Health Literacy & Medication Safety

A Pediatrics Perspective

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Overview.

I. Medication Errors in the U.S.

II. The Patient Side of Safety

II. The ACPF/IOM Drug Labeling Initiative

II. Improving Consumer Medication Information

II. Additional Challenges
I. Medication Errors in U.S.
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 annually²

• 1 in 6 children taking an Rx drug will experience a medication dosing error

¹Institute of Medicine, Preventing Medication Error, 2006
II. Patient Side of Safety
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?
93 million U.S. adults (43%) have limited literacy skills
# Pediatric Dosage Chart

**Drops, Syrup, & Chewables**

<table>
<thead>
<tr>
<th>Age</th>
<th>Approximate Weight Range*</th>
<th>Drops</th>
<th>Syrup</th>
<th>Chewables 80 mg</th>
<th>Chewables 160 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>† Under 3 mo</td>
<td>Under 13 lb</td>
<td>½ dropper</td>
<td>¼ tsp</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>† 3 to 9 mo</td>
<td>13-20 lb</td>
<td>1 dropper</td>
<td>½ tsp</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>† 10 to 24 mo</td>
<td>21-26 lb</td>
<td>1½ droppers</td>
<td>¾ tsp</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>2 to 3 yr</td>
<td>27-35 lb</td>
<td>2 droppers</td>
<td>1 tsp</td>
<td>2 tablets</td>
<td>—</td>
</tr>
<tr>
<td>4 to 5 yr</td>
<td>36-43 lb</td>
<td>3 droppers</td>
<td>1½ tsp</td>
<td>3 tablets</td>
<td>1½ tablets</td>
</tr>
<tr>
<td>6 to 8 yr</td>
<td>44-62 lb</td>
<td>—</td>
<td>2 tsp</td>
<td>4 tablets</td>
<td>2 tablets</td>
</tr>
<tr>
<td>9 to 10 yr</td>
<td>63-79 lb</td>
<td>—</td>
<td>2½ tsp</td>
<td>5 tablets</td>
<td>2½ tablets</td>
</tr>
<tr>
<td>11 yr</td>
<td>80-89 lb</td>
<td>—</td>
<td>3 tsp</td>
<td>6 tablets</td>
<td>3 tablets</td>
</tr>
<tr>
<td>12 yr and older</td>
<td>90 lb &amp; over</td>
<td>—</td>
<td>3-4 tsp</td>
<td>6-8 tablets</td>
<td>3-4 tablets</td>
</tr>
</tbody>
</table>

† Consult with physician before administering to children under the age of 2 years.

Dosage may be given every 4 hours as needed but not more than 5 times daily.

How Supplied:

- **Drops:** Each 0.8 ml dropper contains 80 mg (1.23 grains) acetaminophen.
- **Syrup:** Each 5 ml teaspoon contains 160 mg (2.46 grains) acetaminophen.
- **Chewables:** Regular tablets contain 80 mg (1.23 grains) acetaminophen each. Double strength tablets contain 160 mg (2.46 grains) acetaminophen each.

* If child is significantly under or overweight, dosage may need to be adjusted accordingly.

The weight categories in this chart are designed to approximate effective dose ranges of 10-15 milligrams per kilogram. (Current Pediatric Diagnosis and Treatment. 8th ed. CH Kempe and HK Silver, ed. Lange Medical Publications: 1984, p. 1079)
Education Disparities: It Begins with Kids

High School Drop Out Rates in 2005*:
- 6% White
- 10% Black
- 22% Hispanic

*16-24 year olds w/o H.S. diploma or equivalent.

Source: U.S. Department of Education, National Center for Education Statistics

A Health Literacy Perspective.

- Simplify the health care experience
- Support comprehension, action
- Maintain communication

Health Literacy = Patient-Centered Care
III. A Broken System

Findings of the IOM/ACPF Drug Labeling Advisory Committee
IOM/ACPF Rx Advisory Committee.

Co-Chairs:
Michael S. Wolf, PhD, MPH  Feinberg School of Medicine, Northwestern University
Ruth M. Parker, MD  Emory University School of Medicine

Members:
Carolyn Clancy, MD  Agency for Healthcare Research and Quality
Frank Frederico, RPh  Institute for Healthcare Improvement
Charles Ganley, MD  Food and Drug Administration
William H. Shrank, MD  MSHS Brigham and Women’s Hospital; Harvard Medical School
Scott Smith, PhD PharmD  Agency for Healthcare Research and Quality
Roger Williams, MD  U.S. Pharmacopeia
Alastair Wood, MD  Symphony Capital, LLC
Albert Wu, MD MPH  Johns Hopkins Bloomberg School of Public Health

ACPF Staff:
Robert L. Harnsberger, MBA, VP/COO  American College of Physicians Foundation
Jean A. Krause, EVP/CEO  American College of Physicians Foundation

IOM Staff:
Rose Martinez, PhD  Institute of Medicine

Acknowledgements:
John Swann, PhD  Food and Drug Administration
Diane Wendt  Smithsonian Institution
Committee Charge

• Investigate current system for patient Rx communication

• Primary target: Rx labeling

• Describe problem(s) → identify root causes → consider steps for improvement

Seek a Standard and Integrated System of Patient Medication Information
7 Primary Findings.

1. Many patients and families have an inadequate understanding of Rx regimens.
Value of Rx Labels

- Tangible
- Brief
- Repeatedly used
- Only source for many
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Value of Rx Labels

- Tangible
- Brief
- Repeatedly used
- Only source for many

54%

Davis, et al., J Gen Intern Med, 2006
Value of Rx Labels

- Tangible
- Brief
- Repeatedly used
- Only source for many


54% < 10% read them
7 Primary Findings.

1. Many patients and families have an inadequate understanding of Rx regimens
2. Lack of standards for consumer medication information places patients at risk for error.
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.

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

Take one tablet orally once every day.

Take 1 tablet by mouth every morning.

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>Dosage</th>
<th>Indication</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Lipitor 10 mg tabs  | Take one tab QD | for high cholesterol | - "Take one tablet daily."
- "Take 1 tablet by mouth for high cholesterol."
- "Take one (1) tablet(s) by mouth once a day."
- "Take one tablet by mouth every day for high cholesterol." |
| Fosamax 5 mg tabs   | Take one tab QD | osteoporosis prevention | - "Take 1 tablet by mouth daily."
- "Take one tablet by mouth every day for osteoporosis prevention. Do not lie down for at least 30 minutes after taking."
- "Take 1 tablet every day, 30 minutes before breakfast with a glass of water. Do not lie down."
- "Take one tablet every day.” |
| Bactrim DS tabs     | Take one tab BID | UTI                        | - "Take one tablet by mouth twice daily for UTI"
- "Take one tablet by mouth twice daily for urinary tract infection."
- "Take 1 tablet by mouth 2 times a day."
- "Take 1 tablet twice daily for 3 days.” |
| Ibuprofen 200 mg tabs | Take 1-2 tabs TID PRN pain | pain | - “Take 1 to 2 tablets by mouth as needed for pain."
- "Take 1 to 2 tablets by mouth three times daily as needed for pain."
- "Take 1 to 2 tablets by mouth as needed for pain ** Not to exceed 4 times a day”
- "Take 1 to 2 tablets 3 times a day as needed for pain.” |

*Wolf, et al., in press, Medical Care, 2008*
A Step Back in Time.

- Problem dates back 50+ years
- Durham-Humphrey Amendment (1951) Labeling for OTC drugs regulated by FDA but less attention to Rx drug labeling
- Assumes physician adequately counsels patients on prescribed meds
7 Primary Findings.

1. Many patients and families have an inadequate understanding of Rx regimens
2. Lack of standards for consumer medication information places patients at risk for error.
3. Several ‘best practices’ are already known.

Provider Perspective
7 Primary Findings.

1. Many patients and families have an inadequate understanding of Rx regimens.
2. Lack of standards for consumer medication information places patients at risk for error.
3. Several ‘best practices’ are already known.
4. Patients need clear, concise ‘sig’ instructions.
Patient Dosage Instructions (‘Sig’).

- Tailored directions, only on container
- Seemingly simple, often unclear
- Require patients to interpret dosage times
- Best practices known!
Patient Dosage Instructions (‘Sig’).

- Tailored directions, only on container
- Seemingly simple, often unclear
- Require patients to interpret dosage times
- Best practices known!

Take two tablets by mouth twice daily
Patient Dosage Instructions (‘Sig’).

- Tailored directions, only on container
- Seemingly simple, often unclear
- Require patients to interpret dosage times
- Best practices known!

Take two tablets by mouth twice daily
Take 2 tablets in the morning, and 2 tablets at bedtime.
7 Primary Findings.

1. Many patients and families have an inadequate understanding of Rx regimens
2. Lack of standards for consumer medication information places patients at risk for error.
3. Several ‘best practices’ are already known.
4. Patients need clear, concise ‘sig’ instructions.
5. Consumer medication information should be viewed as an integrated system.
Standardize Rx Information.

- On the Bottle
- Package Inserts
- Patient Information Leaflets
- Med Guides
7 Primary Findings.

1. Many patients and families have an inadequate understanding of Rx regimens.
2. Lack of standards for consumer medication information places patients at risk for error.
3. Several ‘best practices’ are already known.
4. Patients need clear, concise ‘sig’ instructions.
5. Consumer medication information should be viewed as an integrated system.
6. Improve healthcare provider counseling.
Standardize Rx Information.

Improve Prevalence and Quality of Verbal Patient Counseling
7 Primary Findings.

1. Many patients and families have an inadequate understanding of Rx regimens.
2. Lack of standards for consumer medication information places patients at risk for error.
3. Several ‘best practices’ are already known.
4. Patients need clear, concise ‘sig’ instructions.
5. Consumer medication information should be viewed as an integrated system.
6. Improve healthcare provider counseling.
7. Call for more research to advance science.
IV. Improving Rx Information
Enhanced Label Prototype

Amoxicillin 250 mg 10/22/08
Take For: Ear infection

Patient: Henry Wolf
DOB: 05/17/05
Doctor: Ruth Parker, MD
Quantity: 30 Refills: 0
Discard After: 08/31/09
Pharmacy: NoVA ScriptsCentral (716) 555-1212
Refer to Rx #: 723-4451-03 Rx only

Take:
1 teaspoon in morning
1 teaspoon at noon
1 teaspoon in evening

Morning Noon Evening Bedtime
1 1 1 |

Important!
- Take with meals
- Take all of this medicine
- Please review handout for more information

DOB: 05/17/05

Enhanced Precription Drug Label Design to Support Patient Understanding and Use (R01 HS017687-01; PI Wolf)
## 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></td>
</tr>
<tr>
<td>Take one tablet by mouth three times daily.</td>
<td>Take 1 tablet in the morning</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 tablet at noon</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 tablet in the evening</td>
<td></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.

Webb et al., Patient Education and Counseling, 2008
Patient-Friendly Prescriptions

- Standardize ‘sigs’
- Generate Rx info using EHR
- Structure MD counseling
- Ensure families leave with clear/concise Rx info

Promoting Health Literacy for Newly Prescribed Medications via the EMR; R21 CA13277; PI Wolf

Using IT for Patient-Centered Communication and Decision Making about Medications R18 HS17220; PI: Wolf

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You Have a New Medication

Date: August 1, 2008
Name: John Doe
Doctor: David Baker, MD

Please read the information below. This tells you how to take your medicine.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Lipitor®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generic Name</td>
<td>Atorvastatin (a TORE va sta tin)</td>
</tr>
<tr>
<td>Purpose</td>
<td>This medication can lower “bad” cholesterol.</td>
</tr>
<tr>
<td>Benefit</td>
<td>It can help prevent a heart attack or stroke.</td>
</tr>
<tr>
<td>How to Take</td>
<td>Take 1 tablet by mouth at bedtime.</td>
</tr>
</tbody>
</table>

For How Long

You may need to be on this medication for the rest of your life.

Call Your Doctor

If you have any of these symptoms for more than 1 week:
- Headaches
- Stomach pain
- Diarrhea

Stop Taking and Call Your Doctor

If you ever have:
- Muscle pain
- Muscle weakness
- Joint pain

Important!

- Take this medicine only the way your doctors tells you.
- Tell your doctor or pharmacist if you are pregnant, think you are pregnant, or breastfeeding. You should not take this medicine.
- If you take over-the-counter medicines every day, tell your doctor.
- Limit how much grapefruit juice you drink every day.

Please call NoVA ScriptsCentral Pharmacy at (123) 456-7890 if you have questions or concerns.

These websites can tell you more about your medicine:
NYU Leading National Efforts.

Innovation in Pediatric Rx Dosing Instruction Sheets

Yin, Dreyer, van Schieck, Arch Pediatr Adol Med 2008
V. Other Challenges
Language Concordance
Bailey, et al.

• National Pharmacy Survey (CO, TX/GA, NC)

• 56% limited/no translation capability

• Problem not limited to rural, fewer Latino areas

Over-the-Counter Drug Info
### Drug Facts

**Active ingredient (in each tablet)**
Chlorpheniramine maleate 2 mg  
**Purpose**  
Antihistamine

**Uses**
temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:  
- sneezing  
- runny nose  
- itchy, watery eyes  
- itchy throat

**Warnings**
Ask a doctor before use if you have  
- glaucoma  
- a breathing problem such as emphysema or chronic bronchitis  
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

**When using this product**
- You may get drowsy  
- avoid alcoholic drinks  
- alcohol, sedatives, and tranquilizers may increase drowsiness  
- be careful when driving a motor vehicle or operating machinery  
- excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.  
**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

<table>
<thead>
<tr>
<th>Adults and children 12 years and over</th>
<th>take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children 6 years to under 12 years</td>
<td>take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours</td>
</tr>
<tr>
<td>Children under 6 years</td>
<td>ask a doctor</td>
</tr>
</tbody>
</table>

**Other information**
store at 20-25°C (68-77°F)  
- protect from excessive moisture

**Inactive ingredients**
D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch
Drug Facts

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Is this clear?
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Inactive ingredients  D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch
Medication Reconciliation...
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
Contact Information:

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