Patient-Centered \mathbb{R} Communication

strategies to mitigate/minimize risk

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Disclosures

<u>Federal</u>

- NIH
 - NCI
 - NIA
 - NIDDK
 - NINR
 - NHLBI
 - OBSSR
- AHRQ

<u>Private</u>

- ACOG
- California Endowment
- California Healthcare Foundation
- Missouri Foundation for Health
- PCORI

<u>Industry</u>

- Abbvie
- Deborah Adler Design
- Emmi Solutions
- Luto UK
- Merck
- UnitedHealthcare
- Vivus





Current R_x labeling practices cause patient harm

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- Evidence is available supporting a better way

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- 'Health literacy' best practices are available
- Case example: Med Guides
- Health technologies can be leveraged -

Health, Literacy, & 'Health Literacy'

Health Literacy is...

The <u>cognitive</u> and <u>social skills</u> which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health.

- World Health Organization

Limited Health Literacy

"Keep watch also on the faults of the patients, which often make them lie about the taking of things prescribed"

- Hippocrates

"America's healthcare system is neither healthy, caring, nor a system."

- Walter Cronkite

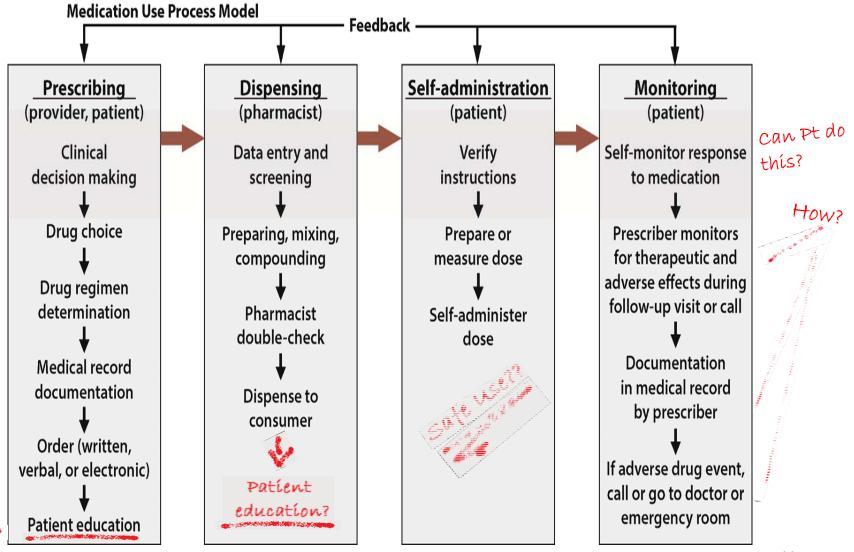
A System Failure?

How are we helping patients

- learn about their medicines?
 - organize multi-drug regimens?
 - problem-solve use?
 - maintain adherence?







The Problem... Simplified

Providers don't often counsel patients on R_x risks, safety, use

X

Pharmacies fail to distribute Med Guides

X

Med Guídes, PMI not understandable, actionable Patients are...

*UNINFORMED

*AT RISK

(errors, ADEs, sub-optimal treatment)

Result is...

*REMS FAILURE

(Med Guides, Communication Plans)

Confusing Patients Less

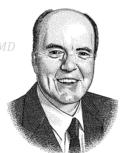
Fix the health system, not patient

- Missed opportunities to counsel patients on safe use by both prescribers and pharmacists
- 'Sig' instructions highly variable



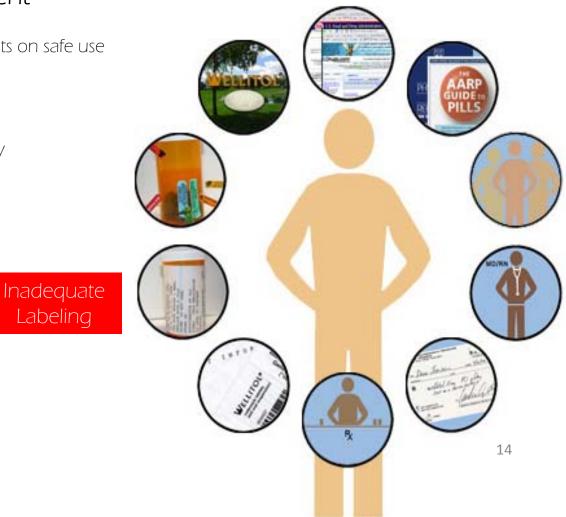
Confusing Patients Less

Labeling



Fix the health system, not patient

- Missed opportunities to counsel patients on safe use by both prescribers and pharmacists
- 'Sig' instructions highly variable
- Rx labeling highly variable, poor quality



Confusing Patients Less

Informal Sources

Fix the health system, not patient

- Missed opportunities to counsel patients on safe use by both prescribers and pharmacists
- 'Sig' instructions highly variable
- Rx labeling highly variable, poor quality
- Limited information seeking skills, confusion w/ 'informal' resources



Risk for Safety, Non-Adherence

- Many adults misunderstand R_x labeling and make dosing errors
 - 75% can't fully identify R_x indication for use = non-adherence, poorer clinical outcomes

(Persell et al Am J Med, 2010, Lenahan et al, J Health Comm 2013)



Risk for Safety, Non-Adherence

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(Persell et al Am J Med, 2010, Lenahan et al, J Health Comm 2013)

- 52% misinterpret auxiliary warning information (Davis et al JGIM 2006)
- 54% demonstrate improper dosing

(Wolf, Davis et al. Ann Intern Med 2006)

- Misunderstanding and improper dosing linked to non-adherence, 20% greater risk of readmission

(Farber J Asthma 2003; Lindquist et al. JGIM, 2012; Serper et al., under review, 2014)



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(Farber J Asthma 2003; Lindquist et al. JGIM, 2012; Serper et al., under review, 2014)

- 43 to 85% over-complicate multi-drug regimens
 (Wolf et al. Arch Intern Med 2011; Lindquist et al, Pat Ed Counsel 2014)
 - Pogimon complexity linked to misunderstanding non a
- Regimen complexity linked to misunderstanding, non-adherence, hospitalization, outcomes

(Gazmararian et al JGIM 2006; Choudhry et al, Arch Intern Med 2011; Neri et al Am J Nephrol 2011; Paquin et al Exp Op Drug Saf 2013)



Missed Opportunities

ORIGINAL INVESTIGATION

The Variability and Quality of Medication Container Labels

William H. Shrank, MSHS, MD; Jessica Agnew-Blais, BA; Niteesh K. Choudhry, MD, PhD; Michael S. Wolf, PhD, MPH; Aaron S. Kesselheim, MD, JD; Jerry Avorn, MD; Paul Shekelle, MD, PhD

> None of the ibuprofen prescriptions were accompanied by FDA-approved official medication guides, as required by law.

> > What patients think doctors know: Beliefs about provider knowledge as barriers to safe medication use

Marina Serper ^{a,b,*}, Danielle M. McCarthy ^c, Rachel E. Patzer ^d, Jennifer P. King ^a, Stacy C. Bailey ^e, Samuel G. Smith ^f, Ruth M. Parker ^g, Terry C. Davis ^h, Daniela P. Ladner ^b, Michael S. Wolf ^{a,b,i}

Physician communication (n=190)

Physician communication (n = 190)

Reviewed medication list 51.3

Explained how to take medicine 77.4

Described side effects 42.9

Pharmacist communication (n = 190)

Explained how to take medicine 43.3

Described side effects 25.8

19

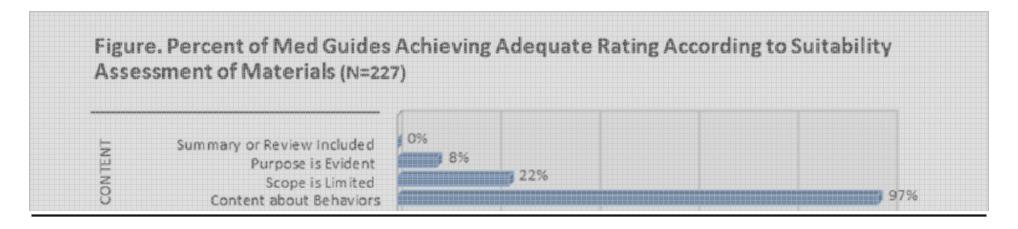
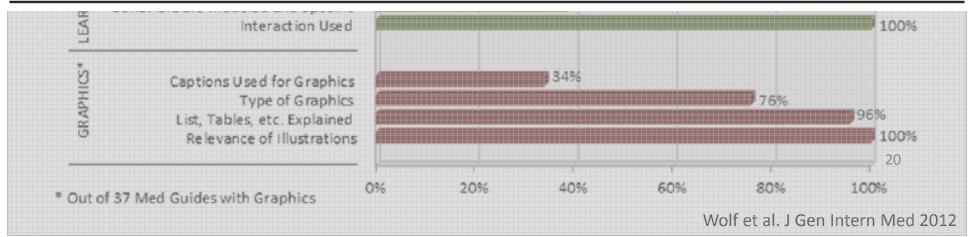


Table 2. Differences in Total and Subcategory Comprehension Scores by Literacy Level

| Score | Overall Score Mean (SD) | Mean (SD) Scores by Literacy Level | | | P value |
|--|---|---|--|---|--|
| | | Low (n = 63) | Marginal (n = 103) | Adequate (n = 283) | |
| Total (out of 99 pts) Decision making prior to use (36 pts) General use and storage (15 pts) Side effects (48 pts) | 52.7 (22.6) 18.3 (9.3) 9.3 (3.0) 25.1 (11.7) | 24.9 (13.8) 8.0 (5.1) 5.9 (2.3) 11.0 (8.1) | 37.8 (15.7) 12.0 (6.0) 7.6 (2.2) 18.3 (9.6) | 64.3 (17.1) 22.9 (7.7) 10.7 (2.5) 30.7 (8.8) | <0.0001 <0.0001 <0.0001 <0.0001 |

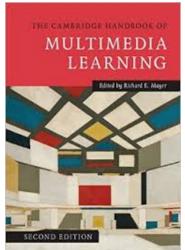


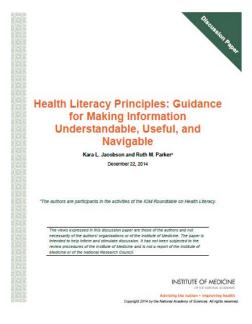
Evidence of a Better Way

■ There is an expanse of literature that identifies ways to optimize written health materials.

 Evidence also robust for multimedia (e.g. web site design, video)

 Despite the science, recommended principles more often not followed





'Vetting' R_x Labeling

- Create a '3rd party' process
- Develop prototype following HL best practices
- Involve patients in process elicit early feedback
- Refine accordingly
- Perform usability testing
- Modify again as necessary

Assessment



■ Patient Education Materials Assessment Tool (PEMAT)

http://www.ahrq.gov/professionals/prevention-chronic-care/

improve/self-mgmt/pemat/

Assesses both Understandability and Actionability

Case Example: Med Guides

- Significant improvements in comprehension, demonstrated use
- Health literacy disparities reduced
- While a 'better' practice, standards can vary

ORIGINAL ARTICLE

Comparative Effectiveness of Patient-centered Strategies to Improve FDA Medication Guides

Michael S. Wolf PhD, MPH,*† Stacy C. Bailey, PhD, MPH, Marina Serper, MD,* Meredith Smith, PhD\$ Terry C. Davis PhD | Allison L. Russell BA,* Beenish S. Manzoor, BA ¶ Lisa Belter, MPH* Ruth M. Parker, MD,# and Bruce Lambert PhD¶

Background: Med Guides are the only Food and Drug Adminwith prescriptions drugs. Despite their potential value, studies have Measures: Tailored comprehension assessment of content from 3 found them to have limited utility.

egies for the design of Med Guides to improve comprehension.

Setting: Two primary care clinics in Chicago, Illinois; one based in a public university hospital and the other within a private academic medical center.

Patients: A total of 1003 adults aged 18-85 years.

Designs A emassectional machinised total

Intervention: The format and layout of content from 3 typical Med Guides (by reading difficulty, length, exposure) were modified several ways to promote information accessibility. Working with patients, the 3 most preferred versions were evaluated. The first used 2 columns to organize content (Column), a second mimicked over-the-counter "Drug Facts" labeling (Drug Facts), and the third

From the *Bladth Literacy and Learning Program, Division of General In-turnal Medicine, Venberg School of Medicine, Northwestern University, Chiago; Till-praintent of Learning Scienzes, School of Education and Social Tolicy, Northwestern University, Branton, IL; [Division of Patramocurizal Conternes and Policy, Enthriam School of Patramoc, University of North Caroline, Chippli 115, INC, [Sithest and Reastern Development, Advisor Res, Vend Chagge, IL; [Dipartment of Medi-Development, Les (Spacintent of Patrancy, Administration, Chicago College of Patrancy, University of Billion, Campaign, IL; and 65th-vision of General Medicine, Emory University School of Medicine, Alleria, GA.

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preparation of the manuscript.

MS.W., S.C.B., and B.L. have previously provided research consultation.

No. M., N. C., and J. L. Good per usually provious restaurant constitutions services to show Ealah. T.C. D. has note township in Abort Ealah. The remaining authors declare no conflict of interest. Reprinter Midstell S. Wolf, Ph.D., MWI, Health Literacy and Learning Program, Division of General Internal Medicine, Femberg School of Medicine, Northwestern University, 750 N. Lake Shore Drive, 10th Moor, Chicago, H. 60611. E-mail: mewolf@northwestern.edu. Speciamental Digital Content is available for this article Direct LBL cita-

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followed health literacy best practices using a simple table format (Health Literacy prototype).

representative Med Guides.

Objective: To evaluate the effectiveness of patient-centered strattypes compared with the current standard (all P < 0.001). The Health Literacy prototype consistently demonstrated the highest commenhension scores, and in multivariable analyses, outnerformed both the Drug Facts [β= -4.43, 95% confidence interval (CI), -6.21 to -2.66] and Column (β=-4.04, 95% CI, -5.82 to -2.26) prototypes. Both older age (older than 60 y: $\beta = -10.54$, 95% CI, -15.12 to -5.96), low and marginal literacy skills were independently associated with poorer comprehension (low: $\beta = -31.92, 95\%$ CI, -35.72 to -28.12; marginal: $\beta = -12.91$, 95% CL -16.01 to -9.82).

> Graciusions: The application of evidence-based practices to the redesign of Med Guides significantly improved patient comprehension. Although some age and literacy disparities were reduced with the Health Literacy format in particular, both older age and low literacy remained independently associated with poorer comprehension. More aggressive strategies will likely be needed to gain assurances that all patients are informed about their prescribed

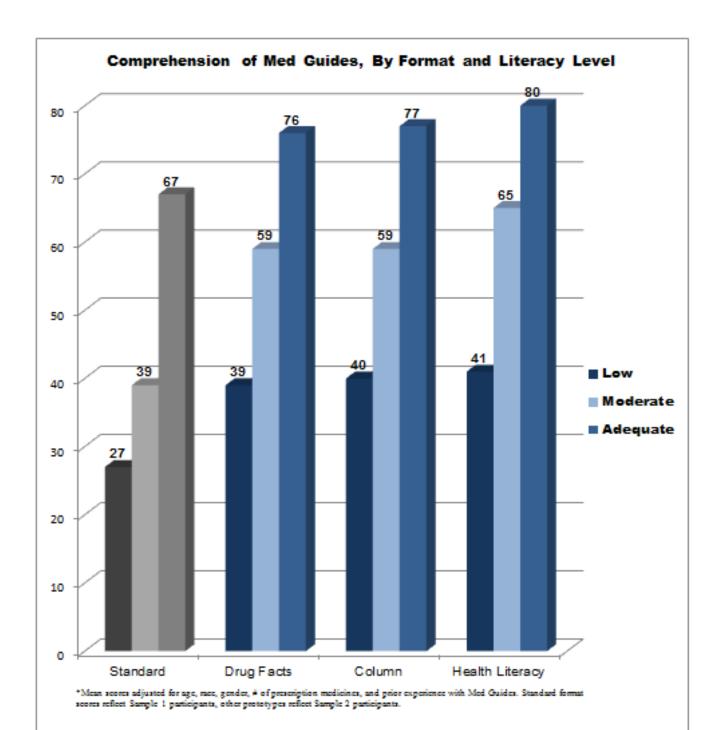
Trial Resistration: Clinical Trials Gov #NCT01731405.

Key Words: prescription, medication information, comprehension, FDA, Medication Guide, Health Literacy, clinical trial

(Med Care 2014:52: 781-789)

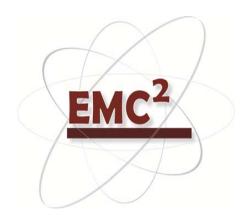
The Food and Drug Administration (FDA) requires the pharmaceutical industry to develop and disseminate consumer-friendly, tangible medication information materials, known as "Medication Guides" (Med Guides) for prescription drugs that are deemed to possess "serious and significant public health concerns." 12 Med Guides are an essential part of the FDA's "risk evaluation and mitigation strategies" (a.k.a. REMS) and one of the very few mandated assurances that patients receive a prescribed drug's safety information before use, potentially preventing serious adverse effects. 3,4 These materials also convey the importance of proper medication adherence to achieve optimal health benefits. The value of Med Guides is further underscored by

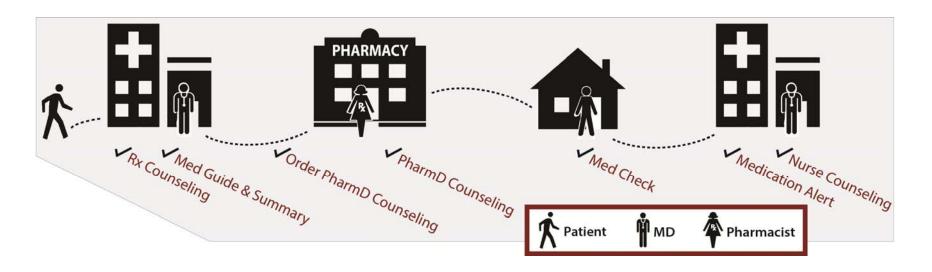
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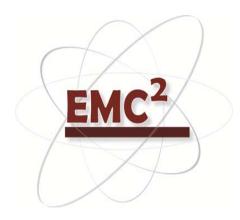


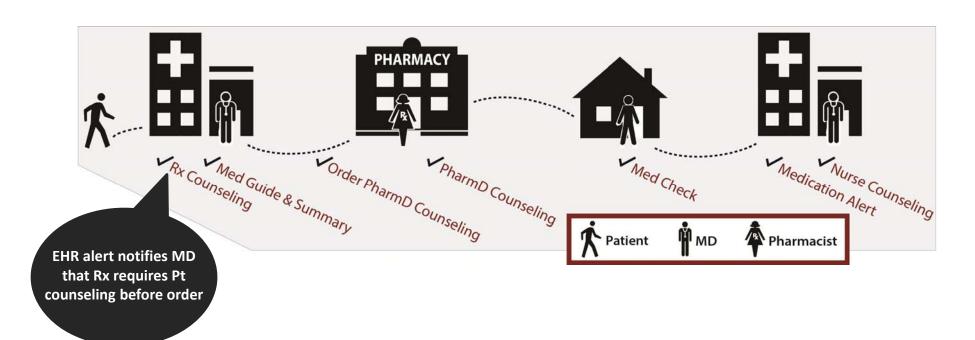
The Solution...

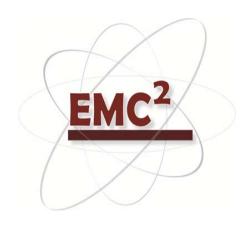
EHR-enabled
Medication
Complete
Communication

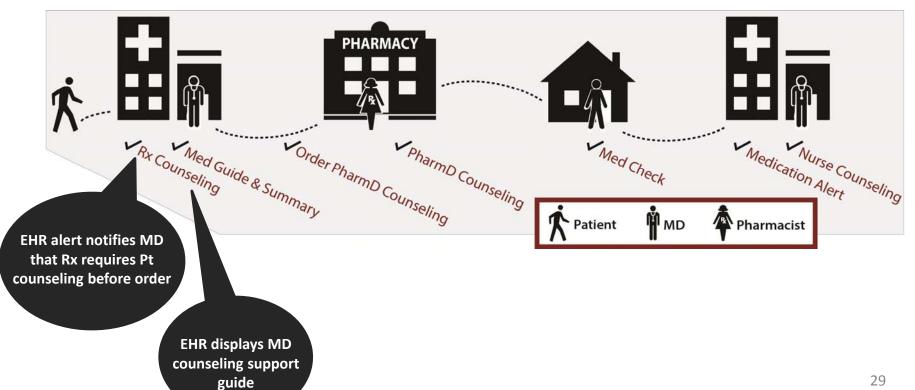


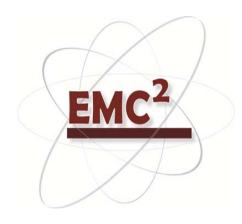


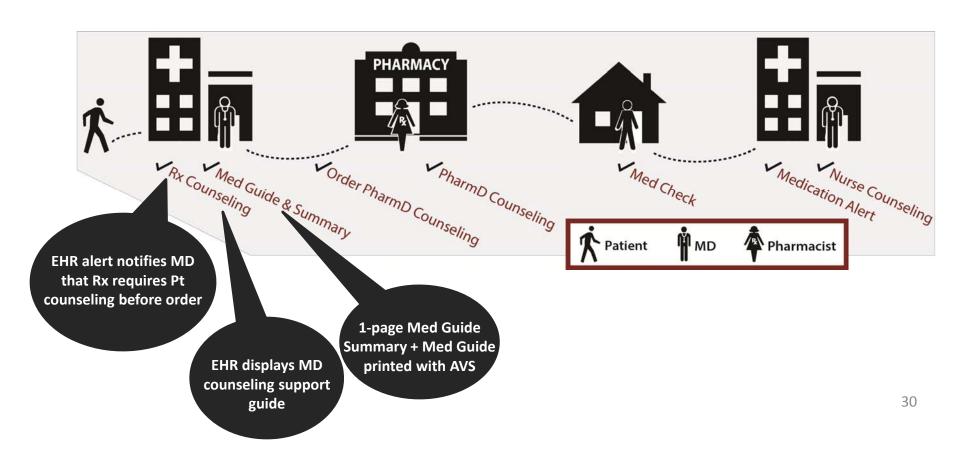












| SOME IMPORTANT THINGS TO KNOW ABOUT YOUR MEDICATION | | | | | |
|---|--|--|--|--|--|
| Generic name | Methylphenidate hydrochloride | | | | |
| Brand name | Ritalin | | | | |
| Purpose | This medicine helps treat Attention-Deficit Hyperactivity Disorder (ADHD) and a sleep disorder called narcolepsy in adults and children older than 6. | | | | |
| Benefit | Ritalin is a central nervous system stimulant that helps increase attention and decrease impulsiveness and hyperactivity. | | | | |
| How to take | Take Ritalin as prescribed by your doctor Ritalin is taken by mouth (pill) Store Ritalin at room temperature, 59 to 86°F, away from light Ritalin is usually taken 2 to 3 times a day, 30-45 minutes before eating Your doctor will tell you how long you should be on this medication. Refill this | | | | |
| For how long | medicine until your doctor tells you to stop. | | | | |
| Important! | Ask your doctor before use if you: • have heart problems, heart defects, or high blood pressure • have mental problems (psychosis, mania, bipolar illness, or depression) • have liver or kidney problems • have seizures or have had an abnormal brain wave test (EEG) • are pregnant, planning to become pregnant, or breastfeeding • are taking anti-depression medicines including MAOIs | | | | |
| Stop taking and call us | Stop taking this medicine and call your doctor right away if you: • have a stroke or heart attack (adults) • have increased blood pressure or heart rate • have new or worse bipolar illness • have new psychotic or manic symptoms • have slowing of growth (children) • have eyesight changes or blurred vision | | | | |
| Call us | Call us if these side effects are severe, last longer than one week, or if you feel concerned: • headache • stomach ache • trouble sleeping | | | | |
| Remember | Talk to your doctor about any questions or concerns you may have regarding this medicine. • Follow up is important to see how well the medicine is working. • Remember the date of your next appointment. | | | | |

You will get more detailed information from your pharmacy. You may find the following website

useful: www.nlm.nih.gov/medlineplus

MEDICATION GUIDE

RITALIN LA®

(methylphenidate hydrochloride) extended-release capsules CII

Read the Medication Guide that comes with RITALIN LA* before you or your child starts taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your or your child's treatment with RITALIN LA*.

What is the most important information I should know about RITALIN LA®?

The following have been reported with use of methylphenidate hydrochloride and other stimulant medicines.

1. Heart-related problems:

- · sudden death in patients who have heart problems or heart defects
- · stroke and heart attack in adults
- · increased blood pressure and heart rate

Tell your doctor if you or your child have any heart problems, heart defects, high blood pressure, or a family history of these problems.

Your doctor should check you or your child carefully for heart problems before starting RITALIN LA®.

Your doctor should check your or your child's blood pressure and heart rate regularly during treatment with RITALIN LA®.

Call your doctor right away if you or your child has any signs of heart problems such as chest pain, shortness of breath, or fainting while taking RITALIN LA®.

2. Mental (Psychiatric) problems:

All Patients

- · new or worse behavior and thought problems
- · new or worse bipolar illness
- · new or worse aggressive behavior or hostility

Children and Teenagers

 new psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious) or new manic symptoms

Tell your doctor about any mental problems you or your child have, or about a family history of suicide, bipolar illness, or depression.

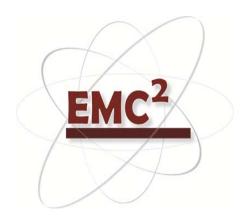
Call your doctor right away if you or your child have any new or worsening mental symptoms or problems while taking RITALIN LA®, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

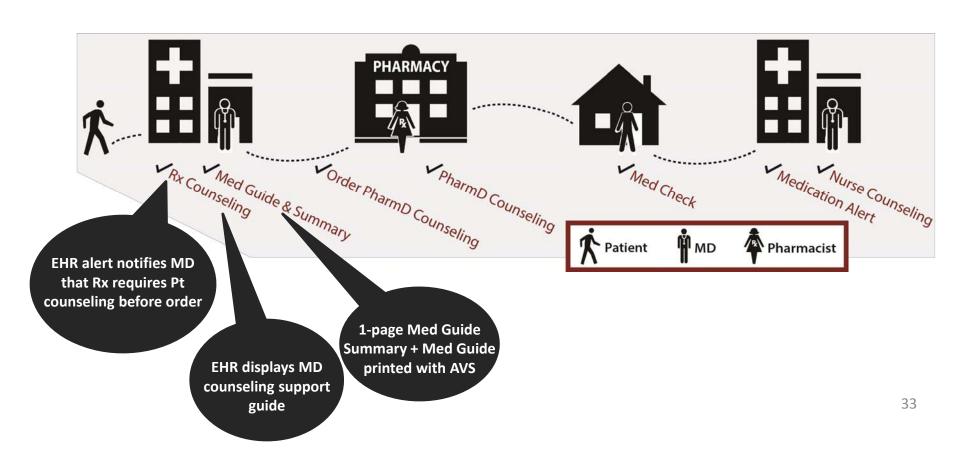
What Is RITALIN LA®?

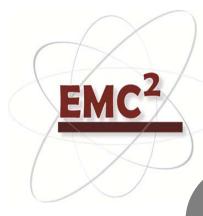
Preliminary Work

- 4 NIH/AHRQ studies led by our team support our ability to:
 - create MD/RN alerts
 - embed counseling support tools, linked to medication
 - automate delivery of PMI with order, printed with AVS
- Familiarity with multiple EHR platforms

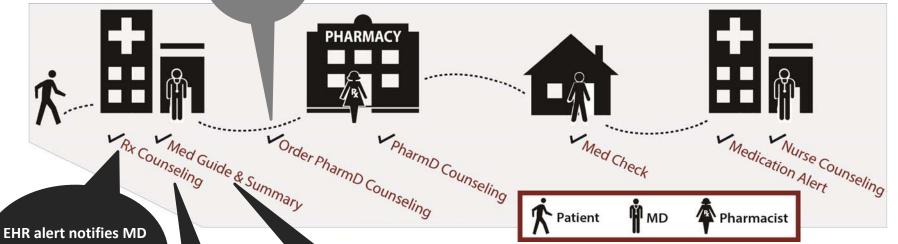
(Epic, Cerner, GE Centricity)







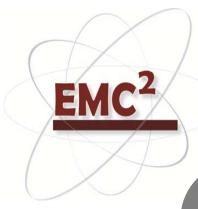
Rx includes request for PharmD to counsel Pt



that Rx requires Pt counseling before order

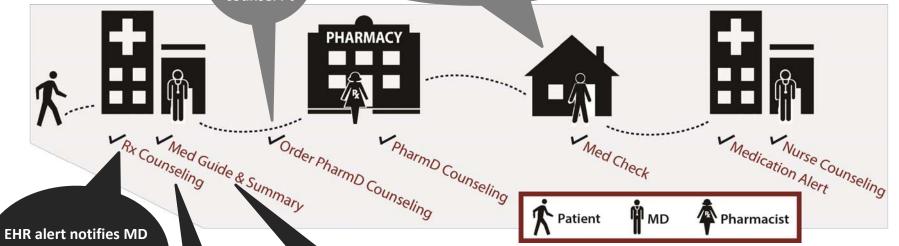
EHR displays MD counseling support guide

1-page Med Guide Summary + Med Guide printed with AVS



Rx includes request for PharmD to counsel Pt

Pt prompted (email, phone) to demonstrate Rx understanding & use via Pt portal (2-3 days)



that Rx requires Pt counseling before order

EHR displays MD counseling support guide

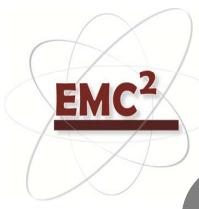
1-page Med Guide Summary + Med Guide printed with AVS

Sample MedCheck Items

| Name 2 common side effects you may have while taking [Drug X]. |
|--|
| You are taking [Drug X] to treata) condition 1, b) condition 2, c) condition 3 |
| Name 3 medications you cannot take while using [Drug X]. |
| If you have these symptoms, do the following: a) call doctor, b) seek care immediately, c) wait until next scheduled |
| visit, d) nothing |
| True or False: You should take [Drug X] with food. |
| How many pills should you take at a time? |
| When do you take [Drug X]? (hours of day) |
| How many pills do you take of [Drug X] in one day? |
| Have you filled your prescription for [Drug X]? |
| Do you have any concerns about the cost of [Drug X]? |
| Have you experienced any side effects since taking [Drug X]? |
| Have you missed a dose of [Drug X] yesterday? The day before? In the past 4 days? |
| Have you ever stopped taking your medicine because you felt worse when you took it? |
| Do you sometimes forget to take your medicine? |
| Do you ever feel annoyed about sticking to your medication schedule? |
| When you feel your symptoms are under control, do you sometimes stop taking your medicine? |

Preliminary Work

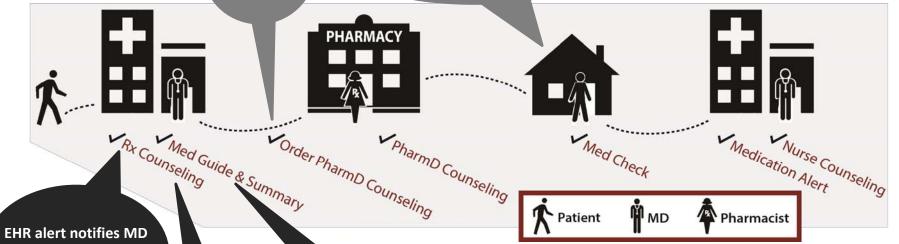
- Multiple published studies by our team use these objective assessment items
- We include validated measures of adherence barriers, as well as risk communication
- Current NIH study work includes use of an untethered patient portal to monitor medication use [R01NR011300]



Our Strategy

Rx includes request for PharmD to counsel Pt

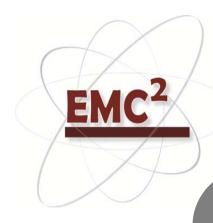
Pt prompted (email, phone) to demonstrate Rx understanding & use via Pt portal (2-3 days)



that Rx requires Pt counseling before order

EHR displays MD counseling support guide

1-page Med Guide Summary + Med Guide printed with AVS



Our Strategy

EHR Care Alert generated for any Pt at risk, as determined by MedCheck

Rx includes request for PharmD to counsel Pt

Pt prompted (email, phone) to demonstrate Rx understanding & use via Pt portal (2-3 days)







Patient



Rx Counseling

Order PharmD Counseling

Counseling

V Med Check

MD

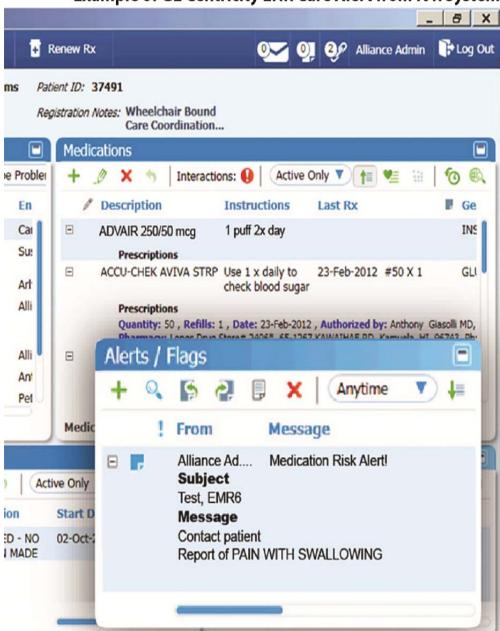


EHR alert notifies MD that Rx requires Pt counseling before order

> 1-page Med Guide Summary + Med Guide printed with AVS

EHR displays MD counseling support guide

Example of GE Centricity EHR Care Alert from IVR System



1 More Evidence-Based HL Practice...

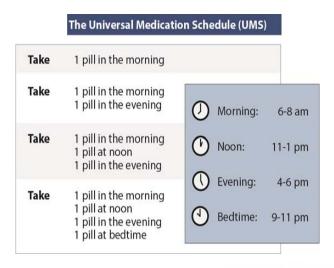
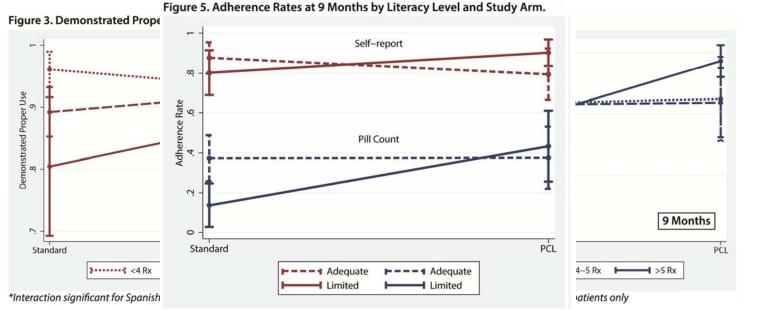


Figure 1. Sample of Patient-Centered Label using the Universal Medication Schedule (UMS). WOLF, MICHAEL DOB: 03/29/1971 WOLF, MICHAEL 09/01/2009 Rx# 6607815 TAKE TWO CAPSULES BY MOUTH TWICE AMOXICILLIN 500MG CAP RANBAXY DOB: 03/29/71 DAILY You have 2 refills Report rash or aller 40 pills Take: 2 PILLS IN THE MORNING reaction. Discard After 09/01/2010 DR RUTH PARKER, MD AMOXICILLIN 500MG CAP (RANBAXY) #40 May interfere with 2 PILLS IN THE EVENING 2 Refill(s) Remain By 09/01/2010 QTY: 40 CAP Discard After: 09/01/2010 NOVA SCRIPTSCENTRAL Noon Evening Bedtime 11-1 PM 4-6 PM 9-11 PM 6400 Arlington Blvd Ste. 120 Falls Church, VA. 22042 (703)532-0158 Dr: PARKER, RUTH MD NDC: 63304-0655 2 NDC# 63304-0655-05 NOVA SCRIPTSCENTRAL Rx Only 6400 Arlington Blvd Ste. 120 Falls Church, VA. 22042

Standard

41



Enhanced



Benefit <u>and</u> Risk communication



- Benefit and Risk communication
- Implementation of health literacy standards for PMI



- Benefit and Risk communication
- Implementation of health literacy standards for PMI
- Better distribution of PMI and Communication Plan tools



- Benefit and Risk communication
- Implementation of health literacy standards for PMI
- Better <u>distribution</u> of PMI and Communication Plan tools
- Patient counseling & shared decision making



- Benefit and Risk communication
- Implementation of health literacy standards for PMI
- Better <u>distribution</u> of PMI and Communication Plan tools
- Patient counseling & shared decision making
- Making numbers matter (visual aids included)



- Benefit and Risk communication
- Implementation of health literacy standards for PMI
- Better <u>distribution</u> of PMI and Communication Plan tools
- Patient counseling & shared decision making
- Making numbers matter (visual aids included)
- Behavior monitoring and event reporting (ETASU)



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