Mental Models of HIV Vaccine Trials & Preventive Misconception among MSM at High Risk for HIV in India

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- Study participants
- Peer outreach workers
HIV in India

- 2 – 3 million persons living with HIV
  - Second highest after South Africa
- Majority (~45%) of PLHA in Tamil Nadu
- HIV prevalence among MSM is ~10-20 times the general population rate
  - With 1+ billion people, a 2% increase in HIV prevalence could overwhelm the healthcare system (20 million)
Mental Models

- Comprehension of new information is contingent on how that information fits within one's pre-existing web of knowledge.
- Simplified cognitive representations of complex external realities:
  - May be incomplete but useful in guiding reasoning, decision-making, and behavior.
  - Ex. HIV = egg; ART →
Vaccine Mental Models

- Have been elicited to support strategies designed to increase uptake of already licensed vaccines
  - parental concerns about childhood vaccines
- New to the context of clinical trials
Purpose

- To identify & explore mental models of experimental HIV vaccines & clinical trials among high-risk MSM in India
  - Facilitate community engagement
  - Support meaningful informed consent
  - Enhance recruitment & retention
  - Ensure ethically conducted clinical trials
METHODS
Mixed Methods Investigation

1 – Qualitative – exploratory; thematic analysis

2 – WTP and HIVVT knowledge/beliefs
   - Survey w/time-space sampling in public sex environments (PSEs)

3 – RCT of enhanced informed consent intervention vs. usual procedures
Sampling & Recruitment

- Purposive sampling
  - CBOs serving MSM communities
  - Public sex environments ("hotspots")
  - Peer networks of MSM
Data Collection

- From 6/2010 - 6/2011
- 12 focus groups (FG) segmented by sexuality/gender expression with diverse, low socio-economic MSM in Chennai (Tamil) & Mumbai (Marathi, Hindi)
- Key important interviews (KII) with MSM community leaders & service providers
Data Analysis

- Narrative thematic analysis & constant comparative method
- Line-by-line, in-vivo & theoretical coding
- FG & KII were recorded, transcribed & translated into English
Results

- Demographics
- Vaccine-induced seropositivity (VISP)
- Fear of vaccine-induced infection
- Preventive misconception
- Placebo & randomization
- “Experimental rats”
## Sociodemographic Characteristics of Focus Group Participants, Chennai & Mumbai (n=68)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Focus group participants n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>28</td>
</tr>
<tr>
<td>Range</td>
<td>20 – 46</td>
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<tr>
<td><strong>Marital Status</strong></td>
<td></td>
</tr>
<tr>
<td>Unmarried</td>
<td>57 (84%)</td>
</tr>
<tr>
<td>Married</td>
<td>11 (16%)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
</tr>
<tr>
<td>Primary (&lt;=5th grade)</td>
<td>10 (15%)</td>
</tr>
<tr>
<td>6th – 11th grade</td>
<td>22 (32%)</td>
</tr>
<tr>
<td>High school degree</td>
<td>18 (26%)</td>
</tr>
<tr>
<td>College degree</td>
<td>18 (26%)</td>
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</tbody>
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7 focus groups (n=43) Chennai; 5 focus groups (n=25) Mumbai
Sociodemographic Characteristics of Focus Group Participants, Chennai & Mumbai (n=68)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Focus group participants n (%)</th>
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</thead>
<tbody>
<tr>
<td><strong>Employment</strong></td>
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<tr>
<td>Community agency staff</td>
<td>15 (22%)</td>
</tr>
<tr>
<td>Daily wage laborer</td>
<td>16 (24%)</td>
</tr>
<tr>
<td>Private company staff</td>
<td>19 (28%)</td>
</tr>
<tr>
<td>Sex work</td>
<td>8 (12%)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>10 (15%)</td>
</tr>
<tr>
<td><strong>Sexual Identity</strong></td>
<td></td>
</tr>
<tr>
<td>Kothi</td>
<td>35 (52%)</td>
</tr>
<tr>
<td>Double-decker</td>
<td>14 (21%)</td>
</tr>
<tr>
<td>Panthi</td>
<td>12 (18%)</td>
</tr>
<tr>
<td>Versatile/Bisexual</td>
<td>4 (6%)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (4%)</td>
</tr>
</tbody>
</table>
Vaccine-induced Seropositivity (VISP)

- Largely unaware of VISP
- Testing “positive for HIV” equated with being infected (“there is HIV”)
- Concerns about how others would react to their testing HIV-positive
  - PPTCT programs: husband is encouraged to be tested for HIV along with his wife
  - Pre-employment HIV screening when applying for jobs abroad
“I am HIV-negative and I have kept myself free of HIV of all these years… If I become HIV-positive because of a [test] vaccine I’ll be punished for a lifetime. I am scared about that.”
(Kothi, FG1, Mumbai)

“One will definitely be shocked even if his result is a false-positive. Yes, a good and strong person may not be afraid of anything but HIV. They are afraid of only one word – ‘HIV’. Do you get it?”
(Double-decker, FG3, Chennai)
Explaining VISP

“We can explain this [VISP] to people....”
(Double-decker, FG3, Chennai)

“We can tell them that similar to the possibilities of having a false-positive HIV test result, even if one’s result comes as HIV-positive, he is not really infected. We know they won’t lament then, okay?”
(Double-decker, FG3, Chennai)
Will a lucky man get AIDS?

- Pulli Raja is a fictitious character in an Indian advertising campaign to promote safer sex.

“The message needs to tell the people that there are chances for false-positive because of participating in such research. This would really help them to believe that they are negative even if they are tested positive.”

(FG5, Chennai)
Fear of Vaccine-induced Infection

VISP associated with actual HIV infection

“You said dead virus is put in; How do we know? …After going in it drinks blood & becomes alive, then?”
(Kothi, FG6, Chennai)
Mental model of HIV vaccine-induced seropositivity among MSM in Chennai and Mumbai, India (n=82)

**Pre-existing mental model**
Testing HIV-positive = HIV-infected
“No one wants to have HIV”

**Assumption 1**
Fear of VISP
“If a vaccine makes me test HIV-positive, it means I have HIV”

**Assumption 2**
Anxiety about VISP
“If I test HIV-positive, I will worry that I really have HIV…even if trial staff tell me I do not have HIV”

**Assumption 3**
Omission bias & anticipatory regret
“I’ve worked hard to avoid HIV all my life by not having unprotected sex. If I contract HIV due to participating in a trial, it would be worse than getting HIV from not using a condom.”
Mental model of HIV vaccine-induced seropositivity among MSM in Chennai and Mumbai, India (n=82)

Pre-existing mental model
Testing HIV-positive = HIV-infected
“No one wants to have HIV”

Assumption 1
Fear of VISP

Assumption 2
Anxiety about VISP

Assumption 3
Omission bias & anticipatory regret

Intervention Strategy
PCR Test

Intervention Strategy
Educate MSM about VISP

New mental model
Participating in an HIV Vaccine Trial May Cause HIV Infection

Alternative mental model
“False-positive is not HIV positive”

Challenge
Family members
General public

Intervention Strategy
Engage male and female partners
Preventive Misconception

- HIV prevention trials provide protection against HIV infection
  - Overestimation of the likely effectiveness of a candidate vaccine
  - Lack of comprehension of “placebo” and randomization
  - Overestimation of one’s chances of being assigned to the experimental arm
  - Prevention trials construed as intervention programs (inferred intentions of Drs. & CBOs)
Preventive Misconception

“If it [candidate vaccine] is not working, then why would they [trialists] be actually testing it?”
(KI6, Chennai)

“Usually one tends to believe that ‘something is better than nothing’. So, even if the volunteers were informed that [trial] vaccine may or may not protect one from getting HIV, they would at least expect some protection from it.”
(KI2, Chennai)
Decreases in condom use among trial volunteers were seen as “natural,” “normal,” “to be expected,” and quite logical.

“Now that one is on vaccine, condoms will be seen as an additional burden. People usually think like that, right?”

(Kothi, FG2, Chennai)
Behavioral Disinhibition

“Kothis will not be careful in using condoms with panthis. Once they are injected with vaccine, kothis will become fully confident that they would never get infection. So they will not insist their panthis to use condoms or they would avoid using condoms.”
(Kothi, FG2, Chennai)

“When I get the vaccine I will feel that nothing is going to happen to me. I can have sex with whomever I want.”
(Kothi, FG1, Mumbai)

“Kothis [in sex work] would think ‘I won’t get HIV because I have been given vaccine.’ So they will not use condoms in their sex work.”
(KI3, Chennai)
Mental model of preventive misconception among MSM in Chennai & Mumbai, India (n=82)

Pre-existing mental model

Vaccines protect 100% against infection

Assumption 1
Overestimation of likely efficacy of candidate vaccine

“Trialist would not be testing a vaccine if it were not very likely to be (100%) effective”

Assumption 2
Overestimation of likelihood of being in the experimental group

“I am very likely to get the candidate vaccine”

Assumption 3
Vaccine trials are prevention programs

“CBOs wouldn’t refer me to the trial if it were not going to protect me from HIV infection”

Pre-existing mental model

Prevention programs help to lower risk of HIV transmission
Mental model of preventive misconception and behavioral disinhibition among MSM in Chennai and Mumbai, India (n=82)

Pre-existing mental model
Vaccines protect 100% against infection

Assumption 1
Overestimation of likely efficacy of candidate vaccine

Assumption 2
Overestimation of likelihood of being in the experimental group

Assumption 3
Vaccine trials are prevention programs

New mental model
Preventive Misconception
“HIV vaccine trial volunteers gain protection against HIV infection”

Intervention Strategy
Most products tested in clinical trials do *not* work

Intervention Strategy
Equal chances of getting the test vaccine or the placebo

Intervention Strategy
Not the same as interventions
“Yes, we want our community to be free of HIV. To develop a vaccine one needs people to participate. But what if then people do not want to use condoms? The work we have put in for several years to promote condom use among MSM will then be wasted.”

(KI1, Chennai)
Terminology

- **Placebo-controlled Trials**
- **Random Assignment**

- None of the focus group participants had heard of “placebo” before
- Double-blind placebo-controlled trials amount to “cheating” by unblinding volunteers who received placebo they can be prevented from becoming careless & engaging in risk behaviors
- Seen as unethical on the part of trialists to not disclose group assignment – an assertion that belies overestimation of experimental vaccine efficacy and suggests endorsement of prevention misconception
“Community will not accept if we tell like this; even people who accepted [to participate] earlier will now not accept, because they would be afraid that they are being cheated… they would not understand”
(Kothi, FG6, Chennai)

“[Trial participants] may not know much information about placebo… They will believe that ‘I have been given HIV vaccine, I can do whatever I want’…”
(KI9, Chennai)

“If you are not going to tell who is on placebo and who is on HIV vaccine, then how would you know whether vaccine is working or not as everyone is counselled to use condoms?”
(KI1, Chennai)
Discussion

- Common mental models regarding HIV vaccine trials
  - Misunderstanding & misconception of procedures fundamental to clinical research
  - It is wrong to conceal something that might harm someone, with a strong value placed on transparency
    - Criticisms of the very basis for RCTs
    - Double-blinding
Implications for HIVVTs

- Engage in discussion of potential benefits & risks of clinical trials from perspectives & belief system of local communities
  - Mental models approach may guide systematic strategy
  - Target most important/challenging concepts

- Inculcating scientific literacy/basic comprehension of key RCT concepts may be abetted by formative research conducted *in situ* before launching clinical trials
Implications

- Colonialist histories with clinical trial participants seen as “guinea pigs” or “experimental rats”
  - Tended to arise more among the *most* educated: advocates, service providers

- Engage directly with mistrust & beliefs respecting the historical experiences behind them

- Support policies & funding mechanisms to ensure access among trial volunteers to products that demonstrate efficacy in trials


