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Nomenclature and Definitions for Emergency Department Human Immunodeficiency Virus (HIV) Testing: Report from the 2007 Conference of the National Emergency Department HIV Testing Consortium

Michael S. Lyons, MD, **Christopher J. Lindsell, PhD**, **Jason S. Haukoos, MD, MSc**, **Gregory Almond, MD, MPH, MS**, **Jeremy Brown, MD**, **Yvette Calderon, MD, MS**, **Eileen Couture, DO, MS**, **Roland C. Merchant, MD, MPH, ScD**, **Douglas A.E. White, MD**, and **Richard E. Rothman, MD, PhD on behalf of the National Emergency Department HIV Testing Consortium**
Department of Emergency Medicine, University of Cincinnati (MSL, CJL), Cincinnati, OH; the Department of Emergency Medicine, Denver Health Medical Center (JSH), Denver, CO; the Department of Preventive Medicine and Biometrics, University of Colorado Denver School of Medicine (JSH), Aurora, CO; New York Medical College, Metropolitan Health Center (GA), New York, NY; the Department of Emergency Medicine, The George Washington University Medical School (JB), Washington, DC; the Department of Emergency Medicine, Jacobi Medical Center, Albert Einstein College of Medicine (YC), Bronx, NY; the Department of Emergency Medicine, Stroger Hospital, Rush Medical School (EC), Chicago, IL; the Department of Emergency Medicine, Warren Alpert Medical School, Brown University (RCM), Providence, RI; the Department of Emergency Medicine, Alameda County Medical Center, Highland Hospital (DAEW), Oakland CA; and the Department of Emergency Medicine, The Johns Hopkins University School of Medicine (RER), Baltimore, MD

Abstract

Early diagnosis of persons infected with human immunodeficiency virus (HIV) through diagnostic testing and screening is a critical priority for individual and public health. Emergency departments (EDs) have an important role in this effort. As EDs gain experience in HIV testing, it is increasingly apparent that implementing testing is conceptually and operationally complex. A wide variety of HIV testing practice and research models have emerged, each reflecting adaptations to site-specific factors and the needs of local populations. The diversity and complexity inherent in nascent ED HIV testing practice and research are associated with the risk that findings will not be described according to a common lexicon. This article presents a comprehensive set of terms and definitions that can be used to describe ED-based HIV testing programs, developed by consensus opinion from the inaugural meeting of the National ED HIV Testing Consortium. These definitions are designed to facilitate discussion, increase comparability of future reports, and potentially accelerate wider implementation of ED HIV testing.

Keywords

human immunodeficiency virus; HIV testing; emergency department; guidelines; definitions; consensus

Address for correspondence and reprints: Michael S. Lyons, MD; lyonsme@ucmail.uc.edu.

All attendees from the 2007 conference are listed as contributing authors in Appendix A.

Need for Consensus Definitions

The importance of human immunodeficiency virus (HIV) testing in the emergency department (ED) has long been recognized,[1] and the Centers for Disease Control and Prevention (CDC) recently charged emergency providers with making HIV testing a "routine" part of clinical emergency medical care.[2] Although still in its infancy, ED-based HIV testing has grown beyond the few initial pioneering centers.[3–12] Ongoing clinical programs, research studies, and demonstration projects are under way in many EDs, often with funding from a variety of organizations, including health departments, the National Institutes of Health (NIH), the Agency for Healthcare Research and Quality (AHRQ), the CDC, and various private foundations. The programmatic details of ED HIV testing are complex and are highly dependent on individual settings. As a result, variations in methods for ED HIV testing are becoming increasingly apparent.[7,11,13–24]

As ED HIV testing evolves beyond feasibility studies to larger-scale implementation, objective data that allow comparison of research and program experiences are needed. Productive debate and translation of knowledge is enhanced by transparent and consistent use of common terminology that decreases the likelihood of misinterpretation or ambiguity. The existence of terminology ambiguity in relation to ED-based HIV testing is already apparent in the literature,[14,17,25] and thus it is timely to develop consensus nomenclature and definitions. In November 2007, an open-invitation panel of experts was convened in part for that purpose.

Consensus Development and Process

An organizing committee of emergency researchers with experience in ED-based HIV testing planned a national meeting to systematically discuss key issues related to ED-based HIV testing, including terminology and definitions, guidelines for reporting practices and research findings, ethical and regulatory issues, operational variables, and screening impact. The inaugural conference of the National Emergency Department HIV Testing Consortium convened in Baltimore, Maryland, on November 12, 2007. Invitations to attend the conference were extended to those known by the conference organizers to be involved in existing or planned ED-based HIV testing at academic and community institutions. Attendees were encouraged to further distribute invitations to other potential participants from other institutions. Selected leadership organizations were also asked to send representatives. In total, there were 98 attendees at the conference, and 42 healthcare institutions from around the country were represented. Organizational representatives included those from the Society for Academic Emergency Medicine (SAEM), the American College of Emergency Physicians (ACEP), the HIV Medicine Association (HIVMA), and the CDC, as well as state health departments, advocacy organizations, and foundations.

A primary goal of the conference was to develop consensus definitions that would provide a common lexicon for the reporting of results from ED-based HIV testing research and clinical programs. A related goal was to develop a reporting guideline using these consensus definitions that would further characterize optimal presentation and content when preparing submissions relevant to ED-based HIV testing. Prior to the meeting, the primary authors of this article prepared a set of terms and definitions with an associated draft reporting guideline for ED-based HIV testing efforts, derived from their combined experiences and knowledge of the field. All conference attendees were encouraged to review a discussion guide, the draft definitions, the reporting guideline, and several pertinent manuscripts,[2,14,17] which were all distributed 1 month prior to the conference. The discussion guide listed questions that would be posed during the conference and specifically highlighted key areas of likely controversy, where there was known ambiguity and new approaches were being proposed.

Conference attendees were divided into four groups of 20–25 persons. Each group attended a 70-minute discussion session focused on development of consensus definitions and reporting guidelines. Conference organizers formed the groups in advance of the meeting and attempted to diversify the group composition to provide a mixture of persons from different academic, clinical, and institutional backgrounds. Each group session was led by a trained focus-group facilitator, and the session proceedings were recorded by video tape, audio tape, and a scribe. One of four moderators (MSL, CJL, JSH, RER; the primary authors) was present at each of the sessions to answer questions and provide any needed clarification about the definitions, the intent of the project, and the scope of the discussion sessions.

The focus group facilitator used a structured guide to direct discussion. Participants were first asked to initiate the discussion with any points they wanted to raise about content, scope, or consensus process. Following these discussions, the facilitators posed predetermined questions that the moderators believed might be the most controversial or contain areas of ambiguity.

After the consensus conference, the primary authors reviewed all comments recorded by the scribe and facilitator. In addition, the lead author reviewed the session recordings to ensure that the scribe and facilitator records accurately and completely reflected the discussion content. The primary authors then revised the definitions according to input from conference participants. Conference participants were sent electronic copies of the revised definitions for further review using an electronic listserv, in the attempt to not only promote critique, but further public discussion.

After reviewing further critiques and then finalizing the consensus definitions, the first draft of this article was developed by the primary authors and distributed to the larger group of core authors for further revision. Finally, the draft was distributed to all conference participants, including organizational representatives, for final comment to ensure that it ultimately reflected consensus. This article contains the final version of the terms and definitions developed via the consensus process described. A follow-up article utilizing these definitions will serve to provide the detailed consensus guideline for reporting on ED HIV testing.

CONSENSUS DEFINITIONS

The global organization of the consensus definitions is illustrated in Figure 1, which shows the categorization of key steps in the HIV testing process according to setting, procedures for recruitment and consent, postconsent program methods, and outcome measures. Each of these four content areas is linked to related tables of terminology and corresponding definitions (Tables 1–4). A table defining key summary measures of the testing process is also provided (Table 5). No further text accompanying the definitions is provided, as they are designed to be self-explanatory. Accordingly, detailed review of problems in prior terminology or specific justifications of each new term or definition are not provided in this report. Notably, conference participants consistently expressed the need for clarification of terminology and demonstrated the ability to achieve consensus via discussion

Utility and Limitations of Consensus Definitions

The suggested utility of these terms and definitions is to provide a blueprint for conceptualizing and describing ED-based HIV testing. The framework outlined here should accelerate knowledge translation by providing a common lexicon to facilitate discussion and interpretation of what would otherwise be an ambiguous evidence base. Clarity of discourse should enhance site-specific operational planning as ED HIV testing expands. These

definitions are not themselves sufficient to constitute a reporting guideline; the definitions will determine the terminology used in reporting, but do not specify what is reported. Accordingly, an article that fully describes consensus guidelines for ED HIV testing reporting will be developed.

It is important to note that these definitions are not intended as a dictum for ways in which HIV testing should be conducted. No element of this guideline is designed to promote or detract from past, current, or future clinical or operational practice. Some definitions are not likely to be relevant to contemporary or future emergency medicine (EM) practice (i.e., mandatory testing) and are included to clarify alternate terms. Further, future studies or reports of ED HIV testing may not include all or even the majority of elements described herein. Finally, the definitions were not developed with consideration of operational practices specific to postexposure situations and therefore do not necessarily pertain to HIV testing after blood or body fluid exposures.

The definitions are intended to have real or potential utility within the context of EM and may not be completely compatible with other healthcare settings. Where these definitions differ from what has been used previously, changes were deemed necessary to be responsive to the EM context. Despite these caveats, the consensus process included participants from a diversity of public health and healthcare backgrounds, and many of the clarifications contained herein may ultimately prove valuable to those involved with testing in other settings as well.

Several key terms deserve special comment.

- The definitions differentiate between “testing” and “screening.” When referring to general processes where no distinction is being made, we chose to use the more general term “testing” as it relates to an HIV test being performed. However, the concepts of testing and screening are not interchangeable and are distinctly defined in this article (see Table 2).
- The term “routine” was judged by consensus to be ambiguous and problematic. For example, “routine” can refer to either: 1) the selection of patients without respect to their acknowledged risk factors (i.e., nontargeted or universal selection criteria); 2) less-exceptional testing practices such as opt-out consent; or 3) both of these.[14] As such, the term cannot precisely describe any specific process element. While potentially useful in a general sense to broadly indicate movements toward less exceptional testing, it is not included as a distinct term herein.
- The term “informed” is not defined or tied by these definitions to the term “consent.” By consensus, it was deemed impossible to define “informed” in a manner that is consistent, precise, and free from significant controversy. However, the term “information” is defined. Consequently, the testing process may be understood in terms of the manner and content of information provided; whether any described process would result in the patient being adequately informed remains a matter of interpretation and local regulation.
- By consensus, the term “written” was also sufficiently ambiguous to preclude precise definition and is therefore not included. “Written” has been used to refer to the format in which information was provided, the manner in which consent is documented, and/or who (patient or provider) documented the consent. Instead, components of information transfer are herein defined in terms of “preresult information” and “program regulations” and the term “signed” is used to indicate the patient’s written signature or mark (Table 2).

- There was difficulty in selecting a single term to encompass the practice of screening patients without respect to their established risk (i.e., the alternative to targeted screening). The term "universal" is well-understood in perinatal screening and has historical precedent. However, it is possible that no EM screening program will ever succeed in universally screening all available patients. Recognizing this, it is entirely plausible that an ED would implement screening on a nontargeted basis without the expectation that all, or even most, of the available population would be screened. Indeed, there have already been several published examples of nontargeted ED screening programs that would not be accurately described with regard to intended or actual approach as "universal."[13,15,18,21] Ultimately, participants agreed that both terms should be defined. As such, while both terms refer to the nontargeted selection of patients, "universal" denotes the degree to which the process would be systematic and reasonably intended to be comprehensive, versus "nontargeted", which refers to selection of any patient within the available population without respect to likelihood of infection but does not imply the expectation of comprehensive inclusion of every available patient (Table 2).
- The consensus definitions do not include a detailed description of criteria that constitute targeted patient selection. This is in accordance with the pre-specified intent to avoid the provision of operational guidance; targeting practices and criteria remain in evolution. We have defined the terms "intended selection criteria," "presumed selection criteria," and "reasons test offered," which will allow clear discussion and reporting of the criteria used in a given practice setting.
- The definitions are intended to apply to registered ED patients, and the term "patient" is used throughout. The term "patient" is general and can refer to each registered visit by individuals to the ED or to a single person for whom there can be multiple ED visits. However, by consensus, the subset of outcomes and key summary measures (Tables 4 and 5 [26,27]) involving confirmed positive patients defines "patient" only in terms of unique persons and not ED visits.

CONCLUSIONS

By examining the diversity of factors relevant to the operation of ED-based HIV testing programs, the complexity and variability inherent in the process become apparent. The definitions provided in this article reflect consensus opinions provided by a convened group of ED clinicians and researchers, public health officials, HIV medicine clinicians, HIV advocates, and other groups. The purpose of the conceptual framework outlined here is to enhance translation of HIV testing to clinical practice by providing a common lexicon to aid interpretation of these programs and research efforts. A standardized nomenclature with which to describe implementation and research in ED HIV testing should facilitate and accelerate knowledge translation as institutions experiment and report on novel approaches to ED HIV testing.

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References

1. Rothman RE. Current Centers for Disease Control and Prevention guidelines for HIV counseling, testing, and referral: critical role of and a call to action for emergency physicians. Ann Emerg Med. 2004; 44:31–42. [PubMed: 15226706]
2. Branson BM, Handsfield HH, Lampe MA, et al. Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings. MMWR Recomm Rep. 2006; 55(RR-14):1–17. [PubMed: 16988643]
3. Baker JL, Kelen GD, Sivertson KT, Quinn TC. Unsuspected human immunodeficiency virus in critically ill emergency patients. JAMA. 1987; 257:2609–11. [PubMed: 3573258]
4. Kelen GD, Fritz S, Qaqish B, et al. Unrecognized human immunodeficiency virus infection in emergency department patients. N Engl J Med. 1988; 318:1645–50. [PubMed: 3163774]
5. Kelen GD, Bennecoff TA, Kline R, Green GB, Quinn TC. Evaluation of two rapid screening assays for the detection of human immunodeficiency virus-1 infection in emergency department patients. Am J Emerg Med. 1991; 9:416–20. [PubMed: 1863293]
6. Rothman RE, Ketlogetswe KS, Dolan T, Wyer PC, Kelen GD. Preventive care in the emergency department: should emergency departments conduct routine HIV screening? A systematic review. Acad Emerg Med. 2003; 10:278–85. [PubMed: 12615596]
7. Lyons MS, Lindsell CJ, Ledyard HK, Frame PT, Trott AT. Emergency department HIV testing and counseling: an ongoing experience in a low-prevalence area. Ann Emerg Med. 2005; 46:22–8. [PubMed: 15988422]
8. Schoenbaum EE, Webber MP. The underrecognition of HIV infection in women in an inner-city emergency room. Am J Public Health. 1993; 83:363–8. [PubMed: 8438973]
9. Alpert PL, Shuter J, DeShaw MG, Webber MP, Klein RS. Factors associated with unrecognized HIV-1 infection in an inner-city emergency department. Ann Emerg Med. 1996; 28:159–64. [PubMed: 8759579]
10. Kelen GD, Hexter DA, Hansen KN, et al. Feasibility of an emergency department-based, risk-targeted voluntary HIV screening program. Ann Emerg Med. 1996; 27:687–92. [PubMed: 8644953]
11. Kelen GD, Shahan JB, Quinn TC. Emergency department-based HIV screening and counseling: experience with rapid and standard serologic testing. Ann Emerg Med. 1999; 33:147–55. [PubMed: 9922409]
12. Goggin MA, Davidson AJ, Cantril SV, O'Keefe LK, Douglas JM. The extent of undiagnosed HIV infection among emergency department patients: results of a blinded seroprevalence survey and a pilot HIV testing program. J Emerg Med. 2000; 19:13–9. [PubMed: 10863112]
13. Centers for Disease Control and Prevention. Rapid HIV testing in emergency departments–three U.S. sites, January 2005–March 2006. MMWR Morb Mortal Wkly Rep. 2007; 56:597–601. [PubMed: 17585288]
14. Lyons MS, Lindsell CJ, Fichtenbaum CJ, Camargo CA Jr. Interpreting and implementing the 2006 CDC recommendations for HIV testing in health-care settings. Public Health Rep. 2007; 122:579–83. [PubMed: 17877304]
15. Lyss SB, Branson BM, Kroc KA, Couture EF, Newman DR, Weinstein RA. Detecting unsuspected HIV infection with a rapid whole-blood HIV test in an urban emergency department. J Acquir Immune Defic Syndr. 2007; 44:435–42. [PubMed: 17224850]
16. Mehta SD, Hall J, Lyss SB, Skolnik PR, Pealer LN, Kharasch S. Adult and pediatric emergency department sexually transmitted disease and HIV screening: programmatic overview and outcomes. Acad Emerg Med. 2007; 14:250–8. [PubMed: 17331918]
17. Rothman RE, Lyons MS, Haukoos JS. Uncovering HIV infection in the emergency department: a broader perspective. Acad Emerg Med. 2007; 14:653–7. [PubMed: 17538079]

18. Silva A, Glick NR, Lyss SB, et al. Implementing an HIV and sexually transmitted disease screening program in an emergency department. Ann Emerg Med. 2007; 49:564–72. [PubMed: 17113684]

19. Barrett TW, Schriger DL, Haukoos JS, Hopkins E, Byyny RL. Denver Emergency Department HIV Testing Study Group. Patient acceptance of rapid HIV testing practices in an urban emergency department: assessment of the 2006 CDC recommendations for HIV screening in health care settings [editorial]. Ann Emerg Med. 2008; 51:310–11. [PubMed: 18282524]

20. Haukoos JS, Hopkins E, Byyny RL. Denver Emergency Department HIV Testing Study Group. Patient acceptance of rapid HIV testing practices in an urban emergency department: assessment of the 2006 CDC recommendations for HIV screening in health care settings. Ann Emerg Med. 2008; 51:303–9. [PubMed: 18191295]

21. Brown J, Shesser R, Simon G, et al. Routine HIV screening in the emergency department using the new US Centers for Disease Control and Prevention guidelines: results from a high-prevalence area. J Acquir Immune Defic Syndr. 2007; 46:395–401. [PubMed: 18077831]

22. Merchant RC, Gee EM, Clark MA, Mayer KH, Seage GR III, Degruttola VG. Comparison of patient comprehension of rapid HIV pre-test fundamentals by information delivery format in an emergency department setting. BMC Public Health. 2007; 7:238. [PubMed: 17850670]

23. Calderon Y, Haughey M, Bijur PE, et al. An educational HIV pretest counseling video program for off-hours testing in the emergency department. Ann Emerg Med. 2006; 48:21–7. [PubMed: 16781919]

24. Gift TL, Hogben M. Emergency department sexually transmitted disease and human immunodeficiency virus screening: findings from a national survey. Acad Emerg Med. 2006; 13:993–6. [PubMed: 16894003]

25. Rothman RE, Merchant RC. Commentary. Ann Emerg Med. 2007; 49:577–9.

26. Murphy G, Charlett A, Osner N, Gill ON, Parry JV. Reconciling HIV incidence results from two assays employed in the serological testing algorithm for recent HIV seroconversion (STARHS). J Virol Methods. 2003; 113:79–86. [PubMed: 14553893]

27. Taylor MM, Hawkins K, Gonzalez A, et al. Use of the serologic testing algorithm for recent HIV sero-conversion (STARHS) to identify recently acquired HIV infections in men with early syphilis in Los Angeles County. J Acquir Immune Defic Syndr. 2005; 38:505–8. [PubMed: 15793359]

APPENDIX A

The following contributing authors attended the consensus conference and were included in the subsequent processes of manuscript review described herein.

Aldridge, Chris MD

Almond, Gregory MD, MPH, MS

Andrade, Roberto MD

Arbelaez, Christian MD, MPH

Archinard, Tommeka MD

Aronin, Steven I. MD

Barrera, Susan

Bateganya, Moses MD

Bell-Merriam, Joanna MD

Bongiovanni, Bob

Brady, Kathleen MD

Branson, Bernard MD

Brosgart, Carol MD

Brown, Jeremy MD

Cadoff, Evan MD

Calderon, Yvette MD, MS

Chaille-Arnold, Linda M. MD

Cheng, Ben MSc

Chiang, William MD

Copeland, Brittney

Cousar, Rosalyn L. RN, PhD

Couture, Eileen DO, MS

Czarnogorski, Maggie MD

Delgado, Kit MD

Erbelding, Emily MD, MPH

Feldman, James MD, MPH

Garcia, Osvaldo

Gaydos, Charlotte A. MS, MPH

Glick, Nancy MD

Gripshover, Barbara MD

Haukoos, Jason MD, MSc

Hayes, Alisa MD

Heffelfinger, James MD

Herrera, Laura MD, MPH

Hilley, Amy MPH

Holtgrave, David PhD

Hoots, Brooke MSPH

Hopkins, Emily SPH

Houry, Debra MD, MPH

Howell, Larry

Hsieh, Yu-Hsiang PhD

Hutchinson, Angela B. PhD, MPH

Jackson, Blanca RN

Jaker, Michael MD

Jones, Kerin MD

Jung, Juliana MD

Kampe, Linda BA

Kan, Virginia MD

Kass, Nancy ScD

Kelen, Gabor D. MD

Kroc, Karen BS

Kurth, Ann PhD, RN

Lampe, Margaret A. RN, MPH

Leider, Jason MD, PhD

Lemanski, Michael MD

Lindsell, Christopher J. PhD

Lyons, Michael MD

McGovern, Sandra RN

Mercer, Seth MD

Merchant, Roland MD, MPH, ScD

Miertschin, Nancy MPH

Miller, Joan

Mitchell, Patricia RN

Nelson, Sarah FNP

Onaga, Linda MPH

Paltiel, David PhD

Paul, Sindy M. MD, MPH

Pollack, Harold PhD

Raffanti, Stephen MD MPH

Randall, Liisa PhD

Rothman, Richard MD, PhD

Sabreen, Akhter DO

Sankoff, Jeffrey MD

Sasso, Vanessa

Saylor, Nathaniel Bernard MD

Schechter, Elissa MD

Schechtman, Barbara MPH

Schrantz, Steven MD

Scribner, Alicia MPH

Shahan, Judy RN, MBA

Skiest, Daniel MD

Spielberg, Freya MD, MPH

Stennett, Irijah S. PA

Sullivan, Patrick DVM, PhD

Teahan, Cathalene RN, MSN

Thompson, Susan

Torres, Gretchen MPP

Totten, Vicken MD

Wagner, Krystn MD

Walensky, Rochelle MD, MPH

Waxman, Michael MD

Weddle, Andrea

White, Douglas MD

Widell, Tom MD

Wilde, James A. MD

Wrenn, Keith MD

Yonek, Juliet

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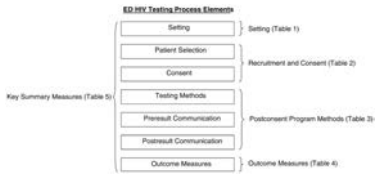

Figure 1.
Article organization. ED = emergency department; HIV = human immunodeficiency virus.

Table 1

Consensus Definitions and Core Theoretical Constructs: Setting

Geography and Epidemiology	
Geographic location	According to the US Census Bureau, regional designation such as East, West, North, or South and classification of urban or rural.
HIV/AIDS epidemiology	Estimated burden of HIV and/or AIDS within the population. Available measures may be known, reported, or estimated and specific to *prevalent infections* (known and unknown diagnoses), *prevalent cases* (known diagnoses), *incident cases* (new diagnoses that may include both prevalent and incident infections), and *incident infections (new infections whether or not diagnosed cases)*.
Regional population	Population of the larger region in which an ED is located (e.g., metropolitan statistical area, county, etc.).
Local population	Population from which visits to a given ED typically arise.
ED population	Population of individual patients visiting a given ED.
Facility	
Institution type	Institution type is defined in terms of the *primary* focus of mission and operations. This includes community hospital (patient care), teaching hospital (patient care + education), and academic hospital (patient care + education + research).
ED environment	ED mission (if different from institution) including affiliation with accredited EM residency, size (number of established beds and annual patient visit census), predisposition to HIV prevention and/or history of ED HIV testing, affiliation with infectious diseases or public health entities, and description of the general demographics of the patient population served.
HIV Testing Program	
ED HIV testing program	Any systematic approach to testing for HIV infection in the ED.
Program funding/resources	Resource support for HIV testing in the ED, whether direct or indirect, categorized according to external or internal direct program funding, indirect support (i.e., laboratory services or administrative oversight), reimbursement for patient care, and clinical or research support.
Program staffing	Personnel charged with various activities required for HIV testing, subdivided by training and expertise, hours of availability, role in testing program, and extent to which they are allocated specifically to HIV testing (exogenous staff) or employed solely as part of regular ED clinical operations (native staff).
Program regulations	Procedures required by national, state, or local law or other regulatory authority or by hospital or departmental policy.

AIDS = acquired immunodeficiency syndrome; ED = emergency department; EM = emergency medicine; HIV = human immunodeficiency virus.

Table 2

Consensus Definitions and Core Theoretical Constructs: Recruitment and Consent

Patient Selection Strategies and Criteria	
Diagnostic testing	Selection or intended selection of patients because of clinical signs and symptoms suspected to be due to HIV infection. Testing might be specifically intended to include detection of acute seroconversion, HIV, and/or AIDS.
Screening	Testing for reasons other than signs and symptoms possibly attributable to HIV infection.
Targeted	Selection or intended selection of all patients from among a defined *subpopulation* that are thought to have an increased likelihood of infection when compared to the base population.
Nontargeted	Selection or intended selection of *any* patient within the available population without respect to risk, but not intended to comprehensively include every available patient.
Universal	Selection or intended selection of *all* patients in the available population on a nontargeted basis; intended to comprehensively include every available patient.
Mandatory offering	The offer of HIV testing is mandated by regulatory or legal authority.
Intended selection criteria	The criteria that are intended to be used in the execution of the patient selection strategy.
HIV Consent	
Mandatory testing	HIV testing in a situation where the patient does not have the right to decline (e.g., if court mandated, prior to blood or organ donation, some exposure situations).
Implied consent	The patient is assumed to have consented for HIV testing by virtue of receiving care in a medical setting. There are no consent elements specific to HIV testing.
Voluntary consent	The patient: 1) has decision making capacity, 2) is aware of the testing prior to it being performed, and 3) has the right and opportunity to decline testing. Some form of independent consent process is required, whether integrated into a general consent for medical care or performed separately.
Default assumption of patient willingness to undergo testing	
Opt-in	Testing presented so the patient would be expected to understand the default is to not test unless he or she states agreement. Assent is not inferred unless the patient agrees to testing.
Opt-out	Testing presented so that the patient would be expected to understand the default is to test unless he or she declines. Assent is inferred unless the patient declines testing.
Patient awareness of right not to undergo testing	
Implicit	Although the patient has the right to decline HIV testing, his or her understanding of that right is assumed without specific and reliable patient notification of that right.
Explicit	The patient is explicitly and reliably notified of his or her right to decline HIV testing.
Patient indication of willingness to be tested	
Verbal	The patient indicates his or her assent (or absence of refusal) by verbal (or absence of verbal) comment. This does not refer to what consent information is given, or the format in which it is transmitted.
Signed	The patient indicates his or her consent (or absence of refusal) by his/her signature or mark. This does not refer to what consent information is given, or whether that information is written.
Integration with consent process for general medical care	
Integrated	Notification of the possibility of HIV testing occurs as part of the process by which general consent for medical care is obtained. This may be on a separate form or may be combined with other forms.
Separate	Notification of the possibility of HIV testing is separate from the process by which general consent for medical care is obtained by differences in either personnel obtaining consent, timing of consent, or location where consent obtained.

AIDS = acquired immunodeficiency syndrome; HIV = human immunodeficiency virus.

Table 3

Consensus Definitions and Core Theoretical Constructs: Postconsent Program Methods

Testing and Assay	
Assay	Diagnostic device used. Categorized according to: • Specimen type (e.g. blood, oral fluid) • Method of obtaining specimen (e.g. swab, finger stick, venipuncture) • Speed or time from test to result availability • Type of assay (e.g., antibody, antigen, nucleic acid) • Name of assay and manufacturer • Time and expertise requirement for performing assay (e.g., number of process steps, difficulty, specialist skills required) • Regulation and oversight (e.g., ED, hospital laboratory, health department, Clinical Laboratory Improvement Amendments [CLIA], manufacturer) • Location of processing (e.g., point-of-care bedside, point-of-care ED-based • laboratory/"near-patient," non-ED hospital laboratory, laboratory not on hospital campus)
Rapid assay	Results expected to be available during ED encounter.
Conventional assay	Results not expected to be available until after the ED encounter.
ED test	Initial assay employed during index visit.
Additional test	Any repeat, confirmatory, or other testing during or after initial ED test, further categorized by assay type, timing, and location where performed.
Anonymous testing	Personal identifiers are not recorded, nor associated with the result.
Confidential testing	The person being tested for HIV provides his or her name and other identifying information.
Preresult Communication	
Testing process information	Basic information about HIV, its illness, and the testing assay. May also include related information such as the epidemiology of HIV infection, current public health recommendations, or other testing options. Minimally intensive and not individualized.
Education	General information about HIV specific to transmission and risk reduction intended to increase health literacy. May not be highly individualized, and falls short of the rigorous requirements for prevention counseling or motivation of behavior change.
Prevention counseling	An interactive process of assessing risk, recognizing specific behaviors that increase the risk, and developing a plan to take specific steps to reduce risks. Highly individualized and expected to motivate behavior change.
Postresult Communication and Methods	
Patient result notification	Process by which the patient is provided with his or her test result, categorized by methods, assigned personnel, timing, and mode of delivery (e.g., in person, by mail, or by phone) and assay result.
Postresult information	Basic information about HIV, the illness caused by HIV, and any other information needed to understand the individual test result.
Referral	Appointments made or referrals given, categorized by assay result, and intended service or provider/agency.
Passive referral	Giving the patient information by which they may seek subsequent services.
Active referral	Actively working to ensure that patients receive care subsequent to their ED visit, such as making an appointment for them and/or attempted remediation of any failed referral or linkage to care.
Result documentation	Any method by which results are documented, including the personnel responsible, location of storing results, regulatory controls on subsequent access to results, and any other pertinent regulations.
Result disclosure	Transmission of test results to an outside entity (e.g., at-risk partners, healthcare entity) categorized by systematic or indication based, receiving entity, and assay result. Does not refer to patient result notification.
Result reporting	Transmission of test results to public health authority to satisfy surveillance requirements.

ED = emergency department; HIV = human immunodeficiency virus.

Table 4

Consensus Definitions and Core Theoretical Constructs: Outcome Measures

Program Operations	
Program costs	Defined generally and variably to include any accounted or estimated monetary or resource expenditure, categorized as directly allocable costs, indirect costs, and costs charged to patient or third-party payers.
Presumed selection criteria	Any patient factors pertinent to intended selection criteria and known *prior to the test offer* that might have or are assumed to have influenced selection in the absence of specific documentation of the precise motivating factors for testing.
Reasons test offered	Actual selection criteria that are *known* to have motivated the offering of a test to a given patient (i.e., the precise indication(s) leading to testing specifically documented).
Patient Characteristics	
Risk profile	Factors known about the patient that are pertinent to likelihood of HIV infection. This may include factors recognized before or after the test was made available.
Reasons for declining	Explanations provided by patients for why they did not want to be tested.
HIV Assay Results	
Negative	Any test result from an assay that has no indication of HIV infection.
Indeterminate	Any test result from an assay that does not differentiate between the presence or absence of HIV infection.
Reactive	Any positive test result from an assay that is not approved or accepted as equivalent to a confirmatory test.
Confirmed positive	Any positive test result from an approved and accepted confirmatory assay indicating that the patient is infected with HIV.
Unknown result	Any testing process for which there is not an available result. This includes rapid assays that are positive or negative but read after the recommended time window for reading the test has expired.
Stage of Illness	
Acute HIV infection	Patient has been infected with HIV but has not completed the development of an initial immunologic response.
Suspected	Clinician suspicion of acute HIV infection based on clinical signs or symptoms
Presumed	Positive virologic test for previously undiagnosed patient not under HIV treatment with concurrently or subsequently obtained negative or indeterminate serologic test.
Confirmed	Evidence of acute seroconversion ultimately followed by a confirmed HIV diagnosis.
Recent infection	Evidence of recent infection by Serological Testing Algorithm for Recent HIV Seroconversion (STARHS)[26,27] or other validated method.
Chronic infection	Patient infected with HIV without evidence of recent or acute infection.
Early diagnosis	CD4 count measured at some point after diagnosis but before therapy that exceeds the CD4 threshold when antiretroviral therapy is routinely recommended.
Intermediate diagnosis	CD4 count measured at some point after diagnosis but before therapy that is below the CD4 threshold for when therapy is routinely recommended, but above 200 cells/μL in a patient with no opportunistic illness at initial HIV diagnosis or within the subsequent year.
Late diagnosis	CD4 count within 90 days of diagnosis of less than 200 cells/μL or opportunistic illness at initial HIV diagnosis or within the subsequent year.
Result Notification and Linkage	
Result notification	Receipt of test result by the patient.
Successful notification	Result notification within 14 days (conventional testing) or during ED visit (rapid testing).
Delayed notification	Result notification more than 14 days (conventional testing) or after ED visit, whether hospitalized or discharged (rapid testing).
Unsuccessful notification	No indication that the patient was notified of his or her test result.
Linkage	Any indication of the patient having received intended HIV related care in a nonemergency setting. Categorized by linkage timing and process by which linkage occurs.
Linkage timing	

Successful linkage	Linkage less than 30 days after the initial ED encounter. Includes patients hospitalized after the ED encounter, provided that the inpatient physician was aware of the diagnosis while the patient was in the hospital.
Delayed linkage	Linkage between 30 and 90 days after the initial ED encounter.
Unsuccessful linkage	Lack of patient linkage within 90 days after the initial ED encounter.
Linkage process	
Independent	Linkage by the patient independent of any referral process available.
Direct linkage	Linkage as a result of active or passive referral process by ED testing program.
Indirect linkage	Linkage as a result of efforts of entities other than ED testing program.
Program Populations	
Eligible population	ED patients for whom it is permissible to provide HIV testing according to all local, state, and national policies.
Target population	Eligible ED patients according to patient selection strategy and intended selection criteria of program.
Offered population	Eligible patients who were offered testing according to actual selection criteria.
Declining population	Eligible patients offered testing and who declined to be tested.
Consenting population	Eligible patients offered testing and who agreed to be tested.
Tested population	Consenting patients who were actually tested.
Population negative	Tested patients who had a negative test result.
Population indeterminate	Tested patients who had an indeterminate test result.
Population preliminarily positive	Tested patients who had a preliminary positive test result.
Population confirmed positive	Tested patients who had a confirmatory positive test result.
Population newly positive	Tested patients who had a confirmatory positive test result and are not previously known to be positive.
Population previously positive	Tested patients who have a confirmatory positive test result who were known to be previously diagnosed as positive.
Discharged population	Tested patients discharged from the ED after initial evaluation, categorized by test result.
Admitted population	Tested patients observed or admitted to hospital after initial evaluation, categorized by test result.
Notified population	Tested patients successfully notified, categorized by test result and method of notification.
Linked population	Tested patients successfully linked, categorized by test result, method of linkage, and intended service or provider/agency.

ED = emergency department; HIV = human immunodeficiency virus.

Table 5

Key Summary Measures

Proportion consenting	Proportion of offered population that consented to testing.
Proportion ED population tested	Proportion of ED population tested.
Proportion target population tested	Proportion of target population tested.
Cost per patient tested	Estimated program costs divided by the number of tested patients.
Proportion receiving confirmatory testing	Proportion of population preliminary positive that receives confirmatory testing.
Proportion positive	Proportion of population tested that are confirmed to be positive.
Positive predictive value of preliminary positive assay	Among patients for whom confirmatory test information is available, the proportion of preliminary positive test results that are confirmed to be positive.
Proportion successfully notified	Proportion of population tested who are successfully notified of their results, categorized *by test result*.
Proportion newly positive— or program prevalence	Proportion of population tested who are confirmed to be positive and not known to be previously diagnosed.
Proportion linked positives	Proportion of newly positive population successfully linked to care.
Confirmed positive CD4 count	Median value of CD4 counts obtained within 90 days of index test for population newly positive.
Proportion late diagnoses	Proportion of population newly positive who have late diagnosis.
Cost per positive	Estimated program costs divided by the number of newly positive persons.
Cost per linked positive	Estimated program costs divided by the number of newly positive persons who were linked to care.

ED = emergency department.