stakeholders (Table 1). Among the patients, 7 used oral PrEP and 6 used LAI PrEP. Stakeholder interviews included a combination of pharmacists, PCPs, administrators, and implementers. On average, Copyright © 2023 Wolters Kluwer Health, Inc. Unauthorized reproduction of this article is prohibited.

practice staff had worked in this setting for 3.2 years. Most of the patients interviewed were recorded as male at birth (n=10) and cisgender male (n=8) (Table 2). Individuals recorded as female made up a small subset of this sample: cisgender woman (n=1), transgender men (n=2). Sixty-nine percent (n=9) of patients identified as married, and 92% were privately insured.

## **Interview Findings**

Below is a summary of barriers and facilitators by CFIR category. An overview of the findings can be found in Figure 1 (see table, Supplemental Digital Content, featuring illustrative quotes of the findings).

### **Inner Setting**

#### *Barriers*

Inner setting barriers to LAI PrEP implementation included lack of LAI PrEP promotion, provider discomfort, provider bias, lack of provider awareness, and limited staff capacity. When considering PrEP in general, participants indicated that providers were not prompted by the electronic medical record (EMR) to have discussion and provide care around HIV prevention. Participants indicated that providers did not feel comfortable because they did not have the knowledge about screening and follow-up for PrEP and they may not discuss LAI PrEP because they lacked knowledge about LAI PrEP specifically. Also, many providers did not feel comfortable having an in-depth discussion comparing the different PrEP options with patients. Both patients and practice stakeholders said that providers that did not share similar social and gender identities as their patients who were more likely to request or need PrEP, were probably less likely to consider PrEP as an option for their patients. Participants were frustrated by



provider bias that tended to target specific populations for their PrEP prescribing, such as gay cisgender and White gay men, instead of offering and promoting the medication without gender identity or sexual orientation bias.

When considering LAI PrEP specifically, as with other changes in medication preparations, there had not been an effort to promote LAI PrEP to providers either in the form of education, informational flyers, or informational emails. Providers who were interviewed mentioned a general lack of awareness of LAI PrEP among their colleagues, who they described as not being familiar with the required monitoring. Lastly, participants described a lack of staff resources to dedicate to population management and tracking and especially for doing outreach to eligible patients. Participants described significant logistical and administrative burden that drained potentially limited resources associated with LAI PrEP.

### *Facilitators*

Inner setting facilitators to LAI PrEP implementation included information and education, provider mindset, and EMR tools. While there was a lack of PrEP promotion within the department, participants described limited emails and training utilized to teach and remind clinicians about LAI PrEP guidelines. The department had a culture that valued awareness and promotion of sexual health education and encouraged clinicians to prescribe all types of PrEP. Further, the health system encouraged use of external resources/trainings to expand their general PrEP and HIV knowledge, and to get certifications in the field. The culture within the practice provided a strong foundation for HIV prevention, especially for LGBTQ+ patients. Despite not being prompted by the EMR about LAI PrEP, participants described the EMR as a tool to

maintain an active PrEP patient list that was shared between providers, pharmacists, and the PrEP navigator.

## **Outer Setting**

### *Barriers*

Outer setting barriers to LAI PrEP implementation included stigma and insurance. Participants described instances where patients did not feel comfortable picking up the medication at the pharmacy as other people might overhear that they were picking up an HIV-related medication. Patients described not wanting to be perceived as “high risk” for HIV and felt that this perception alienated straight individuals while stigmatizing men who have sex with men (MSM) and other LGBTQ+ individuals.

As LAI PrEP was rolled out, it required pharmacists and other clinical staff to learn the variable requirements of different insurance coverage. LAI PrEP was associated with burdensome insurance workarounds to ensure that the medication was covered. Insurance coverage for LAI PrEP was generally unreliable, subject to change, caused delays in receipt of the medication, and was perceived by patients to be a barrier to getting LAI PrEP. Many insurance companies would only cover PrEP as a medical benefit, rather than a pharmacy benefit, which prevented patients from getting the injectable because the health system would not bill for LAI PrEP as a medical benefit.

### *Facilitators*

Outer setting facilitators to LAI PrEP implementation included insurance workarounds, collaboration and consultation, pharmacy support and the PrEP navigator. Participants described how clinic staff, mainly pharmacists, were able to decrease out-of-pocket costs for patients via

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financial assistance programs. Partnerships with other clinics in the same health system and collaboration with outside organizations facilitated LAI PrEP rollout by providing additional guidance.

Pharmacy support and the PrEP Navigator were described as crucial elements of LAI PrEP implementation. The pharmacy team was widely described as an integral resource for managing the PrEP workflow, supporting the rollout of LAI PrEP, and identifying new LAI PrEP-eligible patients. Pharmacists acted as the interface between the patient, providers, and clinic by sending reminders for labs, letting patients and providers know when medication is ready, and reminding patients when they are due for injections. The pharmacy team provided insurance coverage support, including prior-authorizations and financial assistance, in addition to counselling patients about PrEP adherence and side-effects. PrEP Navigators in a health system-wide role assisted in tracking PrEP patients across the health system and making sure they were up to date on labs. PrEP navigators offered full-time support, in collaboration with providers and pharmacists, for systematic issues related to PrEP, such as working with insurance and completing paperwork on behalf of patients and providers.

## **Innovation**

### *Barriers*

Intervention characteristic barriers to LAI PrEP implementation included gaps in LAI PrEP guidelines, injection site reaction, and inconvenience of visit schedules. Participants indicated gaps in the LAI PrEP research and guidelines for patients with higher BMIs and those needing different needles for the injection to be administered (e.g., those with gluteal implants). Participants described a lack of long-term data available for patients, which can impact patient

confidence in receiving LAI PrEP. In addition, cisgender female patients were concerned about the lack of clinical trials for LAI PrEP for them. Participants described patient experiences of pain and swelling around injection sites. Lastly, many participants described the inconvenience of the requirement for in-clinic administration of LAI PrEP and getting labs during business hours every two months.

### *Facilitators*

Innovation facilitators to LAI PrEP implementation included the absence of a pill burden and the ability to walk-in for appointments to improve access barriers. Additional facilitators included finding ways to overcome stigma and evidence that supported advantages of LAI PrEP. Patients appreciate the flexibility of being able to get their injectable in an open window of time (+/- 7 days) during open lab hours without having to make an appointment. For patients worried about stigma, not having a physical pill bottle that could be discovered by others was an advantage of LAI PrEP. Participants cited the benefit of injectable PrEP compared to oral PrEP was not having to remember to take a daily pill. Patients also described feeling peace of mind and not having to remember a daily pill made them feel better protected. Patients who were already taking other oral medications appreciated not having to take more pills.

### **Individuals**

#### *Barriers*

Barriers to LAI PrEP at the individual level included fear of needles, adherence issues, trust in pills over an injectable, and lack of patient awareness. Both providers and patients indicated that a fear of needles predisposed patients to prefer oral PrEP over LAI PrEP. Providers and patients both discussed the potential difficulties of adhering to a bi-monthly clinic visit, and providers

had concerns about patients developing HIV-resistance if not able to adhere. Patients described an apprehension about new medical technologies and concerns about the efficacy of LAI PrEP. Moreover, patients perceived LAI PrEP as “more serious” than the pill and worried that the injectable option is not immediately reversible, especially if they experienced side effects. Lastly, patients and providers described a lack of awareness of LAI PrEP. Patients who weren’t cisgender men often mentioned not knowing if they could take injectable PrEP, as they felt it was not advertised to them in media, by their providers, or within their communities.

### *Facilitators*

Shared decision making was the most prominent facilitator to implementation of LAI PrEP. Providers described a preference for giving patients all the options for oral and LAI PrEP followed by an open conversation about the individual patient’s ability to adhere and maintain visit schedule versus daily oral regimens. In addition, providers described an open mindset without strict criteria for offering PrEP, following their patients’ lead, normalizing the discussion, and leaving the door open even if a patient is not initially interested. Patients felt comfortable speaking to their providers about all their PrEP options and felt that they were enabled/trusted to make the final decision about their care. Patients who were aware of what PrEP was and their PrEP options were more likely to approach their providers about PrEP. Patients often learned about LAI PrEP from social media and their social networks.

### **Implementation Process**

#### *Barriers*

Overall, implementers, PCPs, and pharmacists described very low uptake of LAI PrEP at one year post implementation. During the initial implementation of LAI PrEP it was flagged for

“limited distribution,” which required additional process in order to ensure health system access to the medication. During subsequent implementation, patients and providers encountered issues with workflow and lab work. Patients indicated being confused about the process involved in getting their injections and described the process as being “clunky,” especially during early roll out. Additionally, there were logistical challenges with how to pay/reimburse for LAI PrEP, making it a bit complicated to administer in the office. Nurses would pick up LAI PrEP from the pharmacy to help streamline the workflow for the patients, but this became a logistical issue due to limited capacity. In addition, when providers forgot to order labs before injections, patients and other health professionals had to adapt in order to prevent delays in the patient getting their LAI PrEP within the allotted time. Some patients described being confused about the frequency of testing and when it should be occurring relative to receive their injection.

### *Facilitators*

A few facilitators supported the rollout of LAI PrEP in this setting including engagement of leadership, targeted patient selection, and implementation of other injectables as a guidepost. When starting LAI PrEP roll out in the department, implementers described an approach using targeted selection of specific patient candidates for LAI PrEP. When providers and other health professionals in the department had questions about injectable PrEP, they reached out to specific leaders within the department for guidance. When working to implement injectable PrEP, efforts were focused specifically to the LGBTQ+ clinic, as they would be more likely to prescribe injectable PrEP and it would be easier to implement it. The implementers highlighted the importance of having a champion who supported patient coordination and implementation of injectable PrEP in the department.

## Discussions

This qualitative study used the CFIR framework to describe the early rollout of LAI PrEP in a Family Medicine setting. Overall, stakeholders described a very low uptake of LAI PrEP. Barriers to LAI PrEP implementation included a lack of awareness, insurance and access issues, a lack of streamlined workflow, and a trust in pills over injectables. Facilitators to LAI PrEP implementation included the absence of a pill burden, a culture of shared decision making, and pharmacy support.

The low uptake of LAI PrEP and barriers to its implementation were consistent with barriers to uptake of PrEP overall. We identified the same knowledge and awareness gaps seen in oral PrEP implementation. Distrust in new medical technologies overall was linked to a distrust in the healthcare system, reflecting another major barrier to PrEP<sup>15, 16</sup>. This distrust likely stems from mistreatment of marginalized populations, including people with HIV, substance use disorders, and those in sexual, racial or gender minoritized groups.<sup>16</sup> Our interviews corroborated this distrust as patients described perceived discrimination and stigma surrounding provider discussions around HIV risk and prevention. We also identified access barriers to LAI PrEP, including adhering to bi-monthly visits and lab work and persevering through insurance workarounds. Such barriers may be insurmountable for marginalized populations vulnerable to HIV.

We noted a lack of awareness and confidence among providers in prescribing LAI PrEP. There is a need for programs to train and inform providers about all PrEP modalities to increase comfort among providers and to normalize patient-provider discussions about PrEP and HIV risk. PrEP navigators, an important system-wide resource in this setting, were instrumental in supporting

PrEP prescribing. PrEP navigators can bridge the communication gap between patients and providers and address issues of trust<sup>17, 18</sup>, especially among marginalized groups of patients<sup>19</sup>. Dedicated personnel or personnel skilled at navigating insurance workflows to access LAI PrEP, such as pharmacy staff, was noted to be crucial for LAI PrEP uptake. Clinics and/or health systems should consider incorporating these roles into their practices to ensure access to LAI PrEP. Additionally, as described by our participants, healthcare settings can benefit from harnessing the power of EMR for LAI PrEP care to streamline workflow issues for patients and providers.

Pharmacists in our study were one of the critical facilitators to the rollout and implementation of LAI PrEP. Given their expertise in medication monitoring, safety, and interactions and their training in patient counseling, pharmacists are well-positioned to manage HIV PrEP. As a discipline, pharmacists have some of the highest levels of PrEP awareness and knowledge as compared with medical and nursing providers.<sup>20</sup> Pharmacist-led HIV PrEP programs have been described in various settings including federally qualified health centers<sup>21</sup>, non-clinical settings<sup>22</sup>, university-based HIV and primary care clinics<sup>23</sup>, and the Veterans Health Administration<sup>24</sup>. In some states, through a collaborative practice agreement<sup>25</sup>, pharmacist can operate under a physician's or other license practitioner's oversight, allowing a pharmacist to take on specific patient care responsibilities. During our study, a collaborative practice agreement was initiated in the Family Medicine setting at our institution to streamline processes and free up PCP's time.

Both patients and providers described a patient-centered approach to HIV prevention. Such an approach emphasizes the autonomy of the patient in an environment that fosters mutual trust and respect that centers around patients meeting their HIV prevention needs and social goals.<sup>26</sup> As described by our participants, all PrEP options should be presented to patients and discussed in

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the context of their own preferences and desires to foster trust with patients and empower them to engage in PrEP care.

While this study highlights a range of determinants associated with early rollout of LAI PrEP implementation, it does have some limitations. The study was conducted in only one healthcare setting in the United States. While LAI PrEP was approved in the United States in 2021, it has not yet been widely approved internationally. Moreover, issues that may arise related to LAI PrEP implementation in the United States (e.g. insurance coverage) may not apply to other countries with different healthcare systems and policies.

In sum, while uptake of this new technology has been slow, we have identified several promising strategies for improving rollout and implementation of LAI PrEP. Approaches that can bolster rollout of LAI PrEP include having an interdisciplinary care team that is supported by PrEP navigators and pharmacists. Future interventions to improve LAI PrEP should be informed by a patient-centered model of care that can increase patient engagement and trust.

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### Figure Captions

Figure 1: Barriers and Facilitators to Long-Acting Injectable HIV PrEP Implementation in a Family Setting Organized by CFIR domain.

# BARRIERS AND FACILITATORS TO LONG-ACTING HIV PREP IMPLEMENTATION BY CFIR DOMAIN

CFIR DOMAINS	BARRIERS	FACILITATORS
 <b>INNER SETTING</b>	<ul style="list-style-type: none"> <li>✓ Lack of LAI PrEP Promotion</li> <li>✓ Lack of Provider Awareness/Knowledge</li> <li>✓ Provider Bias</li> <li>✓ Provider Discomfort</li> <li>✓ Limited Staff Capacity</li> </ul>	<ul style="list-style-type: none"> <li>✓ EMR Tools</li> <li>✓ Provider Mindset</li> <li>✓ Information and Education</li> </ul>
 <b>OUTER SETTING</b>	<ul style="list-style-type: none"> <li>✓ Insurance</li> <li>✓ Stigma</li> </ul>	<ul style="list-style-type: none"> <li>✓ Insurance Workarounds</li> <li>✓ Collaborations and Consultations</li> <li>✓ Pharmacy Support</li> <li>✓ PrEP Navigator</li> </ul>
 <b>INNOVATION</b>	<ul style="list-style-type: none"> <li>✓ Inconvenience of Visits</li> <li>✓ Injection Site Reaction</li> </ul>	<ul style="list-style-type: none"> <li>✓ Less Pill Burden</li> <li>✓ Navigating Stigma</li> <li>✓ Walk-in Ability</li> <li>✓ Supporting Evidence</li> </ul>
 <b>INDIVIDUALS</b>	<ul style="list-style-type: none"> <li>✓ Fear of Needles</li> <li>✓ Trust in Pills</li> <li>✓ Inability to Adhere</li> <li>✓ Lack of Patient Awareness</li> </ul>	<ul style="list-style-type: none"> <li>✓ Awareness</li> <li>✓ Intolerance to Oral PrEP</li> <li>✓ Shared Decision Making</li> </ul>
 <b>IMPLEMENTATION PROCESS</b>	<ul style="list-style-type: none"> <li>✓ Lack of Streamlined Workflow</li> <li>✓ Logistical Issues with Lab Work</li> </ul>	<ul style="list-style-type: none"> <li>✓ Engagement of Leadership</li> </ul>

ACCEPTED

**Table 1: Participant Demographics**

<b>Family Medicine Practice Staff</b>	<b>n</b>
Implementers	2
Pharmacists	2
Primary Care Providers	4
System-Wide PrEP Navigators	2
Administrative Managerial	2
<i>Staff Total</i>	<b>12</b>
<b>Patients</b>	
Oral PrEP Patients	7
LAI PrEP Patients	6
<i>Patient Total</i>	<b>13</b>
<b>Participant Total</b>	<b>25</b>

**Table 2: Patient Demographics**

	<b>Oral PrEP Patients n (%)</b>	<b>LAI PrEP Patients n (%)</b>	<b>Total n (%)</b>
<b>Age Range (years)</b>			
	24 – 60	24 – 38	24 - 60
<b>Race</b>			
White	5 (71.4)	3 (50)	8 (61.5)
African American	2 (29.6)	1 (16.7)	3 (23.1)
Two or More Races	0	2 (33.3)	2 (15.4)
<b>Sex</b>			
Male	5 (71.4)	5 (83.3)	10 (76.9)
Female	2 (28.6)	1 (16.7)	3 (23.1)
<b>Gender</b>			
Cisgender Man	3 (42.9)	5 (83.3)	8 (61.5)
Cisgender Woman	1 (14.3)	0	1 (7.7)
Transgender Woman	1 (14.3)	0	1 (7.7)
Transgender Man	1 (14.3)	1 (16.7)	2 (15.4)
Non-Binary	1 (14.3)	0	1 (7.7)
<b>Marital Status</b>			
Never Married	4 (57.1)	5 (83.3)	9 (69.2)



Currently Married	3 (42.9)	1 (16.7)	4 (30.8)
<b>Insurance</b>			
Insurance through a current employer	7 (100)	5 (83.3)	12 (92.3)
Medicaid	0	1 (16.7)	1 (7.7)
<b>Total</b>	<b>7</b>	<b>6</b>	<b>13</b>

ACCEPTED