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

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Acknowledgements/Disclosures

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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
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
  – 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

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

- ≥ 1 ADE: 30%
- ≥ 1 pADE: 30%
- ≥ 1 ADE/pADE: 51%
**Effect of Intervention on Med Errors, ADEs, and pADEs**

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Usual Care Mean (SD) N=428</th>
<th>Intervention Mean (SD) N=423</th>
</tr>
</thead>
<tbody>
<tr>
<td>Med Errors</td>
<td>0.95 (1.36)</td>
<td>0.87 (1.18)</td>
</tr>
<tr>
<td>ADEs</td>
<td>0.40 (0.75)</td>
<td>0.43 (0.74)</td>
</tr>
<tr>
<td>pADEs</td>
<td>0.55 (1.07)</td>
<td>0.44 (0.86)</td>
</tr>
</tbody>
</table>

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

Clinically Important Medication Errors

All patients ($n = 851$)

IRR (95% CI)

0.92 (0.77–1.09)
### 4. Intervention Fidelity

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

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).
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 ($N = 125$)

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