ECONOMIC EVALUATION OF AN HIV TESTING OPT-OUT POLICY

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TABLE OF CONTENTS

EXECUTIVE SUMMARY

The Centers for Disease Control and Prevention (CDC) recommends that clinics and hospitals routinely screen all patients age 13 to 64 for HIV unless the patient specifically declines the test or the local prevalence of undiagnosed HIV is less than 0.1 percent. Under this policy, known as "opt-out screening", the patient is informed that the test for HIV will be performed, and the patient may elect to opt-out of screening.

Opt-out screening aims to:

1. increase the number of patients who are tested for HIV
2. detect an HIV infection at the earliest possible stage,
3. prevent secondary transmissions, and
4. connect HIV positive patients to appropriate medical services.[1]

Following the CDC's recommendation, the Central Health Equity Policy Council (CHEP Council) in Austin, TX is encouraging Federally Qualified Health Centers (FQHCs) and other local safety-net clinics and hospital systems in Travis County to adopt the opt-out screening policy. Given that 17.3 percent of all people living with HIV in Austin are unaware of their HIV status,[2] there is an urgent need to expand screening, identify HIV infections, and link patients to a continuum of care.

CommUnityCare, an FQHC within the Central Health network, has already implemented the opt-out screening policy. In 2017, CommUnityCare screened over 13,000 patients for HIV, detected ten new HIV positive patients, and connected all ten patients to care.[3]

The CHEP Council commissioned the Lyndon B. Johnson School of Public Affairs in Austin to conduct an economic analysis of the opt-out screening policy. The analysis utilizes a combination of cost-effectiveness analysis (CEA) and decision analytic modeling to build an economic evaluation model. The student researchers built an economic evaluation model on Microsoft Excel that estimates the costs and consequences of the opt-out screening policy for timeframes of 1 year, 3 years, and 5 years.

The economic evaluation model generates estimates of life years gained, quality-adjusted life years (QALYs) gained, costs, and new cases of HIV diagnosed. The model uses data from Central Health, CommUnityCare, and previous literature on HIV/AIDs in the tool to generate initial estimates. Each FQHC can input location-specific data to obtain more accurate estimates.

The evaluation estimates that, compared to an opt-in screening policy, implementing opt-out screening costs $2.61 more per patient but gains an additional 28 quality-adjusted life years and diagnoses an additional 1.25 new infections across a population of 7,000 new patients in one year of operation.

Ultimately, the CHEPC can use the economic evaluation tool to determine whether the opt-out screening policy is cost-effective for each FQHC, and the results can be invaluable to convince FQHCs to adopt the policy.

Compared Outcomes of Opt-in and Opt-out Policies					
Decision	Life Years Gained	QALYs Gained	New Secondary Transmissions	Costs	New Cases Diagnosed
Opt-In	97.71	78.17	0.55	$50,825.24	3.46
Opt-Out	132.80	106.24	0.50	$72,355.03	4.71
Difference	35.09	28.07	-0.05	$21,529.79	1.24

**Total costs and outcomes over 1 Year with 7000 New Patients*

INTRODUCTION

Background of Sponsoring Organizations

Central Health is a "public entity that connects low-income, uninsured Travis County residents to high quality, cost effective health care." Central Health works with a network of partners around Travis County and Austin, such as Seton Healthcare Family, Sendero Health Plans, the Community Care Collaborative, the Dell Medical School at the University of Texas at Austin, and CommUnityCare. Many of these partners receive funding from Central Health to provide direct health care services to a total of 95,578 uninsured or underinsured patients in Travis County.

CommUnityCare, a network of nineteen Federally Qualified Health Centers (FQHCs), is one of Central Health's largest partners, and together, FQHCs in the network provide health care services to nearly 90,000 patients around Travis County. Some CommUnityCare patients have medical coverage under Medicaid, Medicare, or CHIP, and Central Health funds health care services for patients who do not have coverage.

In September 2015, Central Health formed the Central Health Equity Policy Council (CHEP Council) to recommend chronic disease prevention policies to both government and health system decision makers in the Austin and Travis County area.[4] The CHEP Council is comprised of sixty community organizations that collectively advance the mission of improving wellness and health equity for residents at or below 200 percent of the Federal Poverty Level in Travis County. The CHEP Council commissioned the current economic evaluation in order to analyze the cost-effectiveness of an HIV "opt-out" screening policy.

Program Context

The CHEP Council is recommending that FQHCs within the Central Health network adopt the “opt-out” HIV testing policy. The opt-out policy, or standard operating policy (SOP), is recommended by the Centers for Disease Control and Prevention, and it mandates that FQHCs automatically conduct an HIV screen on all new patients between the ages of 13 and 64, unless the patient requests to opt-out of screening.

Officials from Central Health requested an economic analysis to forecast the costs and outcomes associated with the change in SOP. Officials plan to use the estimates from the economic analysis to convince decision-makers at FQHCs to adopt the opt-out SOP. CommUnityCare has already implemented the opt-out SOP within their clinics and provided us with data from their clinics. We used the data to create an economic analysis model and tool that other FQHCs within the Central Health network can use to estimate the cost and consequences of adopting the SOP.

Population Affected

Austin Public Health estimates that every 1.5 days, a person in Austin or Travis County is diagnosed with HIV.[5] At the end of 2016, approximately 5,916 individuals in the Austin were living with HIV. Approximately 1,238 (17 percent) of all people living with HIV in Austin are unaware that they are infected.[6] Routine HIV screening decreases the likelihood of a late HIV diagnosis, which can result in early death, increased health care costs, and secondary HIV transmissions.[7]

In Austin, 41 percent of people living with HIV are White, one third are Hispanic, and 21 percent are African American. In Travis County, nearly half of the women living with HIV are African American, and the highest rates of infection are among people under the age of 30.[8]

Purpose of the Program

The CHEP Council supports the opt-out policy as part of a broader community-wide goal of zero new HIV cases. They believe implementing the SOP will reduce stigma around HIV screening, increase overall screening, foster earlier diagnoses and earlier intervention, prevent future transmission of the disease, and support the connection of patients to medical services. This in turn increases the chance that HIV patients will achieve viral suppression and avoid subsequent AIDS diagnoses. Overall, early identification of HIV leads to better health outcomes, reduced mortality, and fewer secondary transmissions.

METHODS

Perspective of Analysis

At the request of Central Health, we performed the majority of this evaluation from the perspective of CommUnityCare. Since CommUnityCare has already implemented opt-out testing, staff supplied us with the data that we needed to evaluate the efficacy of the policy for their clinics. However, we built the economic evaluation model and tool so that decision-makers from each FQHC can input site-specific patient data, costs, and staffing details to generate a more accurate estimate of the cost effectiveness of the SOP. In this way, the evaluation is most helpful to the CHEP Council, who hopes to use it as a tool in advocating for universal implementation of an opt-out HIV screening SOP.

Evaluation Framework and Tools

We conducted a cost-effectiveness analysis using decision analytic modeling to compare the costs and outcomes associated with an opt-in SOP versus an opt-out SOP. The model measures outcomes in both natural units (number of secondary transmissions, number of new HIV diagnoses, and life years gained) as well as in quality-adjusted life years (QALYs). We relied on peer-reviewed literature for data inputs that we did not receive from CommUnityCare. We also found in the literature the average lifetime secondary transmission rates for people living with HIV, as well as the false positive/negative rates of conventional HIV tests.

We employed decision analytic modeling to estimate the costs and consequences of implementing the opt-out screening SOP. Decision analytic modelling incorporates uncertainty into the decision-making process, and the model produces estimates of the expected costs and outcomes associated with each policy decision, thus facilitating the decision-making process. Decision analytic modelling is appropriate for the current economic analysis because Central Health and its affiliated FQHCs are comparing two policy options (i.e. maintaining the current opt-in practice at other FQHCs versus implementing opt-out HIV screening like the one at CommUnityCare). Additionally, decision analytic modelling combines data from a variety of sources into one economic evaluation.[9] This feature is especially useful for the current evaluation, as the data in the analysis come from many different sources, such as research literature, clinical trials, and data collected by CommUnityCare.

The data analytic model also includes a decision tree evaluation model. The decision tree is one of the most common tools for decision analytic modelling, as it is a user-friendly, visual representation of the decision process. The structure allows decision-makers to visualize sequences of events and decision alternatives.[10] Each branch represents an event that may occur; a square represents a decision, and a circle represents a chance event. Uncertainty is incorporated through probability of the occurrence of each chance event. The decision tree model generates payoff estimates and economic analysis from the perspective of the decision-maker, in this case Central Health or an FQHC.

Resources and Benefits

The accompanying spreadsheet allows staff from Central Health or an FQHC to input their own parameters, such as costs, testing rates, incidence rates, and number of new patients. Our initial analysis of CommUnityCare's Opt-Out program utilized the costs outlined in Tables 1 and 2 and the probabilities, outcomes and parameters outlined in Table 3. We included the variable costs associated with testing, the annual cost of an opt-out program coordinator, and the one-time cost of training. Probabilities, outcomes, and parameters include the rates of HIV diagnoses, testing rates, life years gained, patient utility, the number of new patients and the discount rate.

The program coordinator and phlebotomist line items were included, although the total cost was $0. CommUnityCare decided that the phlebotomists' time is irrelevant since the HIV test added no extra time to the existing blood draw time. Additionally, we put 0 percent time for the program coordinator since CommUnityCare's position is grant-funded. We included the zeroed-out lines in the tool, however, so that each FQHC could decide whether to include the costs for their own analyses.

Table 1: Variable Costs Associated with Testing and Diagnosis				
	Total Cost per Item	*Salary*	*Time Required (in minutes)*	*Number of Staff*
HIV Tests (Confirmatory Tests Included)	$8.00			
Phlebotomist time for blood draw	$0	$32,287.00	0	1
Administrative Time for Reporting	$14.81	$61,592.00	30	1
Medical Personnel Time for Positive Counseling	$46.33	$192,720.00	30	1

Table 2: Additional Costs Associated with Opt-Out Policy					
Fixed, Annual Costs					
	Total Cost per Item	*Salary*	*Time Required (in minutes)*	*Perc. of Time on Project*	*Number of Staff*
Program Coordinator	$0	$61,592.00		0%	1
One-Time Costs					
Providers' Time in Training	$2,316.35	$192,720.00	30		50
Training Materials	$500.00				
Cost of Changing the EMR	$461.54	$60,000.00	960		1

Table 3: Probabilities, Outcomes, & Parameters for Opt-in and Opt-out Testing	
Probabilities	
Opt-In Policy: Patient is Not Tested	55.00%[a]
Opt-In Policy: Patient is Tested	45.00%
Opt-Out Policy: Patient is Not Tested	38.84%
Opt-Out Policy: Patient is Tested	61.16%
Incidence Rate	0.11%[11]
False Positive Rate	0.00055%
False Negative Rate	0.0030%
Outcomes	
Utilities[12]	
Unknown Positive Status	0.85
Baseline/Known Negative Status	0.85
Known Positive Status	0.8
False Positive	0.84
Life Years Gained[13]	
Positive Diagnosis	14.1
Negative Status	0
Unknown Positive Status	0
Secondary Transmissions[14]	
Unknown Positive Status	0.0877
Known Positive Status	0.0253
Other Parameters	
New Patients	
Number of New Patients	7000
Discount Rates	
Outcome Discount	3%
Cost Discount	3%

[a] Testing participation rates and annual number of new patients were provided by CommUnityCare

Measurement

The cost data necessary for evaluation of the SOP should be readily available within the FQHC's existing expense system. As shown in Tables 1 and 2, the most complicated expense to track, the cost of medical care provided by the clinics to HIV positive patients, is not included since these costs are reimbursed through the federal Ryan White HIV/AIDS Program. The training costs could include the cost of copies if necessary, as well as food or drink provided during the training. The remaining costs can be measured by tracking the amount of staff time spent on relevant tasks and the staff members' respective salaries.

The benefit and probability parameters were taken from literature about HIV and from CommUnityCare data, but they can be replaced with information specific to a particular FQHC if data are available. For example, a specific FQHC might have a higher or lower opt-in rate or HIV prevalence depending on the population served. If an FQHC wants to input their own opt-in and opt-out rates, it is important that they update their intake procedures to capture that data, for example, through their electronic medical records system.

We decided to use a 3 percent discount rate for costs and benefits that will accrue in the future, which allows us to bring the outcomes to present-day values. This is the rate that is generally accepted for economic evaluations of health care, and it was derived from other published HIV opt-out economic evaluations.[15]

RESULTS

How to Use and Read the Decision Analytic Tool

To estimate the cost and consequences of opt-out screening implementation, we constructed a decision tree with tables of associated parameters and outcomes in a Microsoft Excel workbook. The Excel Workbook includes spreadsheets for analysis of short-term payoffs (one year, three years, and five years after the implementation of the new SOP) from the FQHC perspective.

The tree is housed on the “Decision Tree” tab for each time frame. Each tree begins at the square at the far left-hand end of the tree. The square represents a policy decision for decision-makers at an FQCH: *Should our agency implement the opt-out HIV screening SOP, or should we adhere to the current opt-in HIV screening SOP?* Each decision event—Keep Opt-In Screening and Implement Opt-Out Screening—stems from the square decision node. Figure 1 presents a simplified version of the decision tree from the workbook.

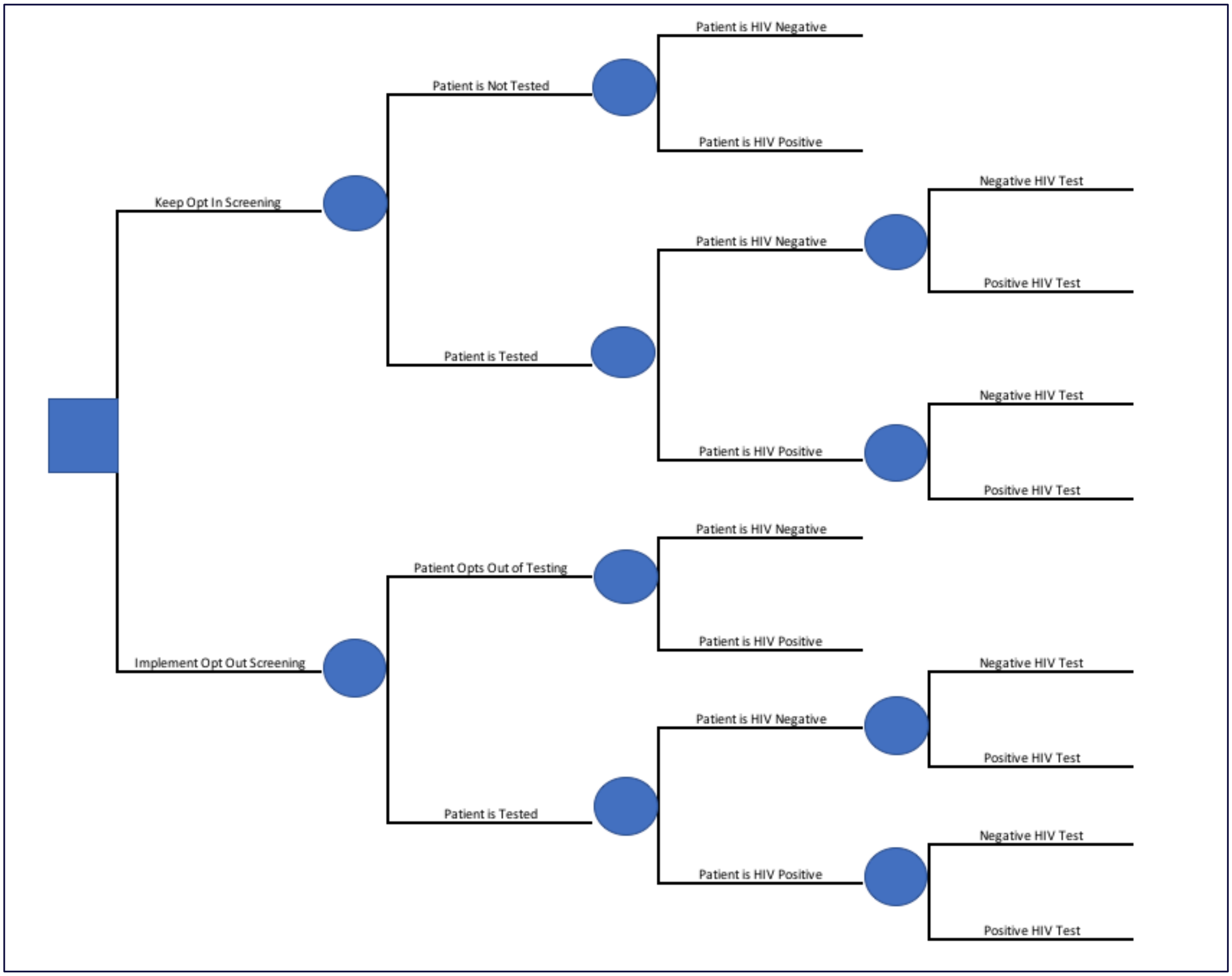

Figure 1: The decision tree modeling the decision options and paths for a patient.

The subsequent first circle is a chance point wherein a patient can choose to be tested or not. From there, two events can occur—the patient is either tested for HIV, or the patient is not tested for HIV. If a patient is tested, the next chance circle incorporates the probability that a patient tests either positive or negative for HIV. If a patient is tested for HIV, the next chance point estimates the risk of an inaccurate test result (i.e. a false positive or false negative). In sum, the decision tree charts twelve possible paths for a patient depending on implementation of the opt-out screening SOP, shown in Table 4.

When the parameters are updated, the spreadsheet calculates final outcomes in the form of an incremental cost-effectiveness ratio (ICER) by “folding back” each branch. The consequences of each branch (i.e. life years, QALYs gained, secondary transmissions, HIV positive patients diagnosed, and costs) are multiplied by the probability of the occurrence of the event. Each branch is folded back until total costs and consequences for the primary decision—whether to implement an opt-out screening SOP—are determined. Then, the total costs and consequences for each decision are compared in ICER format. The ICER estimates the cost per incremental increase of a specific benefit, such as cost per QALY gained. The calculations and total outcomes can be found on the “Outcomes” worksheet.

Table 4: Possible Paths for Patients	
Keep Opt-In Screening > Patient is Not Tested > Patient is HIV Negative	Implement Opt-Out Screening > Patient Opts Out of Testing > Patient is HIV Negative
Keep Opt-In Screening > Patient is Not Tested > Patient is HIV Positive	Implement Opt-Out Screening > Patient Opts Out of Testing > Patient is HIV Positive
Keep Op-In Screening > Patient is Tested > Patient is HIV Negative > Negative HIV Test	Implement Opt-Out Screening > Patient is Tested > Patient is HIV Negative > Negative HIV Test
Keep Opt-In Screening > Patient is Tested > Patient is HIV Negative > Positive HIV Test	Implement Opt-Out Screening > Patient is Tested > Patient is HIV Negative > Positive HIV Test
Keep Opt-In Screening > Patient is Tested > Patient is HIV Positive > Negative HIV Test	Implement Opt-Out Screening > Patient is Tested > Patient is HIV Positive > Negative HIV Test
Keep Opt-In Screening > Patient is Tested > Patient is HIV Positive > Positive HIV Test	Implement Opt-Out Screening > Patient is Tested > Patient is HIV Positive > Positive HIV Test

We included five parameters in the decision tree: life years gained, utilities, QALYs gained, number of secondary transmissions, and costs.[16,17,18] These parameters estimate the costs and consequences related to each event, as well as those of final outcomes of the model.[19] All parametric inputs can be altered by the users of the decision tree tool, which allows the CHEP Council and affiliated FQHCs to input site-specific data. These parameters can be changed within the “Parameters” worksheets, and the final outcomes will be immediately re-calculated in the tables on the “Outcomes” worksheets.

Figures 2 - 5 show the parameter inputs that decision-makers are most likely to alter in the model.

Opt-In Probabilities	
Opt-In Screening, Patient is Not Tested	55.00%
Opt-In Screening, Patient is Tested	45.00%

Figure 2: Current testing rates can be updated in this box.

Opt-Out Probabilities	
Opt-Out Screening, Patient is Not Tested	38.84%
Opt-Out Screening, Patient is Tested	61.16%

Figure 3: Projected testing rates under the new opt-out policy can be updated in this box.

Outcome Parameters	
Utilities	
Unknown Positive Status	0.85
Baseline/Known Negative Status	0.85
Known Positive Status	0.8
False Positive	0.84
Probabilities	
Incidence Rate	0.11%
False Positive Rate	0.00055%
False Negative Rate	0.0030%
Life Years	
Positive Diagnosis	14.1
Negative Status	0
Unknown Positive Status	0
Secondary Transmissions	
Unknown Positive Status	0.0877
Known Positive Status	0.0253
New Patients	
Number of New Patients	7000
Discount Rates	
Outcome Discount	3%
Cost Discount	3%

Figure 4: Probabilities regarding outcomes can be changed in this box. The most likely to be updated – total number of patients – is highlighted in red.

Variable Costs					
Variable Testing & Treatment Costs	Total Cost per Item	Salary	Time Required for Task (in minutes)	Percentage of Time on Project	Number of Staff
HIV Tests (Confirmatory Tests Included)	$ 8.00				
Phlebotomist time for blood draw	$ -	$ 32,287.00	0		1
Administrative Time for Reporting	$ 14.81	$ 61,592.00	30		1
Medical Personnel Time for Positive Counseling	$ 46.33	$ 192,720.00	30		1

Fixed Costs					
Fixed Programatic Costs	Total Cost per Item	Salary	Time Required for Task (in minutes)	Percentage of Time on Project	Number of Staff
Program Coordinator	$ -	$ 61,592.00		0%	1

One Time Costs					
Fixed Programatic Costs	Total Cost per Item	Salary	Time Required for Task (in minutes)	Percentage of Time on Project	Number of Staff
Providers' Time in Training	$ 2,316.35	$ 192,720.00	30		50
Training Materials	$ 500.00				
Cost of Changing the EMR	$ 461.54	$ 60,000.00	960		1

Figure 5: Costs and time dedicated to each program by staff can be altered in these boxes. The most likely to be updated – cost of HIV tests and the program coordinator – are highlighted in red.

In the decision tree, each event following a choice has a specific probability. In the workbook, we used probabilities provided by Central Health and CommUnityCare or by research literature. For example, we used a 61.6 percent testing rate under the opt-out policy, which is CommUnityCare's current new patient testing rate. The testing rate under the opt-in policy is 45 percent, which is People's Community Clinic's current testing rate. Users of the model can update these probabilities in the "Parameters" worksheet. Costs and consequences on the "Outcomes" worksheet will be immediately re-calculated after any change in parameters.

In the example with data from CommUnityCare and the literature, the opt-in SOP resulted in an average per patient of 0.01396 life years gained, 0.01117 QALYs gained, 0.00008 secondary transmissions, 0.00049 new cases of HIV diagnosed, and a per patient cost of $7.26.

In comparison, implementing the opt-out SOP resulted in a gain of 0.01897 life years, 0.01518 QALYs, 0.0007 secondary transmissions, 0.00067 new case of HIV diagnosed, and a total cost of $9.87 per patient. To determine cost per QALY gained, the difference in costs between the two decisions is divided by the difference in QALYs gained. In this example, the ICER is $650.21 per increase of one QALY. The differences in the total annual outcomes of the two policies, assuming one year of operation and 7000 new patients, are outlined in Tables 6 and 7 below.

Table 6: Compared Outcomes of Each SOP Over 1 Year with 7000 New Patients

Decision	Life Years Gained	QALYs Gained	New Secondary Transmissions	Costs	New Cases Diagnosed
Opt-In	97.71	78.17	0.55	$50,825.24	3.46
Opt-Out	132.80	106.24	0.50	$72,355.03	4.71
Difference	35.09	28.07	-0.05	$21,529.79	1.24

Table 7: Incremental Cost-Effectiveness Ratios

Cost per Additional Life Year	Cost per Additional QALY	Cost per Secondary Transmission Avoided	Cost per Additional Diagnosis
$520.17	$650.21	$395,408.61	$14,668.62

How to Interpret Results

While the decision tree provides a helpful visual representation of the decision-making process, leaders at Central Health and associated FQHCs are most concerned with the costs and consequences of implementing the opt-out screening SOP. The “Outcomes” worksheet calculates and displays the average costs and benefits to each patient depending on parameter inputs. The cost and outcomes per patient is multiplied by the total number of participants. This provides an estimate of the total cost of the SOP change based on the input parameters and number of participants in each type of screening.

The Outcomes tab also calculates an ICER, the average per patient outcomes, and the total outcomes in the form of life years gained, secondary transmissions, new diagnoses, QALYs gained, and costs. Together, the estimates that the evaluation tool provides will allow decision-makers to determine whether the change in SOP is cost-effective and worth implementing.

The ICER represents the estimated cost per benefit. For example, the decision tree can calculate the cost per QALY gained or cost per new HIV diagnosis. ICERs are most effective in decision-making when a decision-maker has a threshold ratio. That is, if Central Health is willing to pay up to $50,000 for one additional QALY, the analysis will provide a ratio that may be below, at, or above the threshold depending on parameter inputs. Based on the estimated ICER from the decision tree, decision makers can determine whether the change in SOP aligns with their willingness to pay.

DISCUSSION

Summary of Evaluation

We designed a decision-analytic model to estimate the outcomes of an opt-in and an opt-out HIV screening SOP. The tool allows decision-makers to estimate and evaluate the costs and consequences of implementing the opt-out HIV policy to determine whether FQHCs should adopt the policy. Our model estimates the outcomes of a change in SOP in life years gained, number of secondary transmissions, QALYs gained, new HIV diagnoses, and costs.

Each time a new patient visits an FQHC, a health care professional will administer an HIV test, unless the patient declines the screening. Each patient can follow one of six paths, choosing to get tested or not, receiving a positive or negative test and receiving a test result that confirms their health state.

Strengths

The decision analytic model displays a range of possible outcomes, which is ideal for determining the positive and negative consequences of the opt-out HIV screening SOP. The current policy decision has only one decision point (opt-in or opt-out) and the outcomes are binary (HIV positive or negative). Thus, the model is relatively simple to use. The decision tree also allows us to incorporate the probability that patients under either policy option will choose to be tested or not. This probability will vary for each FQHC, which dramatically effects the outcome of the evaluation.

Limitations

One of the CHEP Council's main motivations for the proposed change in SOP is the reduction of stigma around HIV testing. Unfortunately, our decision analytic model is unable to measure this goal, and we did not find any models in the literature that quantify stigma in an economic evaluation.

Additionally, our decision analytic model does not consider the effects of the SOP on different populations. We know that HIV disproportionately effects certain demographics, such as men who have sex with men, IV drug users, and people of color. While decision-makers can account for these differences by adjusting the testing and HIV incidence rates, this model does not explicitly take those differences in infection rate among diverse populations into account.

Our model also does not incorporate linkage to care. A certain number of HIV positive patients each year will be "lost to follow-up," meaning they receive a positive test but do not respond to the clinic's attempts to contact the person and get them into proper treatment. However, because each positive case is reported to both the city and state health departments for additional follow-up and tracking, the number of patients that fall through the cracks is expected to be quite low.

Finally, this model is only as good as the data that are entered. Many of the parameters we derived from the HIV literature were determined before today's medical advances, including the approval of the oral medication PrEP for HIV prevention and the official conclusion that patients with viral suppression cannot transmit HIV. To get the most accurate results, each FQHC must use valid data for costs and testing rates and other parameters should be updated as new data becomes available.

CONCLUSION

Using data from Central Health, CommUnityCare, and the HIV literature, we have created an evaluation of CommUnityCare's current HIV opt-out policy. The evaluation estimates that, compared to an opt-in screening policy, implementing opt-out screening costs $2.61 more per patient but gains an additional 28 quality-adjusted life years and diagnoses an additional 1.25 new infections across a population of 7,000 new patients in one year of operation.

The CHEP Council hopes to use this adaptable tool to make the case to its other partnering clinics that the opt-out SOP is a low-cost policy that will increase HIV screenings and diagnoses, improve linkage to care for HIV positive patients and decrease secondary transmission rates.

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