



Cross Sectional Volunteers' Satisfaction Survey in Phase 3 Prime-Boost HIV Preventive Vaccine Trial in Thailand

T Woratanarat¹, PA Morgan¹, RM Paris¹, N Sirijongdee¹, MW Benenson¹, P Singharaj¹, P Pitisutthitham², S Rerks-Ngarm³, JH Kim¹

¹ Department of Retrovirology, US Army Medical Component, Armed Forces Research Institute of Medical Sciences, Thailand;

² Faculty of Tropical Medicine, Mahidol University, Thailand;

³ Department of Disease Control, Ministry of Public Health, Thailand.

Background

A vaccine for the prevention of HIV infection remains an urgent need as part of the effort to control the HIV pandemic. This phase III trial using a 'prime-boost' vaccine strategy with ALVAC-HIV (vCP1521) and AIDSVAX gp120 B/E has enrolled and vaccinated 16000 HIV uninfected volunteers in Thailand. Volunteers' satisfaction is believed to be one of key factors for achieving good retention of volunteers. We conducted a survey of study volunteer satisfaction.

Objectives

- 1) To assess volunteers' satisfaction with participating clinical sites in terms of service, staff, and facilities; volunteers' attitude to the trial;
- 2) To determine factors influencing volunteers' satisfaction.

Results

There were 532 participants from 4 sites, two from each study province, i.e. 130 from Chon Buri province and 402 from Rayong province. 239 (45%) were men, and 452 (85%) were in the six-month immunization phase of the study (Table 1). Average scores in each category are displayed graphically by site and gender in Figure 2. All sites had an average score greater than 80% (range 81.5-89.3), but there were significant differences in total score among sites ($p < 0.05$) (Figure 3) and between provinces ($p < 0.01$), consistent across most of sub-categorical scores. Regression analysis showed potential model to predict sum of score in each aspect varying from 68-85% (R^2) including site, gender, and several potential interactions between variables. No difference in total score and subgroups between those in the vaccination or follow-up phases was detected. Interestingly, significant differences in scores were strongly associated with gender ($p = 0.03$). Males tended to have higher scores than females in the study, which may suggest gender related differences in either treatment of the volunteers or the perception of treatment by the volunteers. Additionally, there were many suggestions from the volunteers to be used for improvement of trial conduct. For example, slow services, long waiting time, more seats, provision of reading books or magazines for the volunteers during waiting, snacks and beverages, and more information about the trial and the vaccines in specific areas were recommended.

Methods

A cross-sectional survey was conducted at 4 of the 8 clinical sites using an anonymous voluntary sample and a standardized questionnaire during October-December 2005. All 8 sites in the two provinces were approached and asked for their voluntary participation to this survey; however only Bang Lamung hospital, Sattahip hospital in Chon Buri Province, and Ban Khai hospital, and Klaeng hospital in Rayong Province participated in this study. If they agreed, volunteers were given survey forms by clinical site staff at the end of the clinic visits. The volunteers were asked to fill in the form and to put the completed form into a designated box. No confidential personal identification was collected on the form. Data collected from each volunteer included gender, visit number, a 5-point satisfaction scale scored for 4 aspects from 10 questions, along with comments (see survey form; Figure 4). Descriptive statistics, parametric and/or non-parametric tests were used as appropriate. Multiple logistic regression analysis was also used as needed to explore potential factors.

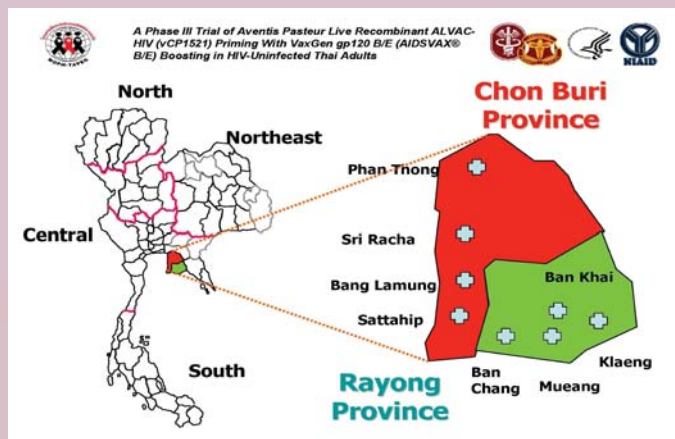


Figure 1: Thailand map and Phase III HIV vaccine trial study provinces (Chon Buri and Rayong)

Variables	Number (%Male)	Scores				
		Facilities	Services	Staff	Trial	Total
Gender						
Male	239 (45)	8.24±0.08*	12.34±0.13	17.70±0.13	4.07±0.05	42.36±0.32*
Female	293 (55)	7.93±0.09*	12.02±0.13	17.48±0.15	4.06±0.05	41.39±0.34*
Provinces						
a) Chon Buri	130	8.62±0.09*	12.87±0.14*	17.98±0.16*	4.12±0.07	43.56±0.39*
Bang Lamung (3)	80 (57.5)	8.71±1.11*	13.17±1.51*	18.1±1.91*	4.25±0.78	44.29±4.29*
Sattahip (4)	50 (50)	8.49±1.00*	12.4±1.59	17.78±1.75	3.92±0.68	42.4±3.89*
b) Rayong	402	7.9±0.06*	11.85±0.1*	17.30±0.11*	4.03±0.04	41.10±0.25*
Ban Khai (7)	37 (59.4)	8.49±1.15*	13.17±1.40*	18.89±1.47*	4.26±0.79	44.67±3.20
Klaeng (8)	365 (40)	7.84±1.25*	11.72±1.91*	17.14±2.14*	4.00±0.75	40.76±4.91*
Trial phase						
Vaccination	452 (85)	8.11±0.08	12.09±0.12	17.38±0.13	4.07±0.05	41.73±0.31
Follow-up	80 (15)	8.5±0.19	12.3±0.28	17.75±0.30	3.97±0.11	42.44±0.72

Table 1: Analyses of scores in each aspect categorized by gender, province.

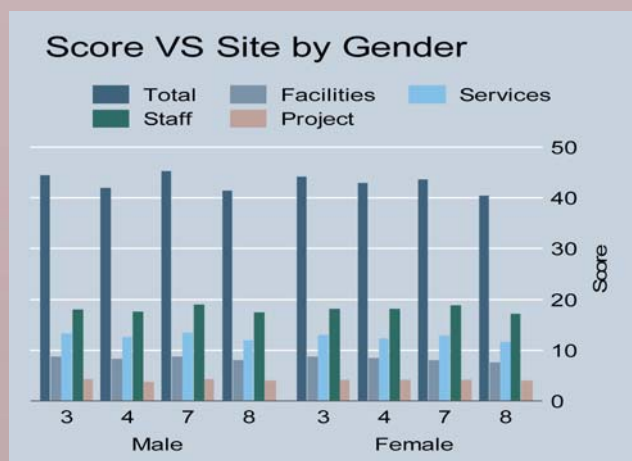


Figure 2: Mean of scores in each aspect categorized by site and gender (3: Bang Lamung, 4: Sattahip, 7: Ban Khai, and 8: Klaeng)

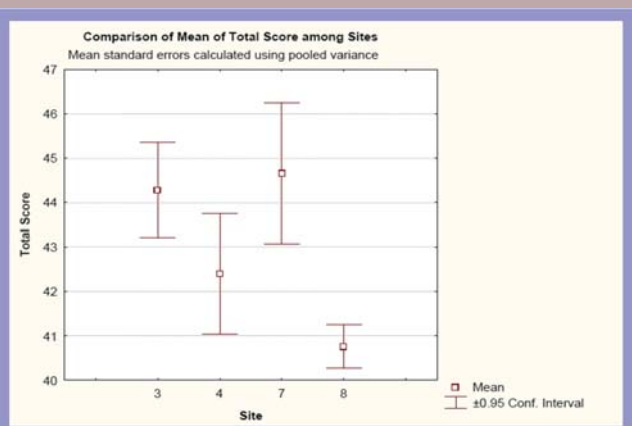


Figure 3: Comparison of total score among four sites. One-way ANOVA showed significant differences ($p < 0.05$) among site 3, 7, and 8.

Site:.....

Volunteer-centered Service Survey for Phase III Trial

We would like to thank you for regular participation in phase III trial. This survey is conducted in order to gather satisfaction information from the volunteers for improving the processes in the study, and help us to understand the problems that may occur. Your answers are anonymous, will not be linked with your name or study details, and will not affect the services that you receive in any way. Thanks again for your help.

Date:.....Month.....Year..... Male Female

Visit: 1 2 3 4 5 6 7 8 Others

Facility Aspect

	Satisfaction Level				
	Very High	High	Medium	Low	Very Low
1. Appropriateness of overall facilities such as drinking water, car park	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Safety and cleanliness of the clinic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:.....

Service Process Aspect

	Satisfaction Level				
	Very High	High	Medium	Low	Very Low
1. Each process in the trial is quick and comfortable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Appropriateness of date and time of the clinic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Adequacy of the time that providers gave to you	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:.....

Service Provider Aspect

	Satisfaction Level				
	Very High	High	Medium	Low	Very Low
1. Providers are polite and in a good manner	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Providers are attentive and willing to give the services	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Providers give correct, useful, and clear information	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Providers could help and resolve the problems appropriately	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:.....

About This Trial

	Satisfaction Level				
	Very High	High	Medium	Low	Very Low
1. Would you recommend participation in this project for friends or family?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:.....

Figure 4: Satisfaction survey form

Conclusion

In conducting large-scale HIV vaccine clinical trials, investigators should periodically evaluate factors that may impact volunteers' satisfaction and thus indirectly affect trial retention. Given linkage between satisfaction and gender observed in this study, this potential factor might be valuable to consider during trial planning process in order to help maximize volunteers' or target group's satisfaction. Well-planned time series satisfaction surveys should also be beneficial.

Contact

Dr.Thira Woratanarat
Department of Retrovirology, USAMC-AFRIMS,
315/6 Rajvithi Road, Bangkok 10400, Thailand
Email: thiraw@afirms.org

Disclaimer

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