Safely Starting, Using, and Stopping Drugs: Indications Rx, Cancel Rx and ADR Monitoring

Gordon (Gordy) Schiff MD

Associate Director Center for Patient Safety Research and Practice
Brigham and Women's Hospital Div. General Medicine

Quality and Safety Director – Harvard Center for Primary Care

Associate Professor of Medicine Harvard Medical School

BRIGHAM HEALTH
BWH BRIGHAM AND WOMEN'S Department of Medicine

CENTER FOR PRIMARY CARE
HARVARD MEDICAL SCHOOL

HARVARD MEDICAL SCHOOL
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FinancialConflicts/Disclosures

- Commercial
  - None

- Other/Grant Funding
  - **Gordon & Betty Moore Fndn - Dx Error/Medication Projects**
  - **CRICO Malpractice Grants–Diagnostic Errors/Pitfalls**
  - **AHRQ –Closing the Loop on Diagnostic Errors**
  - Gold; Leape Family Foundation- Boundaries Issues

HealthAffairs

QUALITY OF CARE

By Gordon Schiff, Maria M. Mirica, Ajit A. Dhavle, William L. Galanter, Bruce Lambert, and Adam Wright

A Prescription For Enhancing Electronic Prescribing Safety

DOI: 10.1377/hlthaff.2018.0725
HEALTH AFFAIRS 37,
NO. 11 (2018): 1877–1883

ABSTRACT **While electronic prescribing has been shown to reduce medication errors and improve prescribing safety, it is vulnerable to error-prone processes. We review six intersecting areas in which changes to electronic prescribing systems, particularly in the outpatient setting, could transform medication ordering quality and safety. We recommend incorporating medication indications into electronic prescribing, establishing a single shared online medication list, implementing the transmission of electronic cancellation orders to pharmacies (CancelRx) to ensure that drugs are safely and reliably discontinued, implementing standardized structured and codified prescription instructions, reengineering clinical decision support, and redesigning electronic prescribing to facilitate the ordering of nondrug alternatives.**

Gordon Schiff (gschiff@partners.org) is associate director of the Center for Patient Safety Research and Practice, Brigham and Women's Hospital, and quality and safety director of the Harvard Medical School Center for Primary Care, both in Boston, Massachusetts.

Maria M. Mirica is a project manager in the Center for Patient Safety Research and Practice, Brigham and Women's Hospital.

Ajit A. Dhavle is founder and CEO of Adviva Health, Inc., in

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- Indications-based Prescribing
  - Background, rationale
  - Prototype development, evaluation
- Conservative prescribing principles, project
  - IHI Course
    - Principle #11 Beware rebound/withdrawal
      - PPI Example- rebound normal volunteers
  - Cons Rx Metrics
    - Principle #5 – Use learn fewer drugs
    - Principle #8 – When possible, start only 1 drug at a time
  - Vigilance for Adverse Reactions
    - Principle #9 – High index of suspicion
- Screening for Adverse Reactions
    - CEDAR
    - Current Moore Project for portal; texting
    - Dimensions of ADR's model
- Cancel Rx
    - Countless errors, status implementation, process improvement

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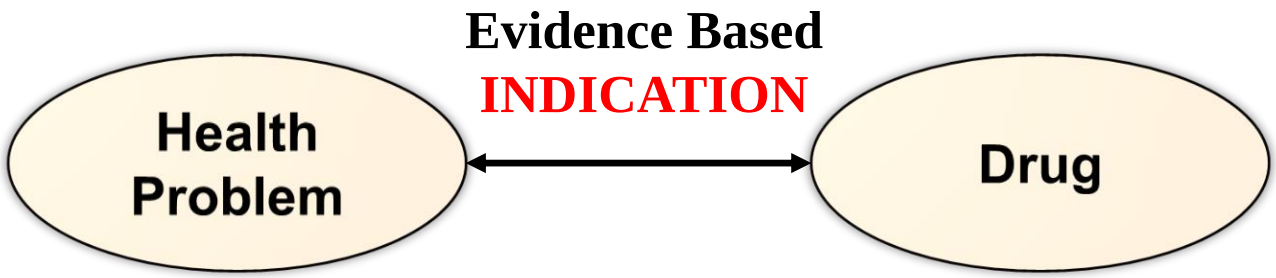
Why Indications-Based Prescribing Is the Missing Link

- Indication is the link between patient's health problem and the drug
- Key link between *evidence* and *prescribing* appropriateness



The NEW ENGLAND JOURNAL of MEDICINE

NEJM 2016

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.

An 1833 article in the *Boston Medical and Surgical Journal* (forerunner of the *New England Journal of Medicine*) explained why prescriptions should be written in Latin to protect patients from knowledge of the names of and indications for the prescribed drugs:

"The question is often asked, why physicians do not write . . . 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 . . . with the indication to be fulfilled in the particular case. . . . The

add to each prescription an ingredient that's currently conspicuously missing: the right indication. This pivotal element affects and complements the other five, and considering it a sixth "right" would inform and enhance the safety of each prescription. With most prescriptions now being written electronically, this addition is particularly timely, since electronic medication ordering provides the vehicle for incorporating the indication into prescribing — and is handicapped in various ways without it.

Indications-based prescribing can contribute to better prescribing and medication use in multiple, synergistic ways (see table). First, when medication choices are narrowed to those indicated for a specific problem, decisions

reason each medication is being prescribed. Having this knowledge has been shown to be associated with better adherence and fewer errors,[2] yet patients often do not know the indications for some or all of their medications.[3] Pharmacists, visiting nurses, and caregiving relatives also need this information, but they are often even more in the dark about the reason for a given prescription. Presented with a choice, most patients prefer instructional leaflets and prescription labels that include indications to those that don't include indications.[4] Knowledge of the indication can also empower patients to question the necessity of a medication.

Third, prescribers need and want help choosing the best drugs for their patients' prob-

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.

NABP
NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

Medication Indication on the Prescription (Resolution No. 100-7-04) (2004 100th Annual Mtg)

Whereas, states do not currently require indication, purpose, or diagnosis be included on the prescription, patient labels or containers; and

Whereas, the lack of this essential patient care information impedes the delivery of pharmaceutical care and can contribute to the incidence of medication errors; and

THEREFORE BE IT RESOLVED that NABP encourage national and state medical associations and other interested parties to support legislative and regulatory efforts in the states to require prescribers to include the indication for the medication on all prescriptions and medication orders issued orally, in writing, or transmitted electronically.

parties to support legislative and regulatory efforts in the states to require prescribers to include the indication for the medication on all prescriptions and medication orders issued orally, in writing, or transmitted electronically.

NCPDP Structured & Codified Sig Format Standards

8.1.5.1 Diagnosis Element -2017
To document and communicate the reason for the prescription, **NCPDP strongly recommends that diagnosis and indication be included in all prescriptions**. Communicating this information will improve patient safety, enhance efficiency and expedite prior authorization. Inclusion of this information will reduce the need for the pharmacist to contact the prescriber for missing information such as that needed for prior authorization or claim processing.

Including the indication/diagnosis **can also support providing patient friendly language for the medication label** and patient information leaflet.

The Boston Globe

HEALTH

We used to sell cigarettes in hospitals. 5 practices that may soon look just as outdated

By MELISSA BAILEY / OCTOBER 21, 2016

We can't buy cigarettes in the hospital anymore. What else is changing?

CLYDE PUTNAM JR. PHOTO/THOMAS ROBINSON

Leave what a drug treats off prescription labels?

Patients get confused about medicine all the time, said Dr. Gordon Schiff of Brigham and Women's Hospital in Boston. One of his patients recently told him she had stopped taking her medicine for depression. "She happened to have her bottles with her," he said. "It turns out the medicine she actually stopped was for diabetes" — which sent her blood sugar out of control.

Schiff, a primary care doctor and patient safety researcher, said it's crazy that we don't put labels on medicine bottles saying what the drug is for. That's really confusing for patients — especially elderly patients who are juggling lots of prescriptions.

So why doesn't the label say what the drug is for? Schiff said it is possible for doctors to write the information into electronic records, but it's not easy, and the pharmacy may not print it on the label. He's now leading a project that attempts to change that.

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Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

EDUCATE *before* YOU MEDICATE
National Council on Patient Information and Education

Your Medicine: Be Smart. Be Safe.

Learn more about how to take medicines safely. Use the wallet card at the back of this booklet to keep track of your medicines.

Questions to ask before you take your medicine:

1. Why am I taking this medicine? _____

_____

_____

_____

2. What are the brand name and generic* name of this medicine? _____

_____

_____

_____

3. Can I take a generic version of this medicine? _____

_____

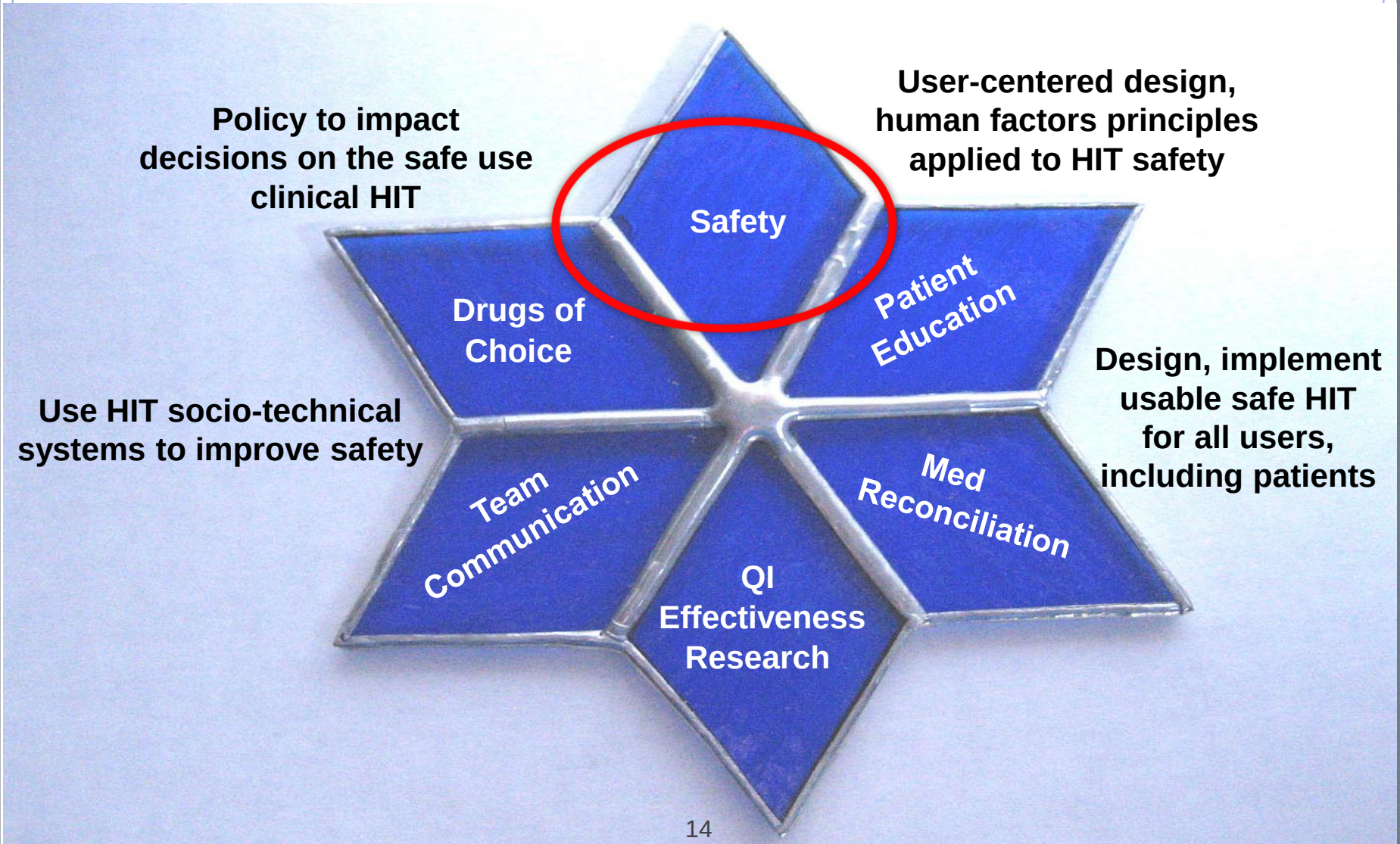
_____

_____

4. Does this new prescription mean I should stop taking other medicines? _____

_____

Indications-based Prescribing Major Links to 4 AHRQ HIT Safety Emphasis Aims, Central to Key Functions



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 HIV). 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

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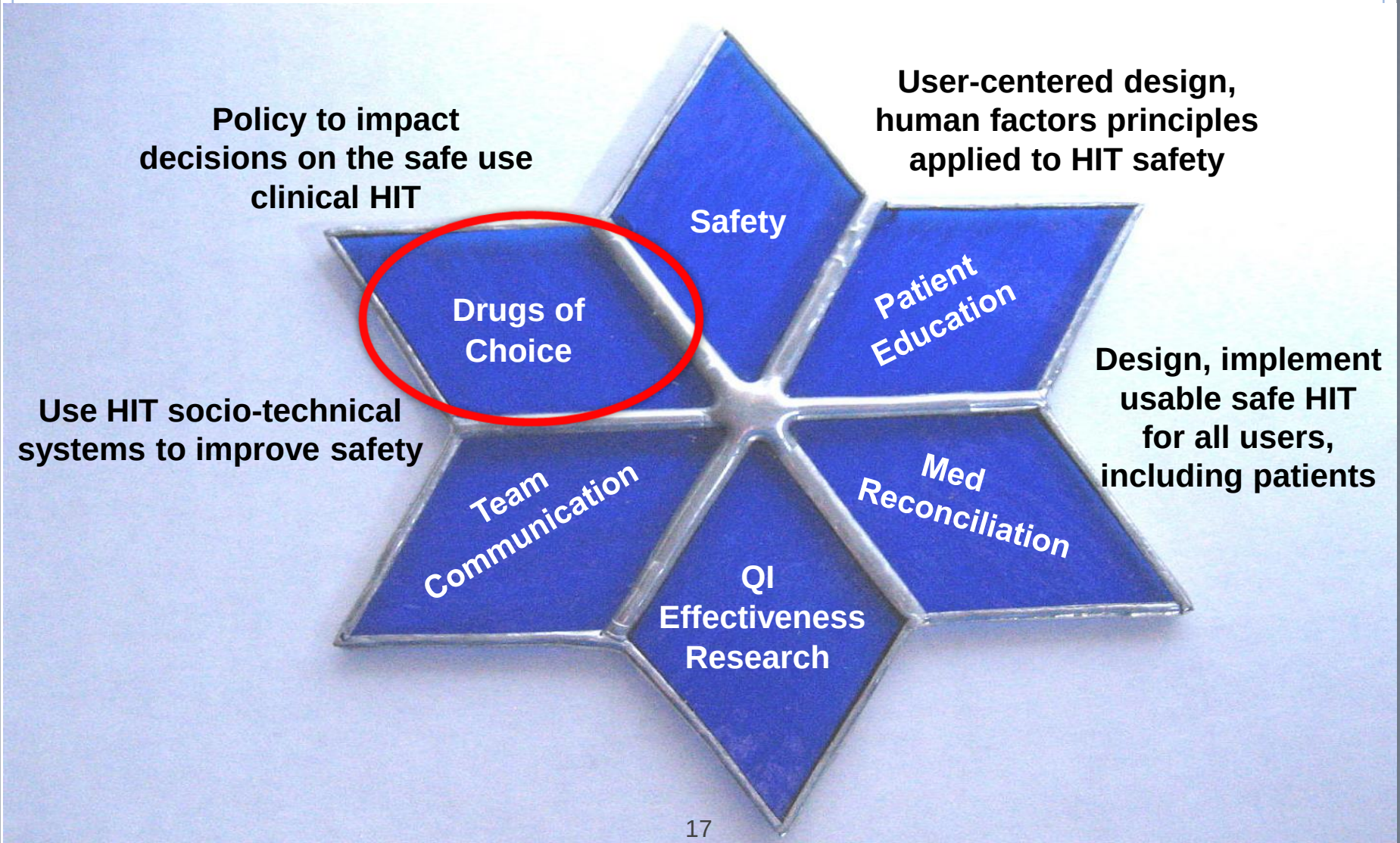
Indications-based Prescribing Major Links to 4 AHRQ HIT Safety Emphasis Aims, Central to Key Functions

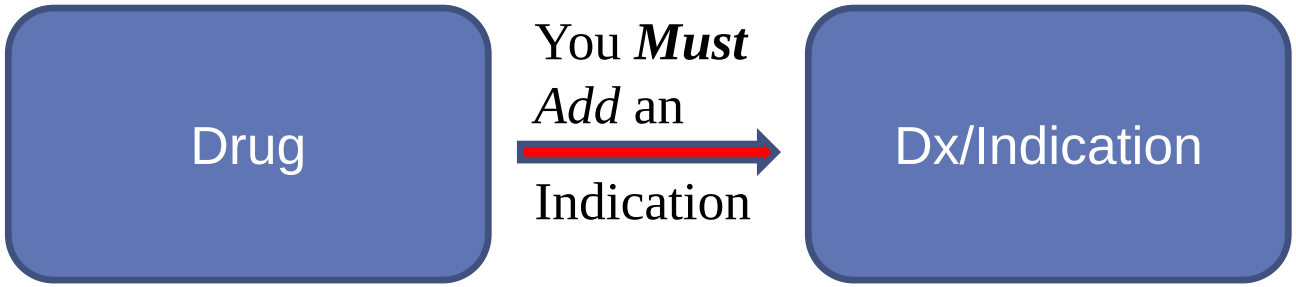


Clinician Perspective

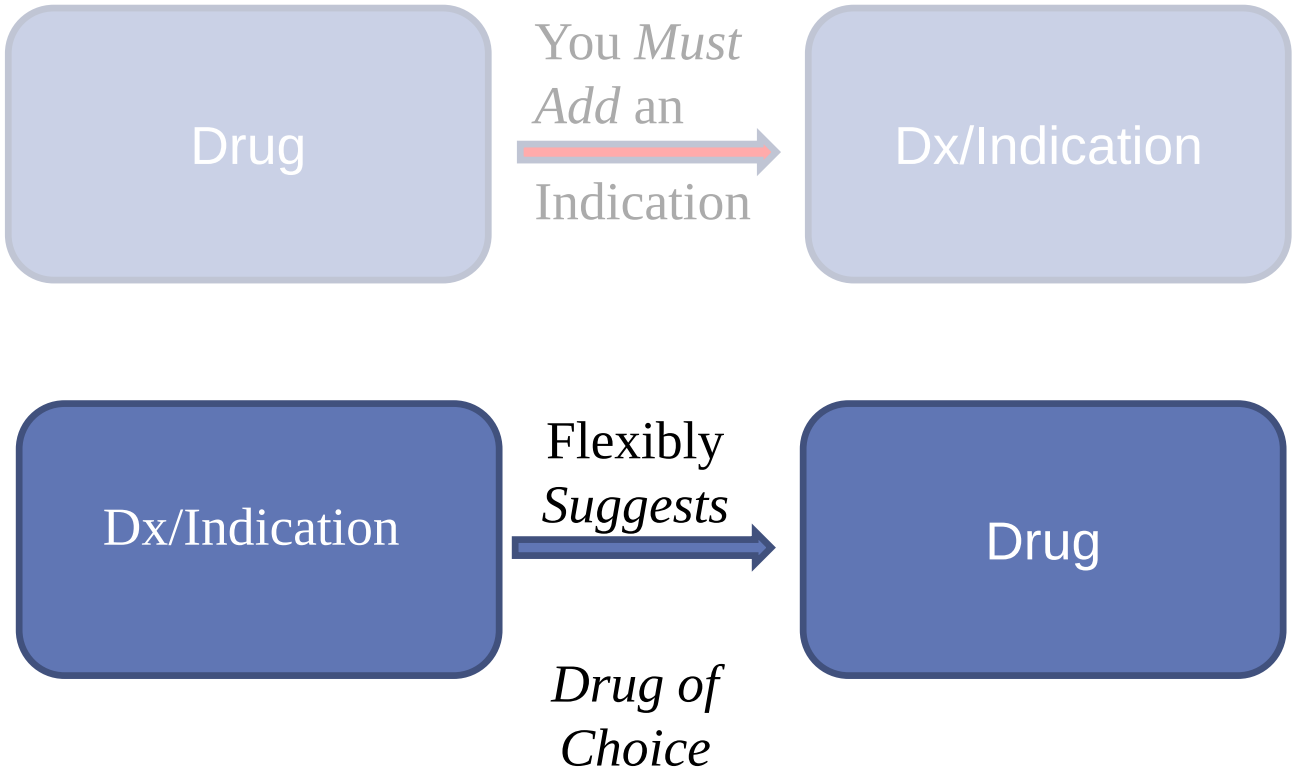
- "Don't tell me what to do"
  - I don't want anyone taking away my clinical autonomy; especially someone who doesn't know my patient, or what is best for him or her like I do.
- "Just tell me what to do"
  - I am so frustrated with all the hassles and back and forth faxes and calls with formulary/non-formulary, 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.

Old Paradigm

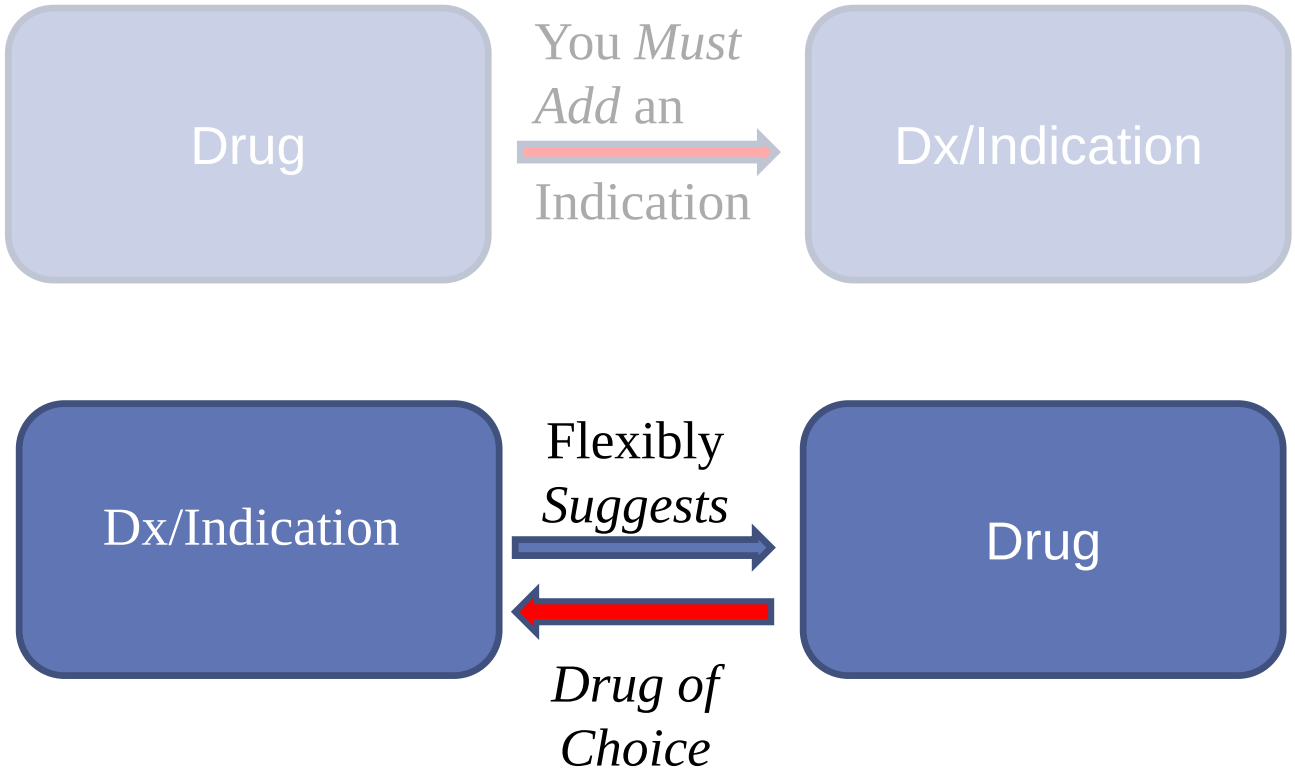
Old Paradigm



New Paradigm

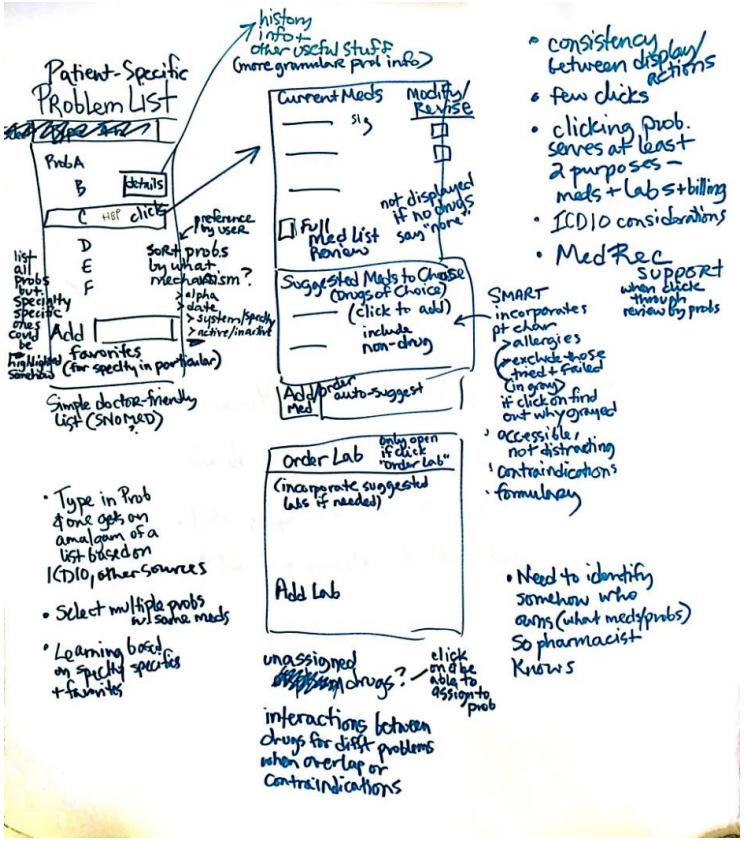


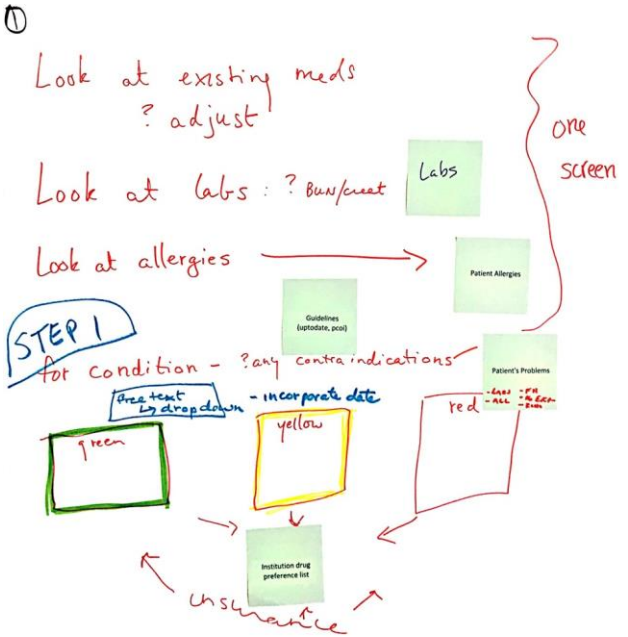
New Paradigm



User Centered Design Results

- Contextual Interview
- Participatory Design Sessions
- Usability Roundtables
- Formative ‘think aloud’ usability testing





Demonstration
Indications Rx Prototype

- http://indicationsrx.partners.org/

JAMA Network Open

Original Investigation | Health Informatics

Comparison of a Prototype for Indications-Based Prescribing With 2 Commercial Prescribing Systems

Pamela M. Garabedian, MS; Adam Wright, PhD; Isabella Newbury, BS; Lynn A. Volk, MHS; Alejandra Salazar, PharmD; Mary G. Amato, PharmD, MPH; Aaron W. Nathan, MS; Katherine J. Forsythe, BA; William L. Galanter, MD, PhD; Kevin Kron, BS; Sara Myers, BS; Joanna Abraham, PhD; Sarah K. McCord, MLIS, MPH; Tewodros Eguale, MD, PhD; David W. Bates, MD, MSc; Gordon D. Schiff, MD

Abstract

IMPORTANCE The indication (reason for use) for a medication is rarely included on prescriptions despite repeated recommendations to do so. One barrier has been the way existing electronic prescribing systems have been designed.

OBJECTIVE To evaluate, in comparison with the prescribing modules of 2 leading electronic health record prescribing systems, the efficiency, error rate, and satisfaction with a new computerized provider order entry prototype for the outpatient setting that allows clinicians to initiate prescribing using the indication.

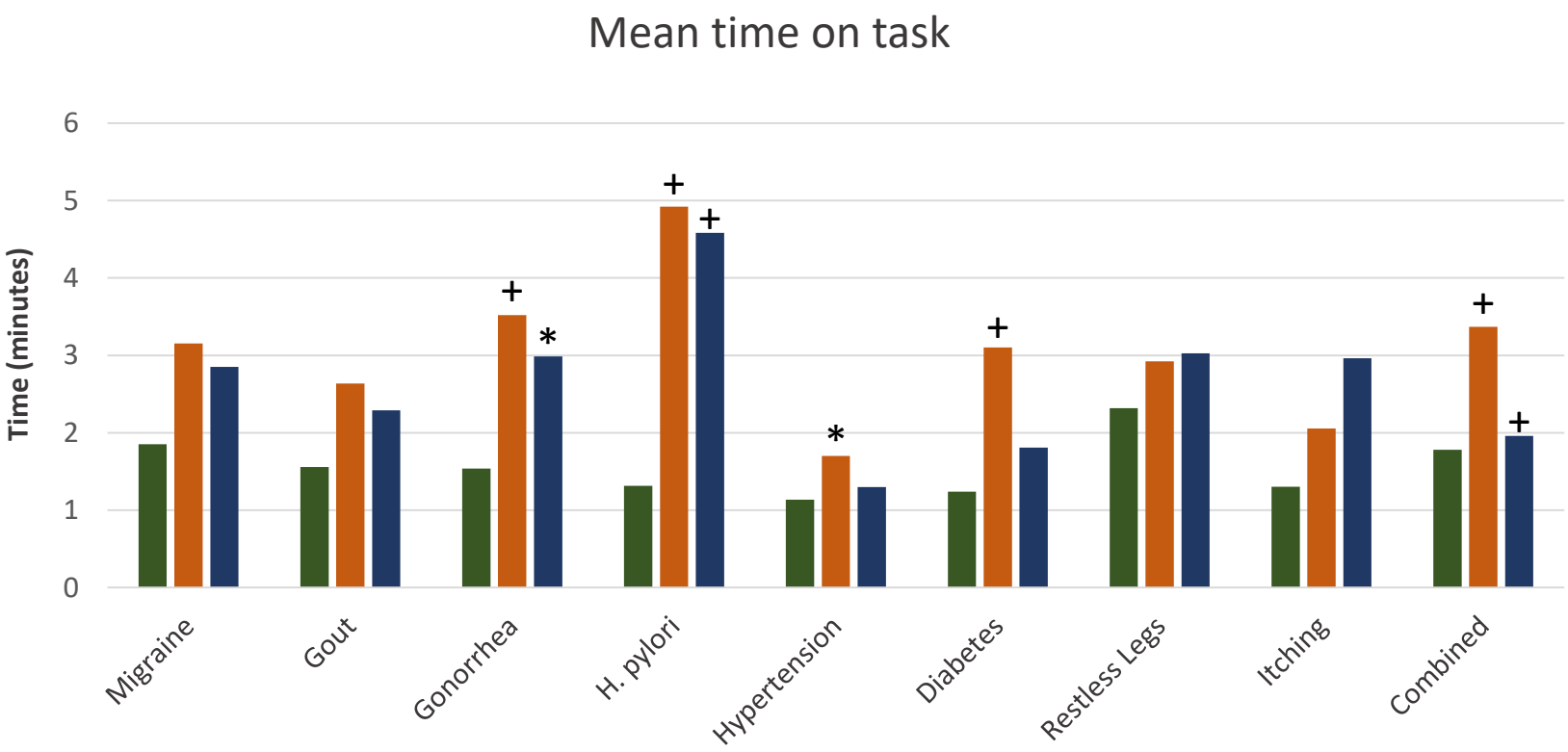
DESIGN, SETTING, AND PARTICIPANTS This quality improvement study used usability tests requiring internal medicine physicians, residents, and physician assistants to enter prescriptions electronically, including indication, for 8 clinical scenarios. The tool order assignments were randomized and prescribers were asked to use the prototype for 4 of the scenarios and their usual system for the other 4. Time on task, number of clicks, and order details were captured. User satisfaction was measured using posttask ratings and a validated system usability scale. The study

Key Points

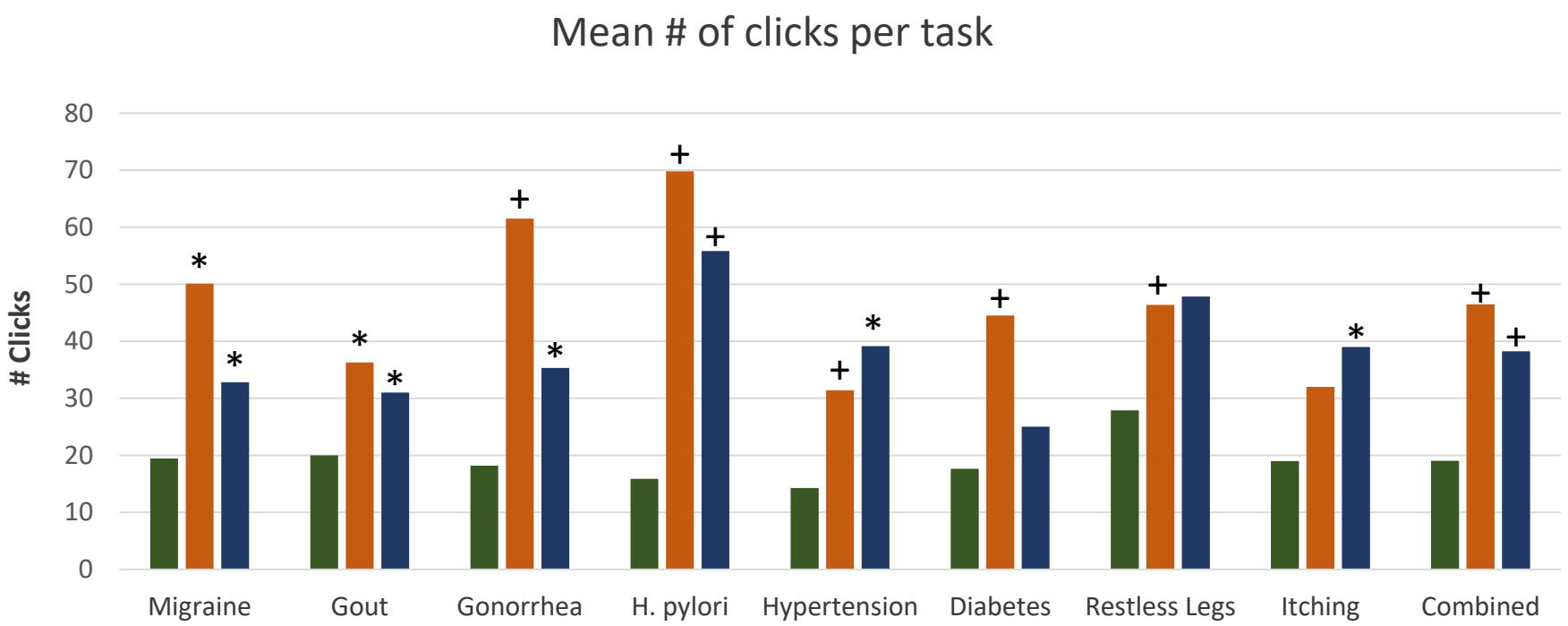
Question Is a redesigned electronic prescribing workflow to better support the incorporation of the indication in the outpatient prescribing process associated with reduced errors and improved clinician experience?

Findings This quality improvement study compared an indications-based electronic prescribing prototype with that of 2 leading electronic health record vendors and found that the usability of the prototype system substantially outperformed both vendors' prescribing systems in terms of efficiency, error rate, and satisfaction

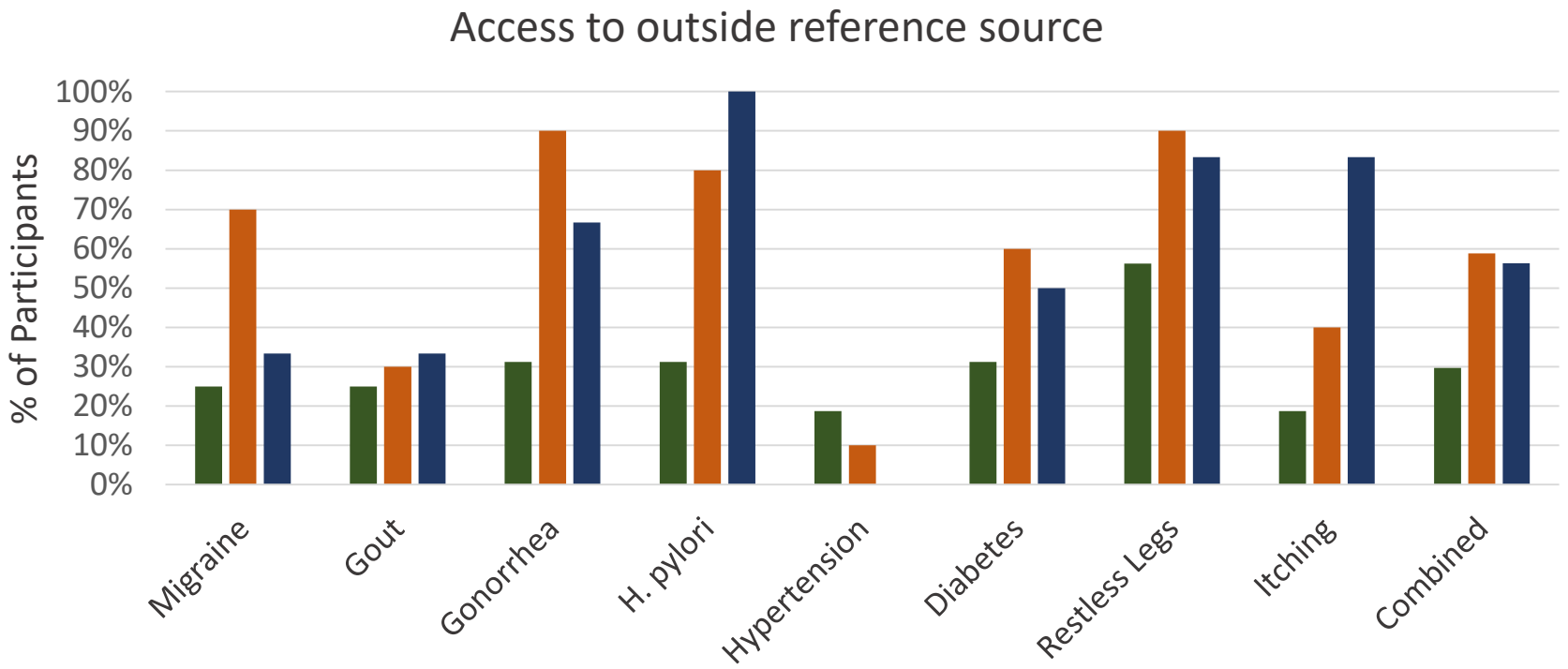
Results



Results


Mean # of clicks per task
Clicks
80
70
60
50
40
30
20
10
0
Migraine
Gout
Gonorrhea
H. pylori
Hypertension
Diabetes
Restless Legs
Itching
Combined

Results


Access to outside reference source
% of Participants
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Migraine
Gout
Gonorrhea
H. pylori
Hypertension
Diabetes
Restless Legs
Itching
Combined

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

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	

Results

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

Results

Single Ease Question (SEQ) (1=Very Easy; 7=Very Difficult)

	Site 1 (n=20)		Site 2 (n=12)	
	Prototype Average	Vendor 1 Average	Prototype Average	Vendor 2 Average
Migraine	1.80	3.90[b]	2.00	2.50
Gout	1.90	3.50[a]	1.50	2.83
Gonorrhea	1.30	4.10 [b]	2.00	2.83
H. pylori	1.80	4.60 [b]	1.33	3.83 [b]
Hypertension	1.10	2.50 [b]	1.67	2.17
Diabetes Mellitus	1.50	3.90 [b]	1.50	2.17
Restless legs	1.70	3.50 [b]	2.67	2.67
Itching	2.00	3.60	2.33	3.00
Combined	1.64	3.7 [b]	1.86	2.75 [b]

[a] Significant at p< 0.05

[b] Significant at p<0.01

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

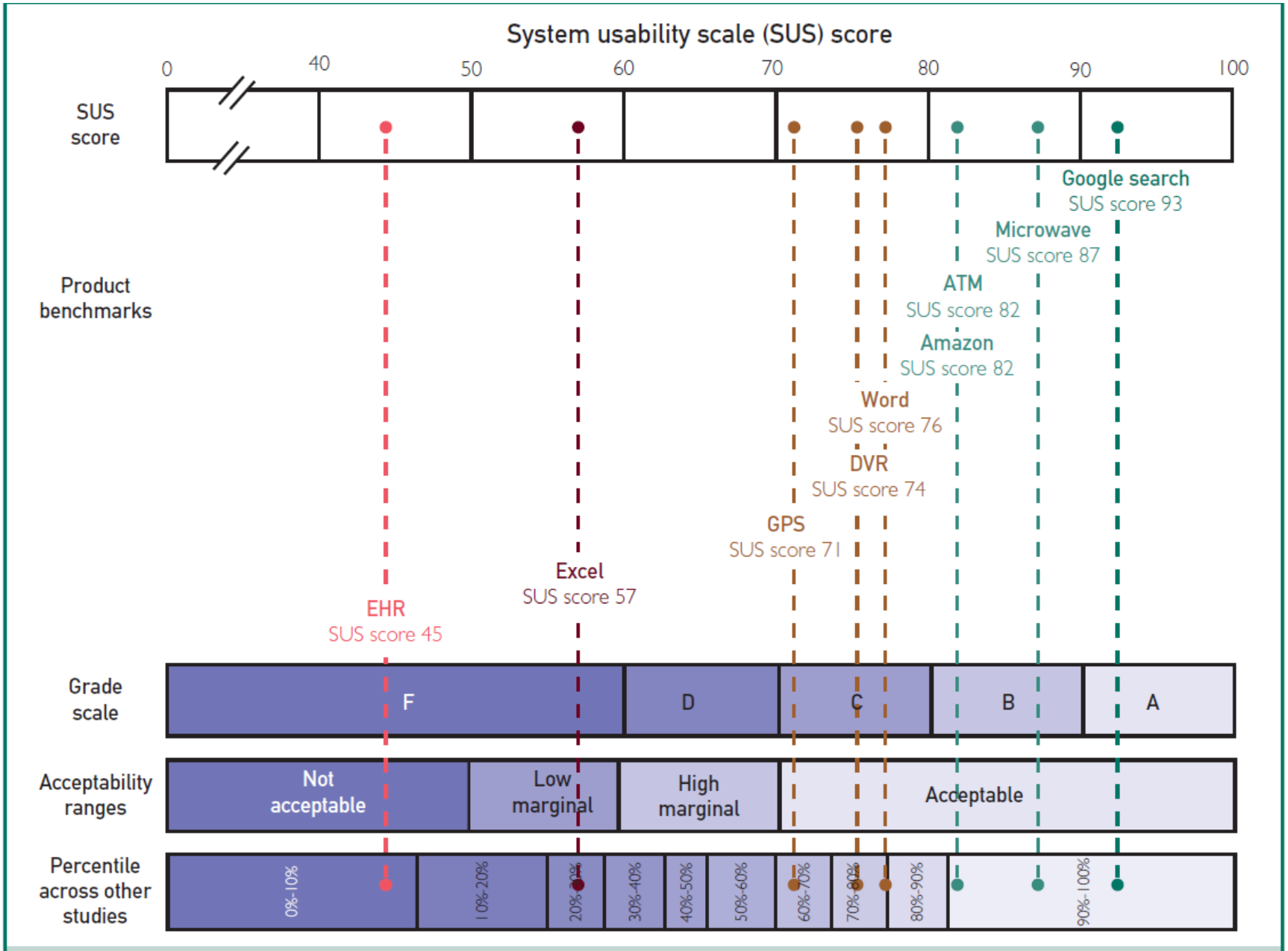


FIGURE 1. System Usability Scale (SUS) score for the electronic health record (EHR) from the analysis reported here and compared across studies in other industries with everyday products mapped onto a grading scale, acceptability ranges, and percentile of scores.

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REVIEW ARTICLE

ONLINE FIRST | LESS IS MORE

Principles of Conservative Prescribing

Gordon D. Schiff, MD; William L. Galanter, MD, PhD; Jay Duhig, MA; Amy E. Lodolce, PharmD, BCPS; Michael J. Koronkowski, PharmD; Bruce L. Lambert, PhD

Judicious prescribing is a prerequisite for safe and appropriate medication use. Based on evidence and lessons from recent studies demonstrating problems with widely prescribed medications, we offer a series of principles as a prescription for more cautious and conservative prescribing. These principles urge clinicians to (1) think beyond drugs (consider nondrug therapy, treatable underlying causes, and prevention); (2) practice more strategic prescribing (defer nonurgent drug treatment; avoid unwarranted drug switching; be circumspect about unproven drug uses; and start treatment with only 1 new drug at a time); (3) maintain heightened vigilance regarding adverse effects (suspect drug reactions; be aware of withdrawal syndromes; and educate patients to anticipate reactions); (4) exercise caution and skepticism regarding new drugs (seek out unbiased information; wait until drugs have sufficient time on the market; be skeptical about surrogate rather than true clinical outcomes; avoid stretching indications; avoid seduction by elegant molecular pharmacology; beware of selective drug trial reporting); (5) work with patients for a shared agenda (do not automatically accede to drug requests; consider nonadherence before adding drugs to regimen; avoid restarting previously unsuccessful drug treatment; discontinue treatment with unneeded medications; and respect patients' reservations about drugs); and (6) consider long-term, broader impacts (weigh long-term outcomes, and recognize that improved systems may outweigh marginal benefits of new drugs).

Arch Intern Med. 2011;171(16):1433-1440.
Published online June 13, 2011.
doi:10.1001/archinternmed.2011.256

I. Think Beyond Drugs

1. Seek non-drug alternatives as a first rather than as a last resort.
2. Consider treatable underlying causes of problems rather than just treating the symptoms with a drug
3. Look for opportunities for prevention rather than just focusing on treating symptoms.

II. Practice More Strategic Prescribing

4. Use the “test of time” as a diagnostic and therapeutic trial whenever possible.
5. Use only a few drugs and learn to use them well.
6. Avoid frequent “impulse switching” of drugs without clear, compelling evidence-based reasons.
7. Be skeptical about “individualizing” therapy.
8. Whenever possible, start only one new drug at a time.

III. Maintain Heightened Vigilance Regarding Adverse Effects

9. Have high index of suspicion for adverse drug effects.
10. Educate patients about possible drug reactions to ensure reactions are recognized as early as possib
11. Be alert to clues that you may be treating withdrawal symptoms.

IV. Exercise Caution and Skepticism Regarding New Drugs

12. Learn about new drugs and new indications from trustworthy, unbiased sources, independent drug bulletins, and colleagues with reputation for integrity and conservative prescribing.
13. Even if seemingly safer or more effective for a particular indication, don't rush to use new drugs.
14. Be certain the drug actually improves patient-centered clinical outcomes, rather than just treating o masking a "surrogate marker."
15. Be vigilant about "indications creep."
16. Do not be seduced by elegant molecular pharmacology or drug physiology.
17. Beware of selective reporting of studies.

V. Work With Patients for a Shared Agenda

18. Do not uncritically succumb to patient requests for new drugs they have heard advertised.
19. Avoid prescribing additional drugs for “refractory” problems, failing to appreciate the potential for patient non-adherence.
20. Avoid (due to a lack of a good drug history) repeating prescriptions for drugs a patient has previously tried unsuccessfully or had an adverse reaction.
21. Discontinue drugs that are not working or no longer needed (deprescribing).
22. Work with patients’ desires to be conservative with medications.

VI. Consider Long-Term, Broader Effects and System Improvements

23. Think beyond potentially beneficial short-term drug effects; consider longer term benefits and risks.
24. Look for opportunities to improve prescribing systems, that can make prescribing and med use safer (e.g indications-based electronic ordering systems to guide to drugs of choice; reliable systems to monitor patients for adverse reactions or lab monitoring of drug therapy, enhanced patient education teaching/tools).

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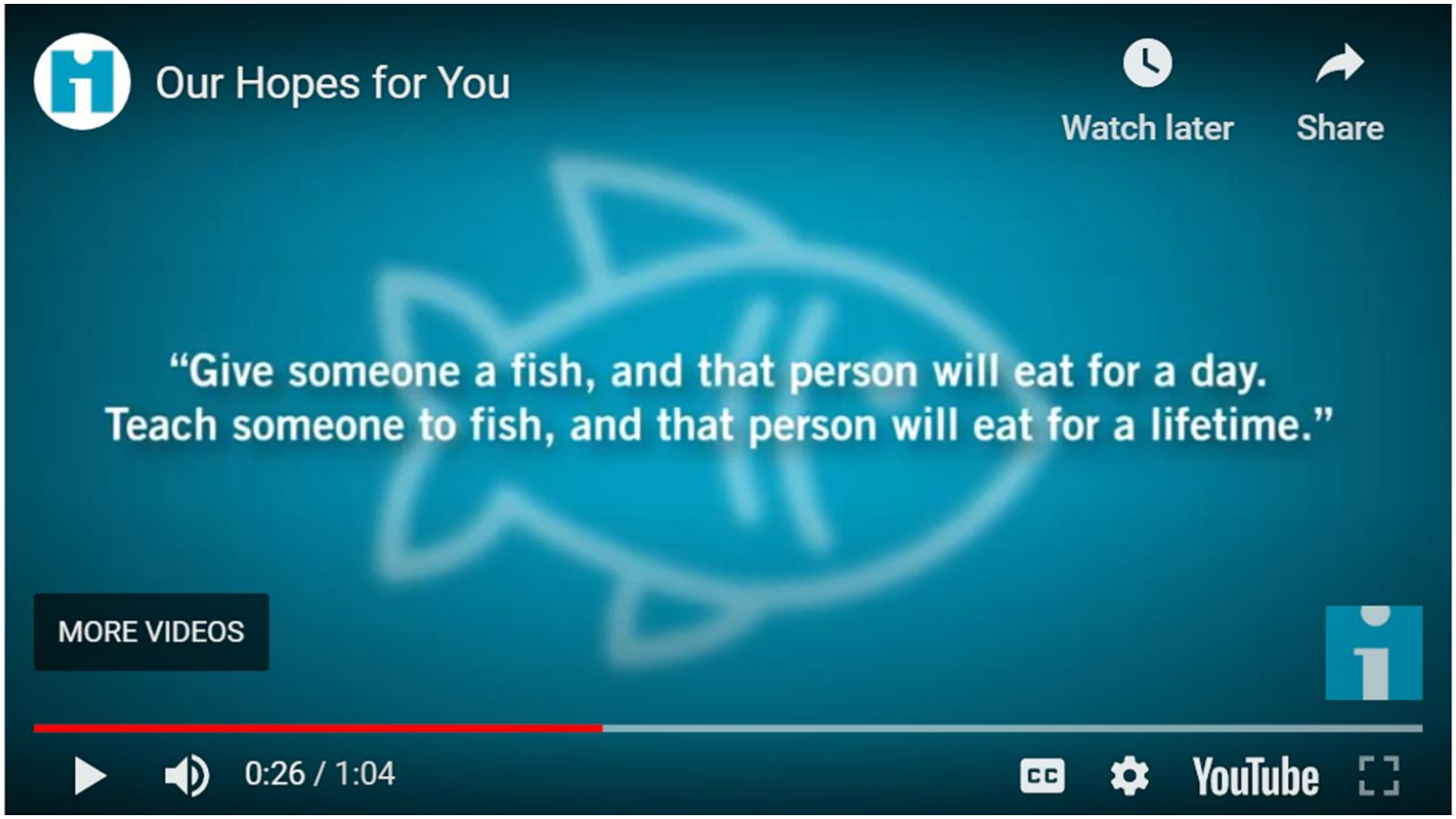
☐ PS 103: Human Factors and Safety*
☐ PS 104: Teamwork and Communication*
☐ PS 105: Responding to Adverse Events*
☐ PS 201: Root Cause Analyses and Actions
☐ PS 202: Achieving Total Systems Safety
☐ PS 203: Pursuing Professional Accountability and a Just Culture
☐ PS x1: Partnering to Heal: Teaming Up Against Healthcare-Associated Infections
☐ PS x2: Preventing Pressure Ulcers
PS x3: Conservative Prescribing [New]


Our Hopes for You
Watch later
Share
“Give someone a fish, and that person will eat for a day.
Teach someone to fish, and that person will eat for a lifetime.”
MORE VIDEOS
0:26 / 1:04
YouTube

PRINCIPLE #11

Be cautious/alert that you may be treating withdrawal symptoms

Don Berwick Discusses Getting Dependent on PPI's

Gastroenterology
OFFICIAL JOURNAL OF THE AGA INSTITUTE
GASTROENTEROLOGY 2009;137:80–87

CLINICAL—ALIMENTARY TRACT

Proton-Pump Inhibitor Therapy Induces Acid-Related Symptoms in Healthy Volunteers After Withdrawal of Therapy

CHRISTINA REIMER,* BO SØNDERGAARD,* LINDA HILSTED,‡ and PETER BYTZER*

*Department of Medical Gastroenterology, Køge University Hospital, Copenhagen University; and the ‡Department of Clinical Biochemistry, Rigshospitalet, Copenhagen, Denmark

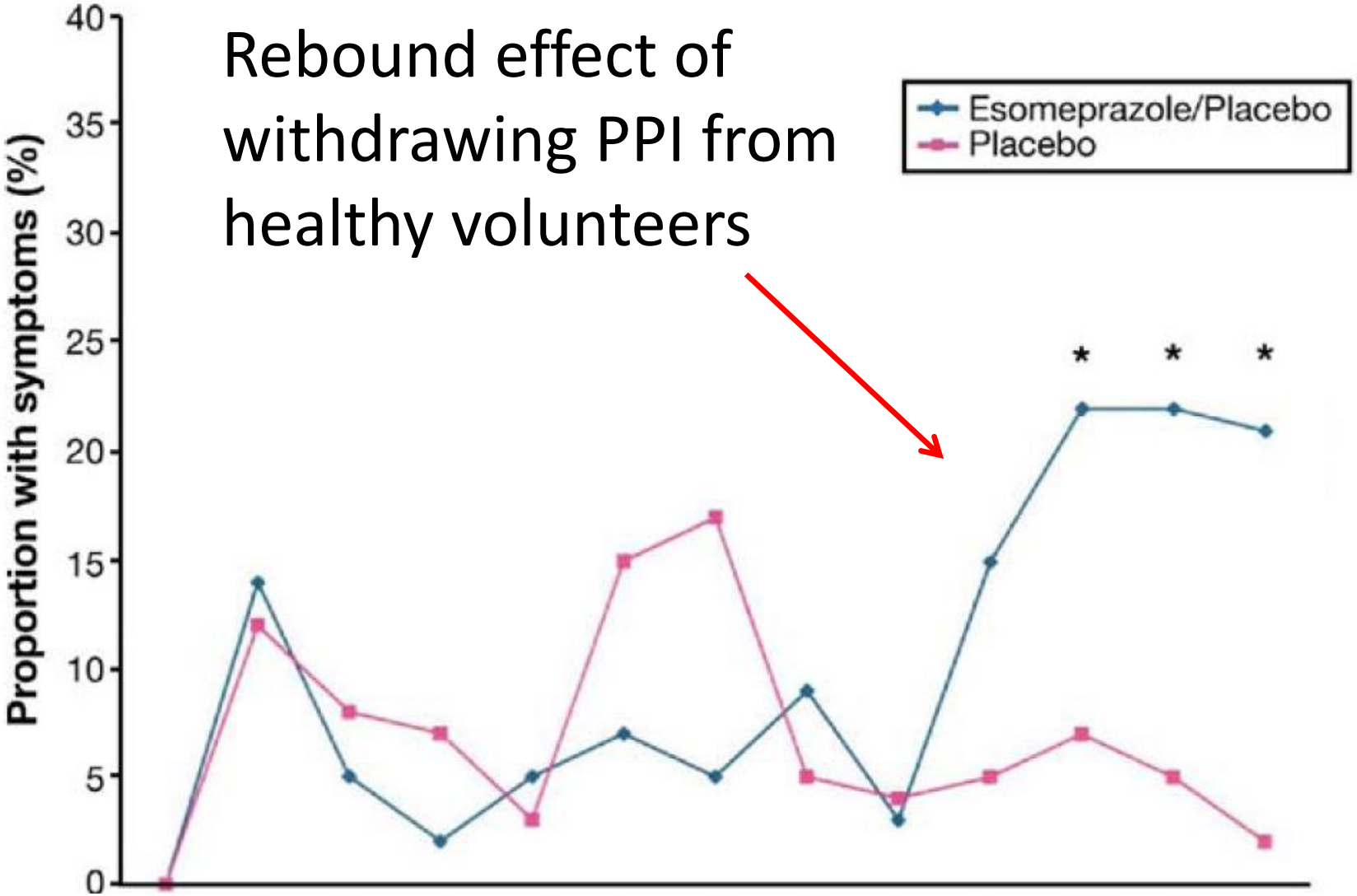
See related article, Arora G et al, on page 725 in *CGH*; see editorial on page 20.

BACKGROUND & AIMS: Rebound acid hypersecretion (RAHS) has been demonstrated after 8 weeks of treatment with a proton-pump inhibitor (PPI). If RAHS induces acid-related symptoms, this might lead to PPI dependency and thus have important implications. **METHODS:** A randomized, double-blind, placebo-controlled trial with 120 healthy

20 to 33 defined daily doses per 1,000 persons per day. In 2006, approximately 7% of the Danish population was treated with a PPI.[1] Although the incidence of new treatments with PPIs remains stable, the prevalence of long-term treatment is rising.[2] The reasons for the increasing long-term use are not fully understood.

Treatment with PPIs is initiated mainly by primary care physicians, usually as empirical therapy for dyspeptic symptoms. Empirical PPI therapy for ≥4 weeks in patients with uninvestigated dyspepsia is supported by dys-

Rebound effect of withdrawing PPI from healthy volunteers

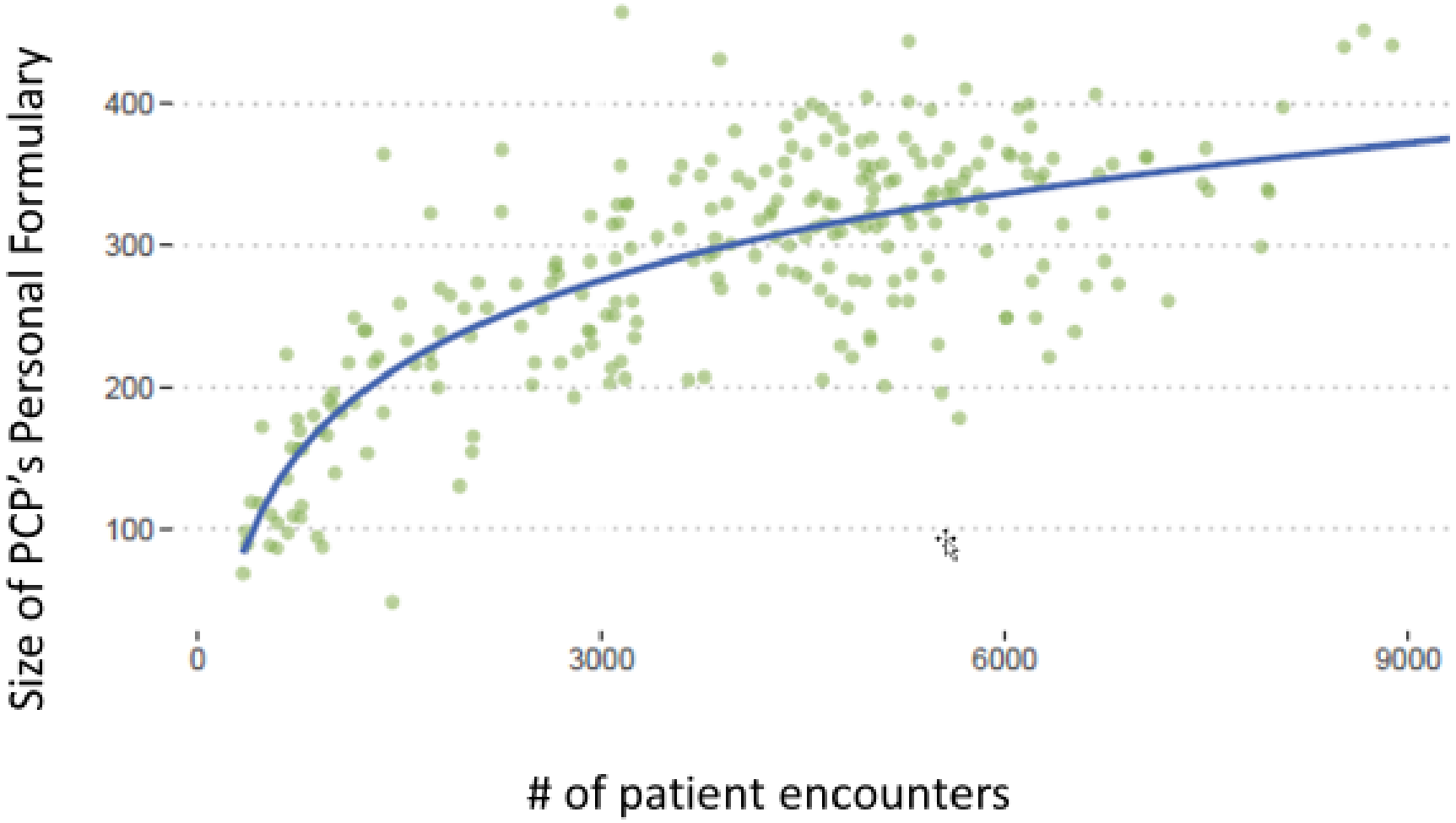


REIMER, GASTROENTEROLOGY 2009

PRINCIPLE #5

Use only a few drugs and learn to use them well

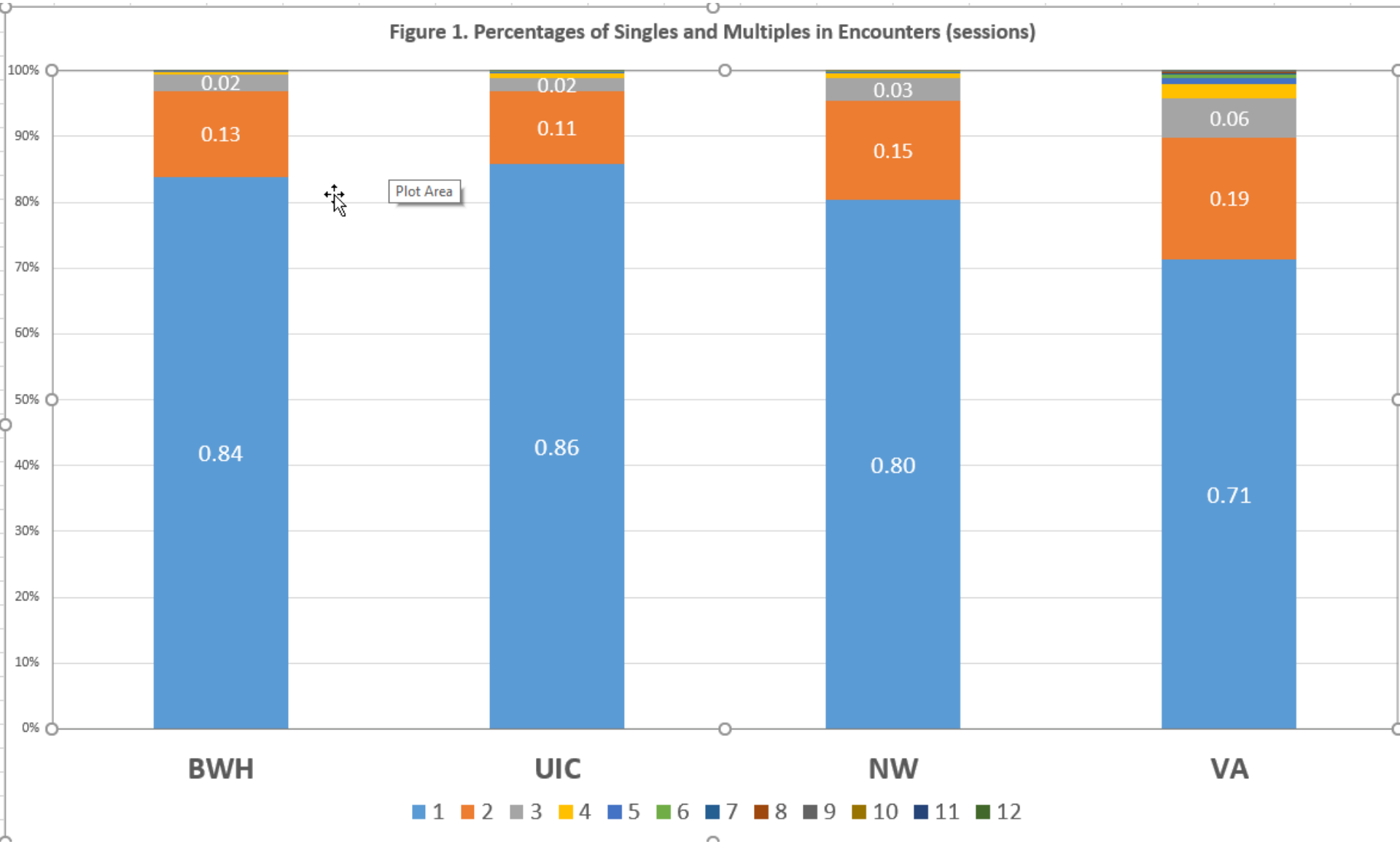
Size of Personal Formulary Wide Variations Even Among PCPs with Similar #'s of Encounters



PRINCIPLE #8

Whenever possible start
only one new drug at a time

Figure 1. Percentages of Singles and Multiples in Encounters (sessions)



	% Prescribing Sessions 2 or more New Drugs Started
BWH	17.91%
UIC	14.22%
NW	18.68%
VA	27.46%

	% Prescribing Sessions 2 or more New Drugs Started	% Drugs Started in the Company of Another New Drug
BWH	17.91%	31.70%
UIC	14.22%	27.25%
NW	18.68%	34.29%
VA	27.46%	49.25%

Draft Rating of Need, Evidence, Desirability of Concurrently Stating a Medication Combination

Meds ***Recommended*** to be ***Given Together***		
A	Evidence that should be started together for particular indication	H.Pylori Rx HIV meds
B	Recommended in combination for clinical situation but lacking evidence need to be started concurrently	Inhaled Albuterol+Fluticasone
Reasonable to give in combination but ***no evidence have to be started*** *at* the ***same time***		
C	Acute clinical or logistical logic (same disease state; travel Rx)	Azithromycin+Benzoate Malaria prophylaxis+ traveler diarrhea Rx
D	Different, chronic diseases	Atorvastatin+amlodipine
Potentially ***problematic*** to ***give or start together***		
E	Overlapping side effects Minor Drug interactions	Lorazepam+trazodone
F	DDIs; Absolute Contraindications	Simvastatin+atazanavir

Principle #9

- Have high index of suspicion for adverse drug effects.

Principle #10

- Educate patients about possible drug reactions to ensure reactions are recognized as early as possible

Suspect new & old drug reactions

- No matter how weird or unlikely

Safely Starting, Using, and Stopping Drugs

- Indications-based Prescribing
  - Background, rationale
  - Prototype development, evaluation
- Conservative prescribing principles, project
  - IHI Course
    - Principle #11 Beware rebound/withdrawal
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  - Vigilance for Adverse Reactions
    - Principle #9 – High index of suspicion
- Screening for Adverse Reactions
    - CEDAR
    - Current Moore Project for portal; texting
    - Dimensions of ADR's model
- Cancel Rx
    - Countless errors, status implementation, process improvement

Table 3. Rates of Adverse Drug Events.*

Variable	Adverse Events	Event Rate
	no. (%)	*no./100 patients*
Total adverse drug events	181	27.4
Severity		
Fatal or life-threatening	0	—
Serious	24 (13)	3.6
Significant	157 (87)	23.8
Preventability		
Ameliorable	51 (28)	7.7
Preventable	20 (11)	3.0
Not preventable	110 (61)	16.6
Serious and preventable or ameliorable	11 (6)	1.7

Gandhi NEJM 2003

Screening for Adverse Drug Events: a Randomized Trial of Automated Calls Coupled with Phone-Based Pharmacist Counseling

Gordon D. Schiff, MD[1,2], Elissa Klinger, SM[1,3], Alejandra Salazar, PharmD[1], Jeffrey Medoff, BA[1], Mary G. Amato, PharmD[4], E. John Orav, PhD[1,2], Shimon Shaykevich, MS[1], Enrique V. Seoane, PharmD[5], Lake Walsh, BA[1], Theresa E. Fuller, BA, BS[1,6], Patricia C. Dykes, RN, PhD, MA[1,2], David W. Bates, MD, MSc[1,2], and Jennifer S. Haas, MD, MSPH[1,2]

[1]Division of General Internal Medicine and Primary Care, Brigham and Women's Hospital, Boston, MA, USA; [2]Harvard Medical School, Boston, MA, USA; [3]Penn Medicine, University of Pennsylvania Health System, Philadelphia, PA, USA; [4]Massachusetts College of Pharmacy and Health Sciences University, Boston, MA, USA; [5]School of Pharmacy, Chapman University, Orange, CA, USA; [6]Northeastern University, Boston, MA, USA.

BACKGROUND: Medication adverse events are important and common yet are often not identified by clinicians. We evaluated an automated telephone surveillance system coupled with transfer to a live pharmacist to screen potentially drug-related symptoms after newly starting medications for four common primary care conditions: hypertension, diabetes, depression, and insomnia.

METHODS: Cluster randomized trial with automated calls to eligible patients at 1 and 4 months after starting target drugs from intervention primary care clinics compared to propensity-matched patients from control clinics. Primary and secondary outcomes were physician documentation of any adverse effects associated with newly prescribed target medication, and whether the medication was discontinued and, if yes, whether the reason for stopping was an adverse effect.

RESULTS: Of 4876 eligible intervention clinic patients who were contacted using automated calls, 776 (15.1%) responded and participated in the automated call. Based on positive symptom responses or request to speak to a pharmacist, 320 patients were transferred to the pharmacist and discussed 1021 potentially drug-related symp-

challenges were encountered using the interactive voice response (IVR) automated calling system, suggesting that other approaches may need to be considered and evaluated.

TRIAL REGISTRATION: ClinicalTrials.gov: NCT02087293

J Gen Intern Med
DOI: 10.1007/s11606-018-4672-7

INTRODUCTION

Use of pharmacologic agents is ubiquitous, with more than half of the US population reporting using a prescription medication in the past year.[1, 2] Medication management dominates medical encounters, with two thirds of adult ambulatory care visits resulting in a prescription or continuation of a medica-

Table 2 Documented Symptoms and Drug Discontinuations, Intervention vs. Control

	Intervention participants $n = 776$	Control patients $n = 776$	p value
Total symptoms collected by IVR system	997	NA	
Total symptoms discussed by pharmacist	1018	NA	
Related to target medication—probable	188 (18.5%)	NA	
Related to target medication—possible	479 (47.1%)	NA	
Related to target medication—unlikely	351 (34.5%)	NA	
Severity of pharmacist-confirmed possible and probable symptoms ($N = 668$)			
Mild	266 (39.8%)	NA	
Significant	400 (59.9%)	NA	
Life-threatening	1 (0.15%)	NA	
Total symptoms documented by MD in notes	277	164	< 0.0001
Number of symptoms per 100 patients	36	21	< 0.0001
Number of patients with symptoms documented by MD	177	122	< 0.0001
Total unique symptoms documented (including IVR documented and MD notes)	1303	164	< 0.0001
Total unique patients with symptoms documented (including IVR documented)	448	120	< 0.0001
Total unique symptoms documented by MD or RPh as probably or possibly related to the drug	753	164	< 0.0001
Total unique patients with symptoms documented by MD or RPh as probably or possibly related to the drug	425	120	< 0.0001
Drug discontinuations (CPOE d/c code reason)	$N = 5106$* No. (%)	$N = 5897$† No. (%)	
Discontinuations 1 year from prescription	1694 (33.2)	1977 (33.5)	0.70
Discontinuations due to adverse event‡	254 (15.0)	217 (11.0)	0.0003

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Patient Portal ADR Surveillance in 3 Primary Care Clinics (8/2019-6/2021)

Newly started medications*	14,448		
Total Phamacist Messages sent	9,485		
Pts opened message	5,448		
Responded	2,641	**18.3%**	Overall response rate
Reporting new symptoms	603	**27.7%**	of responding pts starting the med
Other problems	302		
Not started taking the med	466		

*for patients on Portal only; excluding supplies, vitamins, etc

ADR Pharmaco-surveillance

- Amazing “27%” – report symptoms since starting medication(s).
  - >1 in 4 patients report potential ADR symptom
  - Remarkably consistent 3 studies (Gandhi NEJM 200x, CEDAR 2018, New Portal data)
- Relatively low response rates
  - But ~ 2x rate in Portal vs. prior IVR (robo calls)
  - Biased sample: ? Those with problems more likely to respond
- Patients value opportunity to hear and get help with Other Issues

Other Issues/Requests raised for Pharmacists
Most of these we were able to help

- Drug not working (ineffective)
- Insurance issues /Prior authorization
- Don't understand directions; how to use
- General questions about medication
- Cost issues- unaffordable co-pay
- Interfere with other medications (DDI's)
- Taking with food?; other timing issues
- Questions about other meds
- Need refills of other meds
- Patient questioning of diagnosis
- Logistical issues with clinic, appointment, Zoom link
- (Requesting remuneration for participation)

Could either provide direct answers or refer/connect to other resources

ADR Pharmaco-surveillance Patient Portal….and Texting

- Amazing “27%” – report symptoms since starting medication(s).
  - >1 in 4 patients report potential ADR symptom
  - Remarkably consistent 3 studies (Gandhi NEJM 200x, CEDAR 2018, New Portal data)
- Relatively low response rates
  - But ~ 2x rate in Portal vs. prior IVR (robo calls)
  - Biased sample: ? Those with problems more likely to respond
- Patients value opportunity to hear and get help with Other Issues
- Few patients wanted to convert to phone call from patient Gateway
- HUGE bureaucratic, policy, and some technical obstacles for texting our organization
  - After 2 years of efforts, still have not gone live

Endless Barriers/Hurdles for ADR Texting

Selection of the texting vendor (4 months)
- 13 vendors reviewed
- Reconciliation of different capabilities with the study needs
- Vendor acquisition midway through the project

- Approval to do as QI study
  - Multiple review calls with the IRB
  - Discussion with the MGB Texting committee
- Approval to send text messages to patients (9 months)
  - 2 presentations to the multi-stakeholder Texting committee
  - Discrepancies with the state/federal texting policies
  - Mandated to collect consent prior to sending text messages
  - Proper safeguards for after hours or emergency communications
- Approval from the Patient Experience committee
- Integration with MGB's Texting bus (6 months)
  - Confirmation prior to each text vs. confirmation every 24 hours
  - Permission to extract data from EHR and run the daily script
- Miscellaneous: COVID delays, Buy-in from clinics & clinicians

Safely Starting, Using, and Stopping Drugs

- Indications-based Prescribing
  - Background, rationale
  - Prototype development, evaluation
- Conservative prescribing principles, project
  - IHI Course
    - Principle #11 Beware rebound/withdrawal
      - PPI Example- rebound normal volunteers
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surescripts

CancelRx **FAQs**

Where can a current implementation guide for CancelRx be obtained?

Current implementation guides can be provided by your Surescripts Account Manager or from your Surescripts Integration Manager.

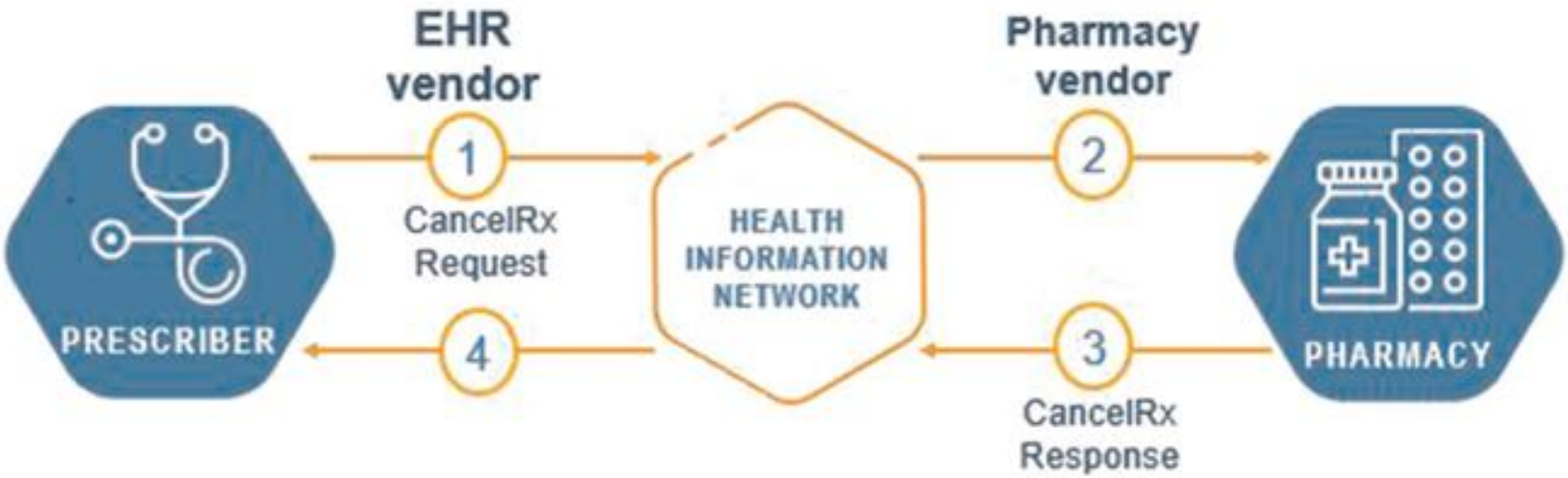
When should a CancelRx request be sent?

1. If the prescriber wants to correct a mistake on a prescription
2. If the prescriber wants to discontinue therapy of a prescription that is still active (i.e. there are refills left on the prescription at the pharmacy)

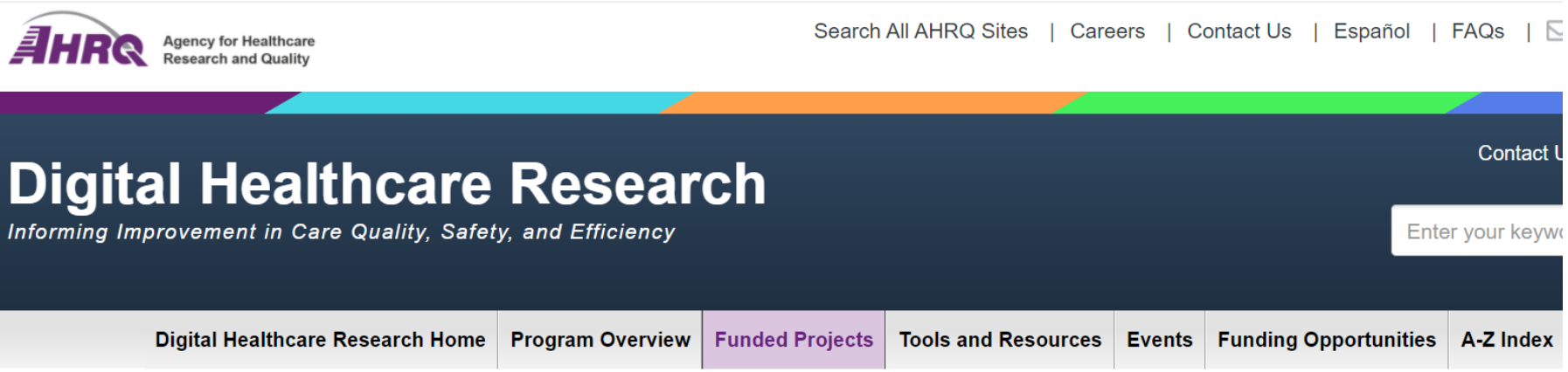
What information should be included in a Cancel Request in order for the pharmacy to identify what is being cancelled?

These basic message elements should be included as a starting point:

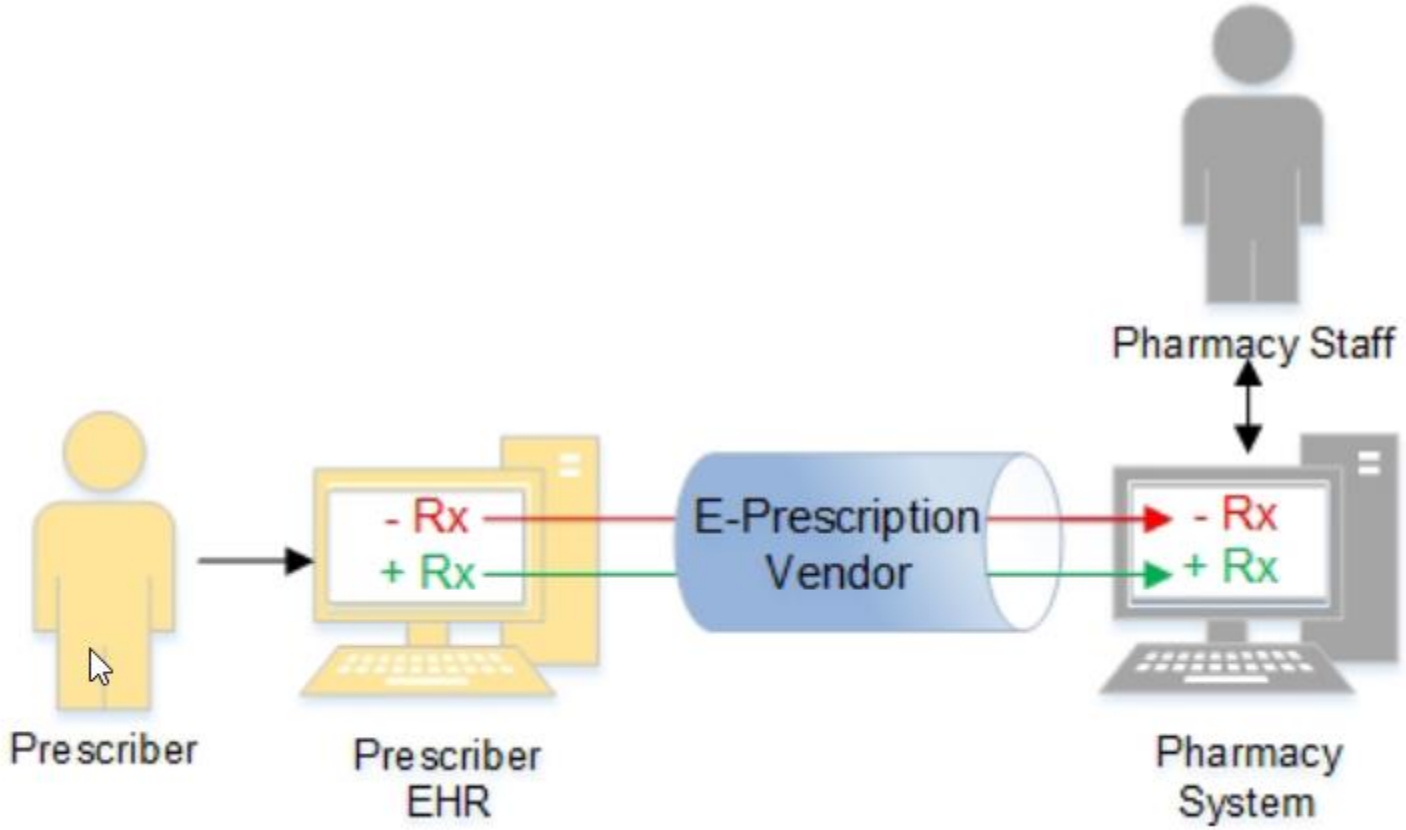
- Relates to Message ID
  - Required as part of Surescripts certification as long as the original message to be cancelled was sent electronically.
- Patient Name
- Patient Date of Birth
- Patient Gender
- Patient Address
- Patient Phone Number
- Medication
  - Name
  - Strength

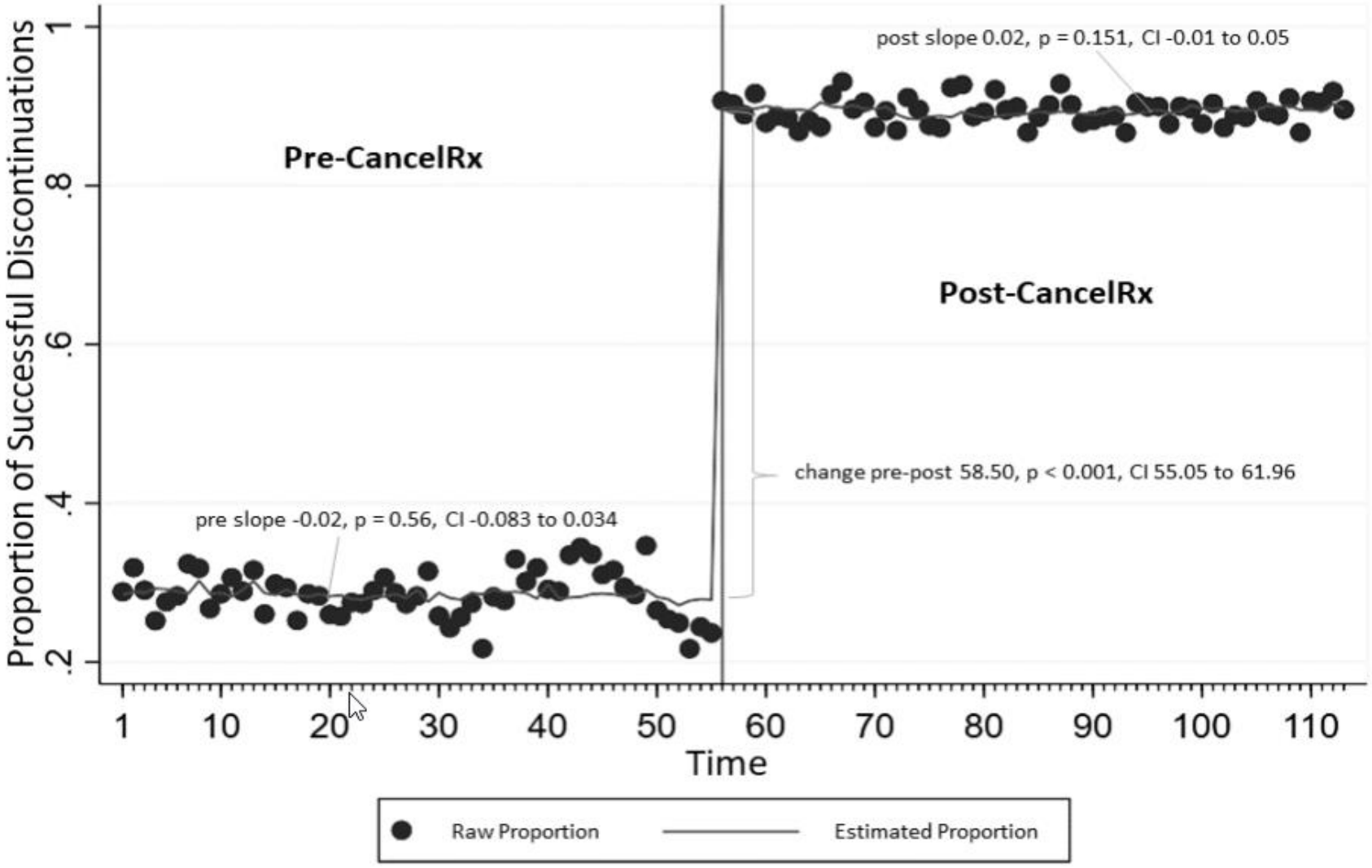


Source: Yang et al., 2018



Project Dates: 08/01/2018 – 7/31/2020 R21HS025793
Institution: University of Wisconsin - Madison
PI: Michelle A. Chui
Team Members: Roger Brown, Lauren Craddock-Nibbler, Edmond Ramly, Peter Kleinschmidt, Taylor Watterson, Jamie Stone
Project Officer: Janey Hsiao


Pharmacy Staff
- Rx
+ Rx
E-Prescription
Vendor
- Rx
+ Rx
Prescriber
Prescriber
EHR
Pharmacy
System



gure 1 Successful Medication Discontinuations Pre- and Post-CancelRx Implementation

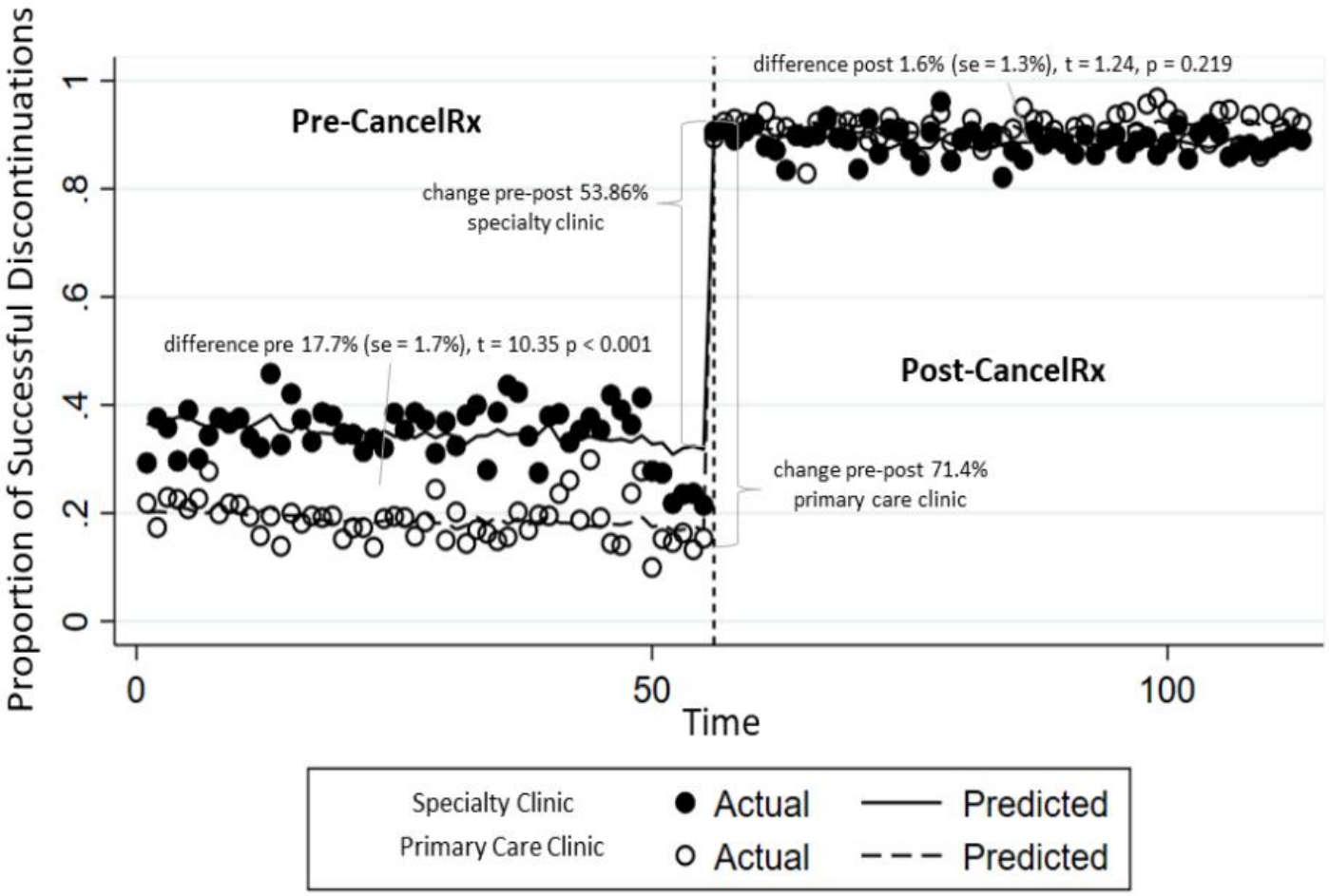
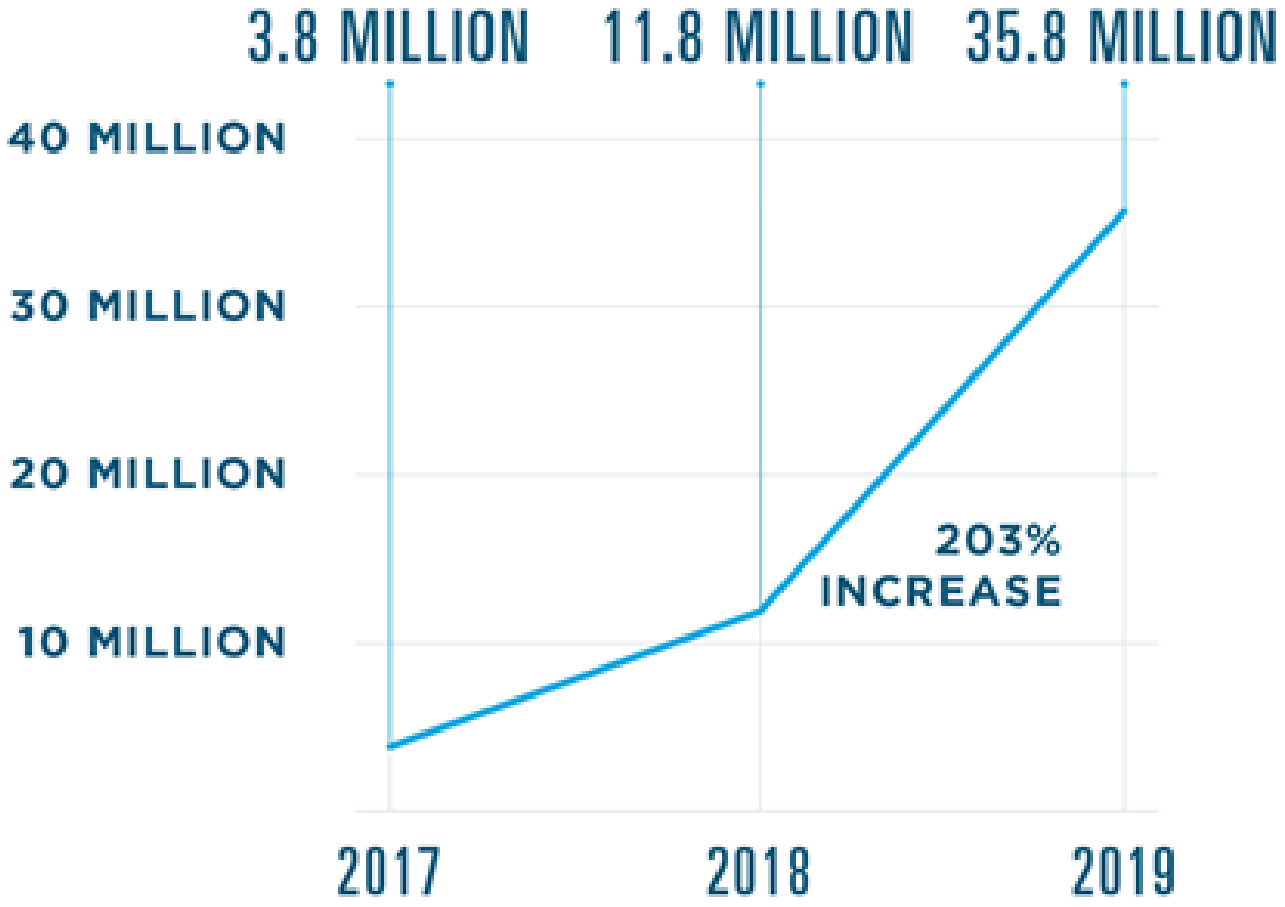


Figure 3 Successful Medication Discontinuations Pre- and Post-CancelRx Implementation by Clinic Type

ome 3: Time to Discontinuation Between Clinic System and Pharmacy Software Over Time

Scope: CancelRx was implemented in October 2017 at an academic health system, UW Health. Data included patients aged 18+ who had one or more medication discontinuations for an e-prescription that originated from the EHR and was sent to one of UW Health's 15 community pharmacies.
Methods: A interrupted time series analysis (ITSA) was conducted on medication discontinuation data 12-months prior and 12-months after implementation. Interviews were conducted with pharmacy and clinic staff
and observations were conducted with pharmacy staff pre-implementation and 3- and 9-months postimplementation.
Results: Pre-CancelRx, 34% of medications that were canceled at the clinic were also canceled at the pharmacy. Post-CancelRx, there was an immediate and significant increase in the proportion of successful medication discontinuations to 93%. Clinic interviews pre- and post-CancelRx revealed a lack of standardized workflow – who, how, and when medications should be discontinued and communicated. Post-CancelRx, pharmacists noted an increase in medication discontinuation messages, not all of which were useful. All participants recognized the implications of CancelRx for patient safety.

Rapid Recent Growth of Cancel Rx Messages



Source: Surescripts 2019 National Progress Report[16]

Clinic Sociotechnical Vulnerability Themes

- error in information acquisition during rooming regarding whether a patient is taking or not taking a medication
- error in documenting whether a patient is taking or not taking a medication
- EHR is complex and duplicative with many areas to note whether patient is taking/not taking a medication
- error in discontinuing a medication or not in EHR
- error in selecting discontinuation reason in the EHR, and ambiguity regarding which tasks clinic staff should and should not be completing.

Pharmacy Sociotechnical Vulnerability Themes

- error in clinic staff contacting the pharmacy regarding discontinued medications
- error in pharmacy identifying, matching, and discontinuing the correct medication for the correct patient
- medication unable to be discontinued in pharmacy system because it was already dispensed or because there was not an active prescription on file.

Transfer of Information Between Clinic and Pharmacy Systems

- technical errors/glitches in the system

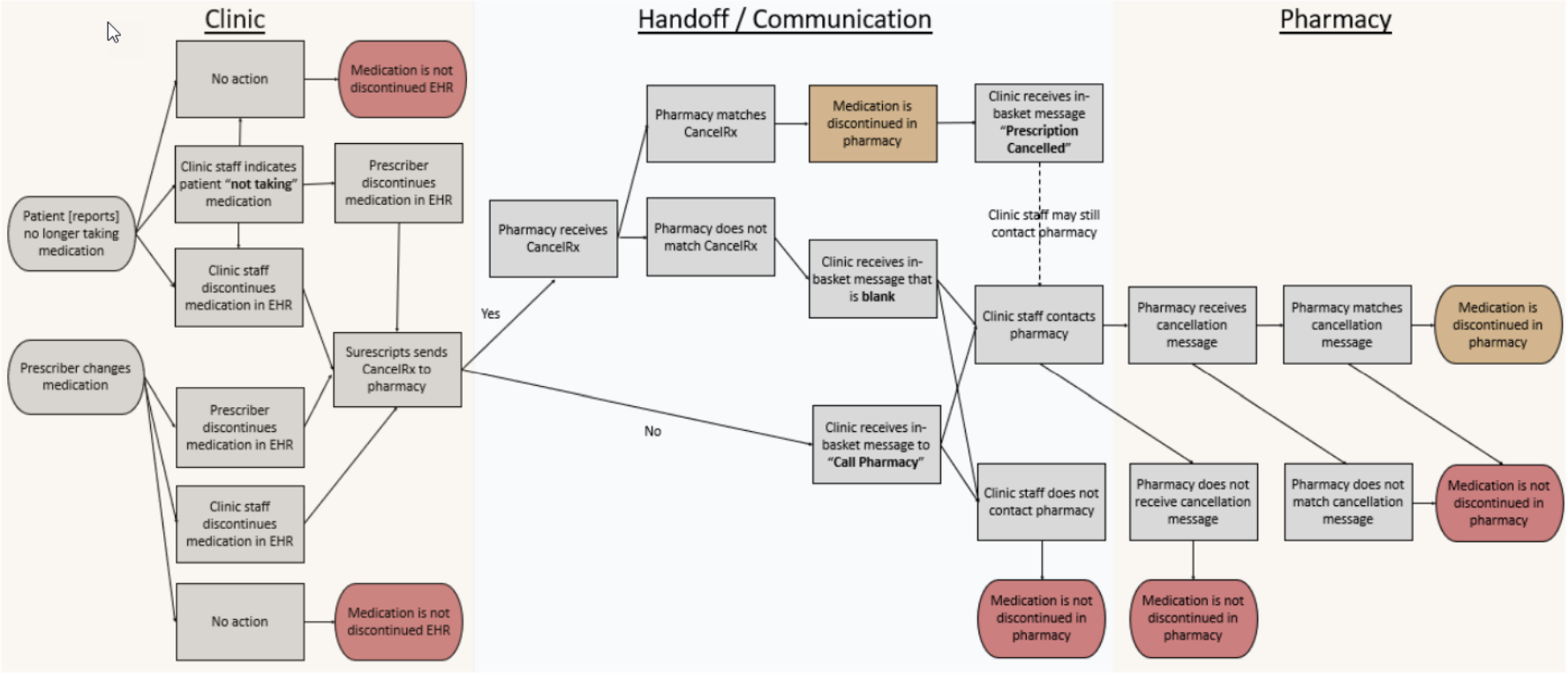


Figure 7 Medication Discontinuation Process Map

Vocabulary/Code Set/Terminology +

Content/Structure –

Admission, Discharge, and Transfer +

Care Coordination for Referrals +

Care Plan +

Clinical Decision Support +

Clinical Notes +

Clinical Quality Measurement and Reporting +

Data Provenance +

Diet and Nutrition +

Drug Formulary & Benefits +

Electronic Prescribing –

- Allows a Long Term or Post-Acute Care to Request to Send an Additional Supply of Medication
- Allows a Pharmacy to Notify a Prescriber of Prescription Fill Status
- Allows a Pharmacy to Request a Change to a Prescription
- Allows a Pharmacy to Request a New Prescription For a New Course of Therapy or to Continue Therapy
- Allows a Pharmacy to Request Additional Refills
- Allows a Pharmacy to Request, Respond to, or Confirm a Prescription Transfer
- Allows a Prescriber or a Pharmacy to Request a Patient's Medication History

Allows a Prescriber to Cancel a Prescription

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●○○○	Yes	$	Yes
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 2017071	Final	Production	●●●●○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration

- Please refer to CMS.gov for more information regarding Medicare Part D electronic prescribing requirements and sign up to receive the latest announcements.
- The following transactions need to be implemented for interoperability purposes:
  - SCRIPT 10.6 -
    - CanRx: a request from a prescriber to a pharmacy to not fill a previously sent prescription.
    - CanRes: a response from a pharmacy to a prescriber to acknowledge a cancel request; the response to a CanRx.
  - SCRIPT 2017071 -
    - CancelRx: a request from the prescriber to the pharmacy to not fill a previously sent prescription
      - must contain pertinent information for the pharmacy to be able to find the prescription in their system (patient, medication (name, strength, dosage form), prescriber, prescription number if available)
      - changes can be indicated in the MessageRequestCode in the CancelRx transaction
    - CancelRxResponse: a response from the pharmacy to the prescriber to acknowledge a CancelRx
      - used to denote if the cancellation is Approved or Denied

Applicable Security Patterns for Consideration

- **Secure Communication** – create a secure channel for client-to- server and server-to-server communication.
- **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery.
- **Authentication Enforcer** – centralized authentication processes.
- **Authorization Enforcer** – specifies access control policies.
- **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos).
- **Assertion Builder** – define processing logic for identity, authorization and attribute statem
- **User Role** – identifies the role asserted by the individual initiating the transaction.
- **Purpose of Use** - Identifies the purpose for the transaction.

Understanding CancelRx: Results of End-to-End Functional Testing, Proactive Risk Assessment, and Pilot Implementation

Samantha I. Pitts[1] Noah Barasch[2] Andrew T. Maslen[3] Bridgette A. Thomas[4] Leonard P. Dorissaint[3] Krista G. Decker[5] Sadaf Kazi[2] Yushi Yang[6] Allen R. Chen[7]

[1] Department of Medicine, Johns Hopkins University School of Medicine, Baltimore, Maryland, United States
[2] Armstrong Institute for Patient Safety and Quality, Johns Hopkins University School of Medicine, Baltimore, Maryland, United States
[3] Information Technology, Johns Hopkins Health System, Baltimore, Maryland, United States
[4] Pharmacy Services, Johns Hopkins Home Care Group, Baltimore, Maryland, United States
[5] Department of Quality Management, Johns Hopkins Home Care Group, Baltimore, Maryland, United States
[6] Armstrong Institute for Patient Safety and Quality, Johns Hopkins Health System, Baltimore, Maryland, United States
[7] Departments of Oncology and Pediatrics, Johns Hopkins University School of Medicine, Baltimore, Maryland, United States

Address for correspondence Samantha I. Pitts, MD, MPH, Department of Medicine, Johns Hopkins University School of Medicine, 1830 East Monument Street, Room 8020, Baltimore, MD 21287, United States (e-mail: Spitts4@jhmi.edu).

Appl Clin Inform 2019;10:336–347.

Abstract

Background CancelRx allows prescribers to send electronic cancellation messages to pharmacies when medications are discontinued. Little is known about its functionality and impact on clinical workflows.

Objectives To understand CancelRx functionality, its potential impact on workflows and medication safety risks, and to develop mitigating strategies for risks introduced by

CancelRx implementation eliminated five of seven failure modes in outpatient prescribing to Johns Hopkins pharmacies, but introduced new risks, including (1) failure to act if an e-cancellation was not sent or was unsuccessful; (2) failure to cancel all prescriptions for a medication; (3) errors in manual matching; and (4) erroneous medication cancellations. We identified potential mitigation strategies for these risks.

During pilot implementation, 92.4% (428/463) of e-cancellations had confirmed approval by the receiving pharmacy, while 4.5% (21/463) were denied, and 3.0% (14/463) had no e-cancellation response.

Table 1 Prescriber intentions, reasons for medication discontinuation, and successful pharmacy outcomes

Prescriber intention	Reason	Successful pharmacy outcome
Prevent an initial fill	Prescribing error—wrong medication, patient, pharmacy, dose, or frequency	Deletion of prescription
	Alternate therapy, e.g., change in decision making or due to cost	Deletion of prescription
Prevent a subsequent fill	Adverse drug reaction	Deactivation of all prior prescriptions for this medication; pharmacy notified of allergy
	Alternate therapy, e.g., due to effectiveness or cost	Deactivation of all prior prescriptions for this medication
	Dose adjustment	Deactivation of all prior prescriptions for this medication
	Therapy completed	Deactivation of all prior prescriptions for this medication
Ensure only one prescription is filled	Duplicate therapy	Deletion or deactivation of one or more prescriptions, retaining a single active prescription
Medication reconciliation without intent to prevent a fill	Therapy completed but may request refill	Maintenance of prescription on profile as completed but able to request refill

Table 4 Failure modes in CancelRx, mitigation strategies in pilot implementation, and future mitigation opportunities

Failure mode	Mitigation strategies for pilot implementation	Recommendations for development
Prescriber does not recognize when an e-cancellation is not sent	• Train prescribers in functionality of CancelRx	• Increase visibility of cancellation status
Prescriber does not recognize that an in-basket message indicates an e-cancellation failure	• Route in-basket messages to trained RN • Train prescribers to locate status in order report	• Increase visibility of cancellation status • Reduce in-basket messages that are not actionable
EHR does not notify prescriber when an e-cancellation is not addressed by a pharmacy	• Monitor frequency	• Notify prescriber when an e-cancellation is not addressed by a pharmacy
Pharmacist cancels active medication when e-cancellation is sent with a renewal request	• Suppress cancellation with prescription renewals	• Transmit cancellation reason
User sends e-cancellation in error during medication reconciliation	• Train prescribers in functionality of CancelRx	• Increase visibility of cancellation status • Control by discontinuing user
Pharmacist matches e-cancellation to wrong prescription	• Monitor frequency	• Reduce manual matches • Provide decision support for manual matches
Prescriber cannot specify if all prior prescriptions of medication should be discontinued—one to one match only	• Assign responsibility for managing e-cancellation messages to pharmacists	• Allow prescriber to specify if all prior prescriptions of medication should be discontinued • Transmit cancellation reason (e.g., adverse drug event) • Consider transmission to multiple pharmacies