

Simplifying Medication Scheduling Can We Confuse Patients Less?

Alastair J.J. Wood MD

Taking Medicines Requires Knowing

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

Successful Drug Therapy Requires

◆ Physician

- Correct choice of drug
- Correct choice of dosage
- Correctly writing Rx

◆ Pharmacist

- Correctly understanding Rx
- Correctly transcribing Rx to bottle
- Correctly transmitting information to patient

Successful Drug Therapy Requires

◆ Patient

- Access to medicines
- Correct use of medicines
 - ◆ Correct understanding of instructions
 - ◆ Correct implementation of instructions
 - ◆ Integration of multiple medicines into schedule
 - ◆ Actually taking medicine(s)

Correctly Taking Medication

- ◆ **Much much harder than it looks!**
 - **When do I take them?**
 - **How much do I take?**
 - ◆ **How many tablets?**
 - **Which medicines do I take when?**

Variability in Label Instructions

“Take 1 pill a day”

◆ Prescriber

- Inter—different prescribers write it 44 ways!
- Intra—same prescriber multiple ways!

◆ Pharmacist

- Inter—different pharmacists transcribe same sig differently
- Intra—same pharmacists transcribe it differently at different times

Prescription Clarity?

5438220

07- 1938 68/F
INS: M98 C130
PI:

06/13/07
OA
VIP: 265
MR#

Patient Name: Thom
Date: 6/13/07 Clinic: Cardiac

NOTE: Please write legibly and fill out form in its entirety. Prescriptions written by non-physicians or at non-Health System facilities cannot be honored by Pharmacies. Prescribe sufficient refills to maintain therapy until next scheduled appointment.

Patient Allergies		Weight:	Age:	Include diagnosis or problem in directions:	
Rx	Drug Name	Strength	Quantity	Refills	Directions For Problem ?
1	Clonidine	0.2 mg	60	5	one tab twice a day
2	L-Sinipul	None	30	5	one tab daily
3	Hydralazine	50mg	40	5	one tab three times a day
4	Lupul XL				
5	Loraz				
6	Alprazolam				
7					

Signature of Physician: _____ Printed name: S
Co-signature (if required): _____ Printed name: _____

NOTE: All prescriptions for controlled substances exp. MRC 23-01 [] Chief of Service

Fill Date 07/18/07 Pt. #:001
Rx No. 02-2358767 Dr. _____

Take 3 tablets by mouth three times a day for blood pressure.

HydrALAZINE 25mg (Q) Tab PAR 1000
MFG PAR PHARM. NDC 49884-0027-10

Prescription Expires 07/18/08 RPh CST
Orig/Date 07/18/07 Refills Left 3.0 Qty 270

Caution: Federal law prohibits transfer of this drug to any person other than patient for whom prescribed.

Transcription of Rx to Label?

5438220

07- 1938 68/F
INS: M98 C130
PI:

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Transcription of Rx to Label Imperfect and Variable

Prescription	Examples of Pharmacy 'Sig' Interpretations
Lipitor 10 mg tabs Take one tab QD Dispense #30 Indication: for high cholesterol No refills	<ul style="list-style-type: none"> - "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	<ul style="list-style-type: none"> - "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	<ul style="list-style-type: none"> - "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 Dispense #30 No refills	<ul style="list-style-type: none"> - "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."

Container Label Variability Varies by Pharmacy

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

Patient Understanding Imperfect

- ◆ 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

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

Patient's Day

◆ 7am

◆ 8am

◆ 9am

◆ 10am

◆ 11am

◆ Noon

◆ 1pm

◆ 2pm

3pm

4pm

5pm

6pm

7pm

8pm

9pm

10pm

Patient's Day

TID Med

◆ 7am	X	4pm	
◆ 8am		5pm	
◆ 9am		6pm	
◆ 10am		7pm	
◆ 11am		8pm	
◆ Noon		9pm	
◆ 1pm		10pm	
◆ 2pm		11pm	X
◆ 3pm	X		

Patient's Day

TID Med & QID Med

◆ 7am	X	4pm	
◆ 8am	X	5pm	
◆ 9am		6pm	
◆ 10am		7pm	X
◆ 11am		8pm	
◆ Noon		9pm	
◆ 1pm	X	10pm	
◆ 2pm		11pm	X X
◆ 3pm	X		

Patient's Day

TID Med & QID Med BID Med

◆ 7am	X	4pm	
◆ 8am	X	5pm	
◆ 9am	X	6pm	
◆ 10am		7pm	X
◆ 11am		8pm	
◆ Noon		9pm	X
◆ 1pm	X	10pm	
◆ 2pm		11pm	X X
◆ 3pm	X		

Patient's Day

TID Med & QID Med BID Med

8 episodes/day!!!

◆ 7am	X	4pm	
◆ 8am	X	5pm	
◆ 9am	X	6pm	
◆ 10am		7pm	X
◆ 11am		8pm	
◆ Noon		9pm	X
◆ 1pm	X	10pm	
◆ 2pm		11pm	X X
◆ 3pm	X		

Proposal

Uniform Medication Schedule UMS

- ◆ Breakfast time
- ◆ Lunch time
- ◆ Supper time
- ◆ Bed time

Proposal

Uniform Medication Schedule UMS

- ◆ As far as possible all medicines should be slotted into the **Uniform Medication Schedule**
 - Breakfast time
 - Lunch time
 - Supper time
 - Bed time

Patient's Day

TID Med

◆ Breakfast time T

◆ Lunch time T

◆ Supper time

◆ Bed time T

Patient's Day

TID Med & QID Med

- ◆ Breakfast time T Q
- ◆ Lunch time T Q
- ◆ Supper time Q
- ◆ Bed time T Q

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

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	

Proportion of Patients' Rxs Covered

◆ 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>
TOTAL	77%
As directed/As needed	<u>15%</u>
TOTAL	92%

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

Wolf, MS personal communication, October 2007

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 ($p < 0.001$)

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

1. _____ Dose: _____ Take for: _____	2. _____ Dose: _____ Take for: _____	3. _____ Dose: _____ Take for: _____																								
Schedule <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <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> <tr> <td style="height: 20px;"> </td> <td> </td> <td> </td> <td> </td> </tr> </table> _____ _____	Breakfast	Lunch	Dinner	Bedtime					Schedule <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <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> <tr> <td style="height: 20px;"> </td> <td> </td> <td> </td> <td> </td> </tr> </table> _____ _____	Breakfast	Lunch	Dinner	Bedtime					Schedule <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <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> <tr> <td style="height: 20px;"> </td> <td> </td> <td> </td> <td> </td> </tr> </table> _____ _____	Breakfast	Lunch	Dinner	Bedtime				
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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

- ◆ 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

Benefits

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

Potential Objections

Drug concentration variability

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

FDA Definition of Equivalence

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

80%-125% of those of branded product

Potential Objections

Drug concentration variability

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

Uniform Medication Schedule

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