Emergency Room "Opt-Out" HIV Testing Pre- and During COVID-19 Pandemic in a Large Community **Health System**

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Abstract

Background: South Florida has the highest HIV rates across the country. Emergency Rooms (ERs) are optimal clinical sites for the identification of people living with HIV. We aimed to evaluate the feasibility and yield of opt-out HIV testing among ER patients in a large community healthcare system in South Florida, and determine the impact of the COVID-19 pandemic on HIV testing. Methods: This was a retrospective study conducted in the Memorial Healthcare System, Hollywood, Florida. HIV test was offered on an "opt-out" basis to patients aged 16 years or older presenting to the ER of the Memorial Regional Hospital between July 2018 and August 2020. Number of ER visits, HIV testing offered, acceptance of HIV testing, tested positive for HIV infection and linkage to care were reviewed and analyzed. Results: A total of 105,264 (53.7%) patients of 196,110 ER visits were eligible for HIV testing and 39,261 (37.3%) completed HIV testing. Of those tested, 206 (0.5%) patients tested positive, with 54 (26.2%) new infected patients and 152 (73.8%) known infected patients who had not disclosed their status. 45 (60%) of 75 patients with known HIV infections who were not engaged in HIV care were successfully relinked into care after testing, and engagement in care increased from 50.7% pre-testing to 80.3% post-testing (p = 0.001). 45 (83.3%) of 54 newly diagnosed patients were successfully linked into care. During the COVID-19 pandemic, there was a significant reduction in both the ER visits and HIV tests as compared with the pre-pandemic period (p = 0.007 and p < 0.001, respectively). **Conclusion:** An "Opt-out" HIV testing program was successfully implemented in a community hospital ERs. The use of this strategy successfully identified patients with undiagnosed HIV infection and improved their engagement in HIV care. Given the impact of COVID-19 pandemic on the testing program, new strategies should develop to reduce service disruption and maintain the progress of "Opt-out" HIV testing.

Keywords

HIV opt-out testing, COVID-19, HIV diagnosis, emergency department, linkage to care

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Introduction

Antiretroviral therapy (ART) reduces the onward transmission of HIV.¹ However, currently in the US, it is estimated that 80% of new HIV transmissions are from persons who do not know they are infected.² The southern US is the region with the highest HIV burden.³ Routine screening is essential to slowing and ultimately ending the HIV/AIDS epidemic in the United States by helping to identify undiagnosed infections.² Diagnosis also enables those who are infected to begin ART as soon as possible, which lowers the amount of HIV viral load in the body and significantly reduce their chances of transmitting HIV to others.¹ HIV testing that is offered by targeted screening for high risk individuals, based largely on indicator conditions and epidemiological risk-factors, such as sexual behavior, are failing to identify many infected patients with HIV.4-6 Clinicians may fail to identify high-risk individuals based

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What Do We Already Know about This Topic?

Opt-out screening in the clinic setting has proved to be highly effective in removing the stigma with HIV testing, earlier diagnosis and treatment, and reducing risk or transmission in the population.

How Does Your Research Contribute to the Field?

Opt-out testing in the emergency room helps to identify an increasing number of high-risk, socioeconomically disadvantaged patients who commonly use the ER as their sole source of medical care, helping link them to care. Linkage to care plays a pivotal role in HIV care- an important step to antiviral therapy, viral suppression, and reduction in risk of transmission.

What Are Your Research's Implications toward Theory, Practice, or Policy?

Implementation of Opt-out testing in the emergency room proves to be an effective practice to increase the number of nontraditional patients missed, reducing the risk of transmission to the population. This strategy can be used to increase testing and treatment initiation in areas with a large burden of undiagnosed HIV disease.

on their epidemiological characteristics, or patients may fail to disclose risk factors.⁶

In recent years, interest in "test and treat" or rapid start strategies to prevent HIV infections and reduce AIDS related deaths has grown significantly. The federal government's National HIV/AIDS Strategy, which was released in early 2021; the National Institute of Medicine; the Centers for Disease Control and Prevention (CDC) and the U.S. Preventive Services Task Force (USPSTF) have all expressed strong support for expanding HIV screening and linkage to care, especially in high-risk communities. The unselected seroprevalence of HIV infection in ER patients ranges from approximately 1%to 5%.⁷⁻⁹ In addition, HIV infection is increasing in nontraditional risk groups (e.g., racial and ethnic minorities, socioeconomically disadvantaged, heterosexual men, and women), that commonly use ERs as their sole source of medical care.^{10,11} As such, ERs remain important clinical sites for HIV identification and linkage into care. Several reports have described the use of "Opt-out" HIV testing to identify patients with HIV infection in the ER, however, this new strategy have not yet been rigorously evaluated, and data to support the clinical effectiveness of various ER-based HIV testing strategies remain uncertain.

In 2018, we implemented "opt-out" HIV testing in the ERs at Memorial Healthcare System (MHS). All patients in the ERs who required a blood draw were given the option of HIV testing, unless they declined. In this study, a retrospective review of data was performed on ER patients who were offered HIV testing



Figure 1. ER visits and enrollment in Opt-Out HIV testing between July 2018 and August 2020. ER, emergency room.

without targeting patients with any risk factors between July 2018 and August 2020. The objectives of this study were to determine the proportions of the ER patients who completed "Opt-out" testing, tested positive for HIV infection, and were successfully linked into medical care for management of their HIV positive status. As the COVID-19 pandemic occurred during the study period, and caused substantial disruptions to health services, we also present preliminary results of the impact of COVID-19 pandemic on "Opt-out" testing for HIV in the MHS.

Methods

Study Setting and Population

This institution based retrospective cohort study was conducted in the MHS Regional Emergency Room, Hollywood, Florida, between June 2018 and August 2020. "Opt-out" HIV screening orders were automatically included in the electronic medical record admission orders to be authorized by the trained nurse. The nurses provided information related to possible HIV testing and the ability to opt-out during the ER registration process, and verbal consent was required for the rapid HIV test to be performed. All individuals aged >16 years who presented to the ERs for routine blood tests during the study period were offered an additional blood test to screen for HIV, unless they declined. Patients were excluded from testing if they opted out, had a previous diagnosis of HIV infection or clinical evidence of HIV infection in the admitted patient's medical record or if they did not understand their right to opt-out. The test performed was an antigen-antibody combination assay for HIV. Testing for HIV was performed on the blood sample at the MHS Laboratory. Patients were informed of their HIV results immediately after results became available, and HIV infected patients were provided with post-test counseling and linkage to HIV care. All patients who were offered blood tests had their decision documented and coded in their electronic file.



Figure 2. Overview of study population and enrollment in Opt-Out HIV testing and linkage to care between July 2018 and August 2020.

Data Sources

Number of ER visits and acceptance or refusal of HIV testing were recorded for all eligible patients. Demographic data including the patient's age, gender, race/ethnicity, the date of the visit, details of behavioral characteristics commonly believed to be related to the transmission of HIV (e.g., IV drug use, sexual preferences), and linkage into medical care were collected for the patients who tested positive for HIV infection. All data were extracted through the linkage of routinely collected administrative datasets in Epic and entered into an electronic database. The programmatic database, managed by the nurse coordinator, is used to track patients' ER visits, HIV testing offered, acceptance of HIV testing, positive test result for HIV infection and linkage to care.

Outcome Measures

The primary outcome measures were proportion of ER visits offered HIV testing, proportion of accepted testing, proportion of positive tests for HIV infection, and proportion of successful linkage into HIV care. Additional outcome measures included the impact of COVID-19 pandemic on number of ER visits and HIV tests.

Data Analysis

Descriptive analysis was performed for all variables. Number of ER visits, number of HIV tests offered, number of HIV tests completed, and number of positive HIV tests were calculated. Continuous variables were presented as median and interquartile range (IQR) for non-normally distributed data or mean \pm standard deviation (SD) for normally distributed data, and categorical variables were reported as numbers or percentages. The chi-square tests were used to assess the difference in demographics between the newly diagnosed cases of HIV infection and the previously known HIV infection, and proportions of the previously known cases engaged in care before and after the HIV testing. Statistical analyses were also conducted to determine whether Opt-out testing performance differed before and after the onset of the COVID-19 pandemic. First, we computed mean values of monthly ER visits and HIV tests for the pre- and post-pandemic periods and used independent t tests to determine whether these values differed significantly. In addition, we conducted an interrupted time series analysis using segmented regression models¹² to assess the significance of changes in level and slope of the regression lines for ER visits and HIV tests in the months prior to the pandemic, at the time the pandemic occurred, and in the months following the pandemic. All data analysis was performed using SPSS Statistics software version 27 (IBM Corp., Armonk, NY) and Prism version 7.0 (GraphPad, San Diego, CA). A two-sided P value < 0.05 was considered statistically significant.

Ethical Approval and Informed Consent

The retrospective chart review protocol was approved by the Institutional Review Board of the MHS (MHS.2019.119). Written informed consent was waived as this study involved only secondary data analysis.

Results

Over the study period, a total of 196,100 patients visited the ERs of MHS regional hospital and 105,264 (53.7%) of patients were offered HIV testing regardless of HIV risk factor. Of those who were offered HIV testing, 39,261 (37.3%) patients completed HIV testing, and 66,003 (62.7%) patients opted out (Figure 1). Of those tested, 206 were confirmed positive, with 54 (26.2%) being new diagnoses of HIV according to a data reconciliation with the Broward County Department of Health and 152 (73.8%)previously diagnosed individuals, yielding a positive rate of 0.5%. The number of patients studied varied by years (Figure 2). The overall number of ER visits, HIV screening offered, and acceptance of HIV testing was 93,055, 46,255, and 15,343 respectively during year 2019-2020 and 103,045, 59,009, and 23,918 respectively during year 2018-2019, indicating an overall decline in ER visits, screening offered, and HIV testing in year 2019-2020 as compared with a similar period in year 2018-2019 (Figure 2).

Characteristics of the confirmed HIV cases are shown in Table 1. Of the 206 patients who tested positive, 30 (14.6%) were female and 176 (85.4%) were male. The median age of this cohort was 46 (IQR, 32-55) years, with 8.7% aged 18-25 years, 23.8% aged 26-35 years, 16.9% aged 36-45 years, 26.7% aged 46-55 years, 18.9% aged 56-65 years, and 4.9% aged > 65 years, respectively. Across all age groups, the

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|---------------------------------------|------------------|-------------------------------|----------------------|---------|--|--|
| Demographics | Total, $n = 206$ | Newly diagnosed HIV, $n = 54$ | Known HIV, $n = 152$ | þ value | | |
| Sex, n (%) | | | | | | |
| Male | 176 (85.4) | 39 (72.2) | 137 (90.1) | 0.001 | | |
| Female | 30 (14.6) | 15 (27.8) | 15 (9.9) | | | |
| Age (years), n (%) | | | | | | |
| 18-25 | 18 (8.7) | 10 (18.5) | 8 (5.3) | 0.003 | | |
| 26-35 | 49 (23.8) | 22 (40.7) | 27 (17.8) | 0.001 | | |
| 36-45 | 35 (16.9) | 3 (5.6) | 32 (21.0) | 0.009 | | |
| 46-55 | 55 (26.7) | 13 (24.1) | 42 (27.6) | 0.766 | | |
| 56-65 | 39 (18.9) | 6 (11.1) | 33 (21.7) | 0.088 | | |
| > 65 | 10 (4.9) | l (1.8) | 9 (5.9) | 0.232 | | |
| Race, n (%) | | × , | | | | |
| White | 31 (15.1) | 5 (9.3) | 26 (17.1) | 0.166 | | |
| Hispanic | 38 (18.4) | 13 (24.1) | 25 (16.4) | 0.215 | | |
| Black | 137 (66.5) | 36 (66.6) | 101 (66.5) | 0.977 | | |
| Mode of transmission, n (%) | | | | | | |
| IDU | 14 (6.8) | 2 (3.7) | 12 (7.9) | 0.293 | | |
| Heterosexual | 105 (50.9) | 24 (44.4) | 81 (53.2) | 0.374 | | |
| MSM | 57 (27.7) | 19 (35.2) | 38 (25.0) | 0.151 | | |
| Unknown | 30 (I4.6) | 9 (16.7) | 21 (13.9) | 0.609 | | |
| | | | | | | |

Table 1. Characteristics of Confirmed HIV Diagnosis Between July 2018 and August 2020.^a

Abbreviations: IDU, injection drug use; MSM, men who have sex with men.

^aValues are presented as n (%). Comparisons of patients by HIV status were conducted using Chi-square tests.

majority were racial and ethnic minorities with 66.5% Black, 18.4% Hispanic, and 15.1% White non-Hispanic.

When the confirmed HIV cases were sub-grouped into the newly diagnosed and previously known HIV groups, age and gender distributions of the HIV cases differed significantly between the 2 groups (p < 0.001 and p = 0.001, respectively), whereas no differences were observed with respect to distributions of race (p = 0.236) and mode of transmission (p = 0.339), as assayed by chi-square tests. The case-positive rates among individuals aged 18-25 years and 26-35 years were higher in the newly diagnosed cases than those seen in the previously known HIV infection (18.5% versus 5.3%, p = 0.003 and 40.7% versus 17.8%, p = 0.001, respectively), whereas in individuals aged 46-55 years, the case-positive rate was higher in the previously known HIV infection than those seen in the newly diagnosed cases (21.0% versus 5.6%, p = 0.009) (Table 1). Of the 206 patients who tested positive, males were more common in the previously known cases of HIV infection than in the newly diagnosed cases (90.1% versus 72.2%, p = 0.001). In the newly diagnosed cases of HIV infection, the case-positive rates for both male and female were higher (30.1% and 14.2%, respectively) in patients aged 26-35 years (Figure 3).

All newly diagnosed cases were offered assistance with linkage to a medical provider of his or her choice. 45 (83.3%) of 54 newly diagnosed patients were successfully linked to care. Of the 152 previously known cases of HIV identified during the study, 75 (49.3%) patients were not previously receiving medical care and were able to be referred. 45 (60%) of those 75 patients not already in care were successfully linked to HIV medical care. The rate of engagement in care in the previously known cases of HIV was increased from



Figure 3. Age- and gender-specific distributions of newly diagnosed HIV cases between July 2018 and August 2020. Data from 54 newly diagnosed cases are reported.

50.7% (77 of 152 patients) to 80.3% (122 of 152 patients) (odds ratio = 3.96; 95% CI, 2.36-6.55; p < 0.0001).

Figure 4 depicts the monthly number of patients who visited ER, screened for HIV testing, and completed HIV testing per month at the MHS between July 2018 to February 2020 (pre-pandemic) and March 2020 to August 2020 (pandemic period). Table 2 shows the monthly average number of patients who presented to the ER decreased from 7,914 during the pre-pandemic period to 6,304 during the pandemic period of 2020 (p = 0.013). The monthly average number of patients who were offered HIV screening decreased from 4,436 during



Figure 4. Changes of monthly ER visits, testing offered, tests completed, and HIV-positive rates before and during the COVID-19 pandemic, between July 2018 and August 2020. ER, emergency room.

| Table 2. Description A | Analysis of Monthly ER | Visits and HIV Tes | sts Before and During | the COVID-19 Pande | emic, Between July | 2018 and August |
|------------------------|------------------------|--------------------|-----------------------|--------------------|--------------------|-----------------|
| 2020.ª | | | | | | |

| | July 2018-February 2020 (20 months) | March 2020-August 2020 (6 months) | P value |
|---------------------|-------------------------------------|-----------------------------------|----------|
| ER visits | 7914 <u>+</u> 290.1 | 6304 <u>+</u> 1749 | 0.013 |
| HIV testing offered | 4436 <u>+</u> 303.7 | 2757 <u>+</u> 693.0 | < 0.0001 |
| HIV tests | 1745 <u>+</u> 265.6 | 726 <u>+</u> 142.8 | < 0.0001 |
| HIV positive rate | 0.52 ± 0.18 | 0.46 ± 0.14 | 0.466 |

Abbreviation: ER, emergency room.

^aData given as mean \pm standard deviation.

| Table 3. Interrupted Time Series Model Parameters Before and During the COVID-19 F | Pandemic, Between Ju | ly 2018 and Aug | ust 2020. |
|---|----------------------|-----------------|-----------|
|---|----------------------|-----------------|-----------|

| Parameter | Estimate | Standard error | t | P value |
|------------------------------------|----------|----------------|-------|---------|
| ER visits | | | | |
| Pre-pandemic slop | 7.00 | 33.2 | 0.21 | 0.835 |
| Change in intercept | -2194.89 | 736.34 | -2.98 | 0.007 |
| Change in slop during the pandemic | 197.46 | 207.35 | 0.95 | 0.351 |
| HIV tests | | | | |
| Pre-pandemic slop | -7.22 | 9.81 | -0.74 | 0.469 |
| Change in intercept | -943.15 | 217.56 | -4.34 | < 0.001 |
| Change in slop post-pandemic | 7.11 | 61.26 | 0.12 | 0.909 |

Abbreviations: ER, emergency room; HIV, human immunodeficiency virus; COVID-19, coronavirus disease 2019.

the pre-pandemic period to 2,757 during the pandemic period (p < 0.0001) (Table 2). The monthly average number of patients who tested for HIV decreased from 1,745 during the pre-pandemic period to 726 during the pandemic period (p < 0.0001) (Table 2). The tested positive rate of HIV infection remained stable from the pre-pandemic, in comparison with the pandemic period (0.52% vs 0.46%, p = 0.466) (Table 2).

Table 3 shows the results of the interrupted time-series analysis of ER visits and HIV testing. ER visits appeared to increase prior to February 2020 by 7 cases per month, but did not reach statistical significance (p = 0.835). In the first month of the pandemic (March 2020), there appeared to be a significant decrease in ER visits (estimate -2194 cases, p = 0.007), followed by a trend of increasing ER visits during the pandemic period, but it did not reach statistical significance (estimate



Figure 5. Segmented regression analysis of ER visits and HIV tests before and during the COVID-19 pandemic, between July 2018 and August 2020. The vertical dashed line marks the onset of the COVID-19 pandemic. The black lines are best-fitting linear models for the pre- and during-the pandemic periods. ER, emergency room.

197 cases per month, p = 0.351). Similarly, there was a trend of HIV tests increase until February 2020, but it did not reach statistical significance (estimate 7 cases per month, p = 0.469). In the first month of the pandemic the occurrence of HIV tests was significantly decreased (estimate -943 cases, p < 0.001). HIV tests had an increasing trend over time during the pandemic periods, but it did not reach statistical significance (estimate 7 cases per month, p = 0.909). Figure 5 depicts a visual display of these results, reflecting the unexpected impact of COVID-19 pandemic on ER visits and "opt-out" testing for HIV.

Discussion

We conducted a retrospective chart review of electronic medical records to assess the viability and yield of routine "Opt-out" HIV testing at the ER in a community healthcare system in South Florida. Of the patients who visited ERs over the 25-month period, 53.7% of the ER patients were eligible for HIV testing, and 37.3% of these opted to have testing for HIV, yielding a HIV positive rate of 0.5%. Of those who were newly diagnosed with HIV infection, 83.3% were linked to care. This finding demonstrates that the "Opt-out" testing in ERs is an effective option in diagnosing unknown HIV infection and referring them to much needed care plans. We also found that HIV-positive out of care individuals were more than twice as common as new HIV diagnoses (73.8% vs 26.2%), and more than two-thirds (122 of 152 patients) were successfully relinked to care. Our analysis also shows that the new case HIV positive testing diagnosed relatively greater percentages (40.7%) of individuals aged 26-35 years, indicating the potential to focus existing testing programs to individuals aged 26-35 years. The study results are strengthened by the large number of ER visits seen in this public healthcare system in South Florida which experiences one of the greatest incidences of HIV in the US.^{3,13}

In the US, routine "Opt-out" screening for HIV has been recommended for individuals aged 13-64 years in all healthcare settings by the Centers for Disease Control and Prevention (CDC) since 2006.9,14 Current guidelines suggest that non-targeted HIV screening is recommended in populations with a prevalence >0.1% of undiagnosed HIV; however, no studies have shown significant difference between different strategies to detect new HIV diagnosis. It has also been proven, however, that early detection and treatment confers better disease prognosis and decrease transmission.^{9,14} Our program showed a 53.7% acceptance rate for HIV testing of all patients being offered this service. In the retrospective review, we were not able to assess factors associated with the acceptance of HIV testing. Several reports have demonstrated a significant heterogeneity in acceptance of "Opt-out" HIV testing.^{9,15-17} The underlying etiology of declining HIV testing may be multifactorial. Social, economic, and psychological factors may all play a role in an individual decision to be tested, nevertheless new strategies should be implemented to increase the acceptance rate in the general population.^{18,19}

Patients who did not disclose their known HIV-positive status may have been reluctant to do so due to HIV related stigma which is prevalent.^{20,21} In our study, of the 206 positive cases, 152 (73.8%) known infected patients had not disclosed their status. Fear of discrimination that can affect the patient wellbeing is likely one of the reasons some of the patients fail to disclose their HIV status. HIV stigma usually leads to feelings of shame, isolation and despair which ultimately leads to fear of disclosure. This may also affect patient's willingness to agree to the test regardless of known HIV status. In the current study, we found that engagement in care in the previously known cases of HIV was increased from 50.7% to 80.3% (OR = 3.96; 95% CI, 2.36-6.55; p < 0.0001), suggesting patient linkage to care can be improved in the setting of Opt-out HIV testing in the ER. This is an important finding as it has been proven that failures in linkage to care are associated with lower levels of viral suppression and greater likelihood of viral resistance.²¹⁻²³

On March 7, 2020, the first case of COVID-19 was confirmed in Memorial Healthcare System. According to the CDC, emergency room visits on a national scale, decreased significantly when compared to previous year during an early four-week period of the pandemic.^{15,24} In our study, we observed a marked decline in the number of ER visits and tests completed from March to August 2020, as compared with the pre-pandemic period. We theorize that the change in the ER work flow during the pandemic, the universal screening for COVID at the time of admission, the staff stress levels associated with care of the multiple patients with COVID-19, the displacement of the Opt-out testing program staff and fear of contracting COVID-19 by the ER personnel were some of the factors associated with the decline in the number of HIV tests done during this period. As the COVID-19 pandemic continues, continuing to assess the pandemic's impact on health services is key to reducing service disruption and maintaining the progress achieved thus far against the HIV epidemic.

Despite the CDC call for normalization of HIV testing in the healthcare setting, a large percentage of ER visits are still unscreened. The percentage of patients who were not offered the screening for HIV may be a limitation to our study. It is worth noting that our analysis focused only on patients who did not Opt-out for HIV testing. As another limitation, we only had 6 periods of data during the pandemic in the time-series analysis and the causal power may not as robust as the one with multiple rounds.²⁵

In conclusion, our program was able to identify new HIV infected patients and link them to care both the pre-pandemic and during the pandemic. We were also able to relink patients that were previously diagnosed with HIV and either were never linked to care or had fallen out of care to a program. Engagement of people in HIV diagnosis and care in our health system through Opt-out HIV testing and treatment initiation was severely impacted by the COVID-19 pandemic. Despite this unforeseen event, Opt-out testing in a busy ER in one of the largest public healthcare systems in the nation was successfully implemented. Strategies to increase Opt-out HIV testing and treatment initiation in areas with a large burden of undiagnosed HIV disease should be implemented to address current and potential future outbreaks of the HIV disease.

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Declaration of Conflicting Interests

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