SPECIFIC AIMS

Methamphetamine (meth) use and fatal overdoses have been rapidly accelerating throughout the U.S.¹ Meth use is strongly intertwined with HIV risk due its prevalence among men who have sex with men (MSM). transgender feminine individuals, and people who inject drugs (PWID).²⁻⁴ Meth use exacerbates HIV risk among these key populations by increasing rates of intravenous drug use and condomless sex.^{5,6} Pre-exposure prophylaxis (PrEP), a highly efficacious HIV prevention medication,⁷⁻¹⁰ offers a critical harm reduction tool for people who use meth. Yet, meth use dilutes the successful prevention of HIV through decreasing PrEP adherence.¹¹⁻¹³ Studies have shown that people who use meth, particularly intravenous meth use, have a fivefold increased odds of PrEP nonadherence leading to a heightened risk of HIV seroconversion.^{11,12} Optimal PrEP adherence (≥7 doses/week) can reduce risk of HIV seroconversion by 83.5% among PWID, including meth.¹² Technology-based interventions offer an unparalleled opportunity to deliver interventions to hard-to-reach populations and leverage familiar modes of communication, such as text messaging, to provide individualized support on a daily basis. Text messaging interventions to support PrEP adherence have been successful among MSM, cisgender women, transgender individuals, and people who use drugs.¹⁴⁻¹⁹ One such text messaging intervention, iTAB (individualized Texting for Adherence Building), developed by Moore and colleagues¹⁹⁻²¹ has proven effective in enhancing antiretroviral therapy (ART) and PrEP adherence and has been established as a evidence-based intervention by the Center for Disease Control and Prevention (CDC).²² iTAB delivers daily, individually-tailored text messages to improve medication adherence with customizable message content and timing to protect privacy. These unique iTAB features align with gualitative research among meth using MSM and transgender individuals who reported that text messaging interventions to improve PrEP adherence must incorporate customizable message content and timing.¹⁶ Previous iTAB research suggested that people who use meth are receptive to using iTAB to support their ART adherence and reduce meth use through text messaging self-monitoring.²⁰ Although promising, it remains unclear how these results will translate to PrEP adherence among people who use meth who are attempting to prevent HIV infection compared to treat an existing, chronic disease with ART. The objective of this K23 Mentored Patient-Oriented Career Development Award research project and linked training goals (TG) is to evaluate the acceptability, appropriateness, and feasibility of iTAB with meth text message self-monitoring to increase PrEP adherence and reduce meth use among people who use meth.

Study Design: We will recruit 60 participants who are HIV-negative, self-report meth use, have HIV risk factors (e.g., MSM, injection drug use) and not currently prescribed PrEP for a 24-week intervention. Participants will be randomized into i) active intervention of iTAB+meth self-monitoring text messages (n=40) or ii) active control of iTAB only (n=20). All participants will participate in an individual exit interview to assess iTAB experiences.

Aim 1. To evaluate the feasibility of utilizing iTAB to improve PrEP adherence among people who use meth (TG 1). iTAB feasibility will be assessed as PrEP adherence using tenofovir diphosphate (TFV-DP) levels in dried blood spots (DBS) at week 12 and 24. Adequate PrEP adherence is defined as having TFV-DP DBS levels commensurate with \geq 4 doses per week, and near-perfect PrEP adherence is defined as having TFV-DP DBS levels commensurate with \geq 7 doses per week.^{8,23} Participants who are lost to follow-up will be characterized as non-adherent in analyses. <u>Hypothesis 1</u>: Participants will have near-perfect PrEP adherence (\geq 6 doses/week) at week 12 and strong adherence (\geq 4 doses/week) at week 24.

Aim 2. To assess the acceptability and appropriateness of iTAB among people who use meth (TG 2). Through individual interviews at week 24, participants will provide detailed qualitative information on their perceptions on iTAB as well as suggestions for improvements. At week 24 participants will also complete two questionnaires to assess their perceived acceptability and appropriateness of iTAB. <u>Hypothesis 2</u>: At least 80% of all participants will rate iTAB as highly acceptable and appropriate.

Aim 3. To explore the impact of meth self-monitoring text messages on reducing meth use in the context of PrEP care (TG 1). Meth use days will be measured via urine toxicology screens at week 12 and 24 as well as self-report through daily text messages (active intervention) or monthly online surveys (control). <u>Hypothesis</u> <u>3</u>: Participants in the active intervention will have less meth use as determined by a) fewer self-reported days of meth use and b) fewer meth positive urine toxicology screens at week 12 and 24 compared to the control group.

Impact and Future Directions: This <u>K23 research project proposal</u> will demonstrate whether iTAB is an acceptable and feasible intervention to enhance PrEP adherence among people who use meth and will determine whether adding meth self-monitoring text messages will simultaneously reduce meth use. Completion of this pilot and training plan will strongly position me to submit an R01 trial investigating the optimization of iTAB to enhance PrEP adherence for patients impacted by the methamphetamine epidemic.

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