Use of Pictogram-based, Patient-specific Medication Instruction Sheets as part of a Health Literacy Intervention to Reduce Parent Medication Administration Errors

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Medication Administration Errors in Children

• Medication administration errors are frequent
  – >50% parents measure liquid medications incorrectly (Simon 1997; Li 2000; Frush 2004; McMahon 1997)
  – ~50% parents do not adhere to their child’s prescribed medication regimen (Winnick 2005)
Children and Liquid Medications

- Liquid medications difficult to administer
  - Variation in accuracy of dosing instruments
  - Different concentrations
  - Different units of measurement
    - mL / tsp / tbsp
Provider-Patient Communication

• Verbal communication of medication instructions suboptimal (Tarn 2006; Metlay 2005)

• Language barriers
  – Majority of NYC pharmacies serving LEP patients everyday don’t regularly provide translated materials (Weiss 2007)

• Literacy barriers
  – Majority of medication information sheets ≥10th grade level (Shrank 2007; Wolf 2006; Kirksey 2004)
Potential Strategies to Decrease Medication Administration Errors

- Plain language
- Illustrations / pictograms
  - Improved knowledge and adherence (Katz 2006; Houts 2006)
  - Illustrated schedules assist with self-management (Kripalani 2007; Morrow 1998)
- Teachback (Schillinger 2003)
- Oral dosing syringes (McMahon 1997; Madlon-Kay 2000)
Medication Instruction Sheet

• Patient-specific
• English/Spanish
• Plain language
• Pictogram representations
  – Preparation
  – Route
  – Frequency
  – Storage
  – Duration
  – Questions

Name: Carlos
Information on your prescription for:
Amoxicillin
To treat an infection of the ear
5 mL (1 teaspoon) by mouth 2 times a day for 10 days

Nombre: Carlos
Información sobre su receta para:
Amoxicillin
Para tratar una infección del oído
5 mL (1 cucharadita) por la boca 2 veces al día por 10 días

Shake well
Agite bien
Take 2 times a day by mouth
Tome 2 veces al día por la boca
Store in refrigerator
Guarde en la nevera

Give this medicine for 10 days,
even if your child is feeling better
Dé esta medicina por 10 días,
aunque su niño se sienta mejor

If you have questions call
(212) 562-5524 day or night
Si tiene preguntas llame la
(212) 562-5524 día o noche

Read instructions from your pharmacist about your prescription. Lea las instrucciones de su farmacéutico sobre su receta.
Medication Reminder/Tracking Sheet

- Dosing Diagram
- Date and Number of Doses
- Log
  - Specific to course of medication
  - Time convenient for family discussed
  - Course start/end time circled

Keeping track of Carlo’s Amoxicillin

5 mL (1 teaspoon) by mouth
2 times a day for 10 days

Anotando las dosis de Amoxicilin de Carlos

5 mL (1 cucharadita) por la boca
2 veces al día por 10 días

Date of first dose: February 4, 2008
Fecha de la primera dosis: Febrero 4, 2008

Parents: Please check (√) the correct box each time you give your child the medicine. 20 checks (√) total.
Familiares: Por favor, marquen con (√) la casilla correcta cada vez que den la medicina a su niño, total de 20 marcas (√).

<table>
<thead>
<tr>
<th>DAY / DÍA</th>
<th>☀</th>
<th>☔</th>
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</thead>
<tbody>
<tr>
<td>Time/Hora:</td>
<td>9 am</td>
<td>8 pm</td>
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<tr>
<td>Monday / Lunes</td>
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<tr>
<td>Tuesday / Martes</td>
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<td>Wednesday / Miércoles</td>
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<td>Thursday / Jueves</td>
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<td>Friday / Viernes</td>
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<td>Saturday / Sábado</td>
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<td>Sunday / Domingo</td>
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<td>Monday / Lunes</td>
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<td>Wednesday / Miércoles</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thursday / Jueves</td>
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</tbody>
</table>

Pediatrician: Please circle the starting dose and ending dose.
HELPix Intervention Description

• Medication counseling using pictogram-based sheets

• Demonstration of dose and teachback using instrument and sheets

• Standardized dosing instrument

• ~1½ minutes
Origin of HELPix

- Child Development / Parenting background
- Designed Bellevue Programs in Pediatric Clinic at Hospital Center in NYC
- Director of Reach Out and Read
  - Making a difference in the children’s language and literacy
  - Any real change needed to address parents’ literacy
Origin of HELPix

• Child Development / Parenting background
• Designed Bellevue Programs in Pediatric Clinic at Hospital Center in NYC
• Director of Reach Out and Read
• AMA Video
  – “Low Health Literacy: You can’t tell by looking”
The HELP Project
Health Education and Literacy for Parents

Waiting area health literacy intervention
The HELP Project (cont’d)

- Uses parents’ existing knowledge and skills as basis for learning new information

- Provides short term educational “activities” which address
  - Strategies to improve children’s health
  - Ideas for improving communication with providers
  - Learning new information beyond what is contained in the activity
We Can Do Better Than This!
"It Takes a Village…"

Helping Health Workers Learn: A book of methods, aids, and ideas for instructors at the village level

by David Werner and Bill Bower
Community Resources

• NYC Poison Control Center
  – Pharmacy perspective
  – Medication information
  – Mentoring

• Literacy Assistance Center
  – Adult literacy perspective
  – Adult education resources
Where Did We Start?

USP Pictogram Library
Modifying Existing Pictograms
Modifying Existing Pediatric Pictograms

Name: Jose
INFORMATION ON YOUR PRESCRIPTION FOR:
AMOXICILLIN 125MG/5ML
To treat an infection of the Throat
1 TEASPOON BY MOUTH 2 TIMES A DAY FOR 10 DAYS
Shake Well Agite bien
Take by mouth tome por la boca
Take 2 times a day tome 2 veces al dia
Store in refrigerator Guare la en la nevera

One Teaspoon = 5cc or 5mL
Una Cucharadita = 5cc or 5mL

Maria
INFORMATION ON YOUR PRESCRIPTION FOR:
AMOXICILINA 250MG/5ML
To treat an infection of the Throat
2 TEASPOON(S) BY MOUTH 2 TIMES A DAY FOR 10 DAYS
Shake well Agite bien
Take by mouth Tome por la boca
Take 2 times a day Tome 2 veces al dia
Store in refrigerator Guare lo en la nevera

Creating New Pediatric Pictograms

Name: Jose
INFORMATION ON YOUR PRESCRIPTION FOR:
AMOXICILLIN 125MG/5ML
Para tratar una infección de la boca
1 CUCHARADITA POR LA BOCA 2 VECES AL DIA POR 10 DIAS
Shake Well Agite bien
Take by mouth tome por la boca
Take 2 times a day tome 2 veces al dia
Store in refrigerator Guare la en la nevera

One Teaspoon = 5cc or 5mL
Una Cucharadita = 5cc or 5mL

Maria
INFORMATION ON YOUR PRESCRIPTION FOR:
AMOXICILINA 250MG/5ML
Para tratar una infección de los oídos
2 CUCHARADITA(S) POR LA BOCA 2 VECES AL DIA POR 10 DIAS
Shake well Agite bien
Take by mouth Tome por la boca
Take 2 times a day Tome 2 veces al dia
Store in refrigerator Guare la en la nevera

Read instructions from your pharmacist about your prescription. Lee las instrucciones de su farmacéutico acerca de su receta.

The H.E.L.P. Project Bellevue Hospital Pediatric Resource Center (212) 562-6321
© 2004 Bellevue Hospital Center * Modified with permission from the USP Pictogram Library
Other Challenges:
“As needed” (prn) Medications

Name: Jennifer    Date: March 11, 2008

Information on your child’s medicine:

Infants’ Acetaminophen Drops
(Also sold as Tylenol Infants’ Drops)

To help reduce fever and relieve pain

Jennifer’s dose is 0.8 mL and 0.8 mL (2 droppers). If needed, you can repeat this dose after 4 hours.

The dose of medicine depends on your child’s weight. This dose will change as your child grows.

- Shake well
- Take by mouth
- Keep out of reach of children
- Keep at room temperature
- After 4 hours, you can give another dose of medicine, if needed
- Important
  - Do not give more than 5 doses in a day
  - If you have questions call (212) 562-6524 day or night

Instructions
Write the time that you give the medicine.
You may not need to use all the boxes.
Other Challenges:
“Step Down” Medications

**Name** Maria

Information on your prescription for:

Zithromax

To treat an infection of the throat

Day 1
10 mL (2 teaspoons) by mouth

Day 2, 3, 4, 5
5 mL (1 teaspoon) by mouth

Shake well

Take 1 time a day by mouth

Keep out of reach of children

Drink

If you have questions, call (212) 692-8524

Date medicine started
May 5, 2006

Parents: Please check (✓) the correct box each time you give your child the medicine. 5 checks (✓) total.

Day 1
10 mL (2 cucharaditas) por la boca

Day 2, 3, 4, 5
5 mL (1 cucharadita) por la boca

Anotando las dosis de Zithromax de Maria

Day 1
10 mL (2 cucharaditas) por la boca

Day 2, 3, 4, 5
5 mL (1 cucharadita) por la boca

Date that medicine was started
May 5, 2006

Day 1
10 mL

Day 2
5 mL

Day 3
5 mL

Day 4
5 mL

Day 5
5 mL

TSP = teaspoon = cucharadita

Piedmont, NC

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The H.E.L.P. Project
Bellevue Hospital
Pediatric Resource Center
(212) 692-8524

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Pilot Testing

• Test for objectives and key messages

• Test materials with the intended audience
  – *How does the sheet work as a whole?*
  – *How do individual pictograms and phrases work?*

Feedback collected from parents who participated in HELP Project: “Learn more about your child’s medicine” activity
Pilot Testing (cont’d)

• Use questionnaires to systematically assess opinions

• Create scenarios to give parents context

• Show alternative pictograms and wordings to find what works best

Feedback collected from parents who participated in HELP Project: “Learn more about your child’s medicine” activity
Pilot Testing (cont’d)

- **Take by mouth with food**
  - **Tome por la boca con comida**

- **After 4 hours, you can give another dose of medicine, if needed**

- **After 4 hours, you can give another dose of medicine, if needed**
Study Objective

• To assess whether a pictogram-based intervention (HELPix) can
  – improve medication knowledge
  – decrease liquid medication dosing errors
  – improve adherence

in low SES caregivers of young children.
Study Design

• Randomized controlled trial

• Urban public hospital pediatric ED

• Eligibility criteria
  – Child
    • >30 days old and <8 years old
    • Prescribed a short course (≤14d) of a liquid medication
  – Caregiver
    • Responsible for administering medication to child
    • English/Spanish language
Study Overview

Enrollment
Jul - Dec 2006

Randomization

Baseline assessment:
- Sociodemographics
- Health literacy (TOFHLA)

Pictogram
(sheet+syringe +teachback)

Control

Follow-up Assessment:
- Medication knowledge
- Dosing accuracy
- Adherence

PRN: 3-5 days
Daily: +/- 1 day of last dose
Assessments of Outcomes

**Medication knowledge**
- Name
- Indication
- Reported and Observed dose
- Frequency
- Preparation
- Storage

**Adherence (daily dose only)**
- Total # doses
Assessments of Outcomes

**Medication knowledge**
- Name
- Indication
- Reported and Observed dose (within 20%)
- Frequency
- Preparation
- Storage

**Adherence** (daily dose only)
- Total # doses (within 20%)
Subject Enrollment

245 randomized

124 Pictogram
- 113 (91.1%) had F/U assessment

121 Control
- 114 (94.2%) had F/U assessment
### Results: Descriptive Data

<table>
<thead>
<tr>
<th>Category</th>
<th>Intervention (n=124)</th>
<th>Control (n=121)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child Age (years)</td>
<td>3.7 (2.2)</td>
<td>3.4 (2.3)</td>
<td>0.3</td>
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<tr>
<td>Hollingshead SES Level 4 or 5</td>
<td>76%</td>
<td>78%</td>
<td>0.8</td>
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<tr>
<td>Caregiver Ethnicity Latino</td>
<td>77%</td>
<td>79%</td>
<td>0.8</td>
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<tr>
<td>Caregiver non-US born</td>
<td>65%</td>
<td>66%</td>
<td>0.9</td>
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<td>Caregiver Education</td>
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<tr>
<td>HS graduate or equivalent</td>
<td>60%</td>
<td>61%</td>
<td>0.9</td>
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<tr>
<td>Caregiver Health Literacy (TOFHLA)</td>
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<tr>
<td>Adequate</td>
<td>70%</td>
<td>69%</td>
<td>0.9</td>
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<tr>
<td>Marginal / Inadequate</td>
<td>30%</td>
<td>31%</td>
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</table>
Results: Effect of Intervention on Dosing Accuracy (by Direct Observation at Follow-up)

Error in dosing defined as measuring more than +/- 20% of prescribed dose

**prn (n=155)**
- ARR = 24.4%
- NNT = 4
- p=0.003

**daily dose (n=83)**
- ARR = 42.4%
- NNT = 2
- p=0.0002
Results: Effect of Intervention on Dosing Accuracy (by Direct Observation at Follow-up)

Daily Dose Medications

52.2% control & 94.6% intervention caregivers measured within 20% of the prescribed dose
**Results: Effect of Intervention on Dosing Accuracy**
(by Direct Observation at Follow-up)

**Daily Dose Medications**

- 32.6% control caregivers measured below prescribed dose

**% Subjects**
- >80-100
- >60-80
- >40-60
- >20-40
- >0-20
- 0-20
- >20-40
- >40-60
- >60-80
- >80-100

**% Deviation From Prescribed Dose**
- Below prescribed dose
- Above prescribed dose

**Legend**
- Red: Control
- Green: Intervention
Results: Effect of Intervention on Dosing Accuracy (by Direct Observation at Follow-up)

Daily Dose Medications

% Subjects

% Deviation From Prescribed Dose

0 5 10 15 20 25 30 35 40 45 50 55

>80-100 >60-80 >40-60 >20-40 >0-20 0-20 >20-40 >40-60 >60-80 >80-100

Below prescribed dose Above prescribed dose

15.2% control & 5.4% intervention caregivers measured above the prescribed dose

Control

Intervention
Results: Effect of Intervention on Adherence (daily dose medications)

Poor adherence defined as **not giving within 20% of total expected doses**

**daily dose (n=93)**
ARR = 28.7%
NNT = 3
p value = 0.002

<table>
<thead>
<tr>
<th>% Subjects Nonadherent</th>
<th>Control</th>
<th>Intervention</th>
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</thead>
<tbody>
<tr>
<td>38.0%</td>
<td></td>
<td>28.7%</td>
</tr>
<tr>
<td>9.3%</td>
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</table>
Results: Other findings

• Improvements also noted in
  – Knowledge of preparation
  – Frequency (daily dose medications only)

• Knowledge of medication name, indication, storage
  – Good accuracy for both groups (>90%)
  – No significant differences between groups
Next Steps: Web-based Application

Web-based Application

- 50+ common liquid and tablet medications
- Daily dose medications, including step-down
- As-needed (PRN) medications
- English / Spanish language

Web-based, hosted on NYUMC server; written in Java & HTML

Database driven, scalable architecture

Currently in testing phase
Next Steps: Web-based Application (cont’d)

- Enter patient name
- Select medication (name, formulation, and strength)
- Select indication
- Enter in dose, frequency, duration
- Select from a menu of available instruments
- Select date to start course
- Select language (currently English, Spanish)
Next Steps: Effectiveness Study

- Examine the effectiveness of the HELPix intervention when used by pediatricians as part of routine clinical care
- Assess the level of provider utilization of the intervention, and barriers to dissemination
Next Steps

- Dissemination
  - Web-based application
    - Bellevue Pediatric Outpatient Clinic
  - PDF Format
    - NYC HHC

- Expansion of scope
  - Additional languages
  - Additional formulations
  - Chronic disease
  - Adaptation for adults
Acknowledgements

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  – The Bellevue Association
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  – HHC Foundation

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