Health Literacy – Prescribing and Medication Management

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Patient Safety

*Medication error: most common medical mistake*

- 90 million Americans have trouble understanding & acting on health information
- Unfamiliar/complex text most difficult to read
- 3 billion Rx written a year
- Pharmacist/physician time is limited
- Elderly fill 30 Rx/year, see 8 physicians
- 2/3rds of all adults use prescription drugs
Medication Errors

• 2006 Institute of Medicine (IOM) Report, Preventing Medication Errors
  – >1/3rd of the 1.5 million adverse drug events in the US each year occur in outpatient settings
  – Poor patient understanding and unintentional misuse of Rx drugs (specifically poor understanding of drug labeling) is a root cause of med errors, poor adherence and poor health outcomes

• 2008 IOM, Standardizing Medication Labels
  – Greater attention on clarity of label instructions

Ref in Davis TC, et al. JGIM 2008; 24(1):57-62
<table>
<thead>
<tr>
<th>Adverse Drug Event†</th>
<th>Cases, No.</th>
<th>Annual Estimate, No. (%)</th>
<th>Hospitalizations*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergic reactions</td>
<td>6890</td>
<td>235,202 (33.5)</td>
<td></td>
</tr>
<tr>
<td>Intentional overdoses</td>
<td>7249</td>
<td>225,298 (32.1)</td>
<td></td>
</tr>
<tr>
<td>Adverse effects</td>
<td>5846</td>
<td>200,887 (28.6)</td>
<td></td>
</tr>
<tr>
<td>Secondary effects</td>
<td>669</td>
<td>24,371 (3.5)</td>
<td></td>
</tr>
<tr>
<td>Vaccine reactions</td>
<td>644</td>
<td>15,790 (2.3)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hospitalized, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.6</td>
</tr>
<tr>
<td>27.8</td>
</tr>
<tr>
<td>18.1</td>
</tr>
<tr>
<td>15.6</td>
</tr>
<tr>
<td>4.8</td>
</tr>
</tbody>
</table>

Over half of hospitalizations from unintended overdoses or supra-therapeutic drug levels

Prescription Warning Labels
Can Patients Comprehend Rx Drug Warning Labels?

NO!

Davis et al. JGIM 2006; 21: 847-851
Simple Familiar Wording Understood by Most Patients

84% (1st grade)

≤6th grade reading level = 78.4% (p=ns)

Davis et al. JGIM 2006; 21: 847-851
More Complex Message
Limited Comprehension

59%

(4th grade)

≤6th grade reading level = 36.5%  
(p<0.001)

Davis et al. JGIM 2006; 21: 847-851
Multi-step Instructions Rarely Understood

8% (10th grade)

≤6th grade reading level = 0% (p<0.001)
Patient Warning Labels

- Low literate patients 3 times more likely to mis-interpret Rx warning labels
  – could result in misuse of Rx
- Patients ≥ 65 yo more likely to mis-interpret labels
- Multi-step instructions are difficult for all patients regardless of literacy level
## Improving Patient Warning Labels

<table>
<thead>
<tr>
<th>Existing Message</th>
<th>Icon</th>
<th>%</th>
<th>Revised Message</th>
<th>Icon</th>
</tr>
</thead>
<tbody>
<tr>
<td>SHAKE WELL. Before using.</td>
<td>![Shake icon]</td>
<td>96</td>
<td>Shake well before using.</td>
<td>![Shake icon]</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>![Pregnancy icon]</td>
<td>96</td>
<td>Do not use if you are pregnant, think you are pregnant, or breast feeding.</td>
<td>![Pregnancy icon]</td>
</tr>
<tr>
<td>Take with food or milk.</td>
<td>![Milk icon]</td>
<td>94</td>
<td>Take with food or milk.</td>
<td>![Milk icon]</td>
</tr>
<tr>
<td>Do not drink alcoholic beverages when taking this medication.</td>
<td>![Alcohol icon]</td>
<td>84</td>
<td>Do not drink alcohol.</td>
<td>![Alcohol icon]</td>
</tr>
<tr>
<td>You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medicine.</td>
<td>![Sun icon]</td>
<td>82</td>
<td>Limit your time in the sun.</td>
<td>![Sun icon]</td>
</tr>
<tr>
<td>May cause drowsiness. Alcohol may intensify this effect. Use care when operating a car or dangerous machinery.</td>
<td>![Drowsiness icon]</td>
<td>51</td>
<td>May cause drowsiness. Be careful when driving a car or using machinery.</td>
<td>![Drowsiness icon]</td>
</tr>
<tr>
<td>For external use ONLY.</td>
<td>![External use icon]</td>
<td>49</td>
<td>Use only on your skin.</td>
<td>![External use icon]</td>
</tr>
<tr>
<td>Obtain medical advice before taking nonprescription drugs. Some may affect the action of this medicine.</td>
<td>![Medical advice icon]</td>
<td>43</td>
<td>Talk to your doctor before using any over-the-counter drugs.</td>
<td>![Medical advice icon]</td>
</tr>
</tbody>
</table>

Prescription Drug Labels
Understanding of Prescription Labels

• 2/3rds of U.S. adults ≥ 60 yo have inadequate or marginal literacy skills

• 81% of patients ≥ 60 yo at a public hospital could not read or understand basic materials such as prescription labels

Health Literacy; accessed Feb 27, 2009
Williams, MV. JAMA, December 6, 1995.
"How would you take this medicine?"

395 primary care patients in 3 states

- 46% did not understand instructions ≥ 1 labels
- 38% with adequate literacy missed at least 1 label

“Show Me How Many Pills You Would Take in 1 Day”

John Smith        Dr. Red

Take two tablets by mouth twice daily.

Humibid LA       600MG
1 refill

Rates of Correct Understanding vs. Demonstration “Take Two Tablets by Mouth Twice Daily”

Improving Understanding of Rx Drug Label Instructions

• Purpose: evaluate whether the use of more explicit language to describe the dose and frequency of prescribed drugs could improve comprehension, especially among patients with limited health literacy

• 359 patients

• 3 commonly prescribed meds
  – Glyburide, metformin, atenolol

• 10 mock pill bottles different dose and frequency

Improving Understanding of Rx Drug Label Instructions

- 3590 responses
- 839 (23% incorrect)
- 78% of patients misunderstood ≥ 1 label
  – 71% adequate
  – 84% marginal
  – 93% low

Low understanding with hourly intervals or times of day

- Take 1 pill by mouth every 12 hrs with a meal (53% correct)
- Take 2 tablets by mouth twice daily (61% correct)

Highest understanding with time periods

• Take 2 pills in the morning and 2 pills in the evening (89% correct)

• Take 1 pill by mouth every day. Take in the morning (89% correct)

# Results

<table>
<thead>
<tr>
<th>Drug/Label instruction</th>
<th>Literacy level</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adequate (n=195)</td>
<td>Marginal (n=109)</td>
</tr>
<tr>
<td>Atenolol, 50 mg</td>
<td>84</td>
<td>78</td>
</tr>
<tr>
<td>[Times per day] Take one tablet by mouth once daily.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>[Time periods] Take 1 pill by mouth every day. Take in the morning.</td>
<td>91</td>
<td>92</td>
</tr>
<tr>
<td>[Specific times] Take 1 pill by mouth every day. Take at 8 a.m.</td>
<td>86</td>
<td>83</td>
</tr>
<tr>
<td>Metformin, 1000 mg</td>
<td>61</td>
<td>51</td>
</tr>
<tr>
<td>[Hourly intervals] Take 1 pill by mouth every 12 hours.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>[Times per day] Take one tablet by mouth twice daily.</td>
<td>90</td>
<td>78</td>
</tr>
<tr>
<td>[Time periods] Take 2 pills by mouth every day. Take 1 with Breakfast and 1 with supper.</td>
<td>88</td>
<td>84</td>
</tr>
<tr>
<td>[Specific times] Take 2 pills by mouth every day. Take 1 at 8 A.M. and 1 at 5 P.M.</td>
<td>85</td>
<td>69</td>
</tr>
<tr>
<td>Glyburide, 5 mg</td>
<td>71</td>
<td>57</td>
</tr>
<tr>
<td>[Times per day] Take two tablets by mouth twice daily.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>[Time periods] Take 2 pills in the morning and 2 pills in the evening.</td>
<td>92</td>
<td>88</td>
</tr>
<tr>
<td>[Specific times] Take 2 pills by mouth at 8 a.m. and 2 pills at 6 P.M.</td>
<td>90</td>
<td>86</td>
</tr>
</tbody>
</table>

*Bracketed text indicates the classification of language used to state frequency of drug use*

Universal Medication Schedule

Roundtable on Health Literacy

5th Workshop

October 12, 2007; Washington, DC.

"Improving Prescription Drug Use Container Instructions: An Issue of Health Literacy and Medication Safety,"

http://www.iom.edu/CMS/3793/31487/43961.aspx
## Transcription of Rx to label
### Imperfect and Variable

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

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Wolf, et al., submitted 2007

Wolf MS et al. Medical Care 2009:47(3)370-373
Transcription of Rxs

- 85 Rx labels evaluated
- Dose frequency omitted on 6% of instructions
- Timing explicitly only stated on 2% of instructions
- Indications only transcribed onto 38% of labels
- Alendronate states not to lie down for at least 30 min after taking – only transcribed 50% of instructions
- Reading difficulty was above recommended levels for 46% of instructions
  - 14% greater than HS level

Wolf MS et al. Medical Care 2009:47(3)370-373
Patient’s day

BID Med & TID Med & QID Med

8 episodes/day!!!

<table>
<thead>
<tr>
<th>Time</th>
<th>AM</th>
<th>PM</th>
</tr>
</thead>
<tbody>
<tr>
<td>7am</td>
<td>X</td>
<td>4pm</td>
</tr>
<tr>
<td>8am</td>
<td>X</td>
<td>5pm</td>
</tr>
<tr>
<td>9am</td>
<td>X</td>
<td>6pm</td>
</tr>
<tr>
<td>10am</td>
<td></td>
<td>7pm</td>
</tr>
<tr>
<td>11am</td>
<td></td>
<td>8pm</td>
</tr>
<tr>
<td>Noon</td>
<td></td>
<td>9pm</td>
</tr>
<tr>
<td>1pm</td>
<td>X</td>
<td>10pm</td>
</tr>
<tr>
<td>2pm</td>
<td></td>
<td>11pm</td>
</tr>
<tr>
<td>3pm</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

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http://www.iom.edu/CMS/3793/31487/43961.aspx
Proposal for Universal Medication Schedule (UMS)

- Breakfast
- Lunch
- Supper
- Bedtime

http://www.iom.edu/CMS/3793/31487/43961.aspx
Patient’s Day
TID Med

- Breakfast time
- Lunch time
- Supper time
- Bed time
Patient’s day

TID Med & QID Med

- Breakfast time:
  - T
  - Q

- Lunch time:
  - T
  - Q

- Supper time:
  - Q

- Bed time:
  - T
  - Q

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http://www.iom.edu/CMS/3793/31487/43961.aspx
Patient’s day

TID Med & QID Med & BID Med

- Breakfast time
  - T
  - Q
  - B

- Lunch time
  - T
  - Q

- Supper time
  - Q
  - B

- Bed time
  - T
  - Q

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http://www.iom.edu/CMS/3793/31487/43961.aspx
Patient’s day
TID Med & QID Med & BID Med

8 episodes/day reduced to 4/day

- Breakfast time
  - T
  - Q
  - B

- Lunch time
  - T
  - Q

- Supper time
  - Q
  - B

- Bed time
  - T
  - Q

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http://www.iom.edu/CMS/3793/31487/43961.aspx
Patient Understanding of UMS

Randomized Trial (Comprehension Testing)

- 500 patients, 2 sites (Chicago, Shreveport)
- BID, TID, QD prescriptions tested
  - Enhanced text only
  - Standard label
  - UMS label

- UMS 5x better comprehension compared to standard label (p<0.001)

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Wolf, MS et al. personal communication, 2007
# Standard Dosing Times on Prescriptions

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

### Additional Instructions
- Take with a meal
- Swallow whole
- Do not drink alcohol
- Limit your time in the sun
- Other

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[NC Program on Health Literacy](#)
Standard Dosing Times on Containers

Glyburide 50mg  09/26/2007
This medicine is for Michael Wolf
To treat Diabetes
Prescribed by Ruth Parker, MD
Filled by Target Pharmacy
123 State Street
St. Paul, MN  12345
(312) 123-4567
You have 11 refills
Refer to Rx# 789-3452-1-0

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

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

- Take with a meal
- Swallow tablet whole
- Do not drink alcohol

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http://www.iom.edu/CMS/3793/31487/43961.aspx
Benefits of Standard Dosing Times on Prescriptions

- Patients, physicians, pharmacists use the same schedule
- Variability in Rx reduced
- Variability in transcription of Rx reduced
- Patients understanding improved
- Patient adherence improved
- Therapeutic outcome improved

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http://www.iom.edu/CMS/3793/31487/43961.aspx
Suggestions for Improving Drug Labeling

• Simplify dosage instructions
• Bold, highlight and enlarge font of content most important to the patient
  – *De-emphasize pharmacy logo & Rx number*
• Container label & accompanying materials should be a complimentary set of info
• Written materials should have simple language, avoid medical jargon, highlight actionable actions
• Patients should be involved in the design of materials

Target’s Clear Rx
Conclusions

• Warning labels & Prescription labels are frequently misunderstood

• New mechanisms for drug labeling are needed
  – UMS may be an option
  – Standardized prescription pads or electronic prescribing
  – Consistency in writing prescriptions

• Prescribing medications with specific directions including time of day improves understanding and may improve adherence
The End

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