Georgetown University Medical Center

Bringing EX® to a Million Hearts

Please answer the following three questions and submit as a Word file or PDF (2 pages max.) via Dropbox:

1. *What, if any, proposed activities were not completed? Briefly describe those activities, the reasons they were not completed and your plans for carrying them out.*

Our project, Bringing EX to a Million Hearts, was conducted as a Quality Improvement Initiative within a large ambulatory care system (MedStar Health) that serves patients in DC and MD. Our goal was to create a standardized clinical workflow within the EHR (Centricity product) that systematically Asked all adult patients (age 18+) about their tobacco use, Advised them to quit if they were tobacco users, and Connected them (AAC Model; Vidrine et al., 2013) with evidence-based smoking cessation resources, including the Truth Initiative's (formerly the American Legacy Foundation's) "Become an EX" no-cost web-based smoking cessation program (Graham et al., 2013). This later step occurred via a paper-based referral to the EX website that was generated as part of patients' exit paperwork. Providers (MD, RN, PA, or equivalents) were to receive training in the new workflow and education about EX, and we partnered with the organization's health research institute to select, sample, and randomize large group practices to receive either no change in their EHR configuration (usual care) (Control Condition: N=10 practices, N~56k patients) or our intervention (Intervention Condition: N=10 practices, N~58k patients). Usual care included patient education and counseling about tobacco use and pharmacologic therapies (OTC or RX) at providers' discretion, and as determined by clinical care committees to be populated within the EHR's resources section or formulary. Our primary outcomes were the number of patients who successfully received the AAC cascade, the number of patients who logged onto the EX website, and population-level smoking prevalence rates.

Prior to beginning our project, we reviewed the available EHR configuration and data regarding tobacco control. We determined that the user interface was suboptimal as it allowed for unstructured data entry (e.g., "smoker", "smokes", "tobacco user"). We worked closely with the EHR team to structure the tobacco-relevant data input fields and to map those and others onto the new clinical workflow, develop and implement the paper-based referral, and test this new process across the Intervention Condition. These steps took longer than we had anticipated, partly due to the ambulatory care system acquiring a large number of new medical practices with EHRs that also needed to be standardized and were prioritized over quality improvements such as ours, and implementing other necessary EHR upgrades.

Our method for training providers (who were more widely geographically dispersed than we expected) could only be implemented remotely via mail, e-mail, and online education. These activities preceded and coincided with the launch of the new EHR configuration.

The clinical workflow and new EHR configuration successfully delivered the AAC cascade to patients in the Intervention Condition. However, the number of patients who logged onto the EX website was extremely low after 9-12 months of evaluation and we determined that this aspect of the project had not successfully met its goal. Our team recognized that a reactive paper-based referral to quit-assistance was like too weak for non-treatment seeking smokers in an ambulatory care setting, and that a more proactive approach was needed.

Dr. Tercyak attended the SCLC's "Beyond the 5 A's" conference on behalf of the research team, and connected with other grantees about their experiences with different models of referrals to quit lines. This was a helpful experience, given our findings. Dr. Tercyak also attended and presented the project's findings at the MDQuit annual training conference, which included a presentation and consultation with Dr. Nancy Rigotti about her experience with EHR system-level interventions.

After much consideration, we opted to implement a more proactive AAC model, re-launching the project with a new 2nd phase of work whereby *all* patients who reported tobacco use would be proactively referred to either the EX website or The Truth Initiative's new text messaging platform for Become an EX, with the option to enroll via e-mail or text message within 24-72 hours of the clinical visit. This required us to again reconfigure the EHR and clinical workflow, and retrain and reeducate our providers, which took more time than expected.

We worked closely with The Truth Initiative to curate their text messaging library messages that were appropriate for ambulatory care patient enrollment invitations, and enlisted the help of an outside expert to assist us with this process (Lorien Abroms, ScD). Previously, MedStar Health did not systematically collect or retain patients' e-mail addresses and mobile telephone numbers, both of which were necessary for us to implement the more proactive referral to EX cessation services. Doing so required a number of institutional approvals (and additional time) that were ultimately secured. The launch of the 2nd phase of the project required that we field-test the interventions for at least 12 months to determine success or failure: this was completed in the Fall of 2015 (and necessitated our additional 1-year no-cost extension of the grant).

MedStar Health has now made available to the research team a flat-file of its relevant EHR data, including ambulatory care visits and tobacco control data, for the patient population of interest for the project sites participating in the quality improvement initiative. We have been meeting on a weekly basis to clean and verify this dataset, which remains in progress. We continue to consult with MedStar Health about key data elements that are needed for analysis, and expect to resolve those aspects in 2016. Ultimately, we plan to submit a manuscript based on our process and outcomes to Translational Behavioral Medicine, which we believe is an appropriate journal outlet for this work. It will, however, take us additional time to complete this step and we are committed to doing so.

In sum, we have worked very hard to faithfully implement the original project as a cluster-randomized design to help impact population-level tobacco control outcomes for ambulatory care patients using no-cost tools and resources. We have created and subsequently optimized the clinical workflow and EHR inputs to systematically capture tobacco control data, advise tobacco users to quit with structured prompts and dialog boxes, and connect tobacco users to a wider range of evidence-based resources, including no-cost public health tools that are widely available on the Internet.

Due to the very low uptake of the EX program by patients in our health care system, it was necessary for us to modify the protocol to accommodate a second phase with more proactive outreach to patients, including the offer of enrollment into the program via e-mail or text message.

Because of our project, MedStar Health now has a clinical workflow that systematically Asks, Advises, and Connects all patients who report tobacco use to an evidence-based smoking cessation resource that is available free, online, and available to patients via text message. This could be deployed system-wide. Also, the Truth Initiative has a new NIDA R01 that is designed to compare and contrast the effects of its web, text, and web+text programs on adherence to stopping smoking. Our findings to date suggest that ambulatory care patients likely require a more proactive engagement at the level of the provider (rather than the EHR) in order to accept the referral for stop smoking assistance, which may then be further bolstered using electronic means.

2. *Briefly tell us about any other unexpected issues, concerns or successes you have had during this reporting period.*

There were three transitions in key personnel. First, Dr. Cassandra Stanton (faculty) of Georgetown University resigned her position at the school. Dr. Stanton was involved in the development of the original project protocol, assisted with the implementation of the first phase of the project, and served as our institutional liaison to The Truth Initiative. Second, Dr. Krista Highland (fellow) of Georgetown University resigned her position at the school. Dr. Highland was the project's manager, tasked with coordinating the day-to-day activities of the work, including the IRB, inter-institutional agreements, meeting schedules, and EHR task-flow management. Third, Dr. Martin Iguchi (faculty) of Georgetown University resigned his position at the school. Dr. Iguchi was the project's principal investigator. Dr. Tercyak assumed the responsibilities of each of these three individuals, and continues to collaborate with Dr. Iguchi.

3. *Is there anything else you want to tell SCLC or Pfizer?*