

# **Simplifying Medication Scheduling Can We Confuse Patients Less?**

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**Alastair J.J. Wood MD**

# Taking Medicines Requires Knowing

- u What to take
- u How many pills to take
- u When to take them

# Successful Drug Therapy Requires

- u **Physician**

  - Correct choice of drug

  - Correct choice of dosage

  - Correctly writing Rx

- u **Pharmacist**

  - Correctly understanding Rx

  - Correctly transcribing Rx to bottle

  - Correctly transmitting information to patient

# Successful Drug Therapy Requires

## u Patient

Access to medicines

Correct use of medicines

- w Correct understanding of instructions
- w Correct implementation of instructions
- w Integration of multiple medicines into schedule
- w Actually taking medicine(s)

# Correctly Taking Medication

u **Much much harder than it looks!**

**When do I take them?**

**How much do I take?**

w **How many tablets?**

**Which medicines do I take when?**

# Variability in Label Instructions

## “Take 1 pill a day”

### u Prescriber

Inter—different prescribers write it 44 ways!

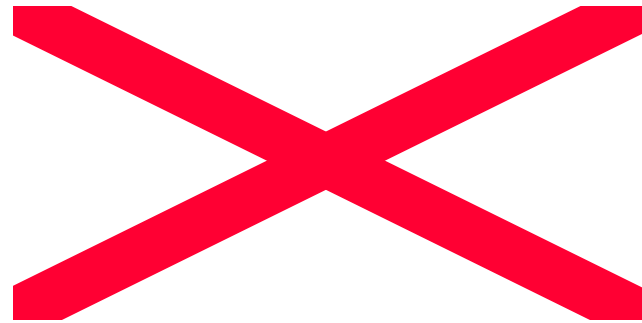
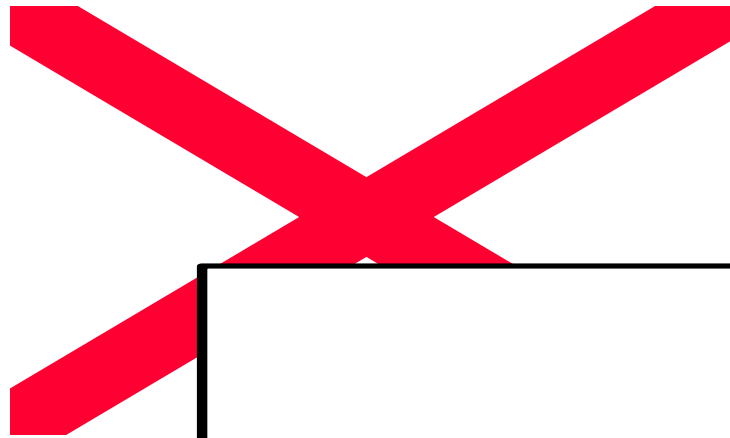
Intra—same prescriber multiple ways!

### u Pharmacist

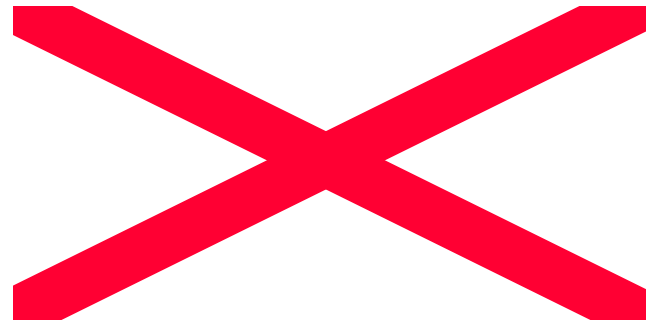
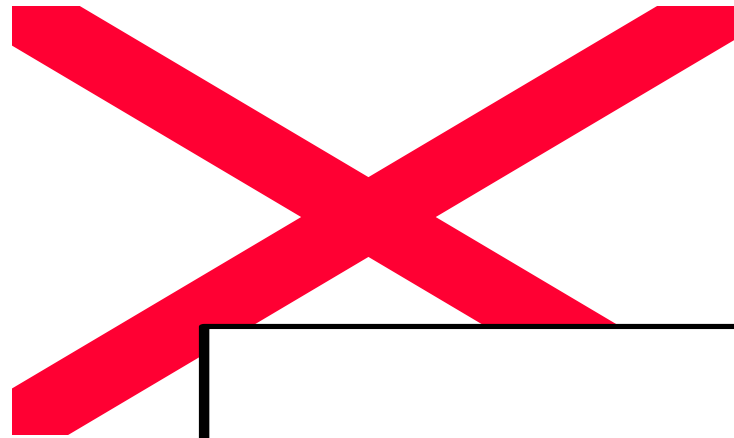
Inter—different pharmacists transcribe same sig differently

Intra—same pharmacists transcribe it differently at different times

# Prescription Clarity?



# Transcription of Rx to Label?



# Transcription of Rx to Label Imperfect and Variable

| Prescription   | Examples of Pharmacy 'Sig' Interpretations   |
|--|--|
| Lipitor 10 mg tabs<br>Take one tab QD<br>Dispense #30<br>Indication: for high cholesterol<br>No refills                                | <ul style="list-style-type: none"> <li>- "Take one tablet daily."</li> <li>- "Take 1 tablet by mouth for high cholesterol."</li> <li>- "Take one (1) tablet(s) by mouth once a day."</li> <li>- "Take one tablet by mouth every day for high cholesterol."</li> </ul>  |
| 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 | <ul style="list-style-type: none"> <li>- "Take 1 tablet by mouth daily."</li> <li>- "Take one tablet by mouth every day for osteoporosis prevention. Do not lie down for at least 30 minutes after taking."</li> <li>- "Take 1 tablet every day, 30 minutes before breakfast with a glass of water. Do not lie down."</li> <li>- "Take one tablet every day."</li> </ul> |
| Bactrim DS tabs<br>Take one tab BID<br>Dispense #6<br>Indication: UTI<br>No refills  | <ul style="list-style-type: none"> <li>- "Take one tablet by mouth twice daily for UTI"</li> <li>- "Take one tablet by mouth twice daily for urinary tract infection."</li> <li>- "Take 1 tablet by mouth 2 times a day."</li> <li>- "Take 1 tablet twice daily for 3 days."</li> </ul>  |
| Ibuprofen 200 mg tabs<br>Take 1-2 tabs TID PRN pain<br>Dispense #30<br>No refills  | <ul style="list-style-type: none"> <li>- "Take 1 to 2 tablets by mouth as needed for pain."</li> <li>- "Take 1 to 2 tablets by mouth three times daily as needed for pain."</li> <li>- "Take 1 to 2 tablets by mouth as needed for pain ** Not to exceed 4 times a day"</li> <li>- "Take 1 to 2 tablets 3 times a day as needed for pain."</li> </ul>                    |

# Container Label Variability Varies by Pharmacy

- u **Most prominent**
  - Pharmacy name
  - Pharmacy phone number
  - Refill number
- u **Less prominent/less clear**
  - Patient instructions

# Patient Understanding Imperfect

- u 46% of patients misinterpret 1 or more Rx instructions on labels

*Wolf MS, et al. Pat Ed Counsel 2007; 67: 293-300*

# Patient Understanding Imperfect

## Dosage Instruction

**Take one teaspoonful  
by mouth three  
times daily**

*Wolf MS, et al. Pat Ed Counsel 2007; 67:  
293-300*

## Interpretation

**Take three teaspoons  
daily**

**Take three table spoons  
every day**

**Drink it three times a  
day**

# Patient Understanding Imperfect

## Dosage Instruction

**Take one tablet by  
mouth twice daily for  
7 days**

## Interpretation

**Take two pills a day**

**Take it for 7 days**

**Take one every day for  
a week**

**I'd take a pill every day  
for a week**

*Wolf MS, et al. Pat Ed Counsel 2007; 67:  
293-300*

# Patient Understanding Imperfect

## Dosage Instruction

**Take two tablets by  
mouth twice daily**

*Wolf MS, et al. Pat Ed Counsel 2007; 67: 293-300*

## Interpretation

**Take it every 8 hours**

**Take it every day**

**Take one every 12  
hours**

# Patient Understanding Imperfect

## Dosage Instruction

**Take one tablet in the morning and one at 5 pm**

## Interpretation

**I would take it every day at 5 o'clock**

**Take it at 5 p.m.**

*Wolf MS, et al. Pat Ed Counsel 2007; 67: 293-300*

# **Current Situation Unsatisfactory Need For Radical Change**

- u Prescriptions unclear**
- u Transcription of Rx to label imperfect**
- u Patient understanding of label poor**
- u Variability excessive**
- u Complexity excessive**

# Patient's Day

|   |             |             |
|---|-------------|-------------|
| u | <b>7am</b>  | <b>3pm</b>  |
| u | <b>8am</b>  | <b>4pm</b>  |
| u | <b>9am</b>  | <b>5pm</b>  |
| u | <b>10am</b> | <b>6pm</b>  |
| u | <b>11am</b> | <b>7pm</b>  |
| u | <b>Noon</b> | <b>8pm</b>  |
| u | <b>1pm</b>  | <b>9pm</b>  |
| u | <b>2pm</b>  | <b>10pm</b> |

# Patient's Day

## TID Med

|   |      |   |      |   |
|---|------|---|------|---|
| u | 7am  | X | 4pm  |   |
| u | 8am  |   | 5pm  |   |
| u | 9am  |   | 6pm  |   |
| u | 10am |   | 7pm  |   |
| u | 11am |   | 8pm  |   |
| u | Noon |   | 9pm  |   |
| u | 1pm  |   | 10pm |   |
| u | 2pm  |   | 11pm | X |
| u | 3pm  | X |      |   |

# Patient's Day

## TID Med & QID Med

|   |      |   |      |     |
|---|------|---|------|-----|
| u | 7am  | X | 4pm  |     |
| u | 8am  | X | 5pm  |     |
| u | 9am  |   | 6pm  |     |
| u | 10am |   | 7pm  | X   |
| u | 11am |   | 8pm  |     |
| u | Noon |   | 9pm  |     |
| u | 1pm  | X | 10pm |     |
| u | 2pm  |   | 11pm | X X |
| u | 3pm  | X |      |     |

# Patient's Day

**TID Med & QID Med** BID Med

|   |      |   |      |     |
|---|------|---|------|-----|
| u | 7am  | X | 4pm  |     |
| u | 8am  | X | 5pm  |     |
| u | 9am  | X | 6pm  |     |
| u | 10am |   | 7pm  | X   |
| u | 11am |   | 8pm  |     |
| u | Noon |   | 9pm  | X   |
| u | 1pm  | X | 10pm |     |
| u | 2pm  |   | 11pm | X X |
| u | 3pm  | X |      |     |

# Patient's Day

**TID Med & QID Med** BID Med

8 episodes/day!!!

|   |      |   |      |     |
|---|------|---|------|-----|
| u | 7am  | X | 4pm  |     |
| u | 8am  | X | 5pm  |     |
| u | 9am  | X | 6pm  |     |
| u | 10am |   | 7pm  | X   |
| u | 11am |   | 8pm  |     |
| u | Noon |   | 9pm  | X   |
| u | 1pm  | X | 10pm |     |
| u | 2pm  |   | 11pm | X X |
| u | 3pm  | X |      |     |

# Proposal

## Universal Medication Schedule UMS

- u **Breakfast time**
- u **Lunch time**
- u **Supper time**
- u **Bed time**

# Proposal

## Universal Medication Schedule UMS

- u As far as possible all medicines should be slotted into the **Universal Medication Schedule**

Breakfast time

Lunch time

Supper time

Bed time

# Patient's Day

## TID Med

u **Breakfast time** **T**

u **Lunch time** **T**

u **Supper time**

u **Bed time** **T**

# Patient's Day

## TID Med & QID Med

u Breakfast time T Q

u Lunch time T Q

u Supper time Q

u Bed time T Q

# Patient's Day

**TID Med & QID Med** BID Med

u **Breakfast time**                    **T**        **Q**        **B**

u **Lunch time**                        **T**        **Q**

u **Supper time**                        **Q**        **B**

u **Bed time**                            **T**        **Q**

# Patient's Day

**TID Med & QID Med** BID Med

8 episodes/day reduced to 4/day

u Breakfast time T Q B

u

u Lunch time T Q

u Supper time Q B

u Bed time T Q

# Proportion of Patients' Rxs Covered

## u Review of 346,844 oral prescriptions

|                              |                   |
|------------------------------|-------------------|
| - Once a day                 | 51%               |
| - Twice a day                | 19%               |
| - Three times a day          | 5%                |
| - Four times a day           | <u>2%</u>         |
| <b>TOTAL</b>                 | <b>77%</b>        |
| <b>As directed/As needed</b> | <b><u>15%</u></b> |
| <b>TOTAL</b>                 | <b>92%</b>        |

- Five or more times a day 1%
- Other 7%

Wolf, MS personal communication, October 2007

# Patient Understanding of UMS

## Randomized Trial (Comprehension Testing)

- u 500 patients, 2 sites (Chicago, Shreveport)
- u BID, TID, QD prescriptions tested
  - Enhanced text only
  - Standard label
  - UMS label
- u UMS 5x better comprehension compared to standard label ( $p < 0.001$ )

# **Patient Understanding of UMS Compared to Standard Label**

**5x better comprehension compared  
to standard label ( $p < 0.001$ )**

# Standard Dosing Times On Prescriptions

**Alastair Wood, MD**

1234 Springfield Drive  
Nashville, TN 54321  
(302) 432-1234

| <p>1. _____</p> <p>Dose: _____</p> <p>Take for: _____</p>  | <p>2. _____</p> <p>Dose: _____</p> <p>Take for: _____</p>  | <p>3. _____</p> <p>Dose: _____</p> <p>Take for: _____</p>  |         |         |  |  |  |  |  |           |       |        |         |  |  |  |  |  |           |       |        |         |  |  |  |  |
|--|--|--|---------|---------|--|--|--|--|--|-----------|-------|--------|---------|--|--|--|--|--|-----------|-------|--------|---------|--|--|--|--|
| <p>Schedule</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="font-size: small;">Breakfast</th> <th style="font-size: small;">Lunch</th> <th style="font-size: small;">Dinner</th> <th style="font-size: small;">Bedtime</th> </tr> </thead> <tbody> <tr> <td style="height: 20px;"> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>_____</p> <p>_____</p> | Breakfast  | Lunch  | Dinner  | Bedtime |  |  |  |  | <p>Schedule</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="font-size: small;">Breakfast</th> <th style="font-size: small;">Lunch</th> <th style="font-size: small;">Dinner</th> <th style="font-size: small;">Bedtime</th> </tr> </thead> <tbody> <tr> <td style="height: 20px;"> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>_____</p> <p>_____</p> | Breakfast | Lunch | Dinner | Bedtime |  |  |  |  | <p>Schedule</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="font-size: small;">Breakfast</th> <th style="font-size: small;">Lunch</th> <th style="font-size: small;">Dinner</th> <th style="font-size: small;">Bedtime</th> </tr> </thead> <tbody> <tr> <td style="height: 20px;"> </td> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> <p>_____</p> <p>_____</p> | Breakfast | Lunch | Dinner | Bedtime |  |  |  |  |
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|  |  |  |         |         |  |  |  |  |  |           |       |        |         |  |  |  |  |  |           |       |        |         |  |  |  |  |
| Breakfast  | Lunch  | Dinner   | Bedtime |         |  |  |  |  |  |           |       |        |         |  |  |  |  |  |           |       |        |         |  |  |  |  |
|  |  |  |         |         |  |  |  |  |  |           |       |        |         |  |  |  |  |  |           |       |        |         |  |  |  |  |
| Breakfast  | Lunch  | Dinner   | Bedtime |         |  |  |  |  |  |           |       |        |         |  |  |  |  |  |           |       |        |         |  |  |  |  |
|  |  |  |         |         |  |  |  |  |  |           |       |        |         |  |  |  |  |  |           |       |        |         |  |  |  |  |
| <p>Additional Instructions</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Take with a meal</li> <li><input type="checkbox"/> Swallow whole</li> <li><input type="checkbox"/> Do not drink alcohol</li> <li><input type="checkbox"/> Limit your time in the sun</li> <li><input type="checkbox"/> Other _____</li> </ul>   | <p>Additional Instructions</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Take with a meal</li> <li><input type="checkbox"/> Swallow whole</li> <li><input type="checkbox"/> Do not drink alcohol</li> <li><input type="checkbox"/> Limit your time in the sun</li> <li><input type="checkbox"/> Other _____</li> </ul> | <p>Additional Instructions</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Take with a meal</li> <li><input type="checkbox"/> Swallow whole</li> <li><input type="checkbox"/> Do not drink alcohol</li> <li><input type="checkbox"/> Limit your time in the sun</li> <li><input type="checkbox"/> Other _____</li> </ul> |         |         |  |  |  |  |  |           |       |        |         |  |  |  |  |  |           |       |        |         |  |  |  |  |

# 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**

| Breakfast | Lunch | Dinner | Bedtime |
|-----------|-------|--------|---------|
| 2         |       |        | 2       |

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

# Benefits

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

# Benefits

- u **Universal Prescription pads**
- u **Universal labels**
- u **Universal medicine reminder boxes**
- u **Uniform medication schedules in pivotal clinical trials for FDA approval**
- u **Consistent format across all domains**
- u **Reduction in errors/variability**

# Potential Objections

## Drug concentration variability

- u Concentrations actually vary enormously among individuals—Biological variability
- u Product variability
- u Brand/Generic Variability
  - FDA requirement for brand/generic equivalence
    - w only requires that for peak and average concentrations (AUC) “90% CI between 80%-125% of branded product”

# FDA Definition of Equivalence

- u 90 % confidence intervals for peak and average concentrations (AUC) must lie within

**80%-125% of those of branded product**

# Potential Objections

## Drug concentration variability

- u **Within patient variability will be improved by Uniform Medication Schedule**  
**And that is what matters!**
- u **Across patient variability is already greater than change produced by UMS**
- u **No physician actually knows when meds taken**

# Uniform Medication Schedule

- u **Simplifies dosing schedule**
- u **No loss of efficacy**
- u **Improves patient understanding**
- u **Improves patient adherence**
- u **Reduces errors**
- u **Reduces variability**
- u **Improves outcome**