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Authors

Goetz, Matthew Bidwell
Hoang, Tuyen
Knapp, Herschel
et al.

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Central Implementation Strategies Outperform Local Ones in Improving HIV Testing in Veterans Healthcare Administration Facilities

Matthew Bidwell Goetz[1,2], Tuyen Hoang[3], Herschel Knapp[3], Jane Burgess[3], Michael Fletcher[3], Allen L. Gifford[4,5], Steven M. Asch[2,3] and the QUERI-HIV/Hepatitis Program

[1] Infectious Diseases Section (111-F), VA Greater Los Angeles Healthcare System, 11301 Wilshire Blvd, Los Angeles, CA 90073

[2] David Geffen School of Medicine at UCLA, Los Angeles, CA

[3] General Medicine (111G), VA Greater Los Angeles Healthcare System, 11301 Wilshire Blvd, Los Angeles, CA 90073

[4] VA Bedford Center for Health Quality, Outcomes & Economic Research, Edith Nourse Rogers Memorial Veterans Hospital, 200 Springs Road, Bedford, MA 01730

[5] Boston University Schools of Public Health and Medicine, Boston, MA

[6] VA Palo Alto Health Care System, Palo Alto, CA

[7] Division of General Medical Disciplines, Stanford University School of Medicine, Palo Alto, CA

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All correspondence should be sent to Dr. Goetz:

Matthew Bidwell Goetz, M.D.

Chief, Infectious Diseases Section (111-F)

VA Greater Los Angeles Healthcare System

11301 Wilshire Blvd.

Los Angeles, CA 90073

Tel: 310-268-3015

Fax: 310-268-4928

Email: matthew.goetz@va.gov or mgoetz@ucla.edu

Abstract

Background: Pilot data suggest that a multifaceted approach may increase HIV testing rates but the scalability of this approach and the level of support needed for successful implementation remains unknown.

Objective: To evaluate the effectiveness of a scaled-up multi-component intervention in increasing the rate of risk-based and routine HIV diagnostic testing in primary care clinics and the impact of differing levels of program support.

Design: Three arm, quasi-experimental implementation research study.

Setting: Veterans Health Administration (VHA) facilities.

Patients: Persons receiving primary care between June 2009 and September 2011

Intervention: A multimodal program, including a real-time electronic clinical reminder to facilitate HIV testing, provider feedback reports, provider education was implemented in Central and Local Arm Sites; sites in the Central Arm received also ongoing programmatic support. Control Arm sites had no intervention

Main Measures: Frequency of performing HIV testing during the six months before and after implementation a risk-based clinical reminder (Phase I) or routine clinical reminder (Phase II).

Key Results: The adjusted rate of risk-based testing increased by 0.4%, 5.6% and 10.1% in the Control, Local and Central Arms, respectively (all comparisons, $p<0.01$). During Phase II, the adjusted rate of routine testing increased by 1.1%, 6.3% and 9.2% in the Control, Local and Central Arms, respectively (all comparisons, $p<0.01$). At study end, 70 – 80% of patients had been offered an HIV test.

Conclusions: Use of clinical reminders, provider feedback, education and social marketing significantly increased the frequency at which HIV testing is offered and performed in VHA facilities. These findings support a multimodal approach toward achieving the goal of having every American know their HIV status as a matter of routine clinical practice.

Introduction

The benefits of identifying and treating asymptomatic HIV-infected individuals are firmly established, yet many HIV infected persons remain undiagnosed (1-4). Testing improves health at cost-effectiveness levels that exceed conventional thresholds even in the general medical population, leading the Centers for Disease Control and Prevention (CDC) to recommend that providers routinely offer it to persons under age 65 (2). Implementation barriers include concerns about patient stigma, injuries to the patient-provider relationship and time constraints (5). Several organizationally-based strategies to improve testing rates both in those at higher risk and the general medical population have been described (6-12). However, what is less clear is how to take testing strategies to a scale that will spread their benefits most widely, especially among patients receiving routine primary care.

We previously developed, implemented and evaluated a multimodal program to promote HIV testing. Components included computerized decision support, provider activation, audit-feedback, and removal of organizational barriers, such as prolonged pre-test counseling (13). Implementation of this program in a small number of facilities more than doubled HIV testing in at-risk patients (14). The intervention had persistent effectiveness after responsibility for program maintenance was transferred from the research implementation team to local staff (15) and could be successfully implemented by non-research staff (16).

These promising results prompted a further study of scaling up this intervention in a large number of diverse Veterans Healthcare Administration **(**VHA) facilities in geographic regions with varying rates of HIV prevalence. We studied the effectiveness in promotion of routine as well as risk-based HIV testing. Finally, to better understand the resources required for the

success of this project, we tested the effect of providing differing levels of organizational support on the magnitude of the impact of the intervention on HIV testing rates.

Methods

Study design

Facilities in a South Central and Northeastern region, otherwise known as VHA Veterans Integrated Service Networks or VISNs, were invited to participate. Facilities consisted of a main clinic often co-located with a hospital and several satellite outpatient clinics. Two facilities declined to participate; three could not participate due to lack of local research capacity or a competing study. To maintain balance in study sites, an additional site in another Northeastern VISN was invited to participate.

We matched the facilities selected to participate in the Central or Local Arms by baseline HIV testing rates and facility complexity (17). We randomly assigned one facility in each pair to the Central or Local Arms. Facilities with similar baseline HIV testing rates and complexity in two other VISNs were selected to serve as controls.

At each Central and Local Arm facility a site-specific study team was established that consisted of an Infectious Diseases specialist, Primary Care team leader and other personnel involved in either the local HIV testing program or Primary Care clinical operations. All teams were given guidance in the conduct of provider activation activities (described below). After project implementation, study teams at Central Arm sites received ongoing support from the Project Management Team; no such support was provided for Local Arm facilities.

The study had two, six-month phases. Phase I assessed the intervention's effect on risk-based HIV testing. Phase II was identical to Phase I except that routine (non-risk-based) rather than risk-based testing was promoted. All facilities participating in Phase I joined Phase II, in addition, 5 Central Arm facilities participated only in Phase II due to facility-level delays in

regulatory approval and rapid implementation of policies to promote routine rather than risk-based testing. Facilities had discretion to use either laboratory-based or site of care (rapid) testing. No facilities undertook initiatives to promote HIV rapid testing during the conduct of this project.

This study was approved by the appropriate Institutional Review Boards.

Intervention components

The components of the intervention included:

1) *A real-time, electronic clinical reminder:* The VHA has a universal electronic health record system with an integrated clinical reminder system. In Phase I, the reminder identified patients who had no evidence of prior HIV testing only if they also had evidence of increased risk for HIV infection (14). In Phase II, as per VHA policy (18), the reminder was modified to identify all previously untested patients regardless of known risk for HIV infection or advanced age. In both Phases, the reminder was resolved by ordering a test, or by documenting a previous test, patient refusal of testing or patient inability to give consent. Patients in whom the reminder was resolved were considered to have been offered an HIV test. The Project Leadership Team ensured that the reminder was properly installed and functional prior to the project launch at all facilities.

2) *Quarterly audit-feedback system:* Reports, which included clinic- and facility-level HIV testing performance regarding HIV testing rates and which compared the rates of testing among all Central and Local facilities, were provided to the facility-specific teams for distribution to healthcare providers (19; 20).

3) *Removal of organizational barriers*: For all Central and Local Arm facilities, the Project Leadership Team ensured that facility-specific HIV testing policies were consistent with VHA-wide policies that as of August 2009 substituted verbal for written informed consent for HIV testing and eliminated requirements for pre-test counseling. Where necessary, local policies were revised to permit telephonic post-test counseling after negative HIV results; in-person post-test counseling was strongly encouraged for all persons with positive tests. At three facilities the intervention began two months before the requirements for written informed consent were eliminated. All other organizational barriers were removed prior to facility-level initiation.

4) *A provider activation program:* Elements included academic detailing, social marketing, and distribution of provider and patient educational materials (20; 21). Provider education materials included scripts developed with patient input to destigmatize testing (5). Prior to, and at the initiation of the project at each site, facility-specific teams were strongly encouraged to maintain a vigorous ongoing provider activation program to promote testing.

Implementation plan

Immediately prior to activation of the HIV Testing Clinical Reminder, the Project Leadership Team travelled to all Central and Local facilities to review the program with administrative, clinical and nursing leadership as well as with the facility-specific team. The project team met with primary care providers to review the relevance of HIV testing, revised VHA policies regarding consent and pre-test counseling for HIV testing, the mechanics of the HIV Testing Clinical Reminder, facility-specific, pre-interventional HIV testing rates, facility-specific procedures for linking newly identified patients to care, and plans for distribution of quarterly clinic- and facility-level audit-feedback reports. Subsequently, the Project

Leadership Team provided the facility-specific teams and Primary Care leadership with quarterly audit-feedback reports comparing rates of HIV testing before and after program implementation.

For facilities in the Central Arm, the Project Leadership Team conducted separate monthly conference calls with each facility-specific team and made an additional in-person follow-up visit 3 – 6 months after the project launch to meet with facility leadership, the facility-specific team, and primary care providers to further promote HIV testing. In contrast, for the Local Arm sites the Project Leadership Team conducted only a single conference call 30 days after the initial in-person site visit. The Project Leadership Team had no contact with Control Arm Sites. All sites could undertake any additional measures to promote HIV testing if they so chose.

Analytic methods

We obtained patient administrative and clinical information from the VHA Corporate Data Warehouse in SAS-formatted datasets, which included outpatient demographics, visit information, diagnostic codes, and laboratory tests from 2008 to 2011.

We sought to evaluate the intervention effects by comparing pre-to-post changes in HIV testing rates in primary care clinics across the Central, Local and Control Arms. The analysis of risk-based testing included only patients with known HIV risk factors while the analysis of routine testing included all patients regardless of risk. Although the duration of the risk-based testing phase at individual facilities ranged from 8 to 15 months, we evaluated the intervention effects in only the first six months.

We performed a separate logistic regression analyses for each phase. Each analysis included two cohorts of patients: those seen in the 6 months prior to the intervention launch (baseline period) and those seen in the first 6 months after the intervention (intervention period). The unit of analysis was a patient who had not received HIV testing. The dependent variable was performance of testing. The independent variables included patient demographic and clinical characteristics; characteristics of the provider who saw the patient most frequently, and the characteristics of the facility where the patient was seen mostly often. Patient characteristics included age, sex, marital status, race/ethnicity, and risk factors for HIV infection. Risk factors were determined by records of laboratory tests and ICD-9 codes (online appendix). Provider characteristics included gender and class (trainee, attending, nurse, etc.). Facility characteristics included the number of unique patients seen in a 6-month period, the proportion of patients with HIV risk factors and VHA complexity level, which is based on patient volume, the breadth of provided services, academic affiliation and research funding (17). We adjusted the analysis for clustering of patients within providers within facilities using Generalized Estimating Equations with 'Exchangeable' correlation structures. We evaluated the intervention effects by comparing pre-to-post changes in adjusted testing rates across the arms, which were obtained by SAS programming LSMEANS statement in PROC GENMOD (SAS version 9.2. SAS Institute, Cary, NC, USA).

Results

Table 1 compares patient, provider, and facility characteristics among the facilities in the Control, Local and Central Arms. These facilities provided primary care to nearly 200,000 unique patients previously untested for HIV infection. Other than for race/ethnicity, patient-characteristics did not differ across the arms, whereas provider-level characteristics differed in regards to gender and provider class distribution.

The adjusted risk-based testing rates in the 6 months before and after Phase I implementation increased by 0.4% (from 4.4% to 4.8%) in the Control Arm, by 5.6% (from 6.0% to 11.6%; $p<0.01$) in the Local Arm, and by 10.1% (from 5.1% to 15.2%; $p<0.01$) in the Central Arm (Table 2; see online appendix for facility-specific results). In both Arms the increase in testing was immediate and sustained (Figure 1). At the end of six months, the proportion of patients with known risk who had had a documented HIV test before or during the intervention increased from 24.1% to 25.7% in the Control Arm, from 33.5% to 39.5% in the Local Arm, and from 30.3% to 39.4% in the Central Arm.

After the conclusion of Phase I, all facilities in the Local and Central Arms entered Phase II, wherein the Clinical Reminder was revised to promote routine, non-risk-based HIV testing for all previously untested patients. In addition, five other sites randomized to the Central Arm implemented Phase II without previous participation in Phase I. The Project Leadership Team visited these five newly participating Central sites at the launch of the program and again 3-6 months later. No further visits were made to previously participating sites. Both previously and newly participating Central Arm sites participated in monthly conference calls during Phase II.

After 6 months of Phase II, the adjusted rate of routine HIV testing increased by 5.4% (from 8.3% to 13.7%; $p<0.01$) in the Local Arm and by 9.2% (from 8.9% to 18.1%; $p<0.01$) in the three previously participating Central Arm facilities (Table 2; see online appendix for facility-specific results). Whereas a 9.1% increase (from 3.6% to 12.7%) in routine testing was observed in the five Central Arm facilities that had no prior engagement in the risk-based intervention, only a 0.5% increase (from 3.9% to 4.4%) occurred in the Control Arm facilities. The temporal pattern of the impact of the routine testing intervention was similar across all Arms and resembled that observed with risk-based testing (Figure 2). After six months, the proportion of patients risk who were documented to have ever had an HIV test increased from 9.8% to 12.2% in the Control Arm, from 13.0% to 25.4% in the Local Arm, and from 10.4% to 28.1% in the Central Arm.

The rate of routine HIV testing increased in all facility-, provider and patient-level groups (online appendix); similar results were found with risk-based testing. The increase in routine testing was significantly greater among patients who were <55 years of age, or seen by physicians rather than by non-physicians or at a facility with a medium patient volume or higher HIV risk prevalence.

Review of practices at one Local Arm facility where very little routine testing was done revealed that the routine HIV testing Clinical Reminder had not been properly maintained by local personnel. A sensitivity analysis demonstrated that exclusion of data from that site did not meaningfully alter any results.

Conclusions

Clinical science has outpaced implementation of that knowledge in HIV, as in many other conditions (22). Yet how to implement that clinical knowledge remains an important area of investigation.

These results demonstrate the generalizable effectiveness of a multimodal implementation of the proven intervention for HIV testing, and have shed light on how to scale-up routine HIV testing. The implementation package increased HIV testing rates across multiple healthcare facilities with heterogeneous patient populations and facility structure. Implementation of this program increased the rate of risk-based testing two to three-fold and increased routine testing three to four-fold. In contrast, HIV testing rates did not meaningfully increase in control facilities despite the VHA-wide encouragement of routine testing, and removal of requirements to obtain written informed consent and perform pre- and post-test counseling. These findings are consistent with prior observations that policy change without active advocacy or other interventions (e.g., decision support, social marketing) is often insufficient to change clinical practice (20; 21; 23-27).

These results from VHA facilities in the Northeastern and South Central regions of the US were remarkably similar magnitude to those from a limited, previous evaluation of this intervention in VHA facilities in the Southwestern US (14; 16). Implementation of this program in the VHA has identified previously unrecognized HIV-infected individuals at a rate greater than the 0.1% prevalence cost-effectiveness threshold (28; 29), diagnosed patients with less advanced disease than with prior testing strategies and successfully linked new patients to care (30; 31).

Scaling up efforts to improve HIV testing requires thoughtful allocation of program resources. One choice that many improvement programs face, both inside and outside the HIV domain, is the degree to which such support should be centralized or distributed to the sites involved in improving care. Centralization improves fidelity and may have economies of scale, but localization may improve commitment of those responsible for implementing change. Our assessment of the relative benefits of central vs. local provider activation and audit feedback showed both to increase testing rates more than controls. However, the 10.1% increase in the 6-month rate of risk-based HIV testing in the Central Arm outpaced the 5.6% increase in the Local Arm. Results were similar for routine testing (9.2% vs. 5.4% increase), suggesting that centralization of resources is a more successful implementation strategy, at least in this integrated system setting.

The strengths of our study include the experimental design in which comparison of pre-to-post testing rates clearly demonstrated the beneficial effect of the intervention on risk-based and routine HIV testing when compared to controls. Furthermore, site randomization provided clear evidence of the benefit of ongoing centralized support for site-specific teams after initial implementation. The results of this very real world intervention were robust with increases in risk-based and routine HIV testing in all evaluated strata. Qualitative evaluations are underway to better understand the resources, sources of support, staffing, and past experience of the host organizations that contribute to the success of this implementation (32).

Limitations of our work include our inability to determine which component of the multimodal approach was most effective at increasing HIV testing rates. A further limitation is that the intervention relied heavily on the VHA quality improvement infrastructure, including the electronic medical record, clinical reminder software and familiarity with performance

measurements. Although this decreases generalizability to healthcare systems that lack these tools, such tools are increasingly common and some components of the intervention, such as provider activation, do not require the infrastructure of an integrated healthcare system. Although we did not evaluate sustainability in this project, we previously found excellent sustainability during the twelve-month period after overall responsibility for the interventional program was transferred to local clinical personnel (15). While the majority of patients remained untested, after the six-month intervention the proportion of patients who had ever had a routine HIV test more than doubled, reaching 25-28% of the total population and 70-80% of all patients had been offered a test. These rates were achieved in a patient population with a mean age of 63-65 years. Of note, 64 is the upper limit at which the CDC recommends HIV testing, whereas VHA recommends HIV testing with no upper age bound (2; 18). In other work we have found that for a facility with 20,000 untested patients, increasing the HIV testing rate by 13% costs approximately $73,000 (33). Finally, modifications of this primary care oriented intervention are necessary to accommodate different work flow patterns in substance abuse clinics and emergency departments and to apply rapid HIV testing, which is particular useful in settings where patients are less likely to return to receive test results (34-37).

Translating clinical research into real world improvements is a challenge that all health care systems must face to reap the benefits of such research. HIV testing is no exception. It demonstrates downstream positive effects on health if patients are linked to care, but first we must learn how to transform our delivery system to provide routine testing reliably. To our knowledge this is first full report of the effectiveness of a broad-scale, structured program to implement routine HIV testing. This increased testing rate facilitates early diagnosis and treatment for these vulnerable patients (30; 31). Similar strategies adapted to other delivery

systems could be used to achieve the goal of the CDC that every American aged 13-64 know their HIV status and the National HIV/AIDS Strategy goal of ensuring that 90% of HIV-infected patients know their status by 2015 (2; 38).

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Conflicts of Interest

Allen Gifford: royalties for authorship of *Living Well With HIV And AIDS*, Ball Publishing Company. Steven Asch: unrestricted travel grant from Trinity Pharmaceuticals. The other authors declare that they do not have no conflicts of interest.

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Table 1

Comparison of patient, provider, facility characteristics among study arms

Patient, Provider, Facility characteristics	Study Arms		
	Control	**Local**	**Central**
Facility level			
Number of facilities	7	7	8
Semi-annual patient load per facility*	11,100 ± 4,000	10,500 ± 3,800	8,000 ± 3,900
Number of patient visits per year	2.6 ± 2.4	2.5 ± 1.8	2.5 ± 2.1
Prevalence of HIV risk *	24% ± 7%	25% ± 5%	23% ± 9%
Complexity level**	2, 2, 1, 1, 1	3, 2, 1, 1, 0	2, 1, 1, 0, 3
Patient level			
Age (Mean, S.D.)	63.4 yrs (14.5)	64.2 yrs (14.6)	64.9 yrs (15.1)
Male (%)	96.8	96.5	96.4
Married (%)	51.3	55.3	55.0
African American (%)***	29.5	32.1	15.7
HIV Risk factors (%)			
-HCV infection	7.4	6.5	6.9
-HBV infection	0.5	0.6	0.5
-Prior STD	1.8	1.6	1.2
-Illicit drug use	12.6	9.9	9.5
-Homeless	6.1	4.5	5.1
Any of the above risk factors	20.5	17.4	17.3
Provider level			
Number of providers seeing the patients during the 6 months of routine testing	529	554	381
Male (%)**	50.3	35.0	52.8
Provider class (%)**			
-Intern/Resident/Fellow	18.0	23.3	34.1
-Attending	68.6	62.5	55.4
-Nurse Practitioner or Physician Assistant	12.1	13.2	8.9
-Missing	1.3	1.0	1.6

* Mean ± standard deviation

** Data indicate facilities in VA complexity levels, 1A, 1B, 1C, 2 and 3, respectively

*** Comparisons among the three arms are statistically significant at p-values<0.01.

Table 2

Comparison of adjusted risk-based and routine testing rates before and after intervention among study arms

Risk-based testing rates					
ARMS	**BASELINE 1 6 months prior to risk-based testing intervention launch**		**PHASE 1 First 6 months of risk-based testing intervention**		**DIFFERENCE in testing rates from baseline 1 to phase 1**
	N	**Testing rate among at-risk and previously not tested patients (%)**	**N**	**Testing rate among at-risk and previously not tested patients (%)**	
7 Control Facilities	15,278	4.4 (3.9, 5.0)	14,698	4.8 (4.2, 5.5)	+0.4
7 Local Facilities	12,797	6.0 (5.3, 6.7)	12,554	11.6 (10.2, 13.1)	+5.6**
3 Central Facilities	7,067	5.1 (4.0, 6.5)	6,659	15.2 (12.7, 18.1)	+10.1**

Routine testing rates					
ARMS	**BASELINE 2 6 months prior to routine testing intervention launch**		**PHASE 2 First 6 months of routine testing intervention**		**DIFFERENCE in testing rates from baseline 2 to phase 2**
	N	**Testing rate among previously not tested patients (%)**	**N**	**Testing rate among previously not tested patients (%)**	
Facilities Impacted By Phase 1					
7 Local Facilities	65,181	8.3 (7.1, 9.5)	59,555	13.7 (11.9, 15.7)	+5.4**
3 Central Facilities	29,774	8.9 (7.4, 10.6)	26,157	18.1 (14.2, 21.4)	+9.2**
Facilities Not Impacted By Phase 1					
7 Control Facilities	69,118	3.9 (3.3, 4.5)	67,943	4.4 (3.6, 5.4)	+0.5
3 Central Facilities	31,128	3.6 (2.8, 4.7)	29,617	12.7 (10.3, 15.6)	+9.1**

[#] Data given as adjusted testing rates and 95% confidence interval

* Difference in adjusted testing rates from baseline to post-intervention (Phase 2) is statistically significant at $p<0.01$

** Comparison in increases of adjusted testing rates between Central /New Central arms versus Local Arm is statistically significant at $p<0.01$).

Figure Legends

Figure 1: **Risk-Based HIV Testing.** Rate of HIV testing among persons seen in primary care clinics during each month of the intervention who had a known risk for HIV infection but no documentation of prior HIV testing. M-2 and M-1 represent rates of HIV testing among such persons during the two months prior to implementing the multi-modal intervention.

Figure 2: **Routine HIV Testing.** Rate of HIV testing among all persons seen in primary care clinics during each month of the intervention who had no documentation of prior HIV testing. Results are shown separately for the sites in the Central Arm that did previously participate in the risk-based HIV testing intervention (Central (Old)) and those that were new to the study (Central (New)) and did not previously participate in the risk-based HIV testing intervention. All sites in the Local Arm had previously participated in the risk-based intervention (Local (Old)). M-2 and M-1 represent rates of HIV testing among such persons during the two months immediately prior to implementing the routine testing intervention.