

Patient-Centered R_x Communication

strategies to mitigate/minimize risk

Michael Wolf, PhD, MPH

Professor, Medicine & Learning Sciences

Associate Chair of Research

Department of Medicine, Feinberg School of Medicine

Associate Division Chief, General Internal Medicine & Geriatrics

Northwestern University

Chicago, Illinois USA

Disclosures

Federal

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

Private

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

Industry

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

Overview

- 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**

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- **Case example: Med Guides**

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- Evidence is available supporting a better way
- ‘Health literacy’ best practices are available
- Case example: Med Guides
- Health technologies can be leveraged -



Health, Literacy, & 'Health Literacy'

Health Literacy is...

The cognitive and social skills 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."

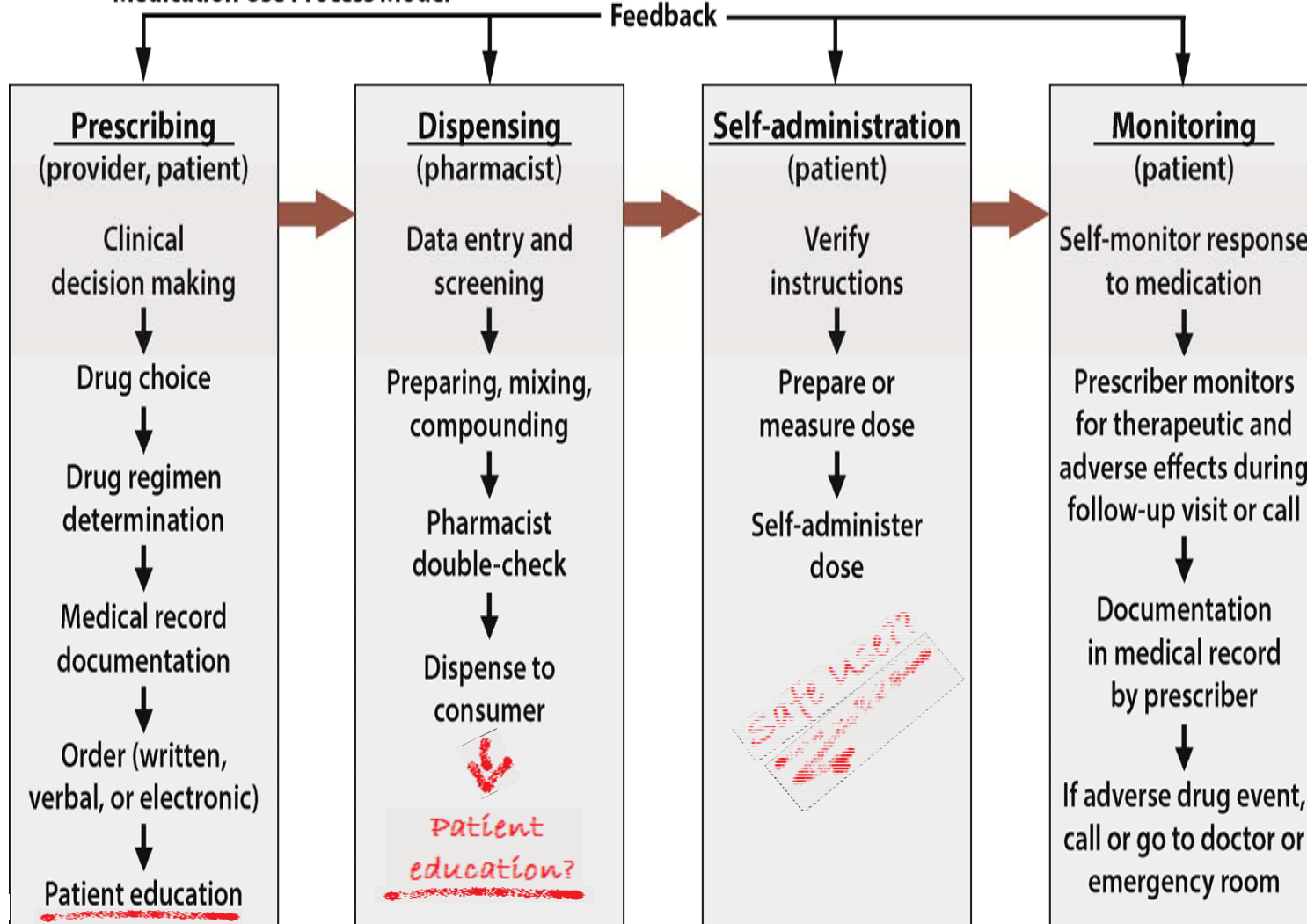
- Walter Cronkite

A System Failure?

How are we helping patients

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

Medication Use Process Model



can pt do this?

How?

The Problem... Simplified

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

X

Pharmacies fail to
distribute Med Guides

X

Med Guides, PMI
not understandable,
actionable

Patients are...

*UNINFORMED

*AT RISK

(errors, ADEs, sub-optimal treatment)

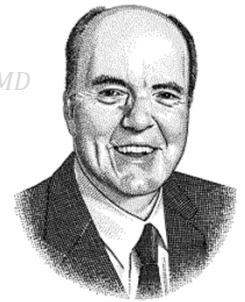
Result is...

*REMS FAILURE

(Med Guides, Communication Plans)

Confusing Patients Less

Alastair Wood, MD



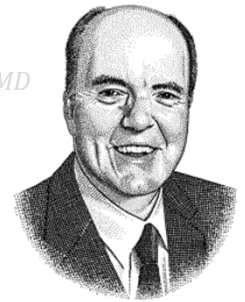
Fix the health system, not patient

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



Confusing Patients Less

Alastair Wood, MD



Fix the health system, not patient

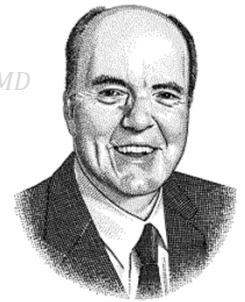
- Missed opportunities to counsel patients on safe use by both prescribers and pharmacists
- 'Sig' instructions highly variable
- Rx labeling highly variable, poor quality

Inadequate
Labeling



Confusing Patients Less

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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 Rx labeling and make dosing errors

- 75% can't fully identify Rx indication for use = non-adherence, poorer clinical outcomes

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



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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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- 43 to 85% over-complicate multi-drug regimens

(Wolf et al. Arch Intern Med 2011; Lindquist et al, Pat Ed Counsel 2014)

- 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-Blats, 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)	
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

Figure. Percent of Med Guides Achieving Adequate Rating According to Suitability Assessment of Materials (N=227)

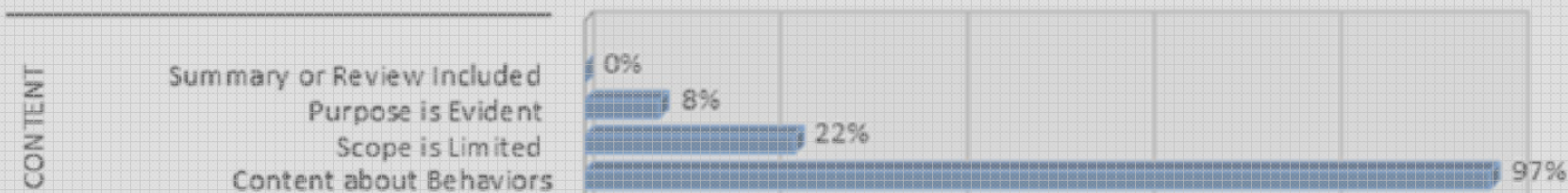
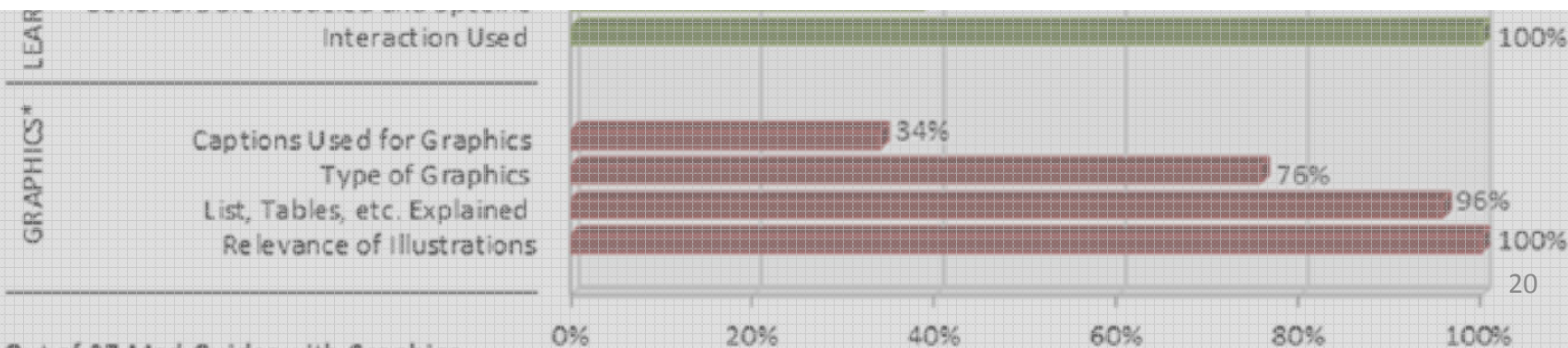




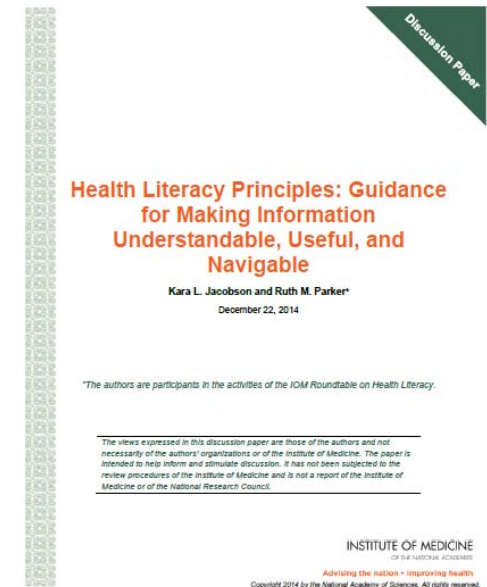
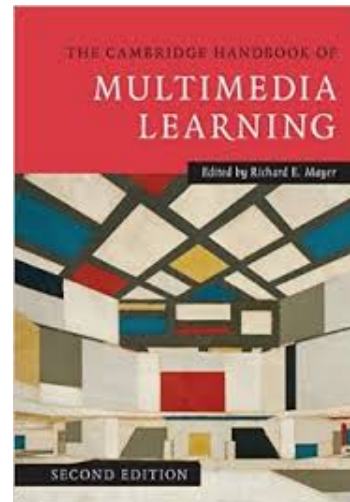
Table 2. Differences in Total and Subcategory Comprehension Scores by Literacy Level

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)	52.7 (22.6)	24.9 (13.8)	37.8 (15.7)	64.3 (17.1)	<0.0001
Decision making prior to use (36 pts)	18.3 (9.3)	8.0 (5.1)	12.0 (6.0)	22.9 (7.7)	<0.0001
General use and storage (15 pts)	9.3 (3.0)	5.9 (2.3)	7.6 (2.2)	10.7 (2.5)	<0.0001
Side effects (48 pts)	25.1 (11.7)	11.0 (8.1)	18.3 (9.6)	30.7 (8.8)	<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

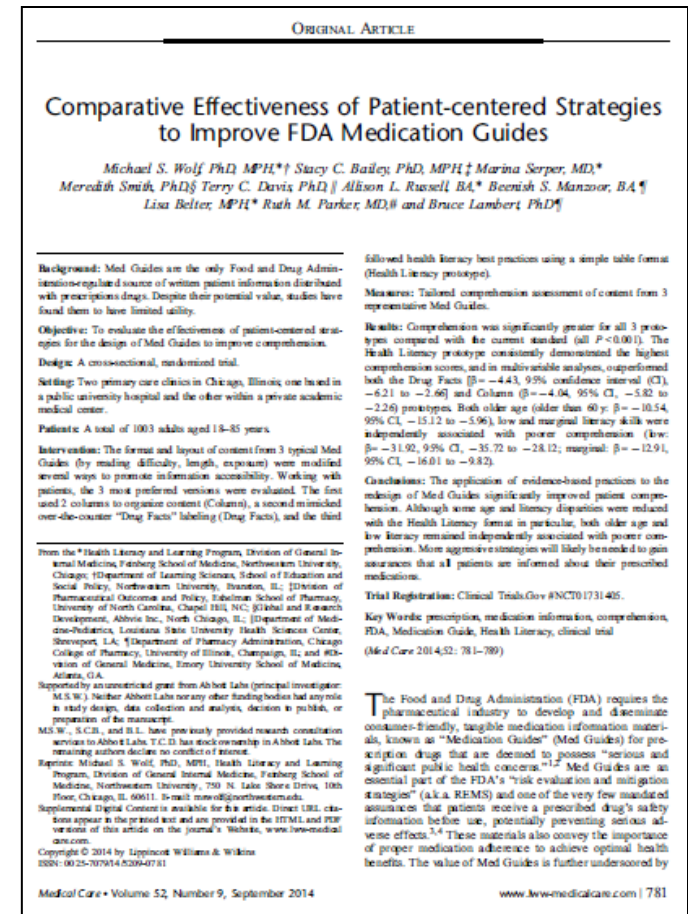
Assessment



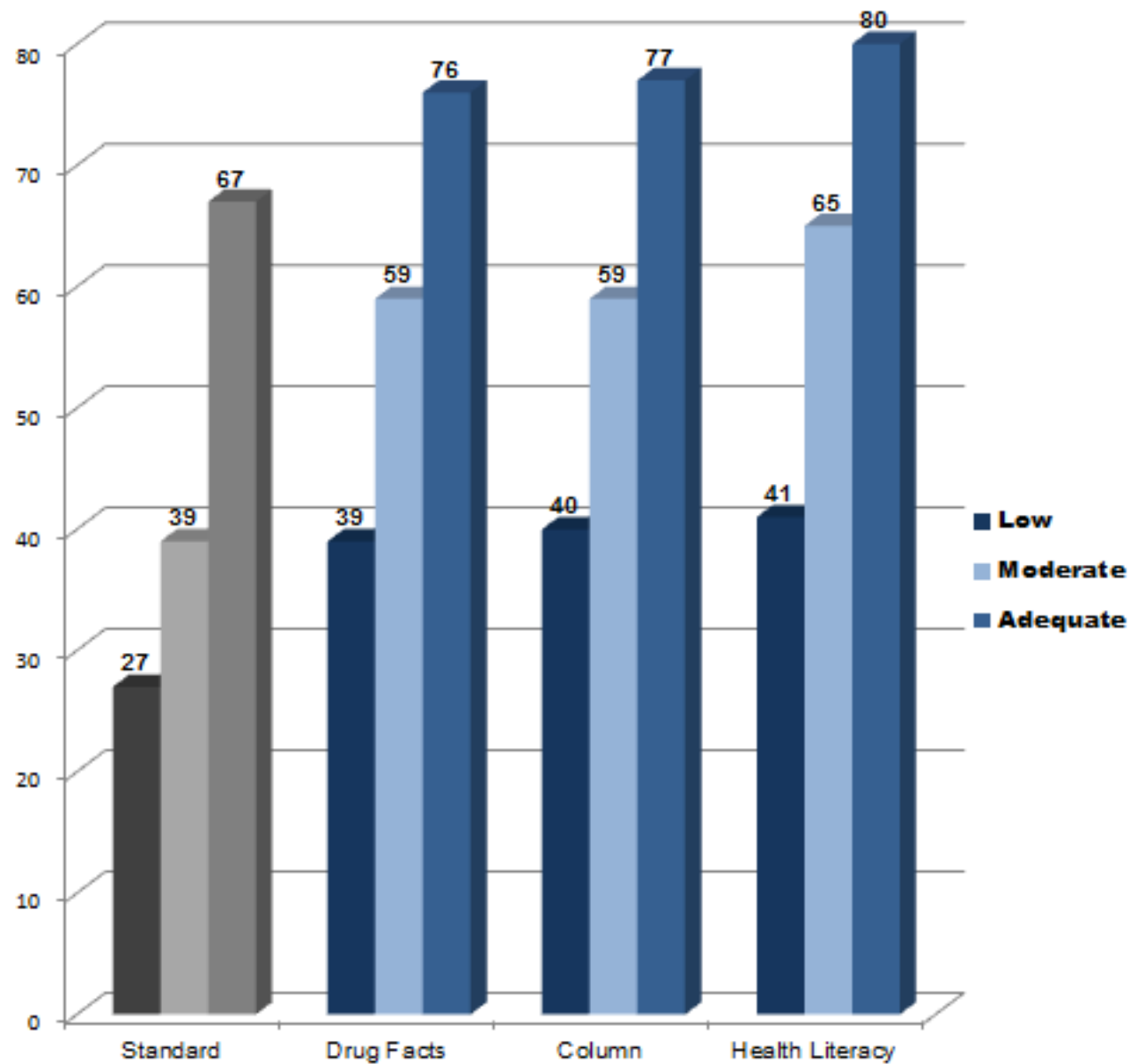
- Patient Education Materials Assessment Tool (PEMAT)
<http://www.ahrq.gov/professionals/prevention-chronic-care/improve/self-mgmt/pemat/>
- Assesses both Understandability and Actionability

Case Example: Med Guides

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



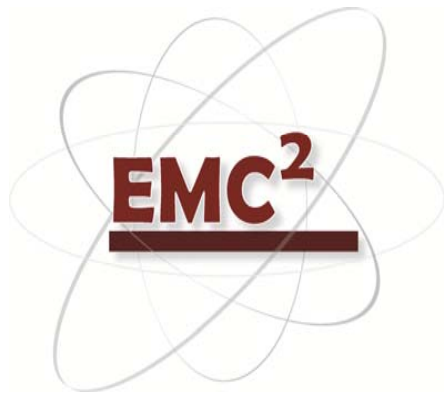
Comprehension of Med Guides, By Format and Literacy Level



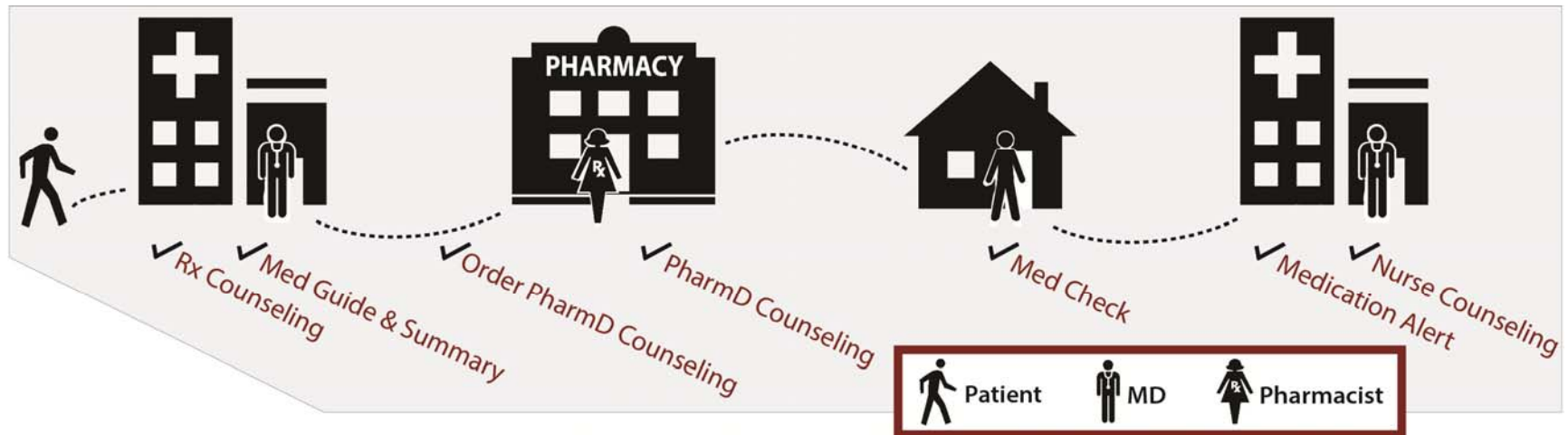
*Mean scores adjusted for age, race, gender, # of prescription medicines, and prior experience with Med Guides. Standard format scores reflect Sample 1 participants, other prototypes reflect Sample 2 participants.

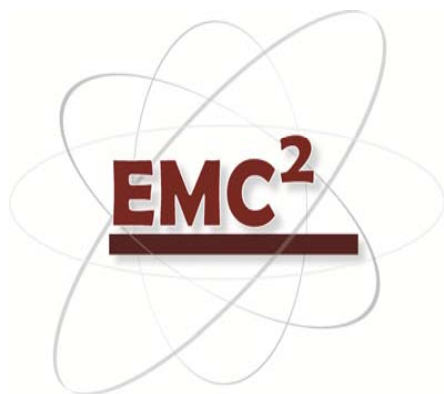
The Solution...

EHR-enabled
Medication
Complete
Communication

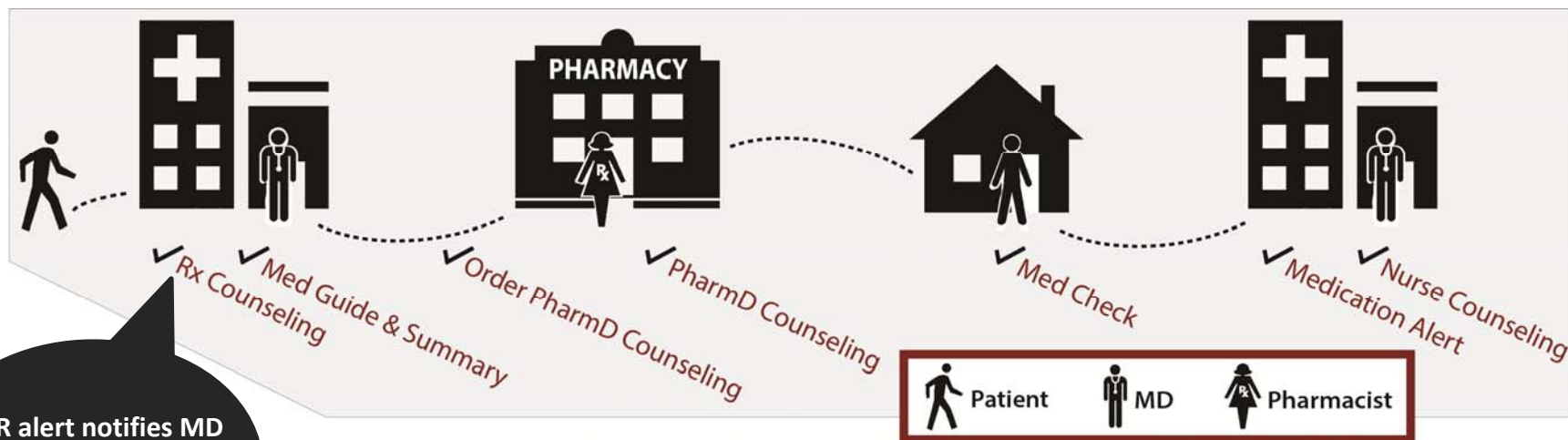


Our Strategy

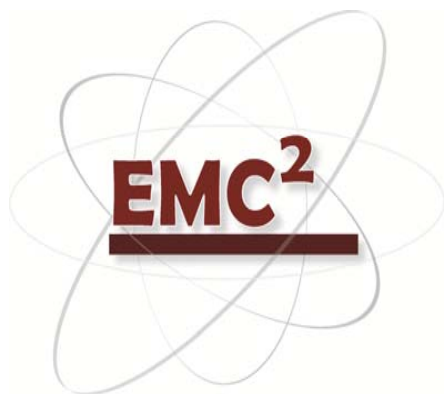




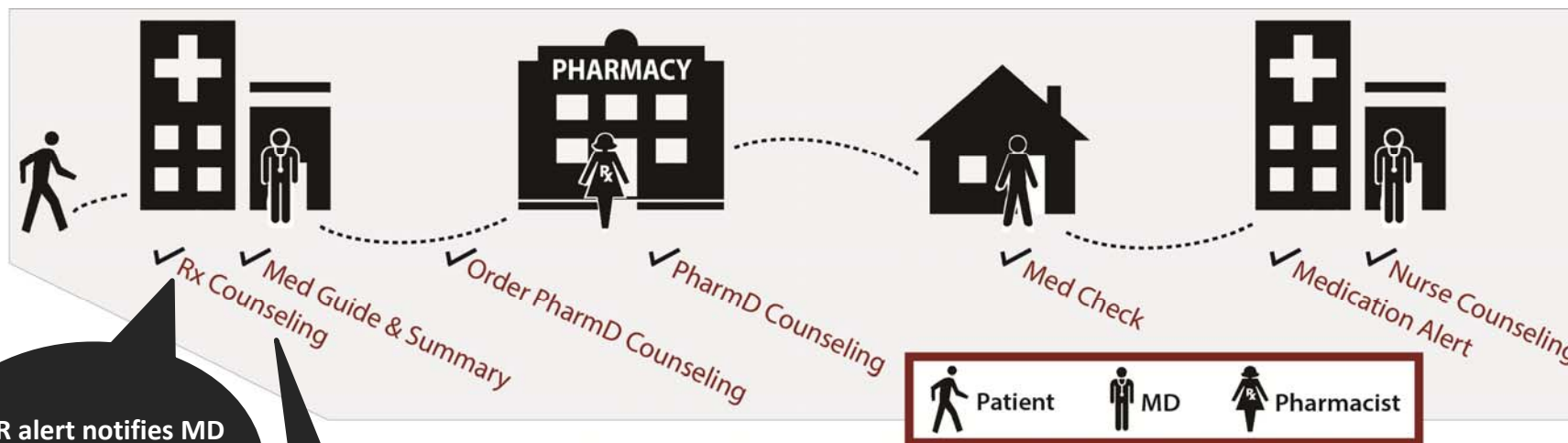
Our Strategy



EHR alert notifies MD that Rx requires Pt counseling before order

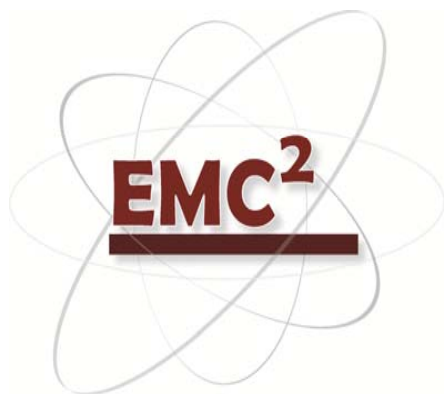


Our Strategy

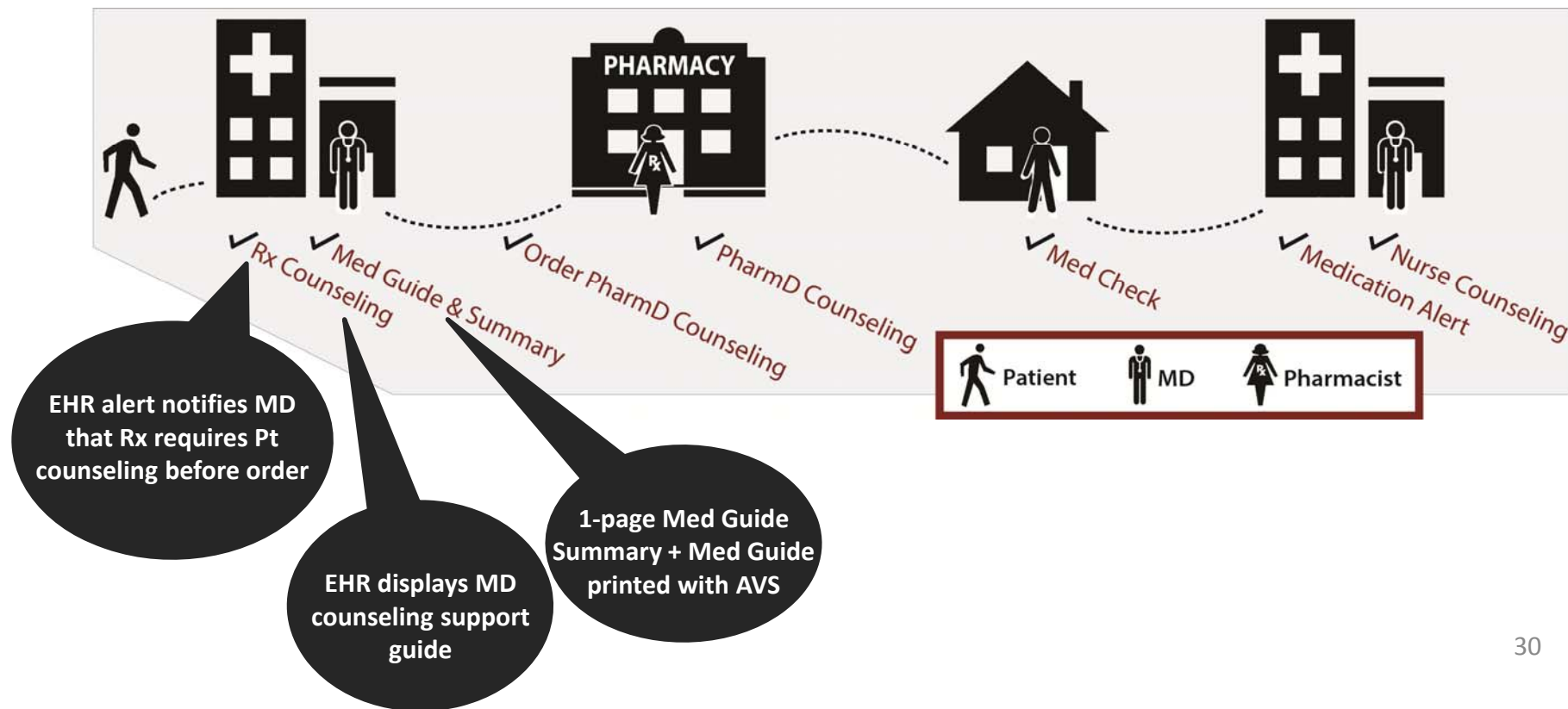


EHR alert notifies MD that Rx requires Pt counseling before order

EHR displays MD counseling support guide



Our Strategy



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	<ul style="list-style-type: none"> 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
For how long	Your doctor will tell you how long you should be on this medication. Refill this medicine until your doctor tells you to stop.
Important!	<u>Ask your doctor before use if you:</u> <ul style="list-style-type: none"> 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	<u>Stop taking this medicine and call your doctor right away if you:</u> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> headache stomach ache trouble sleeping
Remember	Talk to your doctor about any questions or concerns you may have regarding this medicine. <ul style="list-style-type: none"> 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.

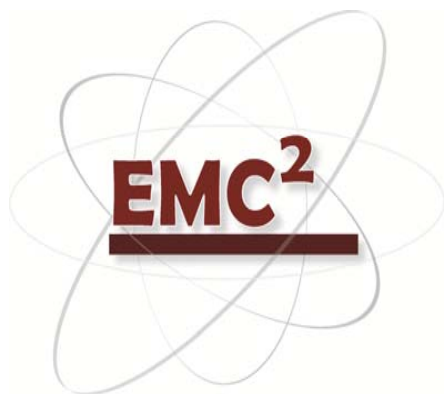
Call your doctor right away if you or your child have any new or worsening mental symptoms or problems while taking RITALIN LA®, especially seeing or hearing things that are not real, believing things that are not real, or are suspicious.

What Is RITALIN LA®?

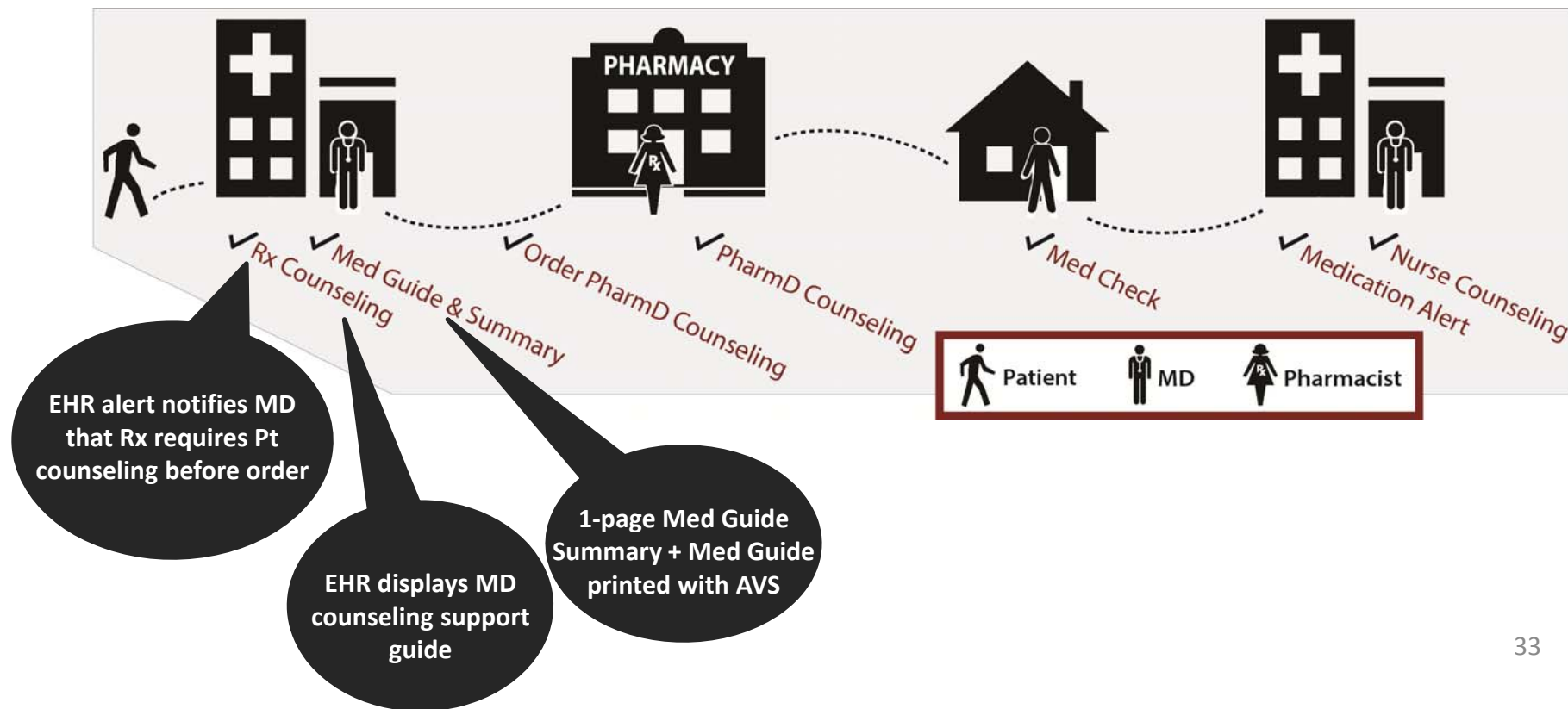
Preliminary Work

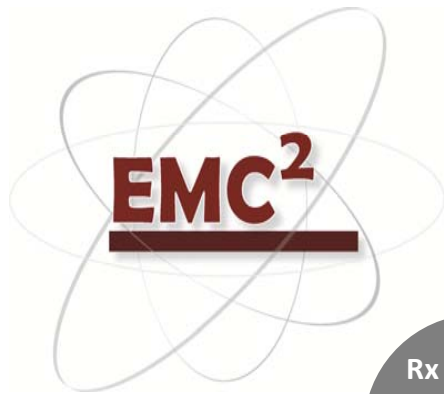
- 4 NIH/AHRQ studies led by our team support our ability to:
 - create MD/RN alerts
 - embed counseling support tools, linked to medication
 - automate delivery of PMI with order, printed with AVS
- Familiarity with multiple EHR platforms
(Epic, Cerner, GE Centricity)

[R18HS17220; R21CA132771; U19HS021093; R01NR012745]

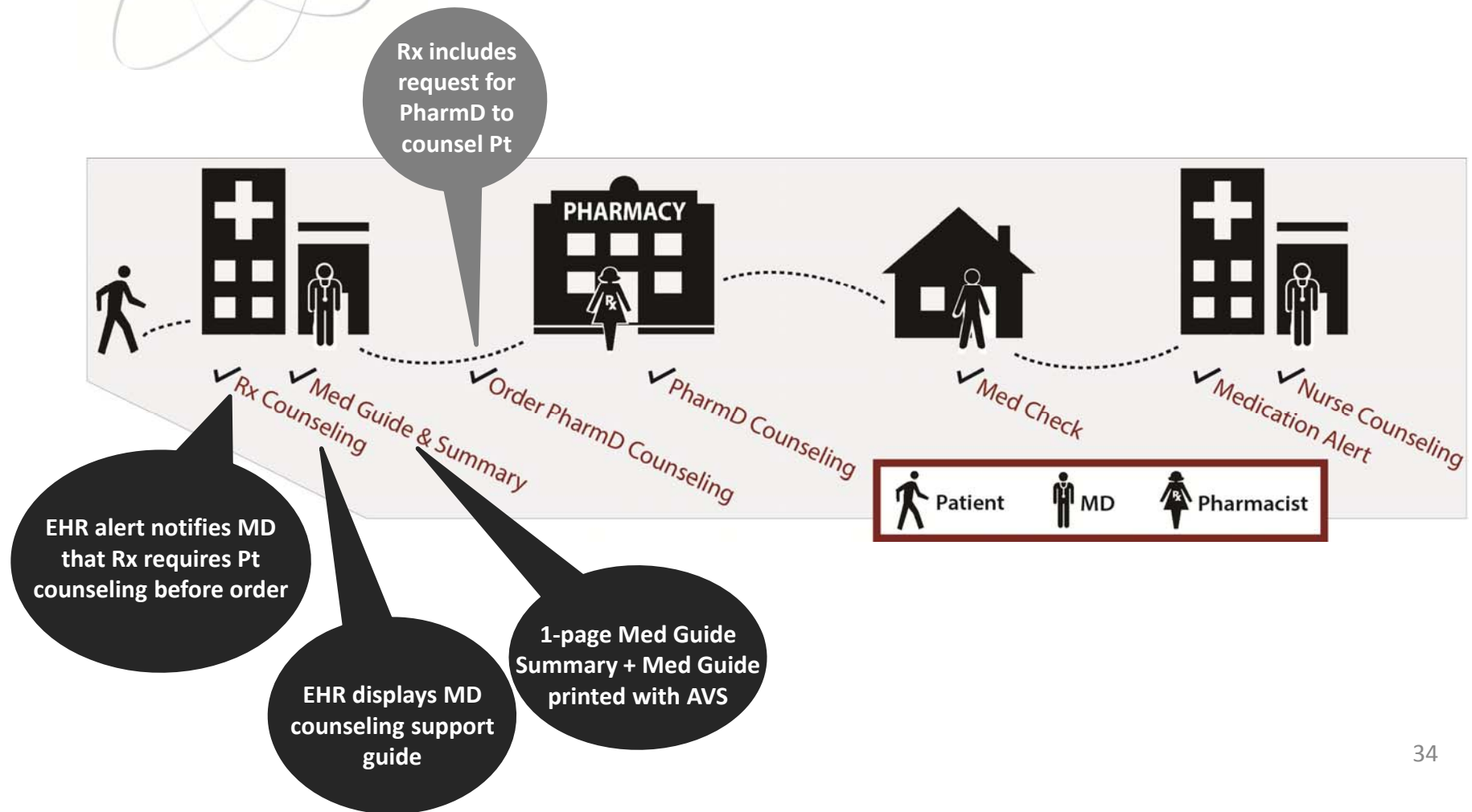


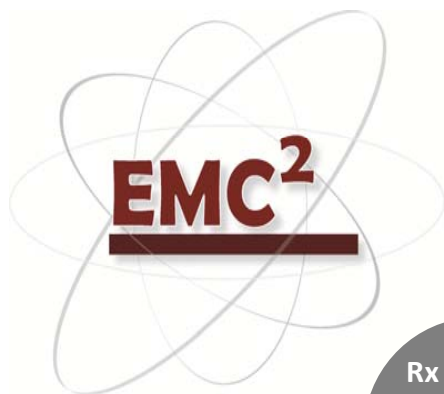
Our Strategy



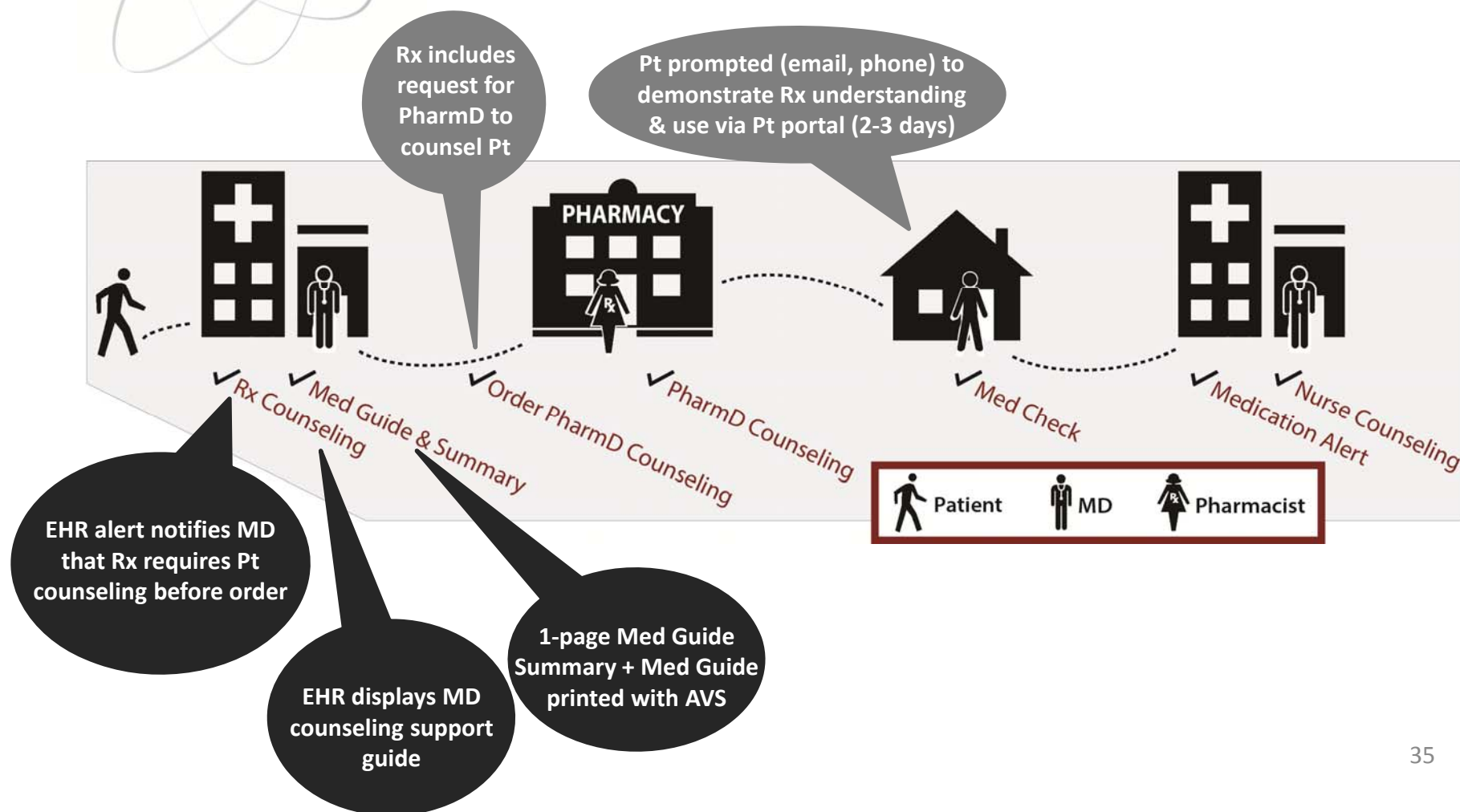


Our Strategy





Our Strategy

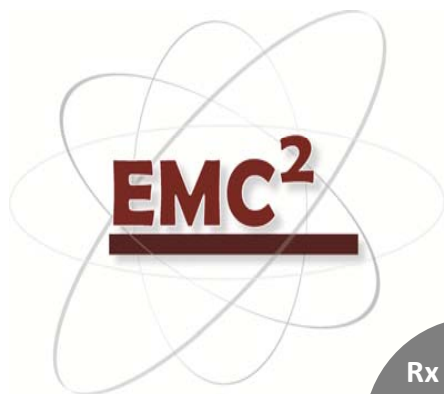


Sample MedCheck Items

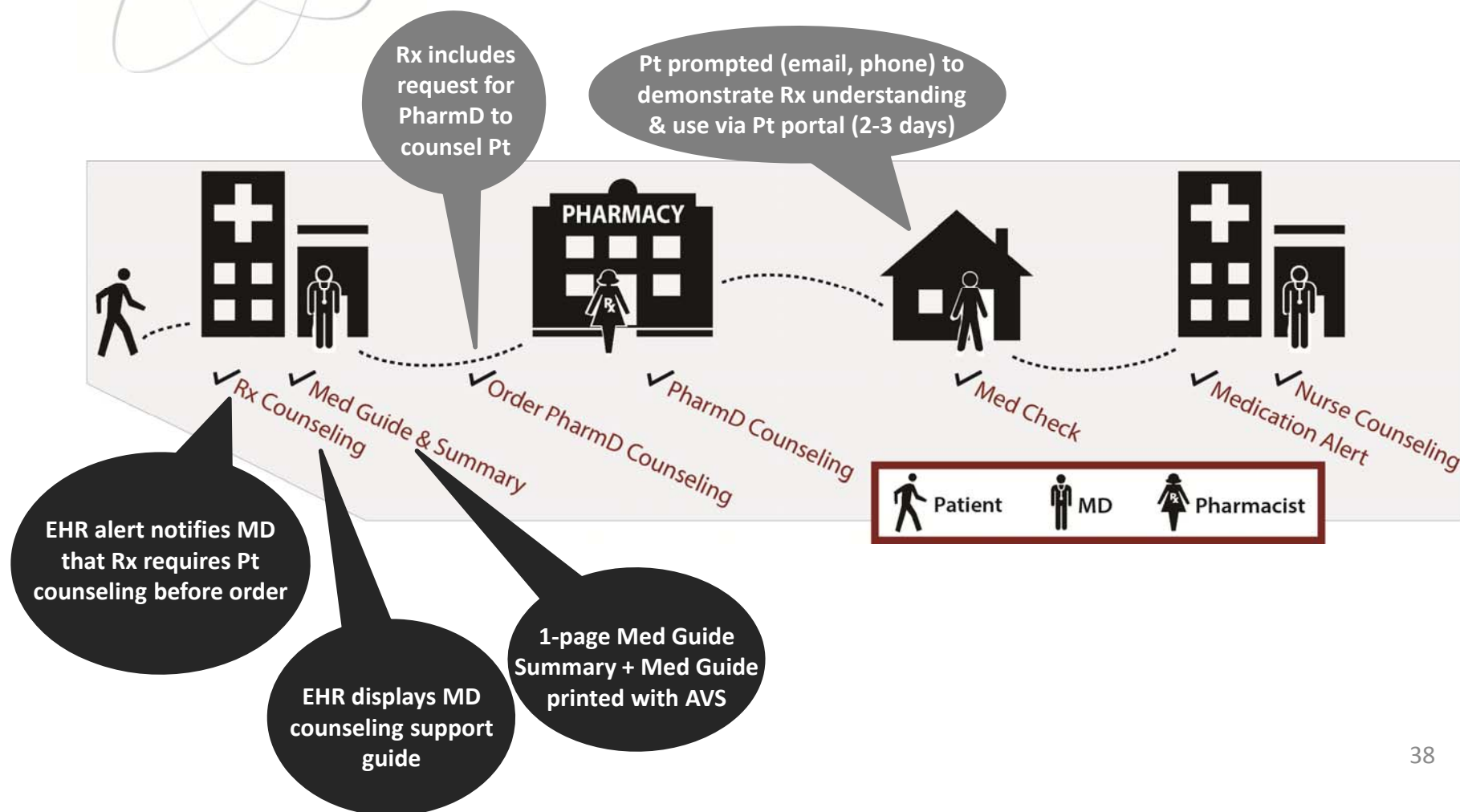
- ☐ Name 2 common side effects you may have while taking [Drug X].
- ☐ You are taking [Drug X] to treat....a) condition 1, b) condition 2, c) condition 3
- ☐ Name 3 medications you cannot take while using [Drug X].
- ☐ If you have these symptoms, do the following: a) call doctor, b) seek care immediately, 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?

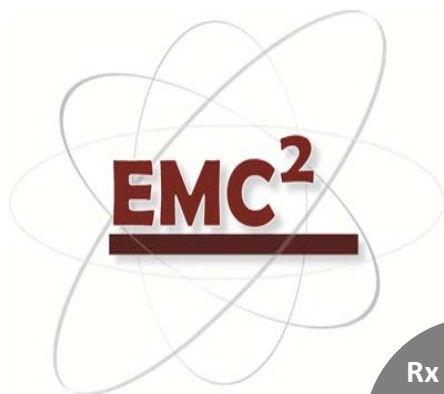
Preliminary Work

- 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]

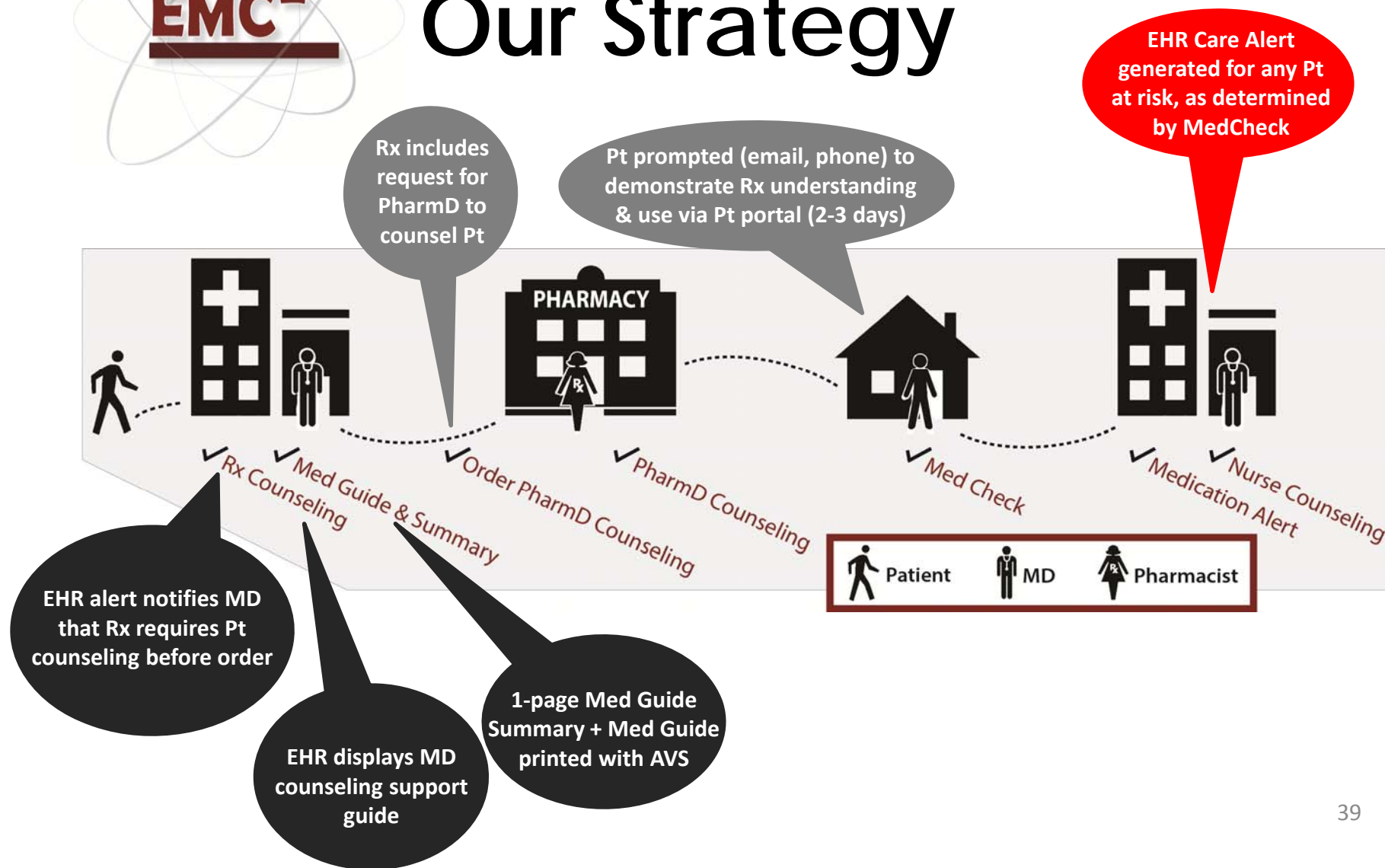


Our Strategy





Our Strategy



Example of GE Centricity EHR Care Alert from IVR System

The screenshot displays the GE Centricity EHR interface. At the top, a navigation bar includes a 'Renew Rx' button, a mail icon with '0', a person icon with '0', a '2' icon, and a 'Log Out' button. Below this, the patient information section shows 'Patient ID: 37491' and 'Registration Notes: Wheelchair Bound Care Coordination...'. The main content area is titled 'Medications' and features a table with columns for 'Description', 'Instructions', 'Last Rx', and 'Ge'. The table lists two medications: 'ADVAIR 250/50 mcg' with instructions '1 puff 2x day' and 'ACCU-CHEK AVIVA STRP' with instructions 'Use 1 x daily to check blood sugar'. A 'Prescriptions' section is also visible, showing 'Quantity: 50, Refills: 1, Date: 23-Feb-2012, Authorized by: Anthony Giasolli MD, PharmD, Licens Drug Stores 24068 EE 1267 KAWATHAE RD, Kamuela, HI 96743, Ph...'. An 'Alerts / Flags' window is overlaid on the bottom right, displaying a 'Medication Risk Alert!' from 'Alliance Ad...'. The alert details include 'Subject: Test, EMR6' and 'Message: Contact patient Report of PAIN WITH SWALLOWING'.

ms Patient ID: 37491

Registration Notes: Wheelchair Bound
Care Coordination...

Medications

Interactions: ! Active Only

Description	Instructions	Last Rx	Ge
ADVAIR 250/50 mcg	1 puff 2x day		INS
ACCU-CHEK AVIVA STRP	Use 1 x daily to check blood sugar	23-Feb-2012 #50 X 1	GLI

Prescriptions

Quantity: 50, Refills: 1, Date: 23-Feb-2012, Authorized by: Anthony Giasolli MD, PharmD, Licens Drug Stores 24068 EE 1267 KAWATHAE RD, Kamuela, HI 96743, Ph...

Alerts / Flags

Anytime

From	Message
Alliance Ad...	Medication Risk Alert!
Subject Test, EMR6	
Message Contact patient Report of PAIN WITH SWALLOWING	

1 More Evidence-Based HL Practice...

The Universal Medication Schedule (UMS)





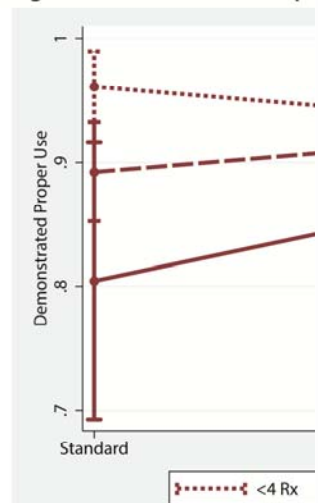
Take	1 pill in the morning	
Take	1 pill in the morning 1 pill in the evening	 Morning: 6-8 am
Take	1 pill in the morning 1 pill at noon 1 pill in the evening	 Noon: 11-1 pm  Evening: 4-6 pm
Take	1 pill in the morning 1 pill at noon 1 pill in the evening 1 pill at bedtime	 Bedtime: 9-11 pm

Figure 1. Sample of Patient-Centered Label using the Universal Medication Schedule (UMS).

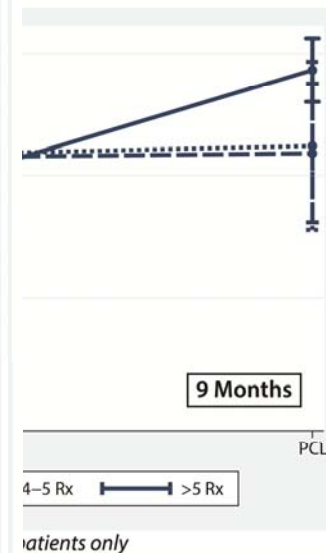
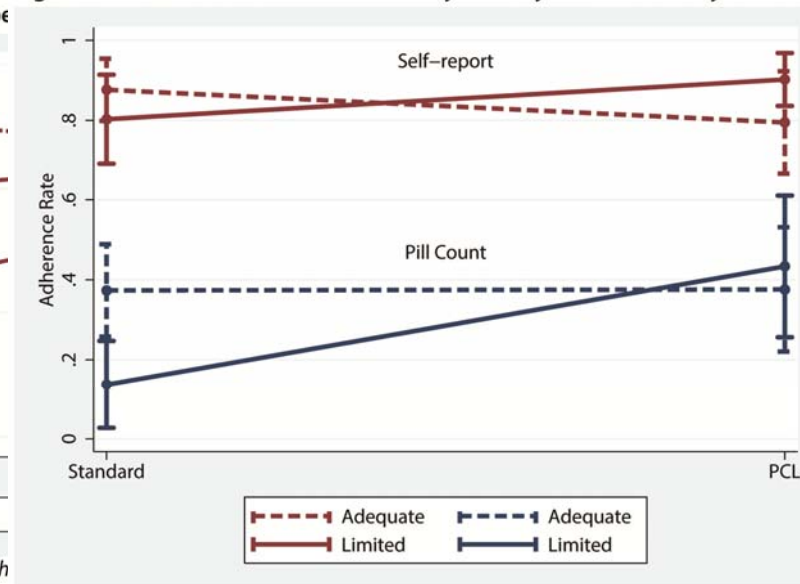


Figure 3. Demonstrated Proper Use



*Interaction significant for Spanish

Figure 5. Adherence Rates at 9 Months by Literacy Level and Study Arm.



What *(I think)* Cares About....

- Benefit and Risk communication

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

What *(I think)* Cares About....

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

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- Patient counseling & shared decision making

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- Making numbers matter (visual aids included)

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

NORTHWESTERN UNIVERSITY

HeLP

Health Literacy & Learning Program



Michael Wolf, MA MPH PhD
Professor, Medicine & Learning Sciences
Associate Division Chief – Research
General Internal Medicine & Geriatrics
mswolf@northwestern.edu