Overview of Findings & Current Research

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Medication Error.

- Most common form of medical error.
- > 500,000 preventable adverse drug events (ADEs) occur in ambulatory care annually.\(^1\)
- Cost: > $1 Billion/year
- Majority of studies among adults
- Recent surveillance (2001): 250,000 ADEs occur in children and adolescents in outpatient settings annually\(^2\)
- 1 in 6 children taking an Rx drug will experience a medication dosing error

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\(^1\)Institute of Medicine, Preventing Medication Error, 2006
Root Cause – Misunderstanding.

- IOM 2006/2008 reports identifies unintentional misuse a leading root cause
- In outpatient care, patients and their families assume quality control, NOT physicians
- MEPS Data (1996-2003) shows increasing trend – patients of all ages taking more Rx drugs

Do patients and their families have the necessary skills?
Value of Rx Labels

• Tangible
• Brief
• Repeatedly used
• Only source for many
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Davis, et al., J Gen Intern Med, 2006
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Beyond the Patient…A Broken System.

• Minimal federal oversight for Rx drugs

• State boards of pharmacy regulate labeling, but currently provide little guidance

• Result: variability in prescribing and dispensing of Rx drugs
Prescribing Variability.

Take one tablet orally once every day.

Take 1 tablet by mouth every morning.

53 Different Ways to Say ‘Take 1 Tablet a Day’

Take one tablet for cholesterol.

Take one tablet by mouth once daily.

Take 1 tablet 1 time daily.

Take 1 tablet one time each day.

Take one pill by mouth at bedtime.

Take one pill by mouth once each day.

Dispensing Variability.

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Instructions</th>
</tr>
</thead>
</table>
| Lipitor 10 mg tabs | - "Take one tablet daily."
| Take one tab QD  | - "Take 1 tablet by mouth for high cholesterol."
| Dispense #30     | - "Take one (1) tablet(s) by mouth once a day."
| Indication: for high cholesterol | - "Take one tablet by mouth every day for high cholesterol."
| No refills       |                                                                             |
| Fosamax 5 mg tabs | - "Take 1 tablet by mouth daily."
| Take one tab QD  | - "Take one tablet by mouth every day for osteoporosis prevention. Do not lie down for at least 30 minutes after taking."
| Dispense #30     | - "Take 1 tablet every day, 30 minutes before breakfast with a glass of water. Do not lie down."
| Indication: osteoporosis prevention | - "Take one tablet every day."
| Do not lie down for at least 30 minutes |                                                                             |
| Bactrim DS tabs  | - "Take one tablet by mouth twice daily for UTI"
| Take one tab BID | - "Take one tablet by mouth twice daily for urinary tract infection."
| Dispense #6      | - "Take 1 tablet by mouth 2 times a day."
| Indication: UTI  | - "Take 1 tablet twice daily for 3 days."
| No refills       |                                                                             |
| Ibuprofen 200 mg tabs | - "Take 1 to 2 tablets by mouth as needed for pain."
| Take 1-2 tabs TID PRN pain | - "Take 1 to 2 tablets by mouth three times daily as needed for pain."
| Dispense #30     | - "Take 1 to 2 tablets by mouth as needed for pain ** Not to exceed 4 times a day"
| No refills       | - "Take 1 to 2 tablets 3 times a day as needed for pain."                   |

Wolf, et al., in press, Medical Care, 2008

Provider Perspective
Improving Rx Information
Enhanced Rx Label Design

Enhanced Prescription Drug Label Design to Support Patient Understanding and Use
(R01 HS017687-01; PI Wolf)

Overall Objective to test the efficacy of an evidence-based, enhanced prescription drug container label design to improve older patients’ understanding of instructions for use.
Methods.

- Actual Use Assessment
- 11 Safety Net Clinics, 1 Central-Fill Pharmacy (Va.)
- Random Assignment to Enhanced vs. Standard Label
- Sample = 960 Diabetic Patients, > 40 years of age
- Assessment: Baseline, 3 months 1 Year
- Outcomes: 1. Functional Understanding  
  2. Adherence  
  3. HBA1C
**MICHAEL WOLF** 04/29/71

**GLYBURIDE 5 mg**

**Take for Diabetes**

<table>
<thead>
<tr>
<th>Breakfast</th>
<th>Lunch</th>
<th>Dinner</th>
<th>Bedtime</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Take 2 PILLS AT BREAKFAST**

**2 PILLS AT DINNER**

*Rx #: 1234567 10/30/2008*

You have 11 refills
180 pills

**Discard after 10/30/2009**

**Provider:** RUTH PARKER, MD
Emory Medical Center
(414) 123-4567

**Pharmacy:** NoVA ScriptsCentral
11445 Sunset Blvd.
Reston, VA
(713) 123-4567

**NDC # 1234567**

- Take with food
- Do not drink alcohol while taking this medicine
- Limit your time in the sun
# Improving Dosage Instructions.

<table>
<thead>
<tr>
<th>Standard</th>
<th>Enhanced no/UMS</th>
<th>Enhanced w/ UMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Take one tablet by mouth daily.</td>
<td>Take 1 tablet at bedtime.</td>
<td>![Table Schedule]</td>
</tr>
<tr>
<td>Take one tablet by mouth three times daily.</td>
<td>Take 1 tablet in the morning, 1 tablet at noon, 1 tablet in the evening</td>
<td>![Table Schedule]</td>
</tr>
<tr>
<td>Take two tablets by mouth twice daily.</td>
<td>Take 2 tablets in the morning, And 2 tablets at bedtime</td>
<td></td>
</tr>
</tbody>
</table>
Findings.

- 96% of patients correctly interpreted UMS + explicit instructions
- 3x greater comprehension of UMS instructions vs. standard label instructions
  (ARR 3.01, 95% CI 1.97 – 4.42)
- Explicit instructions only better than standard, not UMS
  (87%; ARR 1.51, 95% CI 1.11 – 2.77)
- Improvement solely on 2 or 3x daily schedules
  (40% of US prescriptions)
<table>
<thead>
<tr>
<th>Original Message</th>
<th>Revised Message</th>
<th>Icon</th>
</tr>
</thead>
<tbody>
<tr>
<td>SHAKE WELL. Before Using.</td>
<td>Shake well before using.</td>
<td>🥴</td>
</tr>
<tr>
<td>Warning: Do not use if you are pregnant, suspect that you are pregnant, or while breast feeding. Consult your doctor or pharmacist.</td>
<td>Do not use if you are pregnant, think you are pregnant, or breast feeding.</td>
<td>🍼</td>
</tr>
<tr>
<td>Take with food or milk.</td>
<td>Take with food or milk.</td>
<td>🍳</td>
</tr>
<tr>
<td>Do not drink alcoholic beverages when taking this medication.</td>
<td>Do not drink alcohol.</td>
<td>🍸</td>
</tr>
<tr>
<td>You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medicine.</td>
<td>Limit your time in the sun.</td>
<td>☀️</td>
</tr>
<tr>
<td>For external use ONLY.</td>
<td>Use only on your skin.</td>
<td>⚠️</td>
</tr>
<tr>
<td>May cause drowsiness. Alcohol may intensify this effect. Use care when operating a car or dangerous machinery.</td>
<td>May cause drowsiness. Be careful when driving a car or using machinery.</td>
<td>🚗</td>
</tr>
<tr>
<td>Obtain medical advice before taking nonprescription drugs. Some may affect the action of this medicine.</td>
<td>Talk to your doctor before using any over-the-counter drugs.</td>
<td>🔍</td>
</tr>
<tr>
<td>It is very important that you take or use this exactly as directed. Do not skip doses or discontinue unless directed by your doctor.</td>
<td>Do not stop taking unless directed by your doctor.</td>
<td>🏥</td>
</tr>
<tr>
<td>To control your blood pressure take regularly, do not continue unless directed by your doctor.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Improving Rx Warnings.

Do not drink alcohol

Webb et al., Patient Education and Counseling, 2008
Summary.

• Current system of patient Rx info is inadequate

• Prescribing/dispensing variability a likely root cause of errors and ADEs

• View all aspects of Rx labeling as an integrated system of patient information

• Seek improvement, set evidence–based standards

Support not Replace Physician/Pharmacist Counseling
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