MSOS Member Briefings

4/26/2018

MSOS Member Briefings
April 2018

Moderated by: E. Robert Feroli, PharmD, FASHP

Supported by educational grants
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NOVARTIS PHARMACEUTICALS

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DRAFT

1

U.S. FOOD & DRUG ADMINISTRATION

FDA Requirements for Linear and 2D Data Matrix Barcodes

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Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)

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Branch Chief, Supply Chain Strategy & Policy Branch
Office of Drug Security, Integrity and Response (ODSIR)
Office of Compliance (OC)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration (FDA)

DRAFT

Objectives

FDA

- Understand the U.S. regulatory requirements for:
  - Linear barcodes
  - 2D data matrix barcodes
- Discuss commonly reported barcode issues

DRAFT

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Overview of Characteristics for Linear and Product Identifier/2D Data Matrix Barcodes

	Linear Barcode (21 CFR 201.25)	2D Data Matrix Barcode (DSCSA)
Example		 NDC: xxxx-xxxx-xx SERIAL: xxxxxxxxxx LOT: xxxxxx EXP: YYYY-MM-DD
Purpose	• "Verify" that the right drug in the right dose and right route of administration is given to the right patient at the right time. • Help reduce medication errors that occur in healthcare settings.	• Standardized graphic, human- and machine-readable format • The machine-readable format is a 2D data matrix barcode • Used for tracing and verification under the Drug Supply Chain Security Act (DSCSA).
Location	Container Labels and Carton Labeling	Each "package" of product. [Sec. 581(11) of the FD&CA]
Products (some exceptions)	• Human prescription drug products • OTC drug products dispensed pursuant to an order and commonly used in hospitals	• Prescription drug in finished dosage form for administration to a patient without substantial further manufacturing… [Sec. 581(13) of the FD&CA] • Prescription drug for human use subject to Sec. 503(b)(1).
Contains (minimum)	NDC	NDC, serial number, lot #, and expiration date

DRAFT

Discussion of Barcode Issues

DRAFT

Multiple Barcodes

Original	Revised
	

Source: ISMP Community/Ambulatory Care Newsletter, 2015 Jun; 14(6).

- Reasons for multiple barcodes include: regulatory requirements, and verification during the manufacturing process
- Recommend locating regulatory-required barcodes away from other barcodes
- REPORT: Linear barcodes that cannot be accurately read

DRAFT 6

Linear Barcodes Placed Horizontally Around the Curvature of a Vial or Syringe

Original	Revised
	

- Manufacturers may reposition linear barcodes when adding other barcodes
- REPORT: Linear barcodes that cannot be scanned and read

Source: ISMP Acute Care Newsletter, 2017 Oct 19; 22(21).

DRAFT 7

Missing Linear Barcodes

Original

- Most human prescription drug products require a linear barcode on the container label and carton labeling
- REPORT: Prescription drug products without a linear barcode

Source: ISMP Acute Care Newsletter, 2018 Jan 25; 23(2).

DRAFT 8

Inhalation Products and Barcodes

- Some inhalation products have no barcode or affixed label
- LDPE form fill and seal containers packaged without an overwrap are **excepted** from the linear barcode rule because of potential leaching and contamination related to the barcode ink.
- For new product approvals, we recommend avoiding containers that provide poor visual contrast between the container and label information or have no affixed label but deboss or emboss the information on the container itself.

Source: ISMP Acute Care Newsletter, 2002 May 15; 7(10).

DRAFT 9

Resources

- Linear Barcodes
  - 21 CFR 201.25
  - Guidance for industry: barcode label requirements, questions and answers (2011) https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/ucm267392.pdf
- Product Identifiers/2D Data Matrix Barcode under DSCSA
  - FDA's DSCSA webpage for updates and informational resources: https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm.
  - The Drug Supply Chain Security Act is available at: http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm376829.htm.

DRAFT 10

Questions?

DRAFT

ISMP Update

Michael R. Cohen, RPh, MS, ScD (hon.), DPS (hon), FASHP
President, ISMP

DRAFT 12

AHRQ Indications RX Project Incorporating Indications into Electronic Prescriptions

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Associate Dir Brigham Center for Patient Safety Research and Practice
Quality and Safety Director HMS Center for Primary Care

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BRIGHAM AND WOMEN'S HOSPITAL A FOUNDING MEMBER OF PARTNERS HEALTHCARE HARVARD MEDICAL SCHOOL TEACHING HOSPITAL MCPHS UNIVERSITY

Conflict of Interest

Gordon Schiff, MD

Pamela Neri Garabedian, MS

No real or apparent conflicts of interest to report.

Indications Project Funded by U.S. Agency for Healthcare Research and Quality AHRQ HIT Safety Grant HS23694

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Agenda

- Background & rationale – Brigham AHRQ Indications Rx project
- Summarize activities and findings from project aims 1-3
- Demonstrate BWH prototype
- Results of prototype testing
  - Comparisons with Epic and Cerner
- Next steps
  - How might "indications first" be incorporated into EMR?
  - How can we move forward with this?

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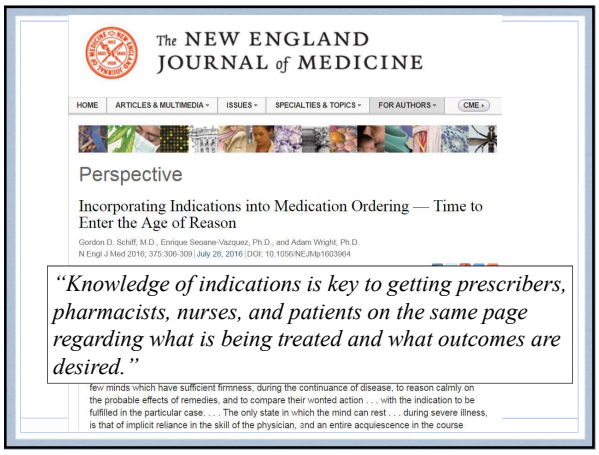

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Perspective

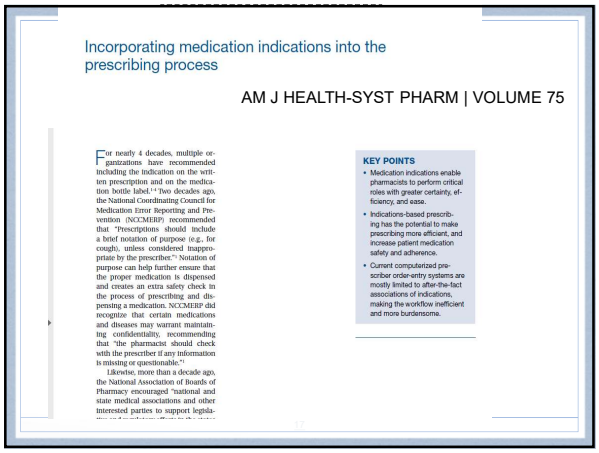
Incorporating Indications into Medication Ordering — Time to Enter the Age of Reason

Gordon D. Schiff, M.D., Enrique Seoane-Vazquez, Ph.D., and Adam Wright, Ph.D.

N Engl J Med 2016; 375:306-309 | July 28, 2016 | DOI: 10.1056/NEJMp1603964

"Knowledge of indications is key to getting prescribers, pharmacists, nurses, and patients on the same page regarding what is being treated and what outcomes are desired."

few minds which have sufficient firmness, during the continuance of disease, to reason calmly on the probable effects of remedies, and to compare their wonted action . . . with the indication to be fulfilled in the particular case. . . . The only state in which the mind can rest . . . during severe illness, is that of implicit reliance in the skill of the physician, and an entire acquiescence in the course



Incorporating medication indications into the prescribing process

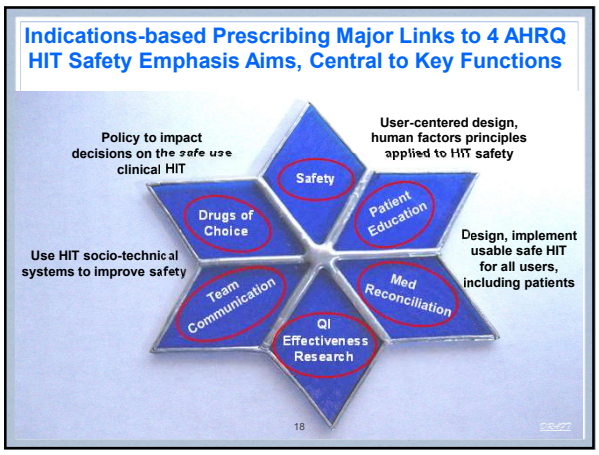
AM J HEALTH-SYST PHARM | VOLUME 75

For nearly 4 decades, multiple organizations have recommended including the indication on the written prescription and on the medication bottle label.[1] Two decades ago, the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) recommended that "Prescriptions should include a brief notation of purpose (e.g., for cough), unless considered inappropriate by the prescriber."[2] Notation of purpose can help further ensure that the proper medication is dispensed and creates an extra safety check in the process of prescribing and dispensing a medication. NCCMERP did recognize that certain medications and diseases may warrant maintaining confidentiality, recommending that "the pharmacist should check with the prescriber if any information is missing or questionable."[2]

Likewise, more than a decade ago, the National Association of Boards of Pharmacy encouraged "national and state medical associations and other interested parties to support legisla-

KEY POINTS

- Medication indications enable pharmacists to perform critical roles with greater certainty, efficiency, and ease.
- Indications-based prescribing has the potential to make prescribing more efficient, and increase patient medication safety and adherence.
- Current computerized prescriber order-entry systems are mostly limited to after-the-fact associations of indications, making the workflow inefficient and more burdensome.



http://www.nccmerp.org/council/council1996-09-04.html

National Coordinating Council for Medication Error Reporting and Prevention

bout NCC MERP

Council Recommendations

Print

Recommendations to Enhance Accuracy of Prescription Writing

The Council recommends:

1. ...all prescription documents be legible. Verbal orders should be minimized. (See the Council's Recommendations to Reduce Medication Errors Associated with Verbal Medication Orders and Prescriptions)
2. ...prescription orders include a brief notation of purpose (e.g., for cough), unless considered inappropriate by the prescriber. Notation of purpose can help further assure that the proper medication is dispensed and creates an extra safety check in the process of prescribing and dispensing a medication. The Council does recognize, however, that certain medications and disease states may warrant maintaining confidentiality.
3. ...all prescription orders be written in the metric system except for therapies that use standard units such as insulin, vitamins, etc. Units should be spelled out rather than writing "U." The change to the use of the metric system from the archaic apothecary and avoirdupois systems will help avoid misinterpretations of these abbreviations and symbols, and miscalculations when converting to metric, which is used in product labeling and package inserts.

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Overall AHRQ Project Aim

"To improve prescribing safety by redesigning medication computerized prescriber order entry (CPOE) by incorporating the medication indication into the prescription order."

3 Year Project Specific Aims

1. Convene 6 stakeholder expert panels on rationale, multi-user needs, operational and interoperability requirements, interface design elements, limitations and barriers, and policy implications of incorporating indication into CPOE; publication of Sounding Board and White Paper
2. Build working prototype indications-enabled CPOE using user-centered design incorporating Aim 1 recommendations
3. Formally test and compare prototype to two widely deployed CPOE systems using use-case clinical scenarios re: ordering speed, error rate, user experience/satisfaction, plus usefulness and safety of the prescriptions generated for pharmacists and patients.

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AbbVie
Academy of Managed Care Pharmacy
Accreditation Council for Graduate Medical Education
Agilex
AHRQ
Albany Medical Center
American Academy of Family Physicians
American Association of Colleges of Pharmacy
American Board of Internal Medicine
American Cancer Society
American College of Physicians
American Heart Association
American Medical Association (AMA)
American Pharmacists Association (APhA)
American Society of Health Systems Pharmacists
Anthem Blue Cross Blue Shield
Ashleigh Fisher Consulting
Athenahealth
Baptist Healthcare System
Baton Rouge General Hospital
Baylor College of Medicine
Becton Dickinson and Company
Betsy Lehman Center for Patient Safety and Medical Error Reduction
Boesen & Snow LLC
Boston Children's Hospital
Brigham and Women's Hospital
California State Board of Pharmacy
Catamaran
Centers for Disease Control and Prevention (CDC)
Centers for Medicare & Medicaid Services (CMS)
Cerner
Cincinnati Children's Hospital Medical Center
CMI Project
Colcamex Resources
Cone Health
Consumer Reports
CVS Caremark
CVS Health
Dartmouth College
Department of Health and Human Services Office of the National Coordinator for Health IT
District of Columbia Board of Pharmacy
DrFirst
Duke University

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Participating Stakeholders' Organizations

Elsevier Clinical Solutions
Emedeon
Enhance Value
Epic
Epilepsy Foundation of America
Fairview Pharmacy Services
First Data Bank (FDB)
First DataBank
Food and Drug Administration (FDA)
Genelex
Government of Western Australia Department of Health
Granada Health, LLC
Harvard Medical School
Harvard Primary Care Center
Healthcare Compliance Packaging Council
Healthy Motivation
Hearst Magazine
Indian Health Service
Indiana University
Institute for Healthcare Improvement
Institute for Safe Medication Practices (ISMP)
International Medical Interpreters Association
International Pharmaceutical Federation
Johns Hopkins University
Kaiser Northwest
Kaiser Permanente
King Fahad Medical City
Kroger
Lee Memorial Health System
Massachusetts College of Pharmacy and Health Sciences University (MCPHSU)
Massachusetts General Hospital
Massachusetts Pharmacy Association
Mayo Clinic Rochester
McKesson
Memorial Pediatrics
Merck & Co., Inc.
Midwestern University
Molina Healthcare
Molina Medicaid Solutions
Montefiore Medical Center
National Academy on an Aging Society
National Alliance of State Pharmacy Associations
National Association of Boards of Pharmacy (NABP)
National Association of Chain Drug Stores

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Participating Stakeholders' Organizations

National Association of Managed Care Physicians
National Community Pharmacists Association
National Council on Patient Information and Education (NCPIE)
National Osteoporosis Foundation
National Patient Safety Foundation
NCPDP
New York State Board of Pharmacy
NextGen Healthcare
Northwestern University
Ohio Pharmacists Association
Ohio Public Employees Retirement System
Oklahoma Health Care Authority
Omnicare, Inc.
OPERS Healthcare
Optum
OptumInsight, Inc.
Oregon Health and Science University
Osterhaus Pharmacy
Partners Healthcare
Patient Safety America
Patients for Patient Safety Canada
Patients Like Me
PDX Inc
Pfizer
Pharmaceutical Research and Manufacturers of America
Pharmacy HIT Collaborative
Phil Burgess Consulting
Point-of-Care Partners
Project Patient Care
Purdue Pharma L.P.
Quantros, Inc.
RAND Corporation
Rite Aid
S and R Consulting Associates
Salem Memorial District Hospital
San Francisco State University
Sanofi
South Carolina Pharmacy Association
Spectrum Health
St. David's Round Rock Medical Center
Stratis Health
SUNY Buffalo
Surescripts
Target

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Participating Stakeholders' Organizations

The Joint Commission
The Lynx Group
The Medical Letter
The PSO Advisory
The University of Alcala de Henares
The University of Illinois at Chicago
Truven Health Analytics
Tufts Medical Center
UCL School of Pharmacy, London
UIC College of Pharmacy
UNC School of Pharmacy
Uniformed Services University of the Health Sciences (USUHS)
United States Pharmacopeia (USP)
Universite Catholique de Louvain
Université Laval
University of Alabama at Birmingham
University of Arizona College of Pharmacy
University of British Columbia (UBC)
University of California Los Angeles (UCLA)
University of Colorado
University of Connecticut
University of Edinburgh
University of Illinois - Chicago
University of Maryland
University of Mass Memorial Medical Center
University of Minnesota
University of Pennsylvania
University of Sydney
University of Washington
US Public Health Service
Vanderbilt University
Veterans Affairs
Veterans' Association
Walgreens
Walmart
Weil Cornell Medical College
Wisconsin Department of Health Services
Wolters Kluwer
Wolters Kluwer, Clinical Drug Information
Yale University
York University, Toronto
Zynx

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Knowing Medication Indication Would Prevent These Errors*

- Rapamune (immunosuppressant) vs. Rapaflo (BPH). Consequence: organ rejection or progressive BPH
- Risperidone (schizophrenia, bipolar disorder) vs. Ropinirole (PD, RLS). Consequence: worsening of symptoms
- Tramadol (pain) vs. Trazodone (depression). Consequence: no pain relief or increase depressive mood
- Lamotrigine (epilepsy) vs. Lamivudine (HBV or IV). Consequences: seizure or liver failure/AIDS (lamivudine indications are dose dependent)
- Prozac (depression) vs. Prograf (transplant rejection). Consequence: organ rejection or worsening of depression

*ISMP List of Confused Drug Names - ISMP National Medication Error Reporting Program
https://www.ismp.org/tools/confuseddrugnames.pdf

Knowing Medication Indication Would Prevent These Errors*

- Brilinta (antiplatelet) vs. Brintellix (antidepressant). Consequence: bleeding risk or worsening of depression
- Chlorpromazine (schizophrenia) vs. Chlorpropamide (DM). Consequence: delusional/hallucinating symptoms or hyperglycemia
- Jantoven (anticoagulant) vs. Januvia (DM). Consequences: bleeding risk or hyperglycemia
- Keppra (epilepsy) vs. Keflex (infection). Consequences: seizure or worsening of infection
- Sulfasalazine (UC, RA) vs. Sufadiazine (infection). Consequence: disease flare/progression or antibiotic resistance/worsening of infection

*ISMP List of Confused Drug Names - ISMP National Medication Error Reporting Program
https://www.ismp.org/tools/confuseddrugnames.pdf

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Can drug indications be used to discriminate between LASA drugs?

- Study done in collaboration with a commercial drug knowledgebase vendor
- Compared high-level indications for commonly confused drug pairs
- Of 281 eligible LASA drug pairs (456 unique drugs)
  - **168 (60%)** had no overlap in indications
  - **58 (21%)** had partial overlap in indications
  - **55 (20%)** had complete overlap in indications
    - Half were drugs with the same active ingredient and route of administration *(e.g., Adderall, Adderall XR)*

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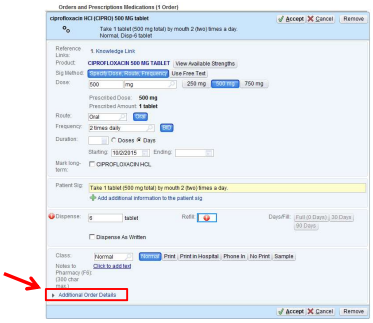
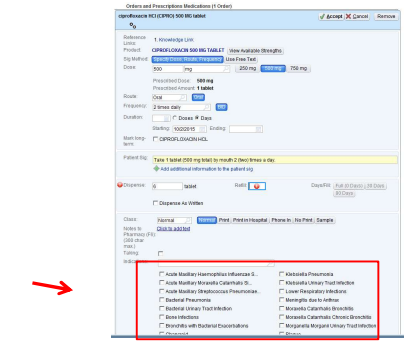
Epic Recognizes, has Functionality to Enter Indications



Epic Recognizes, has Functionality to Enter Indications




Old Paradigm
Drug
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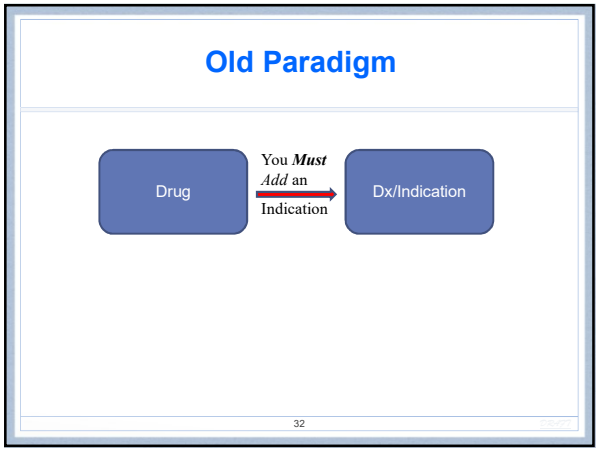
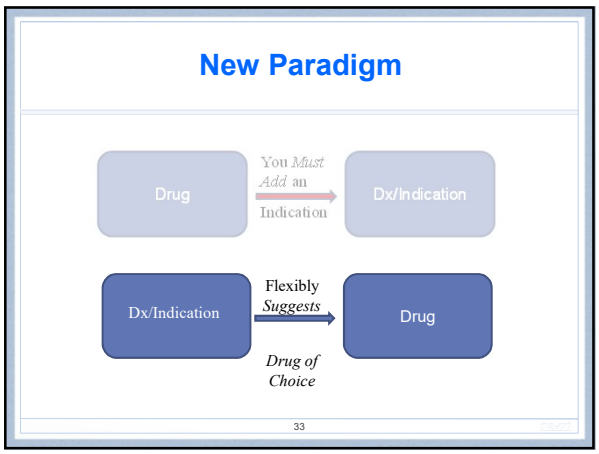

Old Paradigm
Drug
You Must Add an Indication
Dx/Indication
32


New Paradigm
Drug
You Must Add an Indication
Dx/Indication
Dx/Indication
Flexibly Suggests
Drug of Choice
Drug
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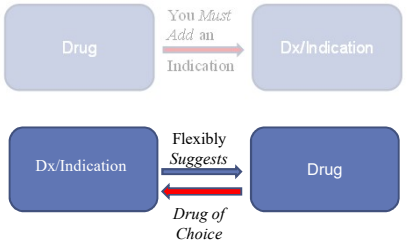
New Paradigm



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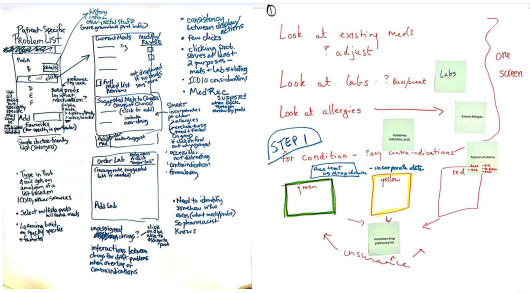
User Centered Design



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Demo

http://indicationsrx.partners.org/

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Methods

- Conducted 32 in-person usability tests with prototype CPOE system and commercial vendors
  - Cerner:
    - Tests done at University of Illinois - Chicago
    - October 2017
  - Epic:
    - Tests done at Brigham and Women's Hospital in Boston
    - May - June 2017

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Methods

- Each usability testing session lasted 40-90 minutes
- Participants were given a brief training on the prototype and time to explore
- Participants worked through 8 clinical scenarios with the IndRx Prototype and Epic or Cerner
  - The task was to review the patients history and order an appropriate medication including the indication for the pharmacist and patient
  - The order of the tasks and systems was alternated to avoid bias
- A usability specialist observed, moderated and recorded the session
  - Morae software was used to capture data including time and clicks
- Participants responded to the Single Ease Question (SEQ) after they completed each task and the System Usability Scale (SUS) for the prototype at the end of the test

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Participant Characteristics

Clinical Role	# of Participants (%)
MD attending	17 (53%)
PA	2 (6%)
Resident (2nd, 3rd, or 4th year	13 (41%)
Total	**32**

Time Using Current System	Vendor		Vendor
< 5 years	4 (33%)	<2 years	4 (33%)
5-10 years	4 (33%)	2 years	14 (70%)
11-15 years	2 (17%)	>2 years	2 (10%)
>15 years	2 (17%)		
Total	**12**		**20**

Level of skill with technology		
1.Novice	1 (3%)	
2.Novice-Intermediate	2 (6%)	
3.Intermediate	15 (47%)	
4.Intermediate-Expert	5 (16%)	
5.Expert	**6 (19%)**	
Total	**32**	

Do you use indications with Epic/Cerner now?	Vendor	Vendor
Yes, link to diagnosis	2 (17%)	5 (25%)
For specific reasons, but not everything	4 (33%)	4 (20%)
Sometimes	1 (0%)	6 (30%)
No	5 (42%)	5 (25%)
Total	**12**	**20**

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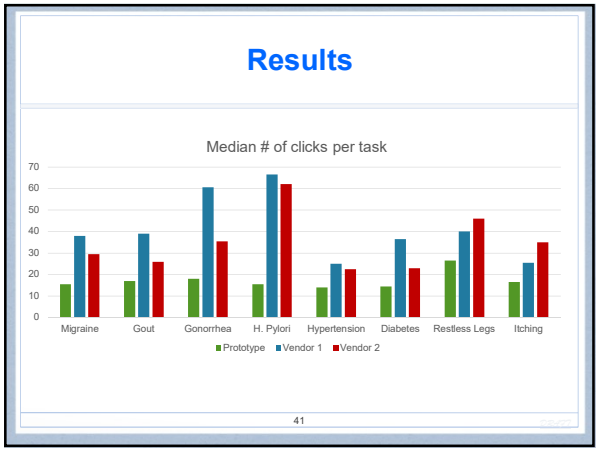

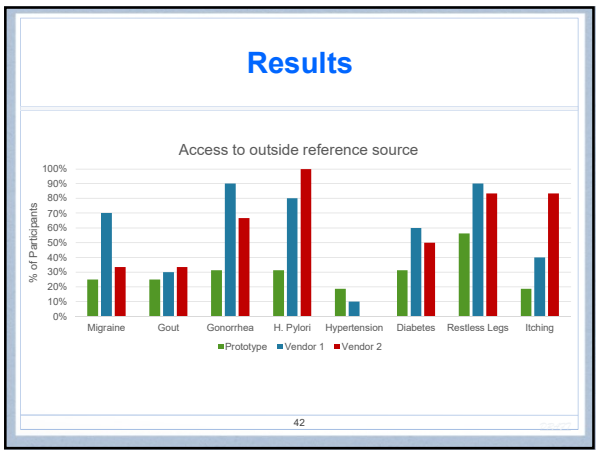

Results

Independent pharmacist review of order details revealed:

- 5% of orders made in the ***prototype*** 'failed' to be appropriate for the patient and indication
- 39% of orders made in ***vendor 1*** 'failed' to be appropriate for the patient and indication
- 15% of orders made in ***vendor 2*** 'failed' to be appropriate for the patient and indication
- <1% of orders had an LASA error in the prototype, 2.5% in vendor 1 and 2% in vendor 2

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Results

Reasons for failure include:

Missing Ceftriaxone as part of therapy for Gonorrhea	Incorrect Route
Missing PPI as part of therapy for h. pylori	Incorrect frequency
Drug for treatment of Migraine not for prevention	Incorrect duration
Capsule strength not available	Disease-drug interaction
Renal function not recommended	LASA error
Drug-drug interaction	Incorrect dose
Dosing Instructions incorrect	Drug-allergy interaction
Conflicting sig instructions	

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Results

Task Success:	% of order sets that successfully included indication with prescription for patient and pharmacist
Prototype	100%
Vendor 1	61%
Vendor 2	62% (electronic prescriptions) 83% (printed prescriptions)

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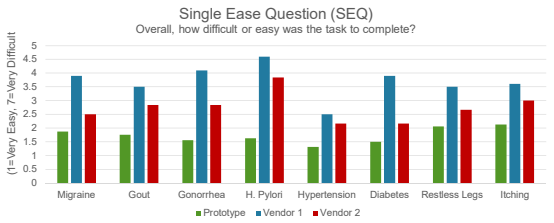
Results



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Results

Post Survey Results (System Usability Scale) (1= Strongly Disagree, 5= Strongly Agree)	Mean Rating
I think that I would like to use this system frequently.	4.72
I found the system unnecessarily complex.	1.38
I thought the system was easy to use.	4.84
I think that I would need the support of a technical person to be able to use this system.	1.47
I found the various functions in this system were well integrated	4.59
I thought there was too much inconsistency in this system	1.38
I imagine that most people would learn to use this system very quickly	4.66
I found the system very cumbersome to use.	1.19
I felt very confident using the system.	4.34
I needed to learn a lot of things before I could get going with this system.	1.63

89.69
Average SUS Score

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Next Steps

- Publicize, present, publish multiple project studies
  - Continue to help create interest, will, amongst key players
  - ISMP, HIMSS, AMIA, SGIM, IHI/NSPF, others
- Work with Epic, Center, other vendors to incorporate
  - ? Stand alone vs. integrated “apps” to CPOE
  - ? Partners potentials
- Develop content to support
  - Drugs and regimens of choice
  - Who/what is “Trusted Source”
- Address other challenges, thorny issues
  - Diagnosis vs. Indication in Surescripts

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Next Steps –Actions You Can Take

- Check the EHR indication-related functionality at your institution
  - Various ways to incorporate, workaround, leverage
  - Push vendors to create functionality similar to our prototype
- P&T committees- think about how this paradigm weaves into drugs of choice; start to designate
  - Re-engineering up stream using indication, operationalize at level of drugs of choice
- Imaging all the places indication would be beneficial; document examples
  - Prevalence and incidence data
  - Common LASA errors reported locally

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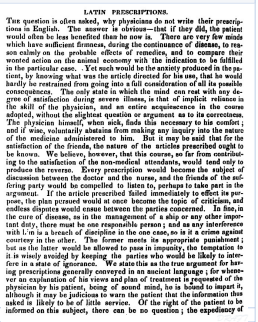
Justification for Latin Prescriptions (1833)

- *The Boston Medical and Surgical Journal; Sep 18, 1833*
- "The question is often asked, why physicians do not write their prescriptions in English. The answer is obvious – that if they did, the patient would often be less benefited than he is now."
- "The only state in which the mind can rest with any degree of satisfaction during severe illness, is that of implicit reliance in the skill of the physician, and an entire acquiescence in the course adopted, without the slightest question or argument."



LATIN PRESCRIPTIONS.

The question is often asked, why physicians do not write their prescriptions in English. The answer is obvious—that if they did, the patient would often be less benefited than he now is. There are very few minds which have sufficient firmness, during the continuance of disease, to reason calmly on the probable effects of remedies, and to compare their wonted action on the animal economy with the indication to be fulfilled in the particular case. Yet such would be the anxiety produced in the patient, by knowing what was the article directed for his use, that he would hardly be restrained from going into a full consideration of all its possible consequences. The only state in which the mind can rest with any degree of satisfaction during severe illness, is that of implicit reliance in the skill of the physician, and an entire acquiescence in the course adopted, without the slightest question or argument as to its correctness. The physician himself, when sick, finds this necessary to his comfort; and if wise, voluntarily abstains from making any inquiry into the nature of the medicine administered to him. But it may be said that for the satisfaction of the friends, the nature of the articles prescribed ought to be known. We believe, however, that this course, so far from contributing to the satisfaction of the non-medical attendants, would tend only to produce the reverse. Every prescription would become the subject of discussion between the doctor and the nurse, and the friends of the suffering party would be compelled to listen to, perhaps to take part in the argument. If the article prescribed failed immediately to effect its purpose, the plan pursued would at once become the topic of criticism, and endless disputes would ensue between the parties concerned. In fine, in the cure of disease, as in the management of a ship or any other important duty, there must be one responsible person; and as any interference with him is a breach of discipline in the one case, so is it a crime against courtesy in the other. The former meets its appropriate punishment; but as the latter would be allowed to pass in impunity, the temptation to it is wisely avoided by keeping the parties who would be likely to interfere in a state of ignorance. We state this as the true argument for having prescriptions generally conveyed in an ancient language; for whenever an explanation of his views and plan of treatment is requested of the physician by his patient, being of sound mind, he is bound to impart it, although it may be judicious to warn the patient that the information thus asked is likely to be of little service. Of the right of the patient to be informed on this subject, there can be no question; the expediency of

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Clinician Perspective

- "Don't tell me what to do"
  - I don't want anyone taking away my clinical autonomy; especially someone who doesn't know my patient, or what is best for him or her like I do.
- "Just tell me what to do"
  - I am so frustrated with all the hassles and back and forth faxes and calls with formulary/nonformulary, prior authorization, multitiered co-payment, that….just tell me what to do and I will do it so I can move on to my next patient and work.

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Questions?

- A copy of today's slides will be posted on our website
- Don't forget to mark you calendar:
  - Our next MSOS Briefings webinar is on Thursday, June 28, 2018, 1-2pm ET.

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