フィリピン共和国エイズ対策追加調査専門家チーム報告書

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平成6年7月

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国際協力事業団
医療協力部

国際協力事業団

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序　文

本年度実施の日米包括経済協議において日米両国が共同して対応すべき全世界的問題の一つとしてエイズが取り上げられ、両国が協調して調査団を派遣して調査を行い相互に意見や情報を交換することが事務レベルで合意された。国際協力事業団医療協力部では、この決定を受けてエイズ対策基礎調査団をアジアにおける当該分野での重要国の一つであるフィリピン共和国に平成６年３月16日から同月24日まで派遣し、同国のＨＩＶ／エイズ感染の疫学的状況の調査と対策の現状を調査した。

その結果、同調査団はＨＩＶ感染サーベイランス体制整備の支援、完全な輸血血液の確保、エイズ対策要員の養成、及びＮＧＯ支援による啓蒙教育促進活動強化の分野での協力を提言した。本専門家チームは上記提言に基づき、協力内容を具体的に調査し協力の早期実施を可能とする目的で平成６年５月25日から６月22日までの日程で派遣され、この度調査結果を報告書として取りまとめる事となった。

今回の派遣にあたって多大なる御協力を賜ったフィリピン共和国政府関係者及び国内協力機関関係者各位に対し深甚なる謝意を表する次第である。

平成６年７月

国際協力事業団
医療協力部長
小早川　隆敏

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1．専門家チームの派遣

1－1　派遣の経緯と目的

エイズは1970年代に発見されて以来、国境、文化、人種、年齢、宗教を越えて蔓延し1992年の時点で 1,300万人が感染したという。現時点でも治療方法は発見されておらず、感染がこのままの状況で進行したと仮定すると2000年には過小に見積もっても約 3,800万人が感染するとみられる。現在アジアにおいては約 100万人が感染しているといわれるが、その時点では、サブサハラアフリカの２倍の人口を持つアジアオセアニア地域は約42％にあたる感染者を有することとなり社会経済的影響が憂慮される。

エイズは前述されたようにすべてのボーダーを越えて蔓延するために、その対応には世界的な規模での協調的対応が要求される。また、ここで強調されるべきことはエイズは最も生産性のある年齢層を中心に感染し、国の経済生産性に重大な損害を与え、経済開発の進度を著しくそこなうこと、及び人間の本能である性行為という動態を介して主に感染し、エイズに関し正しい情報を持ち理解していない場合、多々として感染後は個人の基本的人権を失いせしめることである。

そこで、このほど日米両国は、地球的規模で強調して対応すべき分野の一つとして人口とエイズを選定し、まずエイズ分野でフィリピン共和国（以下、比国と略す）において協力を実施することとし、1994年３月にエイズ基礎調査団を約１週間の期間で派遣した。その調査の結果、比国におけるＨＩＶの感染は1984年に最初の患者が発見されて以来1994年１月までに、患者 125名、無症候感染者 350名、計 475名であり、この数字から同国では約 5,000人から50,000人が感染していると推定され、感染はアジアの中でも小規模に留まっていると言えよう。しかし、エイズ流行の危険因子は同国に存在し、状況は楽観視されない。危険因子の一つは貧困であり、これから派生する売春は広く介在し、予防に肝要なコンドームの使用も宗教及び慣行の違いから余り進んでいない。もう一つの因子は輸血血液検査の不備である。同国の輸血血液の約75％は売血で賄われ、残りが赤十字及び国立病院付属血液センターで補完される。保健省の抜き打ち検査によって、約 300検体に１の割合でエイズ陽性検体が発見されたが、義務付けられた血液の検査は完全な状態で実施されていない。このような状況下で同国は米国と国連保健機構の協力を受けて危険な動態をとるリスクグループを対象としたサーベイランス体制の構築をめざし、そのサーベイランス結果を感染の予防に生かすべくＮＧＯを活用した啓蒙教育促進活動を実施中である。そこで、我が国は米国との協調の上で、比国のエイズ対策方針に則ってサーベイランス、人材育成、啓蒙教育促進の３分野での協力が可能であろうという提言がまとめられた。サーベイランス分野では血液検査の徹底を促進し、人材育成分野では血液検査を含むエイズ関連の検査と研究にかかる研修が対象となろう。啓蒙教育促進分野ではＮＧＯの活動促進のための機材供与が検討されるが、今回の調査とは別に行われる。この度の長期調査は、前述の背景のもとに我が国からの協力が早期実現されるべく、その方法を具体的に調査する目的で実施された。

1－2　チーム構成

担　当	氏　名	所　属
団員　実験室診断	吉原　なみ子	国立予防衛生研究所エイズ検査室長
団員　医療協力	上潟口徳次郎	国際協力事業団医療協力部特別嘱託

1－3　調査日程表

日順	月日	曜日	移動及び業務
第1日	5・25	水	マニラ着、日本国大使館及びＪＩＣＡ表敬及び打ち合わせ
第2日	5・26	木	ＲＩＴＭ、ＵＳＡＩＤとの打ち合わせ
第3日	5・27	金	ＪＩＣＡ、ＢＲＬ／ＤＯＨ打ち合わせ
第4日	5・28	土	資料整理
第5日	5・29	日	資料整理
第6日	5・30	月	Special Concerns, FETP, External Relations, /DOH打ち合わせ
第7日	5・31	火	ＢＲＬ，ＰＩＨＥＳ／ＤＯＨ打ち合わせ
第8日	6・1	水	赤十字打ち合わせ
第9日	6・2	木	ＵＳＡＩＤ打ち合わせ
第10日	6・3	金	日本国大使館打ち合わせ
第11日	6・4	土	資料整理
第12日	6・5	日	資料整理
第13日	6・6	月	ＵＳＡＩＤ，赤十字打ち合わせ
第14日	6・7	火	ＢＲＬ打ち合わせ
第15日	6・8	水	ＢＲＬ打ち合わせ、吉原団員合流、日本国大使館・ＪＩＣＡ打ち合わせ
第16日	6・9	木	ＲＩＴＭ、ＵＳＡＩＤ打ち合わせ
第17日	6・10	金	エイズシンポジアム、ＮＡＭＲＵ、ＳＰＣ／ＤＯＨ訪問
第18日	6・11	土	セブ島赤十字、地域検査所訪問
第19日	6・12	日	ダバオ移動
第20日	6・13	月	ダバオ赤十字、地域検査所、血液銀行、病院訪問
第21日	6・14	火	ＢＲＬ、ＦＥＴＰ打ち合わせ
第22日	6・15	水	国立腎臓病院、Jose Reyes Memorial, Jose Fabella Memoria病院
第23日	6・16	木	ＷＨＯ（吉原団員）、日本国大使館、ＵＳＡＩＤ打ち合わせ
第24日	6・17	金	ＪＩＣＡ報告、ＳＰＣ／ＤＯＨ打ち合わせ、吉原団員帰国
第25日	6・18	土	資料整理
第26日	6・19	日	資料整理
第27日	6・20	月	ＤＯＨ打ち合わせ
第28日	6・21	火	資料整理、日本国大使館、ＪＩＣＡ報告
第29日	6・22	水	マニラ発

Remarks:
- Research Institute for Tropical Medicine（ＲＩＴＭ）
- United States Agency for International Development（ＵＳＡＩＤ）
- Bureau for Research and Laboratories（ＢＲＬ）
- Department of Health, The Philippines（ＤＯＨ）
- Field Epidemiological Training Program（ＦＥＴＰ）
- Public Information & Health Education Services（ＰＩＨＥＳ）
- U.S.Naval Medical Research Unit（ＮＡＭＲＵ）
- Special Concerns（ＳＰＣ）

1－4　主要面談者

保健省
- Carmencita N. Reodica, Assistant Secretary, Special Concerns
- Dennis Maducdoc, AIDS Program Manager, Special Concerns
- Manuel M. Dyrit, Assistant Secretary, Field Epidemiological Training Program (FETP)
- Timoteo J. Badoy, Jr. Project Coordinator ＦＥＴＰ
- Mark White, MD HIV Surveyllance Consultant, WPRO/WHO
- Juan Nanagas, Undersecretary, office of Health Facilities, Stadards & Regulation
- Marieeta Baccay, Director, Bureau of Research & Laboratories (BRL) : 5/30/94で転出
- Juvencio F. Ordona, MD, Director, ＢＲＬ
- Gracela Mina-Ramos, Anatomic and Clinical Pathologist/BRL
- Linda, M. Milan, Assistant Secretary, External Relations

熱帯医学研究所（ＲＩＴＭ）
- Remigio Olveda, Director
- Ofelia T. Monzon, MD, Consultant on AIDS
- Rose Aplasca, OIC, AIDS Research Group
- Fem Paladin, AIDS Research Group

サン・ラザロ病院
- Virgilio L. Gonzales, Medical Center, Chief

ＵＳＡＩＤ
- Emmanuel Voulgaropoulos, Chief, Office of Population, Health & Nutrition
- Corazon R. Manaloto, MD, Public Health Advisor

赤十字ナショナル血液センター
- Cecilia Francisco, MD, OIC, National Blood Program
- Elepoldo Magpusao, MD, Physician In Charge
- Michael Angelo J. Marquez, Jr, Medical Officer

赤十字本部
- Cleso O Samson, MD, Secretary General
- Henia T. Tacumbaba, Administrator

東ビサヤ地域血液センター、セブ市チャプター
- Dr. Cesar M. Lumapas, Physician In Charge

ダバオ市チャプター
- Ms. Xenia Pacumbaba, Chapter Administrator

ダバオ市 City Blood Center(Private)
- Mrs. Irene Padilla

2．要約

今年３月に実施された基礎調査結果の提言に基づき本調査では、サーベイランス、安全な輸血血液の確保、係る研修と研究の分野での協力実施の可能性を追加調査した。尚、ＮＧＯ支援による啓蒙教育促進分野に関しては、今回の調査とは別個に扱われる。

比国におけるこの度のエイズ分野での協力の発端は、米国とのグローバルイシュウズイニチアチブにおける協調であったが、比国ＵＳＡＩＤ事務所でもＵＳＡＩＤが資金供与し、ＷＨＯと保健省（Department of Health：ＤＯＨ）が協力して実施中の AIDS SURVEILLANCE & EDUCATION PROJECT（ASEP）への協調協力が打診された。

従って、サーベイランス部門での協力内容を具体化するために当該部門を統括するＤＯＨ内Field Epidemiological Training Program（ＦＥＴＰ）及び関連部署と協議し、その結果、ネットワークと検査機能強化に必要で我が国から期待され得る機材供与要請案が纏められた。本案には、当初想定されなかった梅毒試薬が含まれるために案を本邦に持ち帰り関係者で検討後、結果を改めてＤＯＨに連絡し第３回目のサーベイランス実施が予定される今年９月を想定した機材供与が必要となる。尚、梅毒試薬要請の背景には、ＨＩＶ試薬の予算が既に確保されていたこと、性病とエイズ対策が統合されていること、性病検査を介してＨＩＶ検査を行っていることが留意される。

安全な血液の確保に関し、前回の調査時は赤十字が献血の50％しかＨＩＶに関し検査していないことが判明し、全血の検査を早急に実施できるような協力の可能性を調査した。赤十字が必要とする機材と研修の供与を実現するには監督者であるＤＯＨ内Bureau of Research and Laboratory（ＢＲＬ）の許可が必要であるが、今年６月に前任者と交代した責任者が、我が国の赤十字への協力に同意した。今回はテストキット及び関連機器の供与が想定される。同国の血液事業には赤十字、国立病院血液センター、売血業者が従事し、ＤＯＨでは将来的には売血を排除し新たに国営の血液センターを設立する構想を持っている。今回の調査では、まず赤十字に限定した安全な血液の確保への協力とした。

Research Institute for Tropical Medicine（ＲＩＴＭ）へ機材を供与し、研修と研究を強化する可能性では、想定されていたフローサイトメターが不要となり、Rolymerase Chain Reaction（ＰＣＲ）装置と関連機材及び試薬を供与することとなろう。ＲＩＴＭで実施中の第３国研修は1996年まで継続するが、終了後はエイズ部門を独立させて内容を充実させた形で発展させる可能性がある。エイズ分野で第２国研修を実施することは、現状不要であり、どちらかといえば、医療技師のＨＩＶ検査技能研修が、特に赤十字に対して必要と考えられた。また、サーベイランスに関連して、検査キット、及びラボの精度管理、検査法の標準化の分野での専門家派遣による協力が必要であろう。

上記の機器供与による協力が円滑にかつ有効に実施されるためには長期専門家が必要であり、もしも適任者が見つからない場合には、年に数回、例えばサーベイランスの実施時期に合わせた短期

専門家の派遣が望ましい。

今回の調査で、上記３部門での協力に対し担当部門で機材供与要請案が纏められた。今後、内容が本邦で調整された後はＤＯＨ内エイズ対策調整部門であるスペシャルコンサーンで統合された要請案として改めて纏められた後、在比国日本国大使館苑提出されることとなる。

3．調査結果

3－1　サーベイランス分野

現在保健省（ＤＯＨ）は、Field Epidemiological Training Program（ＦＥＴＰ）を中心としてＵＳＡＩＤ／ＷＨＯの協力のもと保健所（Social Hygiene Clinic:SHC ）を接点に使った全国レベルでのエイズ感染の監視体制構築を目指している。この計画はＵＳＡＩＤの実施するAIDS Surveillance and Education Program（ＡＳＥＰ）の一部で、その目的は、正確な疫学情報収集体制を確立して感染状況の把握を可能とし、その解析結果を予防政策に反映させようというものである。計画では、1997年を目処に国内で戦略的に選定した30ヶ所から成るＨＩＶ感染監視体制を構築するものであり、ここで６つのハイリスクグループを対象に感染状況の変化と一般大衆への感染の広がりを定期的に監視しようというものである。

エイズの感染は一般的にはまず同性愛者、被輸血者や麻薬常用者の特定集団に限って蔓延し、次には売春婦（夫）のグループに感染し、そして主に異性間性交を媒体として一般大衆へと感染していく。比国では売春婦、フリーランスの売春婦、売春夫、麻薬薬物常用者、同性愛者、男性の性病患者を監視集団に選び、半年に一回各グループ毎に300検体（グループによっては100検体）を検査し感染状況を監視する計画である。血液検体の収集は、売春宿やＳＨＣで行われ、ＨＩＶ検査は最寄りの地域検査所で行われる。そして、結果が陰性でない場合は確認のためにマニラにある中央検査所（ＲＩＴＭ）へ送られるようになっている。計画ではＳＨＣでＨＩＶ検査機能を持つようになっていたが、現時点では不備である。検査方法に関し、麻薬薬物常用者だけは検査の目的が説明されずに実施されるが、代わりに身元も分からないようになっており結果及びカウンセリングも提供されない（unlinked anonymous）。それ以外のグループに対しては検査の目的が説明され同意が得られた後実施される（informed consent）。対象者からは、身元を除いた人口統計データが調べられた後番号が付けられ、検査結果はカウンセリングを受けることを条件として教えられる（voluntary anonymous）。

センチネルサーベイランスは、まず２ヶ所（ケソンシテイー、セブシテイー）で1993年９月に開始され、その後、1994年３月にパサイシテイーとダバオを加えた４ヶ所で実施された。今後もサーベイ箇所は徐々に増やされ、計画期間終了時には目標である30ヶ所になる構想である。ＦＥＴＰの説明では半年に１回ずつの調査を継続する場所（10ヶ所程度）と感染状況により単発的に実施される場所とを併せた場合での30ヶ所であるとのことである。ＳＨＣは市町村（Province）の管理下にあり、ＦＥＴＰでは地方自治体の実施意志があった場合のみ、監視体制構築のための指導と協力をする方針という。このプログラムの監視活動では６つのリスクグループを対象として、半年に一度の調査とそのフォローアップを行っているが、ＳＨＣはＳＴＤクリニックも兼ねることがあり、性産業従事者は２週間に一度検査を義務づけられているので、監視の実施所として選ばれたものであり、無料の梅毒検査を施し、同時にＨＩＶ検査も行っている。同国では1993年に性病（ＳＴＤ）対

策がエイズ対策に統合されたことと、ＷＨＯのＳＴＤ対策を通してのエイズ対策実施という構想がエイズ対策に反映されている。サーベイの対象に関し、ＨＩＶ感染の進行に伴い監視の対象を広げ、体制を強化するために感染が一定水準を越えたら上記６つのグループに産婦と海外契約労働者とその妻が加えられる計画になっている。当該活動内容は、患者の発見と感染状況の監視とに別れるが、最近前述のリスクグループを対象とした動態の監視システム作りに取りかかったという。

×調査団滞在中にサーベイランスに関するシンポジウムがマニラで開催されたが、感染を促進している買春者の調査の必要性が指摘されていた。また、フリーランス売春婦の陽性率は1992年は1,000人当たり0.5であったのが1993年には2.0、1994年は2.8と92年以降上昇しており、感染が広がる危険性を示唆している。パサイ地区では1993年６月から1994年４月までに1,483人中８人（0.005％）のＨＩＶ陽性者が見つかっている。米軍の研究機関であるＮＡＭＲＵの調査ではマニラ首都圏の売春婦の78％がレイテ島とサマール島（第８地域）出身であり、更にクラブ従業者の20％、サウナ従業者の78％が同地域出身者であることが判明し、対策策定に貴重な情報を提供している。

上記の監視体制整備の計画実施上、ＦＥＴＰは計画実施と管理の統括を行い、ＢＲＬとＲＩＴＭの役割は、前者が血液スクリーニング、後者がＢＲＬが行うテストの確認と品質管理となっている。ただし、これはＡＳＥＰに関してのことであり、ＢＲＬは国公立の検査所の技師に対する検査技能の研修、資格の付与、施設の検査、検査手順の定期的な保守等を行い、ＲＩＴＭは、私立の検査所の技師に対する検査技能の研修と資格付与を有料で実施し、他にもエイズ研究活動を実施している。

前回の調査で、この２機関の活動内容の重複が指摘されたが、事実役割分担は建前だけのことで実際は２者とも同じ活動を行っている部分がある。ＢＲＬはＤＯＨの行政機関であるためにＤＯＨの一研究所であるＲＩＴＭと異なりレギュレーターとしての活動が期待されていると前回の調査で指摘された。今回の調査の過程で４、５年前には援助国間でＢＲＬの強化が援助案件として話題になった事が判明したが、今日まで実施されていない。ＢＲＬの現状は人及び施設の面で貧弱であり、本来の機能である検査所の規制と標準保守と更新を十分に行っていない。ＵＳＡＩＤではプロジェクトの実施上必要な機能が欠如していてそれを補ったり強化することは検討できても単に漠然とＢＲＬの強化ということは考えられないということであった。94年５月30日付けでＢＲＬの責任者がバッカイ氏からオルデニア氏に代わった。

さて、当計画では、ＳＨＣでのＨＩＶ検査が想定されているが、現状では、ＳＨＣに機能は無く、最寄りの地域検査所に依存している。地域検査所は全国に14ヶ所あるが、ＢＲＬ／ＤＯＨではこの機能を強化し、将来的には、まず14を５つのゾーンに分けてそこで確認テストが出来るようにする構想を持っている。

前回の調査でマニラ郊外の地域検査所を、今回の調査でセブとダバオの地域検査所を訪問した。これらは一応ＨＩＶ検査機能は持っているが、機器、消耗品の不足、試薬の供給と保存の面で問題を抱えていた。一例として、第１回目のサーベイ時には、クライオジェニックチューブが無かったために250検体の検査が遅れたという。また、遠隔地では検体をマニラまで輸送する際に間違った検

体が送られたり、輸送に時間がかかったりする技術的な問題があるという。事実、ダバオでは今年の３月に実施されたサーベイの検体が未だにマニラへ送られずに冷蔵庫に入ったままであった。この事実から、検体の取扱方法、台帳の整備、ラベルの確認、検査技術の指導と監督が必要である。更に、試薬の保存、精度管理の指導も必要である。一般的に、地域検査所では資金不足を原因として物品が欠如し、医療機器の修理と保守も行われていない傾向がある。地域検査所では耐用年数を越えた冷蔵庫や、予算が無いために修理が出来ない機器があったり、冷却遠心器、保存用冷凍庫及びバックアップ用の冷蔵庫もなかった。サーベイランス実施時は、問診及び採血は調査員が現地（売春宿等）に出向いて行うので通信機器活用による活動の効率向上が必要であろう。また、サーベイ実施時に専門家を派遣し実施状況を視察させ実情を今後の協力に反映させることが必要である。

３－２　赤十字関連

前回の基礎調査で輸血用血液は赤十字、国立病院付属血液センター及び商業血液銀行（売血）で賄われており、全体供給量の約７割を売血に依存している事がわかった。1994年の３月にニュートロピカル医学基金（ＲＩＴＭ内）が実施した国内の血液事業に関する調査結果に基づき、同年５月に売血を徐々に排除することが閣議決定され、更にＤＯＨは既存の赤十字、国立病院付属血液センター、売血のネットワークを作り当座を運用し、将来は売血を無くし国営の血液銀行を設立し事業を運営する計画を作成中である。

赤十字では24時間体制を取り需要に対応すべく努力しているが資金不足を主な理由として供給量はそれほど上がっていない。昨年の採血の実績は約11万単位で、ＨＩＶ検査に関しては約67％の実施実績がある。赤十字で検査を完全に出来ない原因は試薬の不足、施設の不備と検査資格を持つ検査技師の不足であるが、検査技師の研修を担当するＢＲＬも資金不足等を理由に必要な人員を育成出来ない状況である。現在、赤十字全体では約30人の研修が必要であるが、７月の研修で５人を受け入れてくれることになったという。もしも、この30人が一括して研修を受け資格を付与されたら、この後は毎年５人未満の需要しか出てこないという。

専門家チームは、地域のＨＩＶ検査所に指定されているマニラから２時間ほどのところにあるサンタクルーズのラグナチャプターを訪問した。ここでは、29市町村、人口にして約134万７千人を担当し、管轄下には９つの公営病院、27の私立病院、10の検査所がある。このチャプターの運営は４人の職員と２人のボランティアで行われ、検査業務は20代半ばの女性が一人で全てを担当していた。彼女は1993年にＢＲＬの研修を受け、その後血清プーリングの研修を受けている。彼女の記録によると、このチャプターでは１日に１人から15人の献血者あるが、医者がいない（雇えない）ために近くの病院で検診後、戻ってから採血するという。日報からはＨＩＶは無いがＢ型肝炎の多いのに気付いた。この検査技師も６月で辞職し、後任が見つかるまではマニラに検体を送って検査することとなるという。

専門家チームはダバオの赤十字チャプターも訪問した。ここは病院とクリニック等を含めて15ヶ

所を担当しているという。ダバオには赤十字以外に国立のダバオメデイカルセンターと売血所１ヶ所が血液事業に従事している。赤十字には１日当たり平均50人ほどの献血者があるという。訪問した日にも門の近くに多くの人が溢れていた。ここには１人の資格を持つ検査技師を含む７人の検査技師がおり、そのうち４人は市の援助で雇っているという。所長の話では、市長が理解を示し今年度は30万ペソの援助をしてくれたという。ここでも、常駐の医師は不在で、必要な時にボランティアが来てくれることになっている。施設に関しては、整理整頓され管理が行き届いていた。機器面では、遠心分離器はあるが冷凍庫がないことと、冷蔵庫の予備が無いことであった。ＨＩＶのテキストキットはマニラから支給されるが必要全量に満たず不足分を現地調達するが50％ほど高価であるという。プーリングは５本ずつ行っている。

ダバオメデイカルセンターは地域検査所も兼ねるが、赤十字と売血病者から供給を受ける全ての血液を信頼性の面から再度梅毒、肝炎（Ｂ）、ＨＩＶ、マラリアに関しスクリーニングしている。ＨＩＶに関しては、今日までに５件の陽性検体をマニラに確認の為に送ったという。プーリングは10本単位で行い、検査には150ペソの料金を徴収するという。ここでの問題も試薬と消耗品の不足であった。施設は古く、人も機器材も多く活動量が多いのか余り管理が行き届いているようには見えなかった。冷蔵庫の予備として湾岸戦争後の放出品が米国から寄付されていたが、故障していて使用されていなかった。

ダバオの売血業者であるシテイブラッドバンクを訪問した。小さな家屋を改造しただけの施設で、経営者と５人の検査技師で運営されていた。ここでは、売血者の検査にはＰＡ法を、検査機能を持たない病院や検査所及び患者の検査にはアボットを使用し、検査料として400ペソを徴収していた。売血者は平均して40人／日であり、１人当たり130ペソを支払い、病院には400ペソで売っている。この売血所では1993年10月にサンペドロ病院から送られてきた検体から陽性を検出したという。

一般的に、比国では成分採血に関しては遠心分離器及び冷凍庫がないか、又は壊れており、普及していない。また、医師の知識も少なく使用の指示も出来ない状況である。比国では海外労働者が多くＨＩＶ－２型の抗体検査も開始されるべきであろうが、現在のところ実現していないので、早期着手されるべきである。ＨＩＶ感染状況では、赤十字の1993年の陽性率が0.06％であり（47／783,318）であり、日本の約 130倍である。これは前回調査した時の0.027％と比較して、２倍のスピードで感染が進んでいることとなるので、ＨＩＶ検査の100％実施を早急に実現するべきである。今後の血液事業の動向には注意が必要であるが、既存の赤十字の機能を採血だけに限定し、地域検査所、将来的には国立の血液センターで一括して検査し、現行の２重検査に起因する費用を下げようという構想は、検査、採血そして輸血までの時間と運搬及び関連経費がかかり、現実的でないと考えられる。詳細は更なる調査が必要であるが、当座は動向を静観したい。

3－3　熱帯医学研究所（ＲＩＴＭ）における研修及び研究分野

前回の調査では、ＢＲＬの活動量の不足とその機能強化の必要性が指摘された。本来ＢＲＬの業務は検査所の施設と機能の規制と保守であり、それに必要な研究施設とインスペクター等の人員を抱えている。一方、ＲＩＴＭは組織的には半独立し保健長官に直属する熱帯病研究所であったが、現在では多角化し研修や看護にも広く手を広げている。前回の調査結果からは、ＨＩＶ関連の研究を強化するためにＰＣＲ装置とフローサイトメターの供与と係る研修の検討が提言された。

今回はサーベイランス強化に関連した研究と研修、及び安全な血液の確保に関連させた協力の可能性につき調査が行われた。後者につき、まず、赤十字での献血が100％ＨＩＶについて検査されるためには係る検査技師の研修が必要である。赤十字及び国公立の検査所の医療技師研修は本来ＢＲＬの担当であるが、資金その他の原因により満足なレベルでは行われていない。ＲＩＴＭは、ＢＲＬが担当しない私立の病院とラボの技師を対象とした研修と資格の付与を有償で実施している。赤十字はＢＲＬによる研修は無償であるので出来たらＲＩＴＭではなくＢＲＬでの研修実施を希望していたが、今年の研修のめどが立たなかったために、一時はＲＩＴＭに研修の依頼をしている。そこで、ＤＯＨにＲＩＴＭを使って当方の協力で赤十字の技師を研修する可能性を打診したところ、可能ならば実施して良いという同意を得ている。

ＰＣＲ検査法はＨＩＶサーベイランスと検査体制の強化の為、特に母子感染の早期診断とＨＩＶ抗体検査で判定不能な場合の感染の確認に必要であり周辺機器と試薬を含めて供与の検討が必要であろう。この機器がＲＩＴＭに設置された場合は、第３国研修でも使用が可能であるが、装置の使用方法等の指導につき単期専門家の派遣が必要となろう。

前回の調査結果からフローサイトメターの供与も検討されたが、今回の調査で米国海軍医学研究班（ＮＡＭＲＵ）がこの装置を比国に寄付することとなったので、我が国からの供与は不要である。専門家チームはＮＡＭＲＵ研究所も視察したが、米国の研究所の環境に近い条件を維持しており施設の程度は良好である。比国に引き渡された後はＲＩＴＭが運営していくこととなるが、高価な試薬を含め維持管理は容易ではないであろう。また、この装置を使える技師は一人のみで、人材の育成と確保が必要である。

ＲＩＴＭに関して設立当初から関与し、ＲＩＴＭの内情に明るい日本人専門家によると基礎研究力が弱い、人件費予算が不足しプロジェクトベースでの契約雇用者が多いので長期的な視野のもとでの人材育成が出来ていない、エイズに関しても疫学調査の段階迄で研究までは至っていないとの指摘があり、バランスが取れたＲＩＴＭの発展の為にもう１ヶ所研究所が設立される必要があるという意見であった。このような状況下で、現在のＲＩＴＭのエイズ研究部門の人員ではサーベイランス、研修、精度管理、及び研究を遂行するにはマンパワーに欠ける不安がある。参考までに、ＵＳＡＩＤではＡＳＥＰ実施に必要な要員が雇用できるように予算を付けてある。

サーベイランス強化に関連しては、ＡＳＥＰの中でＲＩＴＭは陽性検体の確認、検査手法の決定、品質管理、検査技師の指導と巾広い、どちらかといえばＢＲＬが手掛けるべき責任を与えられてい

る。しかし、現在のＲＩＴＭの実力を考えて判断すると実施中のサーベイランスプログラムを成功させるためにも、検査キットおよびラボの精度管理、検査法の標準化の分野での専門家派遣による協力が必要であろう。

4．提言

今年３月に実施された基礎調査に引き続きマニラ、セブ、ダバオの赤十字センター、地域検査所、私立病院検査所及び私立血液銀行の視察、及びＤＯＨ，ＲＩＴＭ，ＵＳＡＩＤ，ＮＡＭＲＵと意見交換した結果、比国におけるＨＩＶ／ＡＩＤＳ分野での協力は次の３つの項目が必要かつ可能であると考えられる。

1） サーベイランス機能及びネットワークの強化に対する協力

2） 安全な輸血用血液確保の為の赤十字へのＨＩＶ100％実施への協力

3） ＨＩＶ／ＡＩＤＳ検査のための技術者養成研修、検査キット及びラボの精度管理、検査法の標準化、研究活動に対する援助

尚、上記の協力が円滑にかつ有効に実施されるためには長期専門家が必要であり、もしも適任者がない場合には、年に数回、例えばサーベイランスの実施時期に合わせた短期専門家の派遣が望ましい。

附 属 資 料

① 基礎調査団提言

Summary of Recommendations

Fact-Finding Study Team on AIDS control

in the Republic of the Philippines

The prevalence of AIDS and HIV infection in the Philippines is relatively low among Asian countries, with 125 AIDS cases and 350 HIV infections registered so far. Under the epidemiological situation, it is important to implement an effective prevention and control program which addresses the country's potential risk factors.

In this regard, the following three measures are to be taken as the priority:

(1) Strengthening of surveillance of HIV infections through laboratory diagnosis network and blood screening.

(2) Training of health personnel to implement the program.

(3) Promotion of education activities on AIDS.

The Japanese assistance to the AIDS control in the Philippines should follow the same strategies as above, which may include the following projects.

(1) Provision of HIV test kits for;

① promotion of voluntary blood donation through 100 % blood screening and safety assurance for voluntarily donated blood, and

② effective public health laboratory services to establish surveillance network.

As for the screening of voluntarily donated blood, it is necessary to make arrangement between DOH and Red

Cross so that provided test kits can be used at Red Cross blood centers.

The roles and functions of public health laboratories at different levels must be well defined in the AIDS control program, and targets be clearly set by DOH.

(2) Provision of Equipment for AIDS research activities in the Research Institute for Tropical Medicine. In the discussion between the team and RITM members request was made for equipment for PCR and Flow Cytometry.

(3) Manpower training in laboratory diagnosis and related technologies. As for the training of the Filipino personnel, the cooperation and coordination of the Bureau of Research and Laboratory and RITM is desirable, as the former is responsible for public sector training and the latter for private sector training.

In addition to the domestic training, the "third country training program on AIDS" may be jointly offered by RITM and JICA to the neighboring countries in Asia and the Pacific, so the human resources and provided equipment can be utilized for training of researchers and health personnel in those countries.

(4) Provision of Equipment for AIDS Education

There are numbers of non-governmental organization active in AIDS education directed to the general public and various target groups. Measures to support these NGOs by providing with such equipment as personal computers, overhead projectors and video tape

recorders will enhance their effectiveness in raising public awareness and knowledge about AIDS.

The small-scale grant aid program administered by the Foreign Ministry through the Japanese embassy in the Philippines may be utilized for supporting NGOs.

Such Programs as above mentioned are to be implemented in the possible cooperation with the United States Agency for International Development (USAID), especially in the area of AIDS surveillance and Education Project.

For coordinated planning and smooth implementation of the project, it is necessary for JICA to dispatch a project formulation team which will work out the detailed plan with the counterparts in DOH and USAID.

５．提言

エイズ患者ＨＩＶ感染者が相対的に少ない状況において、比国ではＨＩＶ感染者の発生を抑制することが極めて重要な課題である。その対策として、

１）ＨＩＶ感染とエイズ発病状況の正確な把握の為の検査診断能力強化によるサーベイランス体制整備支援

２）エイズ対策関係者への研修強化

３）一般大衆及びリスクグループ等へのエイズ教育啓蒙運動の促進が有効な手段と認められる。

なお、血液事業におけるエイズ対策に関し、比国保健省が実施中の献血促進運動を支援する事とし、赤十字血液センターでＨＩＶテストが１００％実施されるようテストキット供与と関する検査技師研修等実施の可能性を検討する。

上記提言に基ずき、我が国では次の協力を具体化すべく今後ＪＩＣＡ現地事務所、大使館、比国関係省庁との協議を進行させる。

１）サーベイランス体制整備支援

今後エイズ対策を進めていく上で正確なサーベイランス結果が必要となる。そのためにも制度的なリスクグループのモニタリング、献血時の１００％スクリーニングが実施されるべきであり、従ってまずＨＩＶテストキットの供与による診断能力支援が可能である。供与の対象には、保健省内ＢＲＬ及び全国１５ケ所にあるregional lab.とする案、ＵＳＡＩＤが援助の対象とするsocial hygiene clinicsとする案、それに赤十字血液センターが可能であるが、再度調査のうえ協力妥当性を検討し選定する。上記テストキットは試薬等の消耗品が主であり供与期間を設定するが、ＵＳＡＩＤとの協調から同実施プロジェクトＡＳＥＰ終了の１９９７年までとする。供与については、我が国による協力終了時までに比国政府が我が国の協力を得つつ全国的なサーベイランス体制を整備し、テストキット購入を含むエイズ対策予算措置等の自立を達成する準備期間への支援と位置づける。協力開始に先立ち、供与の対象となる機関の施設、人員、テストキットの必要量：ＵＳＡＩＤ実施プロジェクトとの調整：赤十字血液センターの立場等を調査しテストキットの配布計画を策定する為の短期専門家を派遣し保健省と実施体制等の調整を行う。

2）エイズ対策関係者への研修強化

我が国は３年計画によりＨＩＶスクリーニングキットを供与し、サーベイランスネットワーク整備に協力することから、エイズ対策に係る人材の育成を合わせ実施し、協力の効果を高める。また、ＲＩＴＭより調査団に対してａ）第３国研修におけるエイズ特設コースの可能性、ｂ）第２国研修におけるエイズ研修コースの新規開設の提案がなされたが、今後具体的な案の提出を待ち検討する事とする。ＵＳＡＩＤの第３国研修への協調参加は、米国人講師派遣及びコース設置に伴う費用負担に関し可能性を引き続き追求することとする。

3）エイズ教育啓蒙活動の促進

同国においては、従来よりＮＧＯによる社会活動が活発であり、当該分野においても民衆に密着したＮＧＯの活動は極めて効果的に機能しており、同国でエイズ教育啓蒙活動の普及を進めていく上でＮＧＯの活用と支援は有効な手段である。ＵＳＡＩＤはＡＳＥＰというプロジェクトでＮＧＯに対して活動経費を支援しているが、我が国も米国が供与不可能なＩＥＣ機器（コンピューター、ＯＨＰ、ＶＣＲ）を補完的に供与しＮＧＯを支援することが可能であろう。尚、機器の供与は保健長官の助言もありＮＧＯの連合体を通じるアンブレラ方式が検討されよう。

② National HIV Surveillance Operations Manual

National HIV Surveillance Operations Manual

Department of Health
Philippines
March 1994

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INTRODUCTION

Human Immune Deficiency Virus (HIV) is the most devastating disease of the twentieth century and continues to spread unabated in most countries. According to the WHO, HIV has possibly already infected 8-10 million men, women and children worldwide and continues to grow at the rate of 5000 per day. The Philippines is not spared of HIV infection. The government estimates that 30,000 Filipinos now carry the AIDS virus, but many believe that this is a conservative figure. These people will probably all die of Acquired Immune Deficiency Syndrome (AIDS) within the next 10 years, putting a crushing burden on our society and reversing the benefits of development.

In 1992, the National HIV Surveillance System (NHIVSS) completed two surveillance studies in the cities of Baguio and Cebu. Results from the two studies indicate that HIV prevalence rate were below 1%. However, one cannot conclude that HIV seroprevalence is below 1% in the Philippines because HIV infection is primarily a disease of large urban areas and only one large urban area (Cebu) was tested. It will then be important that the succeeding rounds of HIV surveillance be focused on large and highly urbanized areas where higher seroprevalence is most likely to be encountered. Similarly, scarce resources should be focused on groups with high risk behaviors that warrant preventive interventions.

OBJECTIVES

A. Overall Objective

To provide timely early warning of increases in HIV infection or of high risk behaviors that may predispose the country to HIV infection.

B. Specific Objectives

1) to provide early warning of dangerous levels of HIV infection
2) to estimate the incidence/prevalence of HIV infection among surveillance groups (baseline appraisal);
3) to monitor trends in HIV infection;
4) to identify surveillance groups or subgroups and sites with higher and/or lower rates of infection;
5) to identify risky behavior patterns for HIV transmission;
6) to project future occurrence of HIV infections;
7) to provide information for prioritizing and evaluating intervention programs

Section I. Setting Up An HIV Surveillance System

The National HIV Surveillance Strategy is a systematic and regular collection of information on the distribution, and trends of HIV infection in the different high risks groups identified at a given time. This information can be used to develop, prioritize and direct effective education, interventions, and risk reduction activities. It can also be used to evaluate the effectiveness of the control and prevention strategies. It will be timely, simple, flexible, acceptable, sensitive, and representative.

1.1 Selection of Sentinel Groups

When the prevalence of HIV remains low, scarce resources should be focused on groups with the highest risk behaviours. Universally, high risk individuals include those persons who have multiple partners. Blood for HIV screening of these groups can be collected in Social Hygiene Clinics, establishments of work or in areas where they are commonly found. If IV drug use is prevalent or suspected to be, bloods samples can be collected in rehabilitation and treatment clinics of this risk group.

These groups warrant preventive interventions in their own right and represent the most cost-effective application of resources early in the epidemic. Sentinel groups or particular risk groups of the population shall be then selected according to the following criteria:

1. currently believed or known to be infected with HIV;
2. into which HIV is or may be spreading;
3. can be identified and accessed;
4. and whose behavior make them targets for HIV/AIDS prevention and control activities.

1.2 Sample Size of Sentinel Groups

It is important that each site be able to monitor the level and trend of HIV prevalence, since these values may differ substantially between sites. It is therefore required to calculate minimum sample sizes for each sentinel site. Sample sizes should be calculated to detect a 1% prevalance if possible, which requires 300 individuals per risk group. For groups that are difficult to access and collect, such as Freelance FCSWs or MCSWs, the target should be 100 individuals, which will allow detection of 5% prevalence.

1.3 Selection Inclusion/Exclusion Criteria for Sentinel Groups

The selection (interim) of surveillance groups for each sentinel site will be decided by the Technical Staff of the FETP National HIV Surveillance Unit.

A. **Injecting drug users (IDUs)** - are individuals who use or have used injectable drugs recreationally whether intravenous, subcutaneous, and/or intramuscular within the last 5 years.

Inclusion criteria:

a. IDUs who are attending treatment facilities (rehabilitation centers, detoxification centers, etc.) for drug abuse. They may be either residential or treated as out-patient.

b. IDUs outside treatment clinics who are encouraged/ advised to consult treatment centers (e.g. voluntary submissions, prisoners who are incarcerated because of possession or use of prohibited drugs)

Exclusion criteria:

a. IDUs who have not injected drugs during the past 5 years.

b. Re-attending IDUs in treatment centers whose blood has been extracted within the study period since it is likely that such patients have been previously enrolled as subjects.

To verify whether re-attending patients have already been enrolled in the study, subjects should be asked the date of the last visit to check whether blood has been extracted. When no medical record is available to prove the patients claim, blood should be extracted and subsequently enrolled as subjects.

B. **Male patients of STD Clinics** (MSTDs) - are men who consult private and government sexually transmitted disease (STD) clinics for treatment of STD.

Inclusion criteria:

a. men who are consulting private/government STD clinics for the treatment of STD.

b. they may be first time clients or re-attending clients.

Exclusion criteria:

a. re-attending male STD patients whose blood has been extracted within the study period since they are already considered enrolled in the study.

Again, re-attending patients should be asked the date of the last visit to check whether blood has been extracted. The patient is enrolled as subject if no medical record is available.

C. **Female commercial sex workers** (FCSWs) - are women who exchange sex for money and work in establishments for this purpose.

Inclusion criteria:

a. are those who work in establishments and exchange sex for money - whether regular workers or contractuals (dancers and models).

Establishments may include bars, casa, massage parlors, night clubs, beer houses, etc.

Exclusion criteria:

a. ancillary staff, such as cashiers and floor managers who do not engage in sex work.

D. **Male commercial sex workers** (MCSWs) - are individuals who exchange sex for money and work in establishments for this purpose.

Inclusion criteria:

a. men who work in establishments and exchange sex for money. The clients of the male CSW may be male or female.

b. all identified men who engage in sex in exchange for money and voluntarily agree to participate in the study (e.g. paid partners of MSMs).

Exclusion criteria:

a. Ancillary staff such as security guards, floor managers and other staff in the establishment who do not engage in sex for money.

Reminder: Male clients of male CSWs are eligible for inclusion in the "Men who have sex with men" surveillance group. They do not meet the inclusion criteria for male CSWs.

E. **Free lance FCSW (FLSWs)** - are women who exchange sex favors for money and do not work in establishments (streetwalkers)

F. **Men who have sex with other men** (MSMs) - are men who have sex with other men for their own pleasure.

Inclusion criteria:

a. men who negotiate sex with male commercial sex workers.

b. MSMs in establishments or gay venues such as gay bars, beauty parlors, dress shops or gay organizations.

c. all identified MSMs who voluntarily want to participate.

Exclusion criteria:

a. male commercial sex workers

1.4 Surveillance Site Selection

For each sentinel group to be included in the surveillance, accessible sites with sufficient attendees must be identified. Data from previous HIV prevalence assessments can be used to assist in the selection of sites. Selection of surveillance sites will then be based on the following criteria:

1. the number of HIV positive individuals identified in a particular area or known to come from the area;
2. availability of risk or sentinel groups;
3. a reliable laboratory is available to perform serologic tests for HIV;
4. geographical representativeness of the site; and
5. on-site staff must be willing to cooperate and be capable of conducting surveillance for at least 5 years.

1.5 SURVEILLANCE METHODS

A. *SENTINEL SURVEILLANCE GROUPS*

Injecting Drug Users (IDUs)
Female Commercial Sex Workers in establishments (FCSWs)
Free Lance FCSWs (FLSWs)
Men Having Sex with Men (MSM)
Male Commercial Sex Workers (MCSWs)
Male with STD (MSTDs)

B. STRATEGIES FOR COLLECTION OF DATA/SPECIMEN

I. Number of Samples and Method of Testing

Surveillance Group	Sample Size	Method of Testing
IDUs	300	Vol. anonymous
Male STD Patients	300	Anony. unlinked
FCSWs	300	Vol. anonymous
MCSWs	100	Vol. anonymous
MSMs	300	Vol. anonymous
FLSWs	100	Vol. anonymous

II. Method of Testing

1. Unlinked anonymous - this method tests blood drawn for other purposes for HIV antibodies without the subject's knowledge and with all identifying data removed. Thus, counselling cannot be provided.

2. Voluntary anonymous testing - the volunteers do not give identifying information although demographic and other information shall still be collected. The volunteer shall be assigned a code number which can be presented to retrieve results. Results shall be released only if the volunteer agrees to undergo counselling (please note: counselling shall be provided to volunteers whatever is the result). Entrance of selection and information bias shall depend on the credibility of the system for maintaining anonymity of the volunteer.

C. ACCESS TO THE RISK GROUPS

Risk groups will be accessed in their place of work or in places were are they are usually found as stated above. Table 1 summarizes where subjects are likely to be found and where data and specimen will be collected.

Table 1. Place of Access of High Risk Group
National HIV Surveillance System, 1993

Risk Groups	Place of Access
Female Commercial Sex Workers (FCSWs)	Commercial establishments
Male Commercial Workers (MCSWs)	Gay bars and gay venues
Men who have sex with men (MSMs)	Gay bars and sex venues
Male STD patient (MSTDs)	Private and gov't social hygiene and STD clinics
Injecting Drug Users (IDUs)	Rehabilitation clinics/centers
Free lance FCSWs (FLSWs)	Streets of trade

D. STEPS IN ACCESS AND DATA/SPECIMEN COLLECTION

1. Mapping

The purpose of mapping is to determine all possible collection sites where surveillance groups can be accessed as well as to get an estimate of the number of subjects/clients for the duration of the data collection period.

a. Injecting Drug Users (IDUs)

All treatment clinics providing services for IDUs will be identified. The average number of IDUs treated in the clinic per month will also be determined. If the total estimated number of IDUs in all the centers identified exceed the sample size, treatment centers can be randomly selected until the targeted sample size of IDUs is obtained. If the estimated number of subjects are less than the sample size, all potential subjects will be enrolled. IDUs' network of friends can also be potential sources of subjects.

A letter code will be assigned for each treatment clinic. During the mapping process, a point person in each treatment clinic should be assigned to be responsible of all the surveillance activities within the said clinic which include organizing/scheduling of data collection activities, advocacy, and briefing of potential clients. Orientation of the point person and other staff of the treatment clinic may be done during the mapping or may be scheduled at a later date.

b. **Male STD Patients** (MSTD)

All government and private STD/VD clinics in the surveillance site shall be identified and listed. The average number of male patients consulting for STD per month shall be determined (Follow steps in 1a). A letter code for each clinic shall also be provided.

Physicians will be encouraged to request for VDRL for all male STD patients. It must be emphasized that a portion of the blood tested for VDRL will be tested for HIV antibodies and that, the subject will not be told of HIV test and result. VDRLs may be offered to private STD Clinics to ensure and promote cooperation in data/specimen collection.

c. **Male and Female Commercial Sex Workers**

All establishments such as bars, casa, massage parlors, gay bars, etc will be identified. The number of CSWs (male or female) working in each establishments will be determined to estimate the number of eligible CSWs (See 1a for steps to take). A letter code will be assigned to each establishment where the subjects are accessed.

d. **Men who have sex with men**

All entertainment establishments or venues where MSMs can be found such as gay bars, beauty parlors, dress shops, gay organizations and through their network of friends will be located (See 1a for activities to undertake). The number of MSMs in each venue will be determined to estimate the number of subjects who will be recruited.

Gay venues will be assigned a consecutive letter codes. All MSMs in each venue will be identified and taken as subjects. During mapping, the manager or owner of each venue will be oriented on the objectives and activities of the surveillance after which pre-test counselling and data/blood collection of the MSMs will be scheduled.

e. **Free Lance FCSWs**

All areas (streets, plazas, recreation centers, piers) that are frequent ply routes of Free Lance FCSWs must be identified. Access may include their network of friend among FCSWs in establishments, pimps, policemen and their other contacts. A letter code will be assigned to each area where the subjects are accessed.

E. DATA COLLECTION

A. Pre-test Counselling

Pre-test counselling should be conducted before interview to make the subjects aware of the objectives of surveillance, give them assurance that testing is anonymous, explain the confidentiality of the testing process, the meaning of the test results, and the benefits of knowing their results personally. The procedure of data and specimen collection should then be explained and how they can avail of their test results.

Mass pre-test counselling may be conducted when the subjects are collectively gathered or may be given individually as the case may be.

B. Sampling (Recruitment of Subjects/Clients)

Recruitment of subjects shall be done "on-site". The surveillance team, composed of the interviewer, verifier and phlebotomist, will visit these sites (establishments, clinics, treatment centers, etc.) on a pre-arranged schedule. Subjects shall be enrolled sequentially as they voluntarily present themselves for interview.

For IDUs, the physician or the designated person will identify the eligible subjects. Patients will be enrolled sequentially as they visit the centers until the sample size is obtained.

For Male STD patients where testing is unlinked anonymous, all patients with VDRL testing shall be enrolled sequentially as blood samples are taken.

C. Coding

City/Surveillance group/Collection Site Code

The City/Surveillance group/Collection code situated in the right hand corner of each form are four blocks. The first two blocks shall bear the the city code, the third block the surveillance group code, and the fourth block the collections site code.

The city codes for each surveillance site have been previously determined as follows:

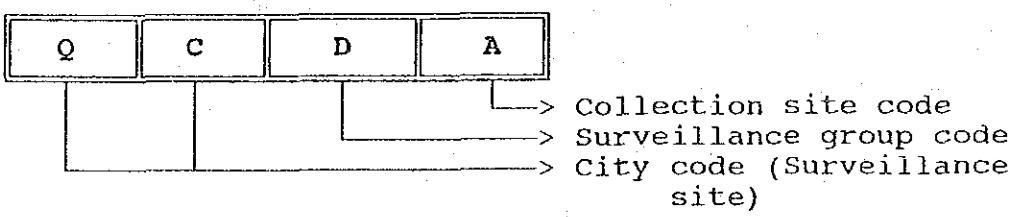
Quezon City - QC
Cebu City - CC
Davao City - DC

The surveillance group code, previously determined shall be entered in the third block as follows:

Injecting drug users - D
Male STD patients - S
Female Commercial Sex Workers - F
Male Commercial Sex Workers - M
Men Who Have Sex with Men - H
Free Lance FCSWs - L

The fourth block shall contain the letter code of the collection site (treatment centers, establishments, etc) previously assigned during the mapping.

Example: City/Group/Collection Site Code for IDUs



Client Codes - shall be assigned sequentially for each subject as a three digit number starting from 001 and so on.

D. Report Forms

Data Collection Form (Form 1)

It is important that accurate information are elicited from the clients. The most effective way is to get an idea of the common jargon that the subjects are familiar with in their place of work.

The information to be collected are the date of interview, middle initial, age, sex, civil status, number of sexual partners per week, condom use, history of IV Drug use in the last 5 years, number of times a week injecting drugs, and history of blood transfusion the last 5 years.

In addition to the information above, for CSWs, the place of work, and the presence or absence of health card shall be asked.

All the data collection form will be forwarded to local sentinel manager for collation in the summary form.

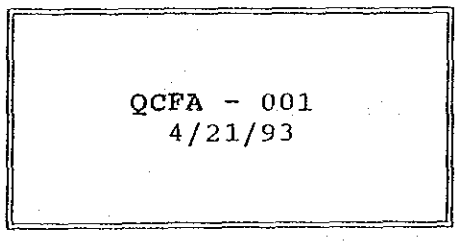
Blood Extraction Form

The blood extraction form shall be accomplished by the interviewer except for the date of blood collection that will be accomplish by the phlebotomist.

Client Cards

The purpose of the client card is to maintain confidentiality. A client card will be issued to all subjects except to male STD patients. The client card shall bear the city, surveillance group, collection site code, and the date of the interview and blood collection. Patients must be instructed to keep the card for them to get their test result. Before issuing the client card, it must be signed by the interviewer.

Example of a Client Card for FCSWs



VDRL Request Form

Since MSTDs will be tested anonymous unlinked, all subjects will be tested for VDRL. Portion of the blood sample for VDRL testing will be tested for HIV antibodies. All STD patients shall be issued a VDRL request form where the patients name, age, and the date of blood collection is written. It should be emphasized that the subjects will not be told that their blood samples will be tested for HIV.

Example of a VDRL request form

To: SHC Date_____

Name _____ Age ___

Request for VDRL

Physician

Summary Report Form (Form 2)

After laboratory testing, results will be entered in the summary form. The summary form will contain all the information collected and the laboratory results. The form will initially be accomplished by the phlebotomist to fill in the client code, and the date of collection. This will also serve as the roster of specimen collected for the day. It will be forwarded to the testing laboratory with the data extraction form. After accomplishing the form it is forwarded to the local sentinel site manager.

It is advisable to have the forms and client cards already pre-coded before going to the collectionsite to save time and avoid confusion in labelling.

F. DATA FLOW and REPORTING

1. Data collection forms: All Data collection forms will be forwarded by the interviewer to the head of the local sentinel site team.

2. For female CSWs, male CSWs, and MSMs where subjects were interviewed in groups, submission of the collection forms can be done by batches.

3. For the IDUs, a designated sentinel site personnel collects the forms from the interviewer in the clinics/centers and forwarded to the head of the local sentinel site for data consolidation.

4. For each site, data collection, entry and analysis will be under the joint supervision of the head of the local sentinel site and FETP.

5. The Site Managers will review the forms to be sure they are filled out correctly. If there are errors, the site manager will contact the interviewers so that they can be corrected. If it is impossible to correct the form, that subject will be excluded and another subject will be collected to take his place.

6. The Local Site Manager will identify an individual to enter the data into the Computer. If there is no computer or person capable of entering the data, these will be provided by FETP.

   a. Data files will be kept on floppy disks, which will be kept in secure places.
   b. At the end of each session of entering data, the data entry clerk will make a copy of the data file and give it to the Site Managers, so there will always be 2 copies of the data.

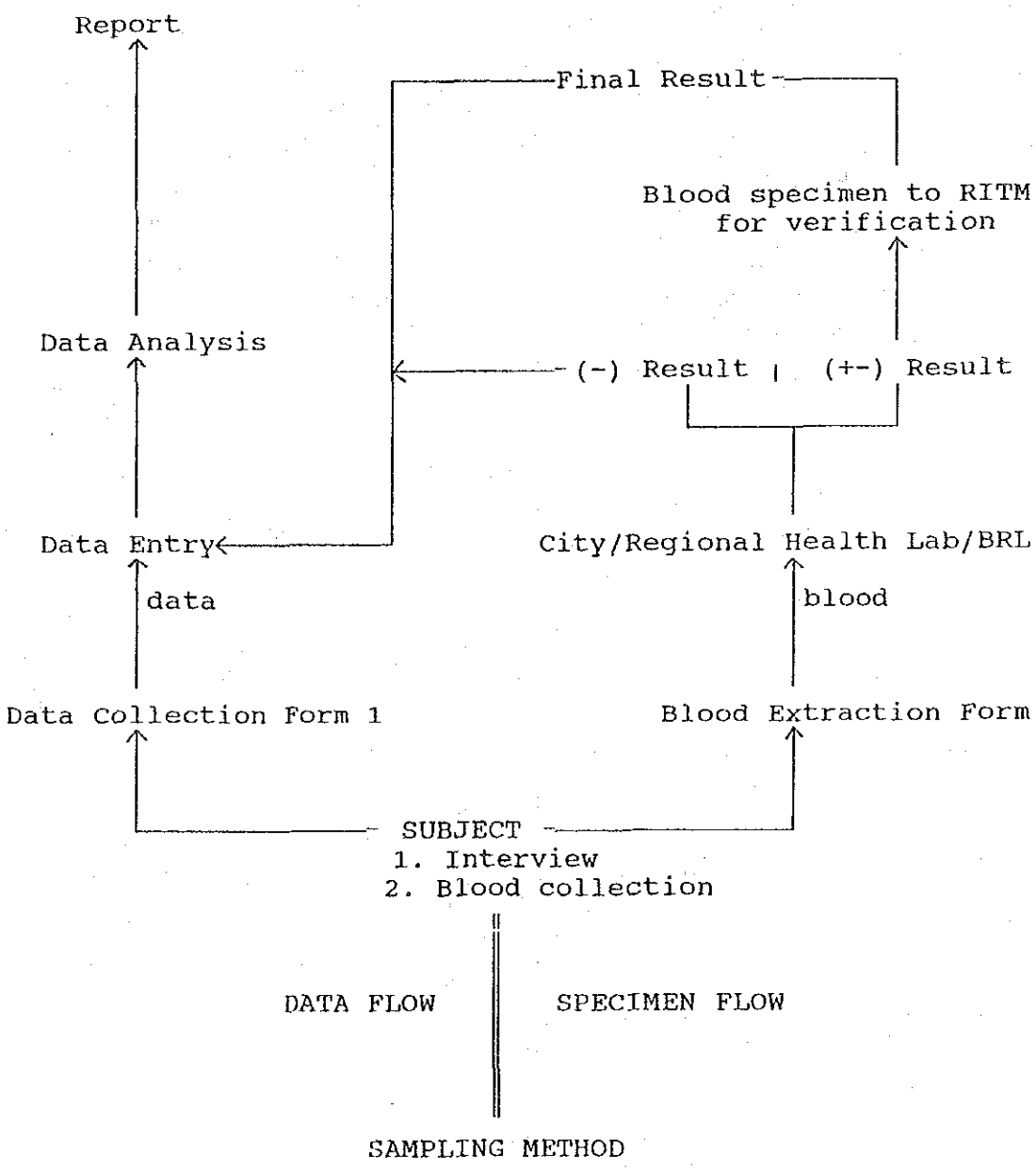
7. Site Managers will review the data files at least once each week to confirm that it is being properly entered.

8. At the end of the data collection period:
   a. copies of the data files will be provided to National HIV Surveillance System (FETP).

   b. The National HIV Surveillance System (FETP) will review local report, consolidate the files and produce a National Report.

   c. All reports will be submitted to the program director of the National HIV Surveillance System (FETP) and discussed with Asst. Sec. Reodica (OSC) and NAPCP before release.

FLOW OF DATA/SPECIMEN



G. SPECIMEN COLLECTION, HANDLING AND TRANSPORT to TESTING LABORATORY

1. Blood Extraction (at the collection site)

1.1 The blood extraction form is detached and the client is directed to the phlebotomist (sentinel medical technologist) or a verifier (also a member of the surveillance team).

1.2 The phlebotomist or the "verifier" shall verify the concordancy of the codes in the blood extraction form and client card. A blood collection tube is then labelled with the same codes as in the blood extraction form and date of blood extraction. The client code and the date of collection is entered into the summary form which also serves as the roster of specimen collection.

1.3 A 5.0 ml of blood is drawn by the trained phlebotomist. Where blood extraction may be staggered, as in IDUs attending treatment clinics, the nurse or the attending physician shall perform the blood extraction.

Note: Personnel who shall extract blood are advised to undergo training in phlebotomy (if necessary) to avoid:

1. specimen hemolysis
2. undue discomfort to the clients
3. accidents like needlestick injury

1.4 Safety Precautions during specimen collection should be practised.

1.4.1 Wear gloves during blood extraction, handling, and transport of specimen.

1.4.2 Collect blood samples with **LAB MAT IN PLACE.**

1.4.3 Never MANUALLY RECAP NEEDLES. "Scoop" needle caps if it is necessary to recap to prevent any accidental exposure.

1.4.4 Discard needles in puncture resistant containers (e.g. soft drink cans). Seal opening of soft drink can with several layers of masking tape. Label can with **"CONTAMINATED".**

1.5 After blood extraction, the phlebotomist affixes initials on the client and the blood extraction form.

1.6 A member of the surveillance team shall see to it that a blood sample is drawn from every client after interview.

1.7 For male STD patients, the physician or a sentinel site phlebotomist extracts blood for VDRL testing. The blood extraction tubes should be labelled with the name of the patient and the date of specimen collection. The blood samples are then referred to the Social Hygiene Clinic for VDRL testing with the corresponding VDRL request form.

1.8 Procedures for Decontamination and Disposal:

1.8.1 For **"Combustibles"**

a. Discard/Dispose all contaminated materials (i.e. gloves, cotton, lab mat sheets, etc..) in a trash (biohazard) bag.

b. Secure trash bags tightly with enough air space. Label bag with **"BIOHAZARD" or "CONTAMINATED".**

c. Endorse contaminated materials to responsible personnel for appropriate disposal.

d. Burn in a designated and secured place within the hospital or city health grounds.

1.8.2 For **"Sharps"**

a. Sealed puncture-resistant cans with used needles soaked in Sodium Hypochlorite can be disposed in two ways:

1) through incineration in hospitals or city health facilities where a functional incinerator is available;

2) by burying in a designated and secured area in the hospital or city health grounds Trash bag - incinerate

Note: To avoid possible reaction if Sodium hypochlorite solution with organic substances present in moist/wet ground leading to the production of toxic, non-environmental friendly substances, the site for burying should be on a dry location.

2. Specimen Handling and Transport (from the collection site to the testing laboratory)

2.1 The specimens should be placed in a test tube rack to maintain them in an upright position and transported in a carrier or collection bag strong enough to protect the contents from physical damage while in transit.

2.2 Submit specimens to the Regional Health/City Health testing laboratory/BRL together with the summary form (Form 2) and the blood extraction forms. The forms should be protected from getting contaminated with the specimen.

2.3 The summary form is countersigned by the personnel in the testing laboratory upon receipt of the specimen.

2.4 Keep specimens refrigerated until processed. If possible serum should be separated within 24 hours to avoid hemolysis.

2.5 For specimens collected from male STD patients:

a) Transfer at least 1.0 ml of serum to a cryogenic vial labelled with the age of the patient and date of collection.

b) Keep refrigerated until transported to the Regional Testing Laboratory.

c) The medical technologist in the Regional Testing Laboratory assigns the client code sequentially and fills up duplicate copies of Form 2, entering the client code, date of collection and age.

H. HIV ANTIBODY TESTING

HIV Antibody Testing shall be performed in the Regional Health Laboratory in Davao; in the City Health Laboratory in Cebu City, and in BRL for Quezon City.

The serum pooling method for HIV antibody testing using the Particle Agglutination Test will be employed. Briefly, individual samples are grouped into batches of 5 and tested as one. The components of a reactive batch or pool are retested. Reactive or equivocal pool(s)and its components are sent to the Research Institute for tropical Medicine (RITM) for confirmation. Results of confirmation shall be forwarded to the Local Sentinel Site Manager and to the Central Office Site Manager if necessary.

I. SERUM POOLING GUIDELINES for HIV ANTIBODY TESTING

The following guidelines must be followed precisely to minimize loss of test sensitivity, validate and monitor the technique and so provide assurance as to the effectiveness of the procedure and the reliability of the results. It is therefor necessary that documentation of specimens as well as the pooling and testing procedures be carefully monitored.

1. DOCUMENTATION: Record serum samples by surveillance group in the Laboratory Form 3: Laboratory Roster, entering the specimen I.D. and date of specimen collection. Individual sera should be grouped in batches of 5 and assigned a Pool I.D. number Bracket groupings. In case where there are only 2 - 3 or 4 serum remaining (i.e end of collection), group these samples appropriately and assign a Pool I.D. number. The Pool I.D. number should bear the city code, the surveillance group code and the pool number.

   Example: QCSP001

City Code	Surv. Grp. Code	Pool Number
QC	S	P001

   Where: QC - Quezon City S - Male STD Patient

2. POOLING PROCEDURE

   2.1 Allow samples to clot fully. Avoid samples which are grossly lipemic, hemolyzed or contaminated. Such samples should be tested as individual samples. Do not include in the pool.

2.2 Label the necessary vials with the appropriate specimen I.D. number and date of collection or pool I.D. number and date of pool preparation. Use clean sterile vial.

2.3 With a micropipette, dispense 100 ul of the individual sera into the corresponding labelled pooling vial, 5 sera per pooling vial. Mix each pool thoroughly. Check with Laboratory Form 3 (see Annex) while dispensing sera to ensure correct pool components. Use sterile tips. Likewise prepare a pool of Pool QC panel in the same manner as the samples everytime the samples are processed (i.e., pooled before testing). Indicate date on Pool QC vial.

2.4 Transfer individual serum samples into appropriate vials. Use sterile pasteur pipettes.

2.5 In situations where a pool of 5 individual samples could not be made yet, transfer any available sera into its appropriate individual vial to prevent hemolysis on standing. Keep refrigerated up to 5 days. Otherwise, freeze (preferably at - 20 C if available) until pools can be prepared.

2.6 Store individual and pool samples in corresponding cryoboxes according to the surveillance group from where the samples were collected.

2.7 Freeze individual samples. Pooled samples may be kept refrigerated if HIV testing will be performed within 5 days. Otherwise, freeze until tested.

3. ASSAY PROCEDURE

3.1 Prepare the necessary reagents and materials as in the normal manner. Dilute the gelatin particles according to the manufacturer's instruction.

3.2 Select the samples to be tested including the Pool QC vial. Mix each pool prior to testing.

3.3 Prepare testing protocol in the Laboratory Form 4 Laboratory Protocol (See Annex). Record the plate identity and the individual well number for the kit positive control, Pool Quality Control (QC) sample and the pool(s) to be tested. Record date of testing, the name of the technologist number/date of expiry and date of testing.

3.4 Proceed with testing following exactly the PA procedure stated in the kit instruction (Annex)

3.5 Record results in the testing protocol (Lab Form 4).

3.6 Retest individual samples from reactive and equivocal pools following the pooled serum HIV testing strategy:

3.6.1 Select the individual sample components of the reactive or equivocal pools. Mix prior to testing.

3.6.2 Prepare testing protocol as in 3.3

3.6.3 Perform assay as in 3.4 Omit Pool QC sample in this step.

3.6.4 Record results.

3.7 Send reactive/equivocal pool(s) and individual components to RITM. This should be accompanied by Lab Forms 3 and 4 indicating the initial screening result.

3.8 Freeze any sera remaining after tests are completed. These sera (with accompanying Lab. Form 3) will be retested/used for quality assurance purposes. (See section 6.4)

3.9 Complete the necessary documentation to enable release of the results, i.e. Lab Form 3 and Summary Report Forms. Countercheck all entries before submitting results to the sentinel site manager. Keep a duplicate file for quality assurance purposes.

II. HANDLING AND TRANSPORT OF SPECIMENS TO RITM for Confirmatory Testing.

4.1 Make sure the specimen vials are tightly capped. Secure cap with parafilm.

4.2 Reactive and individual components should be placed in a double plastic bag with absorbent material (tissue paper or cotton).

4.3 Samples for quality assurance purposes should be placed in corresponding cryogenic boxes. Place box in a plastic bag.

4.4 Samples should be accompanied by Lab Form 3. Do not forget to enter your LABORATORY CODE. Lab. Form 3 should be sealed in a separate plastic bag and wrapped around or attached firmly to the specimen box or bag.

4.5 Transport/send to RITM in an insulated carrier (Styrofoam box) containing ice packing.

4.6 Arrival at RITM should be planned to avoid weekends and holidays. Otherwise, please give advance notice.

III. REPORTING of HIV TEST RESULTS

5.1 Results of HIV testing should be kept CONFIDENTIAL at all times and should only be reported to AUTHORIZED personnel.

5.2 All forms should be kept in a secured place. Access should be limited only to laboratory personnel involved in the surveillance programme.

5.3 Relay any available results (Summary Report Form 2) to the sentinel site manager as soon as possible regardless of pending supplemental (confirmatory) test results.

5.4 Results of confirmation will be reported to the testing laboratory.

IV. LABORATORY QUALITY ASSURANCE

6.1 Pool Quality Control panel for the pooling method will be provided by RITM.

6.2 Records and testing procedure will be reviewed during supervisory visits by RITM and/or BRL personnel.

6.3 A serum pooling proficiency panel will be sent for testing by RITM. The panel should be treated in the usual/routine the pooled serum technique is being carried out under normal conditions. The testing instructions will accompany the panel.

6.4 Selected pools and individual components will be retested at RITM. The procedure for selecting these pools is as follows:

6.4.1 Calculate the number of pools (to be selected) equal to 20% of the total pools prepared for each surveillance group within a collection period of two weeks. That is:

Total # of pools x 20% = No. of selected pools

Example: 30 pools x .20 = 6 pools

6.4.2 Select pools:

$$\frac{\text{Total \# of pools}}{\text{No. of selected pools}} = n^{th} \text{ eligible pool}$$

Example: $\frac{30}{6}$ pools = 5

Therefore, pick out every 5th pool and its corresponding components.

6.4.3 Send to RITM according to Section 4.

6.5 Reactor rates for pooled and individual samples will be monitored using Lab. Form 5: Serum Pooling Monitoring Form (See annex). This form will be submitted to RITM together with the selected pools/component for analysis.

6.6 Based on the results of Quality Assessment, BRL shall provide retraining of laboratory personnel as necessary.

V. GUIDELINES for LABORATORY SAFETY and PRECAUTION in HIV TESTING

HIV can be isolated from types of body fluids, hence exposure to these fluids places laboratory workers at risk. The relative risk of exposure vary for each work place setting. HIV infection is not as easily contracted outside its major routes of transmission. The US Centers for Disease Control recommends the use of "UNIVERSAL PRECAUTIONS" which emphasize that all patients, blood and blood products, and other body fluids should be treated as potentially infectious regardless of the lack of knowledge on their HIV serostatus. Such a practice would greatly limit the possibility of HIV acquisition via exposure to an individual with an undetectable or undocumented HIV infection. The following are among those outlined in the guidelines:

1. Gloves should be worn whenever handling or obtaining specimens of any kind.

2. Laboratory gowns/coats should be worn as protection from splashes of any biological material. They should not be taken to office areas (e.g. cafeteria, etc.).

3. Masks, protective eye wear or face shields should be worn to protect exposure of mucous membranes in the mouth, nose, eyes whenever aerosolization or splattering of blood is anticipated.

4. Any cut or abrasions in the skin should be covered with a waterproof dressing to prevent direct contact with human blood, body fluids or tissues.

5. Dispose needles and other sharp objects in puncture resistant containers situated near the work area. Never MANUALLY recap, bend or break a needle. If recapping is necessary to prevent accidental exposures, use forceps. However, extreme precaution should be taken.

6. Specimens should be transported in well-constructed containers, e.g. enamel trays, test tube racks, etc. Specimens for transport between institutions (referral) should be packed and labelled clearly, double bagged or placed in a second leak-proof, puncture resistant container.

7. Wash hands in between patients, after removing gloves, performance of tests, before leaving the laboratory or as needed. Soap and water or antiseptic hand washes are appropriate. Wash hands and any other surfaces of the body splashed with blood or other body fluids as soon as possible.

8. All contaminated materials used in laboratory tests should be decontaminated. (See below decontaminated procedures).

9. Laboratory work surfaces should be decontaminated with an appropriate chemical germicide after a spill, after work is completed or whenever necessary.

10. Diagnostic equipment which has been contaminated withblood fluids should be decontaminated and cleaned.

The following procedures for decontamination may be employed as appropriate:

1. Immersion in an approved chemical disinfectant. **Sodium hypochlorite (household bleach)** - is recommended for general disinfection because it is effective and cheap. Sodium hypochlorite is used freshly prepared according to the manufacturer's instructions.

2. Boiling for 30 minutes.

3. Autoclaving

4. Incineration

11. Never Pipet by mouth. Use mechanical pipetting devices.

12. Centrifuge specimens with caps tightly secured, and never as open tubes.

13. Wastes should be disposed in properly labelled disposal bags. Biohazard labels and instructions for final disposal should be clearly indicated. Housekeeping personnel should be well instructed about safety-related issues.

14. All accidents of exposure to blood and body fluids, punctures, etc., should be reported to the supervisor for appropriate action in accordance with the infection control policy of the institution.

15. Continuing education, training programs, review of guidelines on laboratory safety and precautions are essential.

Section II. Data Analysis and Presentation of Results

The purpose of analysis and presentation is to make it easy for decision makers to understand the results. Information must be presented simply and clearly. It is especially important the reader understand limitation in the data (such as bias) so they don't overinterpret the report.

Mechanics:

Data entry : The National HIV Surveillance System (FETP) will provide copies of EPINFO and programs for the data entry and analysis. If a site has access to a computer, data can be entered as it is being collected. This allows site personnel to catch and correct errors in the forms. If this is not possible, FETP will enter the data. Diskettes of raw data should be submitted to FETP at the end of data collection.

Analysis: If possible, results can be tabulated and analyzed in each site. The Data Management Unit can assist if this is not possible. The Data Management Unit will tabulate and analyze the national data.

Reports: The local personnel and FETP will review the table and prepare a brief report. The first name on the report should be the leader of the local team. Reports should be submitted FETP and must be approved by Dr. Manuel M. Dayrit before released.

The FETP will produce a national report, which must be approved by the program manager prior to released. It will be addressed to Assistant Secretary Reodica and signed by Assistant Secretary Dayrit and " The HIV Surveillance Group". Name of those who contributed to the report will be listed in the annex.

Use of report: Report are part of the public domain and may be quoted by anyone. It is requested that the DOH HIV Sentinel Surveillance System be acknowledged when this is done.

Access to Raw Data: Individual may wish to use raw data for their own analysis. Raw data belongs to the Department of Health. The entire data set will be made available in EPINFO format to anyone who contributes to the HIV Surveillance System. It can be also provided in Dbase III or ASCII formats if desired. Raw data may be provided to other institutions only with the approval of the Technical Staff of the National HIV Surveillance System (FETP).

Summarizing results:

Rates will be calculated so that results are in small whole number whenever possible. For example, 2 positive out of 2500

test would yield a seropositivy rate of 8 per 10,000 test.

Data from type A Surveillance group such as MSMs and surveys of female CSWs will be presented as proportions. When several of these groups are summarized, they will be presented as medians and ranges.

Data from type B surveillance group including STD clinics, for Free lance FCSWs, and IDUs in rehabilitation clinics will be presented as prevalence rates with confidence intervals if possible. If prevalence are low, LQAS interpretation will be used. If it is possible to get adequate number of unbiased sample, result will be presented in the format for the Type A Groups.

Format of Reports

Interpretation: Each report will begin with a few brief sentences interpreting the result.

Demographics: This section will include ages, occupation, and other general information describing the individual in each group.

Behaviors: This section will describe the high risk behaviors for each group.

Comparisons: This will include relevant trends in time, comparisons between groups or sites.

Recommendations: Each report will contain a few focused, concrete recommendation for action. These must be based on the result.

Presentation of Information

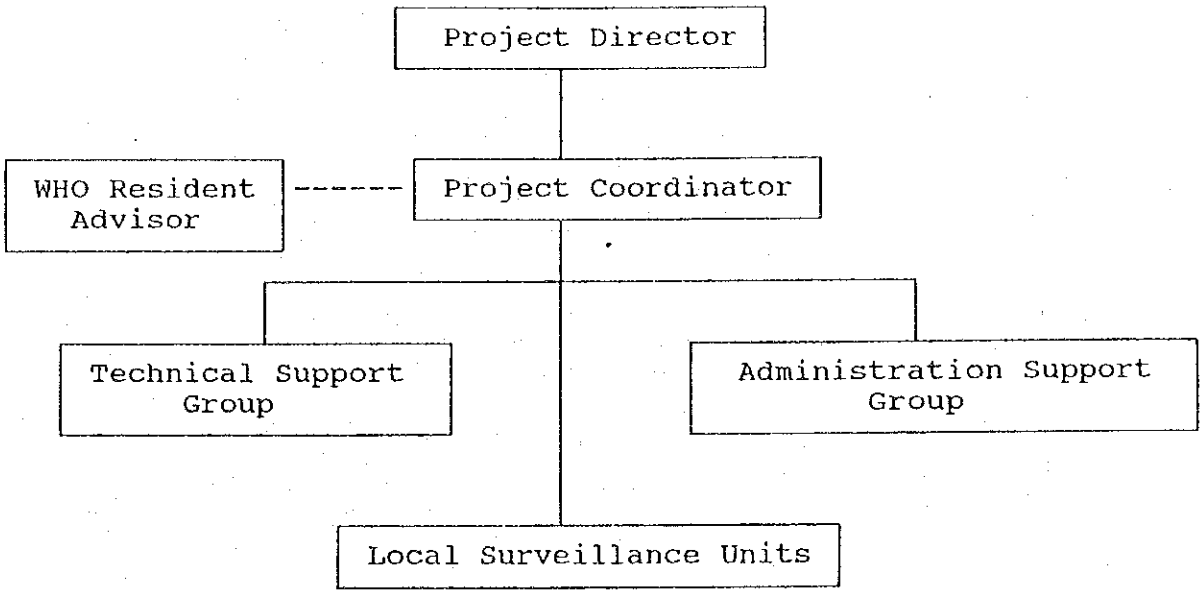
Text: Simple sentences are the clearest way to present a few number.

Tables: Simple tables will be used to summarize data. It is important to remember that tables of may rows and columns are difficult to understand.

Graphs: will be used to show trends and make comparison.

Analyzed results will be send back to the local surveillance manager, Secretary of Health, NAPCP, and other involved agencies.

3.1 HIV Surveillance Structure



3.2 Roles and Responsibilities Within the HIV Surveillance Unit

Director

- Oversee and direct the operations of the National HIV Surveillance
- Acts as spokesperson for the National HIV Surveillance

WHO Resident Advisor

- Provide an overall coordinative focus within the DOH for the National HIV Surveillance System implementation activities.
- Participate with the Program Director of FETP and others in the overall planning, organization, implementation, monitoring and evaluation of the National HIV Surveillance System and associated activities.
- Participate with the Program Director of FETP and others in the development of the annual operational plan which will include detailed activity schedules and budget for approval by USAID and DOH.
- Assist the staff of FETP in the preparation and submission of budget requests for local costs, ensuring the timely availability of operational funds for surveillance activities.
- Participate with the Program Director and others in the development of technical specifications for equipment and other commodities to be procured under the GRANT, ensuring their timely procurement through the WHO supply unit.
- Participate with the Program Director and others in assessing the need for training, technical assistance and operations research to meet the objectives of the National HIV Surveillance Strategy, and to ensure that these requirements are met.
- Ensure the implementation of a quality assurance program designed to maintain accuracy, validity and reliability of the data obtained through the National HIV Surveillance System.
- Assist the staff of FETP in the organization and facilitation of Management and Technical Reviews to be held subsequent to each six monthly round of HIV surveillance. These reviews will identify restraints and resolve management and technical issues relating to surveillance implementation.
- Participate with the Program Director and others in the analysis of the surveillance data and the preparation and dissemination of surveillance reports.
- Participate in the preparation of required progress and financial reports.
- As Technical Advisor, ensure the implementation of human safety assurance program adhering to the WHO safety guidelines for handling potentially infectious materials.

- Undertake liason responsibilities with other units of the DOH and other agencies both government and non-government with regard to the overall planning, development, implementation and evaluation of HIV surveillance activities.

Program Coordinator

- Oversee the implementation of the National HIV Surveillance System at the sentinel sites
- In collaboration with the local point persons, oversee the negotiations undertaken with the sentinel groups
- Assist the surveillance site in accessing, mapping, recruitment, random selection of groups
- Assure availability of logistic requirements of the sentinel sites
- Assure compliance of protocols
- In collaboration with local point persons, initiate and maintain close liason with local government officials affected by the sentinel sites
- Ensure that serum from all sentinel sites has been collected and tests results have been forwarded to the National HIV Surveillance System (FETP)
- Oversee the submission of test results and field reports
- Oversee data management at the surveillance site
- Assist in the preparation of a report on the findings of each round of surveillance
- Coordinate the functioning of the surveillance site with regard to the location of the sentinel groups and collection of serum for testing
- Liase with the local surveillance unit on the location of sentinel groups and all aspects of testing these groups
- Coordinate, in collaboration with local point persons, the activities of the local surveillance units
- In collaboration with the technical group, train local surveillance unit personnel
- Supervise the data collection, handling, storage and transport of serum specimens

Technical Support Group

- Advise the Director and Coordinator on the scientific aspects of the surveillance system
- Set surveillance goals
- Evaluate the achievement of surveillance goals
- Review technical aspects of the HIV surveillance system and determine scientific changes appropriate
- Prepare policy briefs relating to scientific aspects of the surveillance system
- Design and review survey methodologies

- Determine the definitions of and criteria for selection of surveillance groups, sites and sizes
- Determine the definitions of and criteria for selection of special sero-surveys
- Determine the data to be gathered via the surveillance system
- Receive from the regional laboratories or Social Hygiene clinics the completed data forms and results
- Undertake the physical management of the surveillance data
- Analyze result data from the surveillance sites and prepare report on findings of each round of surveillance
- Determine future directions of the HIV Surveillance with regards to sentinel groups, sites and sizes

Administrative Support Group

- Oversee the day-to-day administrative aspects of the National HIV Surveillance System
- Oversee the provision of supplies and equipments to the surveillance sites
- Oversee the receipt of tests results from the Regional Laboratories to the Central Office
- Oversee the transport of serum for confirmatory testing
- Oversee the quality requirements of the HIV Surveillance System
- Assist in the preparation of a reports on findings of each round of surveillance
- In collaboration with the Site Managers, prepare the annual budget for the surveillance system
- In collaboration with the Technical Group, undertake the preparations and convene the semi-annual training workshops for the surveillance implementation

The administration component shall undertake the following tasks within the surveillance system:

1. Acquisition of funds
   - preparation of budget

2. Day-to-day administrative aspects of the National HIV Surveillance System
   - preparation of Department Circulars
   - preparation of vouchers (travel, monetary, etc)
   - preparation of logistics, documentation of meetings

3. Transport of personnel/equipment/supplies/specimens between the Central Office and the sentinel sites.

4. Production of instruments
   - field guidelines/manuals/forms for data collection and reporting

5. Provision of logistics requirements of all laboratories

6. Reporting
   - logistiscs for laboratory and Technical Group
   - supply of reports to NAPCP for IEC/media/policy makers
   - feedback results to the surveillance sites
   - linkages

7. Arrangement of workshops/provisions of secretariat
   - development and orientation of manual of procedures

8. Personnel
   - recruitment/selection/assignmentto surveillance sites
   - preparation of job descriptions
   - preparation of per diem/salaries

Local Surveillance Units

Undertake the day-to-day activities of the sentinel surveillance system

These activities include:

1. Preparation
   - mapping of the surveillance groups
   - orientation of staff
   - acquisition of logistics
   - orientation , networking, and coordination of influentials (LGU, establishments, private STD clinics, hospitals, gay organization)

2. Identification of sentinel groups

3. Involvement in sampling
   -liase with the Social Hygiene Clinics and/or Regional Laboratories concerning collection and testing

4. Data collection
   - collection of the required sera within the timetable for collection

5. Reporting
   - deliver field reports to the central office during and following the completion of each round of surveillance

6. Consultative Workshops
   - participate in the development and conducting of semi-annual surveillance workshops

③ National Surveillance Operations Manual

National HIV Surveillance Operations Manual

Department of Health
Philippines
March 1994

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INTRODUCTION

Human Immune Deficiency Virus (HIV) is the most devastating disease of the twentieth century and continues to spread unabated in most countries. According to the WHO, HIV has possibly already infected 8-10 million men, women and children worldwide and continues to grow at the rate of 5000 per day. The Philippines is not spared of HIV infection. The government estimates that 30,000 Filipinos now carry the AIDS virus, but many believe that this is a conservative figure. These people will probably all die of Acquired Immune Deficiency Syndrome (AIDS) within the next 10 years, putting a crushing burden on our society and reversing the benefits of development.

In 1992, the National HIV Surveillance System (NHIVSS) completed two surveillance studies in the cities of Baguio and Cebu. Results from the two studies indicate that HIV prevalence rate were below 1%. However, one cannot conclude that HIV seroprevalence is below 1% in the Philippines because HIV infection is primarily a disease of large urban areas and only one large urban area (Cebu) was tested. It will then be important that the succeeding rounds of HIV surveillance be focused on large and highly urbanized areas where higher seroprevalence is most likely to be encountered. Similarly, scarce resources should be focused on groups with high risk behaviors that warrant preventive interventions.

OBJECTIVES

A. Overall Objective

To provide timely early warning of increases in HIV infection or of high risk behaviors that may predispose the country to HIV infection.

B. Specific Objectives

1) to provide early warning of dangerous levels of HIV infection
2) to estimate the incidence/prevalence of HIV infection among surveillance groups (baseline appraisal);
3) to monitor trends in HIV infection;
4) to identify surveillance groups or subgroups and sites with higher and/or lower rates of infection;
5) to identify risky behavior patterns for HIV transmission;
6) to project future occurrence of HIV infections;
7) to provide information for prioritizing and evaluating intervention programs

Section I. Setting Up An HIV Surveillance System

The National HIV Surveillance Strategy is a systematic and regular collection of information on the distribution, and trends of HIV infection in the different high risks groups identified at a given time. This information can be used to develop, prioritize and direct effective education, interventions, and risk reduction activities. It can also be used to evaluate the effectiveness of the control and prevention strategies. It will be timely, simple, flexible, acceptable, sensitive, and representative.

1.1 Selection of Sentinel Groups

When the prevalence of HIV remains low, scarce resources should be focused on groups with the highest risk behaviours. Universally, high risk individuals include those persons who have multiple partners. Blood for HIV screening of these groups can be collected in Social Hygiene Clinics, establishments of work or in areas where they are commonly found. If IV drug use is prevalent or suspected to be, bloods samples can be collected in rehabilitation and treatment clinics of this risk group.

These groups warrant preventive interventions in their own right and represent the most cost-effective application of resources early in the epidemic. Sentinel groups or particular risk groups of the population shall be then selected according to the following criteria:

1. currently believed or known to be infected with HIV;
2. into which HIV is or may be spreading;
3. can be identified and accessed;
4. and whose behavior make them targets for HIV/AIDS prevention and control activities.

1.2 Sample Size of Sentinel Groups

It is important that each site be able to monitor the level and trend of HIV prevalence, since these values may differ substantially between sites. It is therefore required to calculate minimum sample sizes for each sentinel site. Sample sizes should be calculated to detect a 1% prevalance if possible, which requires 300 individuals per risk group. For groups that are difficult to access and collect, such as Freelance FCSWs or MCSWs, the target should be 100 individuals, which will allow detection of 5% prevalence.

1.3 Selection Inclusion/Exclusion Criteria for Sentinel Groups

The selection (interim) of surveillance groups for each sentinel site will be decided by the Technical Staff of the FETP National HIV Surveillance Unit.

A. **Injecting drug users** (IDUs) - are individuals who use or have used injectable drugs recreationally whether intravenous, subcutaneous, and/or intramuscular within the last 5 years.

Inclusion criteria:

a. IDUs who are attending treatment facilities (rehabilitation centers, detoxification centers, etc.) for drug abuse. They may be either residential or treated as out-patient.

b. IDUs outside treatment clinics who are encouraged/ advised to consult treatment centers (e.g. voluntary submissions, prisoners who are incarcerated because of possession or use of prohibited drugs)

Exclusion criteria:

a. IDUs who have not injected drugs during the past 5 years.

b. Re-attending IDUs in treatment centers whose blood has been extracted within the study period since it is likely that such patients have been previously enrolled as subjects.

To verify whether re-attending patients have already been enrolled in the study, subjects should be asked the date of the last visit to check whether blood has been extracted. When no medical record is available to prove the patients claim, blood should be extracted and subsequently enrolled as subjects.

B. **Male patients of STD Clinics** (MSTDs) - are men who consult private and government sexually transmitted disease (STD) clinics for treatment of STD.

Inclusion criteria:

a. men who are consulting private/government STD clinics for the treatment of STD.

b. they may be first time clients or re-attending clients.

Exclusion criteria:

a. re-attending male STD patients whose blood has been extracted within the study period since they are already considered enrolled in the study.

Again, re-attending patients should be asked the date of the last visit to check whether blood has been extracted. The patient is enrolled as subject if no medical record is available.

C. **Female commercial sex workers** (FCSWs) - are women who exchange sex for money and work in establishments for this purpose.

Inclusion criteria:

a. are those who work in establishments and exchange sex for money - whether regular workers or contractuals (dancers and models).

Establishments may include bars, casa, massage parlors, night clubs, beer houses, etc.

Exclusion criteria:

a. ancillary staff, such as cashiers and floor managers who do not engage in sex work.

D. **Male commercial sex workers** (MCSWs) - are individuals who exchange sex for money and work in establishments for this purpose.

Inclusion criteria:

a. men who work in establishments and exchange sex for money. The clients of the male CSW may be male or female.

b. all identified men who engage in sex in exchange for money and voluntarily agree to participate in the study (e.g. paid partners of MSMs).

Exclusion criteria:

a. Ancillary staff such as security guards, floor managers and other staff in the establishment who do not engage in sex for money.

Reminder: Male clients of male CSWs are eligible for inclusion in the "Men who have sex with men" surveillance group. They do not meet the inclusion criteria for male CSWs.

E. **Free lance FCSW (FLSWs)** - are women who exchange sex favors for money and do not work in establishments (streetwalkers)

F. **Men who have sex with other men** (MSMs) - are men who have sex with other men for their own pleasure.

Inclusion criteria:

a. men who negotiate sex with male commercial sex workers.

b. MSMs in establishments or gay venues such as gay bars, beauty parlors, dress shops or gay organizations.

c. all identified MSMs who voluntarily want to participate.

Exclusion criteria:

a. male commercial sex workers

1.4 Surveillance Site Selection

For each sentinel group to be included in the surveillance, accessible sites with sufficient attendees must be identified. Data from previous HIV prevalence assessments can be used to assist in the selection of sites. Selection of surveillance sites will then be based on the following criteria:

1. the number of HIV positive individuals identified in a particular area or known to come from the area;
2. availability of risk or sentinel groups;
3. a reliable laboratory is available to perform serologic tests for HIV;
4. geographical representativeness of the site; and
5. on-site staff must be willing to cooperate and be capable of conducting surveillance for at least 5 years.

1.5 SURVEILLANCE METHODS

A. SENTINEL SURVEILLANCE GROUPS

Injecting Drug Users (IDUs)
Female Commercial Sex Workers in establishments (FCSWs)
Free Lance FCSWs (FLSWs)
Men Having Sex with Men (MSM)
Male Commercial Sex Workers (MCSWs)
Male with STD (MSTDs)

B. STRATEGIES FOR COLLECTION OF DATA/SPECIMEN

I. Number of Samples and Method of Testing

Surveillance Group	Sample Size	Method of Testing
IDUs	300	Vol. anonymous
Male STD Patients	300	Anony. unlinked
FCSWs	300	Vol. anonymous
MCSWs	100	Vol. anonymous
MSMs	300	Vol. anonymous
FLSWs	100	Vol. anonymous

II. Method of Testing

1. Unlinked anonymous - this method tests blood drawn for other purposes for HIV antibodies without the subject's knowledge and with all identifying data removed. Thus, counselling cannot be provided.

2. Voluntary anonymous testing - the volunteers do not give identifying information although demographic and other information shall still be collected. The volunteer shall be assigned a code number which can be presented to retrieve results. Results shall be released only if the volunteer agrees to undergo counselling (please note: counselling shall be provided to volunteers whatever is the result). Entrance of selection and information bias shall depend on the credibility of the system for maintaining anonymity of the volunteer.

C. ACCESS TO THE RISK GROUPS

Risk groups will be accessed in their place of work or in places were are they are usually found as stated above. Table 1 summarizes where subjects are likely to be found and where data and specimen will be collected.

Table 1. Place of Access of High Risk Group
National HIV Surveillance System, 1993

Risk Groups	Place of Access
Female Commercial Sex Workers (FCSWs)	Commercial establishments
Male Commercial Workers (MCSWs)	Gay bars and gay venues
Men who have sex with men (MSMs)	Gay bars and sex venues
Male STD patient (MSTDs)	Private and gov't social hygiene and STD clinics
Injecting Drug Users (IDUs)	Rehabilitation clinics/centers
Free lance FCSWs (FLSWs)	Streets of trade

D. STEPS IN ACCESS AND DATA/SPECIMEN COLLECTION

1. Mapping

The purpose of mapping is to determine all possible collection sites where surveillance groups can be accessed as well as to get an estimate of the number of subjects/clients for the duration of the data collection period.

a. Injecting Drug Users (IDUs)

All treatment clinics providing services for IDUs will be identified. The average number of IDUs treated in the clinic per month will also be determined. If the total estimated number of IDUs in all the centers identified exceed the sample size, treatment centers can be randomly selected until the targeted sample size of IDUs is obtained. If the estimated number of subjects are less than the sample size, all potential subjects will be enrolled. IDUs' network of friends can also be potential sources of subjects.

A letter code will be assigned for each treatment clinic. During the mapping process, a point person in each treatment clinic should be assigned to be responsible of all the surveillance activities within the said clinic which include organizing/scheduling of data collection activities, advocacy, and briefing of potential clients. Orientation of the point person and other staff of the treatment clinic may be done during the mapping or may be scheduled at a later date.

b. **Male STD Patients** (MSTD)

All government and private STD/VD clinics in the surveillance site shall be identified and listed. The average number of male patients consulting for STD per month shall be determined (Follow steps in 1a). A letter code for each clinic shall also be provided.

Physicians will be encouraged to request for VDRL for all male STD patients. It must be emphasized that a portion of the blood tested for VDRL will be tested for HIV antibodies and that, the subject will not be told of HIV test and result. VDRLs may be offered to private STD Clinics to ensure and promote cooperation in data/specimen collection.

c. **Male and Female Commercial Sex Workers**

All establishments such as bars, casa, massage parlors, gay bars, etc will be identified. The number of CSWs (male or female) working in each establishments will be determined to estimate the number of eligible CSWs (See 1a for steps to take).. A letter code will be assigned to each establishment where the subjects are accessed.

d. **Men who have sex with men**

All entertainment establishments or venues where MSMs can be found such as gay bars, beauty parlors, dress shops, gay organizations and through their network of friends will be located (See 1a for activities to undertake). The number of MSMs in each venue will be determined to estimate the number of subjects who will be recruited.

Gay venues will be assigned a consecutive letter codes. All MSMs in each venue will be identified and taken as subjects. During mapping, the manager or owner of each venue will be oriented on the objectives and activities of the surveillance after which pre-test counselling and data/blood collection of the MSMs will be scheduled.

e. Free Lance FCSWs

All areas (streets, plazas, recreation centers, piers) that are frequent ply routes of Free Lance FCSWs must be identified. Access may include their network of friend among FCSWs in establishments, pimps, policemen and their other contacts. A letter code will be assigned to each area where the subjects are accessed.

E. DATA COLLECTION

A. Pre-test Counselling

Pre-test counselling should be conducted before interview to make the subjects aware of the objectives of surveillance, give them assurance that testing is anonymous, explain the confidentiality of the testing process, the meaning of the test results, and the benefits of knowing their results personally. The procedure of data and specimen collection should then be explained and how they can avail of their test results.

Mass pre-test counselling may be conducted when the subjects are collectively gathered or may be given individually as the case may be.

B. Sampling (Recruitment of Subjects/Clients)

Recruitment of subjects shall be done "on-site". The surveillance team, composed of the interviewer, verifier and phlebotomist, will visit these sites (establishments, clinics, treatment centers, etc.) on a pre-arranged schedule. Subjects shall be enrolled sequentially as they voluntarily present themselves for interview.

For IDUs, the physician or the designated person will identify the eligible subjects. Patients will be enrolled sequentially as they visit the centers until the sample size is obtained.

For Male STD patients where testing is unlinked anonymous, all patients with VDRL testing shall be enrolled sequentially as blood samples are taken.

C. Coding

City/Surveillance group/Collection Site Code

The City/Surveillance group/Collection code situated in the right hand corner of each form are four blocks. The first two blocks shall bear the the city code, the third block the surveillance group code, and the fourth block the collections site code.

The city codes for each surveillance site have been previously determined as follows:

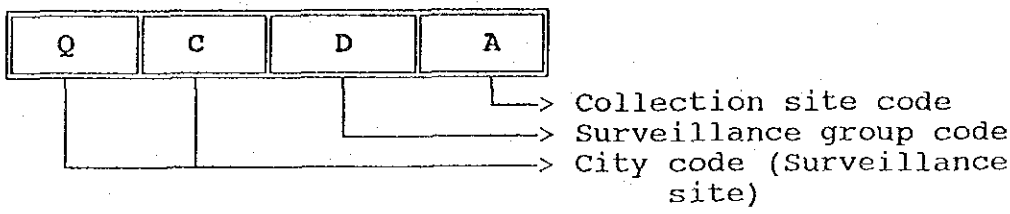
Quezon City - QC
Cebu City - CC
Davao City - DC

The surveillance group code, previously determined shall be entered in the third block as follows:

Injecting drug users	- D
Male STD patients	- S
Female Commercial Sex Workers	- F
Male Commercial Sex Workers	- M
Men Who Have Sex with Men	- H
Free Lance FCSWs	- L

The fourth block shall contain the letter code of the collection site (treatment centers, establishments, etc) previously assigned during the mapping.

Example: City/Group/Collection Site Code for IDUs



Client Codes - shall be assigned sequentially for each subject as a three digit number starting from 001 and so on.

D. Report Forms

Data Collection Form (Form 1)

It is important that accurate information are elicited from the clients. The most effective way is to get an idea of the common jargon that the subjects are familiar with in their place of work.

The information to be collected are the date of interview, middle initial, age, sex, civil status, number of sexual partners per week, condom use, history of IV Drug use in the last 5 years, number of times a week injecting drugs, and history of blood transfusion the last 5 years.

In addition to the information above, for CSWs, the place of work, and the presence or absence of health card shall be asked.

All the data collection form will be forwarded to local sentinel manager for collation in the summary form.

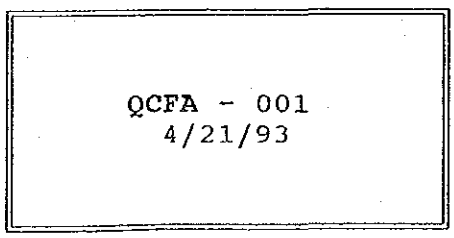
Blood Extraction Form

The blood extraction form shall be accomplished by the interviewer except for the date of blood collection that will be accomplish by the phlebotomist.

Client Cards

The purpose of the client card is to maintain confidentiality. A client card will be issued to all subjects except to male STD patients. The client card shall bear the city, surveillance group, collection site code, and the date of the interview and blood collection. Patients must be instructed to keep the card for them to get their test result. Before issuing the client card, it must be signed by the interviewer.

Example of a Client Card for FCSWs



VDRL Request Form

Since MSTDs will be tested anonymous unlinked, all subjects will be tested for VDRL. Portion of the blood sample for VDRL testing will be tested for HIV antibodies. All STD patients shall be issued a VDRL request form where the patients name, age, and the date of blood collection is written. It should be emphasized that the subjects will not be told that their blood samples will be tested for HIV.

Example of a VDRL request form

To: SHC Date_____

Name _____ Age ____

Request for VDRL

Physician

Summary Report Form (Form 2)

After laboratory testing, results will be entered in the summary form. The summary form will contain all the information collected and the laboratory results. The form will initially be accomplished by the phlebotomist to fill in the client code, and the date of collection. This will also serve as the roster of specimen collected for the day. It will be forwarded to the testing laboratory with the data extraction form. After accomplishing the form it is forwarded to the local sentinel site manager.

It is advisable to have the forms and client cards already pre-coded before going to the collectionsite to save time and avoid confusion in labelling.

F. DATA FLOW and REPORTING

1. Data collection forms: All Data collection forms will be forwarded by the interviewer to the head of the local sentinel site team.

2. For female CSWs, male CSWs, and MSMs where subjects were interviewed in groups, submission of the collection forms can be done by batches.

3. For the IDUs, a designated sentinel site personnel collects the forms from the interviewer in the clinics/centers and forwarded to the head of the local sentinel site for data consolidation.

4. For each site, data collection, entry and analysis will be under the joint supervision of the head of the local sentinel site and FETP.

5. The Site Managers will review the forms to be sure they are filled out correctly. If there are errors, the site manager will contact the interviewers so that they can be corrected. If it is impossible to correct the form, that subject will be excluded and another subject will be collected to take his place.

6. The Local Site Manager will identify an individual to enter the data into the Computer. If there is no computer or person capable of entering the data, these will be provided by FETP.

   a. Data files will be kept on floppy disks, which will be kept in secure places.
   b. At the end of each session of entering data, the data entry clerk will make a copy of the data file and give it to the Site Managers, so there will always be 2 copies of the data.

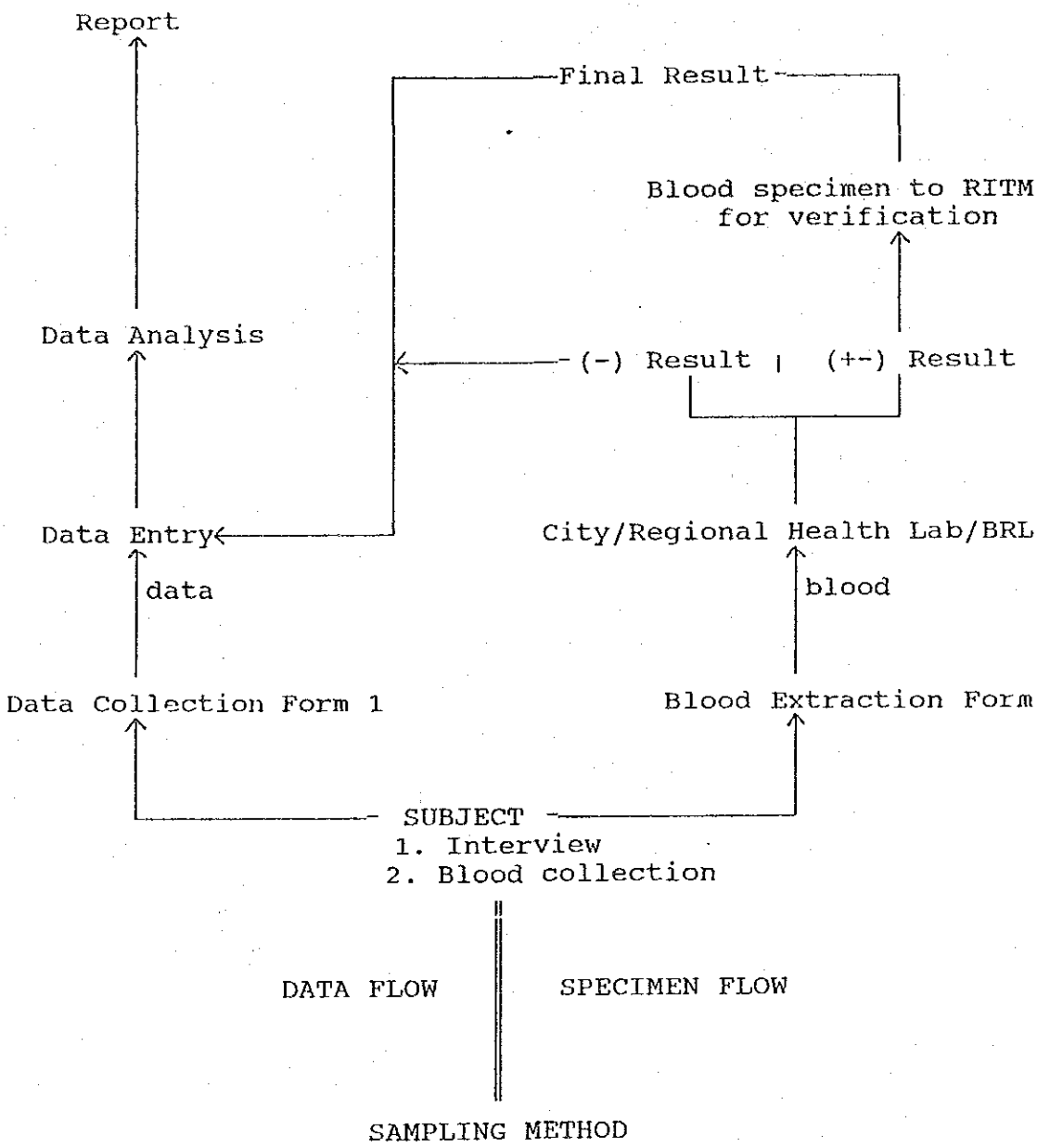
7. Site Managers will review the data files at least once each week to confirm that it is being properly entered.

8. At the end of the data collection period:
   a. copies of the data files will be provided to National HIV Surveillance System (FETP).

   b. The National HIV Surveillance System (FETP) will review local report, consolidate the files and produce a National Report.

   c. All reports will be submitted to the program director of the National HIV Surveillance System (FETP) and discussed with Asst. Sec. Reodica (OSC) and NAPCP before release.

FLOW OF DATA/SPECIMEN



G. SPECIMEN COLLECTION, HANDLING AND TRANSPORT to TESTING LABORATORY

1. Blood Extraction (at the collection site)

1.1 The blood extraction form is detached and the client is directed to the phlebotomist (sentinel medical technologist) or a verifier (also a member of the surveillance team).

1.2 The phlebotomist or the "verifier" shall verify the concordancy of the codes in the blood extraction form and client card. A blood collection tube is then labelled with the same codes as in the blood extraction form and date of blood extraction. The client code and the date of collection is entered into the summary form which also serves as the roster of specimen collection.

1.3 A 5.0 ml of blood is drawn by the trained phlebotomist. Where blood extraction may be staggered, as in IDUs attending treatment clinics, the nurse or the attending physician shall perform the blood extraction.

Note: Personnel who shall extract blood are advised to undergo training in phlebotomy (if necessary) to avoid:

1. specimen hemolysis
2. undue discomfort to the clients
3. accidents like needlestick injury

1.4 Safety Precautions during specimen collection should be practised.

1.4.1 Wear gloves during blood extraction, handling, and transport of specimen.

1.4.2 Collect blood samples with **LAB MAT IN PLACE.**

1.4.3 Never MANUALLY RECAP NEEDLES. "Scoop" needle caps if it is necessary to recap to prevent any accidental exposure.

1.4.4 Discard needles in puncture resistant containers (e.g. soft drink cans). Seal opening of soft drink can with several layers of masking tape. Label can with **"CONTAMINATED".**

1.5 After blood extraction, the phlebotomist affixes initials on the client and the blood extraction form.

1.6 A member of the surveillance team shall see to it that a blood sample is drawn from every client after interview.

1.7 For male STD patients, the physician or a sentinel site phlebotomist extracts blood for VDRL testing. The blood extraction tubes should be labelled with the name of the patient and the date of specimen collection. The blood samples are then referred to the Social Hygiene Clinic for VDRL testing with the corresponding VDRL request form.

1.8 Procedures for Decontamination and Disposal:

1.8.1 For **"Combustibles"**

a. Discard/Dispose all contaminated materials (i.e. gloves, cotton, lab mat sheets, etc..) in a trash (biohazard) bag.

b. Secure trash bags tightly with enough air space. Label bag with **"BIOHAZARD" or "CONTAMINATED".**

c. Endorse contaminated materials to responsible personnel for appropriate disposal.

d. Burn in a designated and secured place within the hospital or city health grounds.

1.8.2 For **"Sharps"**

a. Sealed puncture-resistant cans with used needles soaked in Sodium Hypochlorite can be disposed in two ways:

1) through incineration in hospitals or city health facilities where a functional incinerator is available;

2) by burying in a designated and secured area in the hospital or city health grounds Trash bag - incinerate

Note: To avoid possible reaction if Sodium hypochlorite solution with organic substances present in moist/wet ground leading to the production of toxic, non-environmental friendly substances, the site for burying should be on a dry location.

2. **Specimen Handling and Transport (from the collection site to the testing laboratory)**

2.1 The specimens should be placed in a test tube rack to maintain them in an upright position and transported in a carrier or collection bag strong enough to protect the contents from physical damage while in transit.

2.2 Submit specimens to the Regional Health/City Health testing laboratory/BRL together with the summary form (Form 2) and the blood extraction forms. The forms should be protected from getting contaminated with the specimen.

2.3 The summary form is countersigned by the personnel in the testing laboratory upon receipt of the specimen.

2.4 Keep specimens refrigerated until processed. If possible serum should be separated within 24 hours to avoid hemolysis.

2.5 For specimens collected from male STD patients:

a) Transfer at least 1.0 ml of serum to a cryogenic vial labelled with the age of the patient and date of collection.

b) Keep refrigerated until transported to the Regional Testing Laboratory.

c) The medical technologist in the Regional Testing Laboratory assigns the client code sequentially and fills up duplicate copies of Form 2, entering the client code, date of collection and age.

H. HIV ANTIBODY TESTING

HIV Antibody Testing shall be performed in the Regional Health Laboratory in Davao; in the City Health Laboratory in Cebu City, and in BRL for Quezon City.

The serum pooling method for HIV antibody testing using the Particle Agglutination Test will be employed. Briefly, individual samples are grouped into batches of 5 and tested as one. The components of a reactive batch or pool are retested. Reactive or equivocal pool(s)and its components are sent to the Research Institute for tropical Medicine (RITM) for confirmation. Results of confirmation shall be forwarded to the Local Sentinel Site Manager and to the Central Office Site Manager if necessary.

I. SERUM POOLING GUIDELINES for HIV ANTIBODY TESTING

The following guidelines must be followed precisely to minimize loss of test sensitivity, validate and monitor the technique and so provide assurance as to the effectiveness of the procedure and the reliability of the results. It is therefor necessary that documentation of specimens as well as the pooling and testing procedures be carefully monitored.

1. DOCUMENTATION: Record serum samples by surveillance group in the Laboratory Form 3: Laboratory Roster, entering the specimen I.D. and date of specimen collection. Individual sera should be grouped in batches of 5 and assigned a Pool I.D. number Bracket groupings. In case where there are only 2 - 3 or 4 serum remaining (i.e end of collection), group these samples appropriately and assign a Pool I.D. number. The Pool I.D. number should bear the city code, the surveillance group code and the pool number.

   Example: QCSP001

City Code	Surv. Grp. Code	Pool Number
QC	S	P001

   Where: QC - Quezon City S - Male STD Patient

2. POOLING PROCEDURE

   2.1 Allow samples to clot fully. Avoid samples which are grossly lipemic, hemolyzed or contaminated. Such samples should be tested as individual samples. Do not include in the pool.

2.2 Label the necessary vials with the appropriate specimen I.D. number and date of collection or pool I.D. number and date of pool preparation. Use clean sterile vial.

2.3 With a micropipette, dispense 100 ul of the individual sera into the corresponding labelled pooling vial, 5 sera per pooling vial. Mix each pool thoroughly. Check with Laboratory Form 3 (see Annex) while dispensing sera to ensure correct pool components. Use sterile tips. Likewise prepare a pool of Pool QC panel in the same manner as the samples everytime the samples are processed (i.e., pooled before testing). Indicate date on Pool QC vial.

2.4 Transfer individual serum samples into appropriate vials. Use sterile pasteur pipettes.

2.5 In situations where a pool of 5 individual samples could not be made yet, transfer any available sera into its appropriate individual vial to prevent hemolysis on standing. Keep refrigerated up to 5 days. Otherwise, freeze (preferably at - 20 C if available) until pools can be prepared.

2.6 Store individual and pool samples in corresponding cryoboxes according to the surveillance group from where the samples were collected.

2.7 Freeze individual samples. Pooled samples may be kept refrigerated if HIV testing will be performed within 5 days. Otherwise, freeze until tested.

3. ASSAY PROCEDURE

3.1 Prepare the necessary reagents and materials as in the normal manner. Dilute the gelatin particles according to the manufacturer's instruction.

3.2 Select the samples to be tested including the Pool QC vial. Mix each pool prior to testing.

3.3 Prepare testing protocol in the Laboratory Form 4 Laboratory Protocol (See Annex). Record the plate identity and the individual well number for the kit positive control, Pool Quality Control (QC) sample and the pool(s) to be tested. Record date of testing, the name of the technologist number/date of expiry and date of testing.

3.4 Proceed with testing following exactly the PA procedure stated in the kit instruction (Annex)

3.5 Record results in the testing protocol (Lab Form 4).

3.6 Retest individual samples from reactive and equivocal pools following the pooled serum HIV testing strategy:

3.6.1 Select the individual sample components of the reactive or equivocal pools. Mix prior to testing.

3.6.2 Prepare testing protocol as in 3.3

3.6.3 Perform assay as in 3.4 Omit Pool QC sample in this step.

3.6.4 Record results.

3.7 Send reactive/equivocal pool(s) and individual components to RITM. This should be accompanied by Lab Forms 3 and 4 indicating the initial screening result.

3.8 Freeze any sera remaining after tests are completed. These sera (with accompanying Lab. Form 3) will be retested/used for quality assurance purposes. (See section 6.4)

3.9 Complete the necessary documentation to enable release of the results, i.e. Lab Form 3 and Summary Report Forms. Countercheck all entries before submitting results to the sentinel site manager. Keep a duplicate file for quality assurance purposes.

II. HANDLING AND TRANSPORT OF SPECIMENS TO RITM for Confirmatory Testing.

4.1 Make sure the specimen vials are tightly capped. Secure cap with parafilm.

4.2 Reactive and individual components should be placed in a double plastic bag with absorbent material (tissue paper or cotton).

4.3 Samples for quality assurance purposes should be placed in corresponding cryogenic boxes. Place box in a plastic bag.

4.4 Samples should be accompanied by Lab Form 3. Do not forget to enter your LABORATORY CODE. Lab. Form 3 should be sealed in a separate plastic bag and wrapped around or attached firmly to the specimen box or bag.

4.5 Transport/send to RITM in an insulated carrier (Styrofoam box) containing ice packing.

4.6 Arrival at RITM should be planned to avoid weekends and holidays. Otherwise, please give advance notice.

III. REPORTING of HIV TEST RESULTS

5.1 Results of HIV testing should be kept CONFIDENTIAL at all times and should only be reported to AUTHORIZED personnel.

5.2 All forms should be kept in a secured place. Access should be limited only to laboratory personnel involved in the surveillance programme.

5.3 Relay any available results (Summary Report Form 2) to the sentinel site manager as soon as possible regardless of pending supplemental (confirmatory) test results.

5.4 Results of confirmation will be reported to the testing laboratory.

IV. LABORATORY QUALITY ASSURANCE

6.1 Pool Quality Control panel for the pooling method will be provided by RITM.

6.2 Records and testing procedure will be reviewed during supervisory visits by RITM and/or BRL personnel.

6.3 A serum pooling proficiency panel will be sent for testing by RITM. The panel should be treated in the usual/routine the pooled serum technique is being carried out under normal conditions. The testing instructions will accompany the panel.

6.4 Selected pools and individual components will be retested at RITM. The procedure for selecting these pools is as follows:

6.4.1 Calculate the number of pools (to be selected) equal to 20% of the total pools prepared for each surveillance group within a collection period of two weeks. That is:

Total # of pools x 20% = No. of selected pools

Example: 30 pools x .20 = 6 pools

6.4.2 Select pools:

Total # of pools
---------- = n th eligible pool
No. of selected pools

Example: 30 pools = 5
--
6

Therefore, pick out every 5th pool and its corresponding components.

6.4.3 Send to RITM according to Section 4.

6.5 Reactor rates for pooled and individual samples will be monitored using Lab. Form 5: Serum Pooling Monitoring Form (See annex). This form will be submitted to RITM together with the selected pools/component for analysis.

6.6 Based on the results of Quality Assessment, BRL shall provide retraining of laboratory personnel as necessary.

V. GUIDELINES for LABORATORY SAFETY and PRECAUTION in HIV TESTING

HIV can be isolated from types of body fluids, hence exposure to these fluids places laboratory workers at risk. The relative risk of exposure vary for each work place setting. HIV infection is not as easily contracted outside its major routes of transmission. The US Centers for Disease Control recommends the use of "UNIVERSAL PRECAUTIONS" which emphasize that all patients, blood and blood products, and other body fluids should be treated as potentially infectious regardless of the lack of knowledge on their HIV serostatus. Such a practice would greatly limit the possibility of HIV acquisition via exposure to an individual with an undetectable or undocumented HIV infection. The following are among those outlined in the guidelines:

1. Gloves should be worn whenever handling or obtaining specimens of any kind.

2. Laboratory gowns/coats should be worn as protection from splashes of any biological material. They should not be taken to office areas (e.g. cafeteria, etc.).

3. Masks, protective eye wear or face shields should be worn to protect exposure of mucous membranes in the mouth, nose, eyes whenever aerosolization or splattering of blood is anticipated.

4. Any cut or abrasions in the skin should be covered with a waterproof dressing to prevent direct contact with human blood, body fluids or tissues.

5. Dispose needles and other sharp objects in puncture resistant containers situated near the work area. Never MANUALLY recap, bend or break a needle. If recapping is necessary to prevent accidental exposures, use forceps. However, extreme precaution should be taken.

6. Specimens should be transported in well-constructed containers, e.g. enamel trays, test tube racks, etc. Specimens for transport between institutions (referral) should be packed and labelled clearly, double bagged or placed in a second leak-proof, puncture resistant container.

7. Wash hands in between patients, after removing gloves, performance of tests, before leaving the laboratory or as needed. Soap and water or antiseptic hand washes are appropriate. Wash hands and any other surfaces of the body splashed with blood or other body fluids as soon as possible.

8. All contaminated materials used in laboratory tests should be decontaminated. (See below decontaminated procedures).

9. Laboratory work surfaces should be decontaminated with an appropriate chemical germicide after a spill, after work is completed or whenever necessary.

10. Diagnostic equipment which has been contaminated withblood fluids should be decontaminated and cleaned.

The following procedures for decontamination may be employed as appropriate:

1. Immersion in an approved chemical disinfectant. **Sodium hypochlorite (household bleach)** - is recommended for general disinfection because it is effective and cheap. Sodium hypochlorite is used freshly prepared according to the manufacturer's instructions.

2. Boiling for 30 minutes.

3. Autoclaving

4. Incineration

11. Never Pipet by mouth. Use mechanical pipetting devices.

12. Centrifuge specimens with caps tightly secured, and never as open tubes.

13. Wastes should be disposed in properly labelled disposal bags. Biohazard labels and instructions for final disposal should be clearly indicated. Housekeeping personnel should be well instructed about safety-related issues.

14. All accidents of exposure to blood and body fluids, punctures, etc., should be reported to the supervisor for appropriate action in accordance with the infection control policy of the institution.

15. Continuing education, training programs, review of guidelines on laboratory safety and precautions are essential.

Section II. Data Analysis and Presentation of Results

The purpose of analysis and presentation is to make it easy for decision makers to understand the results. Information must be presented simply and clearly. It is especially important the reader understand limitation in the data (such as bias) so they don't overinterpret the report.

Mechanics:

Data entry : The National HIV Surveillance System (FETP) will provide copies of EPINFO and programs for the data entry and analysis. If a site has access to a computer, data can be entered as it is being collected. This allows site personnel to catch and correct errors in the forms. If this is not possible, FETP will enter the data. Diskettes of raw data should be submitted to FETP at the end of data collection.

Analysis: If possible, results can be tabulated and analyzed in each site. The Data Management Unit can assist if this is not possible. The Data Management Unit will tabulate and analyze the national data.

Reports: The local personnel and FETP will review the table and prepare a brief report. The first name on the report should be the leader of the local team. Reports should be submitted FETP and must be approved by Dr. Manuel M. Dayrit before released.

The FETP will produce a national report, which must be approved by the program manager prior to released. It will be addressed to Assistant Secretary Reodica and signed by Assistant Secretary Dayrit and " The HIV Surveillance Group". Name of those who contributed to the report will be listed in the annex.

Use of report: Report are part of the public domain and may be quoted by anyone. It is requested that the DOH HIV Sentinel Surveillance System be acknowledged when this is done.

Access to Raw Data: Individual may wish to use raw data for their own analysis. Raw data belongs to the Department of Health. The entire data set will be made available in EPINFO format to anyone who contributes to the HIV Surveillance System. It can be also provided in Dbase III or ASCII formats if desired. Raw data may be provided to other institutions only with the approval of the Technical Staff of the National HIV Surveillance System (FETP).

Summarizing results:

Rates will be calculated so that results are in small whole number whenever possible. For example, 2 positive out of 2500

test would yield a seropositivy rate of 8 per 10,000 test.

Data from type A Surveillance group such as MSMs and surveys of female CSWs will be presented as proportions. When several of these groups are summarized, they will be presented as medians and ranges.

Data from type B surveillance group including STD clinics, for Free lance FCSWs, and IDUs in rehabilitation clinics will be presented as prevalence rates with confidence intervals if possible. If prevalence are low, LQAS interpretation will be used. If it is possible to get adequate number of unbiased sample, result will be presented in the format for the Type A Groups.

Format of Reports

Interpretation: Each report will begin with a few brief sentences interpreting the result.

Demographics: This section will include ages, occupation, and other general information describing the individual in each group.

Behaviors: This section will describe the high risk behaviors for each group.

Comparisons: This will include relevant trends in time, comparisons between groups or sites.

Recommendations: Each report will contain a few focused, concrete recommendation for action. These must be based on the result.

Presentation of Information

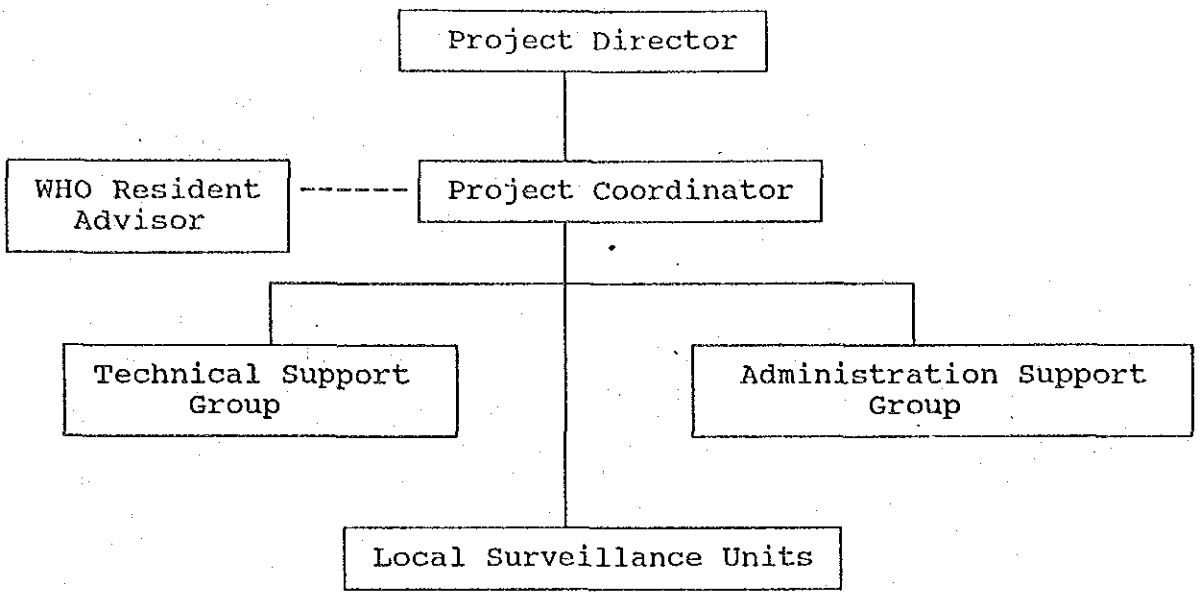
Text: Simple sentences are the clearest way to present a few number.

Tables: Simple tables will be used to summarize data. It is important to remember that tables of may rows and columns are difficult to understand.

Graphs: will be used to show trends and make comparison.

Analyzed results will be send back to the local surveillance manager, Secretary of Health, NAPCP, and other involved agencies.

3.1 HIV Surveillance Structure



3.2 Roles and Responsibilities Within the HIV Surveillance Unit

Director

- Oversee and direct the operations of the National HIV Surveillance
- Acts as spokesperson for the National HIV Surveillance

WHO Resident Advisor

- Provide an overall coordinative focus within the DOH for the National HIV Surveillance System implementation activities.
- Participate with the Program Director of FETP and others in the overall planning, organization, implementation, monitoring and evaluation of the National HIV Surveillance System and associated activities.
- Participate with the Program Director of FETP and others in the development of the annual operational plan which will include detailed activity schedules and budget for approval by USAID and DOH.
- Assist the staff of FETP in the preparation and submission of budget requests for local costs, ensuring the timely availability of operational funds for surveillance activities.
- Participate with the Program Director and others in the development of technical specifications for equipment and other commodities to be procured under the GRANT, ensuring their timely procurement through the WHO supply unit.
- Participate with the Program Director and others in assessing the need for training, technical assistance and operations research to meet the objectives of the National HIV Surveillance Strategy, and to ensure that these requirements are met.
- Ensure the implementation of a quality assurance program designed to maintain accuracy, validity and reliability of the data obtained through the National HIV Surveillance System.
- Assist the staff of FETP in the organization and facilitation of Management and Technical Reviews to be held subsequent to each six monthly round of HIV surveillance. These reviews will identify restraints and resolve management and technical issues relating to surveillance implementation.
- Participate with the Program Director and others in the analysis of the surveillance data and the preparation and dissemination of surveillance reports.
- Participate in the preparation of required progress and financial reports.
- As Technical Advisor, ensure the implementation of human safety assurance program adhering to the WHO safety guidelines for handling potentially infectious materials.

- Undertake liason responsibilities with other units of the DOH and other agencies both government and non-government with regard to the overall planning, development, implementation and evaluation of HIV surveillance activities.

Program Coordinator

- Oversee the implementation of the National HIV Surveillance System at the sentinel sites
- In collaboration with the local point persons, oversee the negotiations undertaken with the sentinel groups
- Assist the surveillance site in accessing, mapping, recruitment, random selection of groups
- Assure availability of logistic requirements of the sentinel sites
- Assure compliance of protocols
- In collaboration with local point persons, initiate and maintain close liason with local government officials affected by the sentinel sites
- Ensure that serum from all sentinel sites has been collected and tests results have been forwarded to the National HIV Surveillance System (FETP)
- Oversee the submission of test results and field reports
- Oversee data management at the surveillance site
- Assist in the preparation of a report on the findings of each round of surveillance
- Coordinate the functioning of the surveillance site with regard to the location of the sentinel groups and collection of serum for testing
- Liase with the local surveillance unit on the location of sentinel groups and all aspects of testing these groups
- Coordinate, in collaboration with local point persons, the activities of the local surveillance units
- In collaboration with the technical group, train local surveillance unit personnel
- Supervise the data collection, handling, storage and transport of serum specimens

Technical Support Group

- Advise the Director and Coordinator on the scientific aspects of the surveillance system
- Set surveillance goals
- Evaluate the achievement of surveillance goals
- Review technical aspects of the HIV surveillance system and determine scientific changes appropriate
- Prepare policy briefs relating to scientific aspects of the surveillance system
- Design and review survey methodologies

- Determine the definitions of and criteria for selection of surveillance groups, sites and sizes
- Determine the definitions of and criteria for selection of special sero-surveys
- Determine the data to be gathered via the surveillance system
- Receive from the regional laboratories or Social Hygiene clinics the completed data forms and results
- Undertake the physical management of the surveillance data
- Analyze result data from the surveillance sites and prepare report on findings of each round of surveillance
- Determine future directions of the HIV Surveillance with regards to sentinel groups, sites and sizes

Administrative Support Group

- Oversee the day-to-day administrative aspects of the National HIV Surveillance System
- Oversee the provision of supplies and equipments to the surveillance sites
- Oversee the receipt of tests results from the Regional Laboratories to the Central Office
- Oversee the transport of serum for confirmatory testing
- Oversee the quality requirements of the HIV Surveillance System
- Assist in the preparation of a reports on findings of each round of surveillance
- In collaboration with the Site Managers, prepare the annual budget for the surveillance system
- In collaboration with the Technical Group, undertake the preparations and convene the semi-annual training workshops for the surveillance implementation

The administration component shall undertake the following tasks within the surveillance system:

1. Acquisition of funds
   - preparation of budget

2. Day-to-day administrative aspects of the National HIV Surveillance System
   - preparation of Department Circulars
   - preparation of vouchers (travel, monetary, etc)
   - preparation of logistics, documentation of meetings

3. Transport of personnel/equipment/supplies/specimens between the Central Office and the sentinel sites.

4. Production of instruments
   - field guidelines/manuals/forms for data collection and reporting

5. Provision of logistics requirements of all laboratories

6. Reporting
   - logistiscs for laboratory and Technical Group
   - supply of reports to NAPCP for IEC/media/policy makers
   - feedback results to the surveillance sites
   - linkages

7. Arrangement of workshops/provisions of secretariat
   - development and orientation of manual of procedures

8. Personnel
   - recruitment/selection/assignmentto surveillance sites
   - preparation of job descriptions
   - preparation of per diem/salaries

Local Surveillance Units

Undertake the day-to-day activities of the sentinel surveillance system

These activities include:

1. Preparation
   - mapping of the surveillance groups
   - orientation of staff
   - acquisition of logistics
   - orientation , networking, and coordination of influentials (LGU, establishments, private STD clinics, hospitals, gay organization)

2. Identification of sentinel groups

3. Involvement in sampling
   -liase with the Social Hygiene Clinics and/or Regional Laboratories concerning collection and testing

4. Data collection
   - collection of the required sera within the timetable for collection

5. Reporting
   - deliver field reports to the central office during and following the completion of each round of surveillance

6. Consultative Workshops
   - participate in the development and conducting of semi-annual surveillance workshops