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# An efficacy trial of an electronic health record-based strategy to inform patients on safe medication use: The role of written and spoken communication



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#### ABSTRACT

*Objective:* We tested the feasibility and efficacy of an electronic health record (EHR) strategy that automated the delivery of print medication information at the time of prescribing.

Methods: Patients (N = 141) receiving a new prescription at one internal medicine clinic were recruited into a 2-arm physician-randomized study. We leveraged an EHR platform to automatically deliver 1-page educational 'MedSheets' to patients after medical encounters. We also assessed if physicians counseled patients via patient self-report immediately following visits. Patients' understanding was objectively measured via phone interview.

Results: 122 patients completed the trial. Most intervention patients (70%) reported receiving MedSheets. Patients reported physicians frequently counseled on indication and directions for use, but less often for risks. In multivariable analysis, written information (OR 2.78, 95% CI 1.10–7.04) and physician counseling (OR 2.95, 95% CI 1.26–6.91) were independently associated with patient understanding of risk information. Receiving both was most beneficial; 87% of those receiving counseling and MedSheets correctly recalled medication risks compared to 40% receiving neither.

*Conclusion:* An EHR can be a reliable means to deliver tangible, print medication education to patients, but cannot replace the salience of physician-patient communication.

*Practice implications*: Offering both written and spoken modalities produced a synergistic effect for informing patients.

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#### 1. Introduction

In 2012, 2.3 billion prescriptions were ordered in ambulatory care and 67.2% of visits involved drug therapy [1]. Approximately 1.5 million preventable adverse drug events occur each year, with more than one-third taking place in outpatient settings at a cost approaching \$1 billion per year [2]. Recent studies have repeatedly highlighted the alarming prevalence of patient misunderstanding and misuse of prescription medications [2–6]. Patients often lack

sufficient information pertaining to medication indications, dosing instructions, side effects, and important risks and warnings. Limited understanding of these aspects of prescription medications can lead to improper use, underreporting of adverse drug events (ADEs) and non-adherence, ultimately resulting in poor health outcomes [2,3,7,8]. This is a concern for both healthcare quality and patient safety, as these individuals may not optimize the benefits of drug therapy, and/or have a higher risk of adverse drug events.

1.1. Insufficient counseling could be a potential reason for patients being inadequately informed about prescribed medicines

Prior studies indicate patient-provider spoken communication about medications is inadequate; both physicians and pharmacists

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frequently fail to discuss the safe use of prescribed medications with patients [9–14]. When counseling does occur, providers may overestimate the clarity of instructions they give to patients [15]. Some physicians are admittedly reluctant to discuss side effects, as they may be worried this will result in non-adherence, or they may assume pharmacists will convey this information [16,17]. However, patients indicate they would like to know about the associated side effects of their new medications and are frequently not provided with this information from their physician [18]. Low quality or non-existent communication about medications from prescribers has been linked to patient misunderstanding, lack of awareness of risks, and/or non-adherence [19–22]. Ineffective verbal communication by both prescribers and pharmacists can also influence whether a prescription will be initiated or remain unfilled or unused [23–25].

In addition to suboptimal counseling, evidence also suggests that the tangible, written materials distributed to patients at the pharmacy are neither understandable nor actionable [26–30]. Whether it be a perceived lack of importance or their complex nature, these medication educational materials more often are neglected by patients, further contributing to the problems of misunderstanding and medication errors.

Subsequently, we developed an electronic health record (EHR) strategy to ensure patients would receive understandable, actionable information at the point of prescribing to support safe medication use. Our objective was to test the feasibility of this strategy, examine naturally occurring provider communication, and test the impact of each on the understanding and proper use of newly prescribed prescription medications.

#### 2. Methods

#### 2.1. Participants and procedure

Study participants were recruited between September 2009 and February 2012 from the Northwestern Medical Faculty Foundation (NMFF) general internal medicine (GIM) clinic in Chicago, IL. Participants were deemed eligible if they were 1) English-speaking, 2) without cognitive, vision, or hearing impairment, 3) without any significant, acute health condition, 4) between the ages of 18-80, and 5) received one or more new or changed prescriptions for the 50 study medications on the day of recruitment. Patients with prescription refills only were not eligible. Clerical and medical staff were made aware of the project, flyers were distributed in patient folders and at checkout, and trained study research assistants (RAs) were in the clinic during high volume periods to invite participants deemed eligible for the study. Immediately after a scheduled patient visit, patients were approached at checkout by an RA to assess interest, confirm eligibility, and obtain consent. Once consented to the study, patients completed a brief baseline battery including an assessment of provider communication. Upon completion of the inperson interview, participants were given \$10 in cash. An RA then administered a follow-up phone call two weeks later to determine if medications were filled, and if so, to assess patient understanding on proper use of the new medication(s). The Northwestern University Institutional Review Board approved the study.

#### 2.2. Intervention

#### 2.2.1. Creation of 'MedSheets'

We consulted the literature, patients, and clinicians (physicians, nurses, and pharmacists) to gain perspective on a prototype for providing clear, understandable, and actionable information to patients receiving a new medication. Topics were logically sequenced from a patient's perspective: drug name, purpose,

benefit, length of treatment, instructions, safe use, important side effects and warnings, when to call your doctor, discussion points, relevant follow-up instructions, and where to get more information. The prototype was vetted and approved by the study team, including clinicians, health literacy and health communication experts, and two patient representatives. The top 500 prescribed medicines for NMFF GIM were reviewed, and 'MedSheets' were developed for 305 medications covering the previously approved topics. Further revisions to specific content and wording were conducted by the team. An outside panel of 3 pharmacists and 1 physician did an ultimate review to confirm accuracy. Lexile analyses were performed on all final MedSheets, confirming that each met a <8th grade readability standard. Two sample MedSheets are shown in Fig. 1.

#### 2.2.2. Delivery of 'MedSheets'

Code was written within Epic's EHR platform (Epic Systems Corporation; Verona, Wisconsin) to link pdf versions of the MedSheets to new or changed medication orders. The intervention was designed to print one of 50 MedSheets when the particular medication was ordered. Due to limited programming resources, only the 50 most frequently prescribed medications in NMFF's GIM clinic were included. The intervention was beta tested for two weeks prior to enrolling participants to monitor the reliability and delivery. Minor modifications were made at the clinic's request for the MedSheets to print at the check-out desk rather than at nurse's stations. This was done as to not disrupt clinicians' workflow and to increase the likelihood the patients would actually receive the MedSheets with their after visit summaries.

#### 2.3. Randomization

A simple 1:1 randomization scheme was not possible, as the EHR function to generate the 'MedSheets' could not be applied at the individual patient level. Rather, Epic did allow us to turn the intervention components on or off by prescriber. Therefore, attending physicians were randomized to either the intervention or usual care arm by first stratifying them by clinical effort (full time, half time), then randomly assigning physicians within each stratification to study arm. Residents were not able to be randomized due to frequent turnover and they were not directly linked with their assigned attending within the EHR, so eligible patients who were prescribed medications by a resident were all assigned to the control group.

#### 2.4. Measures

#### 2.4.1. Patient characteristics

Interview questions included self-report of sociodemographic information (age, gender, race/ethnicity, education, income, work status, marital status) and total number of chronic conditions including diabetes, chronic obstructive pulmonary disease, coronary vascular disease, coronary heart failure, asthma, hypertension, hypercholesterolemia, stroke, arthritis, cancer, depression (0–11). Participants were asked how many prescription and over-the-counter medications they were currently taking. Patient literacy was also assessed using the Rapid Estimate of Adult Literacy in Medicine (REALM), a word-recognition test where patients are asked to read aloud as many words as they can from a list of 66 health related terms [31]. Scores are based on the total number of words pronounced correctly and interpreted as low (0–44), marginal (45–60), or adequate (61–66) literacy.

#### 2.4.2. Medication characteristics

Medications were categorized based on typical prescribing patterns. Medications typically prescribed chronically for regularly

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