VaxCom:
Developing a digital health communication tool to improve recruitment and enrollment of transgender women into Phase I HIV vaccine clinical trials

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CONTINUUM CONFERENCE

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SAN JUAN, PUERTO RICO

Background / HIV Public Health Toolbox:

HIV Epidemiology among Transgender Women:

Estimating the prevalence of HIV and sexual behaviors among the US transgender population: a systematic review and meta-analysis, 2006–2017

JS **Becasen**, CL Denard… - … journal of public …, 2019 - ajph.aphapublications.org

- 88 studies from across the US
- 18.8% HIV prevalence
- 44.2% among Black TW
- 25.8% among Latina TW

HIV PUBLIC HEALTH TOOLBOX

Background / Stages of Clinical Trials:

PHASE I

12 to 18 months

Small group of healthy, HIV negative participants to test safety

PHASE II

Up to 2 years

Hundreds of HIV negative participants to test safety and immune responses, seek best dose or best schedule of administration

PHASE IIb

2-5 years

Several thousand participants at risk for HIV infection to test for safety, immune responses, and to get a first look at efficacy. Tests the concept, and results inform whether to go to Phase III.
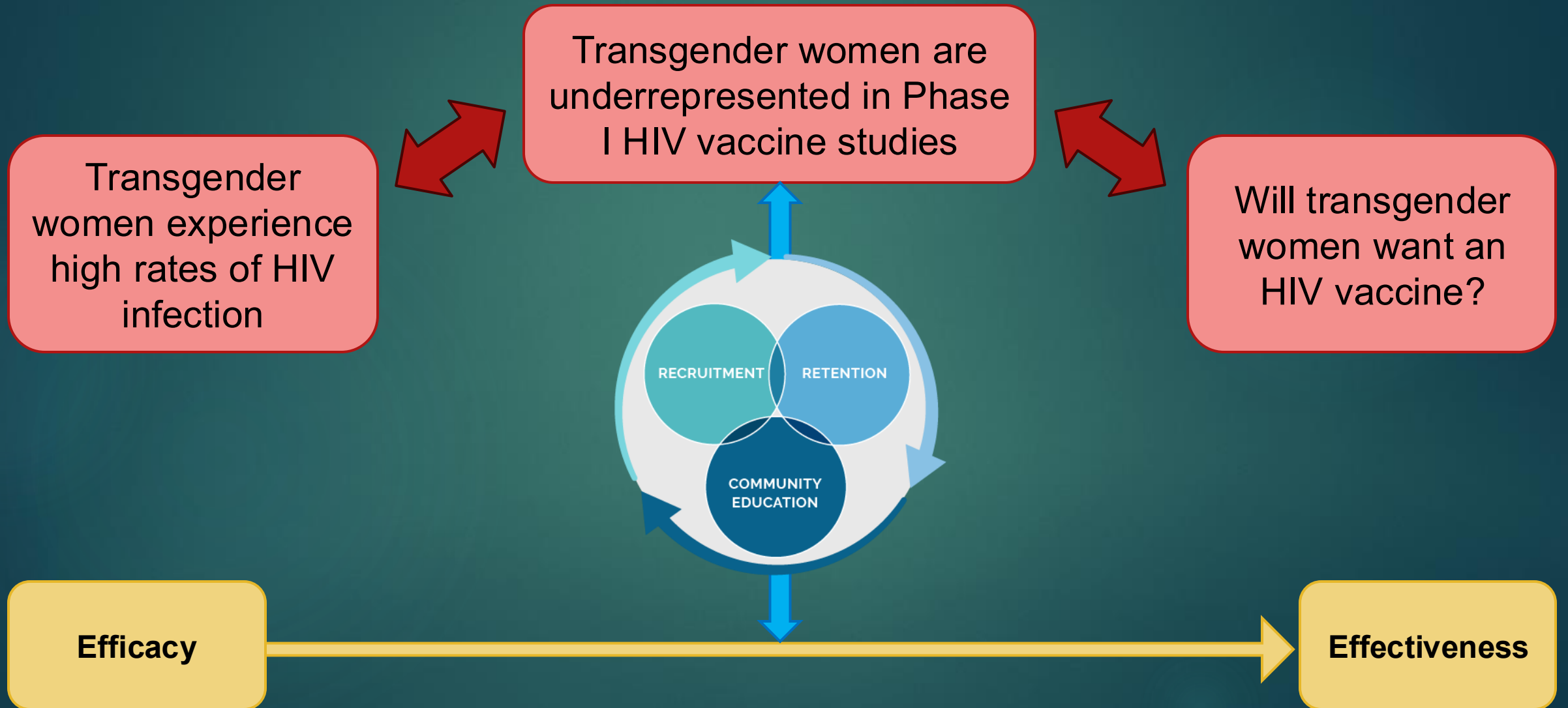
PHASE III

3 to 4 years

Many thousands of participants at risk to test safety and efficacy
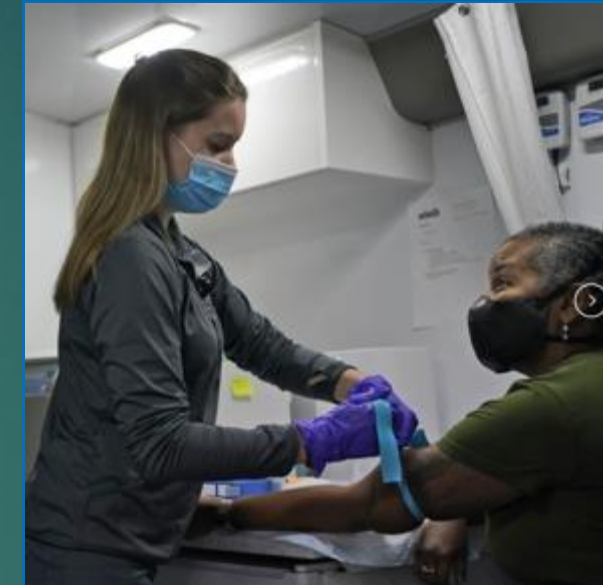
HVTN

Background / Equity in implementation:

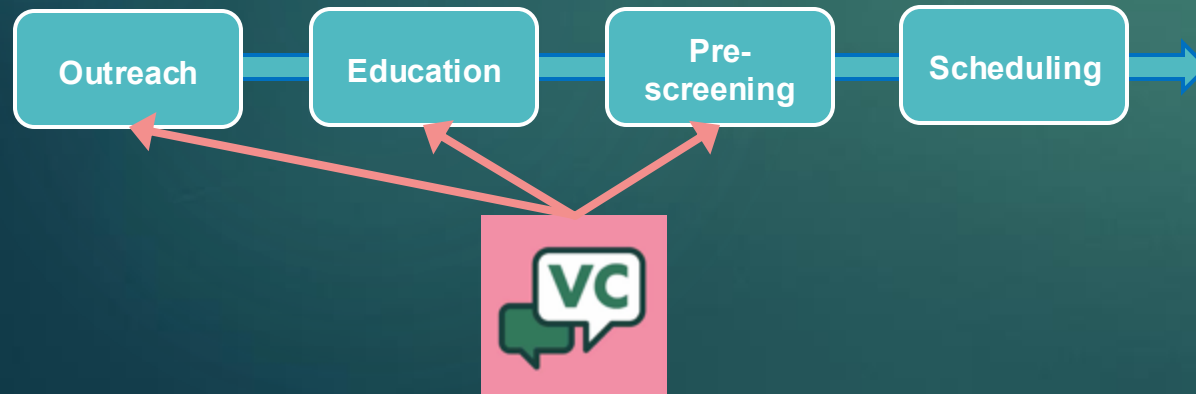Transgender women experience high rates of HIV infection

Transgender women are underrepresented in Phase I HIV vaccine studies

Will transgender women want an HIV vaccine?

RECRUITMENT

RETENTION

COMMUNITY EDUCATION

Efficacy

Effectiveness

Background / Recruitment and Enrollment:

Recruitment

Outreach → Education → Pre-screening → Scheduling →

Enrollment

Education → Informed Consent → Behavioral Screening → Medical Screening →
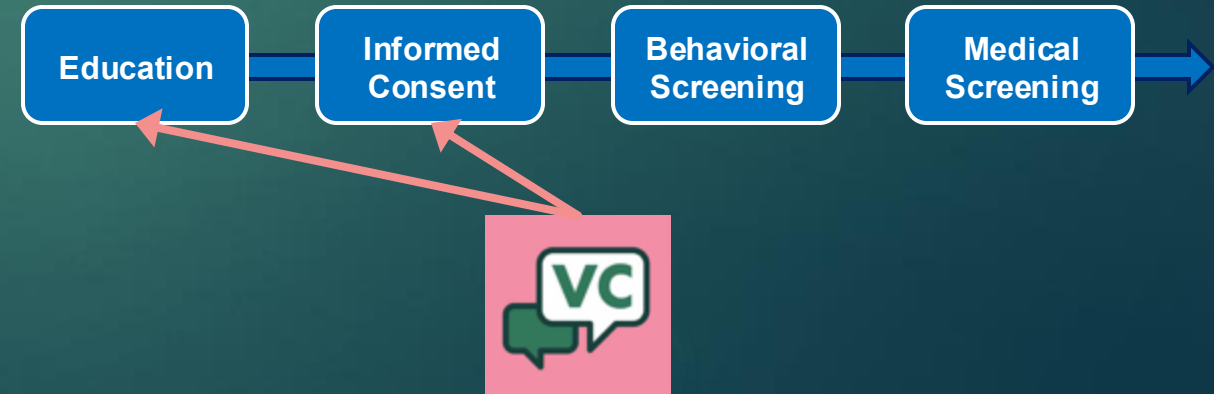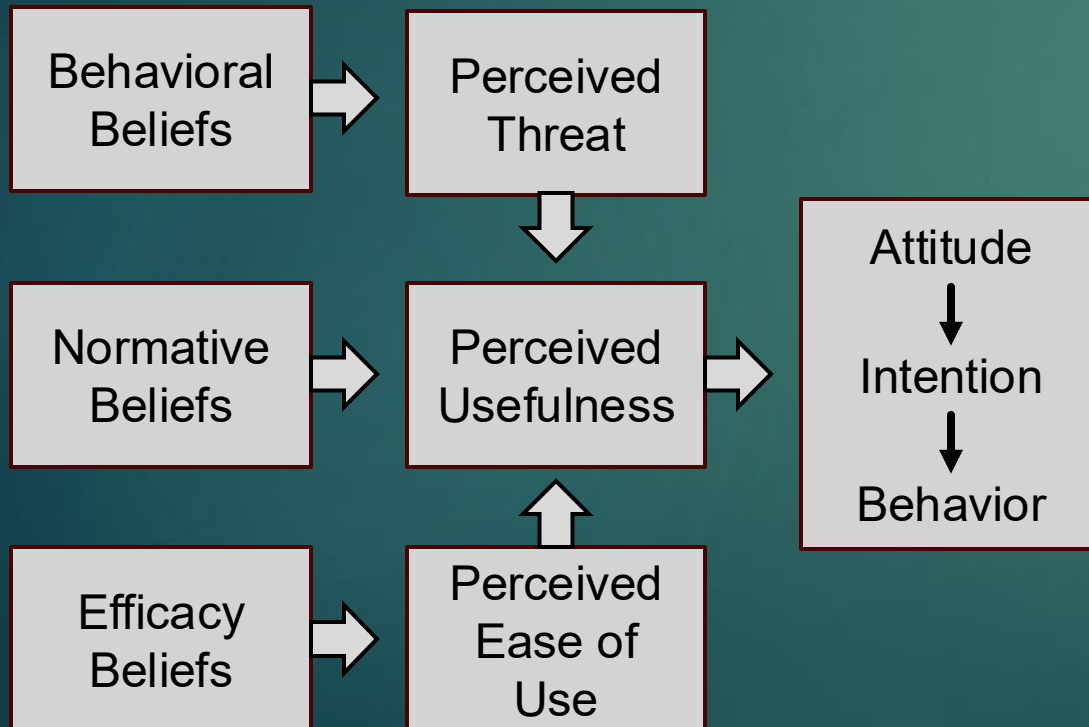
Background / Theory:

❖ **Health behavior models**
❖ **Technology Acceptance Model (TAM)**
   ⬇
❖ **Health Information Technology Acceptance Model (HITAM)**

Behavioral Beliefs	→	Perceived Threat

Perceived Threat ⬇ Perceived Usefulness

Normative Beliefs	→	Perceived Usefulness	→	Attitude ↓ Intention ↓ Behavior

Efficacy Beliefs	→	Perceived Ease of Use

Perceived Ease of Use ⬆ Perceived Usefulness

❖ **Preliminary Work**

► Focus groups (N=29) to assess knowledge of HIV vaccine research (Tieu & Sobieszczyk)

► Interviews (N=30) to develop tailored interventions for delivery and adherence of long-acting PrEP (Rael)

► Letter of support from the HIV Vaccine Trials Network (Broder)

❖ **Findings and conclusions**

► <u>Barriers</u>: fear of cross-interactions with hormone therapy; fear of discrimination in healthcare settings

► <u>Facilitators</u>: sense of altruism; compensation; experience with injection practices

► <u>Information needs</u>: stigma-reduction messaging; explanation of side-effects, managing health priorities; acceptance of digital platforms

Background / Specific Aims:

Aim 1: Conduct IDIs to identify TW's (n=15) and R&ES (n=5) information needs/preferences on a digital tool to enhance TW recruitment/enrollment in Phase 1 HIV vaccine trials.

Aim 2: Develop a digital health communication tool, "VaxCom," designed to meet the specific information and communication needs of target end users, via an iterative, participatory design process with TW (n=10-12) and HIV vaccine trials R&ES (n=5).

Aim 3: Conduct simulated recruitment encounters and enrollment study visits with TW (n=15) and R&E specialists (n=5) to assess:

   a. Feasibility
   b. Acceptability
   c. System usability
   d. Potential for success

Methods: Aim 1 (Eligibility and IDIs)

Transgender Women (n=15)

- ✓ 18 to 55 years old
- ✓ Speaks English
- ✓ AMAB & identifies as a (transgender) woman
- ✓ HIV-negative (self-report)
- ✓ Ever an HIV vaccine study participant (5=Yes; 10=No)

Individual In-depth Interviews (in person + virtual)

- • Knowledge and beliefs about HIV and health
- • Current HIV prevention behaviors
- • Knowledge and beliefs about HIV vaccines and related research (review of community slides)
- • Barriers/facilitators to participating in HIV vaccine clinical research
- • Preferences for a digital communication tool

Recruitment & Enrollment Specialists (n=5)

- ✓ 18+ years old
- ✓ Speaks English
- ✓ Has worked in the role of recruitment and/or enrollment for HIV vaccine clinical trials
- ✓ 3+ months of experience

Individual In-depth Interviews (virtual)

- • Recruitment strategies (general vs. trans women)
  - o Settings and approaches
  - o Presentation (talking points, visuals, etc.)
  - o FAQs and responses from community
- • Enrollment
  - o Presentation (talking points, visuals, etc.)
  - o FAQs and responses from participants
- • Potential utility of a digital communication tool

Enrollment Survey

90 minutes; $50 compensation

Methods: Aim 1 (Recruitment)

Transgender Women

18 contact cards:

6 = FB (4) and IG (2)
5 = Craigslist
5 = Staff approached
3 = Other
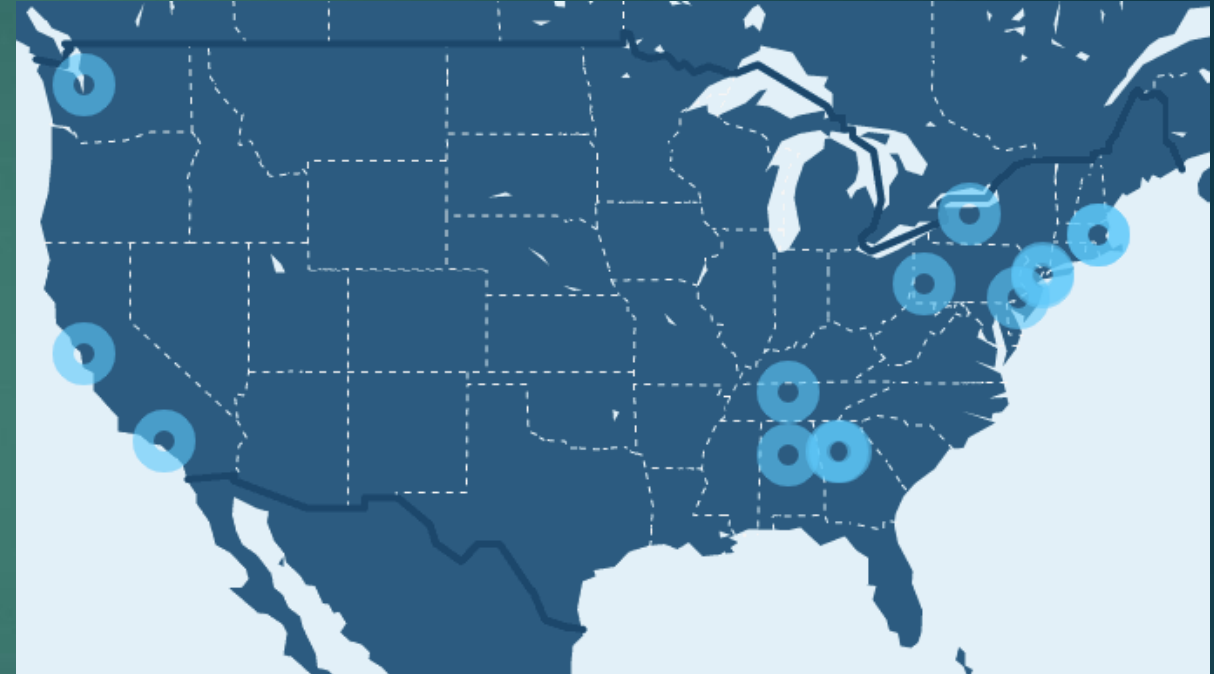

16 enrolled:

13 = never a vaccine
      study participant

03 = ever a vaccine
      study participant

Recruitment & Enrollment Specialists

19 contact cards:

From outreach to staff
at 6 different clinical
research sites in the US

5 enrolled

Results: Aim 1 (Enrollment Survey)

Transgender Women

Sociodemographic and behehavioral characteristics of study participants	
Characteristic	**n=16**
Age	
18 to 29	44%
30 to 40	31%
41+	25%
Education	
HS or less	32%
Some college	12%
College degree	50%
Graduate degree	6%
Latinx ethnicity	38%
Racial identity	
Asian	12%
Black / African American	38%
White	38%
Other	12%
12-month # of sex partners	
1-2	44%
3+	56%
Current PrEP use	19%

Recruitment & Enrollment Specialists

Sociodemographic and work role characteristics of study participants	
Characteristic	**n=5**
Age (mean, years)	
18 to 29	20%
30 to 40	0%
41+	80%
Education	
College degree	40%
Graduate degree	60%
Gender Identity	
Cisgender woman	60%
Transgender woman	20%
Cisgender man	20%
Latinx ethnicity	0%
Racial identity	
Black / African American	40%
White	60%
Years of experience	
5 or less	20%
6 to 10	40%
11+	40%

Results: Aim 1 (Individual In-depth Interview)

Transgender Women

Results	Implications for VaxCom

HIV
knowledge & beliefs

Vaccine
knowledge & beliefs:

"I have not heard any bad rumors about the HIV vaccines, but I have seen the ad, like a television ad … the vaccine already developed, which we can just quit the pills and take the vaccines twice in year or something like that. I heard about it." – 11A

"My concern is that they're not even going to take the time of day to even consider it. I feel like we're so overlooked that at this point I don't think the trans community cares, I think they're in survival mode…" – 15A

- Accurate knowledge about transmission
- Mixed perceptions about HIV vulnerability (self and community)

- Confusion about vaccines and injectable HIV medications
- Overall acceptance of vaccines & benefits; not in personal networks
- Positive responses to vaccine education component

- Basic HIV information may be more important for general population than for transgender women
- Need for HIV epidemiology information that is inclusive of diverse sex and gender groups

- Education critically needed regarding different prevention modalities
- HVTN Community Slides provide good models

Results: Aim 1 (Individual In-depth Interview)

Transgender Women

Results

Implications for VaxCom

Barrier / Facilitators
to participation:

"It's the forever thing. That kind of has me a little, especially seeing that I have antibodies, but those antibodies won't even protect me. That's the only hiccup I'm having. So now I kind of have to live with the stigma that anybody at any point can be like, oh, this person's positive … you go to avoid the stigma just to be stigmatized." – 01A

"Oh yes, I would be willing to, now that I understand what the HIV vaccine actually is or is supposed to be." – 03A

VaxCom Tool
perceptions

- Not wanting to be the first (i.e., in Phase I)
- Stigma related to VISP that is unique to TW
- Common: altruism, side-effects, # of injections, stigma, medical mistrust, compensation, mental health, representation
- ½ Yes, ¼ Maybe, ¼ No

- Is representative
- Explains risks
- Mixed response to design

- VISP remains a major barrier and point for education; must be considered in context of other stigma
- Mental health was the dominant "other health condition" cited by participants → resource / referral functions may be important

- Striking balance between tailoring and "targeting"

Results: Aim 1 (Individual In-depth Interview)

Recruitment and Enrollment Specialists

Results

Implications for VaxCom

Recruitment Strategies

So historically what has been done, it was more transactional … I've shifted the way I've done recruitment. It's more about aspirational first. It's empowering that person to feel good about themselves prior to asking them to be involved in something that they have no idea about. – 03

A person who appears to be trans woman comes up to me and I'm like, hold on, let me get my trans app out so I can, that seems really crazy to me. I could not do that. - 05

Enrollment Strategies

I've realized is that with our studies is that these are the first time they actually have built relationships with a provider that is not judgmental. - 03

- Reserving challenging topics for study visits

- Assessing life circumstances

- Attending/creating trans specific events

- Virtual/phone recruiting

- Addressing common concerns

- VISP is a major concern

- Having a resource section for other needs

- Delivering tailored content, when needed, while minimizing stigma

- Presenting info on common barriers and basic eligibility criteria

- Striking balance between tailoring and "targeting"

Results: Aim 1 (Individual In-depth Interview)

Recruitment and Enrollment Specialists

Results

Implications for VaxCom

VaxCom Tool Functions

Tailor their presentation … so that they get the highest level information that they could potentially understand. – 04

I may be speaking to someone who might have questions about hormones, then maybe having that ahead of time … I know I can Google that before I go out too if I wanted to. But maybe if it was on an app or something easy to just bring up. - 05

Competency

I think it would be helpful to know if there's certain terms or words that shouldn't really be used, if that makes sense like when we're having conversations. That's helpful because you want someone to feel safe and not- I don't want to use something that's kind of outdated. - 02

- Accessibility and learning preferences
- Easy to use in context of other digital tools
- A quick guide vs in-depth information

- Having knowledge about transgender communities
- Having knowledge about HIV prevention and drug interactions related to transgender women

- Information presenting as text, visuals, and audio
- Glossary of terms
- Content delivery in person vs over the phone
- Minimize overlap with other processes; complement vs integrate
- Easy tailoring where possible

- Striking balance between tailoring and "targeting"

Next Steps: Aim 2-3 (Design Sessions)
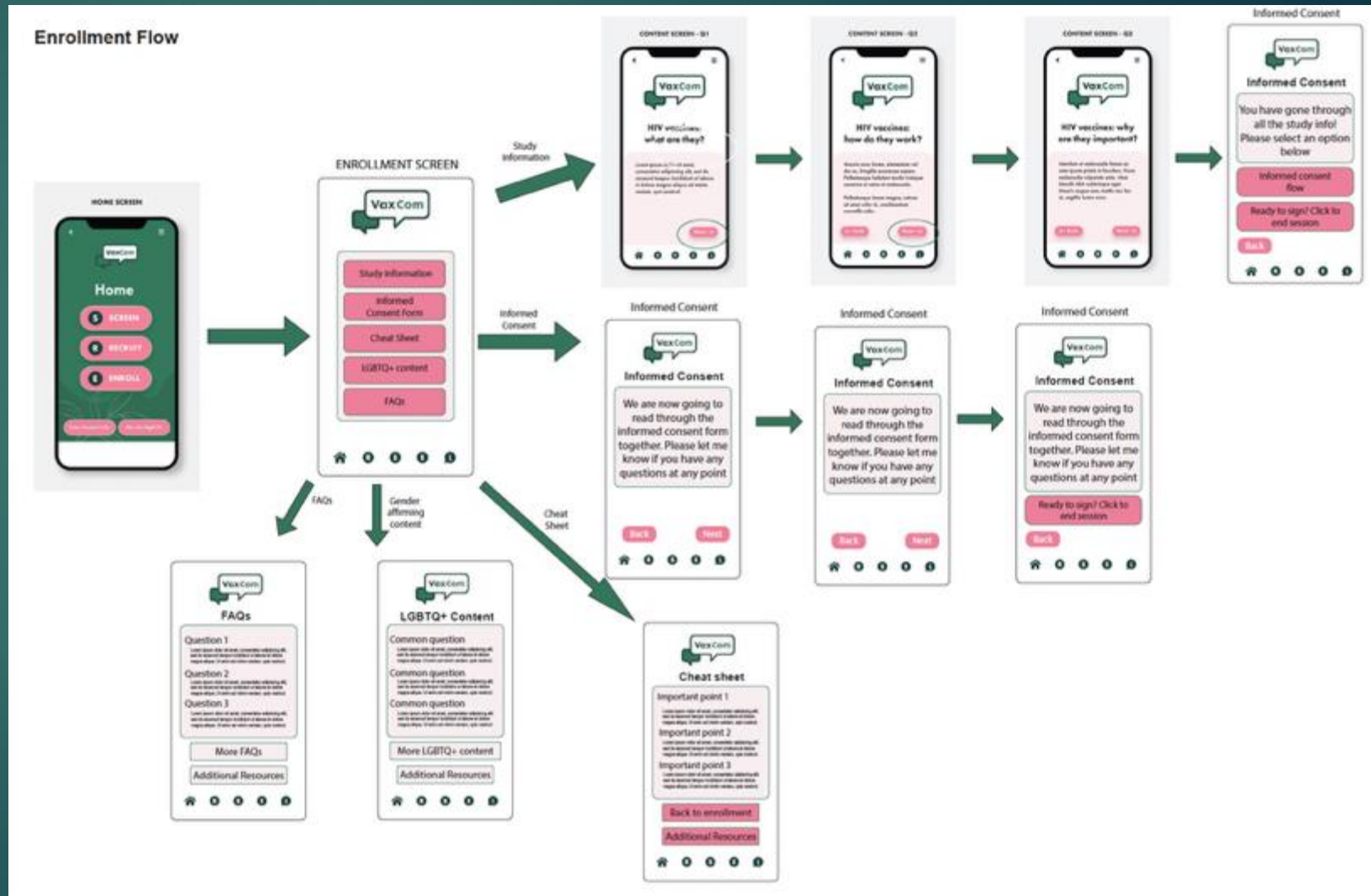
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