Incidence Methodology Timeline

CDC HIV/AIDS TECHNICAL BRIEF August 2008

CDC's publication of the new HIV incidence estimates is the outcome of work carried out during the past ten years. This complex methodology developed from two separate lines of work – the laboratory science of the STARHS (serologic testing algorithm for recent HIV seroconversion) assay and the statistical/surveillance work that provided the incidence estimates and corroboration – each of which were developed, tested, and evaluated.

In keeping with the best scientific practices, CDC 1) periodically convened meetings with other scientists and experts from across the country in order to obtain input on the emerging methods; 2) pilot tested the methods with small groups to ensure feasibility, and 3) published both their methods and findings in peer-reviewed scientific journals. This process ensured that both CDC's methodology and its application represent the best available science and are transparent, explainable, and reproducible.

Science is dynamic, constantly changing through new developments. As such, CDC will continue to adapt and refine these methods to incorporate new innovations and emerging technologies.

Following is a brief chronology of key events in the development of this new technology, the methodology, and its application, which resulted in the publication of national HIV incidence estimates.

1998	CDC publishes a description of the STARHS assay, a laboratory test that can distinguish recent HIV infections from long-standing ones on a population basis. (Janssen RS, Satten GA, Stramer SL, et al. New testing strategy to detect early HIV-1 infection for use in incidence estimates and for clinical and prevention purposes. *JAMA* 1998; 280:42-48.)
2001 (Feb)	CDC holds large consultation with statisticians and surveillance experts to discuss the feasibility of using the STARHS assay to estimate HIV incidence. Conclusion: CDC should establish an HIV surveillance system based on STARHS rather than continuing with serosurveys.
2001 (Fall)	CDC proposes the statistical methods that form the basis of the new incidence system.
2001 (Oct)	CDC convenes a small consultation with statisticians and surveillance experts to discuss the statistical methodology. Conclusion: The statistical theory was solid but behavioral data on HIV testing was needed in order to generate probabilities.
2001 (Oct)	CDC funds 5 areas to pilot the feasibility of employing these techniques to collect data.
2002 (Dec)	CDC funds an additional 19 areas to refine and further develop implementation protocols.

2004 (Jan)	CDC funds 33 areas to conduct incidence surveillance. These areas were to use one of three protocols in light of regulatory requirements regarding informed consent as applied to the STARHS testing (detuned assay).
2005 (Mar)	FDA designates the BED assay as a surveillance, not a diagnostic, test. This designation sets the stage for population-based incidence surveillance. Additional level of consent to employ STARHS testing is no longer needed and all areas could implement one protocol.
2005	CDC funds one additional area to conduct incidence surveillance.
2006 (Mar)	Scientists submit methods paper to *Statistics in Medicine*.
2006 (June)	CDC holds a consultation on the validity of the statistical method (sample survey approach). Outcome: The consultants proposed a simplified approach and the back-calculation method.
2006 (June) – 2007 (Feb)	CDC modifies its statistical methods as recommended at the consultation.
2007 (Feb)	CDC convenes a consultation to present 2005 estimates and methods to peers in order to receive feedback and meet the requirement for CDC Information Quality Peer Review for Influential Scientific Information: http://www2a.cdc.gov/od/peer/review.asp?id=173
2007 (Feb)– 2007 (June)	CDC finalizes its statistical methods by combining the modified sample survey approach and the simplified approach into the stratified extrapolation approach and refined the back-calculation approach.
2007 (June– Oct)	CDC scientific review and clearance.
2007 (Oct)	Methods manuscript accepted by *Statistics in Medicine*.
2007 (Oct)– 2008 (June)	CDC submits HIV incidence manuscript for scientific review, receives and addresses comments, including up-dates with 2006 data.
2008 (June)	Incidence manuscript accepted by *JAMA*.
2008 (Aug)	CDC's methods paper is published in *Statistics in Medicine* (Karon KM, Song R, Kaplan E, Brookmeyer R, Hall HI. Estimating HIV incidence in the United States from HIV/AIDS surveillance data and biomarker HIV test results. *Stat Med.* 2008).
2008 (Aug)	CDC's incidence paper published in *JAMA* (Hall HI, Song R, Rhodes P, et al. Estimation of HIV incidence in the United States. *JAMA* 2008).

For more information on HIV/AIDS surveillance, visit http://www.cdc.gov/hiv/topics/surveillance.

HIV/AIDS RESOURCES

CDC HIV/AIDS
http://www.cdc.gov/hiv
CDC HIV/AIDS resources

CDC-INFO
1-800-232-4636
Information about personal risk and where to get an HIV test

CDC National HIV Testing Resources
http://www.hivtest.org
Location of HIV testing sites

CDC National Prevention Information Network (NPIN)
1-800-458-5231
http://www.cdcnpin.org
CDC resources, technical assistance, and publications

AIDSinfo
1-800-448-0440
*http://*www.aidsinfo.nih.gov
Resources on HIV/AIDS treatment and clinical trials