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The electronic medication complete communication (EMC^2) study: Rationale and methods for a randomized controlled trial of a strategy to promote medication safety in ambulatory care

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ABSTRACT

Background: Adverse drug events (ADEs) affect millions of patients annually and place a significant burden on the healthcare system. The Food and Drug Administration (FDA) has developed patient safety information for high-risk medications that pose serious public health concerns. However, there are currently few assurances that patients receive this information or are able to identify or respond correctly to ADEs.
Objective: To evaluate the effectiveness of the Electronic Medication Complete Communication (EMC^2) Strategy to promote safe medication use and reporting of ADEs in comparison to usual care.
Methods: The automated EMC^2 Strategy consists of: 1) provider alerts to counsel patients on medication risks, 2) the delivery of patient-friendly medication information via the electronic health record, and 3) an automated telephone assessment to identify potential medication concerns or ADEs. The study will take place in two community health centers in Chicago, IL. Adult, English or Spanish-speaking patients (N = 1200) who have been prescribed a high-risk medication will be enrolled and randomized to the intervention arm or usual care based upon practice location. The primary outcomes of the study are medication knowledge, proper medication use, and reporting of ADEs; these will be measured at baseline, 4 weeks, and three months. Intervention fidelity as well as barriers and costs of implementation will be evaluated.
Conclusions: The EMC^2 Strategy automates a patient-friendly risk communication and surveillance process to promote safe medication use while minimizing clinic burden. This trial seeks to evaluate the effectiveness and feasibility of this strategy in comparison to usual care.

1. Introduction

Research has repeatedly demonstrated that patients lack essential information on how to safely take prescribed (R_x) medications [1,2]. This lack of knowledge has been cited as a root cause of unintentional misuse and medication errors, which can lead to serious adverse drug events (ADEs) [2,3]. While the exact prevalence of medication errors and ADEs in ambulatory care is difficult to determine, nearly 4.5 million outpatient physician visits and 1 million emergency department admissions are attributed to ADEs annually [4,5]. Estimates also indicate that among adults who take a medication and are seen in outpatient practices, up to 25% experience an ADE over the course of a year [5,6].

While most prescribed medications carry risks, approximately 400 drugs have been deemed by the Food and Drug Administration (FDA) to possess serious public health concerns, warranting a Risk Evaluation and Mitigation Strategy (REMS) [7]. Yet, few, if any, mechanisms exist to ensure and confirm that primary care patients receive and understand instructions for use, risk information, or instructions on proper actions to take in response to ADEs. Routine monitoring for the safety of patients who use higher-risk medications is also not presently possible. Instead, providers rely heavily upon patients to independently learn about their prescribed medication, identify ADEs, and seek medical support [6]. Thus ADEs are often detected late, if at all, leaving patients at risk for further harm and less effective treatment. From a public health perspective, a more comprehensive method for detecting ADEs could

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provide new information on a medication's safety profile and inform the care of others who are also taking the medication.

To address these shortcomings, we developed the Electronic Medication Complete Communication (EMC^2) Strategy, which seeks to 'hardwire' risk communication and surveillance of higher risk medications in primary care using health information technologies, specifically electronic health record (EHR) and interactive voice recognition (IVR) technology. Herein we provide an overview of the EMC^2 Strategy and describe the methods and rationale for evaluating this approach in a randomized controlled trial (RCT) funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

2. Methods

2.1. The EMC^2 Strategy

The EMC^2 Strategy consists of several components designed to promote: 1) provider counseling on medication use, risks and benefits; 2) dissemination of understandable, actionable medication information to patients; and, 3) routine surveillance of medication use and risks in ambulatory care. To automate implementation and limit use of clinic resources, the EMC^2 intervention takes advantage of EHR and IVR platforms to facilitate patient education and medication monitoring. Specifically, patients enrolled at an intervention site will be exposed to the EMC^2 Strategy, which is comprised of the following key components (Fig. 1):

1. Provider medication alert: when a provider places a new order or dose change for an existing prescription for a high-risk medication, an EHR-generated alert will notify the provider that the medication requires patient counseling. This alert will contain a brief description of the key risks or side effects that patients may experience while taking this medication; this information is directly derived from the FDA-approved Medication Guide for the medication. Providers will also be given the option of clicking on an html link within the alert to view the entire text of the Medication Guide if desired.

2. Automated delivery of FDA Medication Guide + Summary: the medication order will automatically cue printing of: 1) the FDA-approved Medication Guide for the drug in question and 2) a 1-page, patient-friendly summary of the Guide (i.e. Medication Guide Summaries). These materials will be provided to patients with the After Visit Summary following the provider encounter. FDA Medication Guides are required to be distributed for the medications selected for this study at the point of dispensing; however, prior research indicates that pharmacies often fail to provide patients with this information [8]. To ensure that patients receive this essential information, it will be automatically printed and distributed to patients at the point of prescribing in primary care. Medication Guide Summaries were developed by our research team using health literacy 'best practices' to promote patient understanding of medication risks and instructions for use. A prior study conducted among 1003 patients found that the Medication Guide Summaries significantly improved patients' ability to retrieve and apply medication information [9].

3. IVR follow-up phone assessment: within 14 days after enrollment in the study, patients will receive a text message asking them to contact an automated telephone system. Calling this line will initiate an IVR call, which will last <5 min and asks patients to report whether they have: a) filled the prescription, b) are taking the medication, and c) have experienced side effects that are unique to the medication in question. The system also explores barriers to obtaining the medication for patients who had not yet done so and barriers to adherence for patients who report non-adherence. A second IVR call will be placed 4 weeks later to follow up with patients again, using a similar format and series of questions. Automated conversation systems have been used previously by members of our study team to improve clinical screening, counseling, and medication management [10].

4. Clinic follow-up: the results of the IVR telephone assessment will be sent back to the EHR as patient-reported data in the form of a laboratory report. It will be routed to the prescriber of the high-risk medication for which the surveillance is being conducted. In the event that a serious concern is identified, the nature of the issue (e.g., non-adherence, patient-reported side effect, etc.) will be detailed in this report. Clinic staff will monitor reports and respond to any identified concerns by calling and counseling the patient. Clinics have tailored their protocol for responding to reports based upon the resources, needs, and staffing of the individual clinics.

2.2. Study design and aims

To evaluate the impact and scalability of the EMC^2 Strategy, we are conducting a 2-arm RCT. The specific aims of this three-year trial are to: 1) test the effectiveness of the EMC^2 Strategy, compared to usual care, to improve a) patient understanding of medication risks, b) patient use of higher-risk R_x medications, and c) the detection of ADEs; 2) assess whether the EMC^2 Strategy can reduce disparities in medication understanding and use by patient literacy level, English proficiency, and age compared to usual care; and, 3) evaluate the fidelity of the EMC^2 Strategy to promote provider counseling, deliver patient R_x information, monitor understanding and use, and inform providers of potential harms. In addition to evaluating the effectiveness of the EMC^2 Strategy, we will also: 1) explore patient, provider, and health system barriers to implementing the EMC^2 Strategy, and 2) determine the cost of delivering the EMC^2 Strategy in primary care from a health system perspective.

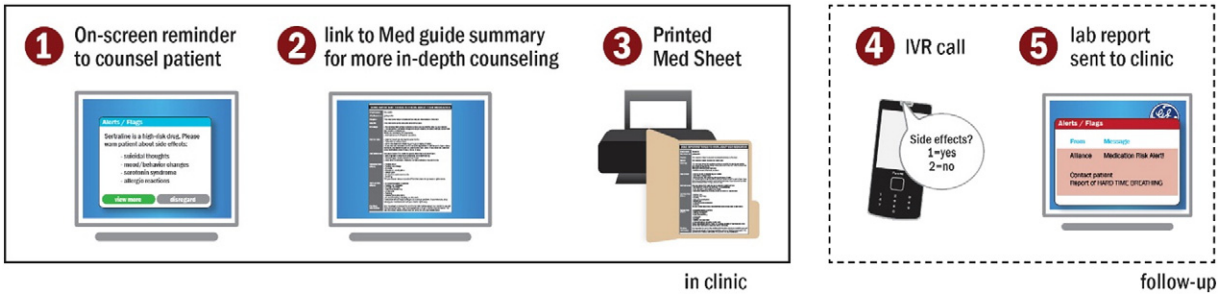

Fig. 1. Sequence of EMC^2 components.