Attachment J. Listings of Surveillance Coordinators in State Health Departments and Expert Consultants

J1. Listings of Surveillance Coordinators in State Health Departments Including Core Surveillance, Incidence Surveillance, VARHS, and EPS

Note: There is some overlap of personnel.

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Atlanta, Georgia ♦ March 25-27, 2003

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4th HIV Incidence Consultation: Strategies & Procedures for Implementation

Atlanta, Georgia ♦ March 25-27, 2003

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5th HIV Incidence Consultation
Laboratory & Specimen Transport Consultation
Wyndham City Center Hotel, Washington, D.C.
December 9, 2004
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Association of Public Health Laboratories (APHL) and the Centers for Disease Control and Prevention (CDC)

5th HIV INCIDENCE CONSULTATION: LABORATORY & SPECIMEN TRANSPORT ISSUES

9 December 2004, Wyndham City Center Hotel, Washington DC

SUMMARY NOTES

Attendees: Berry Bennett, Ulana Bodnar, Bernard Branson, Tony Buckman, Richard DeStephens, Jennifer Donnelly, Tonji Durant, Alison Freeman, Rosemary Humes, Richard Kline, Lisa M. Lee, Laurie Linley, Brian Louie, Kim Lucas, Matthew McKenna, Joseph Prejean, Stacy Saunders, Joseph Schwendemann, Timothy Sherrill, Lou Smith, Patricia Somsel, Kelci Stroud, Brent Sugimoto, David Sundwall, Anthony Tran, Fran Walker, Barbara Werner, Lisa Weymouth, Michael Wilson, Joseph Yao.

Presentation: Matthew McKenna (CDC) – Welcome

Matt McKenna presented background on the need for national HIV incidence surveillance, a more direct measure of HIV transmission, in addition to the existing national surveillance of new HIV diagnoses. The incidence surveillance system will provide critical feedback to HIV prevention programs, helping them to better target prevention activities. It will provide critical data to better characterize the HIV epidemic locally and nationally. The goal of this meeting was to reach consensus on a plan and outline policy considerations for shipping specimens to the CDC-STARHS Laboratory for HIV incidence testing.

Presentation: Lisa M. Lee (CDC) – Introduction & Charge to the Group

Lisa M. Lee welcomed the participants and stakeholders thanking them for their commitment to collaborate in this process. The charge to the group was to: (1) develop ideas for a plan to ship specimens from private and commercial laboratories to the CDC-STARHS Laboratory, (2) reach concurrence on a plan of action, (3) outline any policy issues that may need to be addressed in order to implement the plan, and (4) create a list of action items to follow-up on after the conclusion of the meeting.

Presentation: Barbara Werner (MA State Laboratory for APHL) – Role of APHL in HIV Incidence Surveillance

Barbara Werner presented background information on the Association of Public Health Laboratory's (APHL) mission to promote the role of public health laboratories (PHLs) in support of national and global objectives and continuous progress in improving laboratory practices. APHL represents state, territorial, county, and city PHLs. APHL works closely with Centers for Disease Control and Prevention (CDC) on a number of activities including reference testing, training, consultations, and a cooperative agreement for laboratory activities in AIDS surveillance, HIV counseling and testing, STD, TB, bioterrorism, and epidemiology / laboratory capacity for emerging infectious diseases. APHL has a cooperative agreement with CDC for HIV Incidence surveillance that is designed to facilitate the transfer of HIV positive sera from commercial laboratories to the CDC-STARHS laboratory (currently contracted to the New York State Public Health laboratory) either directly or through the state's PHL.

Presentation: Lisa M. Lee (CDC) – Incidence Surveillance 101

Lisa M. Lee presented an overview of the HIV incidence surveillance system. The purpose of incidence surveillance is to provide national and local population-based estimates of the number of new HIV infections per year. HIV incidence surveillance will be integrated into the existing core HIV/AIDS case surveillance systems in each state. The Institute of Medicine issued a report that emphasized the need for a funding allocation system for HIV prevention that is based on the number of new HIV infections, not the number of AIDS cases and deaths.

The two requirements for HIV incidence surveillance are: (1) an aliquot of serum from all confirmed positive HIV tests done in the US for testing using STARHS (Serologic Testing Algorithm for Recent HIV Seroconversion), and (2) surveillance data, including supplemental testing history information, for inference to the population.

The 33 participating sites represent over 85% of the HIV/AIDS epidemic in the US. Currently the assay used in STARHS is the Vironostika Less Sensitive enzyme immunoassay (EIA). The BED HIV Capture EIA manufactured by Calypte will replace the Vironostika in spring / summer 2005. With the adoption of the BED test, sites will no longer require Institutional Review Board (IRB) approval or patient consent as the BED assay is not under Food and Drug Administration (FDA) Investigational New Drug (IND) or Investigational Device Exemptions (IDE) regulations. The BED test has been labeled for surveillance use only, not for clinical or diagnostic use, therefore results will not be returned to the provider or the patient. Currently only CDC-authorized laboratories can use the BED test to conduct public health surveillance.

Questions & Comments:

Is today's discussion aimed for use with the new BED assay?
Yes. Although the BED assay has not been approved by the FDA, they have issued an opinion stating that the assay may be used for public health surveillance ONLY and therefore does not fall under an IND or IDE. Therefore, informed consent is no longer required and though results can be linked to the patients' surveillance records, results cannot be returned to providers or patients. For at least the first year, all testing will continue to be performed at the CDC-STARHS Laboratory (currently contracted to the NY State Public Health Laboratory).

If consent is not required, then do specimens not need to be unlinked when the BED assay is used?
Unlinking is no longer required. Linkage will be maintained for deduplication purposes both within and across jurisdictions. Incidence data will be a subset of case data which has and will continue to be sent from states to CDC without personal identifiers. Although linked on the local surveillance record, it is extremely important to note that results from the BED assay cannot be returned to the provider or the patient under any circumstances. STARHS is being performed at the request of the public health surveillance system, not a health care provider, therefore results are returned only to the public health department's (PHD) HIV incidence surveillance coordinator, not to the originating laboratory, provider, or client.

Will there be continued development of the BED assay for clinical purposes?
Currently CDC does not intend to develop the BED for clinical use; it was developed for public health (PH) surveillance purposes only. This or other assays may be investigated for clinical use by others, but CDC's current objective is public health surveillance, not clinical use.

Are IND changes going to change implementation procedures? Will local IRBs accept the new FDA decision?
The FDA does not require an IRB-approved protocol because the assay will be used for routine PH surveillance purposes only and does not fall under IND/IDE requirements. The change means that the HIV incidence surveillance activities will come under a different section of the Code of Federal Regulations (CFR), one related to the Department of Health and Human Services (HHS) instead of the section relating to the FDA. Routine PH surveillance deemed non-research by a federal agency is not subject to IRB review. The IRB process is for research protocols and the human subjects legislation allows federal agencies to determine whether an activity is research. If determined to be non-research, then the activity does not enter the IRB process nationally or locally. It is similar to routine surveillance activities (for example, food-borne specimens for PulseNet) that do not need to be approved by local IRBs. However, when state law requires IRB submission of PH surveillance procedures, then the new incidence procedures follow IRB procedures set forth by state law.

Presentation: Richard Kline (CDC) – Laboratory Issues & Proposed Options for Specimen Flow

Richard Kline presented the current status of HIV incidence surveillance and specimen handling flow from PHLs to the CDC-STARHS Laboratory. Currently, most sites that are collecting samples for HIV incidence surveillance are public testing sites or private sites that use the state PHLs as an intermediary before shipping to the CDC STARHS laboratory. The PHLs received support for specimen handling and tracking through the HIV Incidence Surveillance Cooperative Agreement. As commercial laboratories (large national reference laboratories) begin collecting specimens for HIV incidence surveillance, an APHL Cooperative Agreement allows them to bill for specimen handling.

Two specimen flow options were presented:
Option 1: Private laboratories send **all** confirmed HIV positive samples to state PHL; State PHL then interacts with State Incidence Coordinator to determine eligibility, then sends all **eligible** samples to CDC-STARHS Laboratory.

Considerations:

- Samples from private laboratories would be shipped twice.
- Only eligible specimens are sent to CDC-STARHS Laboratory.

Option 2: Both the State PHL and the private laboratories send all confirmed HIV positive samples directly to CDC-STARHS Laboratory. The CDC-STARHS Laboratory then interacts with the 33 state Incidence Surveillance Coordinators to determine eligibility of both public and private specimens. Only **eligible** specimens are then tested using STARHS.

Considerations:

- Samples would be shipped only once.
- This option requires communication between CDC-STARHS Laboratory and all state Incidence Surveillance Coordinators.
- There may be legal or policy considerations about cross-jurisdictional specimen transport.

Questions & Comments:

Is there potential for STARHS testing to be done at the state level or will it always be centralized?

For at least the first year of use of the BED Capture EIA, all testing will be centralized at the CDC-STARHS Laboratory (currently contracted to the New York State Public Health Laboratory). After that time we will re-evaluate. No matter where testing is performed, specimens will still need to move from one point to another and will be done for surveillance purposes only.

Will the Vironostika HIV-1 Plus O assay continue to be validated by CDC?
Not at this time. For the purposes of CDC HIV Incidence Surveillance, the BED assay will be used.

Discussion about Proposed Options

For the purposes of this discussion, there are three main laboratory types. Each laboratory type may need a different specimen transport model.

Laboratory Types:

1) Commercial laboratories that test samples from many states (included in this category are: Quest Diagnostics Inc, Laboratory Corporation of America [LabCorp], ARUP Laboratories, Specialty Laboratories, and Mayo Clinic)
2) Smaller private / university laboratories that operate at the state or local level
3) Public health laboratories (PHLs)

Issues and Clarifications regarding Funding:

1. The precedent for reimbursement for handling of specimens for surveillance, in general, (for example, antimicrobial resistance, food-borne specimens, tuberculosis, and West Nile virus) has relied on cooperation between private laboratories, PH departments, and CDC. Even though funds exist now for handling STARHS specimens, this will likely be the case only during the start-up phase of this system.
2. The APHL Cooperative Agreement will reimburse high volume, cross-jurisdictional commercial laboratories only; private laboratories are not included in the current Cooperative Agreement.

What is the distribution of confirmatory tests done at PH and private/commercial laboratories for each state?
The distribution of the number of confirmatory HIV tests varies by state. Each state can estimate the distribution of confirmatory testing done at each laboratory type based on the origin of laboratory reports to the HIV/AIDS surveillance system.

What proportion of HIV positive tests meet STARHS eligibility requirements?
This is not yet known. Many confirmatory tests are not diagnostic. It depends on many factors (for example, how often patient changes health care providers) and is therefore difficult to estimate.

What identifiers will accompany the specimen to CDC-STARHS Laboratory?
The specimen must be linked between the diagnostic laboratory and the HIV/AIDS Case Report Form (CRF) going to the state PHD. The surveillance system must get a unique specimen number that links laboratory results to the testing history data (either from the counseling and testing system's PEMS software or the CDC provided Testing History Questionnaire) and CRF.

The CDC-STARHS lab will assign each eligible specimen a unique STARHS Lab ID number as follows:

> CDC-STARHS Laboratory Plan for numbering eligible STARHS specimens:
> 9-digit unique number:
> ## - ## - #####
> (1) (2) (3)
>
> Where:
> (1) = Unique site code (e.g., 01) that is specific for each HIV incidence site (specific to the state or local health department that will be receiving STARHS results) and could be specific to each of the 5 commercial laboratories **
> (2) = Year (e.g., 04)
> (3) = Sequential specimen number from the specific site within a particular year
>
> ** A unique site code will allow the CDC-STARHS Laboratory to identify which state PHD the results should be returned to. If specimen came from commercial laboratory, then a new, state-specific number could be assigned to specimen when it reaches the CDC-STARHS Laboratory so that they can return results to the correct PHD.

What is the most efficient way for private and commercial laboratories to aliquot and limit specimen involvement and responsibility?
One suggestion was for commercial laboratories to send all HIV positive specimens to state PHL or other facility (i.e., CDC-STARHS Laboratory) and let state Incidence Surveillance Coordinators determine and inform the CDC-STARHS Laboratory which specimens are eligible for testing using STARHS.

What identification number should private laboratories include with the specimen if they don't have a Counseling, Testing, and Referral Sites (CTR/CTS) or Program Evaluation Monitoring System (PEMS) number (at best the private laboratories may have a hospital identification number)?
All confirmed WB must be reported by the laboratory to the state HIV surveillance system with identifying information. The tube of blood must be sent with the same identifying information. It will be critical for laboratories to report the unique specimen ID (e.g., accession number) to the surveillance system. This is already the case in most areas, but not all. Incidence surveillance coordinators will need to ensure that the specimen ID is transmitted to and stored in HARS/eHARS.

Can each laboratory assign its own identification number before shipping?
Since it would be possible for two different laboratories to have the same laboratory-assigned identification numbering system, coordination is required among the private laboratories, the surveillance site Incidence Coordinator, and the CDC-STARHS Laboratory. The most feasible approach would probably have the private laboratory send samples to the state PHL which will then coordinate eligibility and assignment of the STARHS laboratory ID. The eligibility determination burden should not be the responsibility of the private laboratories.

Discussion Points regarding Sending Samples Directly to CDC-STARHS Laboratory from Private Laboratories:

1. The laboratory accession number will most likely be different than the STARHS number, so the laboratory accession number must be included on the CRF submitted by the laboratory to the state health department. The CDC-STARHS Laboratory will need to be

in close contact with the state Incidence Coordinator (and vice versa) to provide a linkage between the laboratory accession number and the STARHS identification number. The state surveillance department should be able to link the laboratory accession number to the surveillance data.

2. If national commercial laboratories send all HIV positive samples directly to the CDC-STARHS Laboratory, then the samples can be stored at the CDC-STARHS Laboratory until eligibility is determined for STARHS testing. Commercial laboratories should not wait until eligibility is determined before sending samples to the CDC-STARHS Laboratory.
3. The CDC-STARHS Laboratory will need to know the laboratory and other pertinent information and the state in which the sample was drawn so that results are sent back to correct site. This means that there needs to be something encoded in the STARHS number that indicates where to send the results.
4. Electronic reporting systems may be difficult to alter to include laboratory accession number if it is not already reported to the state surveillance system, but this could possibly be included in comments section.
5. Samples from commercial laboratories sent directly to the STARHS laboratory will need to be re-labeled with the STARHS number. This means that potential for error will be introduced. The Incidence Coordinator from each state will contact the CDC-STARHS Laboratory to test specific identification numbers (e.g., laboratory accession numbers), then CDC-STARHS Laboratory will pull only those samples, re-label with STARHS number, and test. Therefore, only samples eligible for STARHS testing will be re-labeled.
6. There was concern about laboratories sending the laboratory accession number to the CDC-STARHS Laboratory because of potential HIPAA concerns since the laboratory accession number can be linked back to the patient's medical record. However, there is a 'carve-out' for public health surveillance activities in the HIPAA legislation which allows such linkage.
7. Commercial laboratories would prefer to send samples directly to CDC-STARHS Laboratory and not have to divide up samples and ship to (potentially) several different state PHLs. The commercial laboratories would also prefer to send all HIV positive samples and not hold for eligibility determination because the time frame for storage is not feasible. Simplicity is key for the commercial laboratories.
8. Other laboratories would prefer to integrate this specimen transport into their current procedures with their local PHL. Many private labs have existing relationships with their state PHL for specimen transport for other diseases, including West Nile virus, salmonella, and tuberculosis. Instead of creating new procedures with the CDC-STARHS Laboratory, they requested to use their state PHL. In this case, the PHL would work with the Incidence Surveillance Coordinator to determine eligibility. The state PHL would assign the eligible samples a STARHS laboratory ID number from a pre-assigned set of IDs generated by the CDC-STARHS Laboratory and distributed to all participating PHLs.
9. Concern was raised about whether the state can legally communicate with the private laboratories to ask them to pull select HIV positive samples for shipment for STARHS testing as that would indicate to the laboratory that sample came from newly reported HIV cases and that samples not requested came from previously diagnosed and reported cases. The fundamental issue is that the information connected to the individual comes into the HIV surveillance system, but that information about the individual does not go out of the system. Given that, we will need to do our work without disclosing anything to the originating laboratory.

Recommendations for Specimen Transport Methods:

1. More than one option for specimen transport is feasible and preferable:
    a. Originating laboratory can send an aliquot of all confirmed HIV positive samples directly to the CDC-STARHS Laboratory
    b. Originating laboratory can send an aliquot of all confirmed HIV positive samples to the state PHL
2. Both methods must address specimen labeling issues and ensure a link between specimen identification number and the STARHS identification number.
3. The originating laboratory may choose which method would be preferable for them.
4. CDC in collaboration with participants of this consultation will draft a specimen transport procedures guidance outlining options for implementation of both methods.
5. Whichever method is chosen by the originating laboratory, an operating plan must be explicit.

Timeline for completion of procedures guidance document:

1. Draft completed within 60 days
2. Review process
    a. Draft will be distributed to consultation attendees for comment.
    b. PHLs will provide input with assistance from APHL.
    c. Medical center and local private laboratories can provide input via state Incidence Surveillance Coordinator.
    d. Legal review will be conducted internally at CDC and at major commercial laboratories for legality and HIPAA interpretation. The procedures may also need to be reviewed by states for HIPAA interpretation.
3. Distribution of Final (Reviewed) Procedures to Incidence Surveillance Coordinators, APHL for PHL directors, ACLA for commercial laboratories

Summary of Policy or Legal Issues to be Considered when Developing Draft Procedures:

1. Simplicity and flexibility of system – simpler system will be more likely to be acceptable
2. Turnaround time required / frequency of shipments – protocol needs flexibility
3. Resources – sufficient funds, time, and personnel for aliquoting and shipping specimens
4. Reports to PH surveillance programs must include laboratory specimen (accession) number so that STARHS result can be linked to surveillance data
5. Many laboratories send EIA positive specimens to a reference laboratory for confirmatory Western Blot (WB) or immunofluorescence assay (IFA). In some states both laboratories are required to report the positive test. In this case, care must be taken to ensure that the appropriate specimen accession numbers are associated with the correct surveillance reports.
6. Confidentiality must be protected and meet standards required for HIV surveillance
7. HIPAA regulations must be addressed
8. Some states have both State and City jurisdictions, which will require coordination between city, state, and private laboratories
9. Packaging and shipping procedures and regulations
    a. Shipping specimens by non-FedEx courier – Some jurisdictions, e.g. San Francisco, are not allowed to use FedEx. A CDC account number may be useful. Need flexibility in choice of shippers.
    b. Diagnostic specimens – Specimens may be shipped as ‘diagnostic specimens’, not ‘dangerous goods’ per change in shipping regulations about 2 years ago.

c. Dangerous goods certification – All laboratories shipping HIV positive samples must still be certified to ship dangerous goods even with the change in regulation allowing samples to be shipped as 'diagnostic specimens'.
d. Tracking shipments – Who will keep track of specimens shipped and received? One suggestion was to use the current system: Laboratories send a fax to the CDC-STARHS Laboratory when specimens are shipped, and receiving laboratory will notify site if specimens are not received.

10. Specimen numbering – How is laboratory accession number assigned? How will laboratory accession number be linked to state information on the individual? What number will be sent to the CDC-STARHS Laboratory?
11. Specimen volume – How much is too little to ship? Or ship all?
12. Rejection criteria must be documented (e.g., sample thawing, breakage, and lost in transit)
13. Sample storage and retention – How long should PHLs and CDC-STARHS Laboratory retain specimens?

<u>Specimen Numbering Issues</u>

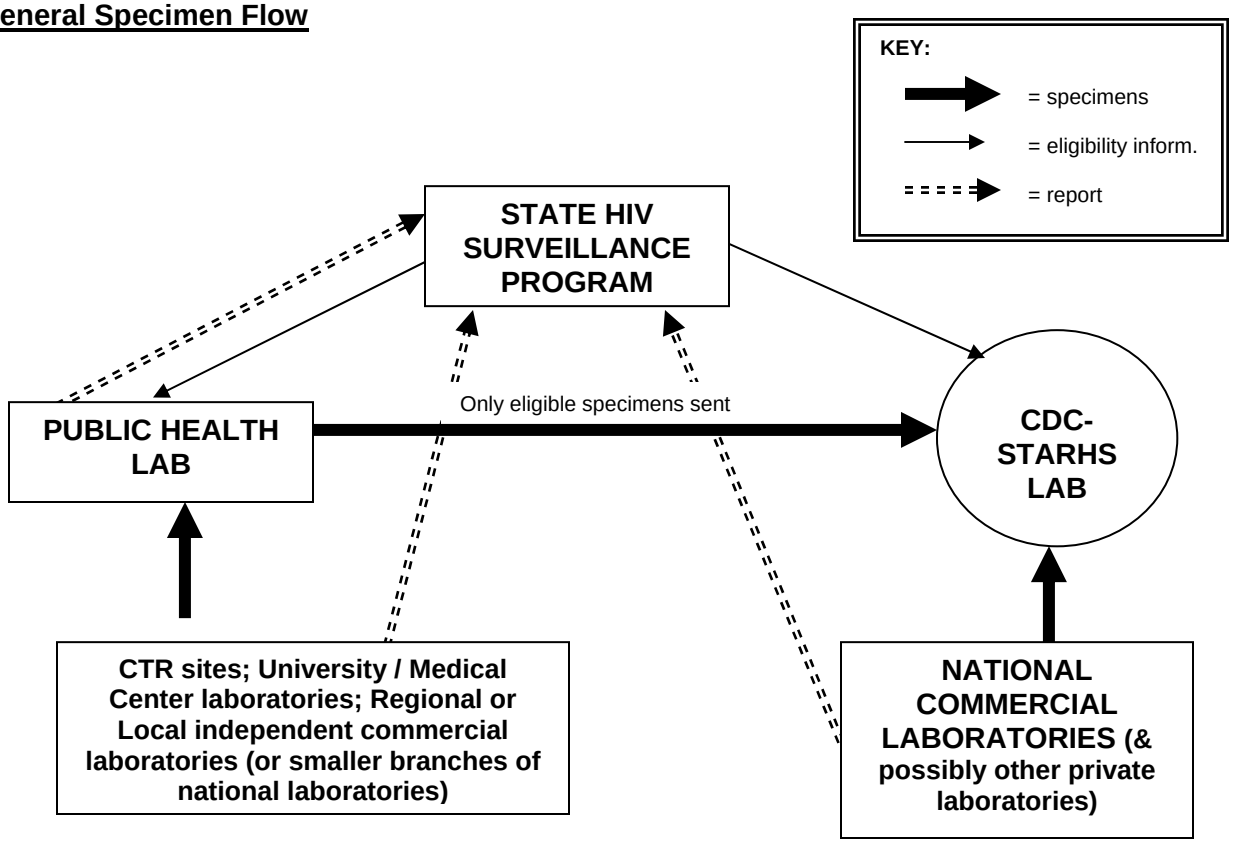
Questions: How is laboratory specimen number assigned? How is specimen number linked to state information on individual? What identification number will be sent to the STARHS laboratory?

1. Specimen needs to be linked with individual's PHD surveillance record.
2. STARHS results also need to be linked with individual's PHD surveillance record, but we do not want STARHS laboratory to link specimen to identifying data or medical record numbers outside of the surveillance system.
3. When samples are tested in the PHLs, the state surveillance Incidence Coordinator tells the PHL which samples are eligible for STARHS so the PHL can aliquot the specimen, label with the STARHS ID in the series assigned by the CDC-STARHS lab, sends a list of specimen IDs and corresponding STARHS IDs to the surveillance program, and sends the eligible specimen (labeled with the STARHS ID) to the CDC-STARHS Laboratory. STARHS ID is entered into the case surveillance record by the Incidence Surveillance Coordinator.
4. For national commercial (or other private) laboratories, the simplest plan is for the laboratory to send all HIV positive samples directly to the CDC-STARHS Laboratory with the originating laboratory's accession numbers. The CDC-STARHS Laboratory will track the laboratory accession number and storage information, retaining samples until eligibility is determined. Once a sample is determined eligible by the state Incidence Surveillance Coordinator, the CDC-STARHS Laboratory will pull and label the sample for testing. The CDC-STARHS Laboratory will provide to the state Incidence Surveillance Coordinator the link of accession number to STARHS number. The linkage is subsequently destroyed at CDC-STARHS Laboratory and only the STARHS number is used to process the testing. Any stored specimens that are not eligible for STARHS testing may be destroyed per appropriate laboratory procedures.
5. It is better (easier, less error prone) for the CDC-STARHS laboratory to assign (apply) labels to tubes and then apply the same label sticker to a line listing of accession numbers, rather than generating a label for a tube from a list of numbers provided by the state PHD.

Can laboratory accession number be disclosed?

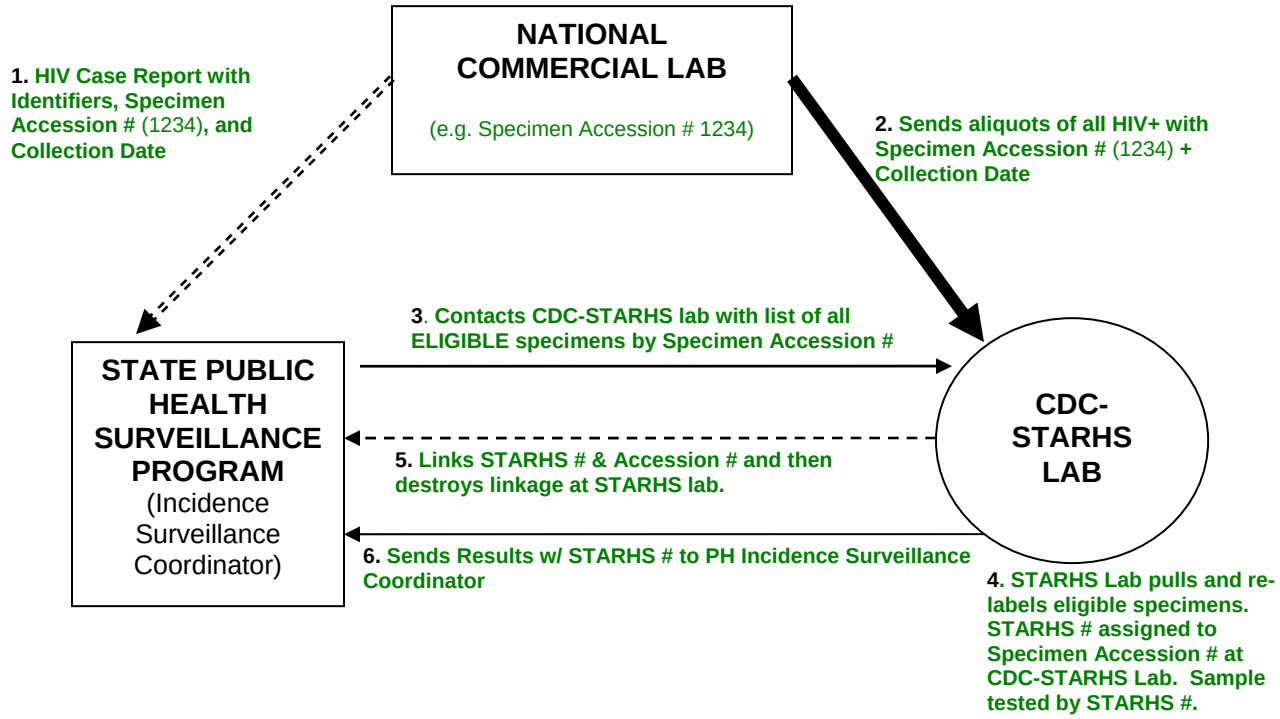
Currently, the testing laboratory sends CRF to the state PHD with various identifying and demographic information and may or may not include the laboratory accession number. It is imperative that the laboratory accession number be reported to the surveillance system with a positive test, as this is the only linkage between the specimen at the testing laboratory and the CDC-STARHS Laboratory ID numbers. It is this link that makes it possible to link STARHS results reported by the CDC-STARHS Laboratory to the Incidence Surveillance Coordinator.

General Specimen Flow



Three Scenarios for Specimen Transfer

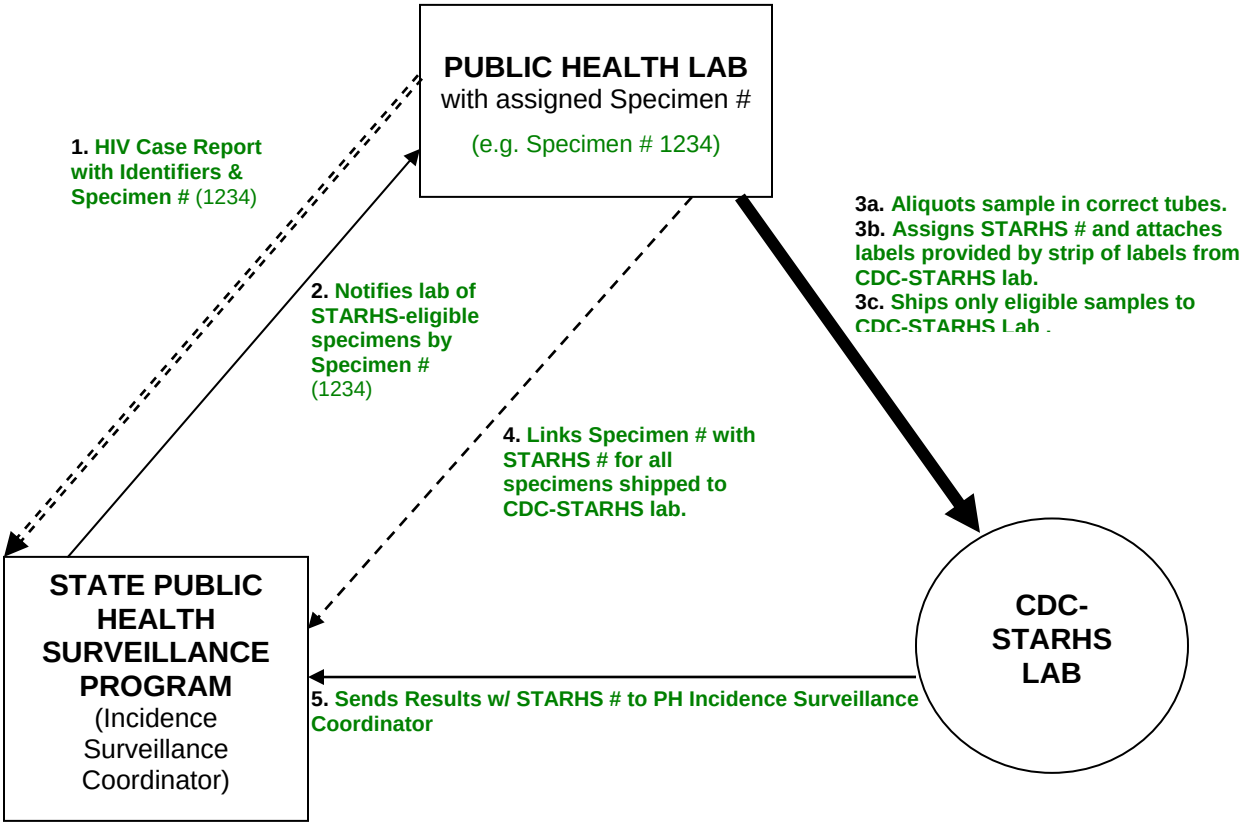
Scenario #1: SPECIMEN ORGINATES AT NATIONAL COMMERCIAL LABORATORY (OR SMALLER PRIVATE LABORATORY) AND IS SENT DIRECTLY TO THE CDC-STARHS LABORATORY



Key Points:

- National laboratory may recycle numbers by year. May need to close out series after appropriate time period (1 year) or may need to add year to number.
- This scenario can also work for other smaller private laboratories (university or small independent laboratories) that would like to ship all remnant samples directly to CDC-STARHS Laboratory instead of state PHL.
- The CDC-STARHS Laboratory will be responsible for re-labeling the aliquoted samples when they are pulled for testing. The CDC-STARHS Laboratory will apply a label to the sample tube and then to a line listing of eligible specimen accession numbers received from the State PH Surveillance Program. The CDC-STARHS Laboratory will send the State Incidence Coordinator the linkage information and then destroy the linkage information. All subsequent testing and results will only refer to the STARHS identification (ID) number and will no longer include the specimen accession number.

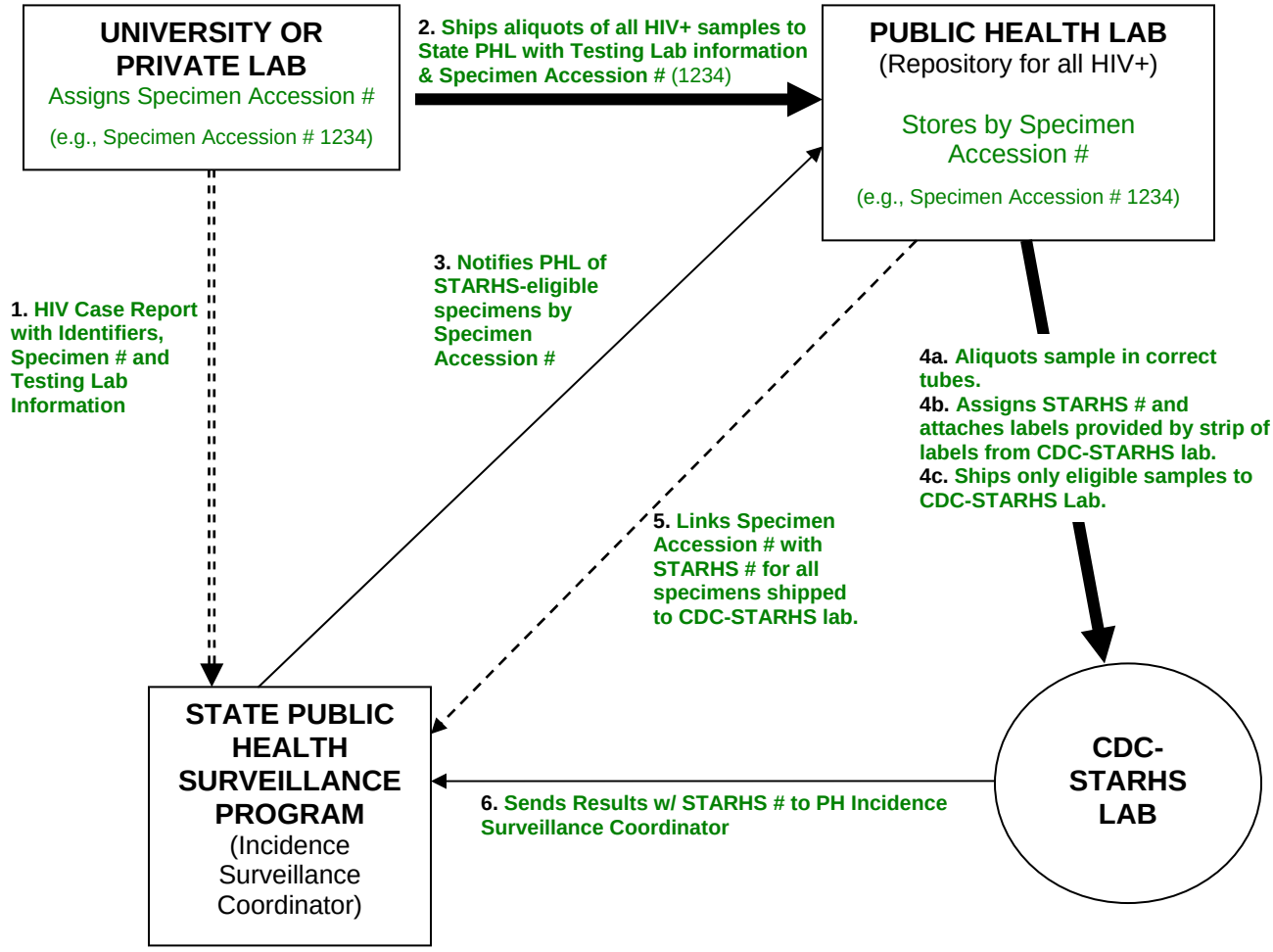
Scenario #2: SPECIMEN ORIGINATES AT A PUBLIC HEALTH LABORATORY (PHL PERFORMED THE CONFIRMATORY HIV TESTING)



Key Points:

- Reports from testing sites **must** include specimen number (CTR/CTS system number on sample) to PH Surveillance Program.
- In most states, the PHL will transfer samples to a new tube for retention purposes, but it retains the same specimen identification (ID) number.
- PHL sometimes assigns new specimen identification number. If so, they must maintain a link between private laboratory number and new specimen identification (ID) number.

Scenario #3: SPECIMEN ORIGINATES AT A SMALLER PRIVATE LABORATORY (e.g., a university hospital laboratory, regional or local independent commercial laboratory) AND SENDS SAMPLE TO STATE PUBLIC HEALTH LABORATORY (SERVES AS A PASS-THROUGH FACILITY)



Key Points:

- Part of this process may already be routine (Steps 1 and 2)
- Counseling, Testing, and Referral (CTR,/CTS) sites may assign specimen number instead of the testing (originating) laboratory.
- The CRF from the private laboratories **must** contain the specimen accession number so that linkage can be made at surveillance site; this may not be routinely reported currently.
- PHL sometimes assigns new specimen identification number. If so, they must maintain a link between private laboratory number and new specimen identification (ID) number.
- Role of PHL is to serve as a repository for samples. Eligibility will be determined by PHL and Incidence Surveillance Coordinator before sending samples collected in these types of private laboratories to the CDC-STARHS Laboratory.

Summary of Next Steps (Matt McKenna, CDC)

1. Summary of meeting notes to all participants for comment
2. Draft of Guidance document in 30-60 days
3. 3 models for specimen movement

There is always tension between 3 concerns: 1) HIV/AIDS is a lethal disease that people want to prevent, 2) equitable dispersal of public funds and 3) privacy concerns for patients.

HIV/AIDS is a very high priority of CDC. Information from incidence surveillance is very important for resource allocation by CDC and other Federal agencies. This collaboration has the potential for synergy between epidemiologists, laboratories, clinicians, laboratory technicians in affecting disease prevention.

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Atlanta, Georgia
April 20 – 21, 2005

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November 29, 2005

Brief write-up on revision of perinatal HIV surveillance case definition
April 20-21, 2005

In April 2005 CDC held a consultation to discuss revisions to the perinatal HIV surveillance case definition. The most recent revision of the HIV surveillance case definition was implemented in 1999; since then HIV testing technologies have improved such that HIV can be diagnosed sooner after infection. However, data from the Enhanced Perinatal Surveillance study reveal that a large percentage of infants born to HIV-infected mothers were classified with an "indeterminate" HIV status using the current surveillance definition (32% indeterminate among EPS births from 1999-2001).

The goals of the consultation were to:

a) review the current HIV surveillance case definition and the proposals for revision,
b) review evidence for changes that would simplify/improve the definition based on current scientific evidence, and ultimately
c) provide recommendations for the revision of the perinatal HIV surveillance case definition.

Consultation participants included domestic and foreign experts in HIV surveillance, pediatric infectious disease, immunology, HIV testing technologies, and community advocacy. In addition to CDC participants, consultants represented the World Health Organization; institutes, universities and schools of public health; hospitals; state health departments; national HIV/AIDS organizations; advocacy groups; and the Department of Health and Human Services.

Upon conclusion of the consultation a plan was drawn up for guideline revision. Tasks have been outlined and assigned to various consultation participants. Currently a working draft of the revised surveillance case is definition under development and will be ready for review by the end of December 2005. This revised definition will be published as an MMWR Reports and Recommendations; the goal is to have the R & R submitted to CDC clearance by the end of March 2006, with publication in June 2006.

Consultation on CDC Adult and Adolescent AIDS Case Definition Sheraton

Doubletree Atlanta Buckhead ■ Atlanta, GA

August 30-31, 2005

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Executive Summary
CDC Adult/Adolescent HIV/AIDS Surveillance Case Definition and Clinical Staging Consultation

Draft as of 2 November 2006

In August 2005, the HIV Incidence and Case Surveillance Branch (HICSB), Division of HIV/AIDS Prevention (DHAP), National Center for HIV/STD/TB Prevention, Centers for Disease Control and Prevention (CDC), convened a consultation in Atlanta, Georgia on the CDC adult and adolescent AIDS case definition for surveillance and clinical staging of HIV to determine whether and how the case definition and/or the clinical staging system should be revised. Attendees included clinical and surveillance experts in the area of HIV/AIDS, representing the World Health Organization (WHO), National Institutes of Health, CDC, Public Health Agency of Canada, Veterans' Administration, Health Resources and Services Administration, State and local health departments, and academia.

The consultation was convened because advances in treatment and diagnostics and knowledge about the spectrum of HIV disease warrant examination of the current HIV classification system and AIDS surveillance case definition. Recent treatment recommendations for the use of antiretrovial (ARV) agents identified asymptomatic persons with CD4+ T-lymphocyte (CD4) counts <350 cells/µL as having a short-term risk of developing an AIDS-defining condition high enough to warrant offering ARV therapy, suggesting that HIV-infected persons with this level of CD4 lymphopenia may warrant specific identification in a disease classification system. Opportunistic illnesses are making smaller contributions to AIDS case surveillance with time. WHO is similarly

examining these issues in the global context in developing their recommendations for revisions to the AIDS surveillance case definition and HIV clinical staging system.

Consultants recommended only minor modification to the adult/adolescent AIDS case definition, and strongly agreed that the immunologic criteria, currently set at CD4+ counts <200 cells/µL or <14% of total lymphocytes, should remain unchanged. Consultants supported a review of the clinical criteria that currently include twenty-six AIDS-defining illnesses for retention in the case definition. The group consensus was that a separately assembled panel of experts address some key unresolved issues, including the addition, maintenance, or exclusion of clinical conditions as AIDS-defining and the classification of primary HIV infection (the period between viral acquisition and initial stabilization of the immune system—approximately six months) in any revised AIDS case definition.

Consultants recommended that the CDC classification system for HIV infection should be changed and not discontinued. This system had been useful to clinicians and, to a lesser extent, surveillance staff. The system has fallen into disuse and should be revised to increase its usefulness. While a specific proposal for the revised system did not emerge from discussants, they agreed that the classification system should apply to HIV-infected persons and include immunologic and clinical components. Recommended revisions stressed that immunologic (CD4) criteria should serve as the backbone of classification, although a category of clinical conditions should remain as “AIDS-defining”. The major recommended revision to the existing classification system was that categories should be mutually exclusive, ordered hierarchically, ordinally, or otherwise with a clear progression from less severe to more severe. While consensus was not reached whether the system

should be applied in a dynamic fashion, with reclassification reflecting improvement and deterioration of the patient's clinical condition, consensus was reached that any developed system could be used in this fashion .

Based on these recommendations, HICSB plans several activities. To best address the consultation recommendations, HICSB will propose a revised HIV infection classification system focused on the status of the patient at the time of diagnosis and completely integrated with one comprehensive HIV/AIDS case definition for public health surveillance. The proposal will be vetted through surveillance partners such as the Council of State and Territorial Epidemiologists (CSTE), field surveillance staff, clinicians, and other affected parties. A second consultation is scheduled for mid-June 2006 with a wider set of stakeholders including those who establish policy, where participants will discuss consensus achieved at the first as synthesized by CDC staff. A more detailed report on the proceedings of this consultation is attached. For comments or questions, please contact Andrew Mitsch (404-639-6192 or ajm0@cdc.gov) or Dr. Kate Glynn (404-639-2003).

The findings and conclusions in this report have not been formally disseminated by CDC and should not be construed to represent any agency determination or policy.

HIV Incidence Estimation Consultation
June 15–16, 2006
Corporate Square, Building 8, Conference Room 1 B/C
Meeting Notes

June 15

Welcome

Introductions — Tim Green

Charge to the Group — Tim Green

Main Objectives

1. Examine the validity of the HIV incidence estimation method proposed by Karon, Song, Kaplan, and Brookmeyer, if the necessary information can be gathered, with respect to
   a. Stochastic uncertainty
   b. Bias (violation of assumptions)
   c. Performance characteristics of the assay
2. Identify other methods of HIV incidence estimation.
3. Determine what sort of an estimate can be produced by December 2006 for calendar year 2005.

Overview of Estimation Procedure — John Karon

1. Background
2. Sample survey approach
3. Potential problems and points for discussion
4. Assumptions about procedure

Discussion of Karon model

1. Stochastic uncertainty
   a. Variances have been worked out for several of the terms that involve uncertainty (e.g., I_o, I_1, I_B).
   b. One big source of variability is the uncertainty in the multiplier in equation 5 of the *Statistics in Medicine* submission (i.e., the coefficient of variation of φ). The estimate is very sensitive to the estimate of the mean window period.
2. Bias and assumptions
   a. Incidence and testing patterns (i.e., hazard, or instantaneous risk, of being tested) remain constant during AIDS incubation period (steady state).
      Problem: These assumptions are quite strong.
      Question: On the basis of these assumptions, can we use simpler models to arrive at a similar estimate?

b. All data are complete and accurate (including results of the assay and all responses to supplemental questions about testing history).

Problem: Realistically, we can only expect about 50% of assay results and an even smaller proportion of data on testing history. Missing data could be a big problem and needs further evaluation.

c. The window period distribution is valid.

Problem: The window period distribution for the BED assay hasn't been fully validated.

d. Testing characteristics of persons who avoid testing (i.e., test-resistant) differ from all others at risk for testing and must be stratified accordingly.

Problem: Conscious delay of testing may not be an accurate reflection of infection, especially if motivation *for* testing is not related to infection (i.e., we must assume a rational motive in both directions: early [soon after person becomes infected] and delayed testing).

3. Testing history information

a. We do not currently use motivation to classify individuals. Supporting information and justification is available from HICSB on request. We will test the sensitivity of the estimate to this assumption.

b. We do not need individual-level information on testing frequency.

c. We can obtain subgroup information from NHBS to determine the intertest distribution.

Problem: NHBS surveys only populations at high risk.

Question: Is it possible to survey HIV-negative persons who receive HIV counseling and testing services (CTS)?

d. We will consider incorporating into simulations the increased risk of testing soon after infection.

e. We have not resolved whether it is necessary to stratify according to whether individuals consciously delay testing.

i. The proportion of persons with AIDS who have not had a previous HIV test seems to be stable. A proportion of this population might be test-resistant.

ii. It may be possible to evaluate test-resistance by using testing frequency information from various populations (e.g., incidence data, NHBS, HITS, SHAS, BRFSS, NHANES, NHIS). We need to investigate whether these data sets are useful for us based on the available data variables and sample sizes.

4. General criticism

a. The group seemed to consider the mathematics valid but to believe that some of the steady state assumptions may be too strong.

b. Some participants felt that because of the steady state assumptions, this approach uses a sophisticated weighting scheme to essentially produce an estimate of the total number of new diagnoses—information that could be obtained more directly from surveillance data.

Status of Implementation

1. Data collection — Maria Rangel
2. Data completeness — Rick Song
    a. Dr. Rangel highlighted the collection of data on testing history and the collection of blood specimens for BED testing.
    b. Dr. Song presented preliminary surveillance data, with emphasis on completeness of data collected during 2005. Of the roughly 29,000 new cases diagnosed during 2005,
        i. More than 80% of reports of cases of HIV infection (not AIDS) were missing data on the most recent negative test result.
        ii. Only 13% of cases of HIV infection were BED tested.
        iii. 24% of cases of HIV infection received a diagnosis of AIDS within 1 month after receiving a diagnosis of HIV infection.
    c. In response to a request, Dr. Rangel presented the testing frequency distribution among cases diagnosed during 2005.

Review of Estimators — John Karon

1. Estimators for persons with a previous negative test result of known date
2. Estimators for persons not previously tested
3. Estimators for persons whose BED test was delayed
4. Extension of estimators to persons for whom data were missing
    a. Stratification
    b. Propensity scores
    c. Incorporation of patterns of missing data into simulations

June 16

Other Estimators and Supplemental Approaches

1. Naïve estimator: Number of newly diagnosed cases scaled to the national population (accounting for persons who will never get tested)

   Problem: Assumes that new diagnoses = new infections.

2. Back-calculation model developed by Rhodes and Glynn
3. Simplified STARHS estimator:

   The following proposal, although less mathematically sophisticated than the Karon et al. proposal, is much simpler. It is based on, but different from, $I_0 + I_B$.

   I_s = (# STARHS-recent) ÷ [P(1)*P(2)*P(3)], where

   P(1) = P(test HIV+ within 1 year | newly HIV infected)

   I.e., the probability that a person will be tested within 1 year after infection (stratified by subgroup).

   P(2) = P(STARHS administered | test result HIV+)

   I.e., the probability that this person receives a STARHS test. This estimate can be obtained from incidence surveillance data (13% for 2005). The number varies, depending on geographic location as well as testing location.

   P(3) = P(detected during window period | STARHS administered within 1 year after HIV infection)

   I.e., the probability the infection will be detected during the window period if STARHS is administered within 1 year after the person becomes infected.

   Discussion:

   a. Local areas may be able to use this estimator to compute local estimates.
   b. Like I_B, the information on testing behavior does not have to be linked to individual test results. Thus, several estimates can be obtained for each component of the estimator and combined to obtain a range of credible estimates for HIV incidence.
   c. Example.

      Number STARHS-recent = 757. This is the current number reported to HIV incidence surveillance for 2005.

      P(1) = 0.48 = 252/527. This is the proportion of newly diagnosed cases with at least 2 HIV tests during the 2 years before diagnosis, based on the data from the pretest questionnaire for incidence surveillance. Because this proportion does not include persons who had never tested before or who did not respond, it is likely to be inflated.

      P(2) = 0.13. This is the proportion of incidence surveillance cases that were STARHS tested in 2005.

      P(3) = 0.42. This is based on the mean window period = 5/12.

   d. Ways to obtain a better estimate of P(1).
      i. Use incidence data to estimate P(1) among HIV+ persons.
      ii. Use NHBS data to estimate P(1) in a population at high risk for infection.
      iii. Use BRFSS or other sources (see list above) to estimate P(1) in a general population.
   e. Seattle data on intertest intervals are linked with results from an incidence assay (probably Abbott).
   f. Try to verify the assumption that P(1) does not actually depend on infection status or how recently one was infected once membership in a population (e.g., MSM, IDU, or heterosexual adults or adolescents at high risk) is accounted for.

4. Direct (back of the envelope) estimator
   a. Use incidence rate and population size data on MSM in NYC.
   b. Scale to all transmission categories and national population.

5. Alternative approaches and issues
   a. To detect trends in incidence, monitor the number of new infections as a proportion of the total number of infections diagnosed over time.
   b. Obtain information on the total number of persons tested during a given period. This would require information on the number of negative test results and an adjustment for repeat testing among both positive and negative individuals—information is generally available only on the number of test kits distributed or the number of tests performed rather than on the number of persons tested.
   c. Obtain the testing frequency in a general population by surveying persons with a negative test result at CTS sites.
   d. Test the independence between the proportion recently tested and the proportion BED tested by site or facility (there should be no association).
   e. Evaluate uncertainty, consistency, and plausibility. Possibly convene an expert working group.
   f. Produce plausible ranges and lower and upper bounds for *N* and for large subgroups.
   g. Compare 2005 estimates with historical estimates for the mid-1990s.
   h. Evaluate window period estimates.
      Questions: Can better estimates of the window period be obtained? Very few data are available on people who have been infected more than 3 years. What about those who remain STARHS-recent even after a long time? Are incidence trends robust to STARHS results that falsely indicate recent infection (i.e., false-recents)?
   i. Investigate whether the probability of being tested within a year after becoming HIV infected is higher than the probability of being tested before infection.
   j. Investigate whether our sample of HIV+ persons whose specimens have been subjected to STARHS is biased because the early implementation of STARHS has been mostly at public testing sites.
   k. Estimate the proportion/number of HIV+ persons determined only by AIDS diagnosis.

l. Investigate what might happen if testing behavior changes.

m. Produce subgroup estimates.
   i. age (young adults 18–25, …)
   ii. sex
   iii. race/ethnicity
   iv. transmission category (male-to-male sexual contact, injection drug use, high-risk heterosexual contact)

Estimates of Window Period Distribution Bob Byers

Need to Adjust for Persons with Very Long Window Periods Meade Morgan

No recommendations were made to adjust the window period or formally incorporate adjustments for false-recents into the BED results.

Next Steps

1. Have draft report of 2005 estimates ready for internal review in 3 months (30 Sep 2006); have final report by 31 Dec 2006.
2. Convene groups to work on each of the estimation methods suggested. Each approach will incorporate data from multiple sources and will account for bias as well as variability.

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CDC Adult/Adolescent Surveillance HIV Case Definition Consultation
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