




# The Importance of Communication in Improving Patient Safety




## A Health Literacy Agenda





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Associate Professor, Medicine & Learning Sciences  
Associate Division Chief, General Internal Medicine  
Health Literacy and Learning Program  
Northwestern University



The speaker has no conflict to disclose.

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**Linking Medicine to:**

- Cognitive Psychology
- Communication
- Human Factors/Engineering
- Learning Sciences/Education
- Marketing/Management
- Neuropsychology

**HeLP**  
HEALTH LITERACY AND LEARNING PROGRAM  
Feinberg School of Medicine  
Northwestern University



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# Overview.

- I. Medication Errors in the U.S.
- II. The Patient Side of Safety
- III. The ACPF/IOM Drug Labeling Initiative
- IV. Improving Patient Communication
- V. Additional Challenges

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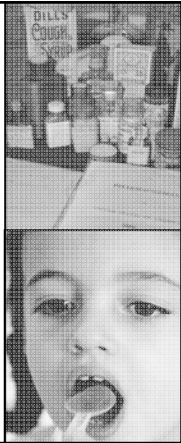
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## I. Medication Errors in U.S.

### Medication Error.

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

<sup>1</sup>Institute of Medicine. Preventing Medication Error, 2006  
<sup>2</sup>Cohen, Budnitz, Weidenbach, et al. J Ped 2008



## 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?



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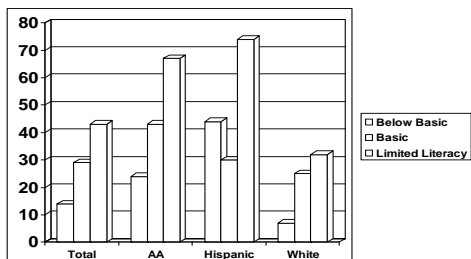
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### Health Literacy Skills of U.S. Adults

National Assessment of Adult Literacy (2003)



93 million U.S. adults (43%) have limited literacy skills

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### Health Literacy: What We Know

- Use of preventive services
- Delayed diagnoses
- Understanding of medical condition
- Adherence to medical instructions
- Self-management skills
- Risk of hospitalization
- Physical and mental health
- Mortality risk
- Greater health care costs

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## A patient problem?




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## ... or a health system problem?

**Pediatric Dosage Chart - Drops, Syrup, & Chewables**

| Age             | Approximate Weight Range* | Drops          | Syrup     | Chewables 80 mg | Chewables 100 mg |
|-----------------|---------------------------|----------------|-----------|-----------------|------------------|
| 1 Under 3 mo    | Under 12 lb               | 1/2 dropper    | 1/2 tsp   | ---             | ---              |
| 1 3 to 6 mo     | 12-20 lb                  | 1 dropper      | 1/2 tsp   | ---             | ---              |
| 1 6 to 12 mo    | 21-28 lb                  | 1 1/2 droppers | 1/2 tsp   | ---             | ---              |
| 2 to 3 yr       | 27-35 lb                  | 2 droppers     | 1 tsp     | 2 1/2           | 3 1/2            |
| 4 to 5 yr       | 36-43 lb                  | 3 droppers     | 1 1/2 tsp | 3 1/2           | 4 1/2            |
| 6 to 8 yr       | 44-62 lb                  | ---            | 2 tsp     | 4 1/2           | 5 1/2            |
| 9 to 10 yr      | 63-79 lb                  | ---            | 2 1/2 tsp | 5 1/2           | 6 1/2            |
| 11 yr           | 80-100 lb                 | ---            | 3 tsp     | 6 1/2           | 7 1/2            |
| 12 yr and older | 90 lb & over              | ---            | 3-4 tsp   | 6-8             | 7-9              |

\*Always use dosage table information as a guide only. For use of 2 years. Dosage may be given every 4 hours as needed but not more than 9 in 24 hours.

Drops: Each 0.8 mL dropper contains 80 mg (0.25 grams) acetaminophen.  
Syrup: Each 5 mL suspension contains 160 mg (0.48 grams) acetaminophen.  
Chewables: Regular tablets contain 80 mg (0.25 grams) acetaminophen.

**CLINIC APPOINTMENT**

CLINIC: Pediatric LOCATION: 1st floor  
DATE: Thurs. DATE: April 2nd HOUR: 10:30 p.m.  
Issued by: \_\_\_\_\_

YOU MUST BRING YOUR PLASTIC CARD WITH YOU

Compensation: Variable Salary

**ARE YOU ELIGIBLE FOR SSI?**

**WHAT IS SSI?**

SSI is a federal cash benefit for people who are aged, blind, or disabled and have limited income and resources. It is paid to people who are unable to work and have no other income.

**HOW MUCH CAN YOU GET?**

The amount of SSI you can get depends on your state. In 2013, the maximum federal benefit was \$795 per month. Some states add a supplement to the federal benefit. The total amount you can get is the federal benefit plus the state supplement.

**OTHER RULES YOU SHOULD KNOW**

You must be a U.S. citizen or a qualified alien to receive SSI. You must live in one of the 48 contiguous states, the District of Columbia, or Puerto Rico. You must be under 65 years old. You must have limited income and resources. You must be unable to work because of age, blindness, or disability.

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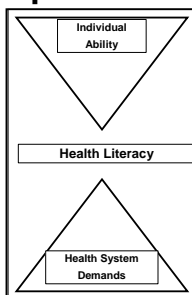
## A Health Literacy Perspective.

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

Clear  
Concise  
Consistent

 communication

Health Literacy = Patient-Centered Care




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### III. A Broken System

Findings of the IOM/ACPF Drug Labeling Advisory Committee

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### 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*

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### 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

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## 7 Primary Findings.

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

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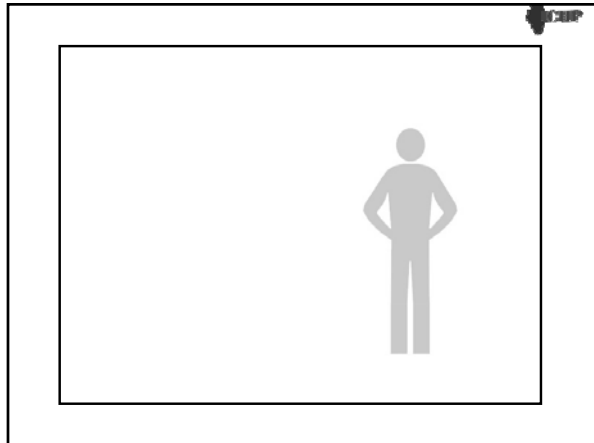
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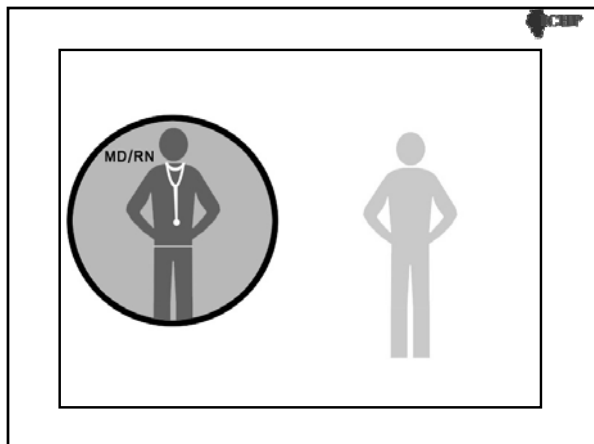
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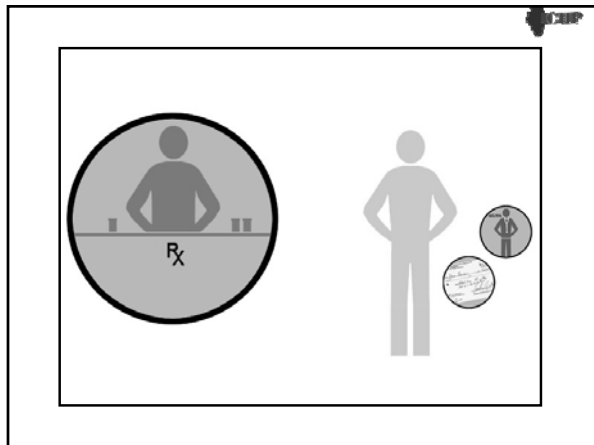
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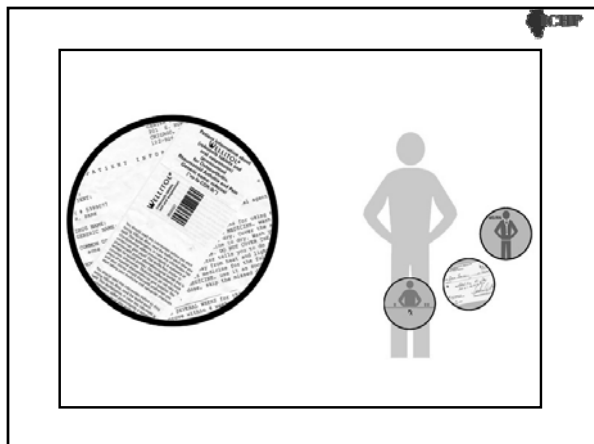
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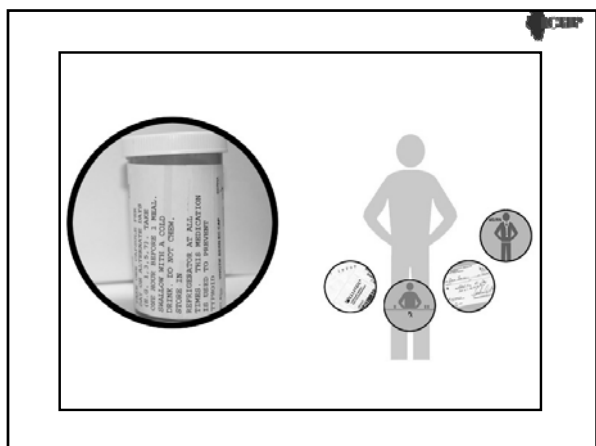
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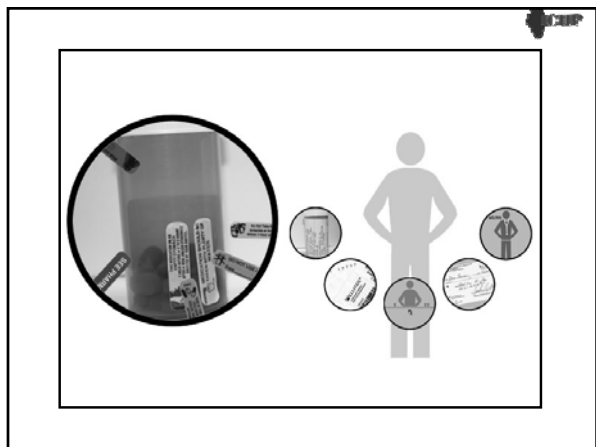
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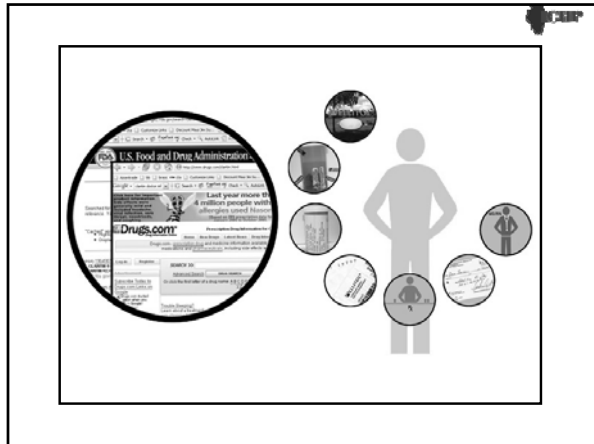
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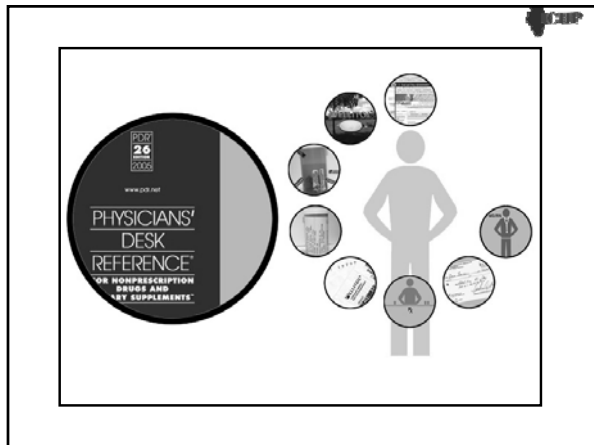
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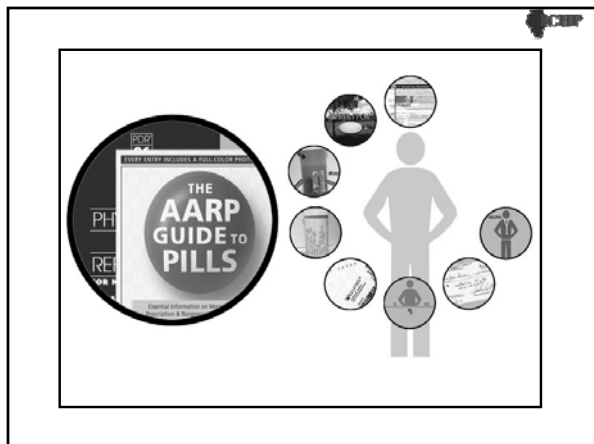
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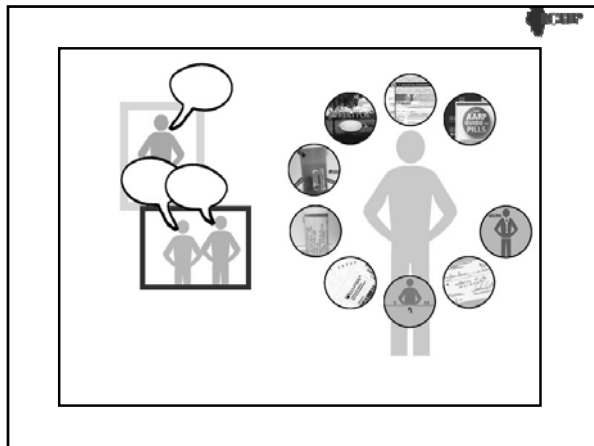
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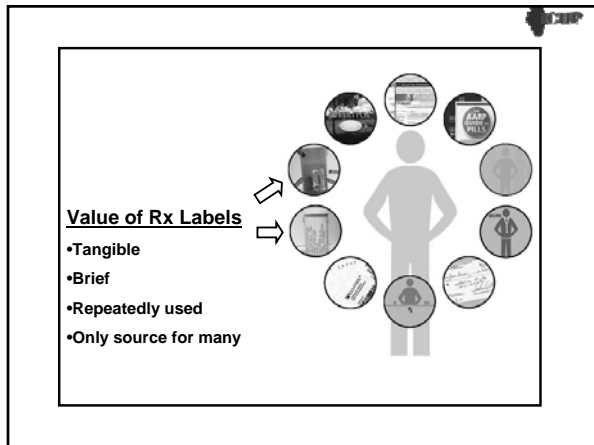
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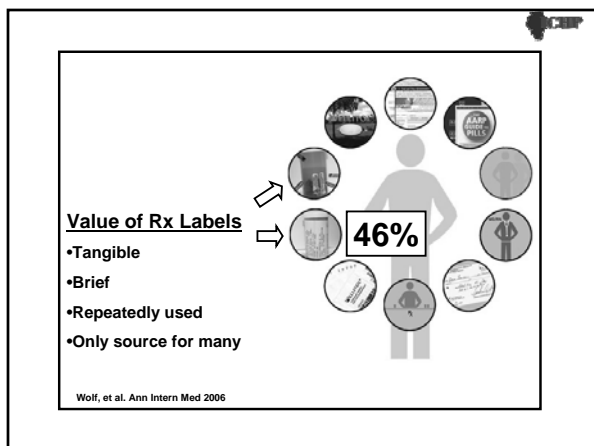
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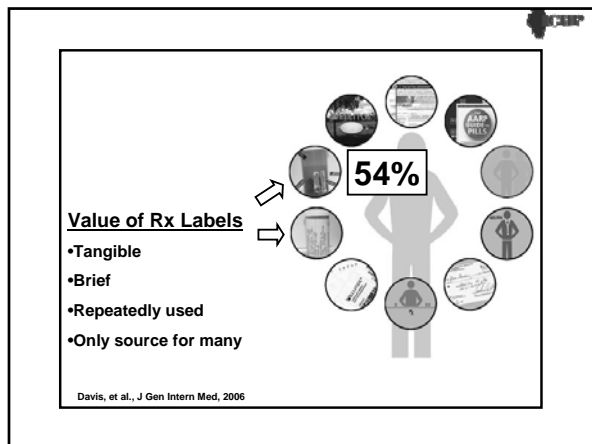
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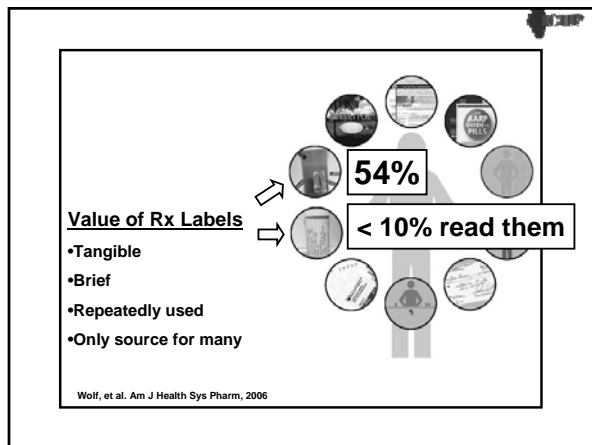
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- ## 7 Primary Findings.
1. Many patients and families have an inadequate understanding of Rx regimens
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## Beyond the Patient...A Broken System.

- 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

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## 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.*

Bailey, et al., Annals of Pharmacotherapy, 2009

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## Dispensing Variability.

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

Wolf, et al., Medical Care, March 2009

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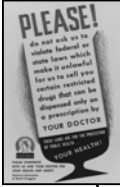
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## A Step Back in Time.

- 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



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## 7 Primary Findings.

1. Many patients and families have an inadequate understanding of Rx regimens
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3. Several 'best practices' are already known.

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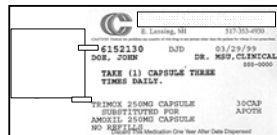
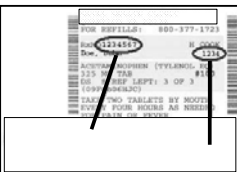
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## Current Practices not Optimal.



Provider Perspective

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### Patient Dosage Instructions ('Sig').

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

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### Patient Dosage Instructions ('Sig').

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Take two tablets by mouth twice daily

Take 2 tablets in the morning, and  
Take 2 tablets at bedtime.

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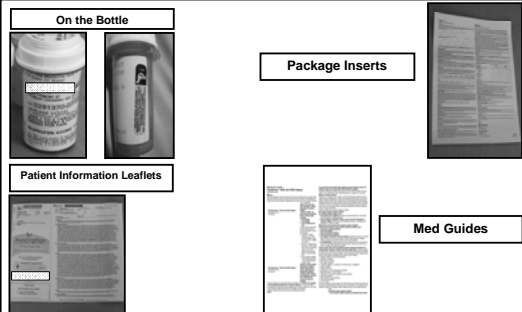
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### Standardize Rx Information.



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6. Improve healthcare provider counseling.

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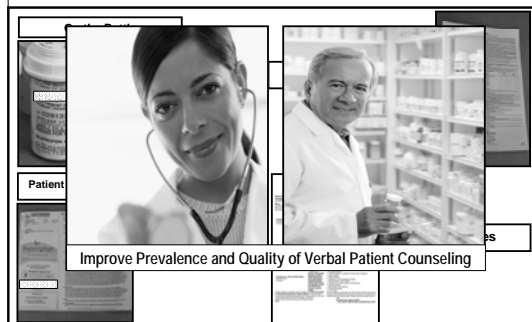
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## Standardize Medication Information.



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5. Consumer medication information should be viewed as an integrated system.
6. Improve healthcare provider counseling.
7. Call for more research to advance science.

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## IV. Improving Consumer Medication Information











### Enhanced Label Prototype

| <b>MICHAEL WOLF</b> 04/29/71<br><b>GLYBURIDE 5 mg</b><br>Take for <u>Diabetes</u><br><b>TAKE 2 PILLS AT BREAKFAST</b><br><b>2 PILLS AT DINNER</b>              |           | Rx #: 1234567 10/30/2008<br>You have 11 refills<br>180 pills<br>Discard after 10/30/2009<br>Provider: RUTH PARKER, MD<br>Emory Medical Center<br>(404) 123-4567<br>Pharmacy: NOVA ScriptCentral<br>11445 Sunbelt Blvd.<br>Roswell, VA<br>(713) 123-4567<br>NDC #: 1234567 | • Take with food<br>• Do not drink alcohol while taking this medicine<br>• Limit your time in the sun |         |   |  |   |  |  |  |  |
|--|-----------|---|---|---------|---|--|---|--|--|--|--|
| <table border="1"> <tr> <th>Breakfast</th> <th>Lunch</th> <th>Dinner</th> <th>Bedtime</th> </tr> <tr> <td>2</td> <td></td> <td>2</td> <td></td> </tr> </table> | Breakfast | Lunch   | Dinner  | Bedtime | 2 |  | 2 |  |  |  |  |
| Breakfast  | Lunch     | Dinner  | Bedtime   |         |   |  |   |  |  |  |  |
| 2  |           | 2   |   |         |   |  |   |  |  |  |  |

  
 Primary Patient Info

  
 Supplemental

  
 Precautions

| Original Message   | Revised Message  | Icon  |
|--|--|---|
| SHAKE WELL. Before Using.  | Shake well before using.   |  |
| Warning: Do not use if you are pregnant, suspect that you are pregnant, or while breast feeding. Consult your doctor or pharmacist.  | Do not use if you are pregnant, think you are pregnant, or breast feeding. |  |
| Take with food or milk.  | Take with food or milk.  |  |
| Do not drink alcoholic beverages when taking this medication.  | Do not drink alcohol.  |  |
| You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medicine.                    | Limit your time in the sun.  |  |
| For external use ONLY.   | Use only on your skin.   |  |
| May cause drowsiness. Alcohol may intensify this effect. Use care when operating a car or dangerous machinery.                       | May cause drowsiness. Be careful when driving a car or using machinery.    |  |
| Obtain medical advice before taking nonprescription drugs. Some may affect the action of this medicine.                              | Talk to your doctor before using any over-the-counter drugs.               |  |
| It is very important that you take or use this exactly as directed. Do not skip doses or discontinue unless directed by your doctor. | Do not stop taking unless directed by your doctor.                         |  |
| To control your blood pressure take regularly, do not continue unless directed by your doctor.                                       |  |  |

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### 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*

#### 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.

|                                  |  |
|----------------------------------|--|
| Drug Name                        | Lipitor®   |
| Generic Name                     | Atorvastatin (a TORIC va sta tin)  |
| Purpose                          | This medication can lower "bad" cholesterol.   |
| Benefit                          | It can help prevent a heart attack or stroke.  |
| How to Take                      | Take 1 tablet by mouth at bedtime.   |
| 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:<br>• Headaches<br>• Stomach pain<br>• Diarrhea   |
| Stop Taking and Call Your Doctor | If you ever have:<br>• Muscle pain<br>• Muscle weakness<br>• Joint pain  |
| Important!                       | <ul style="list-style-type: none"> <li>Take this medicine only the way your doctors tells you.</li> <li>Tell your doctor or pharmacist if you are pregnant, think you are pregnant, or breastfeeding. You should not take this medicine.</li> <li>If you take over-the-counter medicines every day, tell your doctor.</li> <li>Limit how much grapefruit juice you drink every day.</li> </ul> |

Please call Northrup Central Pharmacy at (825) 458-7899 if you have questions or concerns.

These websites can tell you more about your medicine:  
[www.atozdrugs.com](http://www.atozdrugs.com) and [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

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| Mariva   | Mariva   |
|--|--|
| <p>Information on your prescription for</p> <p><b>Amoxicillin</b></p> <p>See an indication of the local</p> <p><b>0.5 ml, 120 mg/ml suspension</b> must be taken <b>4 times a day for 10 days</b></p>  <p>Take with water</p>  <p>Take 1/2 measure of glass of water</p>  <p>Take 1/2 measure of glass of water</p>  <p>Take 1/2 measure of glass of water</p>  <p>Take 1/2 measure of glass of water</p>  <p>Take 1/2 measure of glass of water</p>  <p>Take 1/2 measure of glass of water</p>  <p>Take 1/2 measure of glass of water</p>  <p>Take 1/2 measure of glass of water</p>  <p>Take 1/2 measure of glass of water</p>  <p>Take 1/2 measure of glass of water</p>  <p>Take 1/2 measure of glass of water</p> | <p>Information about the medicine you are taking</p> <p><b>Amoxicillin</b></p> <p>Take this medicine with or without food</p> <p><b>0.5 ml, 120 mg/ml suspension</b> must be taken <b>4 times a day for 10 days</b></p>  <p>Take with water</p>  <p>Take 1/2 measure of glass of water</p>  <p>Take 1/2 measure of glass of water</p>  <p>Take 1/2 measure of glass of water</p>  <p>Take 1/2 measure of glass of water</p>  <p>Take 1/2 measure of glass of water</p>  <p>Take 1/2 measure of glass of water</p>  <p>Take 1/2 measure of glass of water</p> |

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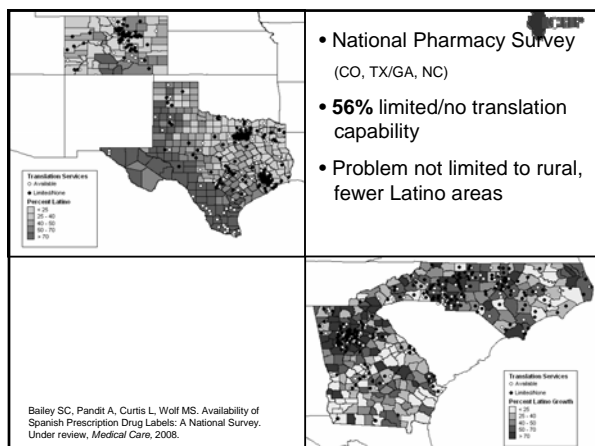
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## Over-the-Counter Drug Info

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Is this adequate?

### 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**

|                                       |  |
|---------------------------------------|--|
| adults and children 12 years and over | take 2 tablets every 4 to 6 hours;<br>not more than 12 tablets in 24 hours |
| children 6 years to under 12 years    | take 1 tablet every 4 to 6 hours;<br>not more than 6 tablets in 24 hours   |
| children under 6 years                | ask a doctor   |

**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

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# Drug Facts

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

**Uses** Temporarily relieves these symptoms due to hay fever or other 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**

adults and children 12 years and over

children 6 years to under 12 years

children under 6 years

|  |
|--|
| take 2 tablets every 4 to 6 hours;<br>not more than 12 tablets in 24 hours |
| take 1 tablet every 4 to 6 hours;<br>not more than 6 tablets in 24 hours   |
| ask a doctor   |

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

**Inactive ingredients** D&C yellow no. 15, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

|  |                                 |
|--|---------------------------------|
| <b>Drug Facts</b>  |                                 |
| <b>Active ingredient (in each tablet)</b><br>Chlorpheniramine maleate 2 mg   | <b>Purpose</b><br>Antihistamine |
| <b>Uses</b> Temporarily relieve these symptoms due to hay fever or other respiratory allergen:<br>• sneezing    • runny nose    • itchy watery eyes    • itchy throat  |                                 |
| <b>Warnings</b><br>Ask a doctor before use if you have<br>• glaucoma    • a breathing problem such as emphysema or chronic bronchitis<br>• trouble urinating due to an enlarged prostate gland   |                                 |
| <b>Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives</b>  |                                 |
| <b>When using this product</b><br>• You may get drowsy    • avoid alcoholic drinks<br>• alcohol, sedatives, and tranquilizers may increase drowsiness<br>• be careful when driving a motor vehicle or operating machinery<br>• excitability may occur, especially in children<br>If pregnant or breast-feeding, ask a health professional before use.<br>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. |                                 |
| <b>Directions</b><br>adults and children 12 years and over<br>take 2 tablets every 4 to 6 hours;<br>not more than 12 tablets in 24 hours<br>children 6 years to under 12 years<br>take 1 tablet every 4 to 6 hours;<br>not more than 6 tablets in 24 hours<br>children under 6 years<br>ask a doctor   |                                 |
| <b>Other information</b> store at 20-25° C (68-77° F) • protect from excessive moisture  |                                 |
| <b>Inactive ingredients</b> D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch  |                                 |

- Current system of consumer medication information is inadequate

- **Variability and poor quality a likely root cause of errors and ADEs**
- **View all aspects of drug labeling as an integrated system of patient information**
- **Seek improvement, set evidence-based standards**

### Support not Replace Physician/Pharmacist Counseling



## First Step to Action is Understanding

**This report, by its very length, defends itself  
against the risk of being read.**

- Winston Churchill

**Broadly speaking, the short words are the  
best, and the old words best of all.**

- Winston Churchill

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## First Step to Action is Understanding

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