

Risk Behaviours and Comprehension among Intravenous Drug Users Volunteered for HIV Vaccine Trial

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Abstract

Out of 91 volunteers enrolled for the HIV vaccine trial, only 33 volunteers were eligible for vaccination. Of 33 volunteers recruited, 59 per cent of them had incomes of more than 5,000 Baht/month. The median duration of drug addicts was 15 years (range 1-26 years) and 42 per cent never used condoms during sexual intercourse. As far as consent comprehension was concerned, all of them understood.

There has been an emerging and rapidly spreading epidemic of HIV/AIDS in Thailand since 1984. Clearly, a significant component of the HIV-1 epidemic in Bangkok is the transmission of HIV among intravenous drug users (IVDUs)⁽¹⁾. HIV prevalence rates among injecting drug users rose from 1 per cent in late 1987 to 32 per cent, and to 43 per cent in late 1988. From 1989 through to 1993, seroprevalence among this group of population stabilized at approximately 35 per cent to 40 per cent⁽¹⁾. In spite of the risk reduction and educational measures, there has been an estimated stable

rate of HIV since 1991-1992 (11 per 100 PY)⁽²⁾. Based on molecular epidemiological studies, over 60 per cent of IVDUs are infected with subtype B⁽³⁾ though this percentage is changing in the IVDUs infected during 1991-1994 and in Bangkok Metropolitan Administration (BMA) cohort in 1995-1996⁽⁴⁾.

So intravenous drug users are the target population for HIV-1 vaccine recipients whenever an effective vaccine is available. The Genentech MN rgp 120/HIV-1 candidate vaccine which is one of the present promising vaccines available against

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subtype B HIV virus^(5,6) has been approved by the Ministry of Public Health to conduct the trial in Thailand by giving to recovering intravenous drug users at the methadone treatment clinic of the Bangkok Metropolitan Administration. This issue of HIV/AIDS vaccine trial in Thailand is quite new and is a very sensitive issue, so the study conducted has to be done in a low risk target population for safety and immunogenicity (Phase I/II). Hence, the assessment of the background behaviour risk is very important in order to select volunteers and/or to minimize their risk once they participated in the vaccine trial and the issue of informed consent procedure is also of concern.

VOLUNTEERS AND METHOD

The MN rgp120/HIV vaccine trial was a double blind placebo controlled study to evaluate the safety and immunogenicity in recovering intravenous drug users. The 91 volunteers came for screening. The screening procedure included the following: history taking, physical examination, blood (CBC, SGPT, SGOT, creatinine) and urine examinations. Only 33 fulfilled the eligibility criteria. All 33 asked to do the 20 true-false questions to evaluate comprehension of the study procedure. All responses were reviewed with participants and corrected to assure that all factual information had been understood prior to the volunteer's signing of the consent form. They were also interviewed in detail about their socio-economic status and risk behavior by questionnaires.

RESULTS

Of 91 volunteers, only 33 passed all the screening procedures. Table 1 lists the reasons for ineligibility by health status and concurrent drug use. Most volunteers were excluded because of medical reasons e.g. 14/91 (15%) were found to be anti-HIV positives, 10/91 (11%) had impaired liver functions in terms of SGPT. Among the 33 volunteers, the mean age was 55.3 years (range 43-69 years). Twenty three out of 33 had secondary level or higher education, 8 had finished primary school, 2 volunteers were illiterate. As far as occupation was concerned, 9 out of 32 (one did not answer) were jobless, one was a government employee, 5 were private sector employees, 8 were laborers and the rest had their own businesses. Most of them (19/32) had an income of more than 5,000 Baht/month (US\$ 200/months). As far as back-

Table 1. Reasons of being ineligible to participate in the HIV-1 vaccine trial.

Reasons	Number
Anti-HIV positive	14
Impaired liver function test	10
High WBC count >10,000/cells/CL	6
Concurrent drug uses (as proved by positive opiates)	8
History suggested of high risk behavior	3
Homeless	1
Ineligible age	1
SLE	1
Afraid of frequent bleeding	14

ground risks were concerned, the median duration of drug addiction was 15 years (range 1-26 years) and they had refrained from intravenous drug use at least two months prior to the study, 14/33 (42%) had never used condoms during sexual intercourse but all of them refused to have sex with commercial sex workers. None was homosexual. Two volunteers had a past history of treated syphilis and 5/33 had a past history of gonorrhoea (as told by volunteers).

Consent comprehension

Table 2 displays in brief the 20 questions. Only two questions (question 4 and 9) were misunderstood by half of the volunteers completing the test. However, all had understood the facts and responded correctly to verbal questioning before signing the consents.

Attitude toward HIV-1 vaccine

Twenty three of 33 (69.7%) felt that successful vaccine against AIDS was likely, 30/33 (91%) believed that the vaccine is effective, however, all agreed to minimize their risk behaviors. 40 per cent of the volunteers felt that the vaccine may enhance the disease progression.

DISCUSSION

There was concern about recruiting a population such as IVDUs for vaccine trial. In this study, the ratio of screened and enrolled volunteers was 3:1. This is because of health problems among this group of population. The IVDUs who passed the screening procedures had mild to moderate background risk behaviors for which we have to mini-

Tabel 2. Pretest questions and percentage of volunteers who had correct response.

	Questions	% correct response
1.	Vaccine was derived from part of protein, not the whole virus	85
2.	You may be infected by the vaccine	88
3.	You may have false positive anti HIV after vaccination	88
4.	False positive serology cannot be differentiated from true positive as a result of HIV infection	48
5.	Participating volunteers should be in the low risk group	88
6.	After vaccination, everyone has to maintain low risk behavior e.g. using condoms, avoiding needle sharing practices	76
7.	You may protect yourself less after vaccination	73
8.	The efficacy of the vaccine was 100%	82
9.	Vaccine may hasten disease progression in HIV infected persons	52
10.	Females, should agree not to become pregrant for 18 months during the study	91
11.	If you have positive urine opiates, you will be excluded from the vaccination programme	100
12.	You will receive a thorough physical examination, blood and urine check up regularly at intervals throughout 18 months	100
13.	You will receive an ID card for the project	100
14.	You should be very proud of yourself for being one who is beneficial to mankind	100
15.	Side effect of the vaccine is mild e.g. pain, swelling and feverish	97
16.	If you have any health problems, you should contact us immediately	100
17.	Every personal matter concerning yourself will be kept confidential	100
18.	You may refuse to participate in the study at anytime	88
19.	If you have any problems after vaccination, you can contact the investigators at anytime	97
20.	If anyone asks you about the project, please feel free to advise and recommend contact directly with the investigators	94

mize their risks and maintain their low risk throughout the study or as long as possible. However, there were nine IVDUs who were free of injected drugs and methadone treatment after one year of the vaccine trial period. This showed that with tentative counselling and effort by counsellors, there is still hope.

As for the consent comprehension, half of them misunderstood questions number 4 and 9. To answer question number 4 and 9, they needed to

have knowledge about the vaccine. Though it was already mentioned in the briefing process, with their level of education, they might not get it the first time. These points had to be explained and stressed by the investigators and counsellors many times both personally and in groups to ensure their understanding before signing the consent forms.

From our study, IVDUs can successfully participate in the trial though the recruitment process took time because of their health problems.

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พฤติกรรมเสี่ยงและความเข้าใจของผู้ติดยาเสพติดที่เข้าร่วมโครงการทดสอบวัคซีนป้องกันโรคติดเชื้อเอชไอวี

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จากจำนวนอาสาสมัครผู้ติดยาจำนวน 91 ราย มีเพียง 33 รายเท่านั้น ที่มีคุณสมบัติครบตามที่ระบุไว้ในโครงการ และสามารถเข้าร่วมโครงการได้ ในจำนวน 33 รายที่เข้าร่วมโครงการ, เกินครึ่งหนึ่ง (59%) มีรายได้มากกว่า 5,000 บาท ต่อเดือน ระยะเวลาที่ติดยาเสพติดโดยเฉลี่ย (median) เท่ากับ 15 ปี (range 1-26 ปี), จำนวนผู้ที่ไม่ใช้ถุงยางอนามัยในระหว่างมีเพศสัมพันธ์สูงถึง 42% อาสาสมัครมีความเข้าใจเกี่ยวกับโครงการดี ก่อนเซ็นใบยินยอมเข้าร่วมโครงการ

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