Preventing Drug Product Confusion Errors: Strategies for the Pharmacy Buyer

Bruce L. Lambert, Ph.D. Department of Pharmacy Administration and Pharmacy Practice University of Illinois at Chicago Iambertb@uic.edu

#### Acknowledgments

- National Patient Safety Foundation
- Agency for Healthcare Quality and Research Grant #1 R01 HS011609-01a2
- Swu-Jane Lin, Robert Gibbons, Paul Luce, Gordon Schiff, Darren Toh, Jason Tan, Richard Lewis

#### **Objectives**

- By the end of this presentation, participants will be able to:
  - Compare and contrast the culture of blame and the culture of safety in health care.
  - Identify the major causes of drug name and drug product confusions.
  - List safe medication practices that can reduce the likelihood of drug product confusion.

MEDICAL CENTER HOSPITAL 500 - 600 W 4TH STREET ODESSA.TEXAS Ph 333 7111

FOR AGE DATE\_E ADDRESS Rendil 20mg Zomgf.0, 0,66mm Ferron Sulfale 300mg # 100 300mg p.0, TID & meals NO REFILLS REFILLS LABEL Humalin N 30 umits SQC PRODUCT SELECTION PERMITTED DISPENSE AS WRITTEN

D.E.A. #

719 637 2.89

IH 88-270

http://www.medmal-law.com/illegibl.htm

#### Plendil or Isordil?

- Isordil<sup>®</sup> prescribed
- Plendil<sup>®</sup> dispensed
- Cardiologist found negligent
- \$450,000 damage award
- First ever award for bad penmanship!

#### Culture of Blame or Safety

- Culture of Blame (still dominant)
  - Error is fault of individual
  - Error should be punished
  - Training, vigilance seen as solutions
- Culture of Safety (ascending?)
  - Errors due to system problems
  - Focus on learning and CQI
  - Non-punitive reactions to error
  - Tangible commitment to safety by leadership

#### Culture of Safety

Safety Climate Survey available (free!) from QualityHealthCare.org:

"In a culture of safety, people are not merely encouraged to work toward change; they take action when it is needed. Inaction in the face of safety problems is taboo, and eventually the pressure comes from all directions — from peers as well as leaders. There is no room in a culture of safety for those who uselessly point fingers or say, "Safety is not my responsibility, so I'll file a report and wash my hands of it."

# Establish A Culture of Safety (from QualityHealthCare.Org)

- 1. Designate a Patient Safety Officer
- 2. Provide Feedback to Front-Line Staff
- 3. Conduct Safety Briefings
- 4. Conduct Patient Safety Leadership WalkRounds™
- 5. Appoint a Safety Champion for Every Unit
- 6. Involve Patients in Safety Initiatives
- 7. Create a Reporting System
- 8. Simulate Possible Adverse Events
- 9. Create an Adverse Event Response Team
- 10. Relay Safety Reports at Shift Changes
- 11. Reenact Real Adverse Events from Your Facility

Obstacles to Adoption of Non-Punitive Culture/Systems

- Need for "accountability," tension between accountability and learning
- Fear of litigation, reprisal
- Lack of trusted and time-tested state and federal statutory protection from discovery
- Lack of knowledge about structure, function, and purpose of non-punitive systems
- Generalized resistance to change

### Wrong-Drug Errors

- Supposed to get Drug A, get Drug B instead
- Flynn et al. (JAPhA, Vol. 43, No. 2, p. 191-200) recently reported that wrongdrug error rate in outpatient pharmacy was 0.13%
- With 3 billion scripts filled per year, this means 3.9 million wrong drug errors per year.

#### Why Do These Errors Happen?

- Similarity- and frequency-based errors in cognitive processing
- Memory (recall and recognition)
- Perception (visual and auditory)
- Motor control (picking wrong drug from dropdown menu)
- Poorly designed systems (e.g., handwritten orders, oral orders, no CPOE, etc.)

#### **Drug Name Confusions**

- Account for 15-25% of all reported medication errors in the US
- Specifically identified by IOM in their report on medical errors
- Mandated initiatives underway at FDA to address the problem
- Several ongoing 'disasters' involving high-profile products

Examples (from USP-MERP)

- Lamisil<sup>®</sup> vs. Lamicel<sup>®</sup>
- Accupril<sup>®</sup> vs. Accutane<sup>®</sup>
- Celebrex<sup>®</sup> vs. Celexa<sup>®</sup>
- Cisplatin vs. carboplatin
- Hydroxyzine vs. Hydralazine
- Zosyn<sup>®</sup> vs. Zofran<sup>®</sup>
- Prilosec<sup>®</sup> vs. Prozac<sup>®</sup>
- Pediapred<sup>®</sup> vs. Pediaprofen<sup>®</sup>
- Prepridil<sup>®</sup> vs. Bepridil<sup>®</sup>

## Confusion not limited to drug names!

### Plaque muddles Luther King killer with Hollywood actor

Officials are blaming a mix-up after a plaque honored the man who killed Martin Luther King instead of actor James Earl Jones.

The actor was the voice of Star Wars' Darth Vader and The Lion King's Mufasa.

The plaque, however, commemorated James Earl *Ray* for "keeping the dream alive"...

#### STAMPS ISSUED IN HONOR OF BLACK HERITAGE



#### Thank you James Earl Ray for Keeping the Dream Aling City of Landerhill

January 19, 2002







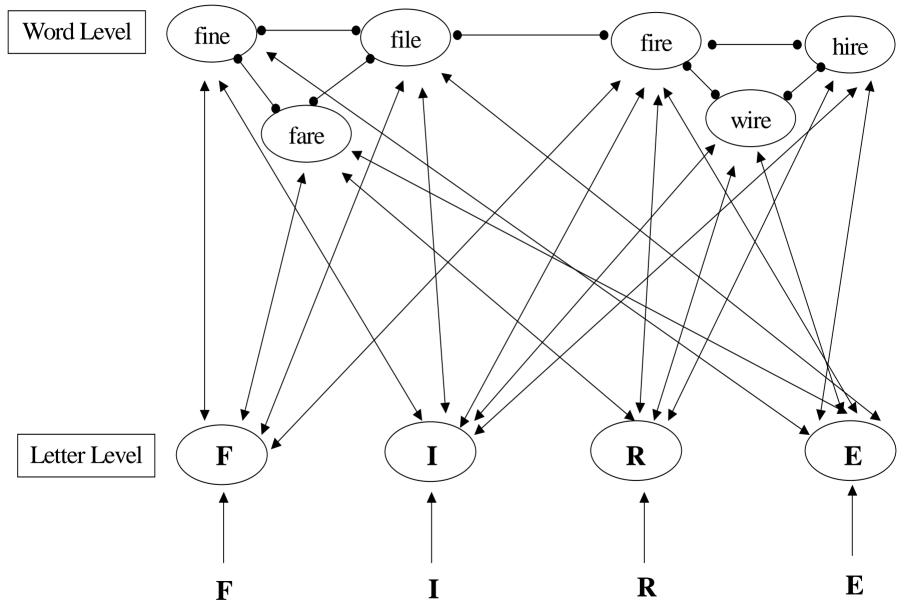
### Objective Measures of Name Similarity

- N-gram measures of spelling similarity (e.g., bigram, trigram)
- Edit distance
- Phonetic measures
- Phonological measures
- Multiple attribute measures
- These measures have been validated in several peer-reviewed publications

#### Visual Perception of Drug Names

- Perceptual features at multiple layers of abstraction (e.g., segment, letter, word)
- Spreading activation between layers
- Activation/competition models
- Influence of similarity and frequency

#### Interactive Activation Model



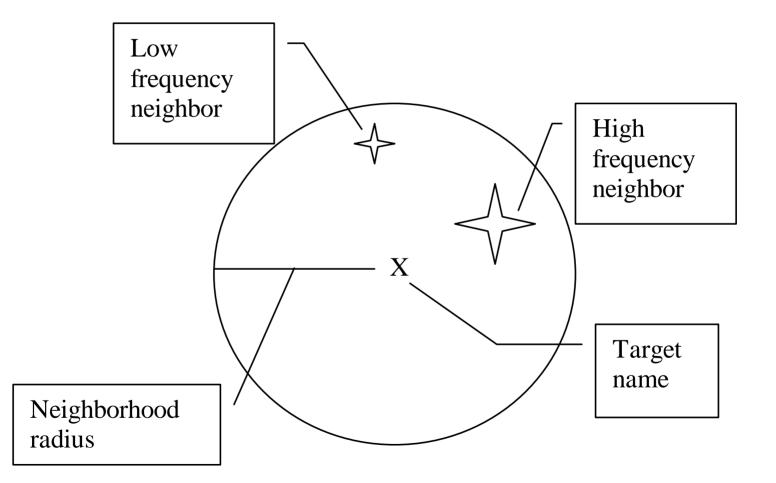
#### Similarity and Frequency

- In general, frequency (of prescribing) increases perceptual accuracy
- In general, similarity (to other names) decreases perceptual accuracy

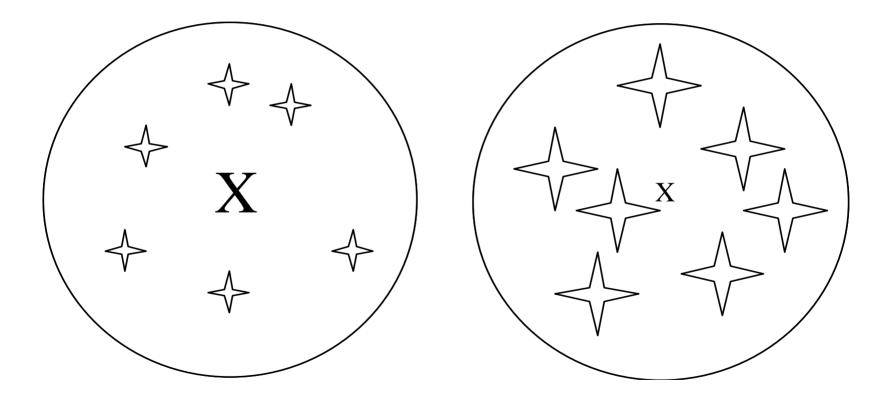
#### Definitions

- Stimulus Frequency: the log prescribing frequency of a given drug
- Neighborhood: the set of names within a given distance (3 edits) of a stimulus name
- Neighborhood density: the number of other names in a stimulus word's neighborhood
- Neighborhood frequency: the mean log prescribing frequency of the names in the neighborhood

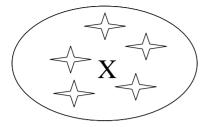
#### **Neighborhood Illustration**



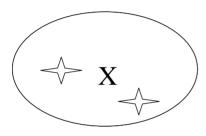
### Dense Neighborhoods: High and Low Frequency



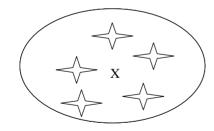
1) High SF, High NF, High ND



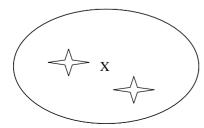
3) High SF, High NF, Low ND



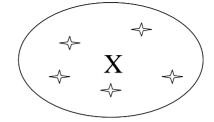
5) Low SF, High NF, High ND



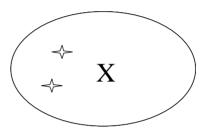
7) Low SF, High NF, Low ND



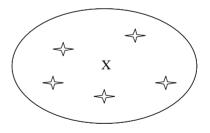
2) High SF, Low NF, High ND



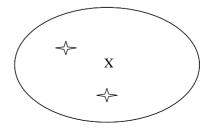
4) High SF, Low NF, Low ND



6) Low SF, Low NF, High ND



8) Low SF, Low NF, Low ND



#### Examples

- High log SF names (log SF > 7): Ventolin<sup>®</sup>, Dyazide<sup>®</sup>, Provera<sup>®</sup>
- Low log SF names (log SF < 3): Vistazine<sup>®</sup>, Antispas<sup>®</sup>, Protaphane<sup>®</sup>
- Name from a sparse neighborhood: Flexeril<sup>®</sup> (no neighbors in NAMCS/NHAMCS)
- Name from a dense neighborhood: Dynabac<sup>®</sup>, Synalar<sup>®</sup>, Rynatan<sup>®</sup>, Dynapen<sup>®</sup>, Dynacirc<sup>®</sup>, Dynacin<sup>®</sup>, Cynobac<sup>®</sup>

#### Hypotheses

- Error rates in visual perception will increase as stimulus frequency decreases
- Error rates in visual perception will increase as neighborhood density increases
- Error rates in visual perception will increase as neighborhood frequency increases

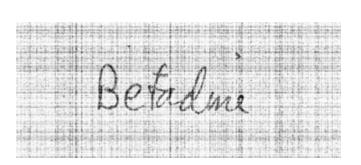
### Stimuli: Drug Names

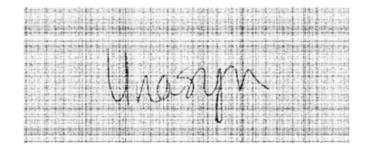
Twenty names each were selected at high and low levels of prescribing frequency (i.e., the log of the number of NAMCS/HAMCS prescriptions), neighborhood frequency (i.e., the average log prescribing frequencies of names within an edit distance of 3 from a given name), and neighborhood density (i.e., the number of names within an edit distance of 3 of a given name).

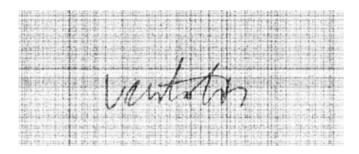
#### Participants and Task

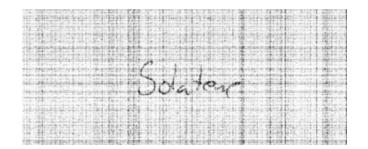
- Participants were licensed, practicing pharmacists drawn from attendees at the 2000 National Community Pharmacists Association annual meeting (N=37)
- Task is a noise-masked visual perception task
- Participant must identify a degraded drug name after 3-second exposure









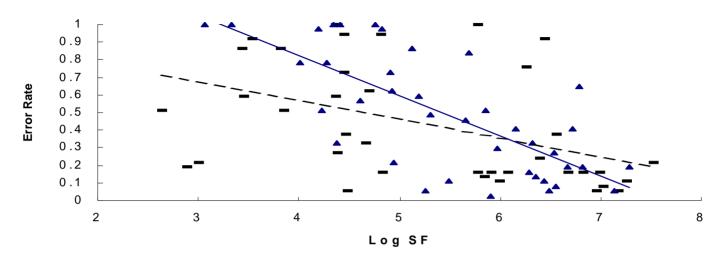


#### Procedure

- Pharmacist seated in front of Macintosh computer
- Drug names appear for 3 seconds
- Names degraded as if sent by a bad fax machine
- Row of XXXXs replaces name after 3 seconds
- Pharmacist types in correct response
- 5 practice trials, 160 test trials

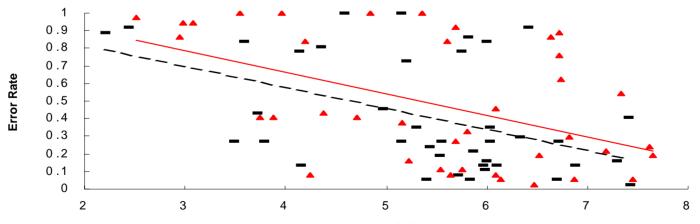
(a) High NF

🔺 High ND - Low ND



(b) Low NF

■Low ND ▲ High ND



Log SF

#### **Discussion and Implications**

- Word frequency effect is extremely powerful. Rare names much more difficult to perceive than common names.
- Dense neighborhoods inhibit perception, especially of low frequency names in high frequency neighborhoods.
- Keep neighborhoods sparse to minimize error.
- Use neighborhood measures as part of preapproval screening.

#### Conclusion

- The less frequently a drug name is prescribed, the more difficult it is to be perceived correctly in a noise-masked visual perception experiment.
- For low frequency words, the presence of similar neighbors significantly increases the probability of a perceptual error.

#### Limitations

- Somewhat contrived, laboratory task
- Relatively small, non-representative sample of pharmacists (NCPA attendees)
- Noise and exposure durations may be unrealistic

#### Patient Safety Lessons

- Similarity and frequency are still basic mechanisms of error. Look for them everywhere.
- Probability of error not most important endpoint
- Minimize harm
- Harm is a function of number of opportunities for error, probability of error and severity of error

#### What about Prevention?

- Pre-approval screening
- Post-event labeling changes (e.g., Lamictal, cisplatin)
- CPOE-based solutions
- Safe prescribing practices
- Doctor-patient interaction
- Dispensing and administration fixes

#### **Pre-Approval Screening**

- FDA and manufacturer's joint responsibility
- Should use validated measures
- Should search on multiple attributes
- Criteria for acceptance/rejection of new names should be rational and explicit
- Companies soon mandated to submit pre-approval info about name confusion

### Labeling Changes



### **CPOE-based Solutions**

- Warnings on known confusing names
- Dose checking
- Indication checking
- Non-alphabetical presentation on menus
- Querying for distinguishing attributes
- "Tall man" lettering

- Prescriptions should clearly specify the dosage form, drug strength, and complete directions.
- Include the product's indication on all outpatient prescriptions and on inpatient *prn* orders.
- With name pairs known to be problematic, reduce the potential for confusion by writing prescriptions using both the brand and generic name.

- Accept verbal or telephone orders only when truly necessary. Encourage staff to repeat back all orders, spell the product name, and state its indication.
- When feasible, use magnifying lenses and copyholders under good lighting to keep prescriptions and orders at eye level during transcription.

•Change the appearance of look-alike product names on computer screens, pharmacy and nursing unit shelf labels and bins (including automated dispensing cabinets), pharmacy product labels, and medication administration records by highlighting, through bold face, color, and/or tall man letters, the parts of the names that are different (e.g., hydr**OXY**zine, hydr**ALA**zine).

- Affix "name alert" stickers to areas where look or sound-alike products are stored (available from pharmacy label manufacturers).
- Store products with look or sound-alike names in different locations. Avoid storing both products in the fast-mover area. Use a shelf sticker to help locate the product that is moved.

## Making Formularies Safer

- Clean and prep formulary database
- Create two subsets
  - Oral solid dosage forms
  - Injectable dosage forms
- Compute similarity scores between all name pairs
- Identify all pairs whose name similarities exceed some threshold and that match on other attributes
- Screen selected pairs for severity of consequences of a confusion
- Propose, implement, and evaluate interventions to deal with the most problematic pairs

### **Drug Product Attributes**

- Brand name
- Generic name
- Strength
- Dosage form
- Route of administration
- Pharmacologic category

# Analysis Plan and Organization of Results

- Select pairs that exceed threshold of similarity or distance
- Sort in ascending order of distance
- Link to known error pairs and indicate which pairs have been previously reported as confusing
- Tally total number of pairs and number of previously reported pairs

## Increasing Levels of Similarity

- Name similarity only (distance<=8)</li>
- 2. Similar name and identical strength
- Name, strength, and one member of pair must be in "high alert" category (e.g., opiates, antineoplastics)
- 4. Name, strength, route of administration

#### **Injectables: Name Similarity Only**

- 3; LIPID 10% INJ; 0.1; LIPID; CALORIC AGENTS; IV PIGGYBACK; LIPID 20% INJ; 0.2; LIPID; CALORIC AGENTS; IV PIGGYBACK; Unreported
- 5; EPOGEN; ; EPOETIN; HEMATOPOLETIC AGENTS; SUBCUTANEOUS; NEUPOGEN; ; FILGRASTIM; UNCLASSIFIED THERAPEUTIC AGENTS; SUBCUTANEOUS; Reported
- 5; TOBRAMYCIN; ; TOBRAMYCIN; AMINOGLYCOSIDES; IV PIGGYBACK; VIBRAMYCIN; ; DOXYCYCLINE HYCLATE; TETRACYCLINES; IV PIGGYBACK; Unreported
- 5; PREMARIN; ; CONJUGATED ESTROGENS; ESTROGENS; INTRAVENOUS; PRIMAXIN; ; IMIPENEM-CILASTATIN; MISCELLANEOUS B-LACTAM ANTIBIOTICS; IV PIGGYBACK; Reported
- 5; LINCOMYCIN; ; LINCOCIN; MISCELLANEOUS ANTIBIOTICS; INTRAMUSCULAR; VANCOMYCIN; ; VANCOMYCIN; MISCELLANEOUS ANTIBIOTICS; IV PIGGYBACK; Unreported

### Injectables: Name, Strength, One Antineoplastic

- 6; MITHRAMYCIN; ; PLICAMYCIN INJ; ANTINEOPLASTIC AGENTS; IV PIGGYBACK; MITOMYCIN; ; MUTAMYCIN; ANTINEOPLASTIC AGENTS; SYRINGE; Reported
- 6; MITHRAMYCIN; ; PLICAMYCIN INJ; ANTINEOPLASTIC AGENTS; IV PIGGYBACK; MUTAMYCIN; ; MITOMYCIN; ANTINEOPLASTIC AGENTS; SYRINGE; Unreported
- 6; STADOL; ; BUTORPHANOL INJ; OPIATE PARTIAL; INTRAVENOUS; TAXOL; ; PACLITAXEL; ANTINEOPLASTIC AGENTS; IV PIGGYBACK; Unreported
- 7; IDAMYCIN; ; IDARUBICIN; ANTINEOPLASTIC AGENTS; SYRINGE; MITOMYCIN; ; MUTAMYCIN; ANTINEOPLASTIC AGENTS; SYRINGE; Unreported
- 7; IDAMYCIN; ; IDARUBICIN; ANTINEOPLASTIC AGENTS; SYRINGE; MUTAMYCIN; ; MITOMYCIN; ANTINEOPLASTIC AGENTS; SYRINGE; Unreported

### Injectables: Name, Strength, One Antineoplastic, Route

- 7; IDAMYCIN; ; IDARUBICIN; ANTINEOPLASTIC AGENTS; SYRINGE; MITOMYCIN; ; MUTAMYCIN; ANTINEOPLASTIC AGENTS; SYRINGE; Unreported
- 7; IDAMYCIN; ; IDARUBICIN; ANTINEOPLASTIC AGENTS; SYRINGE; MUTAMYCIN; ; MITOMYCIN; ANTINEOPLASTIC AGENTS; SYRINGE; Unreported
- 8; ADRIAMYCIN; ; DOXORUBICIN; ANTINEOPLASTIC AGENTS; SYRINGE; IDAMYCIN; ; IDARUBICIN; ANTINEOPLASTIC AGENTS; SYRINGE; Reported
- 8; ETOPOSIDE; ; VEPESID; ANTINEOPLASTIC AGENTS; IV PIGGYBACK; TENIPOSIDE; ; VUMON; ANTINEOPLASTIC AGENTS; IV PIGGYBACK; Unreported
- 8; MITHRAMYCIN; ; PLICAMYCIN INJ; ANTINEOPLASTIC AGENTS; IV PIGGYBACK; VIBRAMYCIN; ; DOXYCYCLINE HYCLATE; TETRACYCLINES; IV PIGGYBACK; Unreported

#### **Oral Solids: Name Similarity Only**

- 2; VITAMIN A; 10,000 UNIT; VITAMIN A; VITAMIN A; ORAL; VITAMIN E; 100UN; VITAMIN E; VITAMIN E; ORAL; Unreported
- 3; THYROLAR-2; 25mcg/100mcg; LEVOTHYROXINE-LIOTHYRONINE; THYROID AGENTS; ORAL; THYROLAR-3; 37mcg/150mcg; LEVOTHYROXINE-LIOTHYRONINE; THYROID AGENTS; ORAL; Unreported
- 4; MOTRIN; 400MG; IBUPROFEN; NONSTEROIDAL ANTI-INFLAMMATORY AGENTS; ORAL; MIDRIN; ; ISOMETHEPTENE-DICHLPHEN-APAP; MISCELLANEOUS ANALGESIC AND ANTIPYRETICS; ORAL; Unreported
- 4; NAPROSYN EC; 375MG; NAPROXEN EC; NONSTEROIDAL ANTI-INFLAMMATORY AGENTS; ORAL; NAPROXEN EC; 500MG; NAPROSYN EC; NONSTEROIDAL ANTI-INFLAMMATORY AGENTS; ORAL; Unreported
- 4; SOMA; 350MG; CARISOPRODOL; SKELETAL MUSLE RELAXANTS; ORAL; SENNA; ; SENOKOT; CATHARTICS AND LAXATIVES; ORAL; Unreported
- 4; PERMAX; 0.05MG; PERGOLIDE; UNCLASSIFIED THERAPEUTIC AGENTS; ORAL; VERMOX; 100MG; MEBENDAZOLE; ANTHELMINTICS; ORAL; Unreported

#### **Oral Solids: Name and Strength**

- 5; NIMODIPINE; 30MG; NIMOTOP; UNCLASSIFIED THERAPEUTIC AGENTS; ORAL; NIFEDIPINE; 30MG; PROCARDIA XL; CARDIAC DRUGS; ORAL; Reported
- 5; CLOZAPINE; 25MG; CLOZARIL; ANTIDEPRESSANTS; ORAL; LOXAPINE; 25MG; LOXITANE; TRANQUILIZERS; ORAL; Unreported
- 5; ADDERALL; 10MG; AMPHETAMINE/DEXTROAMPHETAMINE; RESPIRATORY AND CEREBRAL STIMULANTS; ORAL; INDERAL; 10MG; PROPRANOLOL; CARDIAC DRUGS; ORAL; Reported
- 5; RIMANTADINE; 100MG; FLUMADINE; ANTIVIRALS; ORAL; AMANTADINE; 100MG; SYMMETREL; UNCLASSIFIED THERAPEUTIC AGENTS; ORAL; Reported
- 6; ELAVIL; 75MG; AMITRIPTYLINE; ANTIDEPRESSANTS; ORAL; PLAVIX; 75MG; CLOPIDOGREL BISULFATE; UNCLASSIFIED THERAPEUTIC AGENTS; ORAL; Reported

## Oral Solids: Name, Strength, One Opiate

- 7; **DEMEROL**; 50MG; MEPERIDINE; OPIATE AGENTS; ORAL; **DESYREL**; 50MG; TRAZODONE; ANTIDEPRESSANTS; ORAL; Reported
- 7; CARDENE; 30MG; NICARDIPINE; CARDIAC DRUGS; ORAL; CODEINE; 30MG; CODEINE; OPIATE AGENTS; ORAL; Reported
- 8; FOLTX; ; FOLIC ACID/VIT B6/VIT B12; MULTIVITAMIN b PREPARATIONS; ORAL;
  - **TYLOX**; ; ACETAMINOPHEN-OXYCODONE; OPIATE AGENTS; ORAL;

Unreported

## Oral Solids: Name, Strength, One Cardiac

- 5; NIMODIPINE; 30MG; NIMOTOP; UNCLASSIFIED THERAPEUTIC AGENTS; ORAL; NIFEDIPINE; 30MG; PROCARDIA XL; CARDIAC DRUGS; ORAL; Reported
- 5; ADDERALL; 10MG; AMPHETAMINE/DEXTROAMPHETAMINE; RESPIRATORY AND CEREBRAL STIMULANTS; ORAL; INDERAL; 10MG; PROPRANOLOL; CARDIAC DRUGS; ORAL; Reported
- 6; AMLODIPINE; 5MG; NORVASC; CARDIAC DRUGS; ORAL; FELODIPINE; 5MG; PLENDIL; CARDIAC DRUGS; ORAL; Unreported
- 6; QUINIDINE SULFATE; 200MG; QUINIDINE SULFATE; CARDIAC DRUGS; ORAL; QUININE SULFATE; 200MG; QUININE SULFATE; ANTIMALARIAL AGENTS; ORAL; Unreported
- 7; CARDENE; 30MG; NICARDIPINE; CARDIAC DRUGS; ORAL; CODEINE; 30MG; CODEINE; OPIATE AGENTS; ORAL; Reported

### Oral Solids: Name, Strength, One Antineoplastic

- 8; CAPOTEN; 50MG; CAPTOPRIL; HYPOTENSIVE AGENTS; CASODEX; 50MG; BICALUTAMIDE; ANTINEOPLASTIC AGENTS; Unreported
- 8; ALKERAN; 2MG; MELPHALAN; ANTINEOPLASTIC AGENTS; MYLERAN; 2MG; BUSULFAN; ANTINEOPLASTIC AGENTS; Unreported
- 8; ALKERAN; 2MG; MELPHALAN; ANTINEOPLASTIC AGENTS; LEUKERAN; 2MG; CHLORAMBUCIL; ANTINEOPLASTIC AGENTS; Reported

# Rating Severity of Harm (In Progress)

- Harm=Probability of error X num. opportunities for error X severity of each error X probability of not detecting
- Depends on direction of error
- Depends on duration of exposure
- Depends on patient clinical status
- Exposure to wrong drug vs. failure to receive right drug

### What More Can a Buyer Do?

- Try not to stock look alike drugs together in the pharmacy
- Clarifying when one of the pharmacy staff places an odd order --- are they on the path to a med error?
- Create failsafe systems for stocking automated devices.
- Post common med errors or red label products with high potential for error.
- Communicate with suppliers about confusing names and labels
- Subscribe to, post, and use ISMP Medication Safety Alerts.

### Summary

- By the end of this presentation, participants will be able to:
  - Identify the major causes of drug name and drug product confusions.
  - Describe safe medication practices that can reduce the likelihood of confusion.
  - Develop a specific strategy for reducing name confusion errors in the context of a specific clinical area.
- Did we achieve our objectives?