Does a Tailored Pharmacist Intervention Reduce Post-Discharge Medication Errors?

Kripalani S, Roumie CL, Dalal AK, et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: a randomized trial. Ann Intern Med 2012;157:1–10.

Study Overview

Objective. To evaluate the effect of a pharmacist intervention tailored to patients' level of health literacy on occurrence of post-discharge medication errors.

Design. Randomized controlled trial with concealed allocation and blinded outcome assessors.

Setting and participants. The study took place at 2 tertiary care academic medical centers: Vanderbilt University Hospital and Brigham and Women's Hospital. Participants included adults who were admitted for acute coronary syndromes or acute decompensated heart failure between May 2008 and September 2009. Reasons for exclusion included discharge within 3 hours, inability to communicate in English or Spanish, illness that prevented participation, and active psychosis, bipolar disorder, delirium, or severe dementia. Also excluded were patients who had hearing or visual impairment, who did not manage their own medications, who were unlikely to be discharged to home, who lacked a telephone, or who were in police custody. Patients were randomly assigned to intervention and control groups.

Intervention. Patients in the control arm were assigned to usual care, which included undergoing medication reconciliation and discharge counseling by their treating physicians and nurses. Care providers utilized electronic medical records along with preadmission medication lists generated in-house to perform medication reconciliation. The system used by providers at Brigham and Women's Hospital included additional attributes previously shown to reduce adverse drug events, such as reminders to complete preadmission medication lists and reconcile with new orders as well as the requirement to continue, stop, or change each preadmission medication at admission.

Patients in the intervention arm received 4 measures in addition to usual care: pharmacist-assisted medication reconciliation, inpatient pharmacist counseling, low-literacy medication adherence tools (eg, pillboxes), and follow-up phone calls after discharge. Study pharmacists conducted medication reconciliation, during which time they discussed any relevant discrepancies with treating physicians. The pharmacists conducted inpatient counseling in 1 or 2 sessions prior to or upon discharge and tailored counseling to what they assessed to be each patient's medication literacy, barriers to adherence, and social support. As needed, counseling focused on the differences between the preadmission and discharge medications, approaches to overcome patient challenges to taking medications, avoiding side effects, and the

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special circumstances of high risk medications. Pharmacists used "teach-back" and low-literacy medication tools to maximize patient understanding and adherence. Finally, a research coordinator called patients 1 to 4 days after discharge to ascertain whether patients had experienced any problems with regard to their medications, after which a pharmacist called, as needed, to discuss the problems with the patient and worked in conjunction with other care providers to resolve any issues.

Main outcome measures. The study's primary outcome measure was the number of clinically relevant medication errors per patient within 30 days of discharge. Clinically important medication errors included preventable or ameliorable adverse drug events (ADEs) and potential ADEs due to medication discrepancies or nonadherence issues. Secondary outcome measures included the number of preventable or ameliorable ADEs, the number of potential ADEs due to discrepancies or nonadherence, and the percentage of preventable or ameliorable ADEs that were categorized as significant, life-threatening, or fatal.

Two independent clinician adjudicators characterized the outcomes for each patient after reviewing medical records during the 30 days after discharge as well as the results of phone interviews conducted with each patient 25 to 35 days after discharge. During interviews, research staff asked patients about new or worsening symptoms (to detect possible ADEs), discharge medications (to detect possible discrepancies and nonadherence), and post-discharge health care utilization (to detect extraneous variables). Adjudicators identified ADEs and graded them on their severity, preventability, and ameliorability using a previously validated, standardized approach. As to potential ADEs, adjudicators determined whether a medication discrepancy or instance of nonadherence carried a greater than 50% likelihood of causing harm if left unresolved, and, if so, it was designated as a potential ADE. A standardized adjudication process was used to characterize all ADEs and potential ADEs as significant, serious, life-threatening, or fatal. Adjudicator disagreements were resolved by discussion and, when necessary, assistance from a third adjudicator. Outcomes were analyzed on an intention-to-treat basis; only patients who withdrew consent or died before discharge were excluded.

Main results. 862 patients were randomized: 430 to the intervention group and 432 to the control group. A total of 851 participants were analyzed, and 432 had at least 1 clinically important medication error 30 days after discharge (50.8%). The difference between the mean number of medication errors in the intervention group (0.87 per patient) and baseline group (0.95 per patient) was not statistically significant for either the unadjusted incidence rate ratio (IRR) (0.92, 95% CI 0.77 to 1.10) or adjusted IRR (0.92, 95% CI 0.77 to 1.09). A total of 258 patients (30.3%) experienced 353 preventable or ameliorable ADEs, and the difference between the mean number of preventable ADEs in the intervention group (0.43 per patient) and baseline group (0.40 per patient) was not statistically significant for either IRR (1.09, 95% CI 0.86 to 1.39). A total of 253 patients (29.7%) experienced 424 potential ADEs, and the difference between the mean number of potential ADEs in the intervention group (0.44 per patient) and baseline group (0.55 per patient) was not statistically significant for either the unadjusted IRR (0.80, 95% CI 0.61 to 1.04) or adjusted IRR (0.79, 95% CI 0.61 to 1.01). The adjusted IRR accounts for covariates such as study site, diagnosis at admission, age, marital status, type of insurance, health literacy, cognition, number of prescription medications, medication understanding, self-reported adherence, access to primary care, and number of hospitalizations within the previous year.

Conclusion. Rates of clinically important medication errors were high (50.8% for all subjects) during the first 30 days after hospital discharge, and a pharmacist intervention tailored to patients' level of health literacy did not significantly reduce such errors, ADEs, or potential ADEs.

Commentary

Although awareness of medical errors in acute care hospitals has increased over the last decade, the development of effective interventions to prevent medication-related errors continues to challenge policy makers, hospital administrators, and physicians. The period following hospital discharge is particularly critical for patient safety, as approximately half of adult patients experience at least 1 error in medication continuity, diagnostic workup, or test follow-up [1]. Up to 6.5% of all admissions at hospitals are related to ADEs, and 42% of serious or life-threatening ADEs are preventable [2]. Studies have reported that 19% to 23% of patients experience at least 1 adverse event after discharge, 66% to 72% of which are due to medication errors [3,4]. Approximately 14.3% of

patients who upon discharge have discrepancies between preadmission and discharge medication lists will be readmitted to the hospital within 30 days [5].

Higher 30-day readmission rates are associated with lower overall patient satisfaction and impose significant costs on health systems [6,7]. The effort to reduce readmissions is now reflected in federal policy and spans health care organizations across the United States. The Hospital Readmissions Reduction Program provision of the Patient Protection and Affordable Care Act (PPACA) requires the Centers for Medicare & Medicaid to penalize hospitals with excess readmissions for congestive heart failure (CHF), acute myocardial infarction (AMI), and pneumonia started on 1 October 2012. While a considerable proportion of medication errors are preventable and contribute to readmissions, there appears to be a disconnect between widespread efforts to reduce readmissions and knowledge of the role that medication errors play in readmissions, as well as the ways that information is communicated across the continuum of care. For example, a recent survey of the strategies used by 537 hospitals to reduce 30-day readmissions found that 87% of surveyed hospitals had quality improvement teams for readmission reduction among CHF patients and 54% had teams for AMI patients, but only 25.5% regularly sent discharge summaries to primary care providers [8]. The study also showed that only 28.9% of hospitals had electronically linked inpatient and outpatient prescription records [8]. As such, medication errors are a worthy and open target for interventions to improve overall patient safety after hospital discharge.

As outlined above, this study assessed the effects of a pharmacist intervention (Pharmacist Intervention for Low Literacy in Cardiovascular Disease or PILL-CVD) on clinically important medication errors after discharge when compared with usual care. The investigators found very high rates of medication errors, but also that the pharmacist intervention did not change them in a significant fashion.

The investigators previously demonstrated that inpatient pharmacist counseling and follow-up telephone calls reduced adverse drug events after hospitalization, but did so in a broader patient population at one institution using fewer strategies [9]. Since then, the development and implementation of medication reconciliation tools within the electronic medical record have become more common in tertiary academic institutions [10]. Consequently, the standard of care has improved, potentially making it more difficult for new interventions to demonstrate a statistically significant benefit over baseline.

Despite the results of this trial, the researchers used a unique combination of tactics to prevent medication errors. In addition to using "teach-back" to confirm understanding during counseling, pharmacists also provided low-literacy education aids to patients. These tactics demonstrated a greater treatment effect among patients with inadequate health literacy than the treatment effect among patients with either marginal or adequate health literacy, but was not significant. A noticeable treatment effect was also observed among intervention patients for potential ADEs.

Several limitations in the study are worth noting. First, the study participants were relatively well-educated and health literate, making the results less generalizable and the intervention potentially less impactful overall. The study also was not powered to detect a difference within pre-specified subgroups based on health literacy, so further investigation may be required to see whether PILL-CVD significantly lowers ADEs in patients with inadequate health literacy. Additionally, as previously mentioned, the 2 academic institutions involved already had strong mechanisms in place for medication reconciliation. Further, the participants had cardiovascular conditions that required different medication regimens and treatments from other patient populations.

Future efforts could be directed towards creating novel approaches that can be tailored to patients with adequate to high health literacy in addition to patients with low health literacy. In order to develop interventions tailored to patients within any stratum of health literacy, investigators could first retrospectively determine whether certain medical errors occurred at a greater frequency within a particular stratum and then target that error appropriately. Since the intervention was designed to accommodate patients with low health literacy, future studies could focus on this single population while supplementing the current intervention with other preventative elements.

A systematic review of intervention strategies to reduce 30-day readmission rates showed that a multifaceted strategy has been more effective in reducing 30-day rehospitalizations than interventions implementing a 1-element strategy in isolation [11]. All interventions were categorized as pre-discharge inter-

ventions, post-discharge interventions, or transition interventions. Among the randomized, controlled trials (n = 4) in the review, only 1 study showed a statistically significant reduction in absolute risk for readmission in heart failure or cardiac populations. This study was the only trial to incorporate "patient-centered discharge instructions" or PCDI, a transition intervention, into its bundled strategy [11,12]. Only 5 of 16 randomized controlled trials showed statistically significant reductions in absolute risk across populations. Transition interventions were implemented in 7 of 16 trials, and 4 of these 7 trials demonstrated statistically significant reductions in absolute risk.

Despite the focus on absolute risk reductions in readmissions, the review highlights an important concept that can be applied to most patient safety improvement efforts, including those to reduce preventable and potential ADEs. Future efforts should consider interventions that fully integrate primary care teams responsible for patient care in order to improve transitions from inpatient to outpatient settings. Innovative primary care models such as patient-centered medical homes (PCMHs) are uniquely equipped to improve the quality of care transitions [13], especially if PCMHs have on-site pharmacists who continuously counsel and monitor patients. To this end, future efforts to reduce medical errors using patient-centered, bridging interventions may support a more fluid, sustainable model for quality improvement 30 days after discharge and beyond by linking inpatient and outpatient providers more seamlessly.

Applications for Clinical Practice

Medication errors at discharge are alarmingly common and continue to threaten the safety of patients after hospital discharge. A multicomponent, pharmacist-led inpatient intervention did not significantly reduce the number of medical errors, preventable ADEs, and potential ADEs among patients in 2 academic hospitals with effective medication mechanisms already in place. These results illustrate the difficulty of preventing ADEs after hospital discharge. An urgent need exists for novel pharmacist-led interventions that better integrate inpatient and outpatient team-based care to reduce errors during transitions of care.

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