

Main Section

Overall Aim & Objectives

The goals for this initiative are as follows: 1) Develop a partnership between two existing successful initiatives: the Million Hearts Initiative at the MedStar Health system and the BecomeAnEX.org (EX[®]) online smoking cessation program of the American Legacy Foundation; 2) Advance physician training across MedStar Health clinics in assessment, brief advice, and referral to evidence-based smoking cessation; 3) Work with the Million Hearts Initiative team within the MedStar Health system to include an electronic health record (EHR) referral option for active smokers to now include EX[®]; 4) Evaluate referral option impact by monitoring patient enrollment in EX[®], EX[®] utilization and progress, impact on individual level smoking status at 3 months, BP, and blood lipid results. Overall, we seek to examine products of a unique collaboration between the Million Hearts Initiative within the MedStar Health system and the interactive EX[®] online program offered by American Legacy Foundation to increase the rate of cessation attempts by patients who are identified as smokers.

Current Assessment of Need in Target Area

MedStar Health is a network of nine hospitals and 20 healthcare entities located in more than 100 rural, suburban, and urban communities across the Maryland/Washington, DC region. In 2011, MedStar Health joined the Million Hearts Initiative, a nation-wide partnership of health care systems convened by the US Department of Health and Human Services (DHHS). Million Hearts was started by DHHS under the premise that a dedicated and consistent focus on four primary and secondary interventions can help prevent one million new heart attacks and strokes over five years. These four interventions are framed simply for patients and doctors as, “Remember the ABCs”: A = determining cardiac risk and encouraging aspirin use for those at risk; B = blood pressure screening and appropriate blood pressure control for those diagnosed with hypertension; C = cholesterol screening and appropriate cholesterol control for those diagnosed with hyperlipidemia; and S = determination of smoking status, coupled with aggressive efforts at smoking cessation for those who smoke.

MedStar Health has outreach into its communities of care and most of its ambulatory sites are now on a single Electronic Health Record (EHR) platform. MedStar’s EHR platform facilitates the use of clinical decision support interventions, forms, and reports, and allows implementation of specific interventions, such as the Million Hearts Initiative and our proposed integration of EX[®] as a smoker referral option.

At present, a key identified weak link in the MedStar Health Million Hearts Initiative is a consistent lack of EHR documentation of referral to smoking cessation interventions. A review of current MedStar Health EHR data indicates that, from April to June 2012, 85% of 118,000 unique patients exhibited a valid smoking status field entry, with 10% identified as current smokers. Approximately 70% of identified smokers received advice from their physician to stop smoking or documented referral to a smoking cessation program. An often-stated reason for

the 30% receiving no advice or referral is a general lack of awareness of affordable and effective referrals for smoking cessation.

This intervention will provide physicians and nurses in randomly selected primary care practices with referral prompts delivered by the EHR to free, evidence-based referral resources, as well as information regarding their own performance versus system peers (in aggregate) with respect to smoking status documentation and referrals, as well as data regarding patient follow-through and impact on key aggregate health measures such as smoking status, BP, and lipids. Data on these specific measures is routinely collected as part of MedStar Health's Million Hearts initiative, and the educational/feedback component is an integral part of the initiative.

Technical Approach, Intervention Design and Methods

As described above, the Million Hearts Initiative at MedStar Health provides an ideal platform for the proposed study. An example of the current smoking status and referral screen is provided below in Figure 1.

FIGURE 1: EXAMPLE OF CURRENT MEDSTAR SMOKER REFERRAL SCREEN

Smoking Cessation Counseling-Current Smoker

The patients smoking status is documented as 'current'. Please confirm smoking status and provide smoking cessation advice, counseling, handout(s), and/or prescription if appropriate.

Smoking Status: current every day smoker (10/01/2012)
Smoking Advice last given: yes (11/01/2010)
Smoking Cessation Stage: N/A

- Order Smoking Cessation Med
- Print Handout(s)
- Current every day smoker
- Current some day smoker
- Former Smoker
- Tobacco Use Cessation Counseling Provided - CURRENT SMOKER ONLY
- Advised to quit smoking and follow-up with Primary Care Provider

(C) 2010 Check All Clear All Close

Primary care practices randomly assigned to the enhanced EHR referral intervention, will work with a referral screen that specifically prompts referral to BecomeAnEX.org (EX®) as an option. An example of the enhanced EHR screen is provided below in Figure 2. If the patient accepts the referral, the primary care provider will check the EX® referral box and printed instructions will be provided to the patient. The printed instructions will include the URL for accessing the MedStar Health version of EX®, along with a newly generated respondent ID (with a check sum included at the end), for future linkage back to their EHR records.

FIGURE 2: SAMPLE OF REFERRAL PROMPT SCREEN

Smoking Cessation Counseling-Current Smoker

The patients smoking status is documented as 'current'. Please confirm smoking status and provide smoking cessation advice, counseling, handout(s), and/or prescription if appropriate.

Smoking Status: current every day smoker (10/02/2012)
Smoking Advice last given: yes (11/01/2010)
Smoking Cessation Stage: N/A

- Order Smoking Cessation Med
- Refer to Become an ExSmoker.org
- Print Handout(s)
- Current every day smoker
- Current some day smoker
- Former Smoker
- Tobacco Use Cessation Counseling Provided - CURRENT SMOKER ONLY
- Advised to quit smoking and follow-up with Primary Care Provider

(C) 2010

Check All Clear All Close

At the time of sign in to EX[®], an abbreviated informed consent form will ask the participant for permission to report participation results to their primary care provider at MedStar Health. Entry into the website will not be affected by the individual's response. Periodic reports will be generated by the American Legacy Foundation (Legacy) with each individual's performance metrics at the EX[®] site (only for those providing consent). Performance metrics collected by Legacy will include a brief survey regarding smoking status collected at 3 months post EX[®] program initiation. These reports will be provided to MedStar Health so the primary care provider can be made aware that their patient has accepted their referral.

At the patient's next visit to their primary care provider at MedStar Health, the EHR screen (see Figure 3) will prompt the physician to Ask about current smoking status, whether the patient followed up with the referral, whether the referral was helpful, etc (see Figure 4). An example of what this screen might look like is included in Figure 3 below. The follow up screen will be tailored to provide additional smoking behavior outcome data (in addition to the data provided by Legacy) along with patient level data regarding BP, weight, lipids, self-reported smoking status, etc.

FIGURE 3: EXAMPLE OF POSSIBLE FOLLOWUP VISIT SCREEN

Smoking Cessation Counseling-Current Smoker Become an ExSmoker.org

This patient's smoking status was: current every day smoker on 9/1/2012 and the patient was referred to 'Become an ExSmoker.org on 9/1/2012. Please answer the relevant questions below.

- Order Smoking Cessation Med
- New Referral to Become an ExSmoker.org
- Print Handout(s)
- Current every day smoker
- Current some day smoker
- Former Smoker
- Tobacco Use Cessation Counseling Provided - CURRENT SMOKER ONLY
- Advised to quit smoking and follow-up with Primary Care Provider

- I registered for the Become an ExSmoker website
- I did NOT register for the Become an ExSmoker website
- I found the Become an ExSmoker website helped me to quit
- I did NOT find that the Become an ExSmoker website helped me to quit

(C) 2010

Check All Clear All Close

FIGURE 4: POP UP SCREEN

Care Alert Warning

You have 1 Popup(s) about Napoleon A Dynamite.

Message	Location
This patient was referred to Become an ExSmoker.org+	MPP-WPCP

View Details

This patient was referred to Become an ExSmoker.org
Ask - (1) Are you still smoking?
(2) Are you in the process of stopping smoking?
(3) Did you register for their website?
(4) Did it or is it helping you to stop smoking?

Disable popup care alerts.

Data provided by Legacy will be merged with periodic reports from the MedStar EHR system. The combined data will be managed, monitored, and analyzed by the MedStar Health Research Institute (MHRI) biostatistics group. The study PI and other Georgetown University faculty not employed by MedStar Health will only have access to de-identified data.

About BecomeAnEX.org

BecomeAnEX.org is an evidence-based intervention (Richardson, et al., In Press) developed for web access (including mobile platforms) by the American Legacy Foundation in collaboration with the Mayo Clinic Nicotine Dependence Center. This branded, free intervention was developed in accordance with the 2008 Clinical Practice Guidelines for Treating Tobacco Use and Dependence (Fiore, et al., 2008). The overarching goals of the site are to educate smokers wanting to quit and provide the tools necessary to support their quitting efforts. The site provides smokers with detailed information and action steps to help them “re-learn life without cigarettes,” in part by disassociating smoking from common daily activities that would otherwise function as smoking cues, such as driving or drinking coffee. Core elements of the site include: 1) My Quit Plan, a checklist that helps smokers set a quit date and tracks their progress through the steps of the quit plan; 2) a Cigarette Tracker to help smokers identify and track their smoking triggers; 3) Beat Your Smoking Triggers – a list of common triggers; 4) Separation exercises to teach smokers how to separate a cigarette from its trigger; 5) Support Exercises to help smokers identify who they can turn to for support when quitting smoking; 6) Quit Smoking Resources - a list of national organizations, state quit lines and websites that smokers can turn to get additional information and help to quit smoking; 7) Text and videos detailing the importance of medication and the different types available; and, 8) A large, e-community of current and former smokers.

Evaluation Design

We will use a prospective, single blind, random assignment to intervention or control condition design, with an intent-to-treat (ITT) analysis. Primary care clinics across MedStar Health will be randomized to provide physicians with either the current EHR configuration or an enhanced EHR screen that includes a prompt to refer patient to BecomeAnEX®.org. A Cluster Randomization procedure will be implemented, randomizing by office. Four categories will be used for stratification:

- a. patient panel,
- b. average household income of zip code of office location,
- c. level of education, and
- d. physician’s age.

A percentage of those with less than a high school education will be used for level of education, because of its high correlation with poverty. A weighted physician’s age of office will be used, based upon each physician’s patient panel within the office. Medians will be used to categorize each of the 4 factors into high or low. Because of the low number of offices and high number of factors to stratify by, a sum score for each office will be generated, where a score of 1 will be given for each level in the high category. Randomization will then occur within each of 5 separate strata. We will use a randomized permuted block design of block size two to assign practices to one of two treatment groups in each strata. Student t-tests will be used by treatment groups within each of four categories to insure balance of categories.

Cluster randomization, ie. randomizing clinics/practices in groups, will minimize any potential confounding effect of one practitioner's method of practice on another within the same clinic. Cluster randomization will be computer-generated centrally in consultation with MedStar Health Research Institute (MHRI) Department of Biostatistics and Epidemiology. Adjustments for possible confounders will be made in the analysis.

Analysis Plan:

Baseline characteristics of patients who will take part in this study will be summarized as means (standard deviations) for continuous variables, median (1st quartile, 3rd quartile) for skewed continuous variables, and proportions for categorical variables. The mean number of referrals per month will be compared by study group using a two-sided *t*-test, or the non-parametric equivalent (Wilcoxon test) if the referrals distribution is not normal.

We will examine the impact of the randomization on several characteristics of the practices that participate in this study to identify potential factors that will influence the referral rates, hence affecting the study outcomes. General linear mixed model, which will include demographics as well as administrative data that are associated with EHR usage, will be used to identify predictors of smoking cessation. The biostatistics group at MHRI will extract administrative data (eg. panel size of the practice, and provider reports of proportion of smokers in the practice) from EHR that can be included in these models to improve the discriminatory power of these models.

In this study, we will conduct patient-level analysis using generalized linear mixed model with a logit link to evaluate whether a referred smoker uses the website to account for the clustering effect within practices.

In order to test for differences in smoking cessation rates between patients who will be randomized within practices to standard EHR versus enhanced EHR (BecomeAnEX[®].org), a generalized linear mixed model will be conducted with a logit link to model smoking cessation by EHR intervention assignment adjusted for baseline characteristics.

Additionally, we will be able to quantify the following: a) providers' acceptance of health IT prompts (current and BecomeAnEX[®].org prompts); b) patients' engagement; c) temporal differences in meeting the Million Hearts guidelines for smoking due to the implementation of the enhanced EHR intervention, the BecomeAnEX[®].org versus current EHR configuration between and within providers. We will also be able to conduct comparisons with additional providers who are not part of this study to assess differences in meeting guidelines with regards to the Million Hearts smoking guidelines.

Furthermore, within the time period of this grant, the pathways and infrastructure will be set up to allow for longitudinal follow-up of the cohort in a subsequent grant/extension. Thus, additional exploratory hypothesis-generating analyses will be conducted to evaluate effects on

clinical outcomes of interest, such as patient and physician follow through with recommended interventions related to smoking, life-style changes, and health care utilization. Evaluations of economic impact of the different approaches will also be feasible.

Outcomes: This study will allow us to evaluate outcomes at the programmatic level and the patient level:

At the Programmatic Level, outcomes will include: documentation of smoking status (no entry, non-smoker, prior smoker, current smoker and frequency) at baseline; provision of smoking cessation advice or referral (advice, medication prescription, smoking cessation program and type – including EX[®]) at baseline; proportion of patients participating in referral – as reported at a follow-up visit; number of quit attempts reported by patients at next primary care visit – transformed to either quit attempts per person day or a binary value of attempted versus no attempt; proportion of smokers reporting at least 30 days of abstinence at a follow-up visit; and proportion of patients participating in a smoking intervention referral as reported at the follow-up visit.

At the individual Patient Level, outcomes will include: referral participation; smoking status; number of quit attempts; longest period of abstinence; changes in health status indicators such as BP, weight, lipids, etc.

Study Significance and Innovation:

Implementing research in real world settings is often limited by a lack of experimental control, with the trade-off being greater generalizability and validity. The proposed study holds great potential for determining if adding a free, branded, evidence-based online intervention to the Million Hearts Initiative will result in improved outcomes for smokers. If successful, the intervention could be extended to other Million Hearts Programs across the country. The Million Hearts Model emphasizes the 5A's: Ask, Assess, Advise, Assist, Arrange. The two weak links appear to be Ask and Arrange, as 15% of participants have blank EHR fields, and 30% have no documented referral. Adding EX to the EHR may increase the likelihood of Asking (as an option for treatment is available) and we anticipate that an evidence-based smoking cessation intervention will increase referrals (Arranging).

Detailed Work Plan and Deliverables Schedule

Timeline:

Study Quarter	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Obtain IRB approval/waiver	X	X						
Program EHR screens	X	X						
Create EX mirror site for project	X	X						
Program EX reports and e-mail generator for 3 mo F/U	X	X						
Launch Study			X					
Collect and monitor data from EHR screens			X	X	X	X	X	X
Collect and monitor data regarding EX utilization			X	X	X	X	X	X
EX to collect 3 mo F/U data by e-mail				X	X	X	X	X
Construct and clean data set						X	X	X
Conduct analyses						X	X	X
Write papers							X	X

The timeline provided above divides the two-year study period into quarters. Once funding is received, we will seek IRB approval for the brief informed consent at the EX[®] web site during the first two study quarters. During that time, our colleagues at MedStar Health will initiate EHR screen programming as well as template development for study data reports, while colleagues at Legacy will build a mirror EX[®] web site specifically for the study, develop templates for study data reports, and develop a program to query participants at 3 months by e-mail regarding smoking status and related behaviors.

During Quarter 3, the study will be launched. Data collection will occur using the MedStar Health EHR system as well as Legacy's EX[®] site on an ongoing basis throughout the study. During the last few quarters, we will merge the data from Legacy and MedStar, clean the data set, and conduct analyses. Data management and analysis will be provided by MedStar Health's Biostatistics group in collaboration with the entire project team.