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

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### Evaluation of Opt-Out Rapid HIV Testing in the Emergency Department

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# Background

- ~ 250,000 people in the United States have undiagnosed HIV infection and ~ 56,000 acquire HIV annually
- Undiagnosed HIV infection in the United States continues to significantly contribute to its forward transmission
- The current CDC recommendations for HIV testing in healthcare settings call for increasing opportunities and minimizing barriers for performing routine optout rapid HIV screening

# Background

- Cost effectiveness is critical when considering potential clinical venues for performing routine HIV screening, including in emergency departments (EDs)
- Routine rapid HIV screening carries significant operational costs
- Costs are frequently cited as a barrier to expanding HIV testing
- Costs are an important component in decision-making

# Background

- Several theoretical cost effectiveness models have been developed
- Most conclude that routine HIV screening is cost effective from a societal perspective
- The accuracy of the findings depend on how well the assumptions reflect real-world conditions and the perspective of the analysis
- Thus, outcomes of HIV testing programs based on recommendations and policies suggested by these models need to be evaluated

# Objective

• To compare the cost effectiveness of performing routine opt-out rapid HIV screening with physician-directed diagnostic testing in an urban emergency department

# Setting

- Denver Health Medical Center in Denver, Colorado
- 396-bed urban public teaching hospital and level 1 trauma center
- Integrated healthcare system (public hospital, community health clinics, and public health department)
- Annual ED census ~ 55,000 adult patients
- ~ 70% racial/ethnic minorities and ~ 40% uninsured
- Undiagnosed ED HIV seroprevalence ~ 0.7%

### Methods: Clinical Trial

- Clinical trial aims:
  - 1: Clinical effectiveness (of routine opt-out rapid HIV screening versus physician-directed diagnostic rapid HIV testing)
  - 2a: Clinical efficiency
  - 2b: Cost effectiveness
  - 3: Patient and staff acceptance

### Methods: Design Schema

	Diagnostic (Control)	Opt-Out (Intervention)	Diagnostic (Control)	Opt-Out (Intervention)	Diagnostic (Control)	Opt-Out (Intervention)
Clinical Trial Period	4 Months	4 Months	4 Months	4 Months	4 Months	4 Months
Patient Acceptance Assessment	Survey Develop	ment				
Staff Acceptance Assessment	Survey Develop	ment				
	24 Months					

# Methods: Operational Schema



### Methods: Cost Effectiveness

- Nested cohort study
- Direct program costs were determined using the perspective of the payer
- Costs included startup, personnel, test kit, and supplies and equipment
- Time-motion methodology was used to estimate costs related to the performance of all personnel activities related to each testing method

### Methods: Cost Effectiveness

- Outcome was the number of patients diagnosed with HIV infection
- Outcome stratified by those with newly-diagnosed HIV infection and those with repeat HIV diagnoses
- All data were annualized and reported as average and incremental cost effectiveness ratios
- Sensitivity analyses were performed to evaluate the influence of multiple variables

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

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

Table. Annual program costs for routine opt-out rapid HIV screening and physician-directed diagnostic rapid HIV testing in an urban emergency department (ED).

			Out Screening vention)	Physician-Directed Diagnostic Testing (Control)	
	Unit Cost	Number of	Cost	Number of	Cost
Cost Variable	(U.S. Dollars)	Units	(U.S. Dollars)	Units	(U.S. Dollars)
Startup					
Computer software	N/A	N/A	\$1,844.00	N/A	\$0.00
ED and laboratory staff training	N/A	N/A	\$7,687.31	N/A	\$1,694.19
Personnel					
ED and laboratory staff time	N/A	N/A	\$23,085.64	N/A	\$9,788.59
Administrative staff time	N/A	N/A	\$31,272.80	N/A	\$15,636.40
Test Kit					
Uni-Gold rapid test	\$10.00	7,872	\$78,717.58	254	\$2,541.85
Oraquick rapid test	\$11.60	24	\$276.13	0	\$0.00
Multispot rapid test	\$31.00	8	\$246.00	0	\$0.00
Confirmatory WB test	\$110.00	15	\$1,637.00	5	\$499.93
Supplies and Equipment					
Blood draw supplies					
Entire blood draw kit	\$1.05	2,838	\$2,980.33	254	\$266.89
Blood tube only	\$0.06	5,034	\$302.06	0	\$0.00
Other supplies and printing					
Opt-out consent form	\$0.08	43,467	\$3,477.34	N/A	\$0.00
Patient information sheet	\$0.002	43,467	\$86.93	254	\$0.51
Targeted testing consent form	\$0.002	N/A	\$0.00	254	\$0.51
TOTAL			\$151,652.63		\$30,418.87





**Table.** Cost effectiveness ratios (CERs) and incremental cost effectiveness ratios (ICERs) for routine opt-out rapid HIV screening and physician-directed diagnostic rapid HIV testing by the number of total, new, and repeat HIV diagnoses.

Program	Total Cost [C]	Health Effect [E]	Average CER [C/E]	Incremental Cost [ΔC]	Incremental Effect [ΔE]	ICER [ΔC/ΔE]
Total HIV Diagnoses						
Diagnostic HIV Testing	\$30,419	4.54	\$6,693.07	\$30,418.87	4.54	\$6,693.07
Routine Opt-Out HIV Screening	\$151,653	21.25	\$7,135.34	\$121,233.77	16.71	\$7,255.63
New HIV Diagnoses						
Diagnostic HIV Testing	\$30,419	3.03	\$10,052.46	\$30,418.87	3.03	\$10,052.46
Routine Opt-Out HIV Screening	\$151,653	8.66	\$17,541.01	\$121,233.77	5.63	\$21,522.36
Repeat HIV Diagnoses						
Diagnostic HIV Testing	\$30,419	1.50	\$20,282.04	\$30,418.87	1.50	\$20,282.04
Routine Opt-Out HIV Screening	\$151,653	12.14	\$12.487.46	\$121,233.77	10.64	\$11,389.23



Figure 3.8: Univariate Sensitivity Analysis, Key Variables and the Change in Incremental Cost Effectiveness Ratio (ICER) for Routine Opt-Out Screening Compared to Physician-Based Targeted Testing

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### Conclusions

- Diagnostic rapid HIV testing is more cost effective than routine opt-out rapid HIV screening in the ED
- More effective and or less costly testing strategies may be required to improve identification of patients with undiagnosed HIV infection
- Differences in the lifetime medical costs and transmissions averted between the two arms may impact the relative cost effectiveness of each strategy

