The Importance of Communication in Improving Patient Safety

A Health Literacy Agenda

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The speaker has no conflict to disclose.

Linking Medicine to:
- Cognitive Psychology
- Communication
- Human Factors/Engineering
- Learning Sciences/Education
- Marketing/Management
- Neuropsychology

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
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 annually\(^2\)
- 1 in 6 children taking an Rx drug will experience a medication dosing error

\(^1\)Institute 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?

Abilities Vary…

Health Literacy Skills of U.S. Adults

National Assessment of Adult Literacy (2003)

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

... or a health system problem?

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 Garley, MD, Food and Drug Administration
- William H. Groth, MD, Massachusetts General 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:
- Michael L. Farnonberger, MBA, VP/CEO, American College of Physicians Foundation
- Jean A. Krause, EVP/CEO, American College of Physicians Foundation

IOM Staff:
- Rose Martinez, PhD, Institute of Medicine

Acknowledgements:
- 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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For: et al., J Gen Intern Med, 2006

Value of Rx Labels
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<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.

Lipitor 10 mg tabs
Take one tab QD
Dispense #30
Indication: for high cholesterol
No refills

- “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
Dispense #30
Indication: osteoporosis prevention
Do not lie down for at least 30 minutes

- “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
Dispense #6
Indication: UTI
No refills

- “Take one tablet by mouth twice daily for UTI”
- “Take one tablet by mouth twice daily for urinary tract infection.”
- “Take 1 tablet every day, 2 times before breakfast with a glass of water. Do not lie down.”
- “Take one tablet twice daily.”

Ibuprofen 200 mg tabs
Take 1-2 tabs TID PRN pain
Dispense #30
No refills

- “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.”
- “Take 1 to 2 tablets 3 times a day as needed for pain.”

Dispensing Variability.

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


Wolf, et al., Medical Care, March 2009
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!

Take two tablets by mouth twice daily.
Take 2 tablets in the morning, and
Take 2 tablets at bedtime.
Patient Dosage Instructions ('Sig').

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4. Patients need clear, concise ‘sig’ instructions.
5. Consumer medication information should be viewed as an integrated system.

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

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6. Improve healthcare provider counseling.

Standardize Medication Information.

- On the Bottle
  - Patient Information Leaflets
  - Med Guides
  - Package Inserts

Improve Prevalence and Quality of Verbal Patient Counseling

7 Primary Findings.

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2. Lack of standards for consumer medication information places patients at risk for error.
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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 Consumer Medication Information

Enhanced Label Prototype

Original Message | Revised Message | Icon
---|---|---
SHAKE WELL. Before using. | Shake well before using. | ![icon]
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. | ![icon]
Take with food or milk. | Take with food or milk. | ![icon]
Do not drink alcoholic beverages when taking this medication. | Do not drink alcohol. | ![icon]
You should avoid prolonged or excessive exposure to direct or indirect sunlight while taking this medicine. | Limit your time in the sun. | ![icon]
Use only on your skin. | Use only on your skin. | ![icon]
May cause drowsiness. Alcohol may intensify this effect. Use care when operating a car or dangerous machinery. | May cause drowsiness. Be careful when driving or using machinery. | ![icon]
Seek medical advice before taking any prescription drugs. Some may affect the action of this medicine. | Talk to your doctor before using any over-the-counter drugs. | ![icon]
It is very important that you take as stated exactly as directed. Do not stop taking unless directed by your doctor. | Do not stop taking unless directed by your doctor. | ![icon]
We suggest your blood pressure be regularly, do not continue unless directed by your doctor. | | ![icon]
Old

DO NOT TAKE THIS DRUG IF YOU BECOME PREGNANT

New

Do not use if
- you are pregnant
- think you are pregnant
- breastfeeding

Patient-Friendly Prescriptions

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

You Have a New Medication

Name: John Doe
Rx: [Prescription Details]

- Important:
  - Use the medicine only as your doctor tells you.
  - Follow your doctor's instructions for using this medicine.
  - If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and go back to your regular schedule.

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
Other Notable Innovations.

Innovation in Pediatric Dosing
Instruction Sheets

V. Other Challenges

Language Concordance
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):
Ranitidine HCl (400 mg)

Purpose
- Reduce stomach acid for occasional acid indigestion, sour stomach, or heartburn

Warning
- Ask a doctor before use if you have:
  - Glucose 6-phosphate dehydrogenase deficiency
  - Uncommon or unusual bleeding
  - Abnormal vision

- If pregnant or breast feeding, ask a health professional before use.

Doseage:
- Adults and children 12 years and over: take 1 tablet every 4 to 6 hours, not more than 4 tablets in 24 hours.
- Children 6 years to under 12 years: take 1 tablet every 4 to 6 hours, not more than 3 tablets in 24 hours.
- Children under 6 years: ask a doctor.

Other information:
- Store at 30°C (86°F) and protect from excessive moisture.
- Use by the date on the bottle.

Canister: 30 tablets
- Includes directions and quantity available.
Summary.
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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