



INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH, BANGLADESH

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Memorandum

17 March 2002

To : Dr. Tasnim Azim
Laboratory Sciences Division

From: Professor Mahmudur Rahman
Chairman, Ethical Review Committee (ERC)

Sub : Protocol # 2002-005

Thank you for your memo of 14th March 2002 attaching the modified version of your protocol # 2002-005 entitled "Incidence of HIV, Hepatitis and Syphilis infections and risk behaviour in injecting drug users in Dhaka, Bangladesh". The modified version of the protocol is hereby approved upon your satisfactory addressing of the issues raised by the ERC in its meeting held on 6th March 2002.

You shall conduct the study according to the ERC-approved protocol; and shall be responsible for protecting the rights and welfare of the subjects and compliance with the applicable provisions of the ERC Guidelines. You shall also submit report(s) as required under the ERC Guidelines. Relevant excerpt of the ERC Guidelines is attached for your information and guidance.

I wish you all the success in running the above mentioned study.

Copy: Associate Director
Laboratory Sciences Division



International Centre for Diarrhoeal Disease Research, Bangladesh
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To: Chairperson ERC

From: Tasnim Azim, LSD

Tasnim Azim

Through: Associate Director, LSD

[Signature]

Date: 14. 3. 2001

Subj.: Response to comments by ERC on the protocol entitled "Incidence of HIV, hepatitis and syphilis infections and risk behaviour in injecting drug users in Dhaka, Bangladesh", PI: Dr. T. Azim

The response to comments by the ERC is given below:

- a) ERC face sheet is now attached.
- b) Bangla version of the questionnaire has been attached as annexe 3.
- c) The regular intervals for CD4 counts for HIV positive individuals is usually 3-4 months and this has been added on page 10.

I hope these responses meet with your approval.

Thank you.

I checked the Face sheet and the Bangla version of the questionnaire. There are some minor corrections. The protocol now looks O.K.
H. Begum
15.3.2002

(FACE SHEET)

ETHICAL REVIEW COMMITTEE, ICDDR,B.Principal Investigator: TASNIM AZIM

Trainee Investigator (if any): _____

Application No. 2002-005

Supporting Agency (if Non-ICDDR,B) _____

Title of Study: INCIDENCE OF HIV, HEPATITIS
AND SYPHILIS INFECTIONS AND
RISK BEHAVIOURS IN INJECTION
DRUG USERS IN DHAKA, BANGLADESH

Project Status: _____

☒ New Study☐ Continuation with change☐ No change (do not fill out rest of the form)

Circle the appropriate answer to each of the following (If Not Applicable write NA)

1. Source of Population:

- (a) Ill subjects ☒ Yes ☐ No
 (b) Non-ill subjects ☒ Yes ☐ No
 (c) Minor or persons under guardianship ☒ Yes ☐ No

5. Will Signed Consent Form be Required:

- (a) From subjects ☒ Yes ☐ No
 (b) From parents or guardian ☒ Yes ☐ No
 (if subjects are minor)

2. Does the Study Involve:

- (a) Physical risk to the subjects ☒ Yes ☐ No
 (b) Social risk ☒ Yes ☐ No
 (c) Psychological risks to subjects ☒ Yes ☐ No
 (d) Discomfort to subjects ☒ Yes ☐ No
 (e) Invasion of privacy ☒ Yes ☐ No
 (f) Disclosure of information damaging to subject or others ☒ Yes ☐ No

6. Will precautions be taken to protect anonymity of subjects ☒ Yes ☐ No

3. Does the Study Involve:

- (a) Use of records (hospital, medical, death or other) ☒ Yes ☐ No
 (b) Use of fetal tissue or abortus ☒ Yes ☐ No
 (c) Use of organs or body fluids ☒ Yes ☐ No

7. Check documents being submitted herewith to Committee:

- ____ Umbrella proposal - Initially submit an with overview (all other requirements will be submitted with individual studies)
☒ Protocol (Required)
☒ Abstract Summary (Required)
 ____ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw) (Required)
☒ Informed consent form for subjects
☒ Informed consent form for parent or guardian
☒ Procedure for maintaining confidentiality
☒ Questionnaire or interview schedule*

4. Are Subjects Clearly Informed About:

- (a) Nature and purposes of the study ☒ Yes ☐ No
 (b) Procedures to be followed including alternatives used ☒ Yes ☐ No
 (c) Physical risk ☒ Yes ☐ No
 (d) Sensitive questions ☒ Yes ☐ No
 (e) Benefits to be derived ☒ Yes ☐ No
 (f) Right to refuse to participate or to withdraw from study ☒ Yes ☐ No
 (g) Confidential handling of data ☒ Yes ☐ No
 (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure ☒ Yes ☐ No

* If the final instrument is not completed prior to review, the following information should be included in the abstract summary

1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy
2. Example of the type of specific questions to be asked in the sensitive areas
3. An indication as to when the questionnaire will be presented to the Committee for review

We agree to obtain approval of the Ethical Review Committee for any changes involving the rights and welfare of subjects before making such change.

Tasnim Azim
Principal Investigator

Trainee

RESEARCH PROTOCOL

Protocol No.: 2002-05

FOR OFFICE USE ONLY

RRC Approval: Yes/ No Date:

ERC Approval: Yes/No Date:

AEEC Approval: Yes/No Date:

Project Title: INCIDENCE OF HIV, HEPATITIS AND SYPHILIS INFECTIONS
AND RISK BEHAVIOUR IN INJECTING DRUG USERS IN DHAKA,
BANGLADESH

Theme: (Check all that apply)

- ☐ Nutrition
☒ Emerging and Re-emerging Infectious Diseases
☐ Population Dynamics
☒ Reproductive Health
☐ Vaccine evaluation

- ☐ Environmental Health
☐ Health Services
☐ Child Health
☐ Clinical Case Management
☐ Social and Behavioural Sciences

Key words: HIV, INJECTING DRUG USERS, COHORT

Principal Investigator: TASNIM AZIM

Division: LSD

Phone: 2409

Address: VIROLOGY, LSD, ICDDR, B

Email: tasnim@icddr.org

Co-Principal Investigator(s): SMARAJIT JANA, CARE, BANGLADESH
 DAVID SACK, DIRECTOR, ICDDR, B

Co-Investigator(s): SHAMJEM RABBIANI, CARE, BANGLADESH
 RAMESH CHANDRA HALDER, LSD, ICDDR, B
 MOTIUR RAHMAN, LSD, ICDDR, B

Student Investigator/Intern: NONE

Collaborating Institute(s): CARE, BANGLADESH

Population: Inclusion of special groups (Check all that apply):

- Gender
☒ Male
☐ Females

- Age
☐ 0 - 5 years
☐ 5 - 9 years
☒ 10 - 19 years
☒ 20 +
☐ > 65

- ☐ Pregnant Women
☐ Fetuses
☐ Prisoners
☐ Destitutes
☐ Service providers
☐ Cognitively Impaired
☐ CSW
☒ Others (specify INJECTING DRUG USERS)
☐ Animal

Project / study Site (Check all the apply):

- ☐ Dhaka Hospital
☐ Matlab Hospital
☐ Matlab DSS area
☐ Matlab non-DSS area
☐ Mirzapur
☒ Dhaka Community
☐ Chakaria
☐ Abhoynagar

- ☐ Mirsarai
☐ Patya
☐ Other areas in Bangladesh _____
☐ Outside Bangladesh
 name of country: _____
☐ Multi centre trial
 (Name other countries involved) _____

Type of Study (Check all that apply):

- ☐ Case Control study
- ☐ Community based trial / intervention
- ☐ Program Project (Umbrella)
- ☐ Secondary Data Analysis
- ☐ Clinical Trial (Hospital/Clinic)
- ☐ Family follow-up study

- ☐ Cross sectional survey
- ☒ Longitudinal Study (cohort or follow-up)
- ☐ Record Review
- ☐ Prophylactic trial
- ☐ Surveillance / monitoring
- ☐ Others

Targeted Population (Check all that apply):

- ☒ No ethnic selection (Bangladeshi)
- ☐ Bangalee
- ☐ Tribal groups

- ☐ Expatriates
- ☐ Immigrants
- ☐ Refugee

Consent Process (Check all that apply):

- ☒ Written
- ☐ Oral
- ☐ None

- ☐ Bengali language
- ☐ English language

Proposed Sample size:

Total sample size: 500 ☐

Sub-group _____ ☐

_____ ☐

_____ ☐

_____ ☐

Determination of Risk: Does the Research Involve (Check all that apply):

- ☐ Human exposure to radioactive agents?
- ☐ Fetal tissue or abortus?
- ☐ Investigational new device?
(specify _____)
- ☐ Existing data available from Co-investigator

- ☐ Human exposure to infectious agents?
- ☐ Investigational new drug
- ☐ Existing data available via public archives/source
- ☐ Pathological or diagnostic clinical specimen only
- ☒ Observation of public behaviour
- ☐ New treatment regime

Yes/No

- ☒ ☒ Is the information recorded in such a manner that subjects can be identified from information provided directly or through identifiers linked to the subjects?
- ☒ ☐ Does the research deal with sensitive aspects of the subject's behaviour; sexual behaviour, alcohol use or illegal conduct such as drug use?

Could the information recorded about the individual if it became known outside of the research:

- ☒ ☐ a. place the subject at risk of criminal or civil liability?
- ☒ ☐ b. damage the subject's financial standing, reputation or employability; social rejection, lead to stigma, divorce etc.

Do you consider this research (Check one):

- ☒ greater than minimal risk
- ☐ no risk

- ☐ no more than minimal risk
- ☐ only part of the diagnostic test

Minimal Risk is "a risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical, psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as a part of routine physical examination".

Yes/No

☒ ☐ Is the proposal funded?

If yes, sponsor Name: Avs AID

Yes/No

☐ ☒ Is the proposal being submitted for funding?

If yes, name of funding agency: (1) _____

(2) _____

Do any of the participating investigators and/or their immediate families have an equity relationship (e.g. stockholder) with the sponsor of the project or manufacturer and/or owner of the test product or device to be studied or serve as a consultant to any of the above?

IF YES, submit a written statement of disclosure to the Director.

Dates of Proposed Period of Support

Cost Required for the Budget Period (\$)

(Day, Month, Year - DD/MM/YY)

a. 1st Year 2nd Year 3rd Year Other years

Beginning date 1st JANUARY 2002 27000 48000 48000 _____

End date 30th JUNE 2004 b. Direct Cost: 123,000 Total Cost: 153,750

Approval of the Project by the Division Director of the Applicant

The above-mentioned project has been discussed and reviewed at the Division level as well by the external reviewers. The protocol has been revised according to the reviewer's comments and is approved.

G. BALAKRISHNA

Name of the Division Director

F. Dadi

Signature

for G. B. Nair

20/2/02

Date of Approval

Certification by the Principal Investigator

I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

Signature of PI Jasmin Agin

Date: 20.2.2002

Name of Contact Person (if applicable)

Principal Investigator: Last, first, middle Azim, Tasnim

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x	Check here if appendix is included
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Principal Investigator: Last, first, middle Azim, Tasnim

PROJECT SUMMARY: Describe in concise terms, the hypothesis, objectives, and the relevant background of the project. Describe concisely the experimental design and research methods for achieving the objectives. This description will serve as a succinct and precise and accurate description of the proposed research is required. This summary must be understandable and interpretable when removed from the main application. (**TYPE TEXT WITHIN THE SPACE PROVIDED**).

Principal Investigator

Tasnim Azim, ICDDR,B

Project Name

Incidence of HIV, hepatitis and syphilis infections and risk behaviour in injecting drug users in Dhaka, Bangladesh

Total Budget US\$ 153,750

Beginning Date 1st January 2002

Ending Date 30th June 2004

Injecting drug use is a major problem in Bangladesh and injecting drug users (IDU) are the sub-population group that has been identified to be most at risk of an HIV epidemic in this country. Although Bangladesh continues to be a low prevalence nation for HIV, the national HIV surveillance data shows that hepatitis C rates amongst IDU are 66.7% and syphilis rates are 18.2%. Behaviour surveillance data also shows considerable risk for an HIV epidemic in IDU through risky injection practices and risky sexual behaviour. Injection sharing is at 93.3% in IDU in Dhaka. Despite having a needle/syringe exchange (NEP) in place, high risky behaviour appears to be the norm in IDU in Dhaka. However, in the national behaviour surveillance sampling of IDU was from both in and out of the NEP but previous information showed that the percentage of men sharing were the same in IDU in and out of the NEP although the number of injections shared were higher in those out of the NEP. However, despite the present risky behaviour and high rates of hepatitis C and syphilis an HIV epidemic has not yet occurred. The factors determining when an HIV epidemic will occur are very complex but some of the determining factors include the existing levels of HIV in that community, risky behaviour that will allow the spread of HIV and the sexual networks that will allow spread of HIV in the nation.

In this study we are proposing to describe the incidence of HIV, and those of surrogate markers of risk; syphilis and hepatitis B for sexual behaviour and hepatitis B and C for risk through injections, and the behavioural risks in a selected group of IDU who will be followed up for two years. Such a description will provide a better understanding of the risks for an HIV epidemic in that particular group of IDU. The IDU will be selected from those attending the NEP of the SHAKTI Programme of CARE, Bangladesh in Dhaka city. During the course of the study, those IDU who will be identified, as being HIV positive will be followed up. The HIV positive IDU will be referred to support network groups and to physicians as required.

The information generated from this study will be useful in directing intervention programmes for more effective prevention and also for policy makers.

Principal Investigator: Last, first, middle Azim, Tasnim

KEY PERSONNEL (List names of all investigators including PI and their respective specialties)

Name	Professional Discipline/ Specialty	Role in the Project
1. Tasnim Azim	Virology/Immunologist	PI
2. Smarajit Jana	Public Health Specialist	co-PI
3. David Sack	Microbiologist, and Director, ICDDR,B	co-PI
4. Shamim Rabbani	Sociologist	co-investigator
5. Ramesh Chandra Halder	Virology/Immunologist	co-investigator
6. Motiur Rahman	Microbiologist	co-investigator

DESCRIPTION OF THE RESEARCH PROJECT

Specific Aims:

Describe the specific aims of the proposed study. State the specific parameters, biological functions/ rates/ processes that will be assessed by specific methods (**TYPE WITHIN LIMITS**).

The general aim of the study is to describe the incidence of HIV, hepatitis, and syphilis infections as well as risk behaviours for HIV in selected injecting drug users (IDU) attending a needle/syringe exchange programme in Dhaka, Bangladesh in order to obtain a better understanding of the dynamics of HIV infection or an epidemic in this group of individuals.

The specific aim is to document the incidence of hepatitis B and C infections, syphilis and HIV infections and the risk factors for HIV in selected IDU attending a needle/syringe exchange programme in Dhaka.

Background of the Project including Preliminary Observations

Describe the relevant background of the proposed study. Discuss the previous related works on the subject by citing specific references. Describe logically how the present hypothesis is supported by the relevant background observations including any preliminary results that may be available. Critically analyze available knowledge in the field of the proposed study and discuss the questions and gaps in the knowledge that need to be fulfilled to achieve the proposed goals. Provide scientific validity of the hypothesis on the basis of background information. If there is no sufficient information on the subject, indicate the need to develop new knowledge. Also include the **significance and rationale** of the proposed work by specifically discussing how these accomplishments will bring benefit to human health in relation to biomedical, social, and environmental perspectives. (**DO NOT EXCEED 5 PAGES, USE CONTINUATION SHEETS**).

In Asian countries drug use is increasing and the use of multiple drugs and injectable drugs is common [UNAIDS/UNDCP, 2000]. In Bangladesh the drug that is most commonly used for injecting is buprenorphine. Buprenorphine was introduced into the Indian sub-continent in the 1980s as an antidote to heroin addiction and its use has since become popular because it is considered safer and it is cheaper. In many East and South Asian countries large numbers of injecting drug users (IDU) are infected with HIV; 62% in Myanmar [UNAIDS/UNDCP, 2000], 60-80% in India [UNAIDS/UNDCP, 2000], 30-40% in Thailand [Kitayaporn et al, 1994], 45% in Nepal [Oelrichs et al, 2000]. These high rates are associated with high-risk injection practices including sharing of needles/syringes, no effective cleaning practices, use of professional injectors who inject many users with the same needle/syringe [UNAIDS/UNDCP, 2000]. In Dhaka, most men inject themselves, often sharing drugs and injections in small groups although professional injectors are also used in some settings.

The HIV epidemic in many countries has started with the IDU [Des Jarlais et al, 2001]. Bangladesh is so far a low prevalence nation for HIV [Islam et al, 1999; Bangladesh, 2000a; 2000b; Azim et al, 2000].

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However, high rates of syphilis and hepatitis and risky behaviour conducive to acquiring HIV infection are highly prevalent amongst IDU sampled in the Second Generation Surveillance for HIV in Bangladesh. The third and most recent round of surveillance data shows that the highest rates for HIV (1.7%) are in IDU sampled from the needle/syringe exchange programme (NEP) in Dhaka [Govt of Bangladesh, 2001a]. In the second round of surveillance, in IDU from the same site, 66.7% were hepatitis C positive [Azim et al, 2002]. A similar situation exists in Lahore, Pakistan [UNDCP/UNAIDS, 1999] and Kolkata, India [Panda, 2000] where IDU commonly share injections and have high rates of hepatitis C infection, but low HIV rates. Indonesia, which remained low prevalence for some years, is now reporting an HIV epidemic among IDU and sex workers [MAP, 2001]. In Manipur, India, in the initial years of surveillance no HIV was detected, but after three years, infection rates suddenly rose [Sarkar et al, 1993]. The same is true for Kathmandu, Nepal [Oelrichs et al, 2000]. Therefore in those countries where an HIV epidemic is now raging in IDU, there was an initial phase where no or little HIV was recorded for several years. The duration of this low prevalence state varies and what triggers the shift from low prevalence to an epidemic is not clear. Certain factors can influence the start of an epidemic and whether Bangladesh has an epidemic or not will depend on the interplay of these factors as discussed below:

- i) The size of the population groups that are at most risk of an HIV epidemic
- ii) The prevalence of HIV in a country
- iii) Risk behaviours that allow the acquisition of HIV infection
- iv) Networks of risk behaviour that will allow spread of HIV

i) The size of the IDU population in Bangladesh is not known. The SHAKTI Project of CARE, Bangladesh, that provides some harm reduction for IDU through the NEP (see section on Research Design and Methods under Study Participants and Sampling Site) estimates that Dhaka has approximately 5000 IDU. This estimate is based on snowball sampling techniques used by CARE's Peer Outreach Workers who are themselves current IDU. But these numbers vary and depend on many factors including the availability of the drug and the price. At present a National Rapid Assessment Survey is being conducted in Bangladesh to determine the extent of the problem of opiod/opiate use. However, this survey is not designed to provide numbers of IDU in Bangladesh. Although the total size of the IDU population is not available, it is clear that large numbers of IDU are at risk and many people connected to the IDU, who themselves do not engage in high risk behaviours, are also at risk, as discussed below.

ii) HIV epidemics in IDU are different from those in other sub-population groups as spread is rapid so that once the HIV prevalence rate reaches 10%, it can surpass 40-50% in 1-4 years [Strathdee et al, 1998]. Fortunately, HIV prevalence is still low in Bangladesh [Islam et al, 1999; Govt of Bangladesh, a; 2000b; Azim et al, 2000]. Surveillance for HIV in Bangladesh includes sampling from IDU from the NEP of central and northwest Bangladesh and also from detoxification clinics in central Bangladesh [Azim et al, 2002]. During the third and most recent round of surveillance HIV was found only from the NEP in central Bangladesh, where 1.7% of the 401 IDU sampled were HIV positive and this is the only group where prevalence exceeds 1% [Govt of Bangladesh, 2001a]. Other studies conducted on drug users including IDU in Bangladesh have also found very low levels of HIV infection [Shirin et al, 2000]. Prevention can be effective in IDU only if harm reduction programmes are instituted while prevalence is low.

iii) Behaviours that will allow spread of HIV within the IDU community are their injecting practices as well as sexual behaviour patterns. In Dhaka, 93.4% of over 500 IDU sampled in the Behaviour Surveillance during the last survey, said that they had shared injection equipment in the last week though nearly a third said they had participated in the NEP [Govt of Bangladesh, 2001a]. Subtyping of

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HIV isolated from IDU in the NEP of Dhaka during the second round of surveillance showed that five were subtype C and one E/B [Azim et al, 2002]. Of the five subtype C viruses, four were identical, confirming that sharing is taking place. In addition to risky injection practices, IDU also have risky sexual behaviour as shown by the Behavioural Surveillance data [Govt of Bangladesh, 2001a]; 38.8% of IDU bought sex last month while 19% engaged in non-commercial sex with non-regular partners and consistent condom use was at 11.2% with commercial partners and at <1% with non-commercial partners. Risky sexual behaviour is confirmed by high rates of syphilis (18.2%) in IDU from the NEP in Dhaka [Govt of Bangladesh, 2001a]. With such high risk behaviour in IDU in Bangladesh, once HIV enters the community in adequate numbers, it will spread.

iv) The risky sexual behaviour described above extends beyond the IDU community into the general population because of the sexual interactions between the different sub-population groups so that networks of risk in Bangladesh are both complex and extensive [Govt of Bangladesh, 2001a]. The Behavioural Surveillance showed that 39.6% of IDU were married and IDU also bought sex from female sex workers, male sex workers and hijras (transgenders) [Govt of Bangladesh, 2001a]. And male sex workers in their turn bought sex from women, men and hijras. Therefore once HIV enters this community it will not be restricted to IDU but will spread to others. Such spread has been documented in many countries [Panda et al, 2000; MAP, 2001].

The behaviour evidence and also the data for syphilis and hepatitis C so far available show that IDU in Bangladesh are definitely at risk of an HIV epidemic. So much so that the risk behaviours in Bangladesh are comparable to those in other countries in the region that are experiencing an HIV epidemic [MAP, 2001]. Therefore, a question that is frequently asked is whether there will be an HIV epidemic in Bangladesh. We will attempt to investigate this question by following a group of IDU in the NEP of CARE, Bangladesh and assessing their incidence of infections from HIV, syphilis and hepatitis (B and C) as well as their risk behaviours (both from injection practices and sexual behaviour). Although this will provide a descriptive picture of IDU and their injection risk, such an understanding will only be limited to selected IDU in the NEP of Dhaka; i.e. IDU in the NEP who are less mobile and willing to participate in the study. The findings of this study, therefore, will not necessarily be true for other IDUs.

During this study, linked testing for HIV will be done. This raises ethical concerns such as confidentiality, care and follow-up of HIV positive people. For this purpose, VCT services that have become available at ICDDR,B will be used along with the linking network which is being developed so that once a diagnosis of HIV is made, individuals will be referred to an HIV positive network such as that of CARE, Bangladesh for support. These individuals will be followed up regularly with a medical check-up, CD4 counts and viral loads will be ascertained to monitor progress of illness from HIV. Clinicians who are sensitive to HIV will be part of the linking network so that HIV positive cases can be referred when needed. Although no treatment for HIV will be provided through this study, HIV positive cases will be referred for supportive therapy as is available in the country. These support services will be built upon as the study progresses depending on the needs of the HIV positive IDU.

To summarise, the following will be done in this study:

1. Determination of the incidence of hepatitis, syphilis and HIV infections and behavioural risk factors for HIV infection, in a selected group of IDU.
2. Information will be obtained regarding the needs of IDU following HIV infection up to the end of the study. HIV positive people will receive support as is available and referral services will be enhanced depending on their needs. Available support includes referral to the HIV positive network of CARE and counselling from the counsellors from the VCT at ICDDR,B and CARE

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field staff. Progress of infection will be monitored by regular CD4 counts and measurement of viral load at ICDDR,B. Nutritional status and advice will be provided by nutritionists at ICDDR,B.

3. Establishment of a cohort of IDU who can be used for future studies such as HIV vaccine trials.
4. Information addressing factors influencing an individual to start taking and continue taking drugs, and identifying factors (individual and societal) based on which an efficient recovery programme could be put in place will be made available for the improvement of the intervention programmes for IDU. However, as the IDU selected in this study are a non-random group of individuals, the data will only be applicable to this group of IDU and improvements in the intervention programmes based on the data generated from this study will have to consider these limitations. However, as many of the questions used in this study will be similar to those used in the Behavioural Surveillance of Bangladesh where random sampling of all IDU in Dhaka city is done (Govt. of Bangladesh, 2000a), it may be possible to assess whether the groups covered by the two studies are similar enough so that the data generated from this study may be extrapolated to some extent to other IDUs in the city.

Research Design and Methods

Describe in detail the methods and procedures that will be used to accomplish the objectives and specific aims of the project. Discuss the alternative methods that are available and justify the use of the method proposed in the study. Justify the scientific validity of the methodological approach (biomedical, social, or environmental) as an investigation tool to achieve the specific aims. Discuss the limitations and difficulties of the proposed procedures and sufficiently justify the use of them. Discuss the ethical issues related to biomedical and social research for employing special procedures, such as invasive procedures in sick children, use of isotopes or any other hazardous materials, or social questionnaires relating to individual privacy. Point out safety procedures to be observed for protection of individuals during any situations or materials that may be injurious to human health. The methodology section should be sufficiently descriptive to allow the reviewers to make valid and unambiguous assessment of the project. **(DO NOT EXCEED TEN PAGES, USE CONTINUATION SHEETS).**

Study Participants and Sampling Site:

Injecting drug users attending the NEP of the SHAKTI Project of CARE, Bangladesh in Dhaka city will be the study participants. Approximately 3500 IDU are reached daily by the NEP. The activities of the NEP are described below under three broad categories:

- i) Drop In Centres (DIC)
- ii) Out Reach Services
- iii) Field Office based activities

i) There are eight DIC in different parts of Dhaka city and these are considered as safe places for the IDUs where they socialise, where clinical services are available for the treatment of abscesses, STDs, and other illnesses, and from where they can also be referred for drug treatment and detoxification. At the DIC, education sessions on the harmful effects of drugs, HIV/AIDS, STDs, blood borne infections, etc. are carried out. These are situated within the communities of IDU covered by the Peer Outreach Workers and the local community provides the space. A male physician provides clinical services once every week for approximately two hours. These services are free. Also, at the DIC, is a "dresser" who is a current drug user and who has been trained in dressing minor wounds and draining abscesses and can dispense medicine such as paracetamol for fever. Serious cases are referred. The DIC form the focal point for the team of Peer Outreach Workers however, all except one, in charge of the DIC, are from a non-drug use background.

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ii) The Out Reach Services are provided by trained Peer Outreach Workers who are all current IDU. These Peer Outreach Workers train and educate IDU about HIV and safer injection practices, give out new syringes/needles in exchange of used ones and also distribute condoms. These Outreach activities are carried out at different spots surrounding each DIC and the Peer Outreach Workers assigned to each locale are from that community. The Peer Outreach Workers regularly update a "master list" of IDUs, which provides information of all IDUs in the community. Needle/syringe exchange takes place at the different pre-fixed spots surrounding each DIC. The Peer Outreach Workers collect clean needle/syringes each morning from the DIC for exchange with used ones. During exchange of needle/syringe, condoms are also distributed on demand and free of cost. The used needles/syringes are brought back to the DIC in puncture proof tins where they are stored and then sent at regular intervals to ICDDR,B for incineration.

iii) The Field Office in Dhaka provides administrative and technical support to the field activities of the NEP. It has the technical co-ordinator, project officers and field trainers. Field trainers accompany the outreach workers to the field to ensure comprehensive delivery of needles/syringes and condoms. The project officers are responsible for trouble shooting in the field that often occurs due to harassment by police, mastans (local goons), and if the project officers are unable to handle this, the responsibility is handed over to the technical co-ordinator. The Field Office is also the site for regular meetings between Peer Outreach workers and the staff at the Field Office regarding all related issues. Advocacy through cultural programmes and other tools flip charts, pamphlets, etc. is provided.

For this study the NEP of CARE, Bangladesh will be used to reach IDU. The inclusion criteria for IDU to participate in the study are:

1. Currently injecting drugs
2. Participating in the NEP
3. Not mobile so that they can be followed up for two years
4. Age 18-50 years
5. Male, as the number of female injectors are very few and their social situation is likely to be different from that of men and which will create a bias in the analysis

Training:

Before starting the work, training of a core group of researchers and field staff will be required. Training will be done on the basics of HIV including ethics and the need for confidentiality, a background on drug use and IDU, and on the methodologies to be used in the study. The field staff will be responsible for conducting the questionnaires, collecting blood samples, taking back reports on time, etc. The researchers will be responsible for co-ordination and trouble shooting in the field. They will work closely with the field staff of the NEP.

Preparation of the field:

In the initial phase, in order to select the group of IDU who will become part of the study and the long-term cohort, the field will have to be prepared. For this SHAKTI's NEP set-up will be very helpful. However, in the NEP, individuals are not followed-up for HIV. The main stress is on harm reduction for HIV without HIV testing, except once yearly in the surveillance where testing is unlinked, anonymous. As for the first time in Bangladesh, individuals from a known community will have linked HIV testing and these individuals will be followed up over time, and as HIV is highly stigmatised in this society, preparation of the community is essential. In order to prepare the community several steps have to be undertaken:

- i) To create support groups of drug users and the community - the role of Peer Outreach Workers at present is to distribute condoms and provide new needles/syringes in exchange of old ones. Although

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they are very much exposed to HIV, special training will be required to build up a support group of drug users who will be able to comprehend the purpose of the study and to mobilise other drug users to participate actively. The support group must involve the community and mobilise its support so that no opposition to the work is faced.

ii) Advocacy at the local community level will be necessary so that hindrance from police and local mastaans can be dealt with officially. This will be combined with CARE's activities and includes meetings with Ward Commissioners, the City Mayor, Inspector General of Police, and officials in the Narcotics Control Dept. of the Govt. of Bangladesh.

iii) Setting up of the Office - field co-ordination will require a field office at a site which should ideally be located centrally in terms of access to all locales included in the study. A small office will be rented but prior to renting, support from the community will be obtained.

iv) Service linkages – as individuals participating in the study will be diagnosed for syphilis, hepatitis and HIV, service linkages for these infections are essential. The NEP provides clinical services once weekly; these services may be used for treating syphilis. For hepatitis, referral to Hospitals will be developed. For HIV positive cases several levels of support will be required. All those diagnosed positive will be referred to the HIV positive network of CARE, Bangladesh. Their clinical follow-up will be done regularly for CD4 counts and viral load at ICDDR,B and they will be examined by a physician who will be part of the support group network. Nutritional advice will be provided by nutritionists who are available at ICDDR,B. All other medical support including for concurrent infections will be provided as is available in the country but referral systems will be enhanced. They will receive counselling from the counsellors at the VCT Centre of ICDDR,B and from the field staff of CARE, Bangladesh. For those IDU seeking treatment for drug use, current referral systems will be used to the Central Drug Addiction and Treatment Centre and APON.

VCT services:

A VCT Centre for HIV at ICDDR,B called Jagori, has been established since January 2002. There are two Psychologists at this Centre, one male and the other female. Both have formal training in counselling and have also received training for HIV counselling in India for one month. The Centre is also in communication with Dr. David Miller, a VCT specialist at UNAIDS in New Delhi, who has provided advice in the setting up of the VCT and who will continue to provide advice to the counsellors.

In addition, to the VCT Centre at ICDDR,B, counselling services are available at CARE, Bangladesh. The counsellors of CARE, Bangladesh will provide the initial link-up of HIV positive IDU by visiting the IDU in the field and connecting with the counsellors at ICDDR,B. The counselling services at CARE, Bangladesh and ICDDR,B will work together.

Sample Size:

Sample size calculation is based on the assumption that at the end of three years, the incidence of HIV will be 3%, that of hepatitis C will be 70% and that of hepatitis B infection will be 7%. These assumptions have been made based on figures from the second and third rounds of serological surveillance [Govt. of Bangladesh, 2001b; Azim et al, 2002]. The sample size calculation for each parameter has been calculated using the formula:

$$n = \frac{P(100-P) \times z^2}{d^2}$$

Where: n= sample size, P = proportion with the infection, z = 1.96, d= allowable error

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For HIV, keeping the allowable error at 1.5, the sample size is 502, for hepatitis C with the allowable error at 5, the sample size is 323 and for current hepatitis B with an allowable error at 2.5, the sample size is 400. Therefore, we will aim to enrol 502 IDU. However, a 20% drop-out is expected for which reason initially, 628 IDU will be enrolled.

The NEP of CARE, Bangladesh has experience with working with IDU over three years and anecdotal evidence suggests that approximately 50% of the same IDU have been coming to the NEP. Therefore, follow-up of 500 IDU over two years is possible.

Methodology:

The study will have an initial six months setting-up phase during which time staff will be hired and trained and the Field Office will be set up while at the same time community mobilisation activities will go on. Once staff are trained, an initial baseline survey in all 3500 IDU in the NEP will be conducted using a questionnaire, which will assess the basic demographic characteristics of the group including mobility and level of education. In addition, to the questionnaire in-depth interviews and Focus Group Discussions (FGDs) will be conducted with present and ex-drug users to get their input into the project. Based on these, the 628 IDU for the study will be selected. The selected group of IDU will be surveyed every six months for behaviour and for the laboratory parameters up to two years.

Behavioural questionnaire (annexe 2) – this is designed to obtain information regarding the injection practices, their sexual behaviours, contextual issues around illicit drug use such as harassment by police and others, pattern of drug use, etc. The questionnaire is based on that used by CARE, Bangladesh and the Behavioural Surveillance of the Second Generation Surveillance System but will be pre-tested during the initial six months setting-up phase of the study.

Laboratory methods – tests will be done for HIV, hepatitis C, hepatitis B and syphilis. The methodological details are provided in annexe 1. Measuring of CD4 counts and viral load by PCR will also be done for all HIV positive individuals at regular intervals (usually every 3-4 months). The latter two methods are being set up at ICDDR,B.

It is expected that each survey will take approximately one month. Syphilis tests will be done daily and results will be provided immediately for treatment purposes. HIV and hepatitis tests will be done in batches. Analysis of the behaviour data will be done after each survey and the results will be fed back into the community. After the final survey, the final data analysis will be done. Also throughout the duration of the last two years of the study, those infected with HIV will be followed up and their needs will be assessed and addressed as far as possible.

If an IDU is diagnosed as being HIV positive, the result will be disclosed to the IDU by the counsellor. From that point on the IDU will be under the responsibility of the counsellor from the VCT. The decision of partner notification will mainly rest with the counsellor. The counsellor will motivate the HIV positive IDU to inform his partner and will counsel the HIV positive IDU to take preventive measures so as not infect his partner. However, if the client refuses to inform the partner, whether or not the HIV positive result should be disclosed to the partner will depend on the judgement of a team comprising the counsellor concerned and the Principal Investigators from ICDDR,B and CARE, Bangladesh. Weighing the pros and cons of disclosure for that particular case will base the decision. The decision for each case may therefore be different for which reason set rules cannot be laid down for partner notification. This approach for partner notification is in line with the National HIV/AIDS Policy of Bangladesh.

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Facilities Available

Describe the availability of physical facilities at the place where the study will be carried out. For clinical and laboratory-based studies, indicate the provision of hospital and other types of patient's care facilities and adequate laboratory support. Point out the laboratory facilities and major equipments that will be required for the study. For field studies, describe the field area including its size, population, and means of communications. **(TYPE WITHIN THE PROVIDED SPACE).**

AT ICDDR,B:

The Virology Laboratory has facilities for testing for HIV by ELISA and Western Blot with quality control. Tests for hepatitis B and C have been and are being conducted for the serological component of the Second Generation Surveillance System and similar methods will be used here. PCR machines are available and PCRs and RT-PCRs are regularly conducted for detecting genes of toxins, typing viruses (rotavirus, dengue) and for detecting cytokine mRNA. The methodology for assessing HIV viral load is being set up. A Fluorescence Activated Cell Sorter (FACS) is available at ICDDR,B, and is at present being installed. A Voluntary Counselling and Testing (VCT) Centre has been established at ICDDR,B which started on 20th January 2002.. Two psychologists who have been trained in these techniques will be responsible for counselling. Network with various NGOs, and Government Officials for conducting HIV surveillance is in place and this will be helpful in creating the support network required. ICDDR,B has experienced nutritionists who can examine and provide advice to HIV positive IDU.

AT CARE, Bangladesh:

The NEP of the SHAKTI Programme of CARE, Bangladesh described earlier will provide access to IDU and also all the back-up support in the community and at all levels including policy makers at the central level such as the Narcotics Control Dept. and the Home Ministry of the GoB. CARE has designed its advocacy strategy to not only inform policy makers but also at the field level which has created an enabling environment for the IDU in Dhaka city. CARE also works with a self-help group of IDU. As part of its strategy, CARE organises routine weekly meetings with the policy makers and the self-help group of IDU. HIV Positive Support Network – since December 1998 CARE is running an HIV positive support network to create a supportive environment for HIV positive people and those with AIDS which has as staff, HIV positive people. This network also links the HIV positive people to other social support networks.

Data Analysis

Describe plans for data analysis. Indicate whether data will be analyzed by the investigators themselves or by other professionals. Specify what statistical softwares packages will be used and if the study is blinded, when the code will be opened. For clinical trials, indicate if interim data analysis will be required to monitor further progress of the study. **(TYPE WITHIN THE PROVIDED SPACE).**

The investigators and supervisors will review all data forms for accuracy, consistency and completeness. Whenever necessary an additional visit will be made to clarify inconsistencies or missing data. After editing, data will be entered into databases. Necessary range and consistencies will be in-built. Data will be periodically checked by running and reviewing frequency distributions and cross-tabulations.

Data analysis will be done using software packages SPSS and Epi Info. For descriptive purposes, the relative frequencies of the demographic, socio-economic and other study variables will be obtained for the total group and for each category. The incidence rates of hepatitis, syphilis and HIV will be

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calculated using occurrence of the disease as the numerator and persons years observed as the denominator. Years of observation for each individual will be obtained from the data of follow up period. Logistic regression will be done to determine the risk factors for developing and transmission of diseases adjusting for other variables.

Ethical Assurance for Protection of Human Rights

Describe in the space provided the justifications for conducting this research in human subjects. If the study needs observations on sick individuals, provide sufficient reasons for using them. Indicate how subject's rights are protected and if there is any benefit or risk to each subject of the study.

HIV infects humans and assessing the risk for HIV infection in a group of IDU can only be done in humans.

The risk the individual may have from this study is the stigmatisation from HIV infection so that if the community becomes aware of an HIV positive status this may act against the individual and the whole IDU community as a whole. In order to protect against this, strict confidentiality will be maintained regarding the HIV status of the IDU. The staff will be trained in the importance of maintaining this confidentiality and all records will not have names, but unique identifiers. Also, awareness building regarding the basics of HIV including methods of spread, etc will be provided to the community so that they are more open to the issues around HIV. HIV positive IDU will know their HIV status and will receive counselling from the VCT Centre at ICDDR,B. In addition, they will also receive support at regular intervals at the field level by the counsellors and other field staff of CARE, Bangladesh. Moreover, referral services for HIV as developed for the VCT centre will be used in the case of IDU. The HIV positive support network of CARE, Bangladesh will provide emotional and mental support. In addition, the network around VCT includes support from clinicians and lawyers.

Maintenance of confidentiality will not only be through using identifier numbers on questionnaires and blood tubes, but also through the training that is given to staff during the initial six months of the study when the field preparation activities are ongoing.

The direct benefits to the IDU are that with follow-up they will receive constant attention to their needs including if they become positive for HIV.

Indirectly the IDU will benefit, as this study will provide an understanding of the risk factors for HIV infection in their community, which will be fed back into the intervention programmes. The programmes can then modify their plan of action.

Use of Animals

Describe in the space provided the type and species of animal that will be used in the study. Justify with reasons the use of particular animal species in the experiment and the compliance of the animal ethical guidelines for conducting the proposed procedures.

Animals will not be used.

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Literature Cited

Identify all cited references to published literature in the text by number in parentheses. List all cited references sequentially as they appear in the text. For unpublished references, provide complete information in the text and do not include them in the list of Literature Cited. There is no page limit for this section, however exercise judgment in assessing the "standard" length.

Azim T, Bogaerts J, Yirrell DL, et al. 2002. Injecting Drug Users in Bangladesh: Prevalence of Syphilis, Hepatitis, HIV and HIV Subtypes. *AIDS* 16:121-122.

Azim T, Islam MN, Bogaerts J, et al. 2000. Prevalence of HIV and syphilis among high risk groups in Bangladesh. *AIDS* 14: 210-211.

Des Jarlais DC, Dehne K, Casabona J. 2001. HIV surveillance among injecting drug users. *AIDS* 15 (suppl3): S13-S22.

Govt. of Bangladesh, 2000a. Report on the Second National Expanded HIV Surveillance, 1999-2000, Bangladesh: AIDS and STD Control Program, Directorate General of Health Services, Ministry of Health and Family Welfare.

Govt. of Bangladesh, 2000b. Report on the sero-surveillance and behavioural surveillance on STD and AIDS in Bangladesh, 1998-1999. AIDS and STD Control Program, Directorate General of Health Services, Ministry of Health and Family Welfare.

Govt. of Bangladesh, 2001a. HIV in Bangladesh: where is it going? A background report on the third round of HIV and behavioral surveillance in Bangladesh. AIDS and STD Control Program, Directorate General of Health Services, Ministry of Health and Family Welfare.

Govt. of Bangladesh, 2001b. World AIDS Day report, December 2001. AIDS and STD Control Program, Directorate General of Health Services, Ministry of Health and Family Welfare.

Islam MM, Karim E, Mian MA, et al. 1999. An update on the prevalence of HIV/AIDS in Bangladesh. *Southeast Asian J Trop Med Public Health* 30:246-250.

Kitayaporn D, Uneklabh C, Weniger BG, et al. 1994. HIV-1 incidence determined retrospectively among drug users in Bangkok, Thailand. *AIDS* 8:1443-1450.

MAP, 2001. The status and trends of HIV/AIDS/STI epidemics in Asia and the Pacific. October 4th 2001, Melbourne, Australia

Oelrichs RB, Shrestha IL, Anderson DA, et al. 2000. The explosive human immunodeficiency type 1 epidemic among injecting drug users of Kathmandu, Nepal, is caused by a subtype C virus of restricted genetic diversity. *J Virol* 74:1149-1157.

Panda S, Chatterjee A, Bhattacharya SK, et al. 2000. Transmission of HIV from injecting drug users to their wives. *Int J STD AIDS* 11:468-473.

Panda S. 2000. Rapid situation assessment: opioid/opiate drug use in Calcutta (1999-2000).

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Sarkar S, Das N, Panda S, et al. 1993. Rapid spread of HIV among injecting drug users in north-eastern states of India. Bull Narc 45:91-105.

Shirin T, Ahmed T, Iqbal A, et al. 2000. Prevalence and risk factors of hepatitis B virus, hepatitis C virus and human immunodeficiency virus infections among drug addicts in Bangladesh. J Health Popul Nutr 18:145-250.

Strathdee SA, van Ameijden EJC, Mesquita F, Wodak A, Rana S, Vlahov D. 1998. Can HIV epidemics among injecting drug users be prevented? AIDS. 12: S71-S79.

UNAIDS/UNDCP, 2000. Drug use and HIV vulnerability; policy research study in Asia. Task force on drug use and HIV vulnerability, October 2000.

UNDCP/UNAIDS, 1999. Baseline study of the relationship between injecting drug use, HIV and hepatitis C among male injecting drug users in Lahore. December 1999.

Dissemination and Use of Findings

Describe explicitly the plans for disseminating the accomplished results. Describe what type of publication is anticipated: working papers, internal (institutional) publication, international publications, international conferences and agencies, workshops etc. Mention if the project is linked to the Government of Bangladesh through a training programme.

Results will be disseminated through national workshops, seminars and meetings involving policy makers, members of the community and implementing organisations as well as UN organisations, donors and international bodies concerned with HIV/AIDS. Also dissemination at the regional and international level through seminars, conferences and meetings will be done.

Publications as reports and in peer-reviewed journals will be done. The findings will be used by CARE itself for its own intervention programme and by other NGOs involved in harm reduction. Also the policy makers will be further sensitised to issues of IDU.

Collaborative Arrangements

Describe briefly if this study involves any scientific, administrative, fiscal, or programmatic arrangements with other national or international organizations or individuals. Indicate the nature and extent of collaboration and include a letter of agreement between the applicant or his/her organization and the collaborating organization. **(DO NOT EXCEED ONE PAGE)**

Dr. John Kaldor, Deputy Director and Professor of Epidemiology, National Centre in HIV Epidemiology and Clinical Research, Darlinghurst NSW 2010, Australia. Dr. Kaldor will be providing technical and intellectual support in the planning of the study and its final analysis.

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Biography of the Investigators

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

Name	Position	Date of Birth
Tasnim Azim	Associate Scientist and Head, Virology, Laboratory Sciences Division, ICDDR,B	22 nd September 1956

Academic Qualifications (Begin with baccalaureate or other initial professional education)

Institution and Location	Degree	Year	Field of Study
Holy Cross School, Dhaka	Secondary School Certificate	1973	Science
Holy Cross College, Dhaka	Higher School Certificate	1975	Science
University of Dhaka	MBBS	1983	Medicine
University of London	Ph.D.	1989	Immunology

Research and Professional Experience

Concluding with the present position, list, in chronological order, previous positions held, experience, and honours. Indicate current membership on any professional societies or public committees. List, in, chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. **(DO NOT EXCEED TWO PAGES, USE CONTINUATION SHEETS).**

1983-1984 - Internee doctor at Dhaka Medical College Hospital, specialising in Medicine.

1989 onwards at ICDDR,B:

March 1989 to September 1995 - Assistant Scientist, Immunology, Laboratory Sciences Division

September 1995 to April 1997- Associate Scientist, Immunology, Laboratory Sciences Division

May 1997 to date - Associate Scientist and Head, Virology Laboratory, Laboratory Sciences Division

PUBLICATIONS in the last three years:

1. Unicomb L, Banu NH, **Azim T**, Islam A, Bardhan PK, Faruque ASG, Hall A, Moe CL, Noel JS, Albert MJ and Glass RI. Astrovirus infection in association with acute, persistent and nosocomial diarrhea in Bangladesh. *Ped. Infect. Dis. J.* 1998; 17:611-614.
2. **Azim T**, Rashid A, Qadri F, Sarker MS, Hamadani J, Salam MA, Wahed MA and Albert MJ. Antibodies to shiga toxin in the serum of children with *Shigella*-associated haemolytic uraemic syndrome. *J. Med. Microbiol.* 1999; 48:11-16.
3. Francisco A de, Hall AJ, Alam N, **Azim T**. Hepatitis B infection in Bangladeshi mothers and infants. *Southeast Asian J Trop Med Public Health.* 1999; 30:296-298.
4. **Azim T**, Ahmad SM, Khuda S, Sarker MS, Unicomb LE, De S, Hamadani JD, Salam MA, Wahed M A and Albert MJ. Immune response of children who develop persistent diarrhea following rotavirus infection. *Clin Diagn Lab Immunol* 1999; 6: 690-695.

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5. **Azim T**, Islam MN, Bogaerts J, Mian MAH, Sarker MS, Fattah KR, Simmonds P, Jenkins C, Choudhury MR and Mathan VI. Prevalence of HIV and syphilis among high risk groups in Bangladesh. *AIDS* 2000; 14: 210-211.
6. Hawkes S, **Azim T**. Health care systems in transition III. Bangladesh, Part II. Bangladesh's response to HIV-AIDS. *J Public Health Med.* 2000; 1: 10-3.
7. **Azim T**, Islam LN, Sarker MS, Ahmad SM, Hamadani JD, Faruque SM, Salam MA. Immune response of Bangladeshi children with acute diarrhoea who subsequently develop persistent diarrhoea. *J Pediatr Gastroenterol Nutr* 2000; 31: 528-35.
8. Schnorr Jens-Jörg, Cutts FT, Wheeler JG, Akramuzzaman SM, Alam MS, **Azim T**, Schneider-Schaulies Sibylle, ter-Meulen V. Immune modulation after measles vaccination of 6-9 months old Bangladeshi infants. *Vaccine.* 2001 19:1503-10.
9. Bresee JS, Arifeen SE, **Azim T**, Chakraborty J, Mounts AW, Podder G, Gentsch JR, Ward RL, Black R, Glass RI, Yunus M. Safety and immunogenicity of tetravalent rhesus-based rotavirus vaccine in Bangladesh. *Ped. Infect. Dis. J.* 2001 20:1136-1143.
10. **Azim T**, Bogaerts J, Yirrell DL, Banerjee AC, Sarker MS, Ahmed G, Amin MMM, Rahman ASMM, Hussain AMZ. Injecting Drug Users in Bangladesh: Prevalence of Syphilis, Hepatitis, HIV and HIV Subtypes. *AIDS* 2002 16:121-122.

Reports on HIV published in last three years:

1. Report on the Second National Expanded HIV Surveillance, 1999-2000, Bangladesh: AIDS and STD Control Program, Directorate General of Health Services, Ministry of Health and Family Welfare, Govt. of Bangladesh, 2000.
2. Report on the sero-surveillance and behavioural surveillance on STD and AIDS in Bangladesh, 1998-1999. AIDS and STD Control Program, Directorate General of Health Services, Ministry of Health and Family Welfare, Govt. of Bangladesh, 2000
3. HIV in Bangladesh: where is it going? A background report on the third round of HIV and behavioral surveillance in Bangladesh. AIDS and STD Control Program, Directorate General of Health Services, Ministry of Health and Family Welfare, Govt. of Bangladesh, November 2001.

Principal Investigator: Last, first, middle Azim, Tasnim

Name	Position	Date of Birth
Smarajit Jana	HIV Program Co-ordinator, Health and Population Sector	21st July, 1952

Academic Qualifications (Begin with baccalaureate or other initial professional education)

Institution and Location	Degree	Year	Field of Study
i) Calcutta University	MBBS	1978	Medicine
ii) STM, Calcutta	Diploma on Tropical Medicine (DTM&H)	1982	Tropical Medicine
iii) (SPM) from AIHH&PH, Calcutta University	MD	1984	

Research and Professional Experience

Concluding with the present position, list, in chronological order, previous positions held, experience, and honours. Indicate current membership on any professional societies or public committees. List, in chronological order, the titles, all authors, and complete references to all publications during the past three years and to representative earlier publications pertinent to this application. **(DO NOT EXCEED TWO PAGES, USE CONTINUATION SHEETS).**

Previous Work:

February 1992 to July 1999 - Project Director, STD/HIV Intervention Program (Sonagachi), the most successful primary intervention program in India. In the capacity of Project Director, I planned, implemented and supervised a community based intervention programme covering a population of 80,000 spreading in Sonagachi and eleven other red light districts in Calcutta, India targeting female sex workers and their clients. In the capacity of Project Director, I did supervise about 400 different category of employee worked under this project.

Present Assignment:

HIV Program Co-ordinator; CARE-Bangladesh. In the capacity of Project Coordinator, I supervise following intervention activities: (I) Brothel based Female sex workers intervention (population size 700). (II) Street based female sex workers intervention (population size 4000). (III) Intervention among the IDUs (population size 5000). (IV) Intervention among the Transport workers throughout the country covering roughly 65000. (V) Intervention among the Dock and port workers (22000). (VI) Intervention among the MSM Population, (VII) Partnership with other NGOs, (VIII) Supervise HIV positive people support network, (IX) A pilot project on HIV & trafficking (cross border).

Consultancy Experience (Selected Few):

- Consultant to International centre of sexual health, Manchester, U. K. since 1996.
- Worked as a Member of the Technical Advisory Group (TAG) of Horisons' (Population Council), Washington D C, Virginia during the year 1998.
- Worked as a member of the Scientific Planning Committee of 12th World AIDS Conference 1998 held at Geneva.
- Worked as a Technical Advisor to Project Management Unit of DFID, U.K. to run sexual health project in West Bengal, India from July 1994 to Sept 1996.

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- (e) Worked as a Consultant to Shakti Project, Dhaka, Care Bangladesh helping to develop Qualitative and Quantitative studies and to develop Intervention programmes among the high risk groups during 1996 and 1997.
- (f) Worked in the capacity of a Temporary Advisor to UNAIDS at Geneva from 23rd June to 4th July '97 to review UNAIDS and GPA projects on sex workers and MSM and help developing UNAIDS strategies in these areas.
- (g) Acted as a Regional Co-ordinator (Asia – Pacific) of Network of sex work project (NSWP) during 1998-1999.
- (h) Working as a Faculty member of International sex worker Foundation for Art, Culture and Education California, USA since 1997.
- (i) Worked as a consultant to OXFAM, India to review home leased care program in Manipur, India, during 1998.
- (j) Acted as a resource person for STD planning workshop for Programme Managers organised by NACO, Govt. of India during the period 1994 to 1997
- (k) Worked as a Member of the Advisory board of the European Commissions programme on AIDS & STDs – India during period 1996 to 1998.
- (l) Acted as a member of the Technical Advisory sub-committee on STDs – under NACO, Ministry of Health & Family Welfare, Govt. of India from '94 - '97 and member of two Technical Advisory Group (TAG) at national level namely, Targeted Intervention and Intravenous Drug Users and AIDS from February 1998 to August 1999.
- (m) Worked as a member of the Technical Committee of FHI to help assessing at risk population in Maharastra to initiate USAID supported intervention program during the year 1998 & 1999.
- (n) Member of the National Core Team on child protection in Bangladesh stressed by UNICEF.

RELEVANT PAPERS/PUBLICATIONS:

1. There are about 24 scientific articles to my credit, published in different peer reviewed journals (National and International) and about 100 abstract submitted in different international conferences between 1994 to 2000.
2. Papers in more than 30 international seminar/conference etc. besides delivered few hundred lectures in different fora on broader health and development issues. Took part in several campaign programs on health and environment in India.
3. Contributed as author or co-author in several publications e.g.:
 - (a) Asudh na Velki (on useless medicines, translated in the regional languages). Published in three different languages.
 - (b) Unnata Prajukti Unnata Asukh (Health hazards of computer technology).
 - (c) On Employees Health Insurance Scheme.
 - (d) Activist's handbook of Occupational health & safety.
 - (e) India's state of Health etc.

JOURNAL PUBLICATION & EDITING:

Worked as a Co-editor/Member of editorial Board of:

- a) Radical Journal of Health dealing with policies & strategies of Public Health & related issues during the period ('84 - '85).
- b) Utsha Manush, journal dealing with popular science, health, consumer culture, superstition etc. published from Calcutta during ('83 - '92).
- c) Drug-Disease-Doctor, A journal on medicine and therapeutics (from 1985 to till date).
- d) Safe-energy and Environment, journal dealing with the ecology and other related issues (from 1986-1987).
- e) Indian Journal of Public Health, during ('95 - '96).

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**International Centre for Diarrhoeal Disease Research, Bangladesh
Voluntary Consent Form**

Title of the Research Project: Incidence of HIV, hepatitis and syphilis infections and risk behaviour in injecting drug users in Dhaka, Bangladesh

Principal Investigator: Tasnim Azim

Before recruiting into the study, the study subject must be informed about the objectives, procedures, and potential benefits and risks involved in the study. Details of all procedures must be provided including their risks, utility, duration, frequencies, and severity. All questions of the subject must be answered to his/ her satisfaction, indicating that the participation is purely voluntary. For children, consents must be obtained from their parents or legal guardians. The subject must indicate his/ her acceptance of participation by signing or thumb printing on this form.

We are conducting a study to determine the rates of infection from HIV, hepatitis B and C and syphilis. We will also ask you questions using a questionnaire about your injection taking behaviour and also about your sexual behaviour. The blood tests will be done and questions will be asked using a questionnaire every six months for two years. All blood tests results will be provided to you. If your results show that you have syphilis, we will provide treatment. If the results for hepatitis B or C are positive we will refer you to specialists for clinical management. If you are HIV positive we will provide counselling to you, and refer you to CARE's HIV positive network for support. Also, we will refer you to a clinician for your physical examination. We will also refer you to a nutritionist for advice on your nutrition. If you are found to be HIV positive, we will collect blood samples from you at regular intervals to check how your HIV infection is progressing and if you need special care we will refer you to a specialist. All information collected here will be confidential, no names will be used in the test tubes for blood or in the questionnaires; instead unique identifier numbers will be used.

The information generated from this study will benefit you directly by providing you with care and support and if you have any infection including HIV you will be referred appropriately. Indirectly you will benefit, as this study will provide an understanding of the risk factors for HIV infection in your community, which will be used by the intervention programmes to better address your needs.

For the purpose of the study, during each survey, we will collect 5 ml (one teaspoonful) of blood from the vein in your arm. This is a harmless procedure and is associated only with the mild discomfort of drawing blood. The decision to participate in this study is yours and if you do not want to participate, you will still continue to receive the services of this centre as before.

If you agree to participate in this study, please put your signature or left thumb impression at the specified space below:

Thank you for your co-operation.

Signature of Investigator/ or agents
Date:

Signature of Subject/ Guardian
Date:

Continuation Sheet (Number each sheet consecutively)

Principal Investigator: Last, first, middle Azim, Tasnim

Detailed Budget for New Proposal

Project Title: Incidence of HIV, hepatitis and syphilis infections and risk behaviour in injecting drug users in Dhaka, Bangladesh

Name of PI: Tasnim Azim

Protocol Number:

Name of Division: Laboratory Sciences Division

Funding Source: AusAID
Overhead (%) US\$ 30,750 (25%)

Amount Funded (direct): US\$123,000 Total: US\$ 153,750

Starting Date: 1st January 2002

Closing Date: 30th June 2004

Strategic Plan Priority Code(s) :

Principal Investigator: Last, first, middle Azim, Tasnim

Sl. No	Account Description	Salary Support			US \$ Amount Requested		
		Position	Effort %	Salary/month	1st Yr (for 6m)	2 nd Yr	3 rd Yr
	Personnel						
	Tasnim Azim (NOC)		25		0	0	0
	David Sack		1		0	0	0
	Ramesh Chandra Halder (NOB)		5		0	0	0
	Motiur Rahman (NOB)		5		0	0	0
	Field co-ordinator (GS5)	1	100	333	2,000	4,200	4,400
	Field attendants (GS2)	12	100	179	12,900	27,100	28,400
	Sub Total				14,900	31,300	32,800
	Consultants						
	Local Travel				600	1,200	1,200
	International Travel						
	Sub Total				600	1,200	1,200
	Supplies and Materials (Description of Items)						
	Office supplies				3,000	2,000	2,000
	Laboratory reagents and consumables				5,000	10,000	10,000
	Sub Totals				8,000	12,000	12,000
	Other Contractual Services						
	Repair and Maintenance						
	Rent, Communications, Utilities						
	Training Workshop, Seminars				2,500	3,000	2,000
	Printing and Publication				500	500	
	Staff Development						
	Sub Total				3,000	3,500	2,000
	Interdepartmental Services						
	Computer Charges						
	Pathological Tests						
	Microbiological tests						
	Biochemistry Tests						
	X-Rays						
	Patients Study						
	Research Animals						
	Biochemistry and Nutrition						
	Transport				300		
	Xerox, Mimeographs etc.				200		
	Sub Totals				500		
	Other Operating Costs						
	Capital Expenditure						

TOTAL DIRECT COST (US\$)

27,000 48,000 48,000

Overhead 25%

6,750 12,000 12,000

TOTAL

33,750 60,000 60,000

S. Ha

20 Feb 2002

Principal Investigator: Last, first, middle Azim, Tasnim

Budget Justifications

Please provide one page statement justifying the budgeted amount for each major item. Justify use of man power, major equipment, and laboratory services.

5% increase in salary of personnel has been calculated for each year.

Check List

After completing the protocol, please check that the following selected items have been included.

- | | |
|--|---|
| 1. Face Sheet Included | x |
| 2. Approval of the Division Director on Face Sheet | x |
| 3. Certification and Signature of PI on Face Sheet, #9 and #10 | x |
| 4. Table on Contents | x |
| 5. Project Summary | x |
| 6. Literature Cited | x |
| 7. Biography of Investigators | x |
| 8. Ethical Assurance | x |
| 9. Consent Forms | x |
| Detailed Budget | x |

ANNEXE 1

Laboratory methods

The methodologies to be followed for laboratory tests are shown below:

a) Blood collection, separation, storage, labelling and transport

Blood will be collected by venepuncture into sterile, plain Vacutainers (Becton Dickinson, Rutherford, NJ, USA). 0.5 ml of whole blood will be transferred to an eppendorf tube containing EDTA for extraction of DNA for genetic analysis. From the remaining volume of blood, serum will be separated by centrifugation. Whole blood and serum samples will be transported to the ICDDR,B laboratory by maintaining a cold chain. All samples will be stored at -20°C till assays are conducted.

b) HIV testing:

Samples will be initially tested by a commercial enzyme linked immunosorbent assay (ELISA) kit (Organon Teknika) and positive results will be confirmed by a Line Immunoassay (LIA, Organon Teknika). An indeterminate result by LIA will be followed-up for re-testing three months later. Quality control will be done using standard quality control sera for HIV obtained from overseas laboratories. Testing will be done in batches.

c) Testing for syphilis:

The Rapid Plasma Reagin test (RPR) and Treponema pallidum haemagglutination assay (TPHA) will be performed on all samples. Samples reactive in both assays will be considered to be positive. Testing will be done as soon as possible so that results can be given to the individuals within two weeks of blood collection for treatment purposes.

d) Testing for Hepatitis B:

IgM Antibodies to the Hepatitis B core antigen (Anti-HBc IgM) will be assayed for on all samples from IDUs by a commercial ELISA kit. This is a marker for acute infection. Hepatitis B surface antigen will also be tested for using commercially available kits. Testing will be done in batches.

e) Testing for Hepatitis C:

Antibodies to Hepatitis C virus will be tested for on all samples from IDUs by two ELISAs using different sets of antigens; samples positive in the first ELISA will be re-tested by a second ELISA. Discrepant samples will be tested using a Line Immunoassay. Samples positive by two tests will be considered as positive. Testing will be done in batches.

Principal Investigator: Last, first, middle Azim, Tasnim

ANNEXE 2 Questionnaire

BACKGROUND CHARACTERISTICS:

1. Age in years : _____
2. Sex : Male/Female/Hijra
3. Marital Status:
 - Married
 - Unmarried
 - Divorced
 - Widowed
 - Separated
 - Living with lover

Number of wives: _____

4. Where is your home district? _____
5. How often do you visit your home? _____
6. Where do you live?
 - Residential area
 - Slum
 - In the street
 - Other: _____
7. How long have you been in this area? _____
8. How often do you change your residential area?
 - < Three times / year
 - Three times / year
 - Six times / year
 - > Six times / year
9. What are the reasons for changing your residential area?

10. Living with Family: Yes _____ No _____
If not with whom do you live? _____
11. Completed years of education _____
12. Main source of income in the last six months:
 - Business
 - Service
 - Student
 - Unemployed

Principal Investigator: Last, first, middle Azim, Tasnim

- Rickshaw puller
- Drug peddling
- Ragkipper (tokai)
- House owner
- Other

13. Income :

Daily Minimum _____ Daily Maximum _____ Monthly average income _____

DRUG USE:

14. Does any member of your family use drugs? Yes/No

If yes, what relation is the person to you? _____

15. For how long have you been using drugs (any kind)? _____ Years _____ Months (if <1 yr)

16. What induced you to start taking drugs?

17. How long have you been injecting drugs? _____ Years _____ Months (if <1 yr)

18. How old were you when you first injected drugs? _____ Years

19. Why did you start injecting drugs?

20. Which of the following types of drugs have you used in the past one month?

- Heroin
- Cannabis
- Phensidyl
- Tablet
- Alcohol
- Injecting
- Other (Specify) _____

21. When did you last inject drugs?

- Today
- Yesterday
- 2-3 days before
- One week before
- 2-4 weeks before

22. Which drug have you been injecting most of the time?

- Tidijesic
- Heroin
- Pethidine
- Others

23. During the past one month how often would you say you injected drugs?

- Only once
- 2-3 times

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- About once a week
 - 2-3 times a week
 - 4-6 times a week
 - About once a day
 - 2-3 times a day
 - 4 or more times in a day
24. During the past one week, how often would you say you injected drugs?
- Only once
 - 2-3 times
 - About once a day
 - 2-3 times a day
 - 4 or more times in a day
25. How many of the last 7 days injections were intravenous _____, intramuscular _____?
26. How much do you spend for injecting in a day? Tk. _____
27. Where do you obtain your needle and syringe?
- Pharmacist/chemist
 - Drug store
 - Health worker
 - Friends
 - Other drug users
 - Drug dealer
 - Needle exchange program
 - Buy on street
 - Other (Specify) _____
28. Have you tried to stop taking drugs? Yes/No
29. If yes, how often? _____
30. Why do you think your efforts to stop taking drugs failed?
- _____
- _____
31. What sort of support do you need to help you stop taking drugs?
- _____
- _____

NEEDLE SHARING BEHAVIOR

32. When you last injected drugs, did you use a needle or syringe that had previously been used by someone else? Yes/No.
33. How often did you use a needle or syringe that had previously been used by someone else in the last month?
- Always
 - Most of the times
 - About half of the times

Principal Investigator: Last, first, middle Azim, Tasnim

- Occasionally
- Never

34. How often did you use a needle or syringe that had previously been used by someone else in the last 7 days?

- Always
- Most of the times
- About half of the times
- Occasionally
- Never

35. How many times did you pass on a new needle/syringe you just used to someone else in the past one month?

- Always
- Most of the times
- About half of the times
- Occasionally
- Never

36. How many times did you pass on a new needle/syringe you just used to someone else in the last 7 days?

- Always
- Most of the times
- About half of the times
- Occasionally
- Never

37. The last time you injected with others, how many people shared the same needle/syringe? _____ persons/don't know.

38. Who do you usually share drugs with?

- Friends
- Family *member*
- Unknown people
- Others

39. Who do you usually share needles/syringes with?

- Friends
- Family *member*
- Unknown people
- Others

40. The last time you injected with others, did you clean the needle/syringe between people? Yes/No

41. In the past one month, when you injected with needles or syringes that had previously been used, how often did you clean them first?

- Always
- Most of the times
- About half of the times
- Occasionally
- Never

42. If cleaned, how did you usually clean them?

- Cold water

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- Hot water
- Boiling
- Bleach
- Alcohol
- Cotton
- Dettol/savlon
- Blowing clean
- Tree leaves
- Paper
- Other

43. How many injections were cocktails in the last 7 days? _____ in the last month? _____
44. How many times did you boot the injection in the past 7 days? _____ in the last month? _____
45. How many times were the injections front (or back) loaded in the past 7 days? _____ in the last month? _____
46. Have you ever sold blood for money? Yes/No

Answer questions 47-48 if above answer is yes, otherwise proceed to question 49

47. How many times did you sell blood in the past one year? _____
48. How long ago was it that you last sold your blood? _____
49. How long have you been in the needle/syringe programme of CARE? _____ (months)
50. If you have been sharing injections while in the NEP, why is that so? _____

SEXUAL HISTORY and BEHAVIOR:

51. Have you ever had sexual intercourse? Yes/No
52. At what age did you first have sex? _____ Years
53. When did you last have sex? _____ (specify whether days, weeks or years)
54. During the last sex act did you use condom? Yes/No/Not Applicable
55. Have you had sex with a sex worker? Yes/No

Answer questions 56-59 if above answer is yes, otherwise proceed to question 60

56. How many times did you buy sex from a sex worker in the last month? _____
In the last year? _____
57. In the past month, how many were female _____, male _____, hijra _____?
58. How often did you use condom with commercial partner in the last month?
- Always

Principal Investigator: Last, first, middle Azim, Tasnim

- Most of the times
- Sometimes
- Never

59. How often did you use condom with commercial partner in the last year?

- Always
- Most of the times
- Sometimes
- Never

60. How many times did you have sex with someone you did not pay (girlfriend/wife/lover) in the past month? _____ in the past year? _____

61. How many of these partners were female _____, male _____, hijra _____?

62. How often did you use condoms with non-commercial partners?

- Always
- Most of the times
- Sometimes
- Never

SEX DISEASES

63. In the past year did you have any of these:

- | | |
|---------------------------|--------|
| • Discharge from penis | yes/no |
| • Pain when urinating | yes/no |
| • Pain in genitals | yes/no |
| • Genital sores | yes/no |
| • Pain during intercourse | yes/no |
| • Pus and bloody anus | yes/no |

64. The last time you had one of these sex diseases did you seek treatment? Yes/no

Answer questions 65-68 if above answer is yes, otherwise proceed to question 69

65. How long after noticing symptoms did you seek treatment? _____ (in days)

66. Where did you first go for treatment?

- Hospital
- Private doctor
- Private clinic
- NGO clinic
- Traditional practitioner
- Friends
- Other

67. Did you go for treatment somewhere else after that? Yes/No

If yes, where?

- Hospital
- Private doctor
- Private clinic
- NGO clinic
- Traditional practitioner

Principal Investigator: Last, first, middle Azim, Tasnim

- Friends
- Other

68. How much money did the treatment cost altogether? _____

SOCIAL ENVIRONMENT:

69. As an injecting drug user, do you have access to health facilities? Yes/No

If yes, where do you access health facilities? _____

70. As an injecting drug user, do your children have access to health facilities? Yes/No

If yes, where do they access health facilities? _____

71. As an injecting drug user, do you have access to education facilities? Yes/No

If yes, where? _____

72. As an injecting drug user, do your children have access to education facilities? Yes/No

If yes, where? _____

73. Do you face harassment as an injecting drug user? Yes/No

74. If yes, please state from whom? _____

75. Please state nature of harassment _____

Thank you very much for taking time to answer these questions. We appreciate your help.

আইসিডিডিআরবি

সম্মতি পত্র

Title of the Research Project: Incidence of HIV, hepatitis and syphilis infections and risk behaviour in injecting drug users in Dhaka, Bangladesh.

Principal Investigator: Tasnim Azim

আমরা এইচ আই ভি , হেপাটাইটিস বি ও সি এবং সিফিলিসের সংক্রমণের হার নির্ণয়ের জন্য একটি গবেষণা চালাচ্ছি । প্রশমালার মাধ্যমে আপনার শিরায় ইন্জেকশন গ্রহন ও যৌন আচরণের বিষয়ে কিছু প্রশ্ন করব । দুই বৎসর পর্যন্ত প্রতি ছয়মাস অন্তর রক্ত গ্রহন ও প্রশমালা পুনর করা হবে । রক্ত পরীক্ষার সব ফলাফল আপনাকে দেওয়া হবে । পরীক্ষায় যদি আপনার সিফিলিস ধরা পরে তবে আপনি চিকিৎসা পাবেন । যদি আপনার হেপাটাইটিস বি অথবা হেপাটাইটিস সি ধরা পরে তবে আপনাকে বিশেষজ্ঞের নিকট পাঠানো হবে । আর যদি আপনার এইচ আই ভি ধরা পরে তবে আপনাকে উপদেশ দেয়া হবে এবং সহযোগিতার জন্য CARE এর এইচ আই ভি পজেটিভ নেটওয়ার্কে পাঠানো হবে। এছাড়াও আমরা আপনার শারীরিক পরীক্ষার জন্য একজন ডাক্তারের নিকট এবং পুষ্টি পরামর্শের জন্য একজন পুষ্টি বিশেষজ্ঞের নিকট পাঠাব । আপনি এইচ আই ভি পজেটিভ হলে নির্দিষ্ট সময় অন্তর আপনার রক্ত পরীক্ষা করে রোগের অগ্রগতি জানব এবং প্রয়োজনে বিশেষ ব্যবস্থার জন্য বিশেষজ্ঞের নিকট পাঠাব। সংগৃহীত সকল তথ্য গোপন রাখা হবে। সংগৃহীত রক্তের টেস্ট টিউব এবং প্রশমালায় কোন নাম থাকবে না । পরিবর্তে বিশেষ আই ডি নং থাকবে।

এ গবেষণায় প্রাপ্ত ফলাফলের মাধ্যমে আপনি সরাসরি এইচ আই ভি ও অন্যান্য সংক্রমণের পরামর্শ বা ব্যবস্থাপনার মাধ্যমে উপকৃত হবেন। পরোক্ষভাবে শিরায় নেশা গ্রহনকারীদের মধ্যে কি করে এইচ আই ভি ছড়ায় তা জেনে রোধ করার মাধ্যমেও আপনি উপকৃত হবেন।

এ গবেষণার জন্য আপনার বাহুর শিরা থেকে ৫ মিঃ লিঃ (এক চা চামচ) রক্ত নেয়া হবে। এতে একটু অস্বস্তি ছাড়া কোন ক্ষতি হবে না। এ গবেষণায় অংশ গ্রহন আপনার একান্ত ইচ্ছা এবং এতে অংশ গ্রহন না করলেও আপনি কেন্দ্রের সব সুবিধাদি পাবেন।

আপনি এ গবেষণায় অংশ গ্রহন করতে চাইলে নির্দিষ্ট স্থানে আপনার সই বা বাম বৃদ্ধাঙ্গুলীর ছাপ দিন।

আপনার সহযোগিতার জন্য ধন্যবাদ।

গবেষক/ প্রতিনিধির স্বাক্ষর

অংশ গ্রহনকারী/ অভিভাবকের স্বাক্ষর

ANNEXE 3

প্রশ্নমালা

মূল বৈশিষ্ট্য :

১। বয়স (বৎসর) : _____

২। লিঙ্গ : পুরুষ / মহিলা / হিজরা

৩। বৈবাহিক অবস্থা :

- বিবাহিত
- অবিবাহিত
- তালাক প্রাপ্ত
- বিচ্ছিন্ন
- প্রেমিক /প্রেমিকার সঙ্গে বাস

জ্বর সংখ্যা : _____

৪। আপনার বাড়ী কোন জেলায় ? _____

৫। কত দিন পরপর বাড়ী যান ? _____

৬। কোথায় থাকেন ?

- আবাসিক এলাকায়
- বস্তিতে
- রাস্তায়
- অন্যান্য _____

৭। কতদিন যাবৎ এই এলাকায় থাকেন ? _____

৮। কতবার বাসস্থান পরিবর্তন করেন?

- বৎসরে তিন বারের কম
- বৎসরে তিন বার
- বৎসরে ছয়বার
- বৎসরে ছয়বারের বেশী
-

৯। বাসস্থান পরিবর্তনের কারণ কি?

১০। পরিবারের সঙ্গে থাকেন : হ্যাঁ _____ না _____

পরিবারের সঙ্গে না থাকলে কার সঙ্গে থাকেন ? _____

১১। কত বৎসর লেখা পড়া করেছেন ? _____

১২। গত ছয়মাসে আয়ের প্রধান উৎস

- ব্যবসা
- চাকুরী
- ছাত্র
- বেকার
- রিকশাচালক
- মাদক পাচারকারী
- টোকাই
- বাড়ীওয়াল
- অন্যান্য

১৩। আয়ঃ

দৈনিক কমপক্ষে _____ দৈনিক সর্বাধিক _____ গড়ে মাসে _____

মাদক ব্যবহার :

১৪। পরিবারের কেউ কি মাদকদ্রব্য ব্যবহার করেন ? হ্যাঁ/ না
যদি করেন তবে সে আপনার কি হয়? _____

১৫। কতদিন যাবৎ মাদক দ্রব্য (যে কোন) ব্যবহার করেছেন ? _____ বৎসর _____ মাস (যদি ১ বৎসরের কম হয়)

১৬। কিভাবে মাদক দ্রব্য ব্যবহারে উদ্বুদ্ধ হলেন?

১৭। কতদিন যাবৎ ইঞ্জেকশনের সাহায্যে শিরায় মাদক দ্রব্য গ্রহণ করেন? বৎসর _____ মাস _____ (যদি ১ বৎসরের কম হয়)

১৮। কত বৎসর বয়সে আপনি প্রথম ইঞ্জেকশন দ্বারা মাদকদ্রব্য গ্রহণ করেন ? _____ বৎসর

১৯। আপনি কেন ইঞ্জেকশনের মাধ্যমে শিরায় মাদক দ্রব্য গ্রহণ করেছিলেন?

২০। গত একমাসে কোন মাদকগুলো গ্রহন করেছেন?

- হিরোইন
- গাঁজা
- ফেনিডিল
- বড়ি
- এলকোহল(মদ)
- ইনজেকশান
- অন্যান্য _____

২১। সর্বশেষ কবে ইজেকশান নিয়েছেন

- আজ
- গতদিন
- ২-৩ দিন আগে
- এক সপ্তাহ আগে
- ২-৪ সপ্তাহ আগে

২২। কোন ইজেকশানটি বেশী গ্রহন করেছেন?

- টিডিজেন্সিক
- হিরোইন
- পেথিডিন
- অন্যান্য _____

২৩। গত একমাসে কত বার ইজেকশান নিয়েছেন ?

- মাত্র একবার
- ২-৩ বার
- সপ্তাহে একবার
- সপ্তাহে ২-৩ বার
- সপ্তাহে ৪-৬ বার
- দিনে এক বার
- দিনে ২-৩ বার
- দিনে ৪ বার বা বেশী

২৪। গত সপ্তাহে কত বার ইজেকশান নিয়েছেন ?

- মাত্র একবার
- ২-৩ বার
- দিনে একবার
- দিনে ২-৩ বার
- দিনে ৪ বার বা বেশী

২৫। গত ৭ দিনে কতবার শিরায় _____ পেশীতে, _____ ইজেকশান নিয়েছেন?

২৬। দিনে কতটাকা ইঞ্জেকশানের জন্য খরচ করেছেন? _____ টাকা

২৭। কোথেকে সূঁচ ও সিরিঞ্জ পান?

- কার্মাসিট / কেমিষ্ট
- ঔষদের দোকান
- স্বাস্থ্য কর্মী
- বন্ধু
- অন্য মাদক ব্যবহারকারী
- মাদক ব্যবসায়ী
- সূঁচ বিনিময় কার্যক্রম
- রাস্তায় জম
- অন্যান্য _____

২৮। মাদক গ্রহণ বন্ধের চেষ্টা করেছেন? হ্যাঁ / না

২৯। হ্যাঁ হলে কত বার? _____

৩০। কেন মাদক গ্রহণ বন্ধের চেষ্টায় ব্যর্থ হচ্ছিলেন?

৩১। কি সহযোগিতা পেলে মাদক গ্রহণ বন্ধ করতে পারবেন?

সূঁচ অংশীদারী আচরণ

৩২। গত ইঞ্জেকশানের সময় অন্যের ব্যবহৃত সূঁচ বা সিরিঞ্জ ব্যবহার করেছিলেন?

হ্যাঁ / না

৩৩। গত মাসে অন্যের ব্যবহৃত সূঁচ বা সিরিঞ্জ দিয়ে কতবার ইঞ্জেকশান নিয়েছেন?

- সব সময়
- বেশীরভাগ সময়
- প্রায় অর্ধেক সময়
- মাঝে মাঝে
- কখনো না

৩৪। গত ৭ দিনে অন্যের ব্যবহৃত সূঁচ বা সিরিঞ্জ দিয়ে কতবার ইন্জেকশান নিয়েছেন?

- সব সময়
- বেশীরভাগ সময়
- প্রায় অর্ধেক সময়
- মাঝে মাঝে
- কখনো না

৩৫। গত এক মাসে নতুন সূঁচ / সিরিঞ্জ ব্যবহার করার সাথে সাথে অন্যকে কতবার দিয়েছেন?

- সব সময়
- বেশীরভাগ সময়
- প্রায় অর্ধেক সময়
- মাঝে মাঝে
- কখনো না

৩৬। গত ৭ দিনে নতুন সূঁচ / সিরিঞ্জ ব্যবহারের সাথে সাথে অন্যকে কতবার দিয়েছেন?

- সব সময়
- বেশীরভাগ সময়
- প্রায় অর্ধেক সময়
- মাঝে মাঝে
- কখনো না

৩৭। শেষ বার যখন অন্যের সঙ্গে ইন্জেকশান নিয়েছিলেন একই সূঁচ বা সিরিঞ্জ কতজন ব্যবহার করেছিলেন?

_____ জন / জানিনা।

৩৮। কাদের সঙ্গে সচরাচর মাদক ব্যবহার করেন?

- বন্ধু
- পরিবারের সদস্য
- অপরিচিত লোক
- অন্যান্য

৩৯। কাদের সঙ্গে সচরাচর সূঁচ / সিরিঞ্জ শেয়ার করেন?

- বন্ধু
- পরিবারের সদস্য
- অপরিচিত লোক
- অন্যান্য

৪০। শেষবার অন্যের সঙ্গে ইন্জেকশান গ্রহণের মাঝে সূঁচ / সিরিঞ্জটি একজন অন্যকে দেওয়ার আগে পরীক্ষার করেছিলেন? হ্যাঁ / না

৪১। গত একমাসে অন্যের ব্যবহৃত সূঁচ / সিরিঞ্জে ইন্জেকশান নেয়ার সময় কতবার তা প্রথমে পরীক্ষার করেছেন?

- সব সময়
- বেশীর ভাগ সময়
- প্রায় অর্ধেক সময়
- মাঝে মাঝে
- কখনো না

৪২। যদি পরীক্ষার করে থাকেন তবে সাধারণত কিভাবে ?

- ঠান্ডা পানি দিয়ে
- গরম পানি দিয়ে
- সিদ্ধ করে
- ব্লিচিং দিয়ে
- স্পিরিট / এলকোহল দিয়ে
- তুলা দিয়ে
- ডেটল / সেন্ডলন দিয়ে
- ফুটিয়ে
- গাছের পাতা দিয়ে
- কাগজ দিয়ে
- অন্যান্য ভাবে

৪৩। কতগুলো মাদক মিশ্রিত ইঞ্জেকশান নিয়েছেন গত ৭ দিনে _____ গত মাসে _____

৪৪। কতবার ইঞ্জেকশানটি বুট করেছেন? গত ৭ দিনে _____ গত মাসে _____

৪৫। ব্যাক / ফ্রন্ট লোডিং কত বার করেছেন ? গত সাত দিনে _____ গত মাসে _____

(নিডল খুলে নিয়ে আর একটা সিরিঞ্জের মূখো মুখি এনে নেশা দ্রব্য মিশিয়েছেন অথবা পিষ্টন খুলে নিয়ে সিরিঞ্জের পেছন দিক দিয়ে নেশাদ্রব্য মিশিয়েছেন)

৪৬। কখনো টাকার জন্য রক্ত বিক্রি করেছেন ? হ্যাঁ / না

(৪৬ নং প্রশ্নের উত্তর হ্যাঁ হলে ৪৭-৪৮ নং এর উত্তর করুন অন্যথায় ৪৯ নং প্রশ্নে চলে যান)

৪৭। গত বৎসর কত বার রক্ত বিক্রি করেছেন?

৪৮। কত আগে শেষ বার রক্ত বিক্রি করেছেন?

৪৯। কেয়ার এর সুঁচ / সিরিঞ্জ বিনিময় কার্যক্রমে কত দিন আছেন? _____ মাস

৫০। সুঁচ / সিরিঞ্জ বিনিময় কার্যক্রমে থাকা অবস্থায় ইনজেকশান শেয়ার করে থাকলে কেন?

যৌন আচরন ও ইতিহাস

৫১। কখনো কি যৌন মিলন করেছেন? হ্যাঁ / না

৫২। কত বৎসর বয়সে প্রথম যৌন মিলন করেছেন? _____ বৎসর

৫৩। শেষ কখন যৌন মিলন করেছেন? _____ (দিন/সপ্তাহ ঠিক করে বলুন)

৫৪। শেষ বার যৌন মিলনের সময় কনডম ব্যবহার করেছিলেন? হ্যাঁ / না, প্রযোজ্য নয়

৫৫। যৌন কর্মীর সঙ্গে কখনো যৌন মিলন করেছেন? হ্যাঁ / না

(৫৫ নং প্রশ্নের উত্তর হ্যাঁ হলে ৫৬-৫৭ নং প্রশ্ন করুন অন্যথায় ৬০ নং প্রশ্নে চলে যান)

৫৬। কত বার যৌন কর্মীর সঙ্গে টাকা দিয়ে যৌন মিলন করেছেন? গত মাসে কত বার _____ ?
গত সপ্তাহে কত বার _____ ?

৫৭। গতমাসে যৌন মিলনের সময় কত জন মহিলা _____ / পুরুষ _____ / হিজরা _____ ছিল?

৫৮। গতমাসে যৌন কর্মীর সাথে যৌন মিলনের সময় কতবার কনডম ব্যবহার করেছেন?

- সব সময়
- বেশীর ভাগ সময়
- মাঝে মাঝে
- কখনো না

৫৯। গত বৎসর যৌন কর্মীর সঙ্গে যৌন মিলনের সময় কতবার কনডম ব্যবহার করেছেন?

- সব সময়
- বেশীর ভাগ সময়
- মাঝে মাঝে
- কখনো না

৬০। কতবার এমন কারো সাথে (বন্ধু/স্ত্রী/প্রেমিকা) যৌন মিলন করেছেন যার জন্য মূল্য
দিতে হয়নি? গত মাসে _____ গত বৎসর _____ ?

৬১। এদের মধ্যে কতজন মহিলা _____ পুরুষ _____ হিজরা _____ ?

৬২। কতবার যৌন কর্মী ছাড়া অন্যের সঙ্গে যৌন মিলনের সময় কনডম ব্যবহার করেছেন?

- সব সময়
- বেশীর ভাগ সময়
- মাঝে মাঝে
- কখনো না

যৌন রোগ সমূহ

৬৩। বিগত বছরে নিম্নের সমস্যাগুলো ছিল কি?

- | | |
|--------------------------|------------|
| • গিল নিঃসরণ | হ্যাঁ / না |
| • জ্বলাযুক্ত প্রস্রাব | হ্যাঁ / না |
| • যৌনাস্থে ব্যাধা | হ্যাঁ / না |
| • যৌনাস্থে ক্ষত | হ্যাঁ / না |
| • যৌন মিলনের সময় ব্যাধা | হ্যাঁ / না |
| • পুঁজ ও রক্তাক্ত পায়ু | হ্যাঁ / না |

৬৪। বিগত সময়ে এ রোগের চিকিৎসা নিয়েছেন? হ্যাঁ / না

(উপরের উত্তর হ্যাঁ হলে ৬৫-৬৮ নং প্রশ্নের উত্তর লিখুন অন্যথায় ৬৯ নং প্রশ্নে যান।)

৬৫। রোগের লক্ষণ ধরার পর কতদিন চিকিৎসা নিয়েছেন? _____ (দিন)

৬৬। চিকিৎসার জন্য প্রথম কোথায় গিয়েছিলেন?

- হাসপাতাল
- প্রাইভেট ডাক্তার
- প্রাইভেট ক্লিনিক
- এন জি ও ক্লিনিক
- হাতুড়ে ডাক্তার
- বন্ধু
- অন্যান্য _____

৬৭। এর পর অন্য কোথাও চিকিৎসার জন্য গিয়েছিলেন? হ্যাঁ / না

হ্যাঁ হলে কোথায়?

- হাসপাতাল
- প্রাইভেট ডাক্তার
- প্রাইভেট ক্লিনিক
- এন জি ও ক্লিনিক
- হাতুড়ে ডাক্তার
- বন্ধু
- অন্যান্য _____

৬৮। সব মিলিয়ে চিকিৎসায় কত টাকা খরচ হয়েছিল? _____ টাকা

সামাজিক পরিবেশ

৬৯। ইজেকশানে নেশাখহনকারী হিসাবে কোথাও স্বাস্থ্য সুবিধা পান?

হ্যাঁ / না

হ্যাঁ হলে কোথায় ?

৭০। ইজেকশানে নেশাখহনকারী হিসাবে আপনার ছেলেমেয়েরা কি স্বাস্থ্য সুবিধা পায়?

হ্যাঁ / না

হ্যাঁ হলে কোথায় ?

৭১। ইজেকশানে নেশাখহনকারী হিসাবে কোথাও কি শিক্ষা সুবিধা পান?

হ্যাঁ / না

হ্যাঁ হলে কোথায় ?

৭২। ইজেকশানে নেশাখহনকারী হিসাবে আপনার ছেলেমেয়েরা কি শিক্ষা সুবিধা পায়?

হ্যাঁ / না

হ্যাঁ হলে কোথায় ?

৭৩। ইজেকশানে নেশাখহনকারী হিসাবে কখনো কি নির্ষাভনের শিকার হয়েছেন ?

হ্যাঁ / না

৭৪। হ্যাঁ হলে কার নিকট থেকে ?

৭৫। দয়া করে নির্ষাভনের ধরন বলুন

এ প্রশ্নগুলোর উত্তর দেওয়ার জন্য ধন্যবাদ। আপনার সহযোগিতার জন্য ধন্যবাদ।

Title: Incidence of HIV, hepatitis and syphilis infections and risk behaviour in injecting drug users in Dhaka, Bangladesh.

Summary of Referee's Opinions: Please see the following table to evaluate the various aspects of the proposal by checking the appropriate boxes. Your detailed comments are sought on a separate, attached page.

	Rank Score		
	High	Medium	Low
Quality of project		Medium	
Adequacy of project design		Medium	
Suitability of methodology		Medium	
Feasibility within time period		Medium	
Appropriateness of budget		High	
Potential value of field of knowledge	High		

CONCLUSIONS

I support the application:

a) without qualification

b) with qualification

- on technical grounds

I support the application with qualification on technical grounds as described in the later section

- on level of financial support

I do not support the application

Name of Referee:

Signature: AC

Date: 31 Jan 2002

Position:

Institution:

Detailed Comments

Please briefly provide your opinions of this proposal, giving special attention to the originality and feasibility of the project, its potential for providing new knowledge and the justification of financial support sought; include suggestions for modifications (scientific or financial) where you feel they are justified.

(Use additional pages if necessary)

Title: Incidence of HIV, hepatitis and syphilis infections and risk behaviour in injecting drug users in Dhaka, Bangladesh.

PI: Tasnim Aziz and Smarajit Jana

Reviewer: Anindya Chatterjee

Studies of incidence of HIV and other blood borne infections among drug injecting populations in Asia are rare. Only in a few countries of Asia (e.g. Thailand) incidence figures are available. Therefore the present proposal is particularly relevant.

Secondly, the needle exchange programme of CARE Bangladesh provides easy access to large numbers of drug injecting population in the community who are otherwise not in contact with any treatment or helping agency. Therefore, the proposal is highly feasible. However, the proposal needs to address the following issues:

- 1) How specific aim 2 ("address the issues about living with HIV stigmatization and access to care") will be achieved is not clear from the proposal. VCT, development of referral network, peer support etc. are part of other ongoing activities of ICDDR, B and CARE Bangladesh. Exploring this issue as part of a research project would need studying coping skills, mental health, quality of life, relevance of social support etc. Studying these and other relevant psychosocial dimensions would also mean developing and standardizing a whole set of methodologies to measure and study psychosocial dimensions of HIV/AIDS. If this cannot be achieved, the specific aim may be dropped
- 2) I'm seriously concerned with the fact mentioned in the proposal that despite a large- scale needle exchange in the city, sharing of needles remained very high (93.3% of the IDUs shared needles in the last week). This is strikingly in contrast with the international experience. The proposal should explore (apart from describing risk behaviours) the reasons behind such a phenomenon. This, for me, should be one of the key research question which has very important public health implication
- 3) No inputs have been obtained from drug users themselves at this stage. Such consultation (e.g. particularly with the peer educators) would provide valuable practical knowledge regarding implementation of the project
- 4) Is Hep B part of the standard immunization schedule in Bangladesh? If that was so, all negative individuals should be given options for immunization for Hep B
- 5) The services (under 'service linkages' page 9) needs to be described more concretely particularly treatment of opportunistic infections, drug use treatment and STD treatment

- 6) Similarly, secondary sexual transmission (and prevention) of syphilis, HIV, Hep B (considering 40% of male IDUs married and a major proportion sexually active) could be a specific part of the enquiry
- 7) I have noted a discrepancy in the adjustment of the drop out rate in calculating the sample size. A 20% drop out rate has been assumed where as it was also mentioned in the proposal that only 50% of the IDUs come regularly to the Needle Exchange Programme.
- 8) Maintaining 'strict confidentiality' by having 'unique identifiers' for HIV test result is not adequately described in the proposal. The process and the exact method how this would be implemented needs elaboration in the proposal

RESPONSE TO REVIEWERS COMMENTS

REVIEWER #1:

1. As suggested by this reviewer the second aim has been dropped. The second aim was: "To address the issues about living with HIV, stigmatisation and access to care by HIV positive IDU"
2. The data shown here is from Behaviour Surveillance conducted during the third round of surveillance. This surveillance accesses individuals both in and out of the NEP. In this case only one third of the IDU were from the NEP. Also, it is believed that at the time of this surveillance round, the NEP was in a transitional stage so that the programme was not operating at full scale. This is unlike the data from the 1st and 2nd rounds of surveillance, where sharing was shown to have declined substantially. However, a couple of questions in the questionnaire (Annexe 2, nos. 37 and 38) are designed to address some of the issues relating to reasons for sharing despite being in the NEP.
3. Inputs from the drug users will be obtained during the first 6 months of the study and this has been specified in the proposal on pg 8, "Preparation of the Field", # (i).
4. Immunisation for hepatitis B is still not part of the routine immunisation schedule.
5. It has already been mentioned in the proposal, pg. 9, under "Preparation of the field" # (iv, Service Linkages). For treatment of infections the IDU will be referred to physicians and that a referral network is in the process of being developed. For drug use treatment, referral to the Central Drug Addiction and Treatment Centre (CTC) and APON will be done as is being done at present for IDU in the NEP.
6. In this proposal we are aiming to establish a cohort of IDU and although it would be desirable to work with their partners, we are not sure of the feasibility of being able to do so at this stage. And that is why this has not been included in the study. Once the cohort is well established, we can get into more detailed studies of their networks and other factors associated with spread.
7. The NEP reaches approximately 3500 IDU daily and anecdotal evidence suggests that of these, 50% drop out. At present there is no active follow-up of these IDU. Since CARE has a good rapport with the IDU, it is expected with active and intense follow-up of these IDU that once the 600 IDU who will participate in the study have been identified, not more than 20% will drop out. The sample size has therefore been calculated with a drop out rate at 20%.
8. The process of maintaining strict confidentiality does not only include having identifier numbers rather than names on the questionnaire and blood tubes, but also training of all staff in the study on the issues around HIV, ethics and the

importance of confidentiality. This has been elaborated on pg. 12 under "Ethical Assurance for Protection of Human Rights".

REVIEWER #2:

AusAID, the donor funding the study, sent out the proposal for its own review process prior to approval. AusAID, has verbally informed the External Resources and Institutional Development Office of ICDDR,B that they their reviewer has approved the proposal and does not recommend any changes.

(FACE SHEET)

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator: TASAM AZIM

Trainee Investigator (if any): _____

Application No. 2002-005

Supporting Agency (if Non-ICDDR,B) _____

Title of Study: INCIDENCE OF HIV,

Project Status: _____

HEPATITIS AND SYPHILIS INFECTIONS
AND RISK BEHAVIOURS IN INJECTING
DRUG USERS IN DHAKA, BANGLADESH☒ New Study☐ Continuation with change☐ No change (do not fill out rest of the form)

Circle the appropriate answer to each of the following (If Not Applicable write NA)

1. Source of Population:

- (a) Ill subjects ☒ Yes ☐ No
 (b) Non-ill subjects ☒ Yes ☐ No
 (c) Minor or persons under guardianship ☐ Yes ☒ No

5. Will Signed Consent Form be Required:

- (a) From subjects ☒ Yes ☐ No
 (b) From parents or guardian ☐ Yes ☒ No
 (if subjects are minor)

2. Does the Study Involve:

- (a) Physical risk to the subjects ☒ Yes ☐ No
 (b) Social risk ☒ Yes ☐ No
 (c) Psychological risks to subjects ☒ Yes ☐ No
 (d) Discomfort to subjects ☒ Yes ☐ No
 (e) Invasion of privacy ☒ Yes ☐ No
 (f) Disclosure of information damaging to subject or others ☒ Yes ☐ No

6. Will precautions be taken to protect anonymity of subjects ☒ Yes ☐ No

3. Does the Study Involve:

- (a) Use of records (hospital, medical, death or other) ☒ Yes ☐ No
 (b) Use of fetal tissue or abortus ☐ Yes ☒ No
 (c) Use of organs or body fluids ☒ Yes ☐ No

7. Check documents being submitted herewith to Committee:

- ☐ Umbrella proposal - Initially submit an with overview (all other requirements will be submitted with individual studies)
☒ Protocol (Required)
☒ Abstract Summary (Required)
☒ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw) (Required)
☒ Informed consent form for subjects
☐ Informed consent form for parent or guardian
☒ Procedure for maintaining confidentiality
☒ Questionnaire or interview schedule*

4. Are Subjects Clearly Informed About:

- (a) Nature and purposes of the study ☒ Yes ☐ No
 (b) Procedures to be followed including alternatives used ☒ Yes ☐ No
 (c) Physical risk ☒ Yes ☐ No
 (d) Sensitive questions ☒ Yes ☐ No
 (e) Benefits to be derived ☒ Yes ☐ No
 (f) Right to refuse to participate or to withdraw from study ☒ Yes ☐ No
 (g) Confidential handling of data ☒ Yes ☐ No
 (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure ☒ Yes ☐ No

* If the final instrument is not completed prior to review, the following information should be included in the abstract summary

1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy
2. Example of the type of specific questions to be asked in the sensitive areas
3. An indication as to when the questionnaire will be presented to the Committee for review

We agree to obtain approval of the Ethical Review Committee for any changes involving the rights and welfare of subjects before making such change.

Tasam Azim

Principal Investigator

Trainee

ANNEXE 3

প্রশ্ন মালা

মূল বৈশিষ্ট্য :

১। বয়স (বৎসর) : _____

২। লিঙ্গ : পুরুষ / মহিলা / হিজরা

৩। বৈবাহিক অবস্থা :

- বিবাহিত
- অবিবাহিত
- তালাক প্রাপ্ত
- বিচিহ্ন
- প্রিয়/প্রিয়ার সঙ্গে বাস
সুস্থ/সুস্থ?

৪। জীবন সংখ্যা : _____

৫। আপনার বাড়ী কোন জেলায় ? _____

৬। কত দিন পরপর বাড়ী যান ? _____

৭। কোথায় থাকেন ?

- আবাসিক এলাকায়
- বস্তিতে
- রাস্তায়
- অন্যান্য _____

৮। কতদিন যাবৎ এই এলাকায় থাকেন ? _____

৯। কতবার বাসস্থান পরিবর্তন করেন?

- বৎসরে তিন বারের কম
- বৎসরে তিন বার
- বৎসরে ছয়বার
- বৎসরে ছয়বারের বেশী

১০। বাসস্থান পরিবর্তনের কারণ কি?

১০। পরিবারের সঙ্গে থাকেন : হ্যাঁ _____ না _____

পরিবারের সঙ্গে না থাকলে কার সঙ্গে থাকেন ? _____

১১। কত বৎসর লেখা পড়া করেছেন ? _____

১২। গত ছয়মাসে আয়ের প্রধান উৎস

- ব্যবসা
- চাকুরী
- ছাত্র
- বেকার
- রিকশাচালক
- মাদক পাচারকারী
- টোকাই
- বাড়ীওয়ালা
- অন্যান্য

১৩। আয়ঃ

দৈনিক কমপক্ষে _____ দৈনিক সর্বাধিক _____ গড়ে মাসে _____

মাদক ব্যবহার :

১৪। পরিবারের কেউ কি মাদকদ্রব্য ব্যবহার করেন ? হ্যাঁ/ না

যদি করেন তবে সে আপনার কি হয়? _____

১৫। কতদিন যাবৎ মাদক দ্রব্য (যে কোন) ব্যবহার করেছেন ? _____ বৎসর _____ মাস
(যদি ১ বৎসরের কম হয়)

১৬। কিভাবে মাদক দ্রব্য ^{গুরুত্বপূর্ণ} উদ্ধৃত হলেন? _____

১৭। কতদিন যাবৎ ^{ইনস্ট্রাকশন দেওয়া হয়েছে} শিরায় মাদক দ্রব্য গ্রহণ করেন? বৎসর _____ মাস _____
(যদি ১ বৎসরের কম হয়)

১৮। কত বৎসর বয়সে আপনি প্রথম ^{ইনস্ট্রাকশন দেওয়া হয়েছে} মাদকদ্রব্য গ্রহণ করেন ? _____ বৎসর

১৯। আপনি কেন ^{ইনস্ট্রাকশন দেওয়া হয়েছে} শিরায় মাদক দ্রব্য গ্রহণ করেছিলেন?

২০। গত একমাসে কোন মাদকগুলো গ্রহন করেছেন?

- হিরোইন
- গাঁজা
- কেকিডিল
- বড়ি
- এলকোহল(মদ)
- ইনজেকশান
- অন্যান্য _____

২১। সর্বশেষ কবে ইনজেকশান নিয়েছেন

- আজ
- গতদিন
- ২-৩ দিন আগে
- এক সপ্তাহ আগে
- ২-৪ সপ্তাহ আগে

২২। কোন ইনজেকশানটি বেশী গ্রহন করেছেন?

- টিভিসেসিক
- হিরোইন
- গেমিডিন
- অন্যান্য _____

২৩। গত একমাসে কত বার ইনজেকশান নিয়েছেন ?

- মাত্র একবার
- ২-৩ বার
- সপ্তাহে একবার
- সপ্তাহে ২-৩ বার
- সপ্তাহে ৪-৬ বার
- দিনে এক বার
- দিনে ২-৩ বার
- দিনে ৪ বার বা বেশী

২৪। গত সপ্তাহে কত বার ইনজেকশান নিয়েছেন ?

- মাত্র একবার
- ২-৩ বার
- দিনে একবার
- দিনে ২-৩ বার
- দিনে ৪ বার বা বেশী

২৫। গত ৭ দিনে কতবার শিরায় _____ গ্রহণে, _____ ইনজেকশান নিয়েছেন?

গোপনীয়

২৬। দিনে কতটাকা ইনজেকশানের জন্য খরচ করেছেন? _____ টাকা

২৭। কোথেকে সূচ ও সিরিঞ্জ পান?

- কার্মাসিষ্ট / কমিষ্ট
- ঔষদের দোকান
- স্বাস্থ্য কর্মী
- বন্ধু
- অন্য মাদক ব্যবহারকারী
- মাদক ব্যবসায়ী
- সূচ বিনিময় কার্যক্রম
- রাষ্ট্রীয় ঋণ
- অন্যান্য _____

২৮। মাদক গ্রহণ বন্ধের চেষ্টা করেছেন? হ্যাঁ / না

২৯। হ্যাঁ হলে কত বার? _____

৩০। কেন মাদক গ্রহণ বন্ধের চেষ্টায় ব্যর্থ হচ্ছিলেন?

৩১। কি সহযোগিতা পেলে মাদক গ্রহণ বন্ধ করতে পারবেন?

সূচ অংশীদারী আচরন

৩২। গত ইনজেকশানের সময় অন্যের ব্যবহৃত সূচ বা সিরিঞ্জ ব্যবহার করেছিলেন?
হ্যাঁ / না

৩৩। গত মাসে অন্যের ব্যবহৃত সূচ বা সিরিঞ্জ দিয়ে কতবার ইনজেকশান নিয়েছেন?

- সব সময়
- বেশীরভাগ সময়
- প্রায় অর্ধেক সময়
- মাঝে মাঝে
- কখনো না

৩৪। গত ৭ দিনে অন্যের ব্যবহৃত সূচ বা সিরিঞ্জ দিয়ে কতবার ইনজেকশান নিয়েছেন?

- সব সময়
- বেশীরভাগ সময়
- প্রায় অর্ধেক সময়
- মাঝে মাঝে
- কখনো না

৩৫। গত এক মাসে নতুন সূঁচ / সিরিঞ্জ ব্যবহার করার সাথে সাথে অন্যকে কতবার দিয়েছেন?

- সব সময়
- বেশীরভাগ সময়
- প্রায় অর্ধেক সময়
- মাঝে মাঝে
- কখনো না

৩৬। গত ৭ দিনে নতুন সূঁচ / সিরিঞ্জ ব্যবহারের সাথে সাথে অন্যকে কতবার দিয়েছেন?

- সব সময়
- বেশীরভাগ সময়
- প্রায় অর্ধেক সময়
- মাঝে মাঝে
- কখনো না

৩৭। শেষ বার যখন অন্যের সঙ্গে ইন্জেকশান নিয়েছিলেন একই সূঁচ বা সিরিঞ্জ কতজন ব্যবহার করেছিলেন?
_____ জন / জানি না। ✓

৩৮। কাঁদের সঙ্গে সচরাচর মাদক ব্যবহার করেন?

- বহু
- পরিবার (১০০)
- অপরিচিত লোক
- অন্যান্য

৩৯। কাঁদের সঙ্গে সচরাচর সূঁচ / সিরিঞ্জ শেয়ার করেন ?

- বহু
- পরিবার (১০০)
- অপরিচিত লোক
- অন্যান্য

৪০। শেষবার অন্যের সঙ্গে ইন্জেকশান গ্রহণের মাঝে সূঁচ / সিরিঞ্জটি একজন অন্যকে দেওয়ার আগে পরিষ্কার করেছিলেন ? হ্যাঁ / না

৪১। গত একমাসে অন্যের ব্যবহৃত সূঁচ / সিরিঞ্জ ইন্জেকশান নেয়ার সময় কতবার তা প্রথমে পরিষ্কার করেছেন?

- সব সময়
- বেশীর ভাগ সময়

- প্রায় অর্ধেক সময়
- মাঝে মাঝে
- কখনো না

৪২। যদি পরিষ্কার করে থাকেন তবে সাধারণত কিভাবে ?

- ঠান্ডা পানি দিয়ে
- গরম পানি দিয়ে
- সিদ্ধ করে
- ব্লিচিং দিয়ে
- স্পিরিট / এলকোহল দিয়ে
- তুলা দিয়ে
- ডেটল / সেন্ডলন দিয়ে
- ফুটিয়ে
- গাছের পাতা দিয়ে
- কাগজ দিয়ে
- অন্যান্য ভাবে

৪৩। কত ভালো মাদক মিশ্রিত ইন্জেকশান নিয়েছেন? গত ৭ দিনে _____ গত মাসে _____

৪৪। কতবার ইন্জেকশানটি বুট করেছেন? গত ৭ দিনে _____ গত মাসে _____

৪৫। ব্যাক / ফুট লোডিং কত বার করেছেন? গত সাত দিনে _____ গত মাসে _____
(নিডল খুলে নিয়ে আর একটা সিরিঞ্জের মুখে মুখি এনে নেশা দ্রব্য মিশিয়েছেন অথবা পিস্টন খুলে নিয়ে সিরিঞ্জের পেছন দিক দিয়ে নেশাদ্রব্য মিশিয়েছেন)

৪৬। কখনো টাকার জন্য রক্ত বিক্রি করেছেন? হ্যাঁ / না
(৪৬ নং প্রশ্নের উত্তর হ্যাঁ হলে ৪৭-৪৮ নং এর উত্তর করুন অন্যথায় ৪৯ নং প্রশ্নে চলে যান)

৪৭। গত বৎসর কত বার রক্ত বিক্রি করেছেন?

৪৮। কত আগে শেষ বার রক্ত বিক্রি করেছেন?

৪৯। কেয়ার এর স্ট্র / সিরিঞ্জ বিনিময় কার্যক্রমে কত দিন আছেন? _____ মাস

৫০। স্ট্র / সিরিঞ্জ বিনিময় কার্যক্রমে থাকা অবস্থায় ইনজেকশান শেয়ার করে থাকলে কেন?

যৌন আচরন ও ইতিহাস

৫১। কখনো ^{দিক} যৌন মিলন করেছেন ?

হ্যাঁ / না

৫২। কত বৎসর বয়সে প্রথম যৌন মিলন করেছেন ?

বৎসর _____

৫৩। শেষ কখন যৌন মিলন করেছেন ? _____ (দিন / সপ্তাহ ঠিক করে বলুন)

৫৪। শেষ বার যৌন মিলনের সময় কনডম ব্যবহার করেছিলেন?

হ্যাঁ / না প্রয়োজ্য নয়

৫৫। যৌন কর্মীর সঙ্গে কখনো যৌন মিলন করেছেন ?

হ্যাঁ / না

(৫৫ নং প্রশ্নের উত্তর হ্যাঁ হলে ৫৬-৫৭ নং প্রশ্ন করুন অন্যথায় ৬০ নং প্রশ্নে চলে যান)

৫৬। কত বার যৌন কর্মীর সঙ্গে টাকা দিয়ে যৌন মিলন করেছেন? গত মাসে ১০০ ? গত সপ্তাহে ১০০ ?

৫৭। গতমাসে যৌন মিলনের সময় কত জন মহিলা _____ ? / পুরুষ _____ / হিজরা _____ ?
ছিল?

৫৮। গতমাসে যৌন কর্মীর সাথে যৌন মিলনের সময় কতবার কনডম ব্যবহার করেছেন?

- সব সময়
- বেশীর ভাগ সময়
- মাঝে মাঝে
- কখনো না

৫৯। গত বৎসর যৌন কর্মীর সঙ্গে যৌন মিলনের সময় কতবার কনডম ব্যবহার করেছেন?

- সব সময়
- বেশীর ভাগ সময়
- মাঝে মাঝে
- কখনো না

৬০। কতবার এমন কারো সাথে (বন্ধু / স্ত্রী / ^{স্বামী}প্রিয়া) যৌন মিলন করেছেন যার জন্য মূল্য দিতে হয়নি? গত মাসে _____
গত বৎসর _____ ?

৬১। এদের মধ্যে কতজন মহিলা _____ পুরুষ _____ হিজরা _____ ?

৬২। কতবার যৌন কর্মী ছাড়া অন্যের সঙ্গে যৌন মিলনের সময় কনডম ব্যবহার করেছেন?

- সব সময়
- বেশীর ভাগ সময়
- মাঝে মাঝে
- কখনো না

যৌন রোগ সমূহ

৬৩। বিগত বৎসরে নিম্নের সমস্যা গুলো ছিল কি?

- | | |
|--------------------------|------------|
| • লিঙ্গ নিঃসরণ | হ্যাঁ / না |
| • জ্বালাযুক্ত প্রস্রাব | হ্যাঁ / না |
| • যৌনালে ব্যাধা | হ্যাঁ / না |
| • যৌনালে ক্ষত | হ্যাঁ / না |
| • যৌন মিশনের সময় ব্যাধা | হ্যাঁ / না |
| • পুঁজ ও রক্তাশ্রু-পায়ু | হ্যাঁ / না |

৬৪। বিগত সময়ে এ রোগের চিকিৎসা নিয়েছেন? হ্যাঁ / না

(উপরের উত্তর হ্যাঁ হলে ৬৫-৬৮ নং প্রশ্নের উত্তর লিখুন অন্যথায় ৬৯ নং প্রশ্নে যান।)

৬৫। রোগের লক্ষণ ধরার পর কতদিন চিকিৎসা নিয়েছেন? _____ (দিন)

৬৬। চিকিৎসার জন্য প্রথম কোথায় গিয়েছিলেন?

- হাসপাতাল
- প্রাইভেট ডাক্তার
- প্রাইভেট ক্লিনিক
- এন জি ও ক্লিনিক
- হাতুরে ডাক্তার
- বন্ধু
- অন্যান্য

৬৭। এর পর অন্য কোথাও চিকিৎসার জন্য গিয়েছিলেন? হ্যাঁ / না

হ্যাঁ হলে কোথায়?

- হাসপাতাল
- প্রাইভেট ডাক্তার
- প্রাইভেট ক্লিনিক
- এন জি ও ক্লিনিক
- হাতুরে ডাক্তার
- বন্ধু
- অন্যান্যঃ

৬৮। সব মিলিয়ে চিকিৎসায় কত টাকা খরচ হয়েছিল? _____ টাকা

সামাজিক পরিবেশ

৬৯। ইজেকশানে নেশাগ্রহনকারী হিসাবে কোথাও স্বাস্থ্য সুবিধা পান? হ্যাঁ / না
হ্যাঁ হলে কোথায় ?

৭০। ইজেকশানে নেশাগ্রহনকারী হিসাবে আপনার ^{হোমসেভেয়ার} বাচ্চা স্বাস্থ্য সুবিধা পায়? হ্যাঁ / না
হ্যাঁ হলে কোথায় ?

৭১। ইজেকশানে নেশাগ্রহনকারী হিসাবে কোথাও ^{শিক্ষা} শিক্ষা সুবিধা পান? হ্যাঁ / না
হ্যাঁ হলে কোথায় ?

৭২। ইজেকশানে নেশাগ্রহনকারী হিসাবে আপনার ^{ছোটবেলায়} বাচ্চা ^{বাচ্চা} স্বাস্থ্য সুবিধা পায়? হ্যাঁ / না
হ্যাঁ হলে কোথায় ?

৭৩। ইজেকশানে নেশাগ্রহনকারী হিসাবে কখনো ^{নির্যাতনের} শিকার হয়েছেন? হ্যাঁ / না

৭৪। হ্যাঁ হলে কীর নিকট থেকে ?

৭৫। দয়া করে নির্যাতনের ধরন বলুন

এ প্রশ্নগুলোর উত্তর দেওয়ার জন্য ধন্যবাদ। আপনার সহযোগিতার প্রশংসা করি।

২৩ ৪/২০২০