Detection and Management of Adverse Drug Events and Potential Adverse Drug Events at Care Transitions

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Disclosure

Financial relationships with commercial interests listed below are not relevant to the CME activity:

• Otsuka Pharmaceuticals - Speakers Bureau
Learning Objectives

• Define medication safety terms including ADEs and pADEs
• Describe the impact of medication management services initiated at care transitions on healthcare costs, quality, and safety
• List resources available to help organizations initiate or advance medication management services at care transitions
Outline

• Significance of medication-related problems at care transitions
• Medication safety definitions: ADEs vs PADEs
• USC CMMI project experience and other recent care transition projects
• Resources for improving medication-related outcomes at care transitions
Medication-Related Problems in U.S.

- ½ of prescription medications taken every year in the US are used improperly (CDC, 2013)
- 90% of chronic diseases require medications as first-line therapy (Medco, 2010)
- Adverse effects from medications ~ 4th leading cause of death in U.S. (FDA)
- For every dollar spent on medications in the US (~$374 billion annually), another dollar is spent correcting problems due to suboptimal medication use (IOM, NEHI)
Medication-Related Problems Related to Care Transitions

• 60% of all medication errors occur during care transitions (JAGS 2003;52;556-7)

• 1 in 5 patients discharged from hospitals experiences an adverse event, 72% of which are attributable to medications (Optimizing Medication Reconciliation, ASHP/APhA 2012)

• 75% of hospital readmissions among seniors are avoidable, primarily through better use of medications (James J., Health Affairs 2013, http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=102)
Outline

• Significance of medication-related problems at care transitions

• Medication safety definitions: ADEs vs PADEs
ADVERSE DRUG EVENT (ADE):
“Injury resulting from the use of a drug”
ADVERSE DRUG EVENT (ADE):
“Injury resulting from the use of a drug”

ADVERSE DRUG REACTION (ADR):
“Harm directly caused by a drug at normal doses, during normal use.” (aka Side Effects)

http://www.nccmerp.org/aboutMedErrors
http://www.pbm.va.gov/vamedsafe/Adverse%20Drug%20Reaction.pdf
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ADVERSE DRUG REACTION (ADR): “Harm directly caused by a drug at normal doses, during normal use.” (aka Side Effects)

MEDICATION ERROR: “A preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of a health care professional, patient, or consumer.”

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POTENTIAL ADVERSE DRUG EVENT (pADE): “Medication errors that are stopped before harm can occur, i.e., near misses”

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http://www.pbm.va.gov/vamedsafe/Adverse%20Drug%20Reaction.pdf
# USC Medication-Related Problems Form

**PATIENT INFORMATION**

<table>
<thead>
<tr>
<th>Date</th>
<th>Site</th>
<th>MRN</th>
<th>DOB</th>
<th>Gender</th>
<th>Insurance</th>
<th>Ethnicity &amp; Language</th>
<th>Point of Care</th>
<th>Initials</th>
<th>Entered in computer database</th>
</tr>
</thead>
<tbody>
<tr>
<td>/</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>☐ M ☐ F</td>
<td>/</td>
<td>/</td>
<td>/</td>
<td>☐</td>
<td></td>
</tr>
</tbody>
</table>

**MEDICATION THERAPY INTERVENTION & SAFETY DOCUMENTATION FORM** (version 8, 9/12/11)

**INTERVENTION:** Each row is for an individual intervention (i.e., one MRP per row)

<table>
<thead>
<tr>
<th>Drug(s) Involved</th>
<th>Indication</th>
<th>Intervention Codes (see table below):</th>
<th>Intervention Accepted? (optional)</th>
<th>Resolved? (optional)</th>
<th>Description of event MUST complete for Severity i or ii in pADEs &amp; all ADEs</th>
</tr>
</thead>
<tbody>
<tr>
<td>A B C D E</td>
<td></td>
<td>I*</td>
<td>II**</td>
<td>IV***</td>
<td><strong>Problem</strong> Recommendation Outcome**</td>
</tr>
</tbody>
</table>

### I. MEDICATION-RELATED PROBLEM (MRP)

- Appropriateness and effectiveness
- Untreated medical problem
- Drug dosing not adequate for treatment goals (dose, interval, or duration)
- Treatment not optimal based on current evidence/guidelines
- Monitoring standards not being followed
- Safety (pADE/ ADE)
- Drug dosing excessive for treatment goals (dose, interval, or duration)
- Incomplete/improper directions
- No indication for medication prescribed
- Polypharmacy (Rx not needed)/duplication
- Contraindication
- Adverse drug reaction (ADR)
- Allergy
- Drug interaction
- Lab/diagnostic test indicated, not ordered

### II. pADE/ADE CLASSIFICATION

- Potential Adverse Drug Event (pADE)
  - A: No med errors/event, but potential for ADE identified
  - B: Med error/event DID NOT reach patient
  - C: Med error/event reached patient, but no harm
  - D: Med error/event reached patient, monitoring or intervention required to confirm no harm

- Adverse Drug Event (ADE)
  - E: Event occurred, resulting in temporary harm and requiring intervention
  - F: Event occurred, resulting in permanent harm and requiring hospitalization
  - G: Event occurred, resulting in permanent harm/disability
  - H: Event occurred, life-threatening
  - I: Event occurred, resulted in death

### III. pADE SEVERITY RATING

- Potential for minimal (would require self-management) or no harm
- Potential for moderate harm (would require healthcare professional intervention or hospitalization to resolve)
- Potential for severe harm (permanent disability or death)

### IV. INTERVENTION/RECOMMENDATION

- DC drug(s)
- Substitute drug(s)
- Add drug(s)
- Change dosage/dose interval
- Change duration of tx/alt.
- Change PRN to schedule
- Change schedule to PRN
- Order lab/dx/test
- Educate patient
- Refer to other service
- Clarify Rx
- Substitute dosage form
- Make appt w/provider
- Provide Rx compliance box
- Other

---

# 28 Problem Categories

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
</table>
| Medication-Related Problem (MRP) | 14. Abnormal lab result not addressed  
15. Pharmacy / dispensing error  
16. Medication overuse or misuse  
17. Dose discrepancy between patient use & prescribed therapy  
18. Using expired medication(s)  
Nonadherence and Patient Variables | 19. Medication underuse / poor adherence  
20. Dosage form is not reasonable for patient  
21. Inadequate patient self-management of lifestyle and other non-drug variables  
22. Patient dissatisfied or refuses treatment, no rational reason given  
Miscellaneous | 23. Drug not available in prescribed strength  
24. Inadequate refills between scheduled visits  
25. Nonformulary / not cost effective drug choice  
26. Illegible prescription  
27. No follow-up appointment with PCP  
28. Other |

### 1. Medication-Related Problem (MRP)

1. Untreated medical problem  
2. Drug dosing not adequate for treatment goals (dose, interval, or duration)  
3. Treatment not optimal based on current evidence / guidelines  
4. Monitoring standards not being followed  

### Safety (pADE / ADE)

5. Drug dosing excessive for treatment goals (dose, interval, or duration)  
6. Incomplete / improper directions  
7. No indication for medication prescribed  
8. Polypharmacy (Rx not needed) / duplication  
9. Contraindication  
10. Adverse drug reaction (ADR)  
11. Allergy  
12. Drug interaction  
13. Lab/diagnostic test indicated, not ordered  

- Lifestyle and other non-drug variables  
- Other
Outline

• Significance of medication-related problems at care transitions
• Medication safety definitions: ADEs vs PADEs
• USC CMMI project experience and other recent care transition projects
$12 million USC / AltaMed CMMI Project: Specific Aims

10 teams
Pharmacist + Resident + Clinical Pharmacy Technician

OUTCOME MEASURES
✓ Healthcare Quality
✓ Safety
✓ Total Cost / ROI
✓ Patient & provider satisfaction
✓ Patient access

UNIVERSITY OF SOUTHERN CALIFORNIA
National Conference on Best Practices and Collaborations to Improve Medication Safety and Healthcare Quality
Feb 2014 & 2016

Telehealth clinical pharmacy

Resident and technician training for expansion

Web-based pharmacist training and credentialing
USC Patient Targeting and Management Strategy

High cost patients

Frequent and recent acute care utilizers

48 EHR-embedded triggers to detect high risk patients

MD referrals

Clinical Pharmacy
USC School of Pharmacy

Comprehensive Medication Management

Treatment Goal Reached?

Yes

Unstable

Clinical pharmacy tech “check-ins” every 2 months

No
Comprehensive Medication Management is a New Standard of Care

Ensures each patient’s medications are individually assessed.

Assessment determines if medication is:

• appropriate for the patient
• effective for the medical condition
• safe given the comorbidities and other medications being taken
• able to be taken by the patient as intended
Comprehensive Medication Management is Patient Centered

CMM includes:

- individualized care plans that achieve the intended goals of therapy
- appropriate follow-up to determine actual patient outcomes
- patient understands, agrees with, and actively participates in the treatment regimen

CMM optimizes each patient’s medication experience and clinical outcomes
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>MTM</th>
<th>CMM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conduct a comprehensive medication therapy review to identify all medication-related problems</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Confirm medication-related problems including assessment, point-of-care testing, medication-related labs</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Assess ALL medications and medical conditions</strong></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Develop individualized medication care plan to address medication-related problems and ensure attainment of treatment goals</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Add, substitute, discontinue, or modify medication doses</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Generate complete medication record</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Document care delivered and communicate to health care team</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Ensure care is coordinated with other health care providers</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Provide follow-up care in accordance with treatment-related goals</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Requires collaborative practice agreement between pharmacist and physician</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>
Patient Enrollment
USC-AltaMed CMMI Program

• Enrolled 6,000 patients since Oct 2012
  • Predominantly Hispanic, non-elderly women
• 3/4ths have hypertension, 36% uncontrolled
• 2/3rds have diabetes, 60% uncontrolled
• HOWEVER, low to moderate rates of hospitalizations
Control Group Selection

Propensity scoring to match CPS enrollees (treatments) to similar patients receiving care at non-treatment clinics (controls) in three steps:

• Wave 1 treatment patients
• PACE treatment patients from Wave 2
• Non-PACE treatment patients from Wave 2

Covariates used to model the propensity score:
• Demographics
• Health status
• Utilization
• Other
Changes in Clinical Measures (% of Patients with *Uncontrolled* Disease)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Managed Patients</th>
<th>Unmanaged Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>6 months</td>
</tr>
<tr>
<td>High blood pressure (SBP/DBP)</td>
<td>100</td>
<td>39%</td>
</tr>
<tr>
<td>Elevated cholesterol (LDL)</td>
<td>100</td>
<td>38%</td>
</tr>
<tr>
<td>Elevated Blood Sugar (HgA1c)</td>
<td>100</td>
<td>34%</td>
</tr>
</tbody>
</table>

Sample restricted to patients with *uncontrolled* condition at baseline. Unmanaged patients received *usual care* from AltaMed primary care physicians.

**Interpretation**: Program reduced rates of uncontrolled blood sugar (diabetes) by 23 percentage points *relative* to the unmanaged group (*34% vs. 57%*).
Untreated (Cohort) Versus Treated Patients, Preliminary Findings, USC CMMI Program

Mortality rates

- 25.7% absolute difference

Summary of Difference-in-Differences Results for Utilization (Treatment – Control, Probit Analysis)

At 6 month follow-up:

Readmissions per year per patient  \(-16\%\)

Readmissions per year per patient primarily attributed to medications  \(-33\%\)
Medication-Related Problems Identified Through CMMI Clinical Pharmacy Program
67,169 problems among 5,775 patients (Avg 11.6 per patient)

- Medication Nonadherence: 14,059, 21%
- Insufficient Patient Self-Management: 8,267, 12%
- Safety Issues: 13,352, 20%
- Appropriateness / Effectiveness: 22,229, 33%
- Misc: 9,222, 14%
- Insufficient Patient Self-Management: 8,267, 12%

Medication Nonadherence

- Insufficient Patient Self-Management
- Safety Issues
- Appropriateness / Effectiveness
- Misc
Top Actions Taken by Pharmacists to Resolve Medication-Related Problems (excluding education)

- Change Dose or Drug Interval: 14,981
- Add Medication: 5,554
- Order test: 4,230
- Discontinue Medication: 3,847
- Substitute Medication: 2,665
Pre-Implementation Analysis: Medication-Related Problems

Single Admission (n = 51)
- Appropriateness / Effectiveness: 33%
- Safety: 37%
- Non-adherence / Patient Variables: 22%
- Miscellaneous: 8%

Multiple Admissions (n = 85)
- Appropriateness / Effectiveness: 35%
- Safety: 57%
- Non-adherence / Patient Variables: 7%
- Miscellaneous: 1%
Medication-Related Problems

Inadequate / excessive dose
Therapy duplication
Improper directions
Drug interaction
Non-optimal treatment
Unmet monitoring standards
Untreated medical problem
Poor adherence
Inadequate patient self-management
Patient refusal of treatment
Non-formulary drug
Other*

Number of MRPs

*≤3 MRPs per category

Single Admission (n = 51)
Multiple Admissions (n = 85)
Admitting Diagnosis

Number of Diagnoses

- Cardiovascular
- Infection
- Gastrointestinal
- Renal / urological
- Neurologic / psychological
- Diabetes / endocrine
- Respiratory
- Other

Single Admission (n = 50)
Multiple Admissions (n = 203)
Interventions Needed

- Change dose / frequency
- Discontinue drug
- Educate patient
- Clarify prescription
- Add drug
- Substitute drug
- Order lab

Number of Interventions

Single Admission (n = 51)
Multiple Admissions (n = 85)

17
## Risk Factors for 90-Day Readmission

<table>
<thead>
<tr>
<th>Multivariate Analysis</th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Insurance</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicaid</td>
<td>Reference</td>
<td></td>
<td>0.2324</td>
</tr>
<tr>
<td>Medicaid</td>
<td>0.310</td>
<td>0.075 – 1.278</td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td>0.244</td>
<td>0.042 – 1.418</td>
<td></td>
</tr>
<tr>
<td>HMO / Private</td>
<td>0.790</td>
<td>0.143 – 4.377</td>
<td></td>
</tr>
<tr>
<td>HWLA / Uninsured</td>
<td>0.310</td>
<td>0.075 – 1.278</td>
<td></td>
</tr>
<tr>
<td>Medicaid</td>
<td>0.075</td>
<td>1.278</td>
<td>0.042</td>
</tr>
<tr>
<td>Medicare</td>
<td>0.042</td>
<td>1.418</td>
<td>0.143</td>
</tr>
<tr>
<td>HMO / Private</td>
<td>0.143</td>
<td>4.377</td>
<td></td>
</tr>
<tr>
<td>Hospital*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White Memorial</td>
<td>Reference</td>
<td></td>
<td>0.1673</td>
</tr>
<tr>
<td>Citrus Valley</td>
<td>1.273</td>
<td>0.304 – 5.324</td>
<td></td>
</tr>
<tr>
<td>Beverly Hospital</td>
<td>0.377</td>
<td>0.059 – 2.418</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>0.297</td>
<td>0.076 – 1.163</td>
<td></td>
</tr>
<tr>
<td>Admitting diagnosis*</td>
<td></td>
<td></td>
<td>0.3016</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>Reference</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gastrointestinal</td>
<td>3.532</td>
<td>0.552 – 22.586</td>
<td></td>
</tr>
<tr>
<td>Infectious</td>
<td>3.465</td>
<td>0.503 – 23.848</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>4.767</td>
<td>0.960 – 23.657</td>
<td></td>
</tr>
<tr>
<td>Number of MRPs*</td>
<td>1.563</td>
<td>1.048 – 2.330</td>
<td>0.0284</td>
</tr>
<tr>
<td>Received follow-up*</td>
<td>0.130</td>
<td>0.041 – 0.415</td>
<td>0.0006</td>
</tr>
</tbody>
</table>

*For first admission; CI: confidence interval; HWLA: Healthy Way LA
Most Common ADEs and pADEs over 1 yr (n = 2,216)

- Dosing excessive: 716 (32%)
- ADR: 282 (13%)
- Polypharmacy: 282 (13%)
- Rx overuse/misuse: 235 (11%)
- Dose discrepancy: 185 (8%)
- No indication: 167 (8%)
- Drug interaction: 137 (6%)

*Note: Frequencies below 100 not shown*
Most common medication classes associated with ADE / pADE (n = 2,004)

- **INSULIN**: 374 (19%)
- **WARFARIN**: 289 (14%)
- **SFU**: 189 (9%)
- **ACEI/ARB**: 179 (9%)
- **STATIN**: 121 (6%)
- **BB**: 114 (6%)

*Note: Medication classes below 5% frequency not shown*
# Cause of Most Common pADEs

<table>
<thead>
<tr>
<th>MEDICATION CLASS</th>
<th>MEDICATION-RELATED PROBLEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSULIN</td>
<td>• Dose excessive</td>
</tr>
<tr>
<td></td>
<td>• Medication misuse/overuse</td>
</tr>
<tr>
<td></td>
<td>• Dose discrepancy</td>
</tr>
<tr>
<td>WARFARIN</td>
<td>• Dose excessive</td>
</tr>
<tr>
<td>SULFONYLUREAS</td>
<td>• Medication misuse/overuse, Polypharmacy/duplicate (leading to hypoglycemia)</td>
</tr>
<tr>
<td>ACEi / ARBs</td>
<td>• Dose excessive</td>
</tr>
<tr>
<td></td>
<td>• No indication for use</td>
</tr>
<tr>
<td>STATINS</td>
<td>• Dose excessive</td>
</tr>
<tr>
<td></td>
<td>• Drug interactions (simvastatin)</td>
</tr>
<tr>
<td>BETA-BLOCKERS</td>
<td>• Dose excessive (leading hypotension and bradycardia)</td>
</tr>
</tbody>
</table>
Select Lessons Learned from CMMI Program Related to Care Transitions

• 18-30 month follow-up of patients with poor disease control but relatively modest rates of baseline hospitalizations is not likely enough time to evaluate ROI

• ~1/3 of enrolled patients had no insurance, no data (most challenging and sickest patients)

• 30-day readmission rates for care transition patients may have been even lower if more rapid access to discharge information was available
## Patient Engagement / Retention Keys

<table>
<thead>
<tr>
<th></th>
<th>Engagement</th>
<th>Retention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily availability for walk-ins / “warm hand-offs”</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>PCP endorsement to targeted / enrolled patients</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Match team member language skills</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Clinical pharmacy technicians</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Engage family and caregivers</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Consider selective home visits</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Extended hours / weekend availability</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Flyers / media explaining program in lay terms</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>Consider peer-led group appointments</td>
<td>✔</td>
<td></td>
</tr>
<tr>
<td>Continuity of pharmacist / tech provider</td>
<td></td>
<td>✔</td>
</tr>
</tbody>
</table>
Other Pharmacy Programs Focusing on Care Transitions

Program participants had a 50 percent reduced relative risk of readmission within thirty days of discharge and an absolute risk reduction of 11.1 percent. The program saved $2 for every $1 spent.

- Intervention group seniors had 36.5% lower readmission rates
- Estimated annualized cost of avoided admissions: $6.6 million
- Annual cost of the pharmacist services: $1.8 million
- ROI = 2.6:1
Outline

• Significance of medication-related problems at care transitions
• Medication safety definitions: ADEs vs PADEs
• USC CMMI project experience and other recent care transition projects
• Resources for improving medication-related outcomes at care transitions
Where Pharmacists Provide CMM

1. Medical Groups (Pay for Performance, Chronic Disease Management)
   - Cedars-Sinai, Sharp, USC, UCLA

2. Integrated into Medical Homes
   - VA, Kaiser, safety net clinics

3. Community Pharmacies
   - Ralphs, Walgreens, independents

4. Video telehealth - USC, Heritage ACO

5. Telephonic (“low-hanging fruit”)
   - MEDCO, Kaiser Permanente, U of Az, Heritage ACO, USC

http://www.pcpcc.net/files/medmanagepub.pdf
“…medication management services demonstrated an ROI of as high as 12:1 and an average of 3:1 to 5:1.”
A PROGRAM GUIDE FOR PUBLIC HEALTH

Partnering with Pharmacists in the Prevention and Control of Chronic Diseases

National Center for Chronic Disease Prevention and Health Promotion
Background: The California Wellness Plan

- May 2012: Governor Brown issues executive order calling for the development of a ten-year plan to improve the wellbeing of Californians by controlling costs, improving quality, advancing health equity, and identifying obstacles to improve care.
Contents

1. Executive Summary
2. Introduction (Definition of CMM)
3. Background
4. Implementation
5. Methods
6. So. California Case Studies
7. Challenges
8. Appendices / Resources
USC CMM Advanced Practice Pharmacist Certification and Collaborative Learning Network

1. Pharmacist Certification through CMMI-funded program
2. Statewide collaborative learning network to accelerate CMM program development and alignment with key stakeholders
   - Sharing of best practices, tools, resources
   - Live (broadcasted) meetings 2-3 times per year
   - Monthly webinars / teleconferences
   - Regional coaches / consultants
   - Focused training on CMM for high-risk populations

USC CMM resource page:
http://pharmweb.usc.edu/MedicationManagement/
• What did you hear that surprised you or was unexpected?

• What would be your approach to offering medication management services for patients at care transitions?