Willingness to participate in trials and to be vaccinated with new tuberculosis vaccines in HIV-infected adults

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Background: New tuberculosis (TB) vaccines are required to meet global targets for TB control.

Objectives: To determine willingness to participate (WTP) in new TB vaccine trials, willingness to be vaccinated with a newly licensed TB vaccine and associated factors among human immunodeficiency virus (HIV) infected persons.

Setting: Two primary care clinics in South Africa.

Design: Cross-sectional study design. Participants were asked about WTP and willingness to be vaccinated. Demographic, clinical, knowledge of TB and perception of risk information were collected. Log binomial regression was used to determine associated factors.

Results: A total of 827 participants were included in the analysis: 80.4% female, 72.2% on antiretroviral therapy, median age 35 years (interquartile range [IQR] 29–42 years), CD4 count 523 cells/ μ l (IQR 427–659 cells/ μ l). WTP and willingness to be vaccinated were high, at 84.5% and 92.6%, respectively. WTP was associated with knowledge about TB (prevalence ratio [PR] 1.10, 95% confidence interval [CI] 1.03–1.17) and perception of risk (PR 1.07, 95%CI 1.01–1.13). Willingness to be vaccinated was associated with employment (PR 1.04, 95%CI 1.01–1.08) and perception of risk (PR 1.05, 95%CI 1.01–1.09).

Conclusions: There was high WTP in TB vaccine trials and willingness to be vaccinated among HIV-infected patients with good TB knowledge and high perceived risk of contracting TB.

Novel tuberculosis (TB) vaccines, with demonstrated efficacy in infants, adolescents and human immunodeficiency virus (HIV) infected adults, are needed to reduce TB specific morbidity and mortality and meet global targets for TB control and elimination.¹ Currently the only licensed TB vaccine, bacille Calmette-Guérin (BCG), is given at birth and results in variable and waning immunity to TB.² Fifteen TB vaccine candidates have entered Phase I or II clinical trials, three of these in trials conducted among HIV-infected adults.³ Should TB vaccine candidates enter Phase III trials in HIV-infected persons, large numbers of participants would need to be randomised to receive either vaccine product or placebo and followed up to measure outcomes, including incident TB.^{4,5}

There are few data on the willingness to participate (WTP) in future TB vaccine trials and factors associated with it. A recent WTP study in TB vaccine trials among healthy adolescents showed that up to 60% of adolescents and their parents were willing to participate in TB vaccine trials, depending on the procedures involved.⁶

Most published studies on the WTP in vaccine trials have involved healthy HIV-negative adults and HIV vaccines. These studies showed that perceived benefits of the vaccine and self-reported altruism were the main factors associated with WTP.^{7–11} WTP in TB vaccine trials may be different among HIV-infected adults in care.

HIV care programmes in sub-Saharan Africa do not routinely vaccinate HIV-infected adults against common infections. With the development of new TB vaccines, these programmes may have to provide TB vaccines to their patients. A number of factors have been associated with the hypothetical willingness to be vaccinated with a newly licensed vaccine. Studies on the acceptability of hypothetical HIV vaccines have shown that efficacy and duration of protection of the vaccine were associated with high rates of vaccine acceptance, while perceived membership of a low-risk group was associated with low rates.^{12–15} Other factors such as cost, fear of vaccine and side effects have also been associated with low vaccine acceptance.^{15,16} Our study describes the WTP in future TB vaccine trials and willingness to be vaccinated with a newly licensed TB vaccine among HIV-infected patients with high CD4 counts (>300 cells/ μ l).

METHODS

Population and setting

Between June 2011 and June 2012, HIV-infected patients attending HIV services at two primary care facilities in the Ekurhuleni North sub-district of Gauteng Province, South Africa, were invited to participate in a TB vaccine preparedness study designed to estimate TB incidence among HIV-infected patients with CD4 counts >300 cells/ μ l and willingness to participate in TB vaccine trials. The two clinics were located in an urban township, with high levels of poverty and unemployment.

At each of the study clinics, a study recruiter invited HIV-infected patients to participate in the study as they reported for routine HIV care. Interested patients were assessed for eligibility. Eligible patients were referred to a research nurse located in a different part of the clinic for informed consent and enrolment procedures. To be enrolled in the study, patients had to be known as HIV-positive, living/working in the catchment area of the clinic, and with a previous CD4 count result >300 cells/ μ l in the preceding 12 months, whether or not they were taking antiretroviral therapy (ART). Patients with CD4 counts >300 cells/ μ l were selected to recruit a relatively healthy population that

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would have maximal vaccine-induced immune responses if enrolled in trials. Study staff were trained in enrolment procedures and conducting interviews. The questionnaires were piloted before commencing the study.

Data collection and entry

At enrolment, the study nurse administered a questionnaire that included questions on demographic characteristics, history of TB and HIV care, knowledge of TB and its transmission, WTP in TB vaccine trials and willingness to be vaccinated with a hypothetical newly licensed TB vaccine. Participants provided a blood specimen to measure the CD4 count at enrolment. Completed questionnaires were reviewed for accuracy and completeness before being couriered to a central office for entry into an SQL-based study database. Data entry was single, with entry validation checks.

Data analysis, variables and definitions

Data were exported for analysis into STATA 12.0 (Stata Corporation, College Station, TX, USA). Summary statistics were reported using medians and interquartile ranges (IQR) for continuous data and proportions for categorical data, comparing patients on ART to those not on ART, as TB vaccine trials may enrol participants on or off ART. χ^2 , t -test and Wilcoxon rank-sum tests were used to test differences between sub-populations.

Study outcomes were WTP in future studies to test 'a new injection to prevent TB' and willingness to use a new 'licensed injection to prevent TB' once it became available, and were determined from two Likert scales with six items and five items, respectively (Table 1). Items included in the scales were based on factors identified as barriers or facilitators of WTP in vaccine trials or acceptance of licensed vaccines in the literature.^{15,17} Participants' responses were scored as 'strongly agree' (5), 'agree' (4),

TABLE 1 Scales used to determine willingness to take part in future TB vaccine trials and willingness to receive a newly licensed TB vaccine

Scale I: Willingness to participate in future new TB vaccine trials

- I would be willing to take part in studies to test if a new injection to prevent TB works or not
- I would be willing to let my family/household members take part in studies to test if a new injection to prevent TB works or not
- I would be willing to let my children take part in studies to test if a new injection to prevent TB works or not
- I would be willing to let my children take part in studies to test a new injection to prevent TB if I was convinced it would work
- I would be willing to let my children take part in studies to test a new injection to prevent TB even if it was painful
- I would be willing to let my children take part in studies to test a new injection to prevent TB even if it made me a little sick (such as vomiting, rashes, fever)

Scale II: Willingness to be vaccinated with a newly licensed TB vaccine

- Once a new injection to prevent TB has been shown to work in studies, I would be willing to get it if it became available at my clinic
- Once a new injection to prevent TB has been shown to work in studies, I would be willing to get it for my family or household members if it became available at my clinic
- Once the new injection to prevent TB has been shown to work in studies, I would be willing to get it for my children if it became available at my clinic
- Once the new injection to prevent TB has been shown to work in studies, I would be willing to get it even if it made me a little sick (such as vomiting, rashes, fever)
- Once the new injection to prevent TB has been shown to work in studies I would be willing to get it even if I had to pay for it

TB = tuberculosis.

'disagree' (3), 'strongly disagree' (2) and 'I don't know' (1), respectively, and summed for each item in the scale to obtain an overall score. The highest possible score on the WTP scale was 30, a score equivalent to responding 'strongly agree' to all six items on the scale, while the highest possible score on the willingness to be vaccinated scale was 25, equivalent to responding 'strongly agree' to all five items on the scale. The internal consistency reliabilities of the two scales were determined during analysis by computing values of Cronbach's α . $\alpha > 0.7$ was deemed acceptable.¹⁸

A 'willing participant' was defined as a participant who responded 'agree' or 'strongly agree' to ALL questions on the scales (i.e., a score of ≥ 24 on the WTP scale and ≥ 20 on the willingness to be vaccinated scale). The proportion of willing participants was determined separately for each scale. Univariable and multivariable log binomial regression was used to determine factors associated with being willing on each scale. Variables with likelihood ratio $P < 0.2$ in univariable analysis were included in the multivariable analysis.

Ethical considerations

Written informed consent was obtained from all participants prior to enrolment into the study. The informed consent forms were administered in English, Zulu or Sepedi, depending on the participant's preferred language. The study was approved by the University of the Witwatersrand Human Subjects Research Ethics Committee and the Ekurhuleni Municipal Health Department, and conducted according to the International Conference on Harmonisation/Good Clinical Practice (ICH/GCP) guidelines.

RESULTS

Of 2191 patients assessed for eligibility, 839 were enrolled. Of the 1352 patients excluded, the most common reason for exclusion was a CD4 count result < 300 cells/ μ l or a result from > 12 months previously at enrolment ($n = 1325$; Figure 1). A further 12 of the 839 participants enrolled were excluded due to missing records ($n = 5$), duplicate enrolments ($n = 3$) and unknown ART status at enrolment ($n = 4$). Of the final 827 participants included in the analysis, 80.4% were female, the median age was 35 years (IQR 29–42 years), and the median CD4 count 523 cells/ μ l (IQR 427–659), with 597 (72.2%) taking ART. Participants taking ART were more likely to be older, to be female and to have had TB in the past, but were less likely to report symptoms suggestive of TB and prior or current use of isoniazid preventive therapy (IPT; Table 2). Of the 827 participants, 771 (93.2%) responded to all the questions on the WTP scale, while 765 (92.5%) responded to all the questions on the willingness to be vaccinated scale.

Knowledge and perceptions of tuberculosis

The majority of the participants were aware that having close contact or living in the same space with someone who has TB could increase the risk of getting TB (86.5%) and that being HIV-positive made you more likely to get TB (85.2%) and could correctly identify the four main symptoms of TB: cough (71%), weight loss (72.7%), fever (64%), night sweats (72.7%), all four symptoms (53.4%). Only about half of the participants considered themselves to be at risk of TB (53.8%), and a small proportion believed that TB could be a result of witchcraft (10.1%).

Willingness to participate in a tuberculosis vaccine trial

The frequency of scores for items on the WTP scale ($\alpha = 0.92$) are shown in Table 3. Most participants responded 'strongly agree' to

FIGURE Participant flow through the study.

all items on this scale, with 62.5% (482/771) scoring 30 (median score 30, IQR 27–30). The WTP in TB vaccine trials was high, at 84.6% (652/771 responded to all items on the scale). The participants who did not complete all the items on the scale ($n = 56$, 6.8%) were less likely to correctly identify all the four main TB symptoms (cough, fever, weight loss and night sweats; $P = 0.001$), correctly identify a relationship between TB and HIV ($P < 0.001$) and to consider themselves at risk of TB ($P < 0.001$). WTP did not differ for patients taking ART ($P = 0.358$; Table 3).

Table 4 shows the results of the univariable and multivariable analysis of factors associated with WTP in future trials. In the multivariable analysis, WTP was associated with considering oneself to be at risk of TB (prevalence ratio [PR] 1.07, 95% confidence interval [CI] 1.01–1.13) and being able to correctly identify the four main TB symptoms (PR 1.10, 95%CI, 1.03–1.17). Clinical features such as current TB symptoms, low body mass index ($<18.5 \text{ kg/m}^2$), CD4 count categories or taking ART were not associated with WTP. Although current/prior IPT use, prior cotrimoxazole use and a prior history of TB were associated with WTP in trials in univariable analysis, they were not statistically significant in the multivariable analysis. Assuming that participants who did not respond to all items on the scale were unwilling to participate in TB vaccine trials, WTP in this population was lower, at 78.8% (652/827), but remained associated with a self-perceived risk of TB (PR 1.10, 95%CI 1.03–1.18), correctly identifying the relationship between TB and HIV (PR 1.24, 95%CI 1.08–1.44) and correctly identifying symptoms of TB (PR 1.12, 95%CI 1.04–1.20).

TABLE 2 Description of study population comparing participants on ART and those not on ART

Characteristic	All median [IQR] or n (%)	ART ($n = 597$) median [IQR] or n (%)	Not on ART ($n = 230$) median [IQR] or n (%)	χ^2 P value
Age, years, median [IQR]	35 [29–42]	36 [30–42]	33 [27–40]	0.001*
Females	665 (80.4)	493 (82.6)	172 (74.5)	0.011
Employed at enrolment	326 (39.4)	238 (39.9)	88 (38.3)	0.842
Previous history of TB	227 (27.5)	199 (33.3)	28 (12.2)	<0.001
Current TB treatment†	15 (1.8)	12 (2.02)	3 (1.3)	0.652
Presence of any symptoms suggestive of TB	215 (26)	132 (22.1)	83 (35.5)	<0.001
IPT use (current or past)	189 (22.6)	100 (16.8)	89 (38.7)	<0.001
Cotrimoxazole use at enrolment	116 (14)	66 (11.1)	50 (21.7)	<0.001
CD4 count at enrolment, cells/ μl ‡	523 [427–659]	523 [434–648]	525 [407–687]	0.739*
BMI at enrolment, kg/m^2 §	24.1 [21.1–27.8]	24.1 [21.2–27.9]	23.7 [20.9–27.5]	0.611*
Correctly named the four symptoms of TB	442 (53.5)	318 (53.3)	124 (53.9)	0.867
Considered oneself at risk of TB	442 (53.5)	308 (51.6)	134 (58.3)	0.085
Correctly identified relationship between TB and HIV	704 (85.1)	517 (86.6)	187 (81.3)	0.055
Median overall score on the WTP in new TB vaccine trials scale¶	30 (27–30)	30 (27–30)	30 (26–30)	0.054#
Overall scores on the WTP in new TB vaccine trials scale ≥ 24 ¶	652 (84.5)	476 (85.3)	176 (82.6)	0.358
Median overall score on willingness to be vaccinated scale**	25 (23–25)	25 (23–25)	25 (23–25)	0.987#
Overall score on willingness to be vaccinated scale ≥ 20 **	708 (92.6)	517 (93.2)	191 (90.1)	0.301

* P value for Student's t -test.

†Available for 823 participants (594 ART and 229 non-ART).

‡Available for 784 participants (568 ART and 216 non-ART).

§Available for 817 participants (588 ART and 229 non-ART).

¶Available for 771 participants (558 ART and 213 non-ART).

P value for Wilcoxon rank-sum test.

**Available for 765 participants (555 ART and 210 non-ART).

ART = antiretroviral therapy; IQR = interquartile range; TB = tuberculosis; IPT = isoniazid preventive therapy; BMI = body mass index; HIV = human immunodeficiency virus; WTP = willingness to participate.

TABLE 3 Distribution of scores on the two scales

	Number responded to item <i>n</i>	Strongly agree <i>n</i> (%)	Agree <i>n</i> (%)	Disagree <i>n</i> (%)	Strongly disagree <i>n</i> (%)	Don't know <i>n</i> (%)
Scale I ($\alpha = 0.92$)						
I would be willing to take part in studies to test if a new injection to prevent TB works or not	808	678 (83.9)	80 (9.9)	6 (0.74)	34 (4.2)	10 (1.2)
I would be willing to let my family/household members take part in studies to test if a new injection to prevent TB works or not	808	598 (74)	124 (15.4)	19 (2.4)	50 (6.2)	17 (2.1)
I would be willing to let my children take part in studies to test if a new injection to prevent TB works or not	792	584 (73.7)	82 (10.4)	22 (2.8)	89 (11.2)	15 (1.9)
I would be willing to let my children take part in studies to test a new injection to prevent TB if I was convinced it would work	786	612 (77.9)	72 (9.2)	15 (1.9)	82 (10.4)	5 (0.6)
I would be willing to let my children take part in studies to test a new injection to prevent TB even if it was painful	786	603 (76.7)	76 (9.7)	16 (2.0)	83 (10.6)	8 (1.0)
I would be willing to let my children take part in studies to test a new injection to prevent TB even if it made me a little sick (such as vomiting, rashes, fever)	784	578 (73.7)	81 (10.3)	24 (3.1)	96 (12.2)	5 (0.6)
Scale II ($\alpha = 0.69$)						
Once a new injection to prevent TB has been shown to work in studies, I would be willing to get it if it became available at my clinic	805	740 (91.9)	54 (6.7)	3 (0.4)	6 (0.8)	2 (0.3)
Once a new injection to prevent TB has been shown to work in studies, I would be willing to get it for my family or household members if it became available at my clinic	796	696 (87.4)	73 (9.2)	6 (0.8)	19 (2.4)	2 (0.3)
Once the new injection to prevent TB has been shown to work in studies, I would be willing to get it for my children if it became available at my clinic	788	667 (84.6)	53 (6.7)	9 (1.1)	56 (7.1)	3 (0.4)
Once the new injection to prevent TB has been shown to work in studies, I would be willing to get it even if it made me a little sick (such as vomiting, rashes, fever)	799	687 (85.9)	73 (9.1)	9 (1.1)	27 (3.4)	3 (0.4)
Once the new injection to prevent TB has been shown to work in studies I would be willing to get it even if I had to pay for it	798	537 (67.3)	163 (20.4)	35 (4.4)	55 (6.7)	8 (1.0)

TB = tuberculosis.

Willingness to be vaccinated with a newly licensed tuberculosis vaccine

The frequency of scores on the willingness to be vaccinated scale ($\alpha = 0.69$) is presented in Table 4. Most participants (59%, 451/765) responded 'strongly agree' to all items on this scale (median overall score 25, IQR 23–25). The proportion willing to be vaccinated was also high, at 92.6% (708/765 completed all items on the scale). Participants who failed to complete all the items on the scale ($n = 62$, 7.5%) were more likely to be unemployed ($P = 0.018$), but less likely to correctly identify all four TB symptoms ($P < 0.001$), correctly identify a relationship between TB and HIV ($P < 0.001$) and consider themselves at risk ($P = 0.018$). Willingness to receive a newly licensed vaccine did not differ with taking ART ($P = 0.301$), and was associated with a self-perceived risk of TB (PR 1.05, 95%CI 1.01–1.09) and being employed (PR 1.04, 95%CI 1.01–1.08) (Table 5). Clinical features were not associated with willingness to be vaccinated. Assuming that participants who did not respond to all the items on the scale were unwilling, the willingness to be vaccinated was lower (85.6%, 708/827), and associated with considering oneself at risk of TB (PR 1.05, 95%CI 1.00–1.11), correctly identifying the relationship between TB and HIV (PR 1.30, 95%CI 1.14–1.49) and being employed (PR 1.09, 95%CI 1.04–1.14).

DISCUSSION

Our study shows high WTP in future TB vaccine trials and willingness to be vaccinated with a newly licensed TB vaccine. Both outcomes did not differ with taking ART, and were associated with a perception of being at risk for TB, being knowledgeable

about TB and being employed, which was possibly a proxy for the ability to pay for the vaccine or for better education. Neither WTP in trials nor willingness to be vaccinated was associated with demographic or clinical factors.

Our study has implications for the conduct of TB vaccine trials among HIV-infected participants. First, almost half of the participants could not correctly identify all the main TB symptoms and did not consider themselves at risk of TB. As being knowledgeable about TB was associated with WTP, patient education could be strengthened to ensure that HIV-infected persons are aware of symptoms and risk factors for TB. The association between greater awareness and knowledge with increased WTP in vaccine trials and willingness to be vaccinated has been described in studies on other vaccines.^{9,19–21} Second, hypothetical WTP in TB vaccine trials was lower than the hypothetical willingness to be vaccinated with a newly licensed TB vaccine. This trend has been observed in other studies, with concerns about safety of trial products accounting for lower WTP.^{8,22}

Our study is one of the few to evaluate WTP in TB vaccine trials and willingness to be vaccinated with future TB vaccines. Consecutive sampling of patients reporting for care minimised selection bias. We had a large sample size and a good response on the WTP and willingness to be vaccinated scales. Both scales had high and acceptable levels of internal consistency and reliability.

Our study had some limitations. Our findings may not be generalisable to HIV-infected patients recruited from other settings, such as voluntary counselling and testing centres or from communities. Participants in our study were enrolled from HIV services based at primary care clinics, and were in care. This may

TABLE 4 Univariable and multivariable analysis of factors associated with WTP in new TB vaccine trials ($n = 771$)

Variable, category	Score ≥ 24 n (%)	Univariable prevalence ratio (95%CI)	P value*	Multivariable prevalence ratio (95%CI)	P value
Age, years					
≥ 35	349 (80.2)	1.00			
< 35	303 (77.3)	0.96 (0.90–1.02)	0.197	0.99 (0.94–1.04)	0.759
Sex					
Male	129 (76.9)	1.00			
Female	523 (78.7)	0.98 (0.91–1.05)	0.574	—	—
Employed					
No	373 (78.7)	1.00			
Yes	256 (78.5)	0.97 (0.91–1.03)	0.324		
Other†	23 (82.1)	1.03 (0.90–1.19)	0.649	—	—
Prior history of TB					
No	465 (83.0)	1.00			
Yes	187 (86.6)	1.07 (1.00–1.13)	0.037	1.05 (0.99–1.10)	0.102
Presence of any symptoms at enrolment					
No	491 (80.2)	1.00			
Yes	161 (74.9)	0.96 (0.89–1.04)	0.301	—	—
Current ART use					
No	176 (76.5)	1.00			
Yes	476 (79.3)	1.03 (0.96–1.11)	0.376	—	—
Current or prior IPT use					
No	514 (80.6)	1.00			
Yes	138 (73)	0.91 (0.83–0.99)	0.023	0.94 (0.86–1.02)	0.120
Cotrimoxazole use at enrolment					
No	576 (79.7)	1.00			
Yes	85 (73.8)	0.91 (0.82–1.01)	0.079	0.92 (0.84–1.02)	0.117
CD4 category					
< 500 cells/ μ l	392 (79.7)	1.00			
≥ 500 cells/ μ l	260 (77.6)	0.98 (0.98–1.06)	0.925	—	—
BMI < 18.5 kg/m ²					
No	607 (79.2)	1.00			
Yes	45 (73.8)	0.94 (0.83–1.08)	0.419	—	—
Correctly identified all symptoms of TB					
No	376 (85.1)	1.00			
Yes	276 (71.1)	1.11 (1.05–1.19)	0.001	1.10 (1.03–1.17)	0.003
Considered oneself at risk of TB					
No	73 (59.4)	1.00			
Yes	579 (82.2)	1.08 (1.01–1.15)	0.021	1.07 (1.01–1.13)	0.024
Correctly identifies relationship between TB and HIV					
No	280 (72.7)	1.00			
Yes	372 (84.2)	1.07 (0.96–1.20)	0.195	1.04 (0.94–1.16)	0.432

*Likelihood ratio P . Variables with likelihood ratio $P < 0.2$ were included in multivariable analysis.

†Such as students, retired workers, volunteers.

WTP = willingness to participate; TB = tuberculosis; CI = confidence interval; ART = antiretroviral therapy; IPT = isoniazid preventive therapy; BMI = body mass index; HIV = human immunodeficiency virus.

have selected for participants who were knowledgeable about HIV care, motivated to seek or remain in care and to take part in trials or willing to accept a new vaccine once it became available. Although the interviews were conducted in a private and confidential manner, participants may have been unwilling to express negative sentiments to study staff. We did not collect data on education, and we were therefore unable to adjust for confounding by education. Another limitation was that items on the scales were hypothetical, and our findings may not translate into actual participation in a trial or being vaccinated when the vaccine becomes available.²³ We used Likert scales, which have inherent disadvantages, such as 1) social desirability bias, i.e., participants presenting false impressions of their attitudes and reporting what they thought was expected of them; and 2) uniform scale intervals,

i.e., the difference between the intervals in the scales was considered equal in the analysis but may not represent equal differences in participant attitudes. Lastly, the two scales used had not been previously validated. We are not aware of any validated scales to measure WTP in TB vaccine trials or willingness to be vaccinated with a newly licensed vaccine.

CONCLUSION

HIV-infected persons in care are likely to be willing to participate in TB vaccine trials and to be vaccinated with a newly licensed TB vaccine. Education to increase knowledge about TB and appreciation of risk of infection and disease may further increase the WTP in trials and willingness to be vaccinated.

TABLE 5 Univariable and multivariable analysis of factors associated with willingness to vaccinate with newly licensed TB vaccine ($n = 765$)

Variable, category	Score ≥ 20 n (%)	Univariable prevalence ratio (95%CI)	P value*	Multivariable prevalence ratio (95%CI)	P value
Age category, years					
≥ 35 years	368 (91.5)	1.00			
< 35 years	340 (93.8)	1.02 (0.98–1.06)	0.261	—	—
Sex					
Male	139 (92.7)	1.00			
Female	569 (92.6)	1.00 (0.95–1.05)	0.951	—	—
Employed					
No	388 (90.7)	1.00			
Yes	298 (95.5)	1.05 (1.01–1.10)	0.008	1.04 (1.01–1.08)	0.014
Other†	22 (88)	0.97 (0.84–1.13)	0.694	0.97 (0.84–1.11)	0.639
Prior history of TB					
No	451 (81.4)	1.00			
Yes	180 (85.3)	0.98 (0.94–1.03)	0.501	—	—
Presence of any symptoms at enrolment					
No	532 (93.2)	1.00			
Yes	176 (90.7)	0.97 (0.93–1.02)	0.298	—	—
Current ART use					
No	191 (91)	1.00			
Yes	517 (93.2)	1.02 (0.98–1.07)	0.331	—	—
Current or past IPT use					
No	551 (92.8)	1.00			
Yes	157 (91.8)	0.99 (0.94–1.04)	0.688	—	—
Cotrimoxazole use at enrolment					
No	611 (92.9)	1.00			
Yes	97 (90.7)	0.98 (0.92–1.04)	0.465	—	—
CD4 category					
< 500 cells/ μ l	423 (92.2)	1.00			
≥ 500 cells/ μ l	285 (93.1)	1.01 (0.97–1.05)	0.608	—	—
BMI < 18.5 kg/m ²					
No	654 (92.4)	1.00			
Yes	54 (94.7)	1.03 (0.96–1.09)	0.444	—	—
Correctly identified all symptoms of TB					
No	307 (90)	1.00			
Yes	401 (94.5)	1.05 (1.01–1.10)	0.022	1.03 (0.99–1.06)	0.180
Considered oneself at risk of TB					
No	310 (89.6)	1.00			
Yes	398 (95)	1.06 (1.02–1.11)	0.005	1.05 (1.01–1.09)	0.02
Correctly identifies an association between TB and HIV					
No	80 (87)	1.00			
Yes	628 (93.3)	1.07 (0.99–1.16)	0.09	1.05 (0.97–1.14)	0.223

*Likelihood ratio P . Variables with likelihood ratio $P < 0.2$ were included in multivariable analysis.

†Such as students, retired workers, volunteers.

TB = tuberculosis; CI = confidence interval; ART = antiretroviral therapy; IPT = isoniazid preventive therapy; BMI = body mass index; HIV = human immunodeficiency virus.

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Cadre : De nouveaux vaccins contre la tuberculose (TB) s'imposent pour atteindre les objectifs mondiaux de lutte contre la TB.

Objectif : Déterminer chez les personnes infectées par le virus de l'immunodéficience humaine (VIH) la volonté à participer (WTP) à des essais pour un nouveau vaccin TB récemment autorisé, ainsi que les facteurs qui y sont associés.

Contexte : Deux polycliniques de soins primaires en Afrique du Sud.

Schéma : Etude transversale. On a interrogé les participants concernant le WTP et la volonté à se faire vacciner. On a recueilli les informations démographiques et cliniques, celles concernant le degré de connaissance de la TB et la participation au risque.

Résultats : On a inclus 827 participants dans l'étude : 80,4% étaient

des femmes ; 72,2% étaient sous traitement antirétroviral ; l'âge médian était 35 ans (écarts interquartiles [IQR] 29–42) ; décompte de CD4 523 cellules/ μ l (IQR 427–659). Le WTP et la volonté à se faire vacciner sont élevés (respectivement 84,5% et 92,6%). Le WTP est en association avec la connaissance de la TB (ratio de prévalence [PR] 1,10 ; IC95% 1,03–1,17) et avec la perception du risque (PR 11,07 ; IC95% 1,01–1,13). La volonté à se faire vacciner est en association avec le fait d'avoir un emploi (PR 1,04 ; IC95% 1,01–1,08) et la perception du risque (PR 1,05 ; IC95% 1,01–1,09).

Conclusions : Chez les patients infectés par le VIH connaissant bien la TB et percevant très bien le risque de contracter la TB, le WTP à l'égard des essais de vaccins TB et la volonté à se faire vacciner sont élevés.

Marco de referencia: Se precisan nuevas vacunas antituberculosas con el fin de cumplir con las metas mundiales de control de la tuberculosis (TB).

Objetivos: Evaluar en una población de personas infectadas por el virus de la inmunodeficiencia humana (VIH) su disposición a participar (WTP) en los estudios clínicos de nuevas vacunas antituberculosas, la voluntad de recibir una vacuna recién aprobada y los factores asociados con estas actitudes.

Entorno: Dos centros de atención primaria de salud en Suráfrica.

Métodos: Fue este un estudio trasversal en el cual se interrogó a los participantes sobre su WTP y su voluntad de recibir una vacuna. Se recogió información sobre las características demográficas y clínicas, sobre los conocimientos en materia de TB y sobre la percepción del riesgo de contraer la enfermedad. Los factores asociados se analizaron mediante una regresión logística binaria.

Resultados: Participaron en el estudio 827 personas: 80,4% eran

mujeres y 72,2% recibían tratamiento antirretrovírico, la mediana de la edad fue 35 años (intervalo intercuartil [IIC] de 29 a 42) y el recuento de células CD4 523 células/ μ l (IIC de 427 a 659). Se observó una buena WTP en 84,5% de las personas interrogadas y 92,6% expresaron la voluntad de ser vacunados. La WTP se asoció con los conocimientos en materia de TB (razón de prevalencia [RP] 1,10; intervalo de confianza [IC] del 95% 1,03–1,17) y con la percepción del riesgo de contraer la enfermedad (RP 1,07; IC95% 1,01–1,13). La voluntad de recibir una vacuna se asoció con el hecho de contar con un empleo (RP 1,04; IC95% 1,01–1,08) y con la percepción del riesgo (RP 1,05; IC95% 1,01–1,09).

Conclusiones: Con la encuesta se demostró que los pacientes infectados por el VIH manifiestan una gran disposición a participar en los estudios clínicos de las nuevas vacunas antituberculosas y expresan su voluntad de ser vacunados, cuando cuentan con buenos conocimientos sobre la TB y perciben un alto riesgo de contraer la enfermedad.