Clinical Effectiveness of Routine Opt-Out Rapid HIV Screening in the Emergency Department: Results from an Ongoing Prospective Clinical Trial

Jason S. Haukoos, MD, MSc, Emily Hopkins, MSPH, Richard L. Byyny, MD, MSc, Jessica Forsyth, MSW, Anne Marlow-Geter, Steven Johnson, MD, Mark W. Thrun, MD, for the Denver Emergency Department HIV Testing Study Group, Denver, Colorado

BACKGROUND

Approximately 250,000 unrecognized HIV infections exist in the United States and 56,300 new infections occur annually.

In 2006, the CDC published revised recommendations for performing HIV testing in healthcare settings, calling for routine opt-out HIV screening of persons 13-64 years of age in all healthcare settings, including emergency departments (EDs).

The impact of these recommendations has not been assessed.

OBJECTIVE

The objective of this study is to evaluate the clinical effectiveness of performing routine opt-out rapid HIV screening when compared to physician-directed diagnostic rapid HIV testing in an urban ED.

METHODS

A prospective quasi-experimental equivalent time-samples clinical trial performed in the ED at Denver Health Medical Center (DHMC) in Denver, Colorado.

DHMC is an urban, inner-city hospital with an annual adult ED census of ~55,000 and an undiagnosed HIV seroprevalence of ~0.7%.

Routine opt-out rapid HIV screening (intervention) and physician-directed diagnostic rapid HIV testing (control) were alternated in four-month time periods.

During intervention periods, all ED patients (≥16 years) were offered rapid HIV testing on an opt-out basis by registration.

During control periods, emergency physicians used a diagnostic approach to offer rapid HIV testing. Each method was fully integrated into ED operations (**Figures 1** and **2**).

Figure.

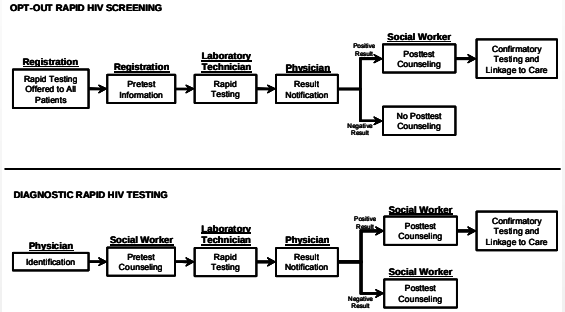

Table 1. Patient characteristics for those who were eligible to be tested for HIV infection and those actually tested during each study phase.

	Physician-Directed Diagnostic Rapid HIV Testing	Opt-Out Rapid HIV Screening
Total number of eligible patients	29,171	30,281
Total number of eligible patient-hours	163,976	161,973
Median age (range)	40 (16-103)	40 (16-104)
Male sex	16,540 (57%)	17,165 (57%)
Race/Ethnicity		
African-American	4,069 (14%)	4,199 (14%)
Asian	296 (1%)	321 (1%)
Caucasian	11,571 (40%)	11,651 (38%)
Hispanic	9,816 (34%)	10,260 (34%)
Other	445 (2%)	535 (2%)
Unknown/Missing	2,974 (10%)	3,314 (11%)
Admitted to the hospital	6,415 (22%)	6,882 (23%)
Opt-Out		
Yes	- -	22,829 (75%)
No	- -	7,098 (23%)
Incomplete registration	- -	354 (1%)
Tested	166 (0.6%)	5,377 (18%)
Diagnosed with HIV infection		
Yes	3 (1.8%)	14 (0.3%)
No	163 (98.2%)	5,363 (99.7%)

Table 2. Patient demographics for those who were tested for HIV infection and those who were identified with HIV infection.

	Physician-Directed Diagnostic Rapid HIV Testing	Opt-Out Rapid HIV Screening
Total tested for HIV infection	166 -	5,377 -
Median age (range)	39 (17-74)	39 (16-96)
Male sex	118 (71%)	2,806 (52%)
Race/Ethnicity		
African-American	29 (17%)	901 (17%)
Asian	1 (1%)	38 (1%)
Caucasian	75 (45%)	1,955 (36%)
Hispanic	50 (30%)	2,069 (38%)
Other	1 (1%)	323 (2%)
Unknown/Missing	10 (6%)	91 (6%)
Confirmed Positive	3 -	14 -
Median age (range)	46 (40-50)	35 (21-58)
Male sex	3 (100%)	12 (88%)
Race/Ethnicity		
African-American	0 (0%)	1 (7%)
Asian	0 (0%)	0 (0%)
Caucasian	1 (33%)	5 (36%)
Hispanic	2 (67%)	6 (43%)
Other	0 (0%)	2 (14%)
Unknown/Missing	0 (0%)	0 (0%)

METHODS (Cont.)

Rapid HIV testing was performed by the hospital's laboratory using whole-blood and a two-step multiple testing algorithm (Uni-Gold™ Recombigen® HIV Test, Trinity Biotech and OraQuick Advance® HIV 1/2, OraSure Technologies).

The outcome was the number of patients identified with HIV infection.

RESULTS

Between April 2007 and August 2008, two intervention and two control periods were completed.

During the control period, 29,171 eligible patients presented to the ED and 166 (0.6,%) completed rapid HIV testing. Of these, 3 (1.8%, 95% CI: 0.4% - 5.2%) were diagnosed with HIV infection.

During the intervention period, 30,281 eligible patients presented to the ED and 5,377 (18%) completed rapid HIV testing. Of these, 14 (0.3%, 95% CI: 0.1%-0.4%) were diagnosed with HIV infection.

Patients characteristics between the two study phases are provided in **Tables 1** and **2**.

The incidence rate of HIV identification during the intervention and control periods were 0.9 cases and 0.2 cases per 10,000 patient-hours, respectively. The incident rate ratio was 4.7 (95% CI: 1.3-25.6).

All but one HIV-infected patients were linked into care.

CONCLUSIONS

Preliminary findings suggest that routine opt-out rapid HIV screening is more clinically effective than physician-directed diagnostic rapid HIV testing in the ED.

DENVER EMERGENCY DEPARTMENT HIV TESTING STUDY GROUP

Denver Health ● Denver Public Health ● Children's Hospital of Denver ● Colorado Department of Public Health and Environment ● University of Colorado Denver and Health Sciences Center