An EPIC Based BPA to Enhance Quit Line Referral and Use

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JHM IRB - eForm A – Protocol

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1. Abstract

a. Provide no more than a one page research abstract briefly stating the problem, the research hypothesis, and the importance of the research.

Smoking is the number one cause of preventable death in the United States. Given the magnitude of the problem, interventions aimed at promoting smoking cessation have the potential to make large changes in improving health outcomes. Resources to aid with smoking cessation such as telephone-based counseling are generally underutilized. The electronic medical record (EMR) in use at Johns Hopkins has limited decision support to promote referral to the Maryland Quit Line, a free smoking cessation counseling resource. We propose a cluster randomized trial with a waitlist control at 22 Johns Hopkins Community Physicians (JHCP) sites, which offer primary care. The intervention will include a multi-modality intervention to promote provider use of smoking cessation resources which include an Epic-based Best Practice Advisory (BPA) that allows providers to electronically refer to the Maryland State Quit Line, educational materials, and provider visits with Quit Line representatives to review use of smoking cessation practices (academic detailing). Sites will be randomized to one of three arms with increasing support: 1) six-month waitlist control; 2) BPA with optional educational modules; 3) BPA with online educational modules, a quick-reference educational document, and additional academic detailing. We hypothesize that by implementing a new Epic BPA that allows providers to easily refer to the Maryland Quit Line electronically, we will increase use of this resource. We also hypothesize that adding additional educational materials and having Quit Line representatives perform educational outreach visits will further increase use of the Quit Line and will increase prescription of medications to assist with smoking cessation. Ultimately we hope to improve patient care by increasing providers' use the Maryland Quit Line and pharmacotherapy. We hope that the use of these resources will decrease smoking rates and thereby improve patient health and outcomes while improving JHCP quality metrics.

2. Objectives (include all primary and secondary objectives)

The primary goal of this study is to test the effectiveness of instituting an Epic BPA in increasing Maryland Quit Line referrals. The secondary goals are to measure the BPA's effect and the effect of additional provider education on patient engagement with the Quit Line, and on prescription of medications that aid in smoking cessation. A third goal is to obtain initial provider feedback on the BPA to inform roll-out of this BPA across the health system.

Aim 1: In a three-arm, cluster randomized trial, to test the effectiveness of an Epic BPA with provider educational support and provider detailing in provision of smoking cessation services.

Hypothesis 1: An Epic-based BPA to prompt providers to electronically refer people who are ready to quit smoking to the Maryland Quit Line will increase use of this service compared to waitlist control.

Hypothesis 2: An Epic-based BPA supplemented with educational materials and academic detailing will increase Quit-Line referral compared to control.

Hypothesis 3: Additional provider support including educational materials, in-person academic detailing, will increase successful referrals to the Quit Line and prescription of cessation pharmacotherapy compared to waitlist control and BPA only

3. Background

Smoking remains the number one cause of preventable death in the United Sates. Despite decades of declining rates of smoking, the burden of disease caused by smoking remains high.[1] 22.2% of adults in the U.S. smoke, and 18.4% smoke daily.[2] This issue remains a difficult but potentially high-yield area of medicine to improve health outcomes by improving implementation of behavioral and medical therapies. Though phone-based smoking cessation counseling has been shown to be beneficial in improving quit rates[3], physicians do not regularly refer their patients for this intervention. There is no decision support tool or automatic referral mechanism embedded in the EMR used at Johns Hopkins. EMR based-interventions have been shown change provider behavior to increase quit line referrals in the outpatient setting[4] and the inpatient setting.[5] And while prompts embedded in EMRs modestly increase documentation of tobacco use and referral to counseling, more research is needed in this area to improve the effectiveness of these prompts.[6] Thus we see an opportunity to institute interventions that is aimed at changing provider behavior and improving patient care.

Educating providers about smoking counseling has been shown to increase their engagement with patients regarding smoking cessation.[7] One intervention, educational outreach visits, or academic detailing, have been shown to have a small but consistent effect on physician prescribing behaviors.[8] We hope to use a multi-modality educational intervention, including academic detailing, to enhance the effects of the EMR tools and increase use of smoking cessation resources.

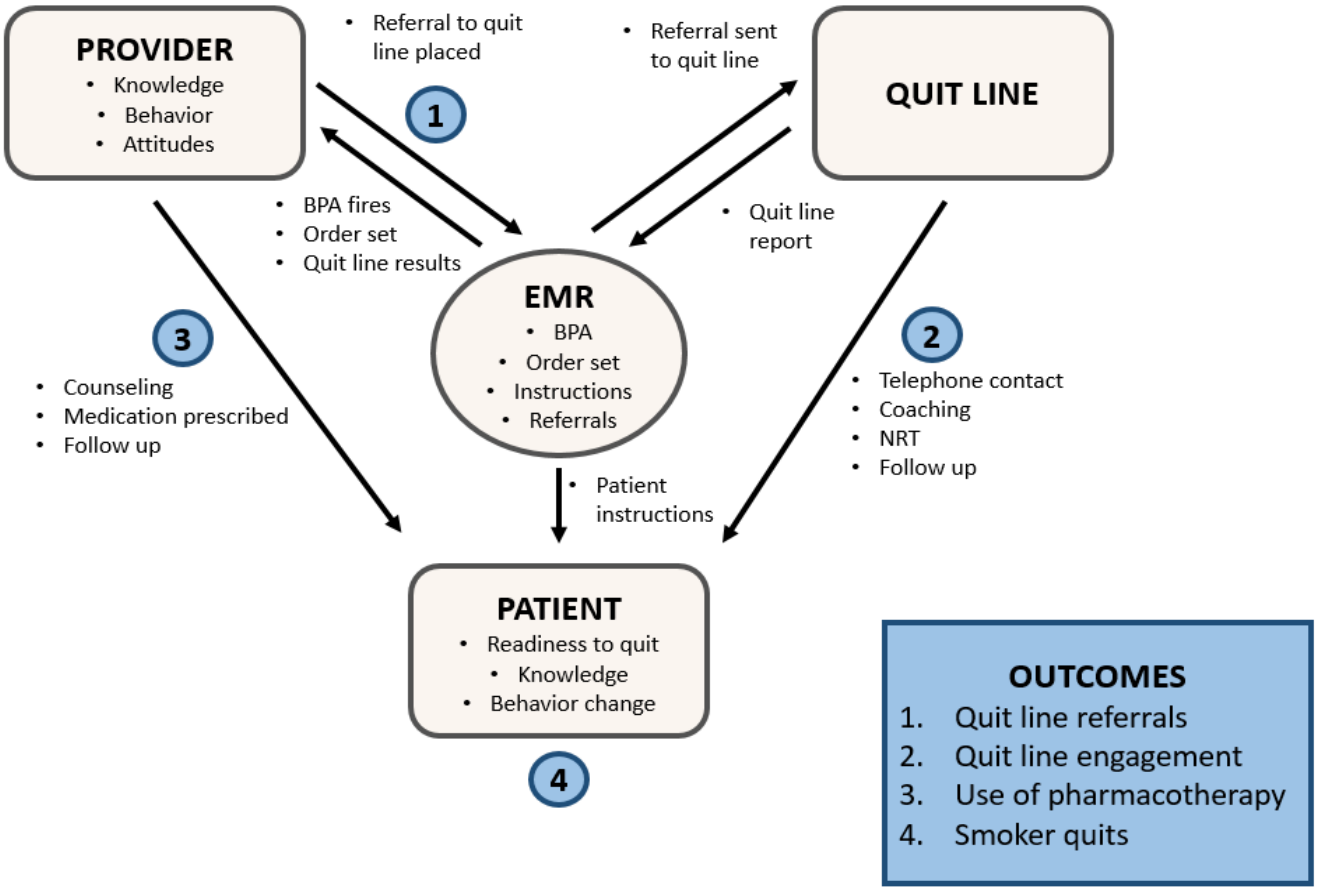
By incorporating decision support tools, facilitating use of the Quit Line, and educating clinicians about counseling and pharmacotherapy, we hope to improve the use of these services and increase engagement between clinicians and patients about smoking cessation and to ultimately decrease smoking across the health system

4. Study Procedures

a. Study design, including the sequence and timing of study procedures (distinguish research procedures from those that are part of routine care).

Overview: We propose a cluster randomized trial to test the effectiveness of an Epic-based BPA with and without supplemental education and academic detailing on 1) Quit Line referrals, 2) Patient Quit Line engagement, 3) Prescription of pharmacotherapy, and 4) Smoking cessation. To this end, we will randomize the 35 sites from Johns Hopkins Community Physicians to one of three arms: 1) Cluster C: no intervention initially, BPA added after 6 months; 2) Cluster B: BPA alone with emailed link to MD Quit Line educational material; 3) Cluster A: BPA with online educational modules, a quick-reference educational document, and additional academic detailing. Outcomes will be assessed at 6 and 12 months.

Conceptual Model:



Study design: This will be a **waitlist-control, cluster randomized trial**. JHCP sites will be randomized to Arm A (BPA plus educational interventions), Arm B (BPA only), or Arm C (control group, no intervention). After 6 months, Cluster C will be granted access to the BPA.

Study Population: The study will include all JHCP practices and primary care providers at those sites. JHCP is the largest health specialty group practice in Maryland and cares for over 230,000 patients at 22 practice sites throughout Maryland and Washington, DC. There are approximately 190 adult primary care providers at these sites. Patients will be at least 18 years of age and will be active smokers as indicated in the EMR.

Recruitment: All JHCP sites that provide adult primary care will be included. Providers (physicians and office health professionals like CMAs) will be the target of the intervention. Patients will not directly know about the study but there will be a smoking cessation handout available at each office if patients are interested.

Consent: Because this is an evaluation of an EMR intervention, looking at outcomes in aggregate only, not by provider or by patient, we are applying for a waiver of consent.

Randomization: Randomization to one of the three clusters will occur at the level of each JHCP site. Sites will be stratified by size and a randomization sequence will be generated by an online random number generator.

Intervention: There are several components to the intervention:

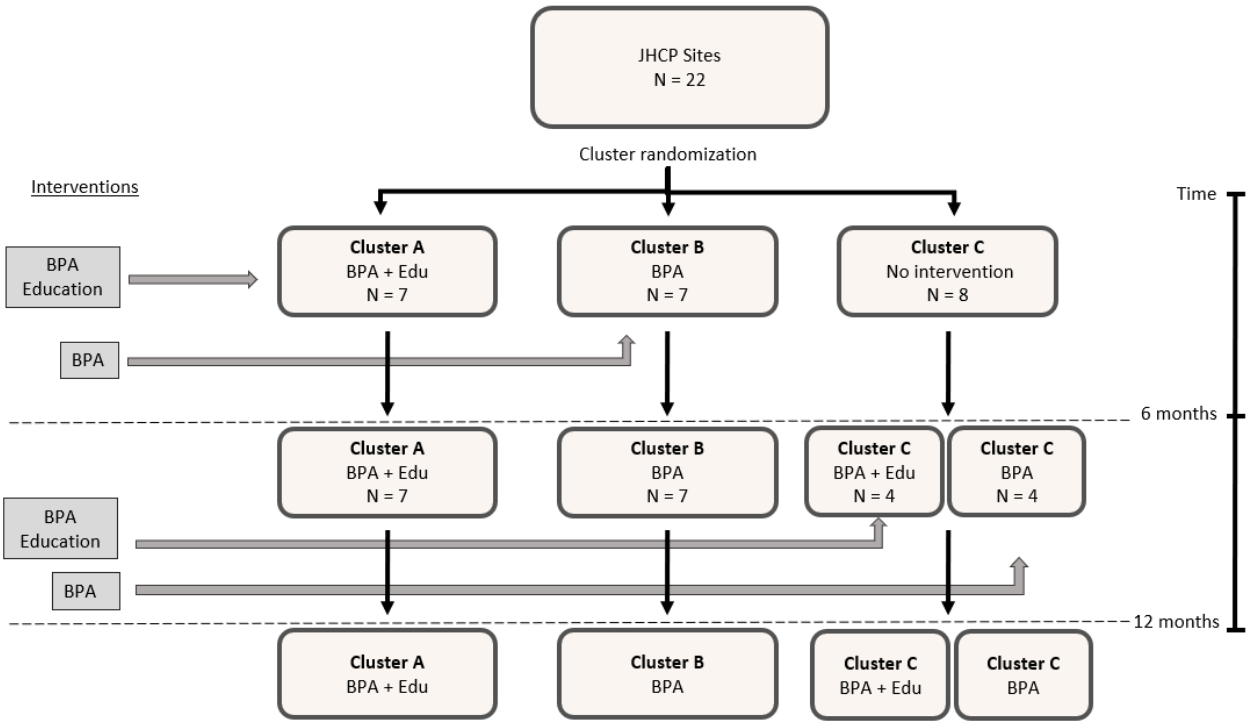
1. **BPA**: The BPA is an Epic prompt that fires when a provider opens an encounter with a patient who is actively smoking. Providers will be asked to assess smoking cessation readiness and to refer patients to the free Maryland Quit Line if the patient is receptive. The Quit Line will receive an electronic referral with the patient's details. A Quit Line certified smoking cessation counselor will then call the patient at a later date and provide counseling. Receptive patient will receive up to four calls. They will receive counseling from a trained quit coach and be offered free access to NRT.
2. **Quit Line**: This free telephone-based counseling service is offered to smoker in Maryland. Services offered include on-the-phone smoking cessation counseling and free nicotine replacement.
3. **Consolidated educational hand out**: A one-page hand out will be sent to providers electronically for quick reference. The hand out will include a summarization of counseling, pharmacotherapy, cessation referrals, and coding for cessation counseling.
4. **Online modules**: Providers will be directed to optional, self-paced educational modules. The Maryland HABITS program is a series of online modules that include general concepts in smoking cessation, pharmacotherapy, and counseling skills. The modules are text and video based and can be completed in about one hour. Providers can also watch example videos of interviews using these skills.
5. **Academic detailing**: Academic detailing is a tool in which educators visit providers in their practice setting, assessing their knowledge base, providing targeted education on a specific topic, and reinforcing the major points of the education.[9] Academic detailing for this trial will include a single session during a clinic day in which counseling experts from the MD Quit Line will visit providers in their practice setting. They will conduct one-on-one question and answer sessions exploring the providers' views on counseling, practices, and knowledge about medications and community resources. The counselors will provide teaching to each provider based on their individual level of knowledge and openness to the education.
   Detailing as operationalized accommodated individual practice level concerns related to provider time and burden. As such, detailing occurred as an interactive group educational session conducted with a tobacco session experts that was initially offered in-person only and later expanded to include live-webinar with the goal of increasing uptake by providers.

Sites will be randomized to three arms:

Arm A: At JHCP sites randomized to Arm A, clinicians will receive an email describing the new smoking BPA, educational materials offered, and a small tutorial on using the BPA and a new smoking cessation smart set in Epic. Education materials will include the educational hand out and academic detailing from Maryland Quit Line counselors.
Arm B: At JHCP sites randomized to Arm B, clinicians will receive an email describing the BPA and order set, along with internet links to MD Quit Line without additional supplemental education. This will allow us to compare use of the BPA alone to the BPA plus supplemental education.

Arm C: This last Arm will serve as the waitlist control, receiving no intervention initially. After six months, clinicians in Arm C will receive either the BPA intervention similar to Arm B without additional education or BPA + education, similar to ARM A Arm C not only serves as a control condition, but also allows for the gradual roll out of the BPA across JHCP to ensure that the MD state Quit Line can handle the increase in referral volume.

These three arms will help us determine how best to roll out this BPA across the Hopkins Health System.



1 Year Analysis: Primary and Secondary outcomes measured

Control: JHCP sites randomized to Arm C will receive no intervention, serving as controls for the first 6 months of the trial period. After six months, Arm C will be randomized to receive either the Epic BPA or the BPA + education..

Measures:

	Outcome	**How outcome is measured**
Primary outcome	Provider electronic referrals to the Maryland Quit line	Orders are tracked though Epic
Secondary outcomes	Patient prescribed nicotine replacement, bupropion, or varenicline	Orders are tracked though Epic
	Patient engagement with Quit Line (number of interactions, use of services)	Maryland Quit Line collects data during encounters and will provide this information to the study group
	Patient-reported smoking cessation after 1 year	The patient's smoking status as logged in Epic

Provider feedback on BPA:
We will obtain initial provider feedback on the BPA 6 months after initial roll out. Only providers at sites where the BPA has been implemented will be asked to fill out the survey. We will not collect names, but will collect site (to verify that BPA was active), years in practice and provider type. On the survey we will include the statement that participating in this survey serves as consent to the study. To protect confidentiality, no names or DOB will be collected. Data will be stored on the Johns Hopkins Secure Server and site data will be presented only in aggregate, by cluster (e.g. we will not report on individual sites, but rather by assigned cluster condition).

b. Study duration and number of study visits required of research participants.
Study duration will be 1 year.

c. Blinding, including justification for blinding or not blinding the trial, if applicable.

Providers will be notified about this implementation study and will know what arm they have been randomized to.

d. Justification of why participants will not receive routine care or will have current therapy stopped.
The control group will receive routine care from their provider, which can include counseling, pharmacotherapy, and Quit Line referral. The study will not prevent any provider from assisting smokers to quit with all guideline-based care.

e. Justification for inclusion of a placebo or non-treatment group.
While implementing the BPA to increase electronic referrals to the Quit Line is quite easy since the interface is already built, it is important for the health system to determine the added value of additional training for providers to use this referral effectively. We think a delay of 6 months in the added training does not increase risk beyond expected benefits. In addition, the Maryland State Quit Line will need this time to see if they can handle the increased volume.

To evaluate the effectiveness for the BPA, we feel a control group is needed. Arm B (the educational control) is necessary to evaluate whether the BPA with education is better than a BPA launched alone without education.

f. Definition of treatment failure or participant removal criteria.
Not applicable.

g. Description of what happens to participants receiving therapy when study ends or if a participant's participation in the study ends prematurely.
Not applicable.

5. Inclusion/Exclusion Criteria

BPAInclusion criteria: Sites are JHCP primary care practices.

Exclusion criteria: There are no exclusion criteria.

Survey: Providers will be included if they practice at the original sites randomized to either the BPA or the BPA + education

6. Drugs/ Substances/ Devices

a. The rationale for choosing the drug and dose or for choosing the device to be used.
Not applicable.

b. Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or participant populations are changed.
Not applicable.

c. Justification and safety information if non-FDA approved drugs without an IND will be administered.
Not applicable.

7. Study Statistics

a. Primary outcome variable.

- Provider electronic referrals to the Maryland Quit line

b. Secondary outcome variables.

- Patient prescribed nicotine replacement, bupropion, or varenicline
- Patient engagement with Quit Line (number of interactions, use of services)
- Patient-reported smoking cessation after 1 year

c. Statistical plan including sample size justification and interim data analysis.

Based on prior research with a comparable tool used in the inpatient setting where compared to control arm physicians, intervention physicians were more likely to order tobacco treatment medication (24% v. 9%, P = 0.0001, Fisher's exact test), and make a referral to the state smokers' quitline (19% v. 0%, P < 0.0001, we expect a 20% absolute increase in the percentage of the population of active smokers who are referred to the Quit Line among providers that receive the BPA, and a 30% increase among providers receiving the BPA + educational materials/detailing, compared to the control condition. Our main outcome, is quitline referral, which is a dichotomous outcome. We will use logistic regression accounting for clustering by site and provider to determine the difference in quit-line referral between the BPA only arm, and the waitlist control (B vs C), the BPA + education and the waitlist control (A vs C), and the BPA + educational materials arm and the BPA only arm (A vs B). The two primary testing contrasts will be B vs C and A vs C, each will be evaluated at type I error of 0.025 to safeguard the overall type I error for testing the 2 primary contrasts. The secondary contrast of A vs B is exploratory in nature, to estimate the potential incremental increase in quitline referral with additional provider education. The difference in % referral between arms and its corresponding 95% CI will be calculated. Due to the design of cluster randomization by sites, provider level and patient level characteristics that are not balanced by randomization between arms will be adjusted for in the logistic regression model.

In this 3-arm trial, we expect 7 JHCP sites per arm, with an average cluster size of 1000 smokers per site (based on current patient numbers in the clinics, number of smokers, and proportion willing to quit). Assuming intracluster correlation of 0.1, and a 5% quitline referral in the control Arm C, we will have 88.6% power to detect a 20% absolute increase in quitline referral in Arm B when testing the contrast of B vs C using a Z-test at type I error of 0.025, and 99.4% power to detect a 30% absolute increase in quitline referral in Arm A when testing the contrast of A vs C using a Z-test at type I error of 0.025.

For the survey, qualitative answers will be read by Drs. Wadlin and Chander, and coded for recurrent themes. These themes will then be summarized for study investigator to inform future roll out of the BPA. Quantitative data will be summarized using descriptive statistics. There are approximately 190 providers at JHCP. We anticipate that 2/3 of providers will have interacted with the BPA, as part of the initial BPA roll out. Thus our maximum sample size is 125 providers.

d. Early stopping rules.
None

8. Risks

a. Medical risks, listing all procedures, their major and minor risks and expected frequency.

We do not expect any more risk to patients than those occurring during the routine management of smoking cessation. We are not proposing any changes to treatment that are not based on evidence-based guidelines. The main risk is some providers and patients will not be exposed to implementation packaged for 6 months.

b. Steps taken to minimize the risks.
Providers have been able to refer smokers to the MD Quit Line for several years and this will still be possible. The delay in full implementation support will only be for 6 months.

c. Plan for reporting unanticipated problems or study deviations.
The principal investigator will report any study deviations to Johns Hopkins Institutional Review Board (IRB).

d. Legal risks such as the risks that would be associated with breach of confidentiality.
None expected.

e. Financial risks to the participants.
Financial risk to participants will be minimal but may include the cost of medications they would have otherwise not been prescribed.

f. Risks Related to Survey Administration: To protect confidentiality, no names or DOB will be collected. Data will be stored on the Johns Hopkins Secure Server and site data will be presented only in aggregate, by cluster (e.g. we will not report on individual sites, but rather by assigned cluster condition).

9. Benefits

a. Description of the probable benefits for the participant and for society.

Patients: All patients will have improved access to smoking cessation support through the state Quit Line. Some patients will have this support immediately and some after 6 months.

Providers: Providers will benefit from access to materials to improve the medical knowledge. They will have access to tools that will make prescribe more efficient, potentially improving work flow. If patients quit as a results of these interventions, the provider's quality metrics will improve.

Society: As discussed previously, smoking remains the number one cause of preventable death in the United States. If our intervention is shown to improve use of state Quit Line, and especially if it shows an improvement in successful smoking cessation, it may serve as a model for implementation more broadly. Such a finding may also be used for continued funding of the BPA and electronic referral system.

10. Payment and Remuneration

a. Detail compensation for participants including possible total compensation, proposed bonus, and any proposed reductions or penalties for not completing the protocol.

We do not plan to provide compensation to medical providers or patients.

11. Costs

a. Detail costs of study procedure(s) or drug (s) or substance(s) to participants and identify who will pay for them.

There are no direct costs associated with this trial.

Education material will be prepared and provided by the study team at no cost. Maryland Quit Line services are offered for free to patients.

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