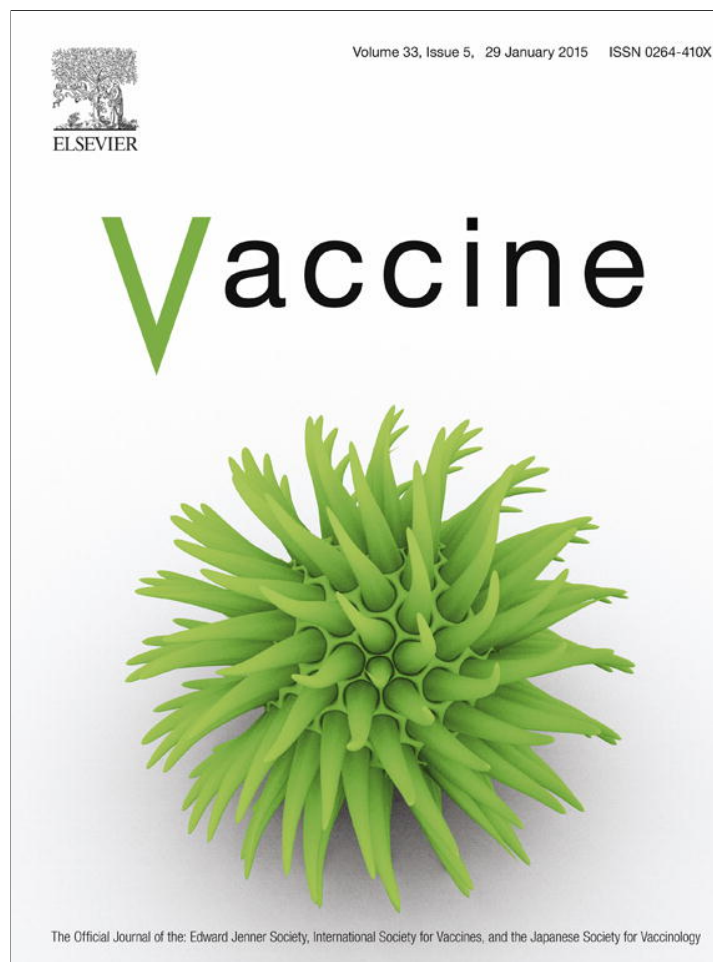


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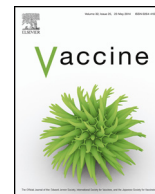
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Factors influencing frontline health service providers' likelihood to recommend a future, preventive HIV vaccine to key populations in Karnataka, south India



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ABSTRACT

The HIV epidemic in the south Indian state of Karnataka disproportionately burdens key populations of men who have sex with men and female sex workers. Despite having successfully reduced HIV incidence among certain key populations through the use of targeted intervention, India's HIV epidemic remains one of its greatest public health issues. The best long-term strategy for managing the global HIV epidemic might involve a preventive vaccine; however, vaccine availability cannot guarantee its accessibility or acceptability. Vaccine recommendations from frontline health service providers have previously been identified as useful strategies to enhance vaccine uptake among target groups. This study used structured interviews to explore frontline health service providers' self-identified likelihood to recommend a future, preventive HIV vaccine to key populations in Karnataka. A modified social ecological model was then used to categorise factors that might prevent health service providers from recommending an HIV vaccine. Overall, 83% of health service providers reported that they would be very likely to recommend an HIV vaccine to men who have sex with men and female sex workers, while less than one-third of participants identified one or more barrier to vaccine recommendation. Intrapersonal, interpersonal, and structural/political factors were most commonly reported to act as potential barriers to future HIV vaccine recommendation among health service providers in Karnataka. This study adds to the limited body of literature focussing on future HIV vaccine acceptability in low- and middle-income countries and highlights some of the several complexities surrounding vaccine acceptability and uptake among key populations in Karnataka.

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1. Introduction

Key populations, notably men who have sex with men (MSM) and female sex workers (FSWs), are disproportionately burdened by India's HIV epidemic [1,2]. The National AIDS Control Organisation (NACO) and state-level government agencies prioritise these key populations for HIV prevention efforts and have implemented

targeted interventions (TIs) to mitigate the effects of the concentrated epidemic [3–5]. While implementation of TIs has been highly successful in reducing HIV incidence, particularly among communities of FSWs [1,6], the HIV epidemic remains one of the country's most serious public health challenges [7], a situation not unique to India. Globally, for the past quarter-century, development of a safe and effective HIV vaccine has been a slow process, though more recently, promising evidence has emerged [8–11]. However, even if an effective HIV vaccine does become available, its acceptability – particularly among key populations – cannot be guaranteed [12]. This was evident in 2009 when two field test studies were launched in the Indian states of Andhra Pradesh and Gujarat to explore the feasibility of introducing two human papillomavirus (HPV)

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vaccines – Gardasil and Cervarix, both approved for use in India in 2008 – into the Indian healthcare system [13]. These post-licensure trials were pre-maturely halted by the national government in response to concerns from activist groups around violations of ethical norms and standards [13–15]. Notably, a women's rights activist group raised concerns around the selection of young girls from exceptionally marginalised communities to participate in the trials and found that there was inadequate provision of education around HPV, cervical cancer, and the vaccines before seeking consent for the girls' participation from their parents [15]. Given this history, similar concerns may emerge if and when an HIV vaccine becomes available.

It will likely prove beneficial to better understand and account for potential context-specific barriers to future HIV vaccine uptake and acceptability while planning vaccination programmes, in order to optimise service delivery. Limited literature specifically addresses issues around future HIV vaccine acceptability and uptake [12], but a number of studies have examined potential barriers and motivators to participate in HIV vaccine trials [16–20]. It is plausible that many factors influencing individuals' willingness to participate in HIV vaccine trials will also influence future HIV vaccine uptake and accessibility. One important, but poorly examined approach to potentially maximise vaccine uptake and acceptability focusses on the engagement of frontline health service providers (HSPs) in the development and implementation of future vaccination programmes [21]. Frontline HSPs have been identified as influential players in key community members' decision-making processes in the context of sexual- and HIV-related health [19,22]. Previous studies of HPV-, other STI-, and (hypothetical) HIV-vaccines have found that endorsements and recommendations from frontline HSPs are important for enhancing vaccine acceptability and encouraging uptake among target recipients in both Western and non-Western settings [23–32]. However, a lack of literature identifies specific roles that frontline HSPs might play in the delivery of vaccines in India [21].

This article uses data from a large, exploratory, multisite research programme in the southern Indian state of Karnataka to: (i) determine the likelihood that frontline HSPs in Karnataka might recommend an HIV vaccine upon its release; and (ii) identify factors that might influence HSPs' decisions to recommend HIV vaccines.

2. Methods

2.1. Study population and setting

Frontline HSPs were sampled from three districts of Karnataka – Bellary, Belgaum, and Bangalore – in which the Karnataka Health Promotion Trust (KHPT) operates. We defined a frontline HSP as anyone working within a KHPT-affiliated organisation that is in regular direct contact with MSM and/or FSWs for the provision of HIV prevention and care services, and/or anyone who makes decisions that directly impact the lives of MSM/FSWs receiving HIV-related services from their organisation. Many HSPs working in these frontline organisations are also members of the MSM and FSW communities to whom they provide services.

A list was compiled of all HSPs working in KHPT-affiliated organisations that provide HIV prevention and care services to MSM, FSWs, and/or people living with HIV (PLH). This list acted as the study's sampling frame and was stratified by site (Bellary, Belgaum, or Bangalore), population served (MSM, FSWs, or all PLH), type of organisation (community-based organisation [CBO], non-governmental organisation [NGO], Karnataka Network of Positive People [KNP+], Community Care Centre [CCC] or government facility), and type of HSP. First-line HSPs were defined as those in most frequent, direct contact with community members (e.g., peer

educators, outreach workers, and community mobilisers), while second-line HSPs included nurses and counsellors and were defined as those in moderately frequent, direct contact with community members. Third-line HSPs were those in least frequent, direct contact with community members, including, but not limited to, doctors, pharmacists, and medical officers.

2.2. Sampling

Quota sampling [33,34] was used to recruit a proportionately representative sample of HSPs from each organisation in each study site. To recruit participants, a manager or director at each organisation was contacted by telephone to inquire whether individuals working within the organisation would be available to participate in the study. Managers were provided with the numbers of each type of HSP the study team wished to interview, and then mutually convenient dates, times, and locations for interviews were arranged with participants. Most often, questionnaires were administered to participants in a private room within the visited organisation.

A target sample size of 375 frontline HSPs – 212 (56.5%) first-line, 52 (13.9%) second-line, and 111 (29.6%) third-line HSPs – was chosen without the use of a sample size calculation. A sample size calculation was deemed infeasible due to the exploratory nature of this study and the lack of known population parameters. The target sample size was based only on the goal of enrolling 20% of each type of frontline HSP employed across all HIV-related organisations in each district.

A total of 65 individuals who were approached for the study did not participate. Reasons for non-participation included: conflicts with personal schedules, unresolvable issues with the facility, and refusal to participate for personal or professional reasons. Response rates were highest among first-line HSPs (95.2%) and lowest among third-line HSPs (64.0%), while 71.2% of second-line HSPs approached agreed to participate. Most deviations ($n=52$, 80.0%) in the target sampling framework occurred within government facilities. To maintain the desired sample size, individuals with the same or similar HSP jobs were randomly selected from other, non-government facilities in lieu of participants who were unable or unwilling to take part in the study. Furthermore, a handful of frontline HSPs approached the field team asking to participate in the study, which led to additional participants being included in our sample.

2.3. Data collection

Face-to-face structured interviews were conducted in Karnataka's local language, *Kannada*, with frontline HSPs working in the three study districts from October through December 2012. Local research assistants, trained in structured interviewing [35] and field coding [36] methodologies, used a questionnaire with pre-coded responses as a structured interview guide. Field coding was carried out as described by Gibb [36]. Interviewers posed open-ended questions to participants, waited for a response, and then coded participants' responses into one or more of the pre-coded response options. An "Other, specify" field was used if interviewers were unable to categorise participants' responses into pre-existing response fields.

Collected data included HSPs' self-reported likelihood to recommend a future HIV vaccine to the MSM and/or FSWs to whom they provide services and HSPs' perspectives on potential barriers to recommending a future HIV vaccine to community members. Each interview lasted 45–60 min. Frontline HSPs were given a small gift for their participation, worth approximately 170 INR (3.00 CAD).

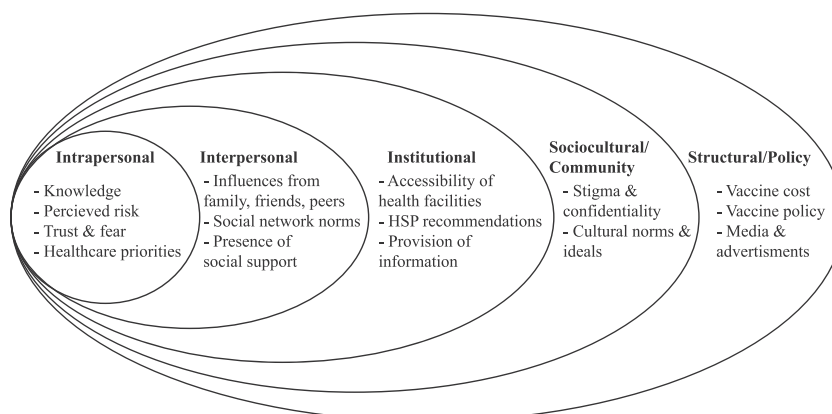


Fig. 1. A modified social ecological model (SEM) as a theoretical framework to explore barriers to future HIV vaccine recommendation among frontline health service providers in Karnataka, south India.

2.4. Data analysis

A modified social ecological model (SEM) was used as a theoretical framework to guide data analysis. Our framework was jointly based upon the original SEM proposed by McLeroy and colleagues [37] and an updated SEM that was developed by Kumar and colleagues [38]. Factors potentially acting as barriers to HSP recommendation of a future HIV vaccine were organised into five different levels – intrapersonal, interpersonal, institutional, socio-cultural/community, and structural/policy (Fig. 1).

Due to the exploratory nature of this study, and the lack of *a priori* hypotheses, all analyses are descriptive in nature with the intent of identifying interesting trends or distributions to generate research questions and objectives for future studies. All frequencies and Chi-square (χ^2) analyses were performed using SPSS v20.0.

2.5. Ethical considerations

Ethical approval was obtained from the University of Manitoba's Health Research Ethics Board and from the Institutional Review Board at St. John's Medical College in Bangalore, India. All participants were required to be ≥ 18 years and agree to and sign an informed consent form in their preferred language – either Kannada or English.

3. Results

3.1. Participant characteristics

In total, 379 frontline HSPs – 213 (56.2%) first-line, 59 (15.6%) second-line, and 107 (28.2%) third-line HSPs – participated in the study, slightly exceeding our target sample size. Demographic characteristics of participants are shown in Table 1. Most HSPs reported being “very knowledgeable” or “fully knowledgeable” about HIV (35.9% or 38.8%, respectively). However, nearly half (43.0%) of all participants said that they did not know whether an HIV vaccine currently exists. Furthermore, 66.8% ($n=253$) of HSP participants reported having received a vaccine in the past and 6.1% ($n=23$) said that they had refused a vaccine that was offered to them at some point as an adult. A significant relationship existed between type of HSP and reports of ever receiving of an adult vaccination ($\chi^2_{(2)}=8.91, p=0.012$). More specifically, 60.6% ($n=129$) of first-line HSPs, 71.2% ($n=42$) of second-line HSPs, and 76.6% ($n=82$) of third-line HSPs reported receiving an adult vaccination at some point, with third-line HSPs being significantly more likely to have received an adult vaccination than first-line HSPs.

3.2. Frontline health service providers' likelihood to recommend a future HIV vaccine

All participants were asked to respond to the question, “As an individual working in the health field, how likely would you be to recommend an HIV vaccine, with proven safety and effectiveness, to the MSM/FSWs that you currently work with?” using a five-point, Likert-type scale with response options ranging from “very likely” to “very unlikely”. A substantial majority ($n=314, 82.8%$) of HSPs reported being “very likely” to recommend an HIV vaccine. Of the participants who did not report being “very likely” to recommend a future HIV vaccine ($n=64, 16.9%$), the majority ($n=62$) reported that they would be “somewhat likely” to recommend.

Chi-square analyses were performed to examine how HSPs' reported likelihood to recommend an HIV vaccine to key populations were influenced by their sociodemographics, work-related characteristics, and personal vaccination histories (Table 2). Among participants with at least some level of education, likelihood to recommend an HIV vaccine increased with highest completed level of education ($\chi^2_{(3)}=2.59, p=0.004$). Likelihood to recommend was not significantly influenced by the particular key population with whom participants worked. Neither work-related characteristics nor past receipt or refusal of an adult vaccine significantly influenced likelihood to recommend an HIV vaccine.

3.3. Potential barriers to recommending a future HIV vaccine, as identified by frontline health service providers

Participants were asked the open-ended question, “What factors do you feel may prevent you from recommending an approved HIV vaccine to the MSM/FSWs that you work with?” While the majority of participants felt that nothing would prevent them from recommending the vaccine, 32.7% ($n=124$) identified at least one barrier. Factors identified as potential barriers to recommendation were organised into the five levels of the modified SEM framework (Table 3). Five factors were named by 15% or more of participants; three of these factors were categorised as intrapersonal, one was interpersonal, while the fifth was a structural/policy issue, described below. Table 4 examines differences in barriers to future HIV vaccine recommendation, as reported by each type of HSP. Although some variation in reported barriers was seen across different types of frontline HSPs, no differences were statistically significant.

Table 1
Descriptive characteristics of frontline health service providers (N = 379).

Sociodemographics	n	%
Sex at birth ^a		
Male	133	35.1
Female	245	64.6
Age range, in years ^a		
18–24	47	12.4
25–34	149	39.4
35–49	145	38.4
≥50	37	9.8
Highest completed level of education ^a		
No formal education	44	11.6
Primary (grades 1–7)	65	17.2
Secondary (grades 8–12)	115	30.3
Post-secondary (undergraduate/graduate/professional degree)	154	40.6
Work-related characteristics		
Workplace district		
Bellary	55	14.5
Belgaum	123	32.5
Bangalore	201	53.0
Type of healthcare organisation		
FSW CBO	169	44.6
FSW NGO	30	7.9
MSM CBO	44	11.6
Government facility	39	10.3
CCC	43	11.3
KNP+	22	5.8
NGO for any PLH	32	8.4
Main source of income		
Job in health field	301	79.4
Job not in health field	78	20.6
Sex work as additional source of income ^a		
Yes	98	25.9
No	280	73.9
Type of health service provider		
First-line	213	56.2
Second-line	59	15.6
Third-line	107	28.2
Interaction with communities in the context of health service provision		
Work directly with FSWs only	203	53.6
Work directly with MSM only	44	11.6
Work directly with MSM & FSWs	125	33.0
Do not work directly with community; involved in decision-making that impacts community members	7	1.8
Years working in health field		
<1	31	8.2
1–4	140	36.9
5–10	147	38.9
>10	61	16.1
Self-reported knowledge of HIV/AIDS		
Fully knowledgeable	136	35.9
Very knowledgeable	147	38.8
Somewhat/fairly knowledgeable	96	25.3
Adult vaccination histories		
Ever received a vaccine		
Yes	253	66.8
No	126	33.2
Ever refused a vaccine		
Yes	23	6.1
No	348	91.8
Do not know	8	2.1

^a n = 378; one participant chose not to answer the question.

Table 2
Influence of HSPs' sociodemographics, work-related characteristics and vaccination histories on likelihood to recommend a future HIV vaccine to MSM and FSWs.

	Likelihood to recommend a future HIV vaccine ^a		χ^2 -statistic, p-value
	Very likely	Not very likely	
	n (%)	n (%)	
Sociodemographics			
Sex at birth ^b			
Male	117(88.0)	16(12.0)	$\chi^2_{(1)} = 3.57, 0.059$
Female	196(80.3)	48(19.7)	
Age range, in years ^b			
18–24	37(78.7)	10(21.3)	$\chi^2_{(3)} = 2.59, 0.459$
25–34	129(86.6)	20(13.4)	
35–49	116(80.6)	28(19.4)	
≥50	31(83.8)	6(16.2)	
Highest completed level of education ^b			
None	20(90.9)	4(9.1)	$\chi^2_{(3)} = 13.08, 0.004$
Primary	45(70.3)	19(29.7)	
Secondary	92(80.0)	23(20.0)	
Post-secondary	136(88.3)	18(11.7)	
Work-related characteristics			
Workplace district			
Bellary	48(87.3)	7(12.7)	$\chi^2_{(2)} = 0.86, 0.652$
Belgaum	102(82.9)	21(17.0)	
Bangalore	164(82.0)	36(18.0)	
Type of healthcare facility			
CBO for FSWs only	134(79.8)	34(20.2)	$\chi^2_{(6)} = 5.33, 0.502$
NGO for FSWs only	25(83.3)	5(16.7)	
CBO for MSM only	35(79.5)	9(20.5)	
Government facility	36(92.3)	3(7.7)	
CCC	37(86.0)	6(14.0)	
KNP+	20(90.9)	2(9.1)	
NGO for any PLH	27(84.4)	5(15.6)	
Number of years working in health field			
<1	25(83.3)	5(16.7)	$\chi^2_{(3)} = 4.31, 0.230$
1–4	112(80.0)	28(20.0)	
5–10	121(82.3)	28(20.0)	
>10	56(91.8)	5(8.2)	
Type of HSP			
First-line	171(80.7)	41(19.3)	$\chi^2_{(2)} = 2.61, 0.271$
Second-line	49(83.1)	10(16.9)	
Third-line	94(87.9)	13(12.1)	
Adult vaccination histories^b			
Has received a vaccine in the past			
Yes	212(84.1)	40(13.0)	$\chi^2_{(1)} = 0.60, 0.438$
No	102(81.0)	24(19.0)	
Has refused a vaccine in the past (as an adult)			
Yes	20(87.0)	3(4.9)	$\chi^2_{(1)} = 0.21, 0.646$
No	289(93.5)	58(95.1)	
Likelihood to personally accept HIV vaccine ^a			
Very likely	265(84.4)	49(15.6)	$\chi^2_{(1)} = 2.51, 0.113$
Not very likely	48(76.2)	15(23.8)	

^a n = 378; Participants responding 'Do not know' have been excluded from analysis.

^b Participants responding 'Do not know' or 'Do not wish to answer' have been excluded from analysis.

4. Discussion

This study begins to fill a gap in the current HIV vaccine acceptability literature. Recent literature has focussed on trends in acceptability of a future HIV vaccine [12], willingness to participate in HIV vaccine trials [16–20], and barriers to utilising currently available HIV treatment and prevention technologies [39,40]. This is the first study to specifically explore frontline HSPs' likelihood to

Table 3
Potential barriers to recommending HIV vaccine to MSM and FSWs (N = 124).

	n	%
Intrapersonal level		
Do not personally believe in vaccines	24	19.4
HIV vaccine may provide a false sense of security from infection and promote higher risk-taking behaviours	22	17.7
Prefer to promote other methods of HIV prevention	20	16.1
Would not recommend an HIV vaccine to someone that is too young to engage in sexual activity	5	4.0
Do not trust new medicines	5	4.0
Prefer non-Western forms of medicine	3	2.4
Interpersonal level		
Too difficult to convince MSM/FSWs to receive HIV vaccine	25	20.2
Difficult to communicate with MSM/FSWs	5	4.0
MSM/FSWs treat HSPs poorly	2	1.6
Difficult to reach community members because people (e.g., lovers, brothel madams) prevent them from going to the clinic	1	0.8
Institutional level		
Lack of information provided to HSPs about vaccines/lack of ability to provide sufficient information to MSM/FSWs	13	10.5
HSPs' lack of awareness about vaccines	1	0.8
Socio-cultural/Community level		
Difficult to discuss HIV vaccine with MSM/FSWs because it would be a sensitive issue	4	3.2
Believe HIV vaccine may perpetuate stigma within and outside of community	3	2.4
Believe that community members lack trust in HSPs	1	0.8
Structural/Policy level		
Do not have time in day to recommend HIV vaccine	26	21.0
Do not have access to appropriate facility/venue to offer HIV vaccine	5	4.0

recommend a future HIV vaccine to key populations in Karnataka, and the first to describe potential barriers to vaccine recommendation. Reported likelihoods to recommend an HIV vaccine are encouraging. Nearly 83% of participants – regardless of sex, age group, years of experience working in the health field, type of HSP, or workplace characteristics – stated that they would be “very likely” to recommend an HIV vaccine, while over three-quarters reported that nothing would prevent them from recommending the vaccine to key community members.

Among participants who did mention at least one barrier to vaccine recommendation, the most commonly reported barrier fell within the structural/policy level of the theoretical framework: 21% of HSPs reported not having time in their day to recommend an HIV vaccine. This finding reiterates themes previously identified in the literature and has specifically been identified as a general barrier to vaccine delivery among HSPs [41]. Though problematic, it is not completely surprising that frontline HSPs – and particularly third-line HSPs – reported lack of time as a barrier to vaccine recommendation given the known lack of health – and human resources in India, particularly in rural districts [42], and other low- and middle-income countries [43]. This deep-seated issue will

not be a “quick fix” and will require serious political commitment, organisation, and forethought to be properly addressed.

It is argued that a first-step in addressing this issue may involve working with peer educators and outreach workers (first-line HSPs) – who are in most direct contact with MSM/FSWs, and often members of key communities, themselves – to build capacity for, and interest in, the development of future HIV vaccination programmes [21]. Findings from this study support this notion, but highlight some potential obstacles. Our results indicate that a lower proportion of first-line than second- or third-line HSPs in Karnataka would be “very likely” to recommend an HIV vaccine, and a higher proportion of first-line than second- or third-line HSPs reported a lack of belief in vaccines and a preference to promote other HIV prevention strategies. These findings may be reflective of first-line HSPs' familiarity with on-the-ground realities that pose obstacles to vaccine uptake or acceptability among key populations, but also may suggest larger, structural issues at the health-systems level that impede vaccine recommendation and overall productivity among first-line HSPs [44,45]. To date, the role of first-line HSPs in Karnataka has been predominantly limited to the provision social services – such as health education, mobilisation, and advocacy – rather than medical services, per se. The involvement of first-line HSPs in future HIV vaccination programme rollout would require substantial task-shifting and changes to the structure of the community-based health services system currently in place in Karnataka. As such, it is possible that first-line HSP participants may have had difficulty conceptualising their specific roles in future HIV vaccine programmes, as described to them in this study. Ultimately, our findings emphasise the importance of involving first-line HSPs in HIV vaccine research and planning for future implementation strategies, to ensure appropriate and optimal utilisation of limited resources.

At the interpersonal level, the anticipated difficulty in “convincing” members of key populations to receive a future HIV vaccine was reported by twenty-five HSPs – 7.5% of first-line, 1.7% of second-line, and 7.5% of third-line HSPs – who had identified at least one barrier to recommendation. The meaning behind this reported barrier could have numerous interpretations, so it will be important to carry out further research to explore the meanings ascribed to this response by participants. It is conceivable that this response – particularly among third-line HSPs who are in less frequent, direct contact with key populations – was implying poor communication between HSPs and key populations in Karnataka, so that HSPs do not feel that it is worth their while to “convince” community members to accept an HIV vaccine. Past studies in Karnataka have indicated that many third-line HSPs hold discriminatory views of FSWs and actively engage in stigmatising discourse around sex work, generally [46], though such attitudes have not been found to be as prevalent among first-line HSPs [22]. Alternatively, this barrier may be related to our finding that HSPs perceive that key populations lack trust in HSPs – a point previously recognised in in India [21,39,40] – and would be hesitant to accept advice from them regarding an HIV vaccine. Finally, it is also possible that participants felt somewhat ambivalent towards the idea of promoting a new HIV prevention strategy among MSM and FSWs, given the sub-optimal adoption of existing HIV prevention practices (e.g., consistent condom use) that has been well-documented within MSM [47] and FSW [48] communities in Karnataka.

Nearly one-fifth of participants who identified at least one barrier to HIV vaccine recommendation mentioned that they do not personally believe in vaccines, and another 16.1% mentioned that they would prefer to promote other methods of HIV prevention. This raises an ethical debate around HSPs' professional obligation to recommend a potentially beneficial product to members of key populations, even if they would not necessarily condone the product in their personal life.

Table 4
Differences in reported barriers to future HIV vaccine recommendation among first-, second- and third-line health service providers.

	Type of frontline health service provider						χ^2 -statistic ^a (df=2)	p-value
	First-line (N=213)		Second-line (N=59)		Third-line (N=107)			
	n	%	n	%	n	%		
Intrapersonal level								
Do not personally believe in vaccines	15	7.0	4	6.8	5	4.7	0.698	0.706
HIV vaccine may provide a false sense of security from infection and promote higher risk-taking behaviours	10	4.7	5	8.5	7	6.5	1.355	0.508
Prefer to promote other methods of HIV prevention	13	6.1	1	1.7	6	5.6	1.829	0.401
Would not recommend an HIV vaccine to someone that is too young to engage in sexual activity	3	1.4	0	0	2	1.9	1.050	0.591
Do not trust new medicines	5	2.3	0	0	0	0	3.949	0.139
Interpersonal level								
Too difficult to convince MSM/FSWs to receive HIV vaccine	16	7.5	1	1.7	8	7.5	2.725	0.256
Difficult to communicate with MSM/FSWs	1	0.5	2	3.4	2	1.9	3.373	0.185
Institutional level								
Lack of information provided to HSPs about vaccines/lack of ability to provide sufficient information to MSM/FSWs	8	3.8	3	5.1	2	1.9	1.343	0.511
Socio-cultural/Community level								
Difficult to discuss HIV vaccine with MSM/FSWs because it would be a sensitive issue	4	1.9	0	0	0	0	3.151	0.207
Structural/Policy level								
Do not have time in day to recommend HIV vaccine	12	5.6	4	6.8	10	9.3	1.537	0.464
Do not have access to appropriate facility/venue to offer HIV vaccine	3	1.4	0	0	2	1.9	1.050	0.591

^a Caution required when interpreting χ^2 -statistic and p-value as Cochran's rule of thumb was violated in Chi-square test.

Almost 18% of HSPs believed that an HIV vaccine may promote behavioural disinhibition, including engagement in riskier sexual practices, due to providing MSM/FSWs with a false sense of protection from other sexually transmitted infections. The idea of sexual disinhibition has been previously identified in the context of the HPV vaccine [24,29] and by individuals involved in promoting participation in HIV vaccine trials to MSM community members [16]. Other studies have specifically found that men feel that receiving an HIV vaccine would allow them to forego condoms and other HIV/STI prevention methods [17,23,26,49–51]. Programmatically, it will be important to consider that the release of an HIV vaccine may coincide with an increase in unprotected sex and may further impede women's ability to negotiate condom use with partners or clients. It is unlikely that a future HIV vaccine will be 100% effective, thus it is crucial that future HIV vaccination programmes aim to maximise vaccine coverage, while continuing to promote current HIV prevention strategies and addressing gendered power dynamics. Furthermore, it will be important for future research and HIV prevention programmes to continuously and closely track the use of other HIV prevention methods upon HIV vaccine rollout, as a way to monitor of trends in safe sexual practice.

4.1. Study strengths and limitations

While the use of structured interviews proved to be conducive to the exploratory nature of this study by incorporating aspects of both qualitative and quantitative methods, the use of field coding is a potential limitation and a point at which interviewer bias may have been incorporated into the study. It is possible that interviewers' interpretations and subsequent coding of participant responses to interview questions were skewed or inaccurate. To minimise interviewer bias, field team interviewers performed mock interviews during a six-day training session, which focussed on ensuring that interviewers' field coding strategies were consistent.

Additionally, because we had underrepresentation of HSPs from government facilities, it is possible that participation biases exist

in our data. Efforts to replace targeted participants with the same type of HSPs from different healthcare facilities were intended to reduce these biases, but it is not possible for our data to accurately represent the views of HSPs at government facilities, who may be more or less likely to hold discriminatory attitudes towards key populations. Furthermore, it is possible that frontline HSPs outside of Karnataka may work in different types of organisations, besides those sampled in this study, thus impacting the national generalisability of our findings.

Another factor limiting generalisability to the broader Indian context is our exclusion of HSPs working with people who inject drugs (PWID). Because injection drug use is relatively limited in Karnataka, and is not yet considered to be a major driver of the local HIV epidemic, very few PWID TIs operate in the state [2], and were therefore not included in the larger research programme of which this study was a part.

Finally, the relatively small number of participants who identified one or more barriers to recommending a future HIV vaccine ($n=124$) limits our ability to unambiguously compare differences in responses across first-, second-, and third-level HSPs. Despite potentially limited generalisability, χ^2 analyses presented in Table 4 provide valuable information about trends in perceived barriers to vaccine recommendation among different types of frontline HSPs in Karnataka.

5. Conclusion

Our findings suggest that, in general, frontline HSPs in Karnataka will be likely to recommend a safe and effective HIV vaccine, if and when it is released, to the MSM and FSWs with whom they work, though a few important barriers to recommendations were identified. Additionally, our findings strongly suggest a role for frontline HSPs in experimental trials examining delivery and rollout strategies for a future HIV vaccine. **This study has provided the first in-depth exploration of the frontline HSPs' likelihood to recommend a future HIV vaccine to MSM and FSWs in India.** Overall,

our findings add to the limited HIV vaccine acceptability literature focussed on low- and middle-income countries. This study highlights numerous complexities surrounding future HIV vaccine acceptability and uptake among key populations in Karnataka. Further, it identifies numerous areas for future research to assess the extent to which these findings are generalisable to other areas.

Conflicts of interest

The authors declare no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.vaccine.2014.12.009>.

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