| Morning 6-8am | Noon 11-1pm | Evening 4-6pm | Bedtime 9-11pm |
|---|---|---|---|

# A Universal Medication Schedule

## to promote patient understanding and use

Stacy Cooper Bailey, MPH
Northwestern University

Ruth M. Parker, MD
Emory University

Terry C. Davis, PhD
Louisiana State University-Shreveport

William H. Shrank, MD
Harvard University

Michael S. Wolf, PhD MPH
Northwestern University

# Acknowledgements.

# Overview.

- Background: Health Literacy & Drug Labeling

- Creating an Evidence-based, Patient-Centered Label

- Field Test Results

- The 'UMS Trial' – Methods & Rationale

- Next Steps

# Background

# Health Literacy and Drug Labeling.

- Current sources of patient Rx information are deficient

- Rx labels most tangible, frequently used sources

- Poor patient comprehension of labeling

  – 46% of patients misunderstood one or more Rx labels

  – Over half (53%) misinterpreted one or more warning labels

  – Patients with limited health literacy most affected

- Clear need for improved labeling to support understanding

# Creating an Enhanced Label

# Evidence Available.

- Group label content

- Emphasize patient info (Rx name, patient name, directions, indication*)

- Write instructions using explicit time intervals (UMS)

- Use numeric vs. alpha characters for dose, frequency

- Separate times with virtual 'carriage returns'

- Provide a visual aid to reinforce the 'sig' instruction

## Value in Standardization!

# An Enhanced Label and 'UMS'

Do not drink alcoholic beverages while taking this medicine

Carry or wear medical identification stating you are taking this medicine

You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medicine

**Michael Wolf**
04/29/71

**Glyburide 5mg**

Take for **Diabetes**

**Take:**
    **2 pills in the morning**
    **2 pills in the evening**

| Morning 7-9 AM | Noon 11-1 PM | Evening 4-6 PM | Bedtime 9-11 PM |
|:---:|:---:|:---:|:---:|
| **2** | | **2** | |

Rx #: 1234567      9/8/2009

You have **11** refills
180 pills
**Discard after 9/8/2010**

Provider:    RUTH PARKER, MD
              Emory Medical Center
              (414) 123-4567

Pharmacy:  NoVA ScriptsCentral
              11445 Sunset Blvd.
              Reston, VA
              (713) 123-4567

**NDC # 1234567**

# Testing the Enhanced Label

# Efficacy Trial.

- Comprehension testing

- 4 clinics in two sites (Chicago, Shreveport); 1 academic, 1 FQHC

- Sample = 500 primary care patients > 18 years of age

- Sequential assignment to standard, UMS, UMS + graphic

- Outcome: Functional understanding of 3 hypothetical regimens

# Study Arms.

| Standard | UMS | UMS + Graphic Aid |
|----------|-----|-------------------|
| Take one tablet by mouth daily. | Take 1 tablet at bedtime. | Morning / Noon / Evening / Bedtime — 1 at Bedtime |
| Take one tablet by mouth three times daily. | Take<br>1 tablet in the morning<br>1 tablet at noon<br>1 tablet in the evening | Morning / Noon / Evening / Bedtime — 1 Morning, 1 Noon, 1 Evening |
| Take two tablets by mouth twice daily. | Take<br>2 tablets in the morning,<br>And 2 tablets at bedtime | Morning / Noon / Evening / Bedtime — 2 Morning, 2 Bedtime |

# Findings.

- 91% of patients correctly interpreted UMS instructions
- Benefit strongest with more complex regimens (%):

| Times per day | Standard | UMS | UMS + Graphic |
|---|---|---|---|
| 1 | 89 | 94 | 85 |
| 2 | 77 | 88 | 84 |
| 3 | 44 | 91 | 91 |

- GEE Model: greater comprehension of UMS instructions vs. standard label instructions (ARR 1.33, 95% CI 1.25 – 1.41; p<0.001)

- Addition of Graphic Aid of limited value for single drug review (ARR 0.93, 95% CI 0.89 – 0.97; p<0.001)

  – Improvement for 2 or 3x daily schedules (40% of US prescriptions)

# Findings (cont.).

- Impact of limited literacy mitigated (REALM – low (n=101): ARR 0.95, 95% CI 0.86 – 1.04; p=0.25)

- Significant interactions found – Patient w/ low literacy had greatest benefit from the UMS (ARR 1.39, 95% CI 1.14-1.68, p<0.001)

- Regimen complexity and UMS – greater complexity, greater benefit (ARR 2.00, 95% CI 1.44-2.42, p<0.001)

# Present Study – the 'UMS' trial

**<u>Objective</u>: to test the effectiveness of the evidence-based, enhanced prescription drug container label design to improve patients' understanding of instructions for use.**

# Methods.

- **Actual Use Assessment**

- 11 Safety Net Clinics, 1 Central-Fill Pharmacy (Va.)

- Sample = 960 Diabetic/Hypertensive Patients, > 30 years of age

- Random Assignment to Enhanced vs. Standard Label (all meds)

- Assessment: Baseline, 3 months, 9 months

- Outcomes:   1. Functional Understanding
              2. Adherence (self-report, pill count, refill data)
              3. HBA1C/Blood Pressure

# Current Progress, Next Steps.

- 5 clinics activated.

- 323 patients identified, 126 recruited to study. Response rate 67%.

- 3 month interviews (w/ adherence outcomes) have begun

- Remaining clinics to be engaged in systematic manner

- Need repeatedly identified for language concordant services

- Work with others (i.e. USP) to set Rx label standards

## Contact Information:

Stacy Cooper Bailey, MPH
Clinical Research Associate and Director
Health Literacy and Learning Program
Division of General Internal Medicine
Northwestern University
Feinberg School of Medicine
750 N. Lake Shore Drive, 10th Floor
Chicago, IL  60611
(312) 503 – 5586
stacy-bailey@northwestern.edu