ENGELBERG CENTER for Health Care Reform at BROOKINGS

Expert Workshop: The Science of Communicating Medication Information to Consumers

The Brookings Institution
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Session I Speakers

- Angela Fagerlin
  University of Michigan and Ann Arbor VA Health Services Research and Development Service
- Jann Keenan
  The Keenan Group, Inc and The Clear Language Group Consortium
- Dorothy Smith
  Consumer Health Information Corporation
- Terry Davis
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Methods for effectively communicating medical information to patients

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Challenges to communicating medical information to patients

- Numeracy
  - What is a bigger risk: 1%, 5%, 10%?

Presenting risks in terms of absolute risks vs. relative risks

Absolute vs. relative risk

- What if I told you a drug could reduce your risk of breast cancer by 50%? (Relative risk presentation)
- What if I told you a drug could reduce your risk from 2% to 1%? (Absolute risk presentation)
- Drug has same effect in both cases, but in first description it sounds much better.

Recommendation

- If you are trying to inform a patient (and not persuade) a patient then you absolutely should use absolute risk presentation.
- If you ever use relative risk, must be accompanied by absolute risk information.

Presenting information using frequencies vs. percentages

Percents just aren't understandable

- Studies have shown
  - Even doctors better understand and can better use frequencies in their decision making (compared to percentages).
  - People with low numeracy view 10% differently than 10 out of 100 (10 out of 100 seems more risky).
    - Probably due to 10% being more abstract, more difficult to imagine.

Recommendation

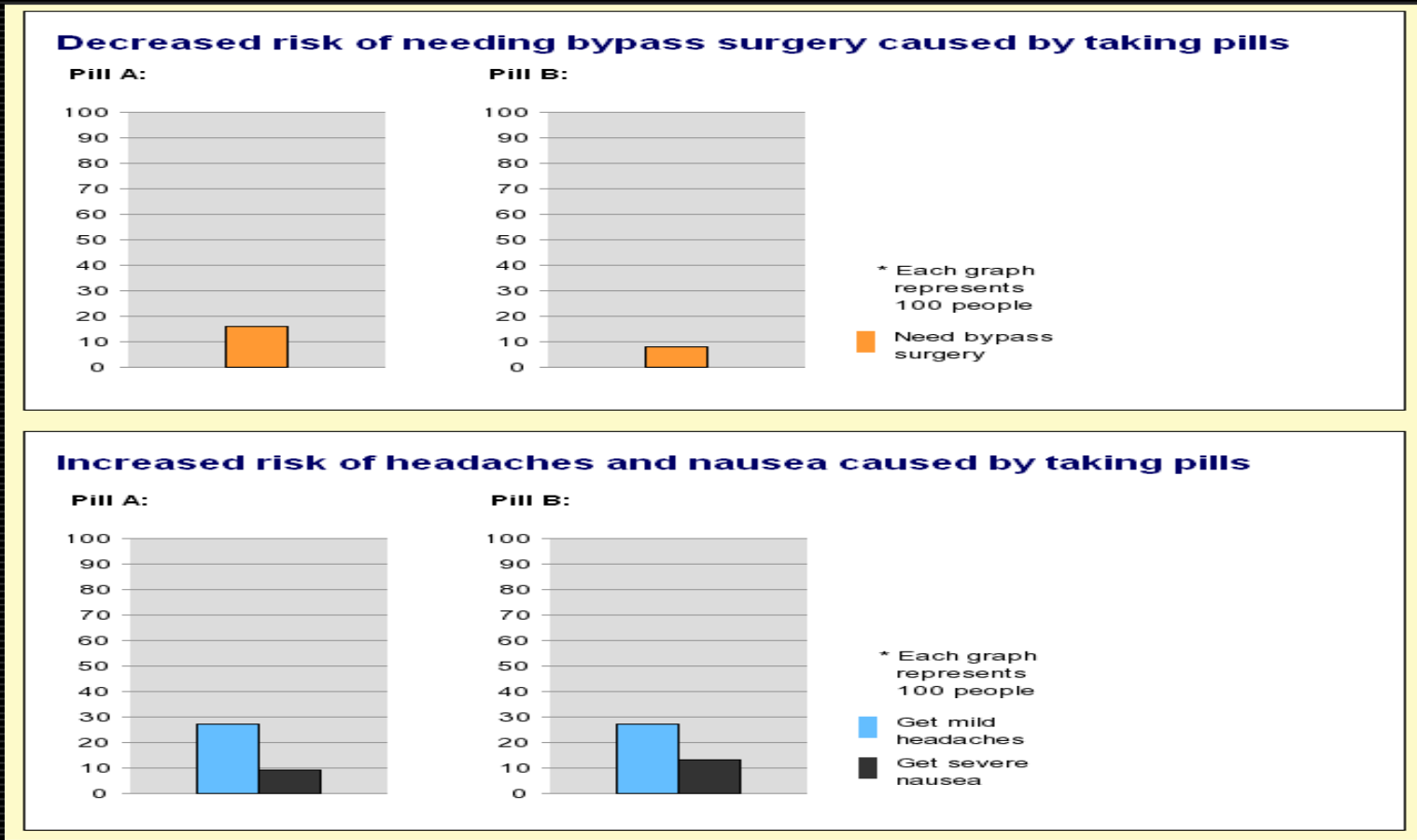
- Present numbers in frequencies
  - 10 out of 100 patients who have treatment X, experience moderate nausea for up to 2 weeks.
- If you want to use percentages, add it to the frequency presentation.
  - 10 out of 100 (10%) patients who have treatment X, experience moderate nausea for up to 2 weeks.

Graphical Format

Graphical format

- To help improve people's ability to understand numerical information, graphical representations of risk are often used.
- But which format to use? Lots of choices, but little information about which is best for communicating health information.

Bar graphs


Decreased risk of needing bypass surgery caused by taking pills
Pill A:
Pill B:
100
90
80
70
60
50
40
30
20
10
0
* Each graph represents 100 people
Need bypass surgery
Increased risk of headaches and nausea caused by taking pills
Pill A:
Pill B:
100
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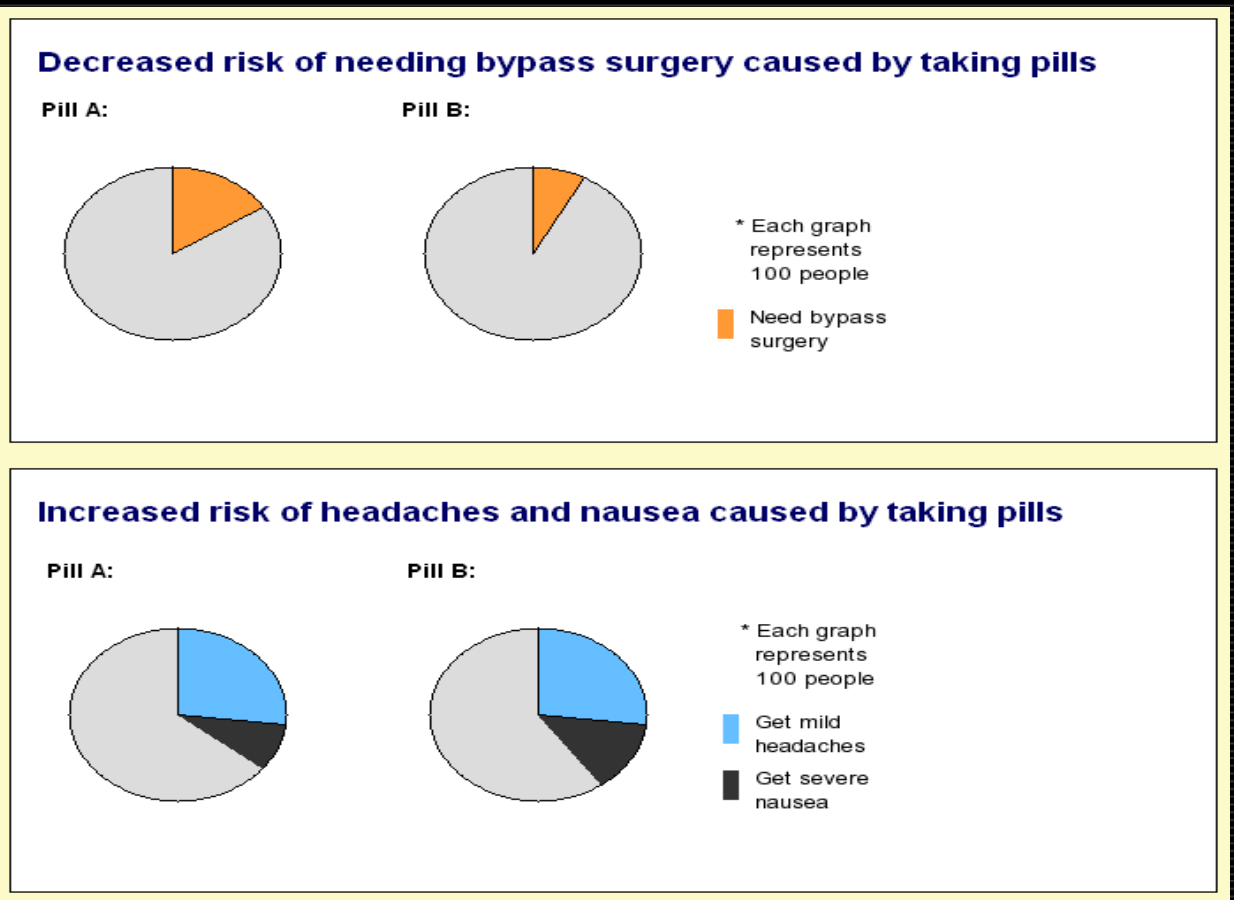
40
30
20
10
0
* Each graph represents 100 people
Get mild headaches
Get severe nausea

Pie graphs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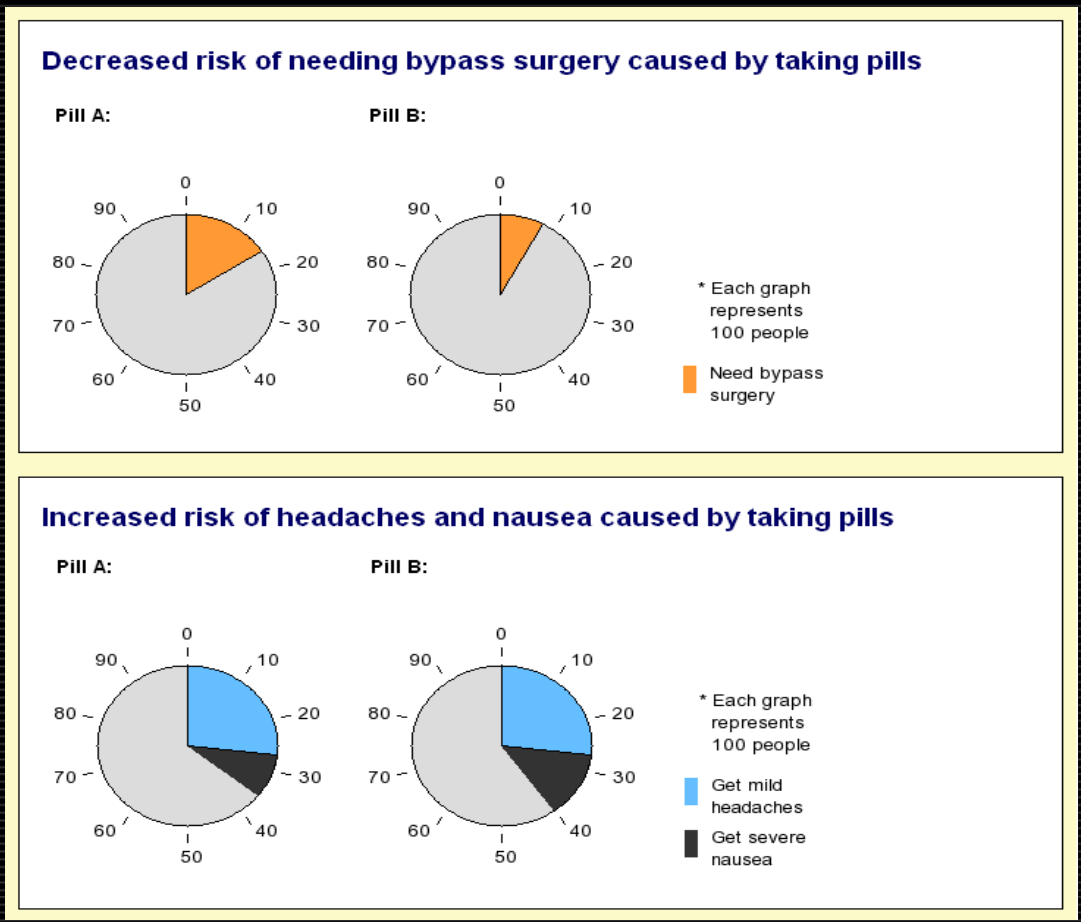
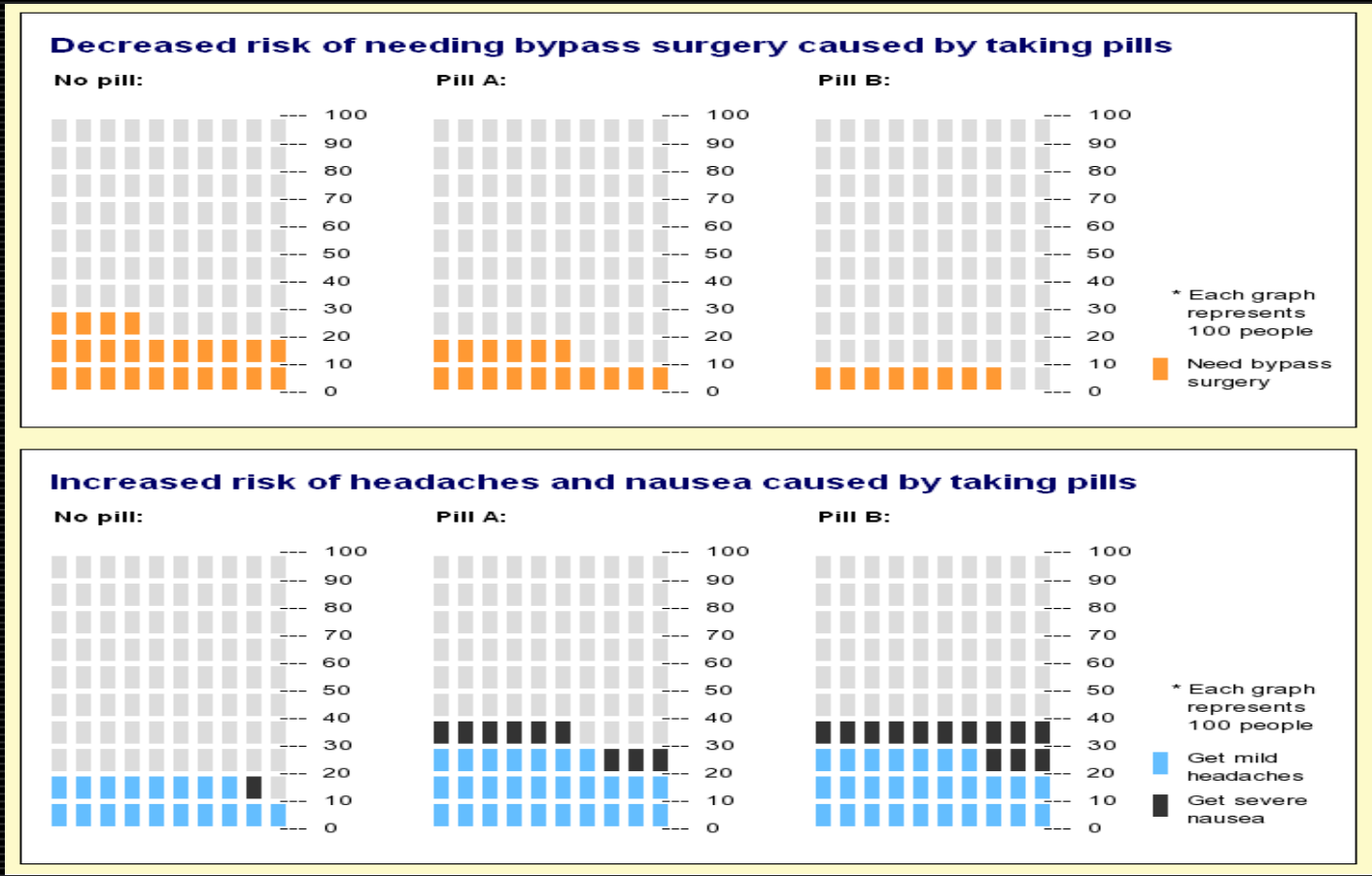
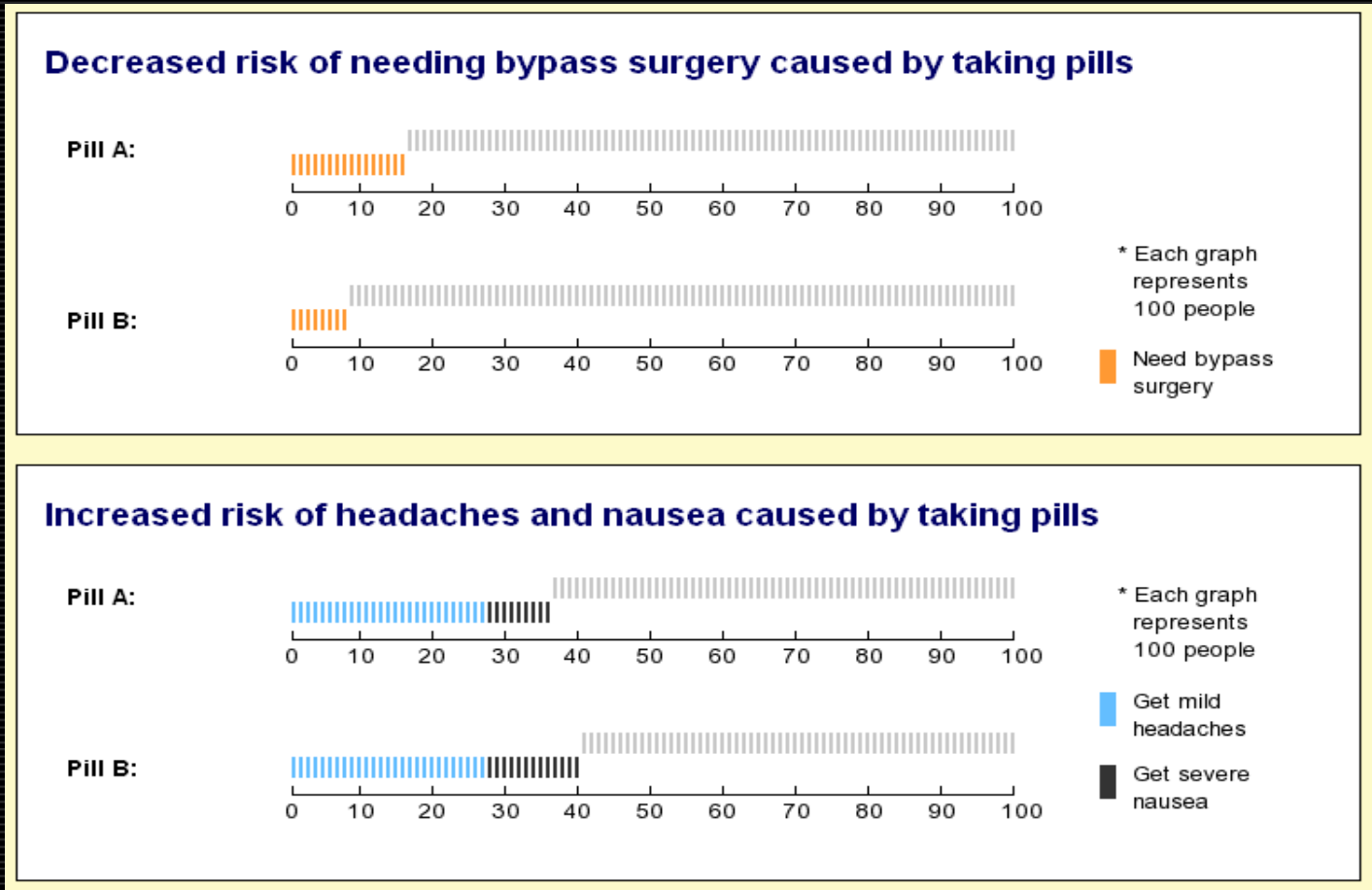
Clock graphs (modified pie)



Pictographs



Sparkplug graphs (Modified pictograph)



Methods: Knowledge Questions

- 6 knowledge questions
  - 2 “gist knowledge” questions asked which treatment yielded the best (or worst) outcome (e.g., more likely to experience nausea with Pill A or Pill B?).
  - 4 “verbatim knowledge” questions asked the number of patients affected by a treatment and to calculate numerical differences between treatments.

Gist Knowledge

- Pie
- Pictograph
- Clock
- Sparkplug
- Bar

Verbatim Knowledge

- Pictograph
- Sparkplug
- Bar
- Clock
- Pie

Which graph to use?

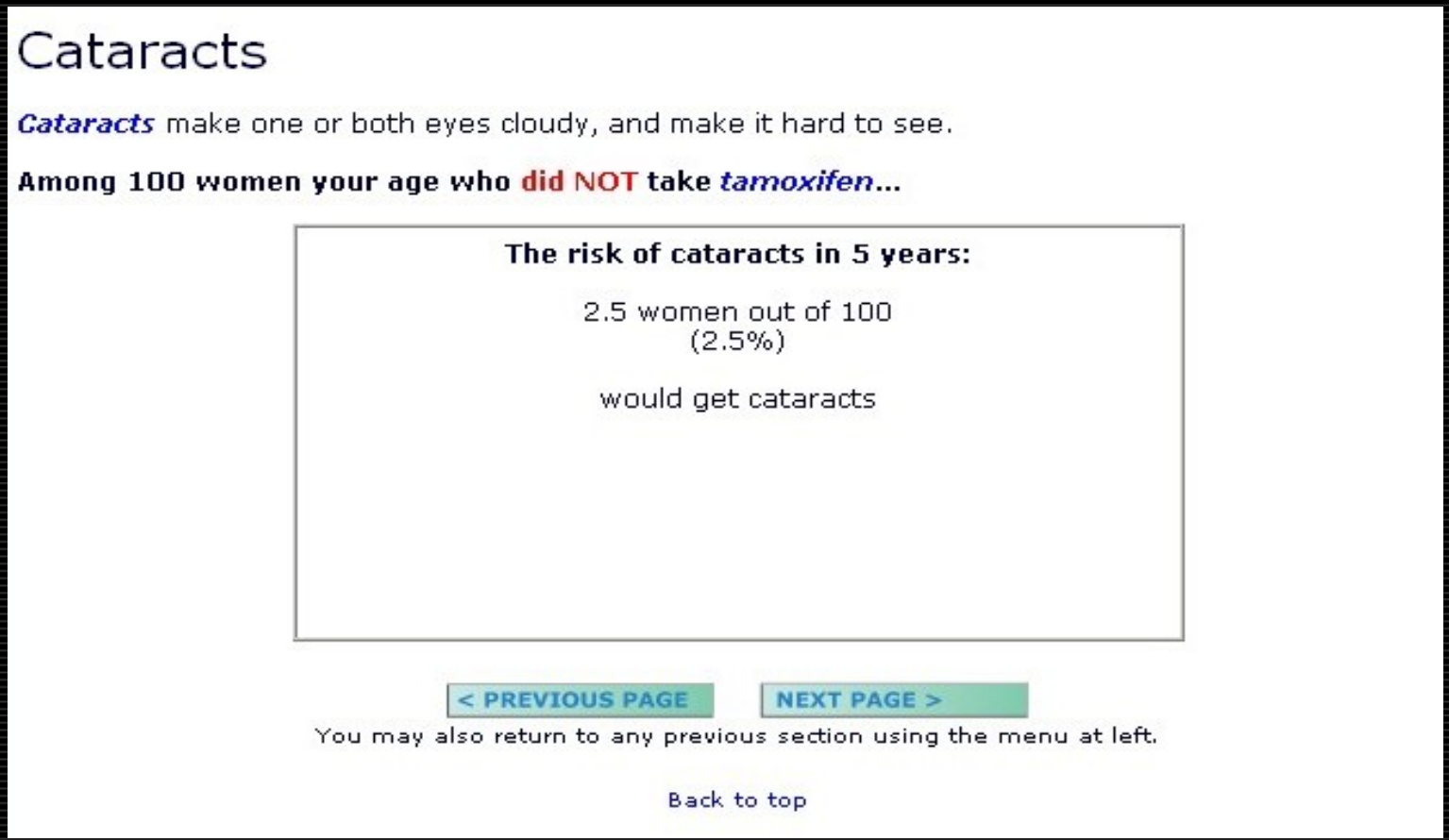
- People's gist and verbatim understanding of risk varied significantly across graphs.
  - For gist knowledge questions, pie graphs were effective, but pies were ineffective for verbatim knowledge questions.

Which graphs produced best knowledge?

- People's gist and verbatim understanding of risk varied significantly across graphs.
  - For gist knowledge questions, pie graphs were effective, but pies were ineffective for verbatim knowledge questions.
  - Pictographs were the only graph that consistently led to more accurate knowledge across both gist and verbatim questions.

Incremental risk presentation

Total Risk Table
Baseline risk



Cataracts

Cataracts make one or both eyes cloudy, and make it hard to see.

Among 100 women your age who did NOT take *tamoxifen*...

The risk of cataracts in 5 years:

2.5 women out of 100
(2.5%)

would get cataracts

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You may also return to any previous section using the menu at left.

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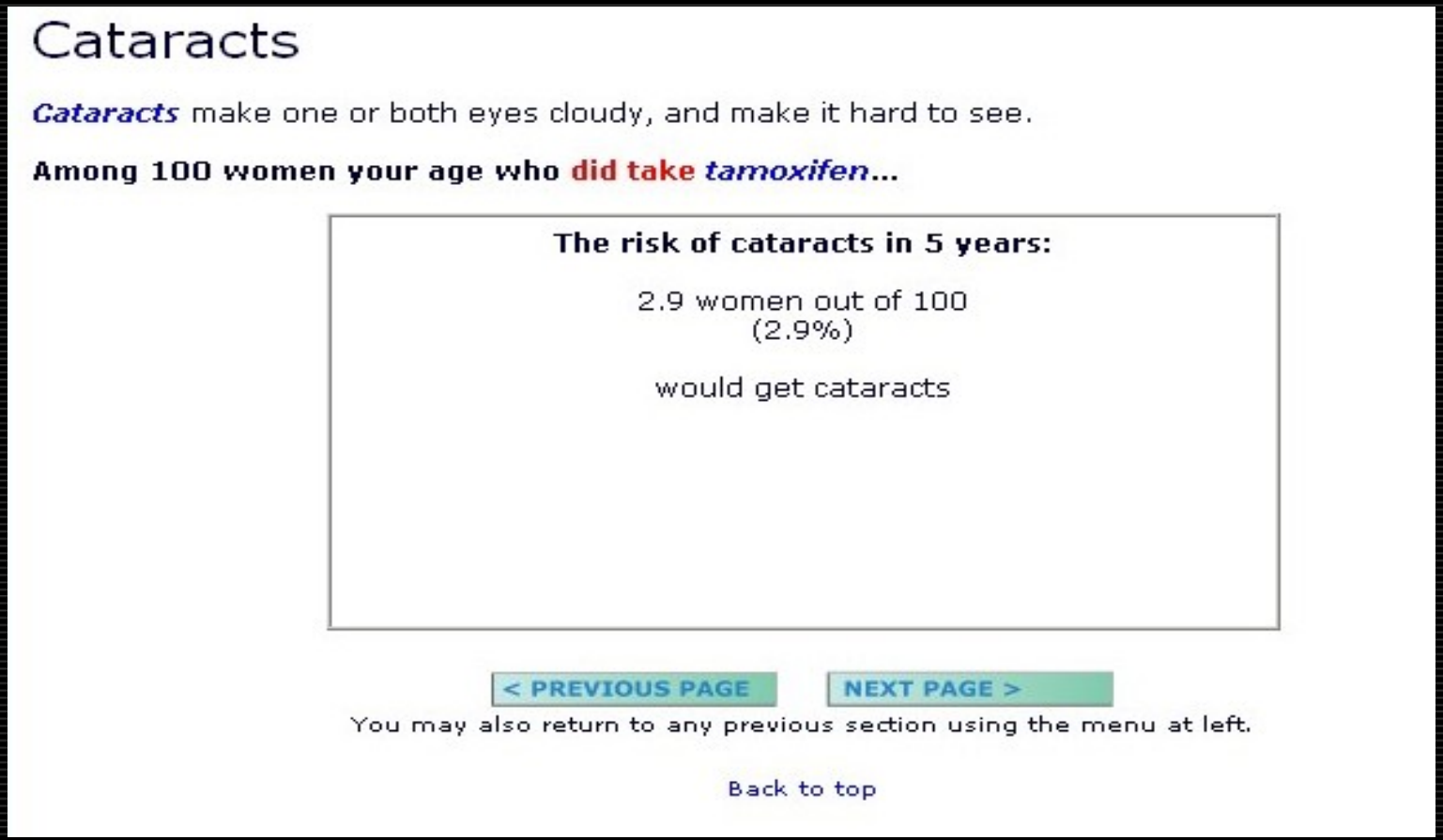
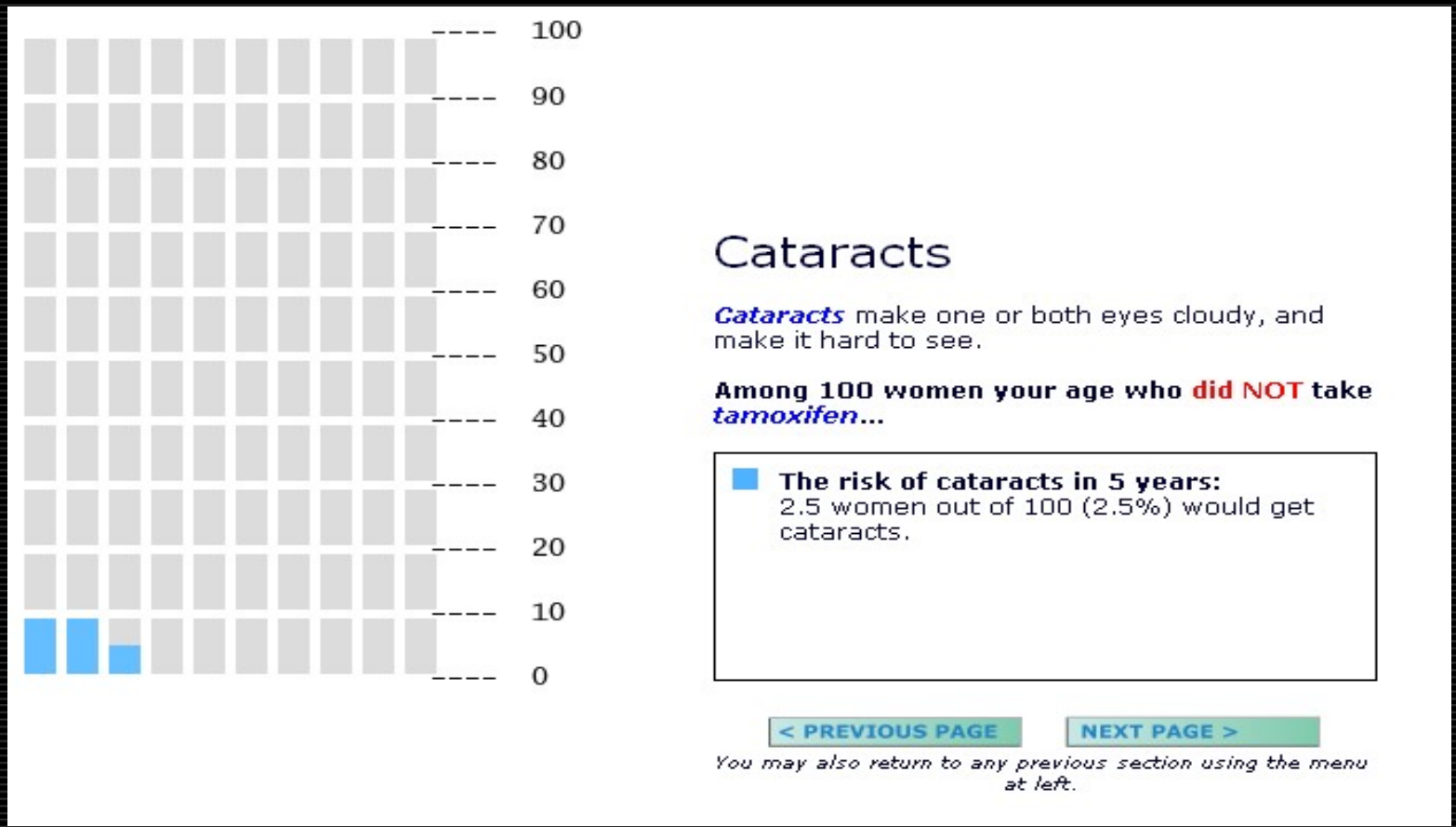
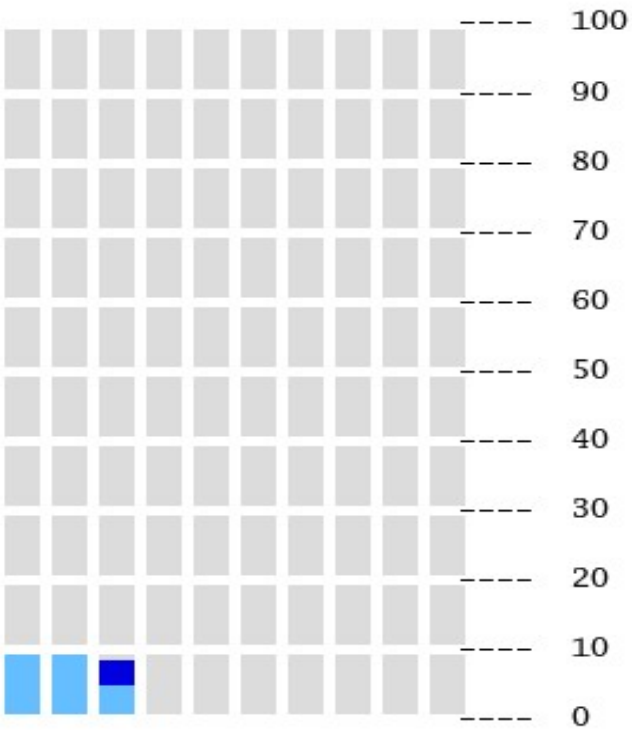
Total Risk Table
Risk with Tamoxifen



Incremental Risk Pictograph Baseline risk



Incremental Risk Pictograph Risk with Tamoxifen



Cataracts

Cataracts make one or both eyes cloudy, and make it hard to see.

Among 100 women your age who did take *tamoxifen*...

The additional risk caused by taking tamoxifen:
0.4 **more** women out of 100 (0.4%) would now get cataracts.

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You may also return to any previous section using the menu at left.

Results

- Decreases perceptions of worry, likelihood.
- Some evidence of increased comprehension

Is less more?

Adjuvant Online

Shared Decision Making

Name: _____ (Breast Cancer)
Age: 59 General Health: Good

Estrogen Receptor Status: Positive Histologic Grade: 3
Tumor Size: 2.1 - 3.0 cm Nodes Involved: 0
Chemotherapy Regimen: CMF-Like (Overview 2000)

Decision: No Additional Therapy

70 out of 100 women are alive in 10 years.
23 out of 100 women die because of cancer.
7 out of 100 women die of other causes.

Decision: Hormonal Therapy

7 out of 100 women are alive because of therapy.

Decision: Chemotherapy

3 out of 100 women are alive because of therapy.

Decision: Combined Therapy

9 out of 100 women are alive because of therapy.

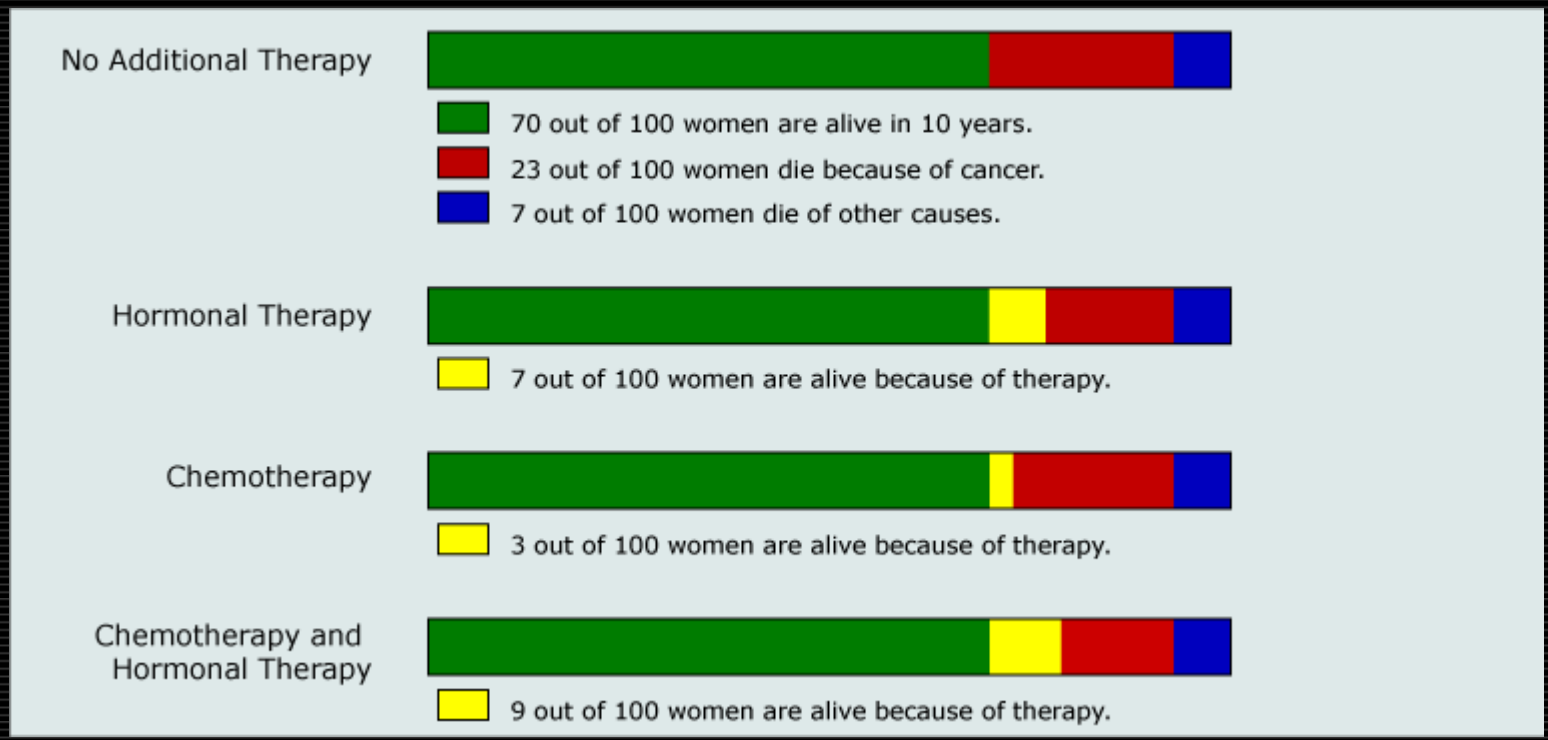
Can We Do Better?

- Four treatment options shown
- BUT: Only 2 options are likely to be relevant to a single patient
  - If ER+ (so hormone therapy is strongly recommended)
    - Hormone therapy
    - Hormone therapy + chemotherapy
  - If ER- (so hormone therapy is not recommended)
    - No adjuvant therapy
    - Chemotherapy

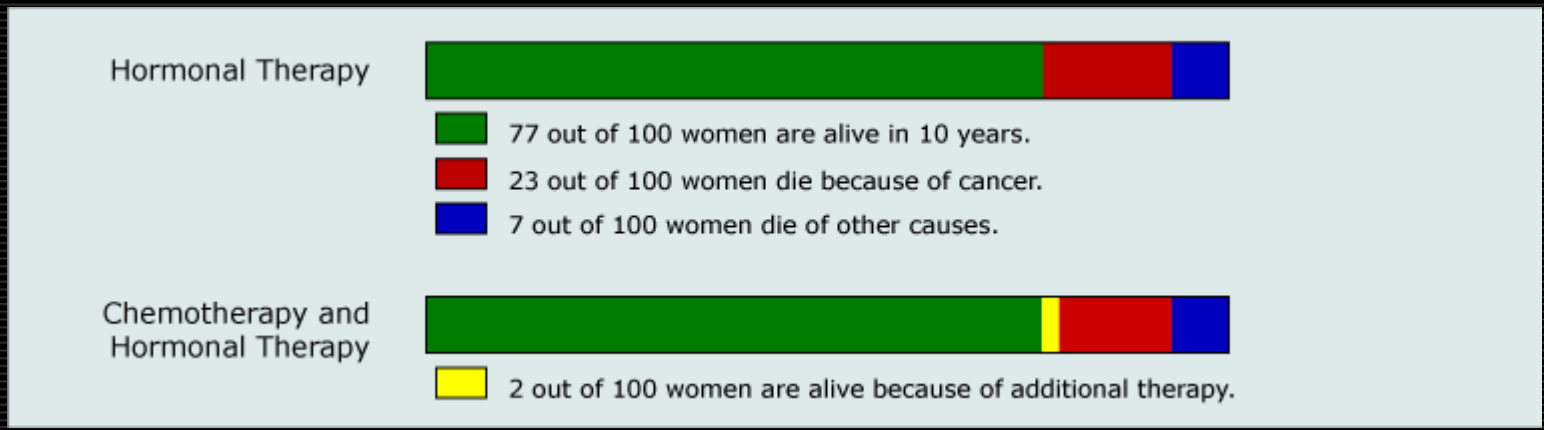
Less is More?

- Including *less* information can help choice and comprehension of the *critical* information.

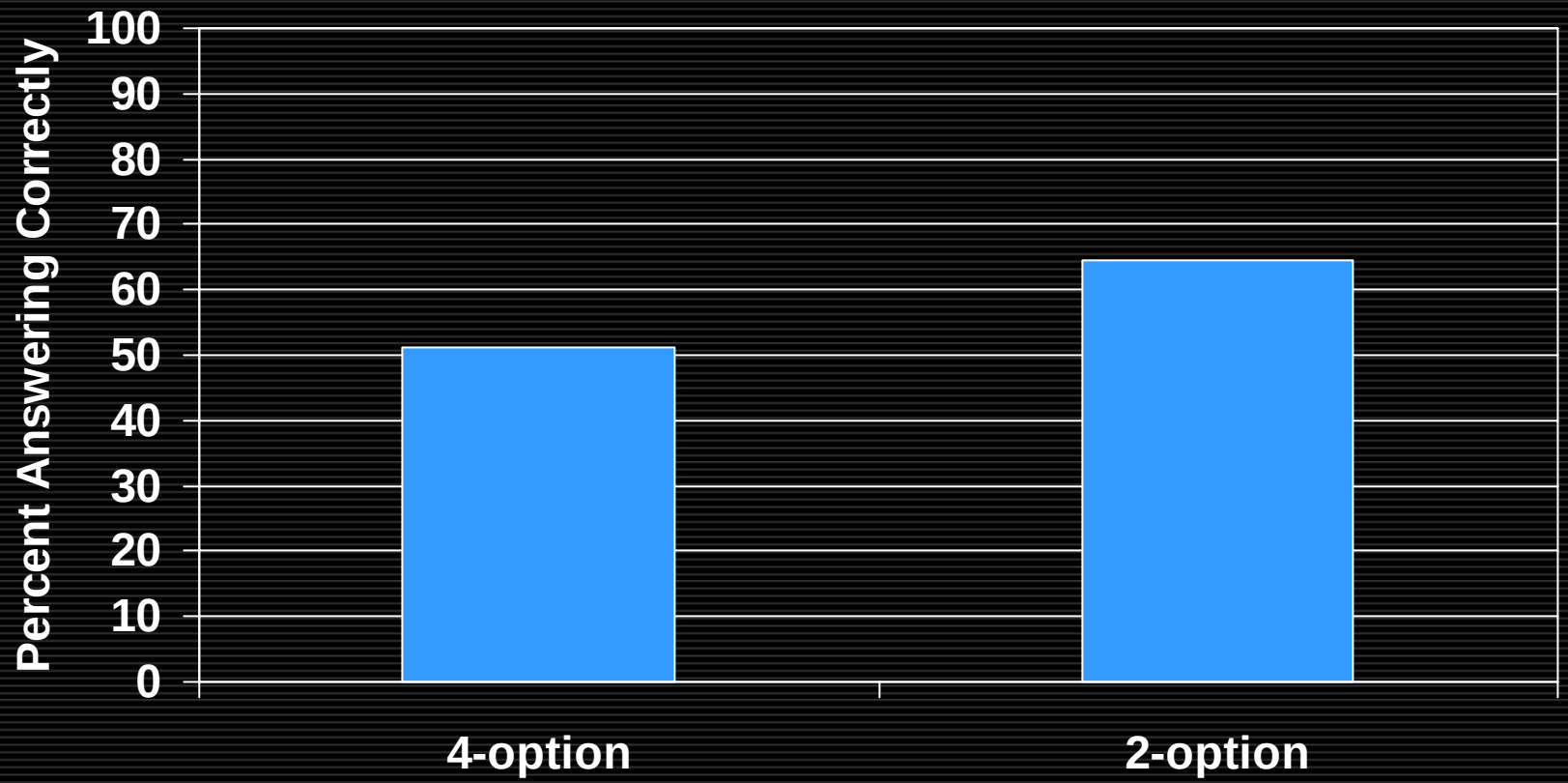
Original Format



Simpler Format



Knowledge of incremental benefit of chemotherapy



Contact Information

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Medication adherence: Moving people from the thinking phase to taking action…in a page (or two?)

Designing useful written prescription drug information for patients

Jann Keenan, Ed.S.

Keenan Group, Inc. - Experts in Health Literacy

Founding Member, The Clear Language Group Consortium

The Big 4—plus 2 more & Health literacy principles

- Big 4
  - Looking at what hinders adherence and how we can address in this print piece
- + 2 more
  - Considering culture/health beliefs –beyond cultural stereotypes
  - Considering educational theories
- Incorporating effective HL and PL techniques

Consider writing from patient perspective…

- 40% rates of non-adherence.[1] Harder to stay on a medical regime with “silent” conditions (high bp vs. ob)
- Harder to stay on treatment plan with chronic conditions, multiple doses, or when feeling better [2]
- Less adherence when patient has negative beliefs about their meds & concerns about harmful effects and overuse of meds [3]

1. Cutler D. Everett W. Thinking outside the pillbox- medication adherence as a priority for health care reform. New England of Medicine. April 29, 2010.
2. Saini S. Schoenfeld P. *Effect of Medication Dosing Frequency on Adherence in Chronic Diseases Am J Managed Care. 2009;15(6):e22-e33.*
3. Horne R. Weinman J. Patients' beliefs about prescribed medicines and their role in adherence to treatment in chronic physical illness. Journal of Psychosomatic Research (1999) Volume: 47, Issue: 6, Pages: 555-567

Still...we need to work within scope

- We know written information alone does not achieve optimum level of patient's understanding of the risks and benefits of meds.

- When accompanied by a pharmacist's oral counsel, computer print outs can be effective. Consider adding pharmacist campaign?

Big 4 (there are more of course… older adults, teens, chronic diseases, side effects, limited literacy, low health literacy, confusing and lofty materials, LEP +)

- Most common misuses are:
  - Taking incorrect doses
    - Let's not forget…1 in 5--share meds[4] (cultural belief +)
  - Taking doses at wrong times
  - Forgetting to take a dose
  - Stopping medicine too soon[5]

4. Goldsworthy R. Schwartz N. Beyond abuse and exposure: Framing the impact of prescription medication sharing Am J Public Health. 2008;98.

5. America's Medicine Cabinet. Institutes for Safe Medicine Practice American Pharmacists Association Power Point Presentation

Plus 2 more to consider when designing this piece

- Health beliefs/ cultural beliefs
- Health education and adult learning theories to prompt action

Tall order for a little piece…

Address the “Big 4”
Call to action

- Taking correct dose. Give examples of twice a day--2 times a day means every 12 hours.
- Taking at correct time (sun/moon...fill in blank with examples)
- Remembering to take meds. Give directives and actions--Set a watch or cell phone, put note on fridge, use pill box
- Thinking of stopping? Call your doc 1st!

Include CLEAR directions

- What is a light snack? Low-fat snack? Ideas on a high-fat snack?
- And what about food choices for person from another culture? Or not mixing meat and dairy as an example...Tough one...

Health beliefs

- Patient may believe that the body needs periodic rests from medicines during long-term therapy [6]
- May believe that daily medicine is dangerous because it can lead to addiction
- May believe in sharing meds (20% do...)

6. Nichols-English, G. Poirier S. Optimizing Adherence to Pharmaceutical Care Plans. Available at http://liunet.edu/cwis/cwp.library/workshop.citama.htm

Cultural beliefs- make the document culture appropriate

- When discussing pharmaceutical treatment for many disease, the use of traditional & alternative approaches to treatment may be worth addressing

- One example of cultural awareness? Traditional health beliefs is one cultural issue we can address

We should be aware that the issue of using traditional remedies to treat applies to many individuals living in the U.S.

This would include among others, people who embrace cultural traditions from:

- Latin America
- The West Indies
- Central America
- South America
- Asia
- Africa
- The American South & Rural America
- Native America

6. Alternative Remedies

THE ISSUE: Men who have diabetes often become frustrated with their doctor and the strict regiment involved in controlling diabetes and turn to herbal and homeopathic remedies. Many of these may have dangerous interactions with prescription drugs and side effects

WHAT CAN I DO?

- If you are having trouble with controlling your diabetes, talk to your family, friends and your doctor about ways to improve your situation.
- If you choose alternative remedies, talk with your doctor about them to learn about possible negative side effects.

May want to add to the standard order...

- Is the patient also using complementary or alternative meds?
- Could the patient have greater confidence in home remedies?
  - Herb teas, black coffee for eye infection, coffee grinds in a bandana for headache, potato peels on the bottom of feet for fever
- Patient also seeing a voodooist or curandera?
- 44.6 million Americans use herbal remedies [7]

7. Eisenberg d. David RB, Ettner SL et al. Trends in alternative use in the US: 1990-97 JAME 1998; 280:1559-1575

Just a quick glimpse for now... theory

- Patient centered…Incorporate self-efficacy, health belief, locus of control (Raises adherence…patient involved. You can do this, done other tough things before, may be tempted to stop….)
- Perhaps use a pictographic visual analogue scale that addresses self-efficacy. (But before we give a thumbs up- better test …thumbs up!)
- Include call to action beyond FDA and manufacturer. (Share with your doctor... Talk with your pharmacist…)

Good news for design- make it look easy to read

- Choose readable typeface*
- Choose readable font size (older adults and adherence?)
- Use upper/lower case - Avoid all caps
- Employ meaningful heads and subs for advanced organizers
- Use bulleted lists
- Limit line depth to 6 lines
- Use rag right in lieu of full justification

Might want to consider in design

- Logical organization—how patients think
- Avoid *italics*
- Use call out boxes with 5% screen
- Limit bolding
- Limit line length to 3.5 - 5 inches for readability
- Double columns can be tougher to find central spot… test it!
- Limit use of [parenthetical]—or test

And there's more design to consider....

- Let's consider pictograms that can work...
- Leave white space...ahh!
- Might want to leave 20% extra room at the bottom if it is to be translated into Spanish at a later date…
  - For Spanish translations- Make sure the document is written with consult from cultural brokers and experts

And the great serif vs.sans serif debate

- **Serif vs. Sans Serif Fonts:** A review of the literature on the merits of using one versus the other, in *hard copy* suggests that it should be a matter of aesthetic choice.
- *www.alexpoole.info/academic/literaturereview.html*
- Even if using serif body text…consider sans serif headers and subs…

Write it so it is easy to understand— more than for folks with low-health literacy

- Use conversational tone
- Use active voice
- Start off with action terms
- Limit 3-syllable words and limit jargon
- Use interactive ? when appropriate
- Aim for readable reading level
- When appropriate—include interactive questions
- Address beliefs and culture

Summary

- Go to where the patient is. Write & design it easy to understand. Good organizational structure for eye flow.
- Address what is limiting adherence-Big 4 + more.
- Consider health beliefs/culture that may lower adherence.
- Incorporate effective health ed theory/adult learning models to move from thinking to taking desired action.

Food for thought…
So maybe we really need 2 pages…

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Metrics for Success in Communicating Prescription Information

Expert Workshop: The Science of Communicating Medication Information to Consumers
Brookings Institution
July 21, 2010

Success of CMI

How will we know when the CMI has been successful?

FDA Goal:

"In order to make informed decisions about health care and to use their medications correctly, consumers need easy access to up-to-date and accurate information about the risks, benefits and safe use of their prescription drugs."

Ref: Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Patient Information Prototypes."*Federal Register* 75:85 (4 May 2010) p. 23775.

Success of CMI

Assumption

The CMI contains all the information a patient needs at each decision-making stage to:

- **Weigh risks against benefits**
- **Use the medicine correctly and safely**

Success of CMI

Recommendation

All metrics need to be patient-centered:

- **Patient is end user**
- **Patient feedback is critical to evaluation**

Patient Decision-Making

10% not convinced they need medicine

50% do not take medicine correctly

Up to 75% drop out by end of first year

Patients make decisions at every stage of the timeline

Patient Decision-Making

Evaluate at what stages of informed decision-making the CMI is most effective

Transtheoretical Model of Change

Evaluate Timing for Risk Information

Should informing patients about risk start in doctor's office before drug is prescribed?

Evaluate Timing for "How to Use" Information

Should physician give patient risk information?

and

Should pharmacist give patient "How to Use" information?

Risk Information

Evaluate CMI Risk Information

- Determine how much CMI helps patients weigh the risks against the benefits and come to an informed decision with the physician.
- Determine if CMI provides patients with practical information on how to manage minor side effects.

Risk Information

Example of risk management information

“Brush gums with a soft toothbrush”

"How to Use" Information

Evaluate CMI "How to Use" Information

Determine if CMI provides patients with practical information on how to:

- **administer the drug correctly**
- **use the device correctly**

Evaluate “How to Use” Information

Types of Questions to Ask Patients

- “Show me how you would use this medicine.”
- “Show me the steps you would take to set up the pen for the first time.”
- “When do you prime the pen?”
- “How long do you press down on the

Keys to Success

Conduct research on CMIs to determine impact on:

- **Patient comprehension**
- **Patient recall**
- **Patient adherence**

Evaluate Patient Comprehension

No Standard Method to Measure Patient Comprehension

- Test questions must be carefully designed so they are specific and understandable
- Use patient education principles to design patient comprehension questions

Evaluate Patient Comprehension

Questions should test if:

- Information in CMI is in most logical order for patients to understand
- Patients need description of medical condition
- Patients need reasons “WHY”
- Patients are more likely to read and understand CMI if it contains simple illustrations tied to simple, understandable words

Ref. Delp Acad Emerg Med 1996; Sojourner Int J Cogn Ergon 1998

Evaluate Patient Recall

Determine patient recall after receiving CMI

- Need realistic expectations of patients
- Content and design must reinforce each other
- Illustrations can help increase patient recall

Patient recall 3 days after ER visit	
No Illustrations	6%
Illustrations	46%

(p<0.001)

Ref. Delp Acad Emerg Med 1996

Evaluate Patient Adherence

Measure how CMI increases patient adherence

- By itself it's a piece of paper
- Needs to be combined with counseling by health professional

VERY COMPLEX

- Patient variables
- Disease variables
- Behavior modification variables
- Drug variables
- Educational variables
- Health care provider variables

Evaluate Patient Adherence

- Pill counts not accurate enough
- Refill prescription data
- Patient reporting might be more accurate IF patient trusts and understands importance to their therapy

Evaluate Patient Adherence

Reasons for Patient Decisions

- Seek feedback from patients for their opinions of usefulness of CMIs
- Find out reasons patients did not refill prescriptions

Evaluate Patient Adherence

If a patient does not refill a prescription, we need to know "Why"

- Determine if patient developed early signs of a side effect which they did not know how to manage
- Determine if physician advised patient to stop taking medication
- Determine if patient decided to stop taking drug because could not see any signs that drug was helping
- Determine if cost of drug was reason

Conclusion

Patients try to make wise decisions …because they have to live with consequences of their decisions.

Risk is a major concern.

If Patient's Needs Met at Each Step of Timeline

1. Patients will understand the information
2. Patients will be motivated to take the correct actions
3. Patients will take medications correctly and safely manage side effects
4. Patient adherence will increase
5. Treatment outcomes will improve
6. Hospital admissions due to patient nonadherence and preventable ADRs will decrease
7. Overall health care costs will decrease and employee productivity will increase

Recommendations

- All metrics need to be patient-centered. Seek feedback from patients for their opinions on usefulness of CMIs
- Conduct research on CMIs to determine impact of content and graphic design on patient comprehension, recall, and adherence
- Evaluate when CMI is most effective for patient decision-making
- Determine risks if CMI does not provide patients with all the information patients need on risks, benefits and safe use

Communicating Rx Information
Metrics for Success

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July 21, 2010

National Action Plan to Improve Health Literacy

Goals (2 of 7)

- Develop and disseminate health and safety information that is **accurate**, **accessible**, and **actionable**
- Promote changes that improve health information and communication

Strategies: Drug Production & Distribution

- Standardize consumer-directed drug information and ensure consumers understand such information.
- Develop and test innovative ways to improve Rx and OTC labels that will help ensure safe and effective use.
- Ensure that instructions and risk and benefit information for use by consumers are written in plain language and **consumer-test for usability**.

*DHHS 2010

‘Health Literacy’ Tasks in Prescription Drug Use

- Navigate the label and handouts
- Read and understand use instructions, contraindications, warnings (information must make sense to consumers)
- Dose properly
  - When to take? (with food?)
  - How many pills (ccs) to take at a time – take with other meds?
  - How long ?
- Problem solve refills and payment
- **Integrate and synthesize information from all sources for all meds taken**

Consumer Input Adds Valuable Perspective in Rx Communication

We have a duty to ask consumers elemental questions to promote clarity and safety.

- What specific elements of current labels and handouts are problematic?
- Are key points easy to pick out and understand?
- What words help consumers understand
  - Directions for use, side-effects, risks & contraindications?
- Do icons help consumers pick out key messages?
- What placement of warning and use instructions and icons help consumers navigate label/leaflets & notice key points?
- Font size is a common complaint.
- Instruction to “consult physician” not practical for many

Metrics for Success

5 Levels of Assessment and What They Evaluate

1. **Readability**
   - Reading grade level of document
2. **Suitability**
   - User-friendliness (layout, format, clarity, organization from consumers perspective, manageable length)
   - Language other than English
3. **Comprehension**
   - Consumer understanding
4. **Demonstration**
   - Ability to dose out
5. **Adherence and Actual Use**
   - How consumers actually take their medicine over time

Readability: Usefulness & Limitations
(Evidence Based)

- *40 formula* estimate reading grade level of material
- Does not measure if consumers can understand and act on the information
- Studies with patients indicate limitations:
  - Adult reading level is below education level
  - Comprehension level is below decoding level

Davis *Fam Prac* 1990; Davis *Pediatrics 1994;* Wolf *PEC 2000*

Suitability: Usefulness & Limitations
(Evidence Based)

- Several checklists assess how information "looks" and how it is organized – this improves materials **but**
  - Does not measure consumers' ability to understand and act on information.
- Studies indicate "user-friendly" material improves patient satisfaction and appeal – most useful to patients with $\geq$ 9th grade reading level.
- Simplified text, more explicit instructions, formatting cues (bolding, boxes, white space) improves comprehension – but people with low literacy still lag behind – *will not resolve literacy problem*

Davis *Pediatrics* 1996; Davis *PEC* 1998; Davis *SGIM* 2008; Wolf *SGIM* 2009

Comprehension: Usefulness & Limitations
(*Evidence Based)*

- "Achievement test" on label /leaflet - asks "how (when, etc) would you take this medicine?", "what would you do if you missed a pill?"
- Content limited to questions asked
- Studies usually asked about 1 med at a time
- Assessment in "research setting" i.e., not at home and often not with patients' medicine
- Clinically: "Teach back" with actual med is a good way to confirm patients' comprehension

Davis *Am Peds* 2002; Davis *South Med J* 2006; Davis *JGIM* 2006; Wolf *Am J H S Pharm* 2006; Wolf *PEC* 2007; Monroe *J Gerontol* 1998; Kripalanc *Prev Med* 2004; Katz *Am J H S Pharm* 2006

Demonstration: Usefulness & Limitations

(Evidence Based)

"Show me when you would take this medicine"

- Research uses pill organizers, stickers
- Indicates patients' comprehension (and numeracy and critical thinking skills)
- Can be used clinically (if patient brings meds)

Davis *Ann Int Med* 2006; Wolf *PEC* 2006

Adherence and Actual Use: Usefulness & Limitations *(Evidence Based)*

- Self report
  - Subjective (i.e. MARS, Morisky, PMAQ)
  - Missed doses
  - Wrong doses
- Pill count
- MEMS caps
- Prescription refills/Pharmacy records
- Medication Errors/ADEs
- Health outcomes /Biomarkers

Dowse *PEC* 2005; Yin *Arch Ped Adol Med* 2008; Shrank *Contemporary Clinical Trials* In Press.

What is Role of Physician and Pharmacist?

7 Things Patients Want To Know

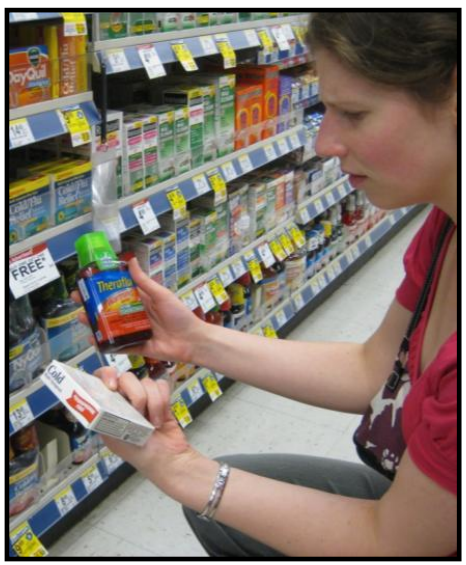
Systematic Review (69 articles)

- Directions for use
- Indication
- Benefits
- Duration
- Side effects
- Drug name
- Warnings

Approximately half of MDs do not mention dose, timing, duration or possible side effects of medication.

Shrank, *Ann Pharmacother, 2007*

Problems That Have Been Identified



- Labels not standardized or designed to optimize consumer understanding of administration directions or warnings.
- Information that is most relevant to the patient (i.e. directions for use) are often not emphasized.
- No RCT studies to date have evaluated effect of improved labels on actual medication use (adherence and medication safety).

Recommendations & Questions

- Focus on *universal precautions* of information
- Limit information and intention – is purpose decision aid or use aid?
- What is the critical information – *what do patients need to know and do and why is it in their best interest*?
- Develop standard, coordinated system of Rx labels, leaflets & oral instruction.
- Who (Industry, FDA, Market researchers) will assess patient comprehension of new labeling?
- How “effective” do leaflets need to be? How effective with those with low literacy? Will there be quality control?

Session I Lead Respondents

- Theo Raynor
  University of Leeds and Luto Research Ltd.

- Sue Stableford
  University of New England

Session II Speakers

- Janet Norden
  Office of Medical Policy, Center for Drug Evaluation and Research

- Amie O'Donoghue
  Office of Medical Policy; Center for Drug Evaluation and Research

Prototype Development and Study Design

Janet Norden, MSN
Office of Medical Policy, CDER

Amie O'Donoghue, Ph.D.
Division of Drug Marketing, Advertising and Communications, OMP, CDER

July 21, 2010

Process and Overview

- **Process**
  - Develop prototypes that convey prescription drug information for consumers
  - Following feedback from experts, refine and consumer-test the prototypes to determine usefulness of content and format
- **Overview**
  - Fictitious drug
  - Prototype development
  - Study design

Fictitious Drug Example: Rheutopia (arixalate)

- Developed as teaching tool for converting professional labeling to the “PLR” format
- Rheutopia’s labeling is intentionally complex
  - Four indications: adult rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis
  - Associated with several serious risks (includes a boxed warning)
  - Meets the criteria for a Medication Guide
  - Administered by injection

Prototype Development Process

- Reviewed and considered:
  - Scientific literature
  - Comments and advice, including September 2009 public workshop
  - Current labeling practices and guidance
- Refining prototypes based on feedback
- Will consumer-test three prototypes

Prototypes

- Prototype #1 - Derived from the content of “Highlights of Prescribing Information” of professional labeling
- Prototype #2 – Same as #1 with additional context
- Prototype #3 - Modeled after OTC “Drug Facts” labeling

Content

- **Core Content**
  - Uses
  - Side effects (serious and common)
  - What to do and what to avoid while taking the drug
  - How to take the drug
  - Where to get more information
- **Variable Content**
  - Prototype 2 – Includes context
  - Prototype 3 – More concise

Content – Topics for Discussion

- Critical information that should be included in a leaflet
- Appropriate balance of risk and benefit information
- Pros and cons of including other types of information
  - Disease awareness
  - Additional context
  - Standard statements

Format

- **Core Format**
  - Bulleting with short sentences/phrases
  - “Chunking” similar concepts
  - Type size
  - White space/bolding
  - Document length
- **Variable Format**
  - Ordering: Boxed warning (Prototype 3)
  - Headers: Q&A (P1 and P2), Action-oriented (P3)

Format – Topics for Discussion

- Ordering information
  - To emphasize important warnings/risks
  - To highlight new information
- Use of headers to signal subsequent content
  - Action-oriented, Q&A, Descriptive
  - Other headers to consider
- Other formatting techniques

Study Design

Three Parts

1. Two or three in-person “pretests”

   (n = 180 ea)

2. Internet with mailed prototype

   (n = 900)

3. Internet with electronic prototype

   (n = 200)

Study Design

- Experimental design—random assignment to conditions
- Each participant will see only one prototype
- Part 1 may include qualitative and quantitative parts

Samples

- Diagnosed with rheumatoid arthritis, ankylosing spondylitis, or plaque psoriasis

- Parts 2 and 3: At least 30% of sample will read at or below 8th grade level

Design

Order	Format: Drug Facts	Format: Minimal Column	Format: Column Plus
Warning First			
Indication First			

Research

Dependent Variables

- Can consumers find the risk information?
- Do people gain accurate understanding of risks and benefits?
- Can consumers accurately understand and apply the information?
- Perceptions, attitude toward medication

Research

Example Questions

- **Open-ended**: What does Rheutopia treat?
- **Yes/no**: should you tell your doctor that you recently lived in France? (yes)
- **Application**: Jack missed his dose of Rheutopia – what should he do?

(multiple choice)

Session II Lead Respondents

- Ruth Parker
  Emory University School of Medicine

- Tom Cantu
  Global Regulatory Affairs, GlaxoSmithKline

Optimal Content, Format, and Evaluation Strategy…..Respondent Comments

Ruth M. Parker, M.D.

Professor of Medicine

Emory University School of Medicine

3 topics of interest to FDA:

- **Is proposed study appropriate to evaluate the prototypes and will results have practical utility?**

-- **Major concerns**:

Internet based study of printed CMI

?Literacy assessment via Internet?

?Validity and reliability of dependent variables using Internet?

?Can findings be generalized?

- **Are study design and assumptions valid?**

Concerns:

Prototypes based on "professional labeling" (FDA approved for healthcare professionals. Issues of product liability as focus.)

We need a **patient-centered** system of medication information seamlessly engineered for safe and effective use.

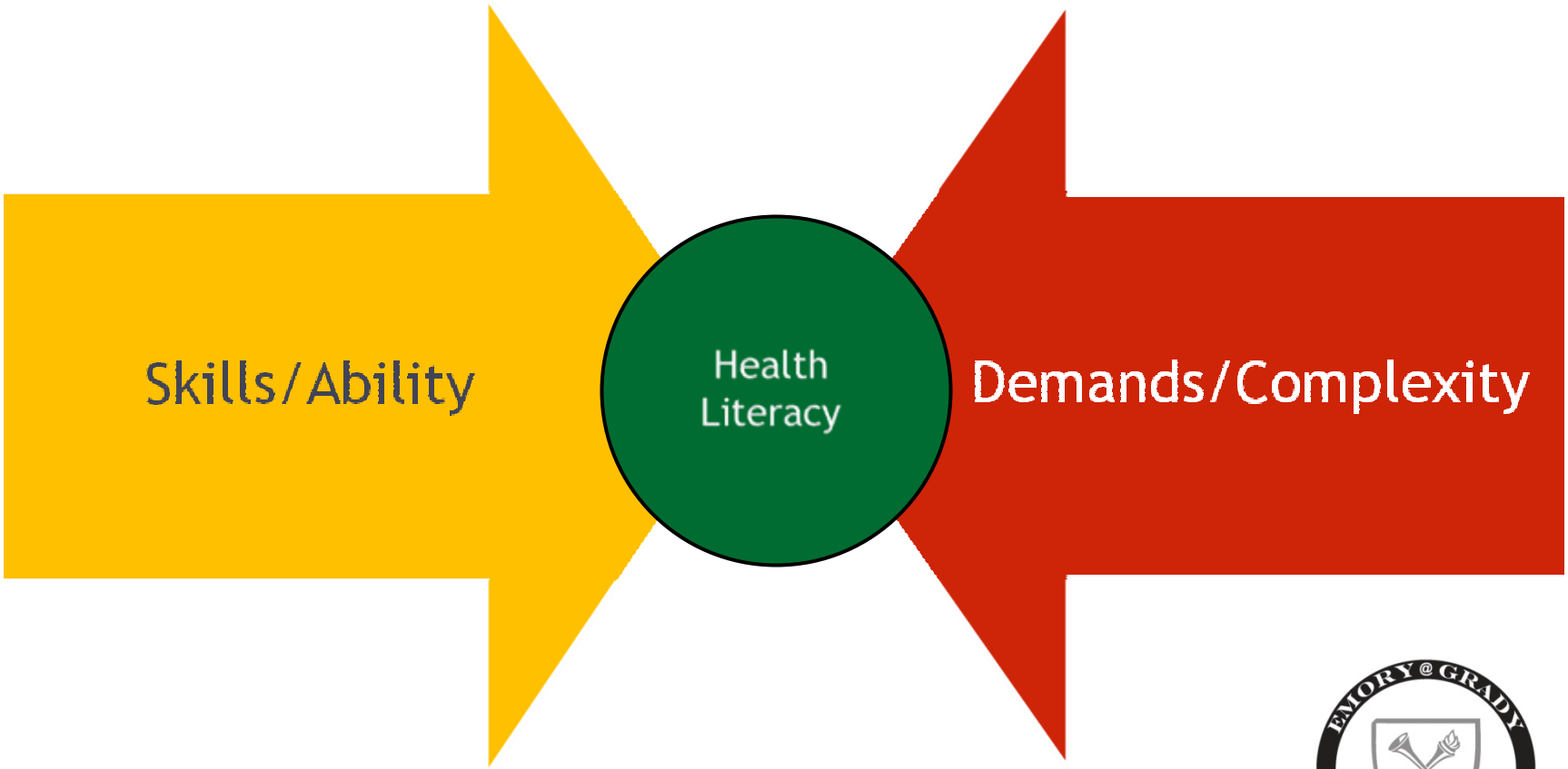
Do **ANY** of current prototypes lend themselves to this patient-centered need?

What modifications?

- Obtain information from experts...patients!!... about optimal design of CMI (formative)
- Would not perform study via Internet
- Clarify measurement of dependent variables
- Ensure prototype can be engineered to seamless patient-centered system of medication information...that will be standardized and regulated

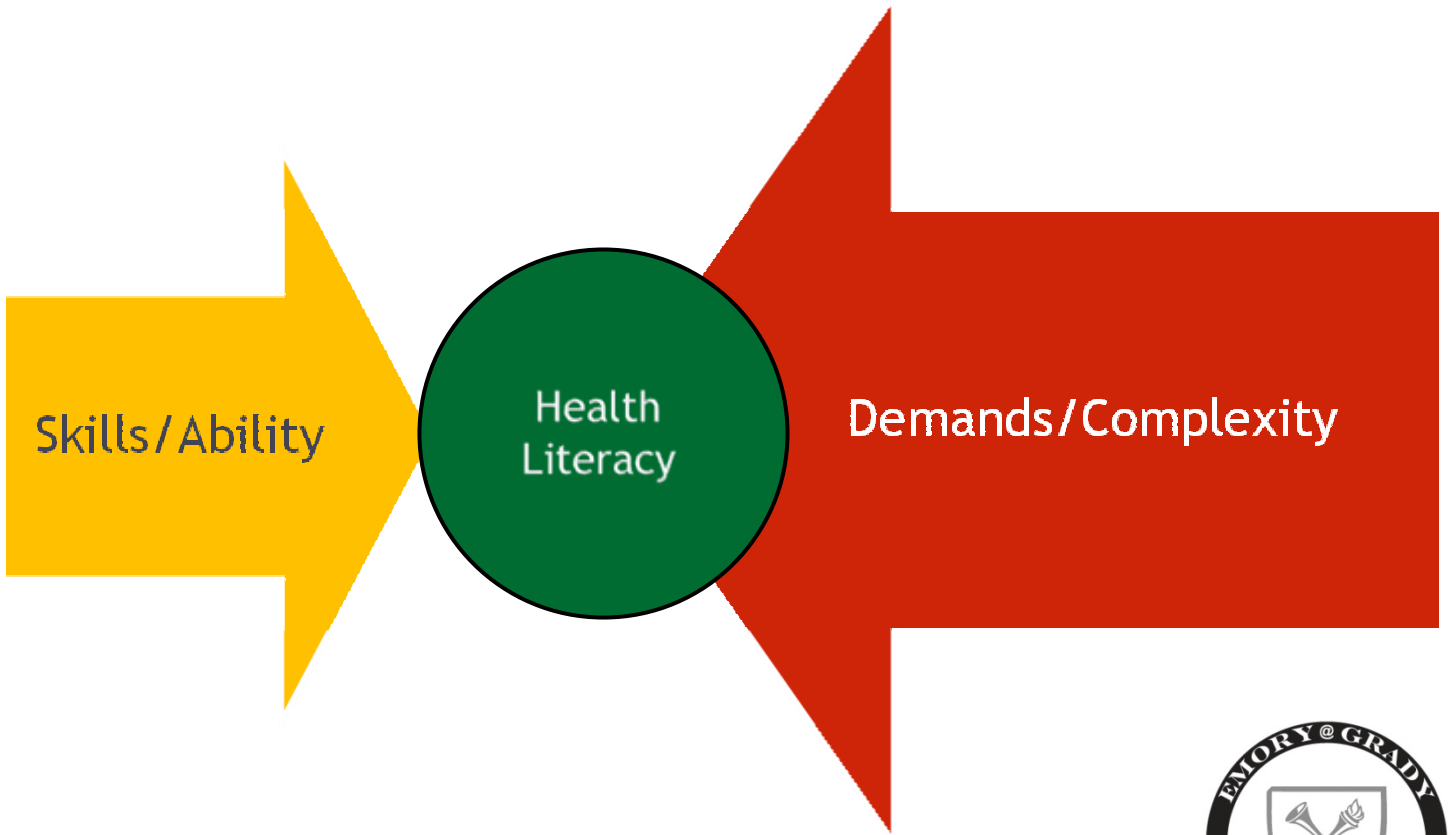
Health Literacy Framework

(Parker)



partnering clinical evidence and patients' voices
R.M. PARKER • K.L. JACOBSON • L. DI FRANCESCO

Not Aligned



The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

Risk of Confusion in Dosing Tamiflu Oral Suspension in Children

TO THE EDITOR: The medical community should be made aware of the serious potential for dosing errors in children prescribed Tamiflu (oseltamivir) oral suspension, as illustrated in the case described below.

After the diagnosis of novel H1N1 influenza, a 6-year old received a prescription for Tamiflu (oseltamivir) oral suspension (12 mg per milliliter) at a dose of 3/4 teaspoon PO BID. However, the parents, one a primary care physician and the other one of the authors, had great difficulty determining the correct dose to administer to their child. The medication bottle was accompanied by a prepackaged syringe with markings of 30, 45, and 60 mg (Fig. 1). The label attached by the pharmacy specified the dose in volume units ("3/4 teaspoonful") but the syringe provided only markings in mass units (milligrams). Despite

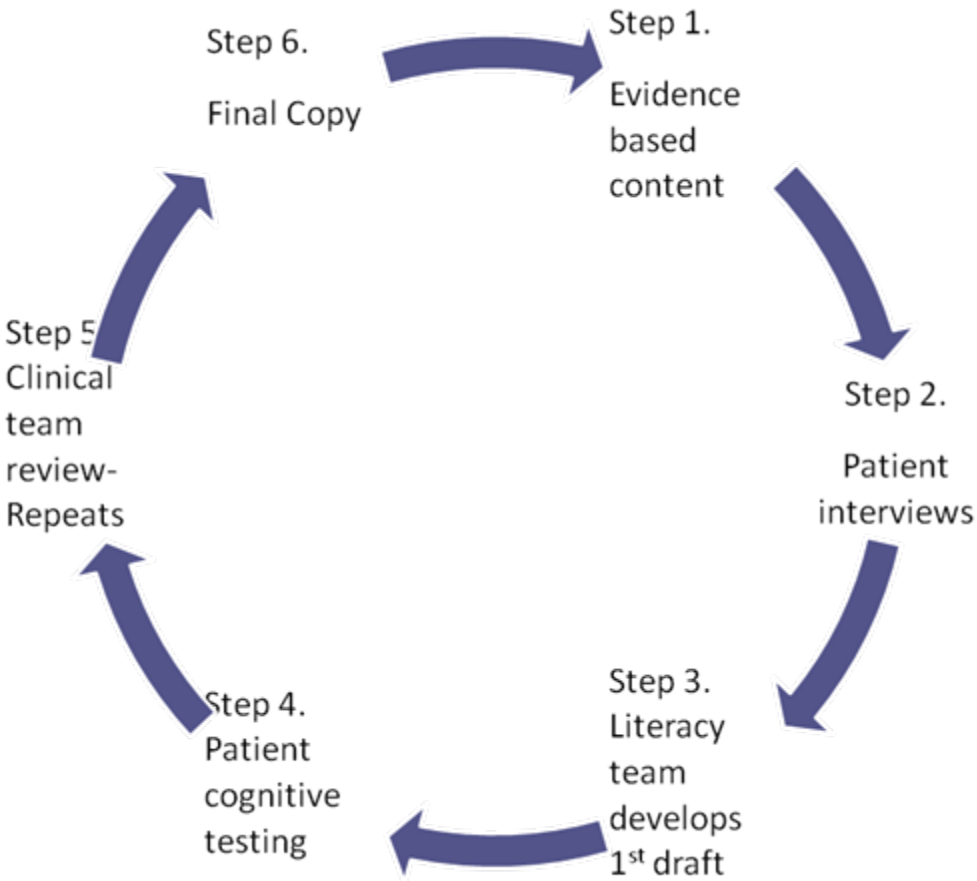
Figure 1. Tamiflu Package, Label, and Syringe Included in Box.

ing and measurement calculations[1] will be re-

Lessons from the field

Patients are the real experts...
partner with them to communicate

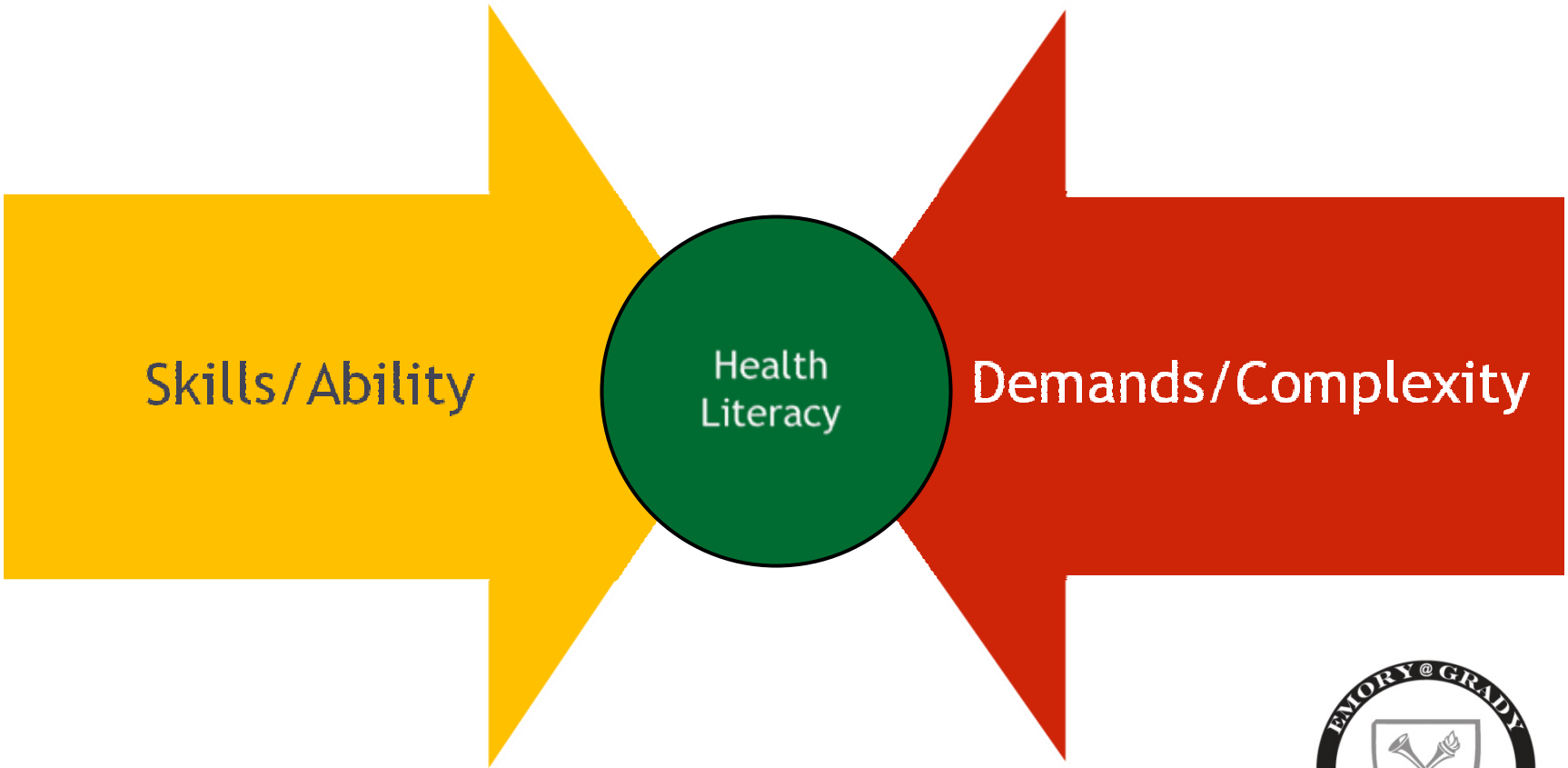
Emory's Approach to Making Materials More Health Literate



Emory Health Literacy Team
EUSM: Ruth M. Parker, MD; Lorenzo DiFrancesco, MD
RSPH: Kara L. Jacobson, MPH, CHES

EMORY UNIVERSITY SCHOOL OF MEDICINE

Advancing Health Literacy



partnering clinical evidence and patients' voices
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Consumer Medical Information: Content & Authoring

Tom Cantu, PharmD

July 2010

General Issues

- How to depict *significant* revisions in CMI (revision date)?
- CMI should focus on the Medication. It should not be a disease-state education document
- PLR labels: Highlights & Section 17 performed quite well in identifying content scope for CMI creation. More consistency in Section 17 may improve this even further
- Authoring CMI – consistency needed in final documents

General Issues

- General advice (non-product specific)
  - Take as directed
  - Don’t give medicine to others
  - Keep away from children/ pets
  - How to dispose of medication
  - How to handle missed doses
  - Disease advice (diet adherence, exercise, weight loss)
  - Product storage requirements
  - Caution in pregnancy and lactation

Omit this information, unless it is related to a specific product safety issue

General Issues

- Excessive redundancy in CMI should be avoided
- Avoid “lack of data” statements
- Include information on required lab tests or procedures during therapy ONLY if part of a key safety requirement – not if part of routine medical care (blood sugars, drug levels, etc)
- Standard text should be created for common messages – e.g., driving precautions, pregnancy risk, suicidality risk
- CMI scope – will CMI be needed for drugs that are only administered in healthcare setting by healthcare professional or for vaccines, which have Information Sheets on CDC website?

FDA's CMI Prototypes: Comments by Section

What Does Product X Treat?

- Reflects Indications & Usage section of US PI
- How specific should the CMI be?
  - "Used to treat depression" vs "Used to treat depression only after other treatments have failed"
- Consider inclusion of potential benefits of medication adherence only if benefits are not obvious (e.g., hypertension, antidepressants or lipid treatments vs seizure medications)
- Consider inclusion of drug class or mechanism ONLY if meaningful to patient (e.g., blood thinner or penicillin)

Important Warning:

- Reflects Boxed Warning section of US PI
- Consider placing this information after “What does Product X treat?”. It may make more sense to tell patients what drug is used for, before getting into risk issues.
- Is the boxed *presentation* informative to patients? Will they recognize the significance of the box?
- Recommend title simply read “Important Warning!” (with exclamation point), but without the risk info in the header
  - Some labels have multiple topics in a boxed warning & some BW concepts may not translate easily or succinctly for a header in CMI (e.g. spinal hematomas, capillary leak syndrome)

What should I tell my Doctor?

- This Header may be confusing with next Header. Consider “What should I know **before** taking Product X?” Then start with “Tell your doctor …”

- Consider including in this section any information that could alter either the decision to prescribe (contraindications) or the initial dosage chosen (renal, hepatic diseases or concomitant medications)

- Is the intent of this section to reflect Contraindications section of US PI? Not all Contraindications are “actionable” by patients – e.g., thrombocytopenia or liver lab values – omit these from CMI?

When should I call my Doctor?

- Consider alternate title “What should I know **while** taking Product X?”
  - FDA prototypes include “Stop using …” advice which may be ok for Rheutopia, but inappropriate for other medications
  - Appropriate patient actions in this section may be to stop the medication or to call the doctor/ pharmacist

- This Section reflects Boxed Warning, Contraindications, Warnings & Precautions, Drug Interactions in US PI
  - any condition (onset of serious side effects, surgery, pregnancy, starting/stopping other medications) that occurs during treatment that could alter the decision to continue treatment, or the dosages used

What are Common Side Effects?

- Reflects Adverse Reactions section of US PI
- For PLR labels, this section should reflect those events listed in the Highlights of the prescribing information
  - Less common, but serious event will be in CMI if they appear in the BW, CI, or W & P sections of the label
- A glossary of side effects translated into patient-friendly terms should be generated for use by CMI authors to facilitate consistency in messages

How do I use Product X?

- Reflects Dosage & Administration and Storage & Handling sections of US PI
- Specific dosing information should only be provided in CMI if the product dosing is consistent across patient groups/ indications.
- If an “Instructional Leaflet” is provided with the product (self-injection products, respiratory devices), reference to that leaflet should be made in the CMI

Miscellaneous

- Recommendations to alter lifestyle issues (avoid alcohol, certain foods, not driving, use of contraception) should be accompanied by clear, simple explanations.

- Drug – drug interactions need careful consideration. Careful not to “over-warn”. Also, blanket statements to “tell your doctor about any medications you use” may not be very helpful.

Session III Speakers

- Michael Wolf
  Feinberg School of Medicine at Northwestern University
- Kala Lapidus Paul
  The Corvallis Group, LLC
- Baxter Byerly
  Catalina Health Resource

Re-Designing Consumer R_x Information

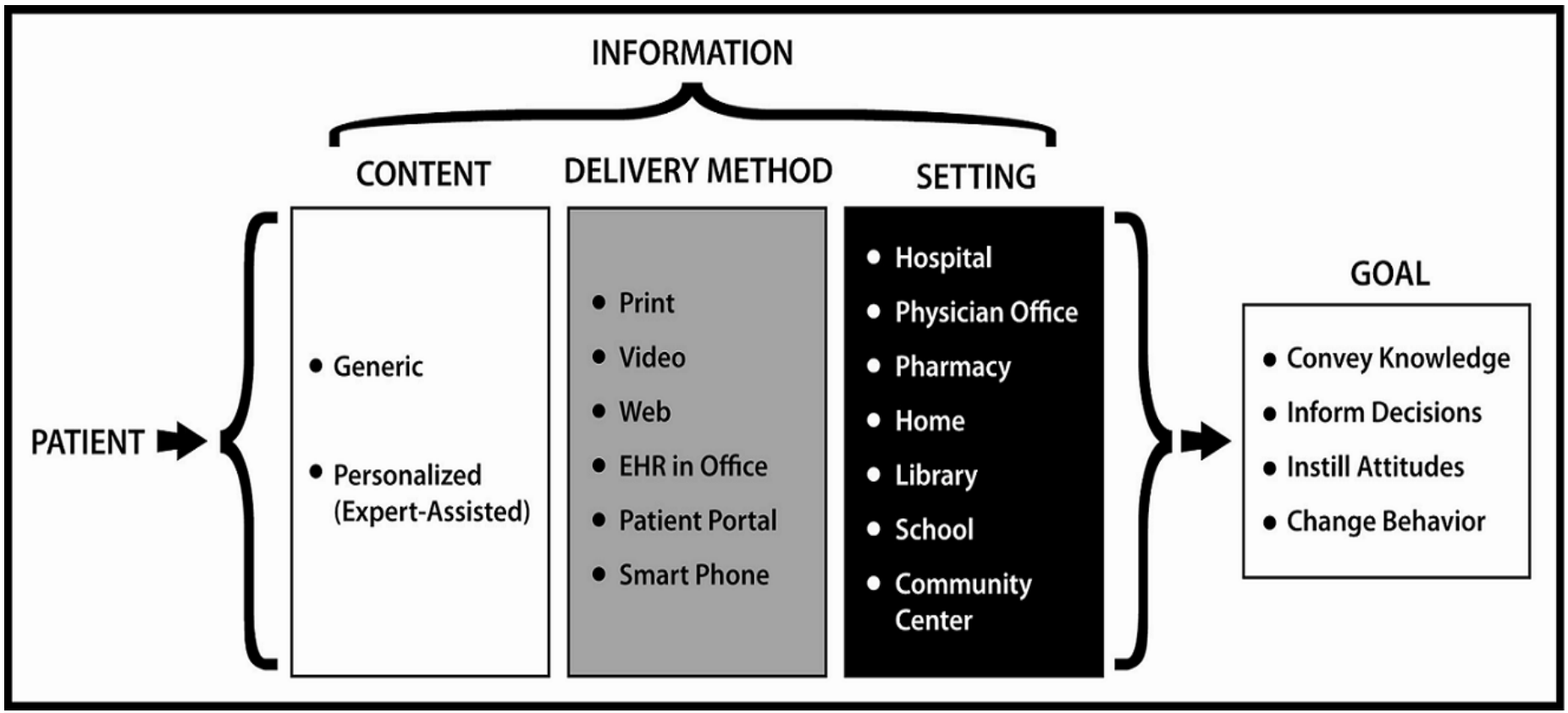
Opportunities for Innovation

Michael S. Wolf, PhD MPH
Associate Professor, Medicine & Learning Sciences
Associate Division Chief, General Internal Medicine
Feinberg School of Medicine
Northwestern University
Chicago, IL, USA

NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE

HeLP HEALTH LITERACY AND LEARNING PROGRAM Feinberg School of Medicine Northwestern University

What, How, Where, When, Why?



Targeting Current Rx Info Attributes

- Paper
  - purpose/orientation
  - format
  - sequence
  - readability
  - length
  - redundancy
- Delivered at Pharmacy
- Disconnected from Providers

Targeting Current Rx Info Attributes

- Paper
  - purpose/orientation

Can we be more innovative?

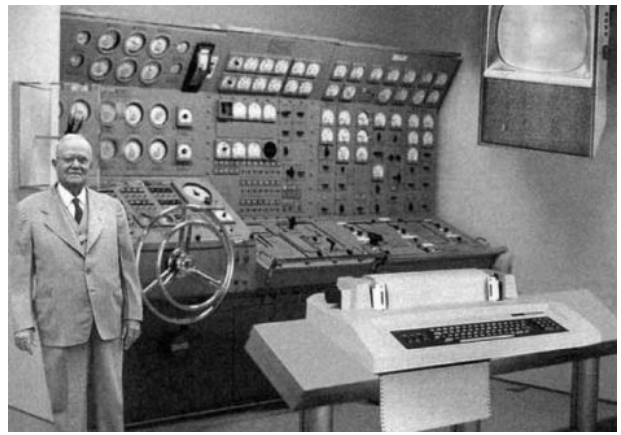
  - readability
  - length
  - redundancy
- Delivered at Pharmacy
- Disconnected from Providers

Targeting Current Rx Info Attributes

- Paper
  - purpose/orientation
  - format
  - sequence
  - readability
  - length
- Delivered at Pharmacy
- Disconnected from Providers

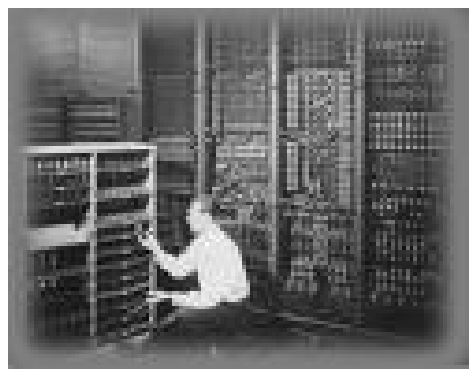
How can we leverage Health IT?

What Falls under 'Health IT'?



<u>Clearly</u> not limited to:

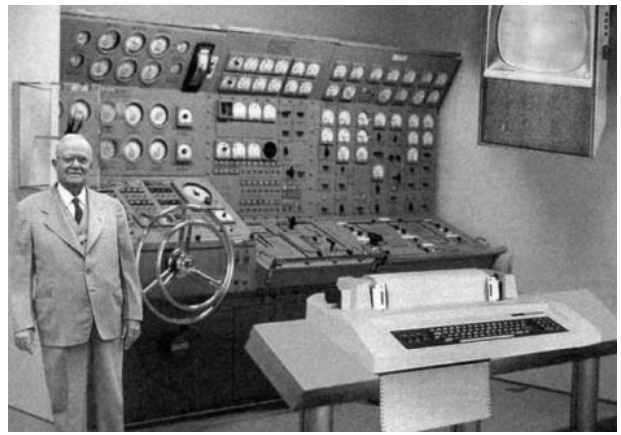
- Telephonic interventions
- EHR + Patient Portals
- Internet
- Interactive video & games
- Handheld devices (cell phone, smart phone, ipad, etc.)
- Medical devices
- Computerized agents



What Falls under ‘Health IT’?

<u>Clearly</u> not limited to:

- Hospitals & Clinics
- Pharmacies
- Schools
- Libraries
- Occupational settings
- Patient homes
- <u>Anywhere</u>



Health IT & Health Literacy

- IOM 2004 HL Report underscored health system complexity as target for intervention
- Various health technologies can be used to:
  - **convey patient information, promote behavior change**
  - **elicit patient issues & concerns, screening**
  - **monitor chronic disease**
  - **standardize clinical protocols**
  - **track patient progress & outcomes**
  - **prompt related health care provider behavior**

Potential Benefits of Health IT

- Expand or target audience
- Tailor tools as needed
- Timeliness of delivery
- Standardization of message(s)
- Layer content
- Automation of processes of care
- Efficiency in resources
- Potential sustainability
- Relative cost for dissemination (depends on tech)

www.medicine.northwestern.edu/divisions/general-internal-medicine

- Patient checks in
- RN encounter
- RN starts video in EHR
- MD encounter
- Decision making
- Tangible print tools to Pt

NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE

Patient Education Tools

Welcome

Improving health communication is one of the most important missions for the Division of General Internal Medicine and its Health Literacy and Learning Program. This is not just an academic goal. We strive to put our research into practice by making the multimedia and print materials we have developed available free of charge. This page provides a list of these materials. You can watch videos online and download print materials.

> Learn about our development process

> How you can use our tools

Get Screened for Colorectal Cancer

Explains the options for CRC screening. Covers Stool Cards and Colonoscopy. **6 minutes.**

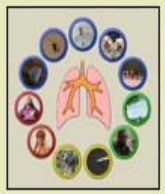
Available in Spanish.

PLAY VIDEO | MORE

Get the Flu Shot

Targeted at African Americans over 65. Explains process and importance of the flu shot, framed by questions. **5 minutes.**

PLAY VIDEO | MORE



Asthma 1-2-3: Triggers

How to manage asthma by controlling or avoiding common asthma triggers . **4 minutes.**

PLAY VIDEO | MORE

Asthma 1-2-3: Medicine

How to use a quick-release inhaler. **4 minutes.**

PLAY VIDEO | MORE

Diabetes Series

A 7-part series discussing how diabetes is

Patient R_x Tools at Point of Prescribing

You Have a New Medication

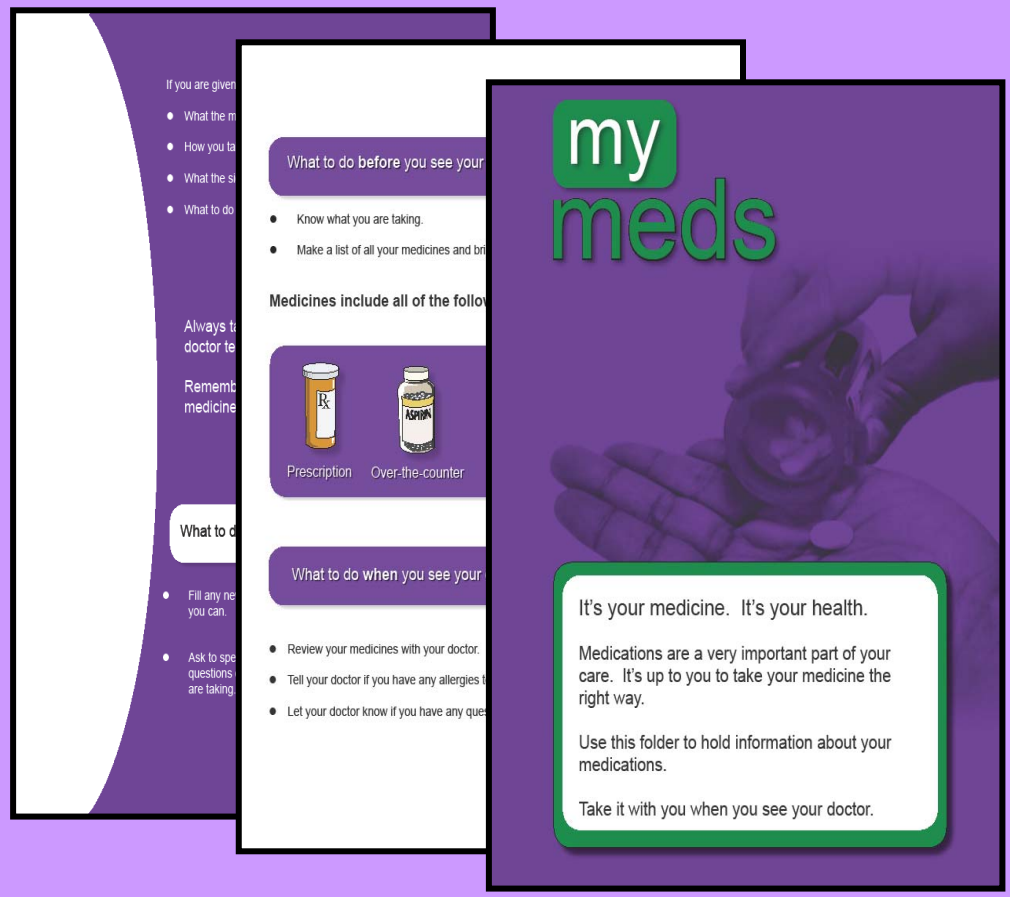
Date: August 1, 2008
Name: John Doe
Doctor: David Baker, MD

Please read the information below. This tells you how to take your medicine.

Drug Name	Lipitor®
Generic Name	Atorvasatin (a TORE va sta tin)
Purpose	This medication can lower "bad" cholesterol.
Benefit	It can help prevent a heart attack or stroke.
How to Take	**Take 1 tablet by mouth at bedtime.** Morning 6:00-8:00 · Noon 11:00-1:00 · Evening 4:00-8:00 · Bedtime 9:00-11:00
For How Long	You may need to be on this medication for the rest of your life.
Call Your Doctor	If you have any of these symptoms for more than 1 week: • Headaches • Stomach pain • Diarrhea
Stop Taking and Call Your Doctor	If you ever have: • Muscle pain • Muscle weakness • Joint pain
Important!	• Take this medicine only the way your doctors tells you. Tell your doctor or pharmacist if you are pregnant, think you are pregnant, or breastfeeding. You should not take this medicine. • If you take over-the-counter medicines every day, tell your doctor. • Limit how much grapefruit juice you drink every day.

Please call **NoVA ScriptsCentral Pharmacy** at **(123) 456-7890** if you have questions or concerns.

These websites can tell you more about your medicine:
www.ahrq.gov/consumer and www.nlm.nih.gov/medlineplus



… w/ structured protocol

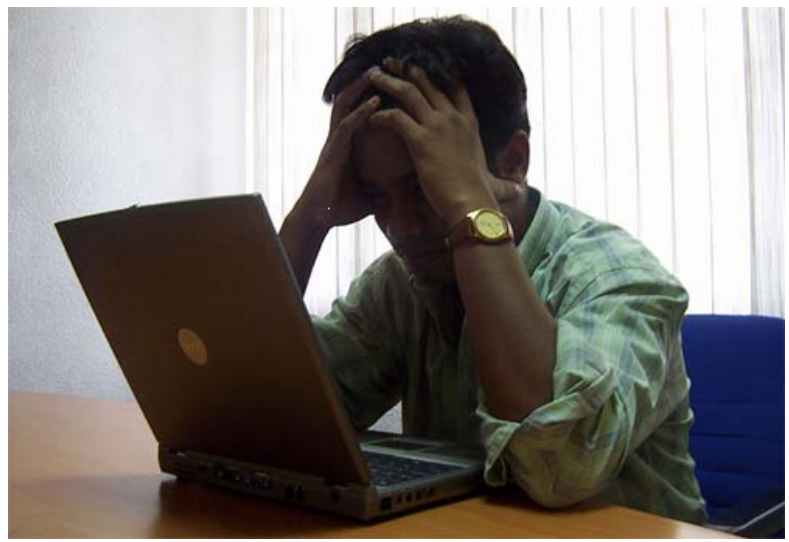
Med list @ check-in	→	UMS-mapped prescriptions	→	Med sheets @ discharge	+	My Meds tools
Patient reviews regimen		UMS sigs on all orders		Patient gets info for new Rx		Patient asked to use regimen table
MD reviews list		Regimen in UMS form on d/c list		Receives new med list		Stored in My Meds folder

Potential Constraints of Health IT

- Access to IT (patient AND provider)
- Patient skills required to interface with IT
- Adaptability of technology to meet user needs
- Limitations of clinical and/or patient environment
- Readiness to accept IT/cultural transformation
- Skills required of relevant staff to interface w/ IT
- Communication barriers between IT systems
- Tethered or untethered platforms
- Risks of automating certain patient/provider activities (lessons from human factors)

http://www....

- 131 Adults w/ limited literacy self-reported less internet access and use (Jensen, et al J Aging Health May 21 2010)
- Anxiety reported with adoption of technologies (N=1204; CREATE Study; Czaja et al Psych Aging 2006)
- Most older adults struggle with basic web navigation and decision making tasks (Czaja, Sharit, Nair, JAMA 2008)



USER TESTING NEEDED FOR ALL MODALITIES

Just Because We Can…

- **FIMDM Systematic Literature Review** (in prep 2010)

  - 21 comparative studies of multimedia v. print tools

  (patient ed, decision making, instill attitudes, behavior change)

  - No true 'winner' emerges

  - Wilson et al. (J Health Comm 2010)

    + procedural v. declarative content matters

    + re-review matters

    + using both video and print matters

Additional Considerations

- Plan for standardization (Bailey et al 2009; Wolf et al 2009; Shrank & Avorn 2008)
- System breakdowns: the case of language access

  (Bailey et al. 2009; Sharif 2010)
- Search for loopholes: e-prescribing and ‘missing data’
- Do ‘they’ know how we work? Needing a CQI plan

Press Play

- **Comprehensive evaluations needed to:**
  - assess fidelity + impact on full list of outcomes (root cause analyses)
  - examine effects by age, literacy level
  - cost?
  - target translation, dissemination
- **Critically consider use of new technologies** (diffusion of innovation)
- **Seek to improve IT linkages across systems**

Contact Information:

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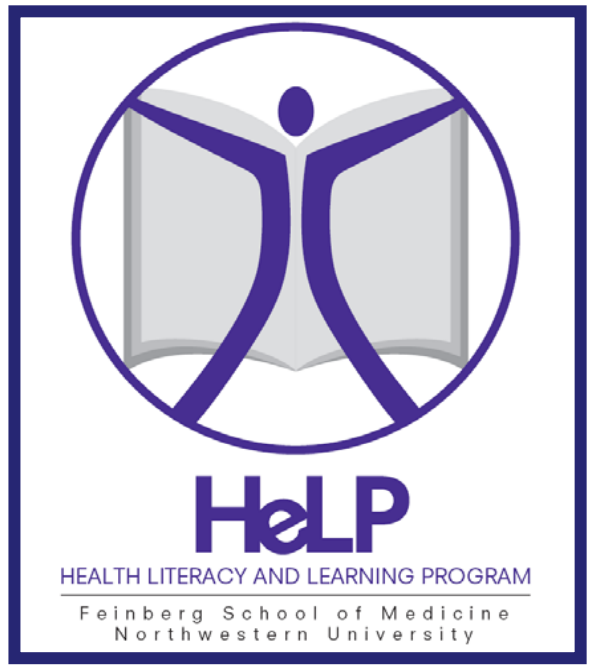


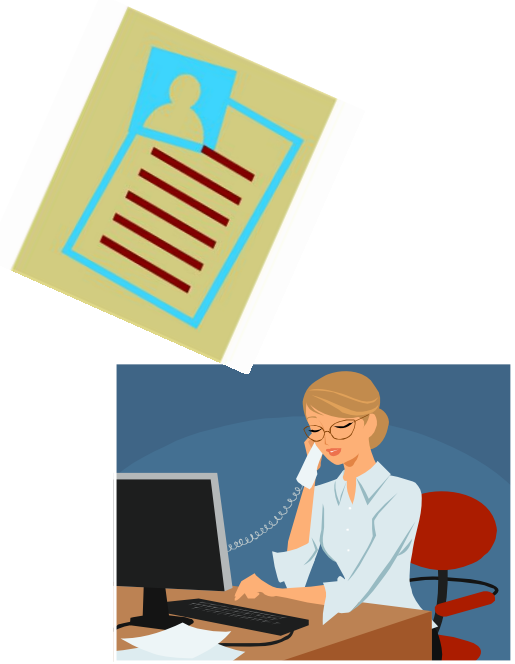
Getting product information to the consumer

Expert meeting on consumer medication information
The Brookings Institution

Kala L. Paul, MD

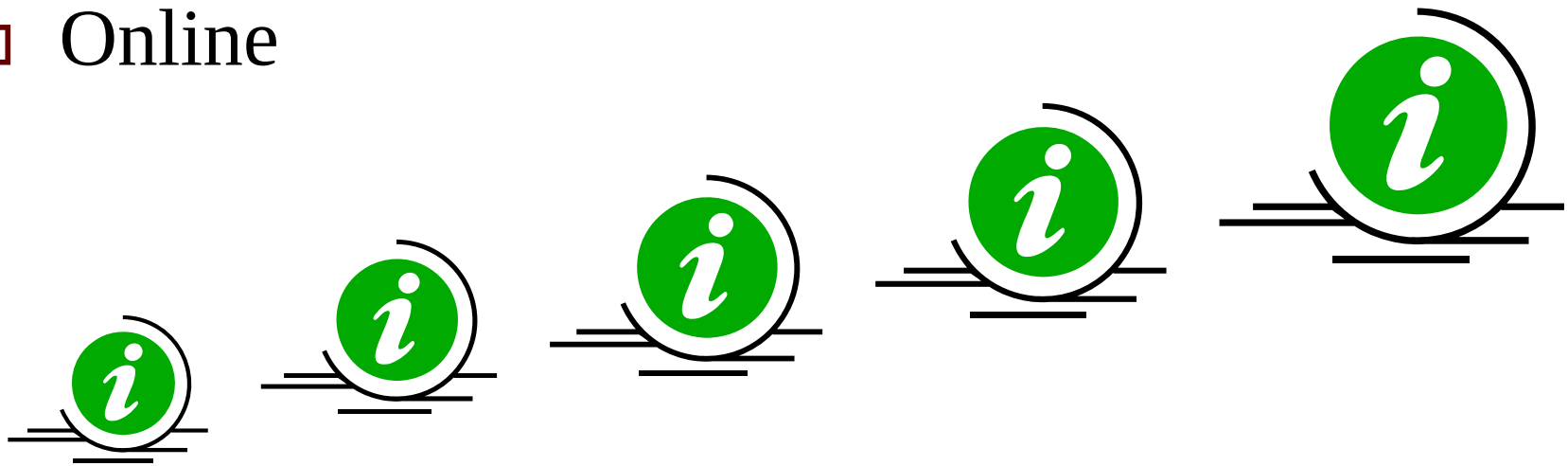
President,
The Corvallis Group, LLC

How do patients get information about their medications?



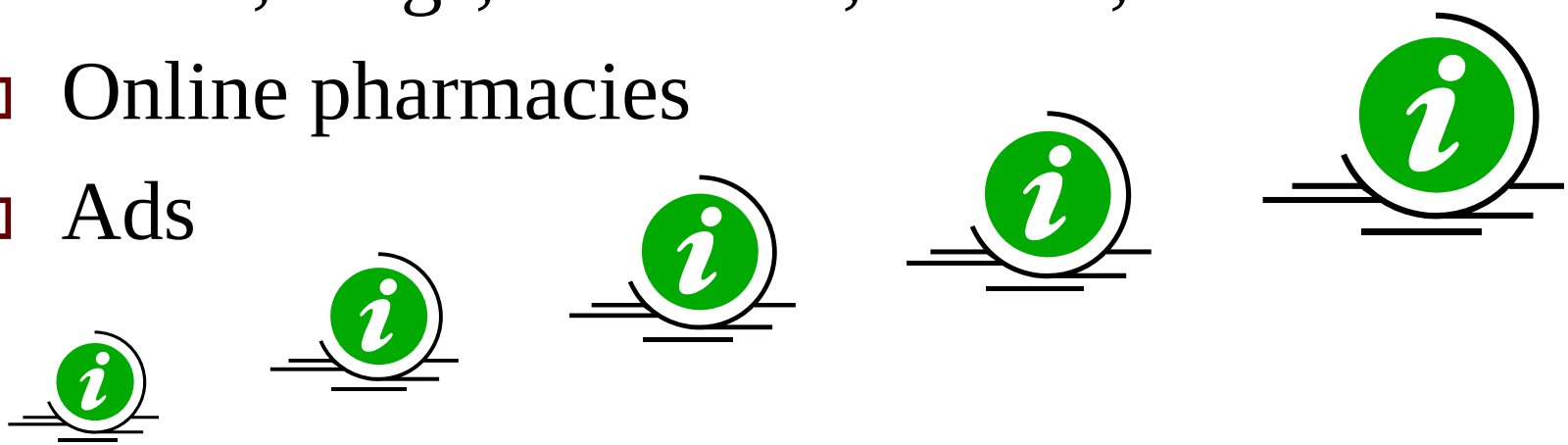
Current methods and venues

- In person
- In print
- On air
- Online



Current online venues do not “push”

- Disease websites and online communities
- Product websites
- FDA website
- Chats, blogs, Facebook,Twitter, e-zines
- Online pharmacies
- Ads



Internet access-US households, 2007-8*

- 81% of US households have at least 1 computer
- Lower proportion in families with <$30,000/year
  - Lowest in Hispanic and African-American households and where head of household not high school graduate
  - Lower in rural areas and homes without cable
  - Lower among households where age is 65 and above
- May have access to public service via libraries, schools, hospitals**
- 75% of Americans say they use Internet**
- Broadband Internet access is growing

http://www.leichtmanreserach.com/press/060707release.html, accessed 09 Jul 2010

** http://e-patients.net/u/2010/07/Demographics_of_Internet_Users_01_05_2010.jpg, Pew Internet, accessed 14 Jul 2010

The Internet provides a venue to push CMI to patients when product dispensed

Effective distribution
Presents options not available for paper
Unknown if more effective than paper
Depends on the format and content of CMI

Internet Distribution of Consumer Medication Information

Getting the words to patients

July 21, 2010

CORVALLIS
THE CORVALLIS GROUP, LLC

Considerations for near-term goals

- Fulfill requirement to provide CMI at point of dispensing
  - Single source of documents across venues
  - Uniform “core”content for all venues
  - Printable –single or double page
  - Handle “customization” with special section formatting, e.g., PREGNANCY AND NURSING, PATIENTS OVER 65

Advantages for Internet distribution

- "Push" information to patients
- Ability to alert patients to new information
  - In e-mails and in document
- Potential for live links
- Can be linked *to* electronic health records, linked *from* other sites
- Potential for engaging formats
- Potential for paper waste reduction
  - Patient can opt out of paper print out

Possible venues for distribution

- Electronic via e-mail from online pharmacy or local pharmacist
  - Linked to dispensing via pharmacy database
- Embedded in patient-accessed electronic health record (EHR) or EHR generated e-mail
- Technology exists, platforms already in use

Online pharmacy scenario

Online Pharmacy

Accessible info databank

Patient

Access via e-mail
•Read
•Save
•Print

Paperless option

- Patient e-mail is already in system
- Databank concept already in use
- Documents approved, same for all pharmacies
- Not a HIPAA issue
- Document sent at time of dispensing

Online pharmacy scenario: paper

Online Pharmacy

Accessible info databank

Access via e-mail
•Read
•Save
•Print

Patient

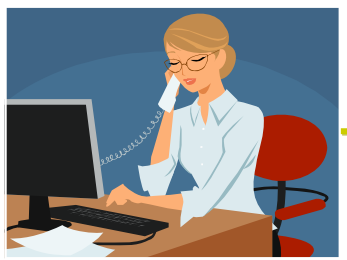
Paper option

• Print paper
• Send with Rx

Local pharmacy scenario

Accessible info databank

Print info
Hand to patient



Paper or paperless option

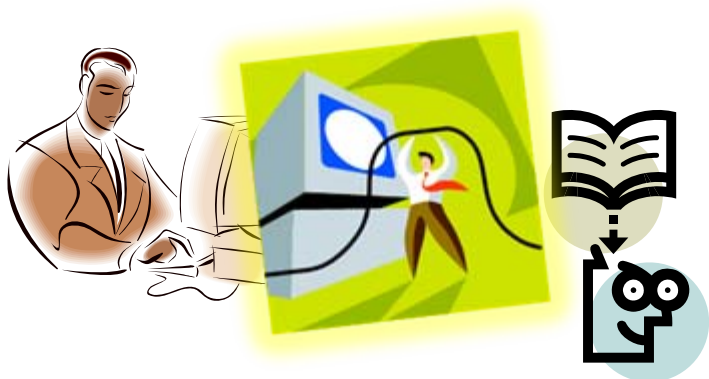
- Send to patient's e-mail
- Access via e-mail
  - Read
  - Save
  - Print

E-document considerations

- Appears on screen (not attachment)
- Patient can search, download, save, print
  - Option for voice-over reading of CMI
- Live links to drill down, training videos, websites
  - Core document formatted to print copy with URLs
- Customization potential
  - Define core of information that *must* be included
  - Allow for choices based on fixed demographic parameters (checklist), e.g., over 65, male or female
  - Who makes choices – patient, dispenser?

Issues for Internet distribution

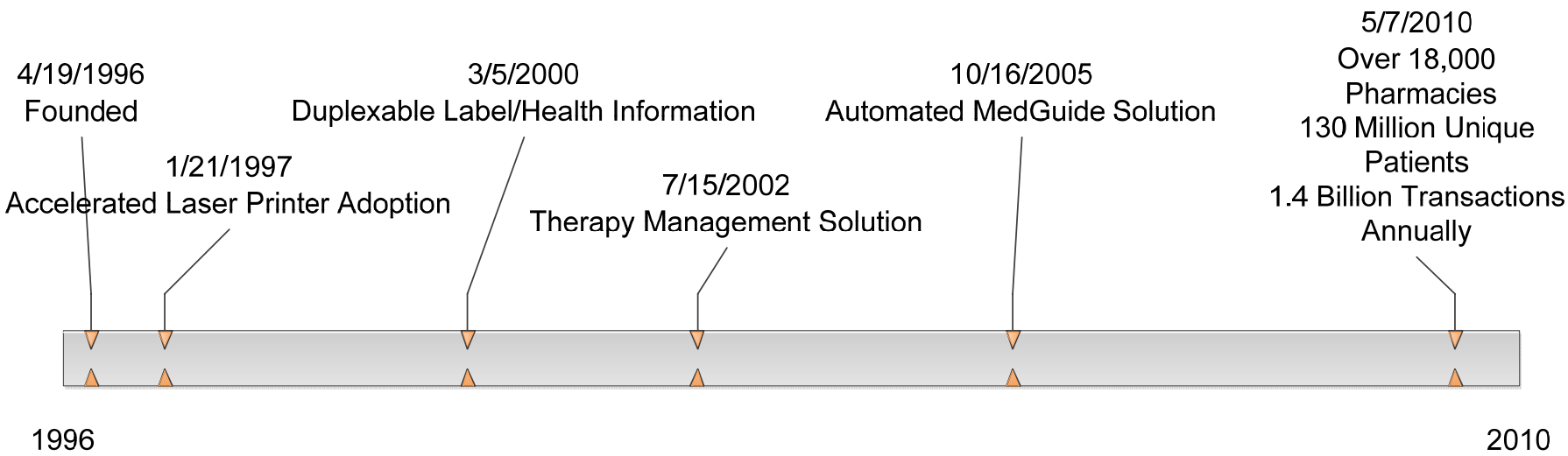
- Databank management and ownership
- Version control issues in databank
  - Who writes, updates, programs, services
- Need for paper options requires keeping documents simple
  - Separate print and e-document files with same content?
- Customization: who chooses what to send?



Baxter Byerly
Vice President Information Technology

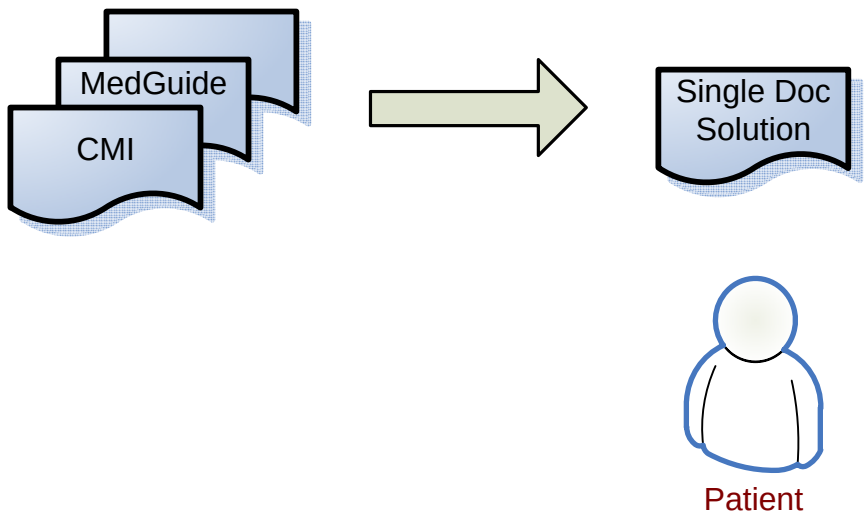
An Introduction to Catalina Health Resource

Catalina Health Resource is a division of
Catalina Marketing Corporation,
headquartered in St. Petersburg, Florida



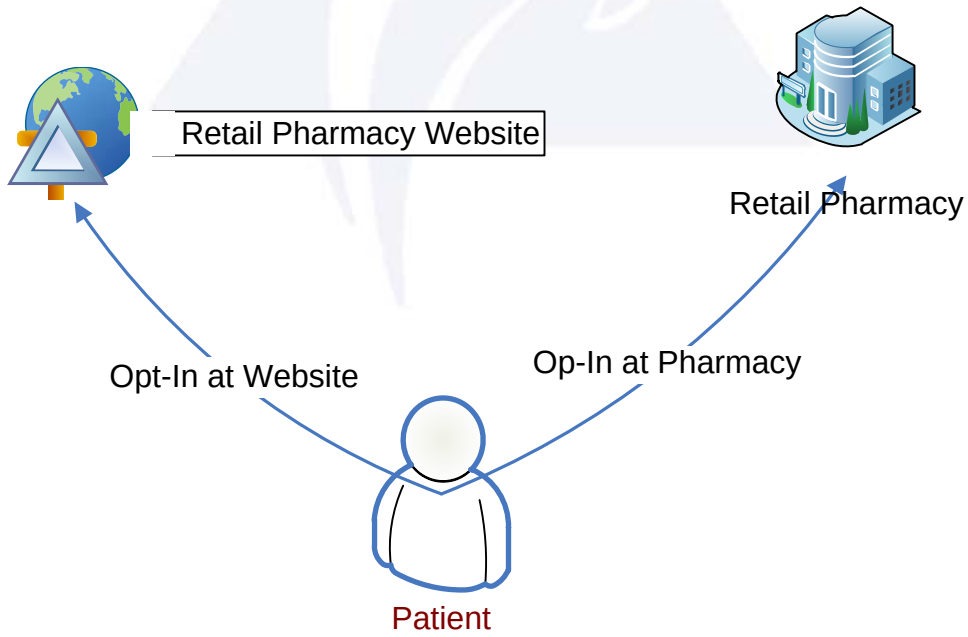
Single Document Solution

- Provide relevant information at the point in time that the patient is most like to respond
- Written from the patient's point of view in clear, easy to understand language
- Real life testing of each format, analyzed to determine the most effective solution



Paper, Digital or Both?

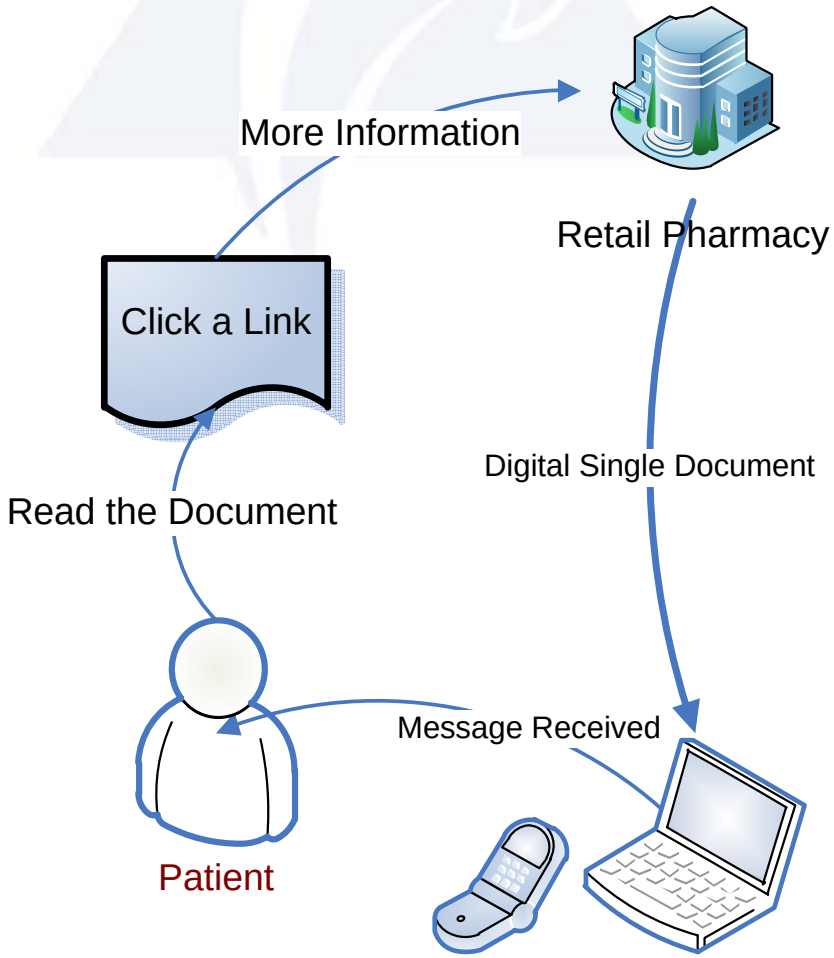
- The paper solution is not going to be replaced anytime soon
- Digital solutions will be opt-in to start, so the patient will have to provide the pharmacy with an email address or mobile number and the preferred method for communication
- When the script is dropped off or sent via an ePrescribing solution, the patient's preference record needs to accessed



If the patient has "opted in" for a digital communication, then no paper message will be printed

Paper, Digital or Both?

- Opting In can be done at the pharmacy, on the web, or by a mobile device
- Email, mobile phone, SMS, IVR, and web all could all be part of the solution
- Patients need to be able to receive information in the format that they desire
- A digital version offers the ability to allow for two way communication
- Links in the digital version could take the patient to additional information sites, or ones that have more details on the medication



How do we get there?

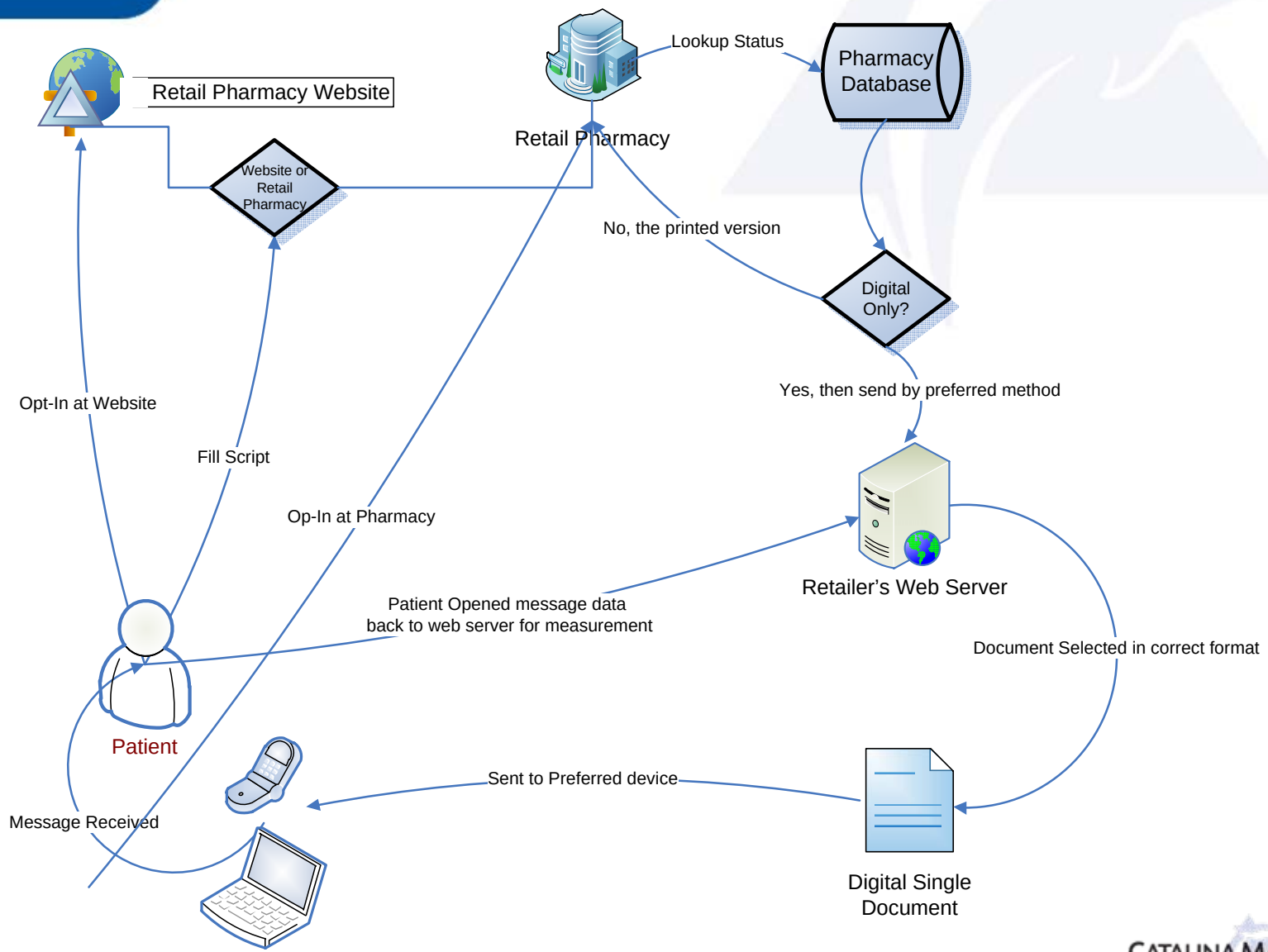
- Pharmacies need to start collecting contact information such as email and mobile phone now in order to have a large enough test group
- Digital version should provide information back to the pharmacy that indicates the message was received and/or opened
- All of this has to be done while protecting PHI, and PII
- Currently pharmacies email patient all the time to let then know that their prescription is ready to be filled, pick-up, etc.
- In each case, no PHI is sent. The message is always limited so that the medication or condition is not revealed
- Even if a patient opts-in for digital communications, there need to be safeguards to protect their privacy
- Since there is no positive way to know the email address provided by the patient is only going to be accessed by the patient, it may be necessary to email a link that then redirects the patient to a secure site

Pilot Options / Conclusion

- Piloting a digital test with a retail pharmacy that has a digital solution for, at a minimum, email
- Create test/control groups using patients that have opted in with matching medical histories of patients that have not
- Run the test for a period of time (6 -12 months) and with a statistically significant sample to determine behavior differences

While digital is the next logical step in the communication process, there is currently not a single step approach that protects PHI and PII

Appendix - What the process might look like



Panel III Lead Respondents

- Art Levin
  Center for Medical Consumers

- Ray Bullman
  National Council on Patient Information and Education

ENGELBERG CENTER for Health Care Reform at BROOKINGS

The Science of Communicating Medication Information to Consumers

Thank you for your participation!