Effect of a Health Literacy Intervention on Clinically Important Medication Errors after Hospital Discharge

Sunil Kripalani, MD, MSc

Vanderbilt University

VANDERBILT UNIVERSITY MEDICAL CENTER

Acknowledgements/Disclosures

- Supported by R01 HL089755 (Kripalani), K23 HL077597 (Kripalani), and K08 HL072806 (Schnipper) from NHLBI; and VA Career Development Award 04-342-2 (Roumie).
- Dr. Kripalani is a consultant to and holds equity in PictureRx, LLC, which did not provide materials or funding for this study.

Medication Errors

- Are common after hospital discharge
- Include:
  - Adverse drug events (ADEs): preventable or ameliorable
  - Potential adverse drug events (pADEs): medication discrepancies and non-adherence
- Lead to excess healthcare utilization and costs
- Potential risk factors:
  - Age, low health literacy, cognitive impairment, complex medication regimen

Annals of Internal Medicine | ORIGINAL RESEARCH

Effect of a Pharmacist Intervention on Clinically Important Medication Errors After Hospital Discharge

A Randomized Trial

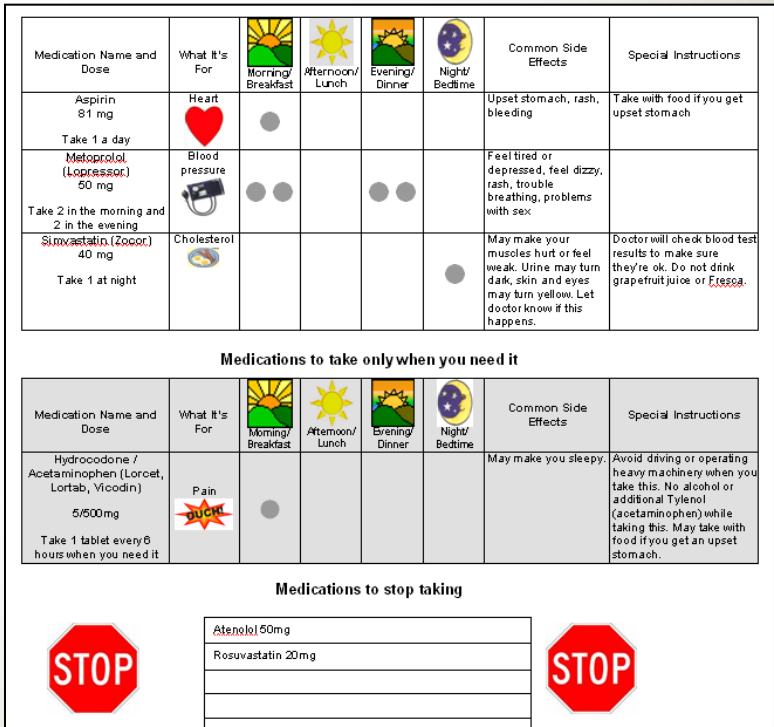
- Setting/Population
  - Vanderbilt University Hospital, Brigham & Women's Hospital
  - Enrollment: May 2008 – Sept 2009
  - Patients admitted with acute coronary syndromes (ACS) or acute decompensated heart failure (ADHF)

- Outcomes: # of clinically important medication errors during first 30 days after discharge
  - Adverse drug events (ADEs)
  - Potential ADEs: medication discrepancies, non-adherence
  - Emergency Department visits, rehospitalization

Kripalani S, et al. Ann Intern Med 2012

Intervention Components

1) Pharmacist-assisted medication reconciliation
2) Medication counseling at enrollment and discharge
   - Pharmacists trained in clear health comm.
3) Low-literacy adherence aids
   - Pillbox
   - Illustrated med. schedule
4) Tailored telephone follow-up
   - Study coordinator
   - Pharmacist when needed



Medication Name and Dose	What It's For	Morning/ Breakfast	Afternoon/ Lunch	Evening/ Dinner	Night/ Bedtime	Common Side Effects	Special Instructions
Aspirin 81 mg Take 1 a day	Heart	●				Upset stomach, rash, bleeding	Take with food if you get upset stomach
Metoprolol (Lopressor) 50 mg Take 2 in the morning and 2 in the evening	Blood pressure	● ●		● ●		Feel tired or depressed, feel dizzy, rash, trouble breathing, problems with sex	
Simvastatin (Zocor) 40 mg Take 1 at night	Cholesterol				●	May make your muscles hurt or feel weak. Urine may turn dark, skin and eyes may turn yellow. Let doctor know if this happens.	Doctor will check blood test results to make sure they're ok. Do not drink grapefruit juice or Fresca.

Medications to take only when you need it

Medication Name and Dose	What It's For	Morning/ Breakfast	Afternoon/ Lunch	Evening/ Dinner	Night/ Bedtime	Common Side Effects	Special Instructions
Hydrocodone / Acetaminophen (Lorcet, Lortab, Vicodin) 5/500mg Take 1 tablet every 6 hours when you need it	Pain OUCH!	●				May make you sleepy.	Avoid driving or operating heavy machinery when you take this. No alcohol or additional Tylenol (acetaminophen) while taking this. May take with food if you get an upset stomach.

Medications to stop taking

STOP

Atenolol 50mg
Rosuvastatin 20mg

STOP

VANDERBILT UNIVERSITY MEDICAL CENTER

Considerations for Health Literacy Research

1. Reporting adjusted treatment effects
2. Missing or incomplete health literacy data
3. Planned subgroup analyses
4. Intervention fidelity
5. Complementary qualitative research

1. Reporting adjusted treatment effects

- PILL-CVD randomized patients in permuted blocks of varying size
- Stratified randomization by site and diagnosis
- Randomization helps balance patient characteristics between intervention and control group
- Residual differences exist

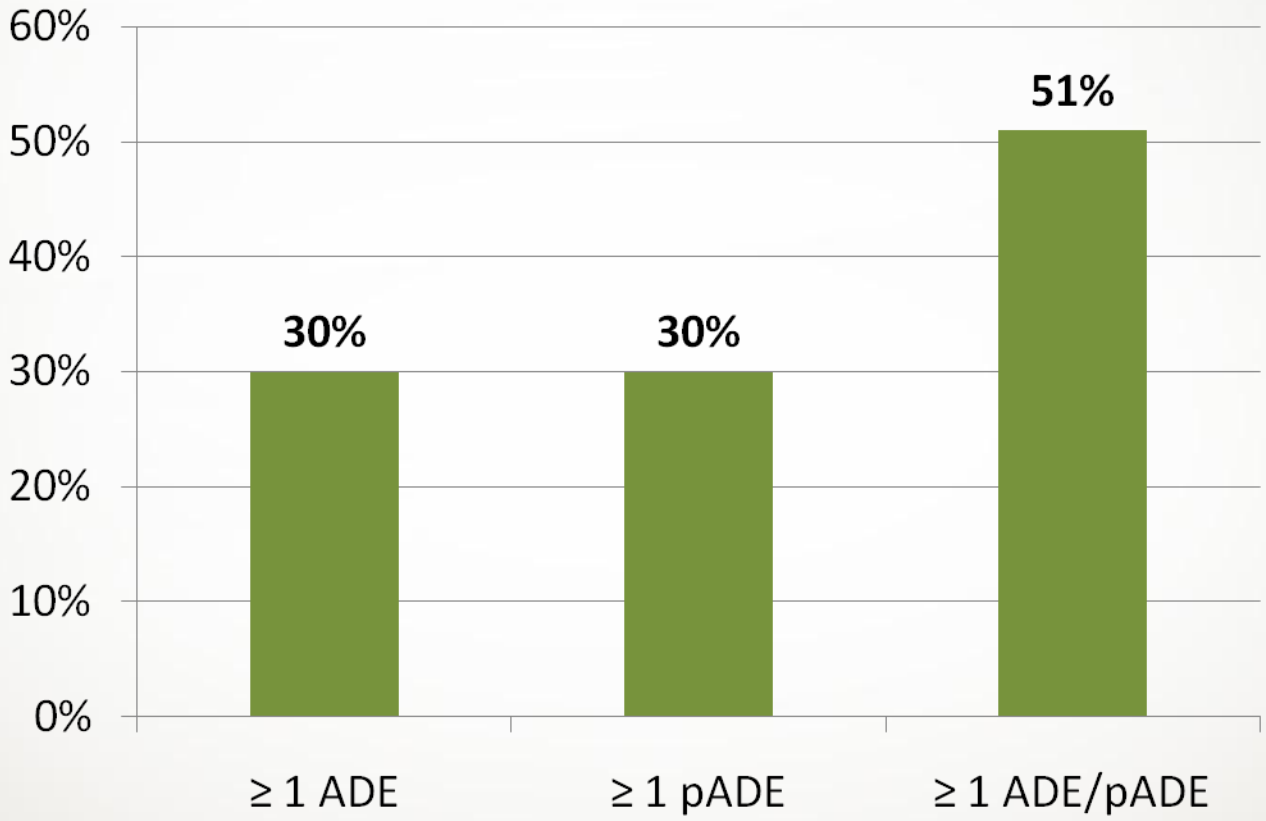
Patient Characteristics		Usual Care (N = 428)	Intervention (N = 423)
Site: Vanderbilt, N (%)		200 (47)	197 (47)
Age, Mean ± SD		59 ± 14	61 ± 14
Female		179 (42)	173 (41)
Race:	White	335 (78)	319 (75)
	Black	71 (17)	77 (18)
	Other	22 (5)	27 (6)
Health Literacy:	Adequate	340 (82)	329 (79)
	Marginal	38 (9)	36 (9)
	Inadequate	39 (9)	49 (12)
Cognitive impairment		46 (11)	52 (12)
Pre-admission meds, Median (IQR)		7 (4-11)	8 (4-11)

1. Reporting adjusted treatment effects

- Main analysis: unadjusted binomial regression
  - Compare # of events by treatment assignment

- Also reported: adjusted binomial regression
  - Covariates determined a priori, possibly related to outcome
  - Site, diagnosis, age, marital status, insurance type, health literacy, cognition, number of preadmission prescription medications, medication understanding, self-reported adherence, access to a PCP, hospitalization during the previous year

30-Day Incidence of ADEs, pADEs, Medication Errors



Effect of Intervention on Med Errors, ADEs, and pADEs

Outcomes	*Usual Care* *Mean (SD)* *N=428*	*Intervention* *Mean (SD)* *N=423*
Med Errors	**0.95** (1.36)	**0.87** (1.18)
ADEs	**0.40** (0.75)	**0.43** (0.74)
pADEs	**0.55** (1.07)	**0.44** (0.86)

Kripalani S, et al. Ann Intern Med 2012

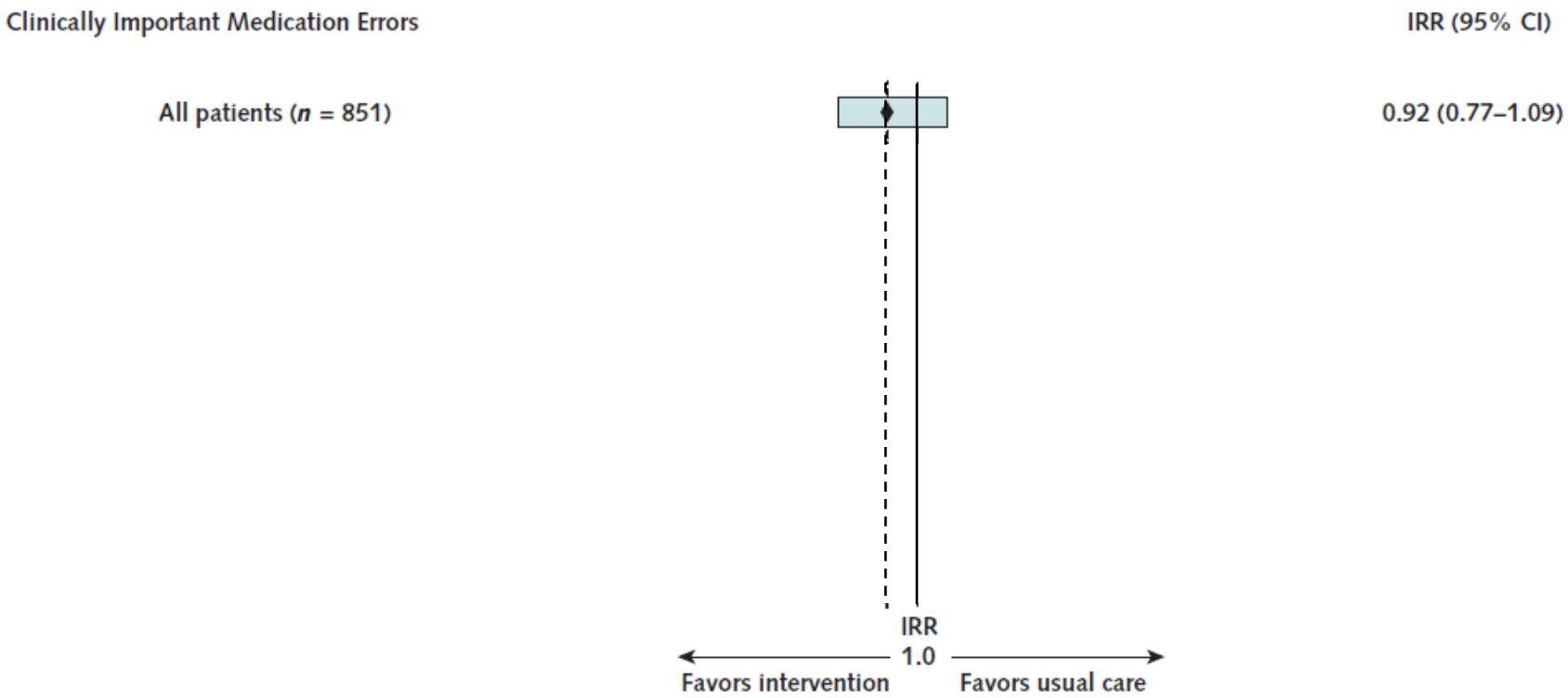
2. Missing/Incomplete Health Literacy Data

- sTOFHLA for 20 patients:
  - Illiterate
  - Couldn't read the form (blurry vision)
  - Quit during the test
  - Skipped a page by mistake
- Most obvious options:
  - Score what they completed, 0, 9
- Performed multiple imputation based on other covariates

3. Planned Subgroup Analyses

- Shouldn't expect the same results in every patient
  - Especially with educational/behavioral intervention
- May vary by site, patient characteristics, disease/medication regimen characteristics

Figure 2. Adjusted treatment effect on clinically important medication errors, ADEs, and potential ADEs, by subgroups



VANDERBILT UNIVERSITY MEDICAL CENTER

Kripalani S, et al. Ann Intern Med 2012

4. Intervention Fidelity

Patient Intervention Delivery	Total (n=430)	VUH (n=200)	BWH (n=230)
2 Separate counseling sessions (initial and discharge) in hospital	247 (57.4)	106 (53.0)	141 (61.3)
1 Combined counseling session in hospital	45 (10.5)	14 (7.0)	31 (13.5)
Initial counseling in hospital and discharge counseling by phone	95 (22.1)	60 (30.0)	35 (15.2)
Both initial and discharge counseling by phone	15 (3.5)	5 (2.5)	10 (4.3)
Initial session in hospital and no discharge counseling*	16 (3.7)	11 (5.5)	5 (2.2)
No intervention†	12 (2.8)	4 (2.0)	8 (3.5)
Postdischarge follow-up phone call completed (1 to 4 d after discharge)	367 (85.3)	181 (90.5)	186 (80.9)

Values are presented as n (%).

*Pharmacist unable to reach patients due to early discharge, inability to reach patient by phone, patient withdrawal from study, death, or patient not having any medications ordered at discharge.

†Among these, 2 died in hospital, 2 withdrew consent, and 8 did not receive intervention for logistical and/or clerical reasons (eg, pharmacist unavailable).

VANDERBILT UNIVERSITY MEDICAL CENTER

Schnipper JL, … Kripalani S. Circ Cardiovasc Qual Outcomes 2010

5. Complementary Qualitative Research

- Structured interviews with patients, pharmacists, and investigators
  - What was most helpful
  - Why we observed what we did
  - What could have been done differently
  - General recommendations

Table 2. Utility of different forms of assistance in hospital discharge transition ($N = 125$)

Item	Very helpful *N* (%)	Somewhat helpful *N* (%)	Not at all helpful *N* (%)	N/A (%)
How helpful was it to …				
1. Talk with the pharmacist about your medicines before you left the hospital?	91 (72.8)	29 (23.2)	3 (2.4)	2 (1.6)
2. Get a daily medication schedule, which uses pictures to show what the medicines are for and how to take them?	87 (69.6)	18 (14.4)	7 (5.6)	13 (10.4)
3. Get a pill box?*	80 (64.5)	9 (7.3)	15 (12.1)	20 (16.1)
4. Have someone call you at home a couple of days after you got out of the hospital to check on how you were doing?	85 (68.0)	30 (24.0)	7 (5.6)	3 (2.4)
5. Get help from friends or family to manage your medicines?	55 (44.0)	21 (16.8)	25 (20.0)	24 (19.2)

Cawthon C, … Kripalani S. J Health Commun 2012

Summary

- Use of rigorous statistical methods can improve precision, help with missing data
- Need to understand exactly what was done
- Don’t be satisfied with measuring the average effect in the average patient; look deeper
- Learn as much as possible!

Acknowledgements

Faculty Co-Investigators, Adjudicators, Consultants

- Jeffrey L. Schnipper, MD, MPH
- Christianne L. Roumie, MD, MPH
- Anuj K. Dalal, MD
- Terry A. Jacobson, MD
- Viola Vaccarino, MD, PhD
- Kimberly J. Rask, MD, PhD
- Tejal K. Gandhi, MD, MPH
- David W. Bates, MD, MPH
- Svetlana Eden, MS
- Ayumi Shintani, PhD
- Kelly Cunningham Sponsler, MD
- L. Jeff Harris, MD
- Cecelia Theobald, MD
- Robert L. Huang, MD, MPH
- Danielle Scheurer, MD, MSc
- Susan Hunt, MD
- Mark V. Williams, MD

Source of funding

- NIH (R01 HL089755, K23 HL077597, K08 HL072806)
- VA (CDA 04-342-2)

Staff and pharmacists

- Courtney Cawthon, MPH
- Alexandra Businger
- Ileko Mugalla, MS, PhD, MPH
- Edith Swain
- Kurt J. Niesner
- Abby Stufflebam
- Jeffrey Kemnitz
- Harry Reyes
- Alison C. Pietras
- Arianne Cordon
- Catherine Liang, MPH
- Ankita Munjal
- Charles Dupont
- Daniel C. Johnson, PharmD
- Erin B. Neal, PharmD
- Stephanie Labonville, PharmD
- Judy Cheng, PharmD
- Heather Dell'Orfano, PharmD
- Radmilla Levinson, PharmD
- Beth Ann Filkins, PharmD
- David Gregory, PharmD
- Pershank Bamarni, PharmD
- Elisha Guadalupe, DPh
- Jill Helmke, DPh, NPh
- Marketa Marvanova, PharmD, PhD

Thank you

What questions do you have?