Evaluation of Attitude, Risk Behavior and Expectations among Thai Participants in Phase I/II HIV/AIDS Vaccine Trials

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Abstract

The Understanding of volunteers in vaccine trials about their role as study participants and their voluntary commitment during the study are always one of the important concerns apart from evaluation of safety and efficacy of vaccine trials, especially in HIV prophylactic vaccine trials. The apprehension of indirectly risky behavior encouragement and deviated expectations among volunteers should be of concern. The current prospective cohort study aimed to assess and monitor the changes of risk behaviors, attitude and expectations among 164 volunteers from 2 studies of different prophylactic HIV vaccines, the Chiron HIV Thai E gp 120/MF59 ± the Chiron HIV SF52 gp120 and Aventis Pasteur Live Recombinant ALVAC HIV (vCP1521) priming with VaxGen gp120B/E (AIDSVAX™ B/E) boosting. 113 males and 51 females with a mean age (± SD) of 28.82 ± 7.97 years old were enrolled from October 1997 to December 1998 and February 2000 to April 2001. Education and risk reduction counseling were regularly performed at every visit and questionnaires about risk behaviors, knowledge, attitudes, social influences and expectations were asked at baseline, 4 months and 12 months. No change of potentially HIV transmission related risk behavior was observed during the studies. There was a statistically significant decrease of risk sexual practices from the beginning of the trials (42.2% *vs* 1%, $p < 0.0001$). While 35.2 per cent from 62.2 per cent of the volunteers at the beginning of the study continued sexual practice with an identified single sexual partner at the end of the study ($p < 0.0001$). All of the volunteers expressed the beneficial expectations as knowledge gain, social contribution, feelings of having gained merit and self-benefits from health check-ups.

Key word : Risk Assessment, Counseling, HIV/AIDS Vaccine Trial

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During the initial phase of the prophylactic HIV vaccine trials, in addition to safety and immunogenicity as the objectives of the trials, volunteers' understanding of the vaccine trials and their role as study participants including risk behavior assessment and community perceptions of the volunteers and the studies were of concern due to fear of vaccine influence of deviated expectations and social stigmatization[1]. These issues led the investigators and sponsors to develop the measurable and practical methods for evaluation of psychosocial changes during study participation in addition to assessment of adherence and preference from volunteers[2]. Questionnaires, education and counseling proved to be valuable strategies to assess the qualifications of the volunteers and to evaluate their psychosocial changes during the studies[3-5]. These strategies should also be used to periodically monitor the changes of thoughts, behavior, and knowledge about HIV transmission on volunteers and form a good relationship between the research staff and the volunteers. To relieve community worries about true voluntarism indistinguishable from conditional agreement and to assess the various prospects on risk/benefits for the volunteers while conducting these studies[6], preparation of questionnaires and the proper counseling process must be planned and discussed during the studies. Documented questionnaires of knowledge about HIV and its transmission, study information, risk behavior evaluation, attitude and expectations with regular counseling were finally recommended.

This study aimed to evaluate the basic knowledge of HIV, understanding of being a volunteer in HIV vaccine studies and psychological reconciliation about HIV vaccines. Risk behavior, attitudes and expectations among the volunteers from two different HIV vaccine trials were also assessed. People's attitudes about HIV vaccines and harm to the community were presumed to be better due to better public education about HIV prevention and transmission accompanied with improvement of staff skills in counseling and education. The other goal was to determine the factors affecting risky behavior or any psychosocial problems. The information during the studies may help to answer doubtful issues about ethical concerns of HIV vaccine trials.

MATERIAL AND METHOD

This current prospective cohort study was composed of two studies of different prophylactic HIV vaccines:

1) A Phase I/II Double-blind, placebo-controlled study of the Chiron HIV Thai E gp 120/MF59 alone or combined with the Chiron HIV SF52 gp 120, sponsored by Chiron Corporation and Walter Reed Army Institute of Research conducted from October 1997 to June 1999 and 2) A Phase I/II Trial of Aventis Pasteur Live Recombinant ALVAC HIV (vCP1521) priming with VaxGen gp 120 B/E (AIDSVAX™ B/E) boosting in Thai HIV-seronegative adults, sponsored by Walter Reed Army Institute of Research conducted from February, 2000 to December, 2001. The time intervals of volunteer enrollment were November 1997 to June 1998 for the former and April to October 2000 for the latter study. All Thai volunteers who voluntarily intended to join these vaccine trials had to be HIV-seronegative, healthy and fulfil the inclusion/exclusion criteria. Age must be 20-50 years old but could be extended to 60 years old in the latter study. Good health was assessed by history taking, complete physical examination and laboratory investigations including complete blood count, urinalysis, liver function, renal function and chest roentgenography. Tuberculosis, immune diseases and psychiatric disorders were in the exclusion criteria of the studies. The volunteers must not take any immunosuppressants that could interfere with the immunogenicity of the vaccines.

All volunteers had to pass the minimum scores (90%) of the Test of Understanding (TOU) and also clinical assessment including psychological evaluation by a counseling process at the screening visit before proceeding to participate in the study. However, repeated explanation of any questions, health education and counseling regarding the study protocol or study vaccine were continuously performed at every visit. They should be available for at least 6 months of follow-up after the last vaccination and the duration was extended to 1 year in the latter study. Female volunteers must not be pregnant or in the lactation period prior to enrollment. HIV risk assessment was done to prove that all volunteers had low risk. The volunteers were vaccinated at 0, 1 and 6 month visits and also visited according to the time schedule of each study.

Questionnaires

There were 3 types of questionnaires made for these two studies. Each was similar and used to detect any problems among the volunteers at each visit. TOU, true-false questions about basic knowledge of HIV and transmission, risk/benefit from study

participation and the meaning of randomization and a placebo-controlled trial, were used as the basic knowledge test at screening visits. TOU was done once for the former study, and twice at 2 screening visits for the latter study. The latter study required 2-4 weeks to evaluate the screening investigations as the required inclusion/exclusion criteria. Therefore, TOU was done twice to make certain that the volunteers still maintained some apprehension about the trial. However, all volunteers were given brief concepts about the requirement of the study participation with proper counseling before testing. At 0, 4 and 12-month visits, the complete questionnaire was arranged for all volunteers to answer the multiple-choice and open questions. This questionnaire included information about sex, alcohol/drug addiction/intravenous drug injection, condom use, history of sexual transmitted diseases, knowledge about HIV, attitudes about condom use, psychological evaluation and reasons/expectations of being volunteers. The other questionnaire was a short assessment of risk behavior and public influences during the study participation. This short questionnaire was scheduled for volunteers at every other visit during the 1-year follow-up. They were asked about the attitude and change of reactions from friends, family and community and their problems during the study participation.

Study site

The data used in this current cohort study was extracted from two studies of HIV vaccines conducted by the Vaccine Trial Center at the Faculty of Tropical Medicine, Mahidol University as part of the Thai AIDS Vaccine Evaluation Group (TAVEG).

Statistical analysis

Information from all questionnaires scheduled at 0, 4 and 12-month visits was compiled to get the frequency and proportion of interesting parameters. Any factors that were related to the increase of risk behaviors, the changes of attitude and expectations were analyzed by Chi-square test. For continuing parameters, mean was used as the representative of data and comparison was done by Student *t*- test.

RESULTS

113 males and 51 females enrolled in 2 studies of these prophylactic HIV vaccines. Mean age (± SD) was 28.82 ± 7.97 years old. Most of the volunteers resided in Bangkok (77.4%). 23.1 per cent were university students and the other two groups of 20.1 per cent were Buddhist monks and laborers. There was a variety of educational levels but most volunteers had finished secondary school level (44.5%). This finding was consistent with the occupational information that most of the volunteers were university students when enrolling in this study. The statistical differences between the groups of volunteers with the highest educational level (equal or higher than secondary school) from the former and latter studies, was found to be 75.8 per cent *vs* 96.9 per cent ($p = 0.0002$). The baseline demographic data of volunteers in each study is demonstrated in Table 1. Myopia (5.5%) and hypertension (1.2%) were the common physical abnormalities found from the screening examination. 70.1 per cent were single while 23.2 per cent were married. Female volunteers accepted and continued using effective contraceptive methods; abstinence from sexual intercourse (62.7%), oral pills (9.8%), condom use (9.8%), tubal ligation (9.8%). 61.6 per cent experienced sexual intercourse practices with mean age (±SD) of the first sexual event at 19.65 ± 3.34 years old. There was no difference of mean age in first sexual experience between the former and the latter studies (19.9 ± 3.9 *vs* 19.27 ± 2.23, $p = 0.308$). Having sex with prostitutes was significantly higher in those with a lower educational level (lower than secondary school level, $p = 0.01$) and older group (age > 40, $p < 0.001$).

Six volunteers (1 of the former and 5 of the latter studies) withdrew consent before the end of the studies, 3 at visit V0 (no vaccination), 1 at visit V1, 1 at visit V2 and 1 at visit V3. The reasons were inconvenience for scheduled visits (n = 3), detection of HIV seropositive status (n = 2) and concurrent accident (n = 1), none of which was related to the HIV vaccine. However, 4 continued visiting for counseling and health follow-up followed by protocol schedules. In the current cohort study, 164 volunteers were enrolled and completely filled all questionnaires for screening prior to enrollment. 162 volunteers answered this questionnaire at the 4 month-visit before the third vaccination (at visit V4 for the former study and visit V5 for the latter study) and 161 volunteers filled this questionnaire at the 12 month-visit and continued the counseling programs through these 1-year visits in the study.

Test of understanding

Basic knowledge tests at screening visits were aimed to evaluate general knowledge about HIV/

Table 1. Demographic data and pre-study parameters before study participation (n = 164).

Parameters	Study	
	Chiron HIV Thai E gp120/MF59 ± Chiron HIV SF52 gp120 (n = 99) %	Aventis Pasteur Live Recombinant ALVAC HIV priming with VAXGEN gp120 B/E (n = 65) %
Enrollment time	13 November 1997 - 12 June 1998	25 April 2000 - 10 October 2000
Mean Age (± SD) in years	30.72 (± 8.66)	25.92 (± 5.73)
Males	75.8	58.5
Single	64.6	78.5
Highest education :		
Secondary school and above	75.8	96.9
Residents in Bangkok	78.8	75.4
Occupation		
Students	7.1	47.7
Monks	25.3	12.3
Laborer	21.2	18.5
Alcohol	39.4	53.8
Smoking	32.3	16.9
Sexual intercourse experience	62.6	61.5
Drug addiction	2	0
STD experiences	14.1	3.1

Table 2. Risk behaviors related parameters during studies.

Parameter	Time			
	Proportion			
	Screening (n = 164) %	At 4 months (n = 162) %	At 12 months (n = 161) %	P-value
Alcohol consumption	51.2	39.5	45.3	0.28
Amphetamine addiction	1.22	0.62	0.62	0.57
Sexual intercourse experience	62.2	35.2	35.4	< 0.0001
Sex with commercial sex workers	42.15	0	1	< 0.0001
History of sexual transmitted disease	9.75	0.62	0	0.0002

AIDS including transmission and prevention, vaccinological concept and voluntary consent. 259 Thais were screened for healthy conditions (both physical and mental) and no risk to low risk for HIV infection. These volunteers underwent counseling and the evaluation of medical and HIV risk history, physical examination and investigations. Only 206 volunteers were asked to answer the TOU after passing the medical and sexual behavioral risk evaluation. They had to pass the minimum requirement of 90 per cent to validate study enrollment.

For the former study, 116 tests of basic knowledge were evaluated and 2 volunteers could not pass the minimum score requirement. The results demonstrated insufficient knowledge about the effects on HIV vaccine (30.2%), study methodology (25%), commitment of participation (7.8%), blood drawn risks (5.2%) and HIV/AIDS (3.5%). The distribution of basic knowledge test scores among the volunteers of the former study demonstrated that there was no statistically significant difference determined by age, sex and education.

The results of the TOU at the first screening visit among 90 examinees from the latter study showed insufficient basic vaccine knowledge (11.1%), insufficient basic knowledge about HIV (10%), no clear understanding of the study goal (4.4%), no clear understanding of blood drawn risks (1.1%). However, only 3.3 per cent and 4.4 per cent of the two studies, respectively, did not know about HIV and the vaccine,

Table 3. Attitude and social harms during study participation.

Attitude	Proportion			
	Chiron HIV ThaiE		Aventis Pasteur Live ALVAC Prime-Boost	
	At 4 months %	At 1 year %	At 4 months %	At 1 year %
Positive attitude	57.6	60.6	79.9	84.6
Neutral attitude	42.4	39.4	20.1	15.4
Refusal from friends	0	0	0	0
Refusal from lovers	0	0	0	0
Refusal from insurance company	1	0	0	0
Comfortable to express of being the volunteer	92.8	96.9	92.2	95.2
Benifits from participation	98	100	100	100
Reconsideration of being volunteer	96.9	92.8	98.4	98.4
Question about the study	10.2	3.1	4.7	3.2

Table 4. Expectations from study participation.

Expectations	Proportion	
	Chiron HIV ThaiE %	Aventis Pasteur Live ALVAC Prime-Boost %
Safety of vaccine	95.9	96.8
Believe in efficacy of vaccine	80.8	69.2
The Usefulness of study to prevent HIV	65.6	84.6
Benefit for the country	96	96.9
Meritoriousness	98	96.9
Health check-up	82.8	76.9
Refunds	11.1	9.2

demonstrating that at the second screening visit, there were improvements among these volunteers after counseling. There was a statistically significant difference in understanding between these two groups of volunteers shown from the TOU ($p < 0.0001$), where good knowledge group in the latter study (77.8%) was greater than the former study (44.8%).

Questionnaires during study

The questionnaires for risk behavior assessment done at 0, 4 and 12-month of each study were evaluated (Table 2). 51.2 per cent had a history of alcohol use but were not alcoholic. Though 25.6 per cent were determined to lower their alcohol intake after the study participation, there was no significant change in amount and frequency during the 12-month follow-up and no significant difference between both studies. Only 2 per cent from the former study accepted that they were addicted to amphetamine but no history of intravenous drug use was found among all the volunteers. At the beginning of the study, 62.2 per cent continued sexual intercourse practices, 42.2 per cent of whom had sex with commercial sex workers. Prior to enrollment, 53.7 per cent were determined not to change their sexual practices and 16.5 per cent intended to continue sex with commercial sex workers. But after 1-year participation of the studies, only 1 had protective sex with a commercial sex worker with condom use, while 35.2 per cent continued sexual practice with an identified single sexual partner, which statistically decreased from the beginning of the trials (62.2% *vs* 35.2%, $p < 0.0001$). The groups of single volunteers who had sexual intercourse at 4 and 12 months' participation (36.8% and 35.1%, respectively) had significantly decreased compared with prior to enrollment (52%) with statistical significance ($p = 0.04$). History of having sex with commercial sex workers was significantly higher in the lower educational level group ($p = 0.01$) and older group; > 40 years old ($p < 0.001$). Mean age (in years

± SD) of first experience in the former study (19.9 ± 3.9) was not different to the latter study (19.27 ± 2.23). 55.4 per cent of this group were 15-19 years old. History of sexual transmitted diseases in the former study was found 14.1 per cent higher than the latter study (3.1%). However, no one complained of any sexually related genital symptoms during the study participation throughout the year. Regular counseling and advice to observe signs of sexually transmitted diseases among their sexual partners was done to diminish the risk of HIV exposure which is probably coexistent. As a result, the sexually transmitted diseases incidence was also diminished. No one expressed uncertainty in the status of sex-related disease among their sexual partners.

Condom use among the volunteers was not common (25%) especially married ones (10%) but 100 per cent condom use was found if they had sex with commercial sexual workers. 33.3 per cent reported that they had never used a condom with their girlfriends or boyfriends while 27.8 per cent seldom used one. Only 27.8 per cent used a condom every time when they had sex with lovers while 11.1 per cent usually used one. Questionnaires about opinion in condom use demonstrated that 59.7 per cent were not confident of HIV transmission prevention by condom use and 33 per cent had unsatisfactory sex if they used a condom. After a year of study participation, 47 per cent were worried about the possibility of HIV transmission and 19.75 per cent were still not satisfied with sex using a condom. Volunteers with the lower schooling level (highest education primary school) reported a history of sexual intercourse ($p < 0.001$) and married status ($p < 0.001$), more than those with the higher schooling level. Psychological assessment could not extract any unaccepted and undesirable conditions among the volunteers during 1 year of study.

Attitude and expectations

Short assessment about community influence, general health, risk behaviors, attitude and expectation was regularly done after vaccination in both studies. No obvious deviation of expectations was found among those visits. By average, 67.7 per cent mentioned the perception of positive attitude during the study, while the rest of the volunteers expressed a neutral attitude. At the 12-month evaluation, no significant increases of social stigmatization or sexual risk were found. No social harm from their partners, family, friends and society was detected. 96.3 per cent could confidently talk to anyone about the HIV prophylactic vaccine and the study.

The volunteers' understanding and expectations on investigational HIV vaccines from both studies were as follows; believe in safety of vaccine (96.3%), efficacy of vaccine in immunological improvement (76.2%) and HIV prevention (73.2%). 58.9 per cent of volunteers' friends and 55.5 per cent of their families believed that the vaccines were safe, but only 38.4 per cent and 44.4 per cent mentioned that their friends and family did not believe that the vaccines were safe. 3.1 per cent of volunteers questioned their health especially the possible relation of concurrent illnesses and vaccination but they were satisfied after counselors advised them and none blamed the vaccine. All volunteers mentioned that they obtained benefits from the study participation. 98 per cent of the volunteers felt personal satisfaction during participation in the study, including self benefits from periodic medical check-up (80.5%), feelings of having gained merit (97.5%) and altruism (100%). Surprisingly only 10.4 per cent mentioned the refund, compensation for traveling expenses and time lost from work. 96.9 per cent would have been volunteers if they had a second chance to reconsider trial participation.

DISCUSSION

HIV prophylactic vaccine is a challenging tool hopefully to prevent the incurable HIV infection and also decrease the still-increasing prevalence of HIV/AIDS worldwide. Thailand, one of the selected first 4 countries by WHO[7], had a good opportunity to conduct these early HIV prophylactic vaccine trials in 1993[8,9]. The 2 studies began 2 years apart during which time the knowledge of HIV infection and transmission should have increased due to public campaign to reduce HIV prevalence in Thailand begun increased. Thai people have become more accepting of HIV infected individuals, and also more willing to join HIV-related studies or projects. We might find the improvement corresponding to the changes of attitude among people and community on HIV/AIDS between these 2 studies at different time setting. Though the proportion of good knowledge group was significantly higher in the latter study, the significant difference of the proportion of higher educational level between the 2 studies could possibly influence this finding. However, the effect resulting from better staff

skills in education and counseling cannot be ignored. The incidence of sexual transmitted diseases in Thailand was presumed to decrease due to the significant decrease of sexually transmitted diseases among the volunteers between the 2 trials (14.1% *vs* 3.1%). This may result from successful HIV campaigns affecting the transmission of sexual transmitted diseases. However, this current study cannot demonstrate the significant improvement in terms of attitude, knowledge, behavioral risks and expectations among Thai volunteers between these two trials. The explanation should be due to the competency of the volunteers in all aspects concerned. At least, all volunteers had to pass the evaluation of psychological and knowledge prior to study enrollment and also regular discussions at the counseling sessions during the study. The scores of the Test of Understanding from the latter study showed better distribution than the former study. Though the questionnaires used in these two studies were not absolutely comparable (not exactly the same questions), it can be presumed that the good outcome may have resulted from the experienced staff who were able to explain more clearly or that there was more publishing available information on HIV and HIV vaccine trials in Thailand.

This study demonstrated a high acceptability in safety (96.3%) and subjective perception of good efficacy of the vaccines (73.2%) among the volunteers. The control of risk behavior changes can be well perceived among the volunteers during immunization and achieved by continuous education and counseling program. The HIV risk finally reflected the effectiveness of the vaccine as the outcome[10, 11]. Most of the volunteers (67.7%) experienced positive thoughts with few consequences from society and their families and seldom perceived risks from trial participation in contrast to previous studies[12,13]. None had a negative point of view from study participation. The psychosocial barriers to HIV vaccine acceptance significantly influenced by alcohol use, smoking and prior sexual experiences[14] could not be found in this study. The Test of Understanding demonstrated better concern of risky behavior by 100 per cent condom use during sex with commercial sex workers and most of the volunteers accepted a single sexual partner or sexual abstinence to lower risk behavior. The results of the study reflect the good impact of education and counseling during vaccine trials which can motivate volunteers to participate in the trial and continue once enrolled. These methods together with friendly relationship between staff and volunteers have been identified as the best approaches and should be the usual practices in every trial.

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การประเมินทัศนคติ พฤติกรรมเสี่ยงและความคาดหวังของอาสาสมัครไทยในโครงการทดสอบวัคซีนป้องกันภาวะติดเชื้อเอ็ชไอวี

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ความเข้าใจเกี่ยวกับบทบาทของอาสาสมัครและการปฏิบัติตัวขณะอยู่ในโครงการทดสอบวัคซีนมีความสำคัญมาก ทัดเทียมกับผลของวัคซีนในเชิงความปลอดภัยและประสิทธิภาพโดยเฉพาะอย่างยิ่งในการทดสอบวัคซีนป้องกันภาวะติดเชื้อเอ็ชไอวี คณะทำงานวิจัยและผู้สนับสนุนมีความกังวลว่าอาสาสมัครอาจเข้าใจไม่ตรงกับจุดมุ่งหมายของการวิจัยทำให้มีแนวโน้มประพฤติเสี่ยงต่อการติดเชื้อจากความคาดหวังที่ไม่เหมาะสม การศึกษานี้จึงเป็นการเฝ้าระวังและประเมินการเปลี่ยนแปลงความเข้าใจ ทัศนคติ พฤติกรรมและความคาดหวังจากการเข้าร่วมโครงการของอาสาสมัครจำนวน 164 คนจากโครงการทดสอบวัคซีนป้องกันภาวะติดเชื้อเอ็ชไอวี 2 การศึกษาที่ดำเนินการวิจัยในช่วงเวลาที่ต่างกัน 2 ปี ได้แก่ โครงการวัคซีน Chiron HIV Thai E gp 120/MF59 $\pm$ the Chiron HIV SF52 gp120 ดำเนินงานระหว่าง ตุลาคม 2540 ถึง ธันวาคม 2541 และโครงการวัคซีน Aventis Pasteur Live Recombinant ALVAC HIV (vCP1521) priming with VaxGen gp120B/E (AIDSVAX^{TM} B/E) boosting ดำเนินงาน ระหว่าง กุมภาพันธ์ 2543 ถึง เมษายน 2544 การศึกษานี้พบว่ามีอาสาสมัครชาย 113 รายและหญิง 51 ราย ซึ่งมีอายุเฉลี่ย 28.82 $\pm$ 7.97 ปี ทั้งหมดจะได้รับทราบข้อมูลของโครงการ และได้รับคำปรึกษาระหว่างอยู่ในโครงการโดยก่อนเริ่มเข้าโครงการ และขณะอยู่ในโครงการได้ 4 เดือนและ 1 ปี จะต้องทำแบบสอบถามประเมินความเสี่ยง ความรู้ทัศนคติ ความคาดหวังและผลกระทบขณะเข้าร่วมโครงการเพื่อนำข้อมูลมาประเมิน ซึ่งพบว่าพฤติกรรมเสี่ยงจากเพศสัมพันธ์ลดลงอย่างมีนัยสำคัญทางสถิติ (42.2% และ 1%, $p < 0.0001$) โดยมีคู่นอนเดียว และอาสาสมัครทั้งหมดได้รับประโยชน์จากการเข้าร่วมโครงการตรงกับความคาดหวังคือได้รับความรู้ เสียสละเพื่อส่วนรวม ได้ทำบุญและผลกับตัวเองคือได้รับการตรวจร่างกายที่สม่ำเสมอ

คำสำคัญ : การประเมินความเสี่ยง, การให้คำปรึกษา, โครงการทดสอบวัคซีนป้องกันภาวะติดเชื้อเอ็ชไอวี

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