# Developing a Comprehensive Statewide Smoking Cessation Plan for IU Health: Leveraging a connection with the Indiana Tobacco Quitline

By

Jason T Schaffer, MD

A Capstone

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CERTIFICATE OF APPROVAL
This is to certify that the Master's Capstone Project of
Jason T. Schaffer, MD
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Has been approved
David Dorr, MD MS

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#### **Abstract**

#### **Problem Statement**

Indiana has the 10<sup>th</sup> highest rate of smokers in the United States with 21.1% of the population who smoke. This costs the state \$2.93 billion in health care dollars and another \$3 billion in lost productivity per year. Indiana has historically been behind other states in smoking cessation investments and programs, but has recently outlined 2020 mission, values, and priorities that will increase the focus and investment in this area. IU Health is aligning with the State of Indiana by developing an internal plan that will leverage state programs and funds to develop a comprehensive program for smoking cessation.

# **Description of Work**

We describe three aims of work here that are the initial steps of developing this comprehensive program. The first aim is to develop an electronic referral to the Indiana Tobacco Quitline which is a federally funded telephone quit assist program administered by the state. We implemented this functionality in the ambulatory setting into the intake workflow. In the second aim, we describe the future work of leveraging this same functionality in the inpatient setting with dedicated readiness-to-quit assessments completed by respiratory therapists prior to referral. In the third aim, we describe a pilot registry of smoking patients identified in six cancer clinics within IU Health. This registry is being developed to follow patients, their cessation plans, and their success over time.

#### **Results**

In the first aim, with the implementation of the electronic referral, we were able to significantly increase both the number of referrals per month (27.1/mo to 296.3/mo, 95% CI 60.5 to 477.7) and enrollments per month (6.3/mo to 39.1/mo, 95% CI 10.7 to 54.7) into the Quitline comparing the six-months preand post-implementation. The second and third aim are future work. For the second aim, we hypothesize that overall referrals will increase and that the proportion of enrolled to referred will

increase as well. In the third aim, we are building a registry that we expect will deliver insights over time.

We hope to better understand the challenges and opportunities in our smoking populations and
leverage the most impactful interventions based on this registry data.

# **Conclusions**

These aims illustrate three separate but related projects that are leading to a comprehensive smoking cessation strategy for IU Health. We have successfully increased referrals and enrollments to the Indiana Tobacco Quitline with the implementation of an electronic referral mechanism. We describe how the electronic referral will be leveraged in the inpatient setting, utilizing more available time and resources, to increase referrals and enrollment. Finally, we describe the implementation of a registry that will lead to better tracking and data analysis over a pilot cohort of patients. These three aims knit together into a basis for a larger comprehensive program.

#### Introduction

Smoking and tobacco use remain some of the highest contributors to morbidity and mortality in the United States. Despite class action law suits, legislation, federal funding, campaigns, and media efforts, all aimed at decreasing tobacco usage, a significant proportion of the US population still smokes. While there has been some decline in smoking rates nationwide, there is still more work to be done, especially in the state of Indiana. In all, 21.1% of the adult population in Indiana smoke; compared to the US average of 17.1%, this is the 10th highest rate in the country. The cost of smoking in health care dollars to the state of Indiana is \$2.93 billion per year. There is an added impact of \$3.17 billion of lost productivity per year related to smoking.

The fact that Indiana lags behind much of the country is no surprise when you look at some of the numbers. Historically, Indiana has spent less than many other states on smoking prevention and cessation programs and continues to do so. In fiscal year 2018, Indiana received \$568 million (estimated) in tobacco settlement payments and taxes. Of this amount, the state allocated a mere \$7.5 million in state funds to tobacco prevention, just 10.2 percent of the Centers for Disease Control and Prevention's annual spending target.<sup>3</sup> For reference, tobacco companies spend \$288 million on marketing in the state of Indiana.<sup>3</sup> Further, the state of Indiana ranks 38<sup>th</sup> in state tax-per-pack of cigarettes at about half the national average (\$0.995 vs. \$1.73) despite clear evidence, in many states, that taxing tobacco products at the point of sales can deter the purchase of those products.<sup>4</sup> Indiana has been behind in many of its regulations on smoking compared to most other states.

Although Indiana is still behind other states, in recent years, the state has shown some signs of increasing its efforts to combat tobacco use. In 2012, Indiana signed in to law a statewide smoking ban

that includes all enclosed public places and workplaces and within 8 feet of an entrance thereto (excluding bars).<sup>5</sup> Around the same time, local bans in larger metropolitan areas, like the city of Indianapolis were being signed. These new bans were more stringent, encompassing bars and casinos. In 2016, the state outlined plans for community-based programs, cessation interventions, public education campaigns, evaluation and surveillance, and infrastructure/administration/management. More recently, the state released a 2020 mission, vision, and priorities around smoking that speaks to an even more comprehensive plan to decrease tobacco use.<sup>6</sup>

Indiana University (IU) Health is aligning with the state's goals of reducing smoking and has chosen to partner with the State of Indiana on tobacco cessation. IU Health is a large, integrated delivery network in the state of Indiana and its footprint spans the majority of the state. IU Health's facilities include a large downtown academic medical center, 5 community and regional hospitals, several critical access hospitals, and numerous clinics around the state. IU Health has 2.7milion outpatient visits and over 110,000 hospital admissions per year. IU Health, as the single largest healthcare organization in Indiana, can have a major impact on tobacco usage in the state. IU Health is working to develop a comprehensive smoking cessation program in order to meet these needs. This paper outlines three aims of this work.

# **Background**

In both the 2016 and the 2020 comprehensive plans, the state of Indiana called out the Indiana Tobacco Quitline (ITQL) as "central to Indiana's comprehensive tobacco cessation network of state and local partners." The Quitline is a national tobacco cessation assistance program that is sponsored by states and the US Department of Health and Human Services. In general, a tobacco cessation Quitline is a

telephone-based quit assist counseling service that includes motivational counseling, behavioral therapy, and case management for identifying other services available to each individual. It employs the fundamentals of the 5 A's of intervention: Ask, Advise, Assess, Assist, and Arrange.<sup>7</sup>

The ITQL is the Indiana state funded connection to that program. The Quitline program is a telephonebased series of calls, connecting tobacco users with trained quit coaches. The telephone quit coach completes a readiness-to-quit assessment and develops a quit plan determining the best approach for each individual smoker. The service is free to users. The individual, with the assistance of the quit coach, sets a goal quit date. The quit date is usually set for 30 to 60 days following the initial call, based on evidence that a quit date in this time frame shows greater success than other time frames.<sup>8</sup> After the readiness-to-quit assessment and encouragement to enroll in the program, the quit coach assesses the resources available to the patient and the enrollee's support system that can help them through the quit attempt. If necessary or desired, the coach can refer the patient to local cessation services or other local resources and help leverage the enrollee's insurance or health plan. The planned calls are often motivational, and the quit coach can offer problem solving advice. Over-the-counter nicotine replacement therapies are an option often employed and the coach is knowledgeable and equipped to deliver up-to-date information regarding nicotine replacement. Quit coaches can also assess whether other pharmacotherapies may be of benefit and refer the enrollee back to the primary care physician for further treatment where appropriate. In general, there are 4 planned calls per enrollment in the program, and the preferred enrollment period is about 60 days but the Quitline will extend the enrollment period out on a per-case basis. At the conclusion of the enrollment, the Quitline sends a summary document back to the patient's electronic medical record reporting on the results of the quit attempt.

Of the 21.1% of people who smoke in Indiana, 65.1% want to quit, and nearly 59.9% have tried to quit at least once in the past year. Using a Quitline can increase the chance that a tobacco user will be successful in their quit attempt. Proactive phone counseling is more effective than less intensive approaches such as self-help materials and tailored mail. A Cochran review of multiple Quitline studies indicated that proactive Quitlines, like the Indiana Tobacco Quitline, showed a 56% increase in quit rates when compared to self-help (people quitting on their own). Also, while smokers can self-refer to a Quitline, this Cochran review showed that recruitment from a healthcare setting increases the success probability of a quit attempt. This knowledge is further motivation for our health care organization to create a more efficient and automated referral mechanism with the ITQL.

Some of the success of Quitline assistance is that it is an external motivating source and can increase accountability of the individual trying to quit. While other organized quit assistance can have the same effect, Quitline assistance can have the added benefit of removing some of the barriers of traditional cessation classes. Some barriers potentially relieved by the Quitline are:

- Transportation
- Child care
- Mobility limitations
- Remote living locations
- Reluctance to participate in a group program
- Off-hours availability: The Quitline is available 7 days a week
- Language limitations: The Quitline is available in 170 different languages

The ITQL has a successful track record. On average, about 10,000 tobacco users in Indiana call the ITQL each year for help quitting tobacco use. Since its beginning in 2006, the Indiana Tobacco Quitline has helped thousands of Hoosiers who want to quit tobacco. In the 12 years of existence, over 110,000 Hoosier tobacco users, including over 2,000 pregnant women, have called the ITQL. Tobacco users who utilize the ITQL report high levels of satisfaction with the services they receive. Over 9 in 10 tobacco users receiving Quitline services were satisfied with the program, and nearly 95% of Quitline clients

would recommend the program to other tobacco users. Quitlines are a cost-effective way to help tobacco users quit. One estimate shows that, in 2014, for every \$1 spent on the Indiana Tobacco Quitline, the Quitline saved an estimated \$17.85 in costs such as medical expenditures and lost productivity.<sup>11</sup>

Quitline referrals are a great first step, but there is recognition that many patients will need assistance beyond Quitlines. While the relative improvement in successful attempts for Quitline users may be over 50%, the absolute increase in the quit rate is more modest ranging from 4% to 30% depending on the control. <sup>10,12,13</sup> These baseline numbers in these studies are general low in the 2 to 6% range. <sup>14</sup> IU Health has a desire to be more aggressive and active in their approach to smoking cessation. We are developing a comprehensive smoking cessation program to include not only the Quitline referral, but counseling, phone and text based automated motivation, group therapy, pharmacotherapy, and for its employees, incentive-based encouragement. Each of these interventions, on their own, have been shown to have some success. Hopefully, that success will be additive or, better yet, multiplicative when the interventions are combined. <sup>15,16</sup>

Pharmacotherapy is an important component of any comprehensive program for smoking cessation.

Evidence shows that pharmacotherapy can increase cessation rates, but that behavioral therapy and combined therapy are more successful than pharmacotherapy alone. There are three pharmacotherapy treatments available: nicotine replacement, bupropion, and varenicline. Nicotine replacement comes in the form of gums, patches, lozenges, nasal sprays, and inhalers, and some of these are available without a prescription. Bupropion is a norepinephrine and dopamine reuptake inhibitor used to treat depression but also has an indication for smoking cessation under the trade name Zyban. The specific mechanism of bupropion for smoking cessation is unknown, but it likely has some

Varenicline (Chantix) is the first, and only, nicotinic acetylcholine receptor blocker. By blocking and antagonizing nicotine receptors, varenicline decreases the body's response to nicotine. Each of these pharmacotherapies have shown some successes in smoking cessation, but likelihood of success is

effect in decreasing smoking associated cravings triggered by the dopamine response to nicotine.<sup>17</sup>

significantly increased with counseling. 10 The preceding pharmacotherapies have variable efficacy and

variable side effects. Many opportunities for smoking cessation exist through insurance, health care

coverage, and direct employer services; however, many patients do not know what exists nor what they

have access to. The ITQL has insight into these options and can direct patients to all the resources

available to them. As such, The ITQL can provide individualized education on and referral to any of

these pharmacotherapies and resources.

The overall goal of this project is to decrease smoking in the state of Indiana by improving IU Health's

ability to assist its patients in their smoking cessation journey. To meet this goal, we outline three aims

of this project here. The first aim is to create and evaluate the impact of an electronic referral to the

ITQL that is built into the intake workflow of ambulatory clinics, at the point of tobacco use questioning.

The second aim is to evaluate the impact of the same electronic referral in the inpatient setting along

with dedicated readiness-to-quit assessment by trained respiratory therapists. The third aim is to outline

the development of the comprehensive program for tobacco cessation including tiered interventions

and referral mechanisms beyond the Quitline.

AIM 1: Implementation and Impact of an Electronic Referral to the Indiana Tobacco Quitline in the

**Ambulatory Intake Workflow** 

Aim 1: Introduction

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The Indiana Tobacco Quitline (ITQL) has been operational since 2006 and since that time, over 110,000 Hoosier tobacco users have called the ITQL. IU Health has long been interested in referring patients to the ITQL but has had limited success in achieving a large number of referrals. Until recently, referring a patient to the ITQL was manual, and required filling out and faxing a paper form to the Quitline. In an effort to increase the ease and opportunity of referring patients to the ITQL, IU Health pursued an electronic connection to the ITQL. The objective of this study is to describe and assess the implementation of an electronic referral process to the ITQL built into the ambulatory workflow at IU Health.

# Aim 1: Background

IU Health has aligned with the state of Indiana in its goal to decrease smoking rates in Indiana. One of the ways to positively impact this goal is to increase the enrollment of patients into smoking cessation programs like the (ITQL). We have outlined some of the benefits of the ITQL above. Establishing an electronic referral to the ITQL has been chosen as our first aim because it has been identified as a central part of the state's comprehensive program to promote smoking cessation. Additionally, as a federal and state funded program, there are no associated connection or subscription fees, so the cost of implementation to IU Health is relatively low. Internally, the costs of implementation are limited to the following program costs: workflow analysis, development of questions and discrete data elements, triggers for HL7 message development, and integration with the State Department of Health's electronic medical record. There are also additional associated costs of legal and compliance review. However, there is no significant custom EMR nor technical build work as part of this implementation.

Enabling this electronic referral is viewed as a first step in a more comprehensive program, and as a central focus for the state of Indiana, electronic interface allows IU Health to align more closely to the state's goals. While we would like to enable an electronic referral in all settings, we chose to focus our efforts on a single setting in order to maximize our chances of success. A workflow analysis was completed that identified 3 potential workflows for implementation of an electronic referral: ambulatory, inpatient, or acute-care setting (emergency, outpatient surgical, urgent care, or others). While the inpatient setting seemed to have the most opportunity for time intensive interventions, the ambulatory setting is the most attractive, as this setting combines efficiency with patient volume and patient focus. Despite evidence that smoking cessation advice can be given, and impact can be made in acute-care settings like the emergency department, <sup>18</sup> it was determined that the program rollout and education would be too complex for a rapid rollout in these settings. The inpatient setting will be the focus of our second Aim and we will defer acute-care settings to a time when the program is more established.

For the reasons listed above, an implementation into the ambulatory workflow was chosen.

There is prior evidence that electronic referrals significantly outpace fax referrals;<sup>19</sup> so we utilized this knowledge to develop an efficient referral process, implementing the ITQL referral mechanism into the intake workflow.

# Aim 1: Methods

This is a pre-post-intervention analysis of the impact of an implementation of an electronic referral to the ITQL on referral and enrolment volumes. We have implemented an electronic referral to the ITQL in the intake workflow for patients presenting to ambulatory clinics at IU Health. The primary endpoints are referral and enrollment volume and enrollment rates. We will

compare the mean enrollment per month of the 6 months prior to and 6 months after the implementation of this electronic referral. We will analyze the data using a two-sample t-test assuming equal variances. The mean number of referred patients and enrolled patients will be compared between the two timeframes. The status of all referrals over these time frames will be reported as well.

Inquiries regarding smoking status, among other social history questions, is standard of care during the intake workflow of ambulatory IU Health clinics. At the point of tobacco questioning and documentation in the Cerner intake forms (Figure 1) we added the following question "Are you motivated to quit smoking in the next 1 to 2 months?". In addition, we included a follow up question regarding openness to referral: "Can we refer you the Indiana Tobacco Quitline who will call you to assist in a quit plan?" We also included the following disclaimer statement for clarification, "By saying yes, you are giving us consent to share your contact information with the ITQL." Debate was had over whether or not these questions should be made mandatory by requiring responses to each question. It was decided that in the initial phase, the questions would not be made mandatory. The hope was that responses to the additional questions would naturally follow due to the close proximity to the mandatory smoking question.

Affirmative answers to the three preceding questions are the trigger for the electronic medical record to generate an HL7v2 message which is sent to the ITQL with the following information:

Patient Name Clinic Location Date Age

Phone number

Once received, the ITQL then attempts to contact and enroll the patient into tobacco cessation services. The ITQL makes a total of 5 attempts to reach the patient by phone over the next several weeks and tracks the response. The referred patients and their enrollment statuses are monitored by the state Department of Health and reported on a monthly basis to IU Health.

## These are reported as:

- Pending: Referred and not yet reached
- Declined Services: Referred, reached, and declined services
- Already Enrolled: Referred but already actively enrolled
- Not Reached: Referred and not reached after 5 attempts no more attempts will be made
- Accepted Services: Referred, reached, and accepted services

Because IU Health is making a connection to an external entity and data source, there are several requirements needed in order to assure compliance with HIPAA. The ITQL is a federal program that is administered by the Indiana State Department of Health (ISDH). A Business Associate Agreement (BAA) must exist between IU Health and ISDH. An existing BAA is in place supporting other data sharing relationships between IU Health and ISDH. We confirmed that this is adequate to cover this program.

In order to share data, consent must be obtained from the patient. The general consent for IU

Health that each patient signs states that IU Health has the right to share data with its data
sharing partners. However, because IU Health is sharing demographic data with the specific
intent that the ITQL will use this information to contact referred patients, we deemed it prudent
to specifically confirm and document consent for this purpose.

Our education and advertisement efforts involved a small campaign through the systemwide ambulatory governance council, ambulatory physician and advanced practice provider meetings,

and standard educational outreach through FAQ's, clinical information services education, and clinical informatics support.

#### Aim 1: Results

Data is available for the 6 months preceding and the 6 months post-implementation of the electronic referral. The electronic referral was activated on 3/17/2018. However, since the electronic referral information was available for only a portion of the month of March, the month of March is excluded from data analysis. For the 6-month period prior to activation of the electronic referral process, IU Health averaged 27.1 referrals per month vs 296.3 in the months after the electronic referral with an increase of 269.1 referrals per month (95% CI, 60.5 to 477.7). There was an increase in enrollment rates from 6.3 enrollments per month to 39.1 enrollments with an increase of 32.8 enrollments per month pre- and post-intervention respectively (95% CI, 10.7 to 54.7). There was a cumulative increase in referrals and enrollments from 163 to 1778 and 38 to 234 respectively between the pre- and post-intervention timeframes. However, the proportion of referred patients that enrolled into services decreased from 23% to 13%. The data is represented in Figure 2.

Of note, it was found that for a period of about 3 weeks in June, the outbound referral messages were being backlogged in the system. This was discovered and resolved in the first few days of July. The messages were not lost but queued in the system, once the fix was applied, the bulk of June referrals were sent. This explains the dip in June referral numbers and the relatively large number of referrals in July.

#### Aim 1: Discussion

With the implementation of an electronic referral to the ITQL, IU Health was able to significantly increase both the number of referrals as well as the number of enrollments into the program.

This was accomplished with minimal staff education, without the addition of mandatory fields in the EMR, and with negligible disruptions to the clinical workflow.

The funding for this project was relatively small. A project manager was employed to keep the project on track, connect the stakeholders, and manage the tasks of the project. The integration team built the HL7 outbound and inbound connections for sending the referral out and receiving the completion record back in to the EMR (Figure 3). The build-team created the data elements and the triggers for messaging, while another team created the documentation elements within the user interface. The project costs were limited to the time these teams spent on the project. The connections with the ITQL and their chosen EMR vendor, Optum, are supported by the state and federal funding of this program.

While we were able to increase referrals and enrollment, we had a significant decrease in the proportion of referred patients who actually enrolled in the program. The decrease in enrollment rate was somewhat expected due to the means with which we deployed this functionality. Building the functionality directly into the standard workflow of a medical assistant (MA) in the clinic is advantageous in that it localizes the referral questions to smoking history questions that are already mandatory in the workflow. However, MA's are not trained nor provided the tools or the time to complete an adequate readiness-to-quit assessment. This is efficient to create a referral, but the key factors in readiness-to-quit are not assessed. Further, the referral questions occur at a time in the workflow when the patient is going through the rote process of answering medical history questions. At this time, the patient is less likely to be

contemplative about their motivations and desires to quit smoking. It would also not be surprising that when the Quitline contacts a referred patient, the patient may not be engaged, and the call might not result in a successful enrollment. With Aim #2 we hope to explore the effects of a dedicated readiness-to-quit assessment, in the in-patient setting, by a trained individual, at a time when patients are focused on the thought process of smoking and smoking cessation.

#### Aim 1: Conclusion

We have shown that an electronic referral to a Quitline can increase the number of referrals and the number of enrollments into Quitline services. In this case, the electronic referral was built into the ambulatory clinical workflow without significant workflow disruption nor a large amount of program development. This intervention significantly increased the number of patients referred-to and enrolled-in the ITQL over the baseline, however, the proportion of patients enrolled to referred decreased.

Aim 2: Implementation and Impact of Readiness-to-quit Assessment by Respiratory Therapy and Electronic Referral to the Indiana Tobacco Quitlne in the Inpatient Setting: Comparison to Ambulatory Workflow without dedicated Readiness-to-quit Assessment

#### **Aim 2: Introduction**

In Aim #1, we have shown the ease of an electronic referral to the ITQL which is effective in increasing the number of patients referred-to and enrolled-in the ITQL cessation program.

However, as part of that study it is apparent that the *proportion* of patients enrolled to patients referred decreased from baseline to post-intervention. The ITQL goal is a 50% enrollment rate

for those that are referred. The enrollment rates in Aim 1 were well below that goal at 23% preintervention and 13% post-intervention. From previous literature, we know that some of the factors that lead to higher enrollment rate are readiness-to-quit, motivation, and setting a quit date within a 60 day timeframe. <sup>8,20</sup> Without dedicated resources, assessments of these factors cannot be adequately completed during a typical ambulatory intake assessment or encounter.

In Aim #2 we will be implementing an electronic referral to the ITQL into the inpatient setting where it can be leveraged by respiratory therapists. This is a future aim that we will be implementing using the same electronic referral mechanisms with a different user workflow. Respiratory therapists are motivated clinical team-members who have time that can be dedicated towards smoking cessation interventions. The purpose of this study is to evaluate the impact of a readiness-to-quit assessment, motivation assessment, and quit date setting on enrollment rates to the ITQL.

# Aim 2: Background

There are several factors that have been noted to increase smoking cessation rates. Readiness-to-quit, higher motivation to quit scores, and setting a quit date have all been shown to be markers associated with successful cessation. Patients with higher readiness-to-quit had significantly more quit attempts (50.4% vs 25.9%; p < 0.001).<sup>8</sup> Also, Smokers with higher motivation, as shown by the "Mondor scale", and higher readiness-to-quit assessment had a significantly longer quit attempt duration (60.1% vs 36.4%, p < 0.001 and 55.1% vs 33.2%,p < 0.001 respectively). Interestingly, the shorter the goal quit date, the higher the probability of success. In one study, the probability of being abstinent at 6 months if the participant selected a quit date in weeks 1, 5, 10, and 13 were 39.6, 22.6, 10.9, and 4.3%, respectively.<sup>21</sup> Validity

studies have demonstrated that a model called the "Contemplative Ladder" is associated with cognitive and behavioral indices of readiness-to-quit.(e.g., intention to quit, nicotine dependence).<sup>8,22,23</sup>

Given these prior study findings, IU Health is planning to implement an inpatient referral program that utilizes evidence-based tools to evaluate readiness-to-quit, motivation to quit, and goal setting. With these assessments, it is felt that we can better target referrals that will result in a higher percentage of enrollments per referrals.

## Aim 2: Methods

For Aim #1, we built mechanisms to capture data elements in the EMR regarding smoking status and readiness-to-quit. Utilizing the electronic referral mechanisms in our first study, we will retool these questions, data elements, and HL7v2 messages to deliver similar functionality to a different workflow. There are several key differences in this second aim. This second aim will be implemented within the inpatient setting. This implementation and venue will allow more time for upfront assessment and counseling with the patient prior to the referral. As opposed to a workflow that is conveniently linked to other mandatory smoking history questions, we will build an opportunity to have a more robust interaction with a patient.

In the inpatient setting, there is often idle time which can be utilized to engage patients and their families for coaching opportunities. For this purpose, we will leverage an engaged group of respiratory therapists. This group is already heavily involved in our COPD population which, for obvious reasons, has significant crossover with our smoking population. Our respiratory therapists are motivated to deliver outreach and education to smokers whether or not they

have been diagnosed with COPD and are excited about a mechanism of education and referral for smoking cessation services.

Patients admitted to the hospital and identified as smokers will be populated to a worklist for the respiratory therapists. This worklist will be run at the discretion of the respiratory therapist team. The goals will be to identify non-ICU patients that are able to participate in readiness-to-quit assessment, motivation assessment, and quit date goals and to complete and document these assessments. Based upon the results of these assessments, respiratory therapy can refer these patients to the ITQL utilizing an order for referral to ITQL via the same mechanism as in AIM #1.

Based on the results of the motivation and readiness to quit assessments, it is expected that the respiratory therapists will be able to triage and refer patients to a targeted level of assistance. Specific tools for this study have not been defined but our respiratory therapists are trained in tools like SBIRT (Screening, Brief Intervention, Referral to Treatment) and the Contemplative Ladder. Using this training and motivational guidance, they will limit referrals to the ITQL to those patients who are truly ready and educate and motivate patients who are lower on the Ladder.

#### Aim 2: Results

The primary endpoint will be the rate (proportion of enrolled to referred) of enrollment into the ITQL program. We will compare enrollment rates between the ambulatory workflow (Aim 1) and the inpatient workflow (Aim 2). While we will track the readiness-to-quit assessments as well as motivation, and quit-date assessments, the primary outcome will be enrollment. There are

recognized confounders between the populations of Aim 1 and Aim 2, but the results are not expected to speak to the weight of the primary interventions nor the individual confounders. The goal of this project is to increase both ITQL referral and enrollment in raw numbers and proportionally. While we intend to collect the data on contributing factors and may present this data in future works, we will be focused on the primary goals. Patient demographics, discharge diagnoses, consultation time, length of stay, and patient location will all be available and reported as secondary measures for analysis. Our hopes are that this data can be used to understand where future efforts can be applied for further investigation.

#### Aim 2: Discussion

it is expected that referrals and enrollment to the ITQL will significantly increase with moving the electronic referral process into the inpatient setting. It is hypothesized that the proportion of patients enrolled to referred will increase as well. Both the increased number of referrals and the increased proportion of enrollments are the desired effects of this aim. The increased proportion means that we are referring more people who are motivated and ready to quit. It is believed that 3 factors will lead to this increased proportion. First, it is logical to believe that patients in an extended acute episode of care, a hospital stay, may be more motivated to improve their health as they transition out of that acute episode. Second, with the addition of a human touch-point, a respiratory therapist, and the opportunity to provide rational, education, and motivation about smoking cessation, it is believed that this can increase the motivation to quit. Finally, the ability of a trained respiratory therapist to complete a more thorough readiness-to-quit assessment, face to face, with the patient will allow for better identification of patients to refer to the ITQL, thus increasing the proportion of enrolled to referred.

#### **Conclusions**

In this aim we expect to show increased referrals and a higher enrollment rate into the ITQL compared to Aim 1. We believe that this electronic referral mechanism will empower motivated and skilled technicians to use their quit coaching skills to refer not only more patients, but the right patients to the ITQL.

Aim 3: Institution of an EHR-generated Smoker Registry and a Comprehensive Tiered Approach to Smoking Cessation for IU Health. Initial Pilot in Cancer patients to inform the Spread to a Systemwide Standard.

#### Aim 3: Introduction

In 2018, IU Health instituted an electronic referral connection to the ITQL. Beyond this referral mechanism, IU Health has a desire to institute a comprehensive smoking cessation program. The ITQL is a great first step that includes minimal investment from IU Health. However, this singular approach is not adequate to provide the necessary assistance for all smokers who desire to quit. The purpose of this program is to build a more comprehensive and personal approach to smoking cessation. While the Quitline will be a first offering, smoking cessation specialists will engage patients, complete a readiness-to-quit assessment, and discuss all of the options available to each individual patient. We will enroll willing patients into the program and build a registry in order to observe them over time, collecting data to understand their habits, motivations, barriers, successes, and challenges in the journey to smoking cessation.

# Aim 3: Background

By building a registry we can collect and organized the clinical data for patients who are smokers. We are able to collect demographic data, data pertinent to their smoking status, social determinants, enrolled cessation programs, and pharmacotherapies used. We will also be able to monitor successes and challenges over time. This full-scale view will allow us to better adjust and target our therapies as time goes on. We know from the available literature that there are several factors associated with more quit attempts and a longer quit duration when a quit attempt is made. These factors are lower-nicotine dependent users, higher-motivated smokers, smokers who have previously quit for more than 1 month, and an intention to quit within 2 months. <sup>8,20</sup> We also know that the combination of pharmacotherapy with behavioral interventions increase the success of quit attempts. <sup>15</sup> With a registry, we will be able capture data points over time for these and other factors and track the relative impact in our population to compare to available evidence.

Over the past several months, we developed a pilot program to begin a registry of patients who use tobacco. This pilot is targeting patients who have registered encounters at one of six clinics within IU Health. These clinics have been selected because they are either primarily oncology clinics or clinics that have a high percentage of oncology patients. The rationale behind targeting this population is that 1. They are likely to be a motivated population to quit smoking especially early after diagnosis. <sup>24</sup> 2. They are likely to have a significant amount of contact with the health care system, and 3. There is significant benefit to these patients to quit smoking, as continued smoking increases risk for other smoking-related diseases, second primary tumors, and disease recurrence. In addition, continued smoking reduces treatment efficacy, increases toxicity and side effects from radiotherapy and negatively affects overall survival. <sup>25</sup> Logistically, the selected

clinics, are in close proximity to each other and can be served by a relatively small number of quit coaches.

#### Aim 3: Methods

Patients that have a scheduled encounter at any of the specified clinics will be identified for enrollment. A report of patients who are smokers and who have an upcoming scheduled encounter will be generated weekly. A group of coordinators and trained quit coaches will receive the report and allocate time each week to approach these patients during their scheduled encounter. The objective is to enroll these patients into the program and the registry and to evaluate available cessation options. The quit coaches will use evidence-based motivational techniques to encourage a quit attempt. They will encourage the enrollment in the Quitline and then evaluate insurance and coverage status and other available opportunities for cessation support and assistance.

We have identified six oncology clinics that are in Adult Academic Health Center of IU Health that are geographically located in close proximity that will allow for coordination and service by relatively few numbers of quit coaches. There are currently 2 full-time coaches with plans to hire 1 to 3 more as the program moves forward. The six clinics identified are the Otolaryngology Clinic, Precision Genomics, Multidisciplinary – Cancer Pavilion, Urology, Bone Marrow Transplant Clinic, and Neurology Clinic. Not all of these clinics are exclusively oncology-based clinics, but those that are not have a high proportion of oncology patients.

Once enrolled, the quit coaches will begin collecting data on these patients to populate the registry. Data will generally be collected at each in-person encounter. Since this pilot involves

oncology patients, it is likely that several enrollees will have encounters more frequently than monthly. So as not to cause undue burden, we will limit data-collection for frequent visitors to no more than monthly. If a patient does not have an in-person encounter within a six-month time frame, we will contact the patient by phone to recollect data; setting a minimum of 6 months between data collection.

We have built a form within the EMR to collect the desired data. We will collect data in several categories with 2 specific aims in mind. The first aim will be to understand pooled patient characteristics, programs, and treatments that are associated with smoking status, quit attempt, and success or failure. The second aim is to document the specific behavioral patterns for each individual patient so that quit coach interventions can be documented, and behavioral barriers and risks can be addressed with each patient contact. See figures 4 and 5 for the data collection form (this is a single form split into two figures for display here). This form creates specific data points in the EMR for pooled data reporting; signing of the form will create a document in the patient record for patient care and for following each patient individually through their smoking cessation program enrollment. The form consists of the following sections:

- Tobacco Treatment Plan Details Date of encounter, treatment plan enrollment status, encounter type, quit coach provider, and session number.
- Clinic where enrolled Clinic where care is being provided and cancer type
- Tobacco use assessment Type of tobacco use, frequency, tobacco withdrawal symptoms, and associated use social behavior assessments including work, home, and sleep patterns of use.
- Tobacco History Length of use, previous quit attempts, previous quit duration, relapse reasons, previous medication use, adherence, and side effects.
- Behavioral assessment barriers to quit, readiness-to-quit, motivations to quit, and setting of quit date.
- Referrals Internal and external referral documentation including the ITQL
- Treatment Plan Pharmacotherapy and behavioral goals.

After initiation of this program, it has been determined that we will need to capture quit confirmation data as well. Several fields will be required for documentation of successful cessation. We will add fields for cessation date, perceived most influential factors for successful quit attempt, and confidence in ongoing abstinence.

#### Aim 3: Results

We extracted data from patients enrolled in these clinics from the period of January 1, 2018 and June 1, 2018 to determine the number of potential patient enrollments to expect for this registry. Over this period, there were 635 unique patient who were identified as smokers in these clinics. This equates to 127 patients per month. We believe that this will give us an opportunity to generate approximately 75 new enrollments per month into the registry. This is a conservative estimate, accounting for staffing and patient acceptance rates. This would generate a registry of approximately 900 patients at the end of one year.

As we build this registry, we will report results in several different ways at quarterly intervals. The primary endpoint will be successful smoking cessation. This will be reported in raw numbers and proportion of enrolled patients. We will also track and report the proportion of unique smokers versus non-smokers within the targeted clinics for this study. With the available data, we also expect to report secondary endpoints including associations between programs, pharmacotherapy, behavioral assessments, and other factors that may have a positive correlation with successful quit attempts.

Important components of this registry are those components that can educate us on which factors have the strongest association with successful cessation in our population. On a macro

level, we will report the number of patients that received each of the interventions and compare those that successfully quit smoking versus those that have not been successful. These numbers will be tracked and reported over time that will allow us to track recidivism to understand the sustainability of smoking cessation related to each factor.

#### Aim 3: Discussion

By identifying and enrolling patients into this program and registry, we will be able to engage and track smokers in this population of oncology patients. The lessons that we learn from this targeted group of patients will allow us to build broader programs around the state and understand what motivates patients and creates successes. We will be able to report on this regularly and track these patients at regular intervals. We will leverage state and federally funded programs including the ITQL while offering more targeted support and opportunities.

We have several hypotheses that we will address in this project. The first is that ITQL referrals by themselves will bring modest gains. Increasing the number of referrals and the number of enrolled patients into the Quitline should be a step forward and create some successful quit attempts, but as the evidence shows, this alone will likely not have as large an impact as desired. The second hypothesis is that engagement with a live quit coach alone will bring better outcomes and increase the success rate over the Quitline rate. Engagement with a live quit coach would be expected to allow for increased personal contact, increased assessment of motivations, barriers, support, and an assessment of opportunities to address these on an individual basis. Our third hypothesis is that pharmacotherapy will increase success rates even more. This notion is supported by the literature and is expected to hold true in our population.

Pharmacotherapy without the behavioral therapy component would be expected to have limited success on its own and similar in the reverse.

With a registry we will be able to assess, over time, the relative value of each of these and other patient factors and variables that we can influence. We can identify our availability of services, understand our patients better, and better determine how to distribute and focus our resources.

#### **Aim 3: Conclusions**

We expect to show through this program and registry, that a comprehensive approach to a defined population of patients can have a large and lasting impact. We have described several hypotheses that are supported by previous evidence. There is limited prospective evidence, in a broad cohort of patients, what interventions work over time. There is also limited local evidence, in our population, as to what interventions make the most impact. Through this registry, we hope to not only decrease the smoking rate in this specific population, but to understand which interventions best impact Hoosiers and to be able to apply these across a broader population.

## **Conclusion**

The state of Indiana has set smoking cessation as one of its 4 primary public health goals through 2020. IU Health is committed to improve the health of the state of Indiana and in this regard has aligned with the state's goals and programs for tobacco cessation. We are leveraging the Indiana Tobacco Quitline as one of the primary programs utilized by the state to engage and support patients in their cessation journey. We recognize that implementing an electronic referral to the ITQL is a relatively inexpensive

first step that will deliver marginal gains for our population; however, this connectivity allows us to set a minimum viable solution for smoking cessation services that we can offer to our patients.

We believe that this electronic referral is a first step towards a comprehensive program for smoking cessation. We plan to leverage this functionality to begin the smoking cessation journey for many patients. We understand that many patients will need services and support beyond the ITQL, and as such, we are building a comprehensive smoking cessation program which will be informed by the registry of patients who are smokers.

We have shown in the first aim of this study that we can increase referrals and enrolments into the ITQL with a small investment and minimal disruption to clinical workflows. In the second aim we hope to build upon this success by using evidence-based tools to assess motivation and readiness-to-quit and to match services accordingly. In the third aim, we hope to capture data that allows us to further understand our patients, their successes, their challenges and our opportunities to make a healthier Indiana. As we move forward with the knowledge gained here, we will work towards broadening this knowledge and these efforts across all of IU Health to develop our comprehensive program.

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Figure 1

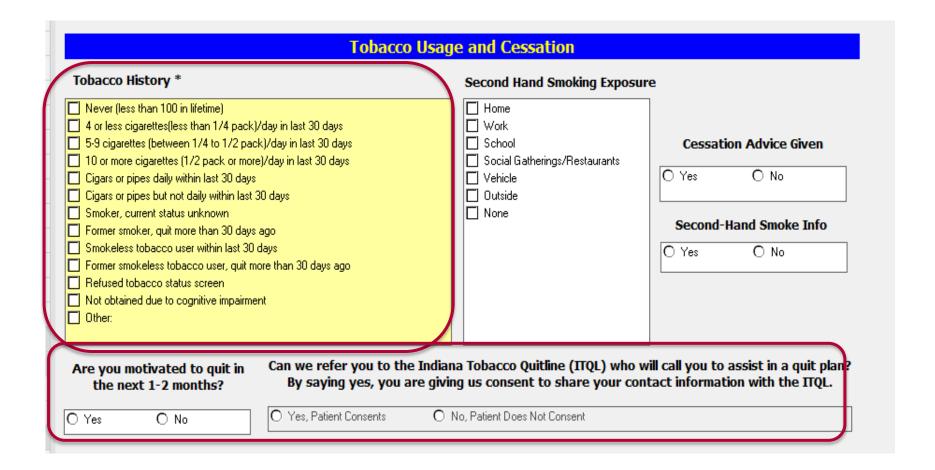
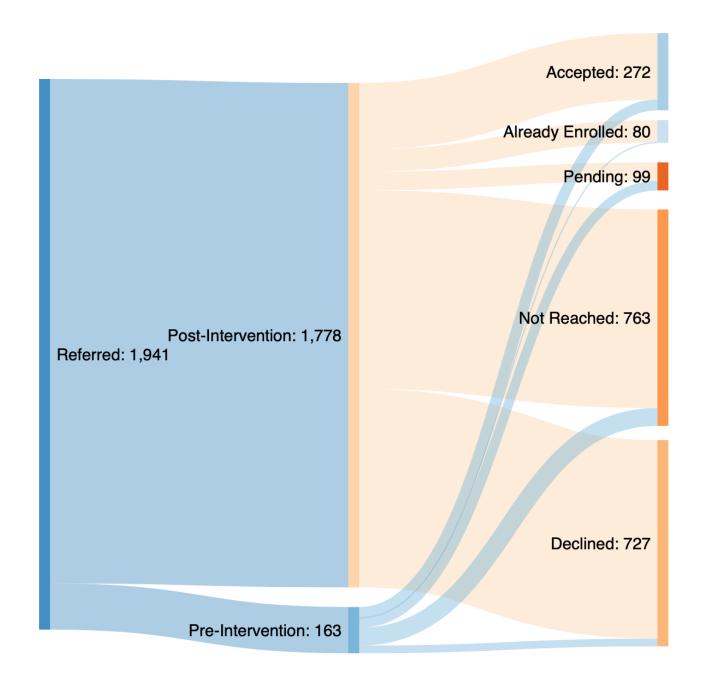


Figure 2



# Figure 3

Heather Quitline 10/23/2014 8:27 AM Orders Only MRN: 2100191	Provider: Th	Female DOB: 10 omas W Bond, I Fm New Haven	MD	
Progress Notes  No notes of this type exist for this encounter.				
Diagnoses				
Cough - Primary		786.2		
Medications Ordered This Encounter				
	Disp	Refills	Start	End
nicotine polacrilex (NICORETTE) 4 MG gum		0	11/10/2014	1/4/2015

#### Orders

# **Orders Placed This Encounter**

Use as directed.

Normal Orders This Visit Ambulatory Referral to Quitline Smoking Cessation [REF212 Custom]

Results are available for this encounter

# Result Summary for Ambulatory Referral to Quitline Smoking Cessation

#### **Result Information**

Status	Provider Status
Final result (10/29/2014 4:07 PM)	Ordered

# 10/29/2014 4:07 PM - Quitline Results Interface

#### **Result Narrative**

Free and Clear contact date: October 23, 2014 Free and Clear call disposition: Multi-Call Free and Clear status: Accepted Services Treatment plan: Planned quit date: November 10, 2014 Nicotine Gum 4 mg - 8 weeks

Figure 4

	Tobacco	Treatme	nt Progr	am						
Tobacco Treatment Program (TTF	P) Entry Date **/**	/×××× <u>+</u>	∨ Date of	last TTP pr	ogram visit	××	/××/×××	÷ 🗸		
Treatment Program Details Treatm				Treatment Status			Type of Visit			
☐ Accepted Referral to ITQL	Receiving Services Elsewhern Declined Undecided	e	O Declined O Initial O Ongoing T O Followup	reatment		-	Person hone Visit			
Provider	Q		Session #		<u>*</u>					
		Cancer Ce	nter							
Primary Service  O Rad Onc O Gyn Onc O Surg Onc O BMT O ENT O Neuro O Med Onc O Other: O Uro	O B O G		C Leukemi	na C C oracic	Sarcoma Urological Other:					
	Tobac	cco Use As	sessment							
Tobacco Type Used /			e of Current		st 30 Davs					
	obacco Time Last Used		igarettes		e Cigars	Ci	nars	ı		
<alpha> <a< td=""><td>lpha&gt;</td><td></td><td>ngarottov</td><td></td><td>o olgan</td><td></td><td>guio</td><td></td></a<></alpha>	lpha>		ngarottov		o olgan		guio			
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		O D4	ays C	Weeks	O Months	O y	ears			
	Tobacco V		Past 24 hou	rs)						
_ ,		ty Concentrating ia	☐ Headad ☐ Increas ☐ None	che	☐ Othe	er:				
Do you relight cigarettes?	O Yes O No									
Time to first use after waking	O Within 30 minute	s O 31-60 mir	utes O >	60 minutes						
Wake during sleep to smoke or u	se tobacco? O Nev	ver O	Some Nights	]						
Leave a social or work setting to	use tobacco?	Never (	) Daily	O Sometim	ies					
	Quit Perception	n / Confidenc	e / Readine	SS						
	*	0 1	2 3	4 5	6	7 8	9	10		
Perceived importance of quitting (0-	-10)									
Confidence for quitting (for recent of	quitter "to stay quit") (0-10)									
How ready to quit (0-10)										
		·	· · · · ·							
Other household members use to	obacco? O Yes	O No	O Liv	es Alone						
Smoking allowed in house?	O Yes	O No								

Figure 5

Age began tobacco use (years old)	Tobacco History	
	y.o. 💂	
Brand of Tobacco	Menthol Brand of Tobacco?	es O No
Number of previous quit attempts	Longest time without tobacco	
Longest quit related to	Most recent quit	Prior reasons for relapse
intentional quit     Hospitalization     Pregnancy     incarceration/institutionalization     Other:	Currently working on >10 years past 30 days past year 1-5 years 5-10 years	
Medications used in past atte	empts Adherence to medications use	d in plan Side effects of medications
O Bupropion SR (Zyban) O Nicotine gum O Nicotine Lozenge O Nicotine patch O Nicotine nasal spray O Nicotine inhaler		
	Behavioral Assessment	
Withdrawal experiences in prior qui	t attempt(s) Previoiusly seen by IU TTP	Previously sought professional assistance?
O Mild O Severe O Moderate O None	O Yes O No	O Yes O No
Why patient uses tobacco	Reasons/motivations to quit toba	Barriers/challenges to quit tobacco
Ready to set quit date ? O Yes	O No O Quit attempt in pro	ocess Quit Date xx/xx/xxxx
	Referrals	
I	Text mobile resource Declined	medication(s)
	Treatment Plan	
	Treatment Plan  Medication(s) Recommended	
☐ Declined ☐ Nicotine Gum 2mg ☐ None ☐ Nicotine Lozenge 4 ☐ Bupropion SR [Zyban] ☐ Nicotine Lozenge 2 ☐ Nicotine Gum 4mg ☐ Nicotine Patch 21n	Medication(s) Recommended  Nicotine Patch 14mg Varenicline (Chantix)  Mang Nicotine Patch 7mg Other:  Mang Nicotine nasal spray	
□ None     □ Nicotine Lozenge 4       □ Bupropion SR (Zyban)     □ Nicotine Lozenge 2	Medication(s) Recommended  Nicotine Patch 14mg Varenicline (Chantix)  Mang Nicotine Patch 7mg Other:  Mang Nicotine nasal spray	
None	Medication(s) Recommended    Nicotine Patch 14mg	Relapse prevention skills training Self-confidence-increase
None	Medication(s) Recommended    Nicotine Patch 14mg	
None	Medication(s) Recommended    Nicotine Patch 14mg	Self-confidence-increase
None	Medication(s) Recommended    Nicotine Patch 14mg	Self-confidence-increase
None	Medication(s) Recommended    Nicotine Patch 14mg	Self-confidence-increase
None	Medication(s) Recommended	Irawal (F17.203)  w-Up Plan  t to f/u with local pharmacy