

Exploring the Promise of Patient Medication Information

Engelberg Center for Health Care Reform
The Brookings Institution
Washington, DC
July 1, 2014



PATIENT MEDICATION INFORMATION

Bryon M. Pearsall, JD, RPh

Division Director, Division of Medical Policy Programs
Office of Medical Policy Initiatives
Center for Drug Evaluation and Research

**Exploring the Promise of Patient
Medication Information**

The Brookings Institution
July 1, 2014

For Today

- Brief History
- Proposed Framework
- Next Steps

History

- September 2009: Public workshop on providing effective information to consumers about drug risks and benefits.
- September 2010: Part 15 Public Hearing on new framework for development and distribution of PMI.
- FDA convened a series of expert meetings and public workshops through a cooperative agreement with the Engelberg Center for Health Care Reform at Brookings:
 - Jul 21, 2010: Expert workshop on content and format PMI
 - Oct 12, 2010: Public forum to discuss patient access to effective PMI
 - Feb 23, 2011: Expert workshop that summarized previous activities and considered pilot studies for PMI distribution

Patient Medication Information

- Patient focused document
- Clear, accessible, and actionable information
- Single page
- Consistent and easily understood format
- Provided with outpatient prescription medication
- Intended for use at home
- Not intended to replace patient counseling or instructions for use

PMI Framework

- Development
- Central Repository
- Distribution
- Quality Surveillance

Development

- Created by product manufacturer based on content, format, and testing standards
- Format examples
 - Single page, black ink only, minimum font size (10)
- Content examples
 - Information based on approved prescribing information, predefined headings

Central Repository

- Single accurate PMI data source
- Open access to patients, health care providers, and pharmacies
- Data standards to control format and content
- Key stakeholder of interest in development:
National Library of Medicine

Distribution

Variety of distribution pathways available

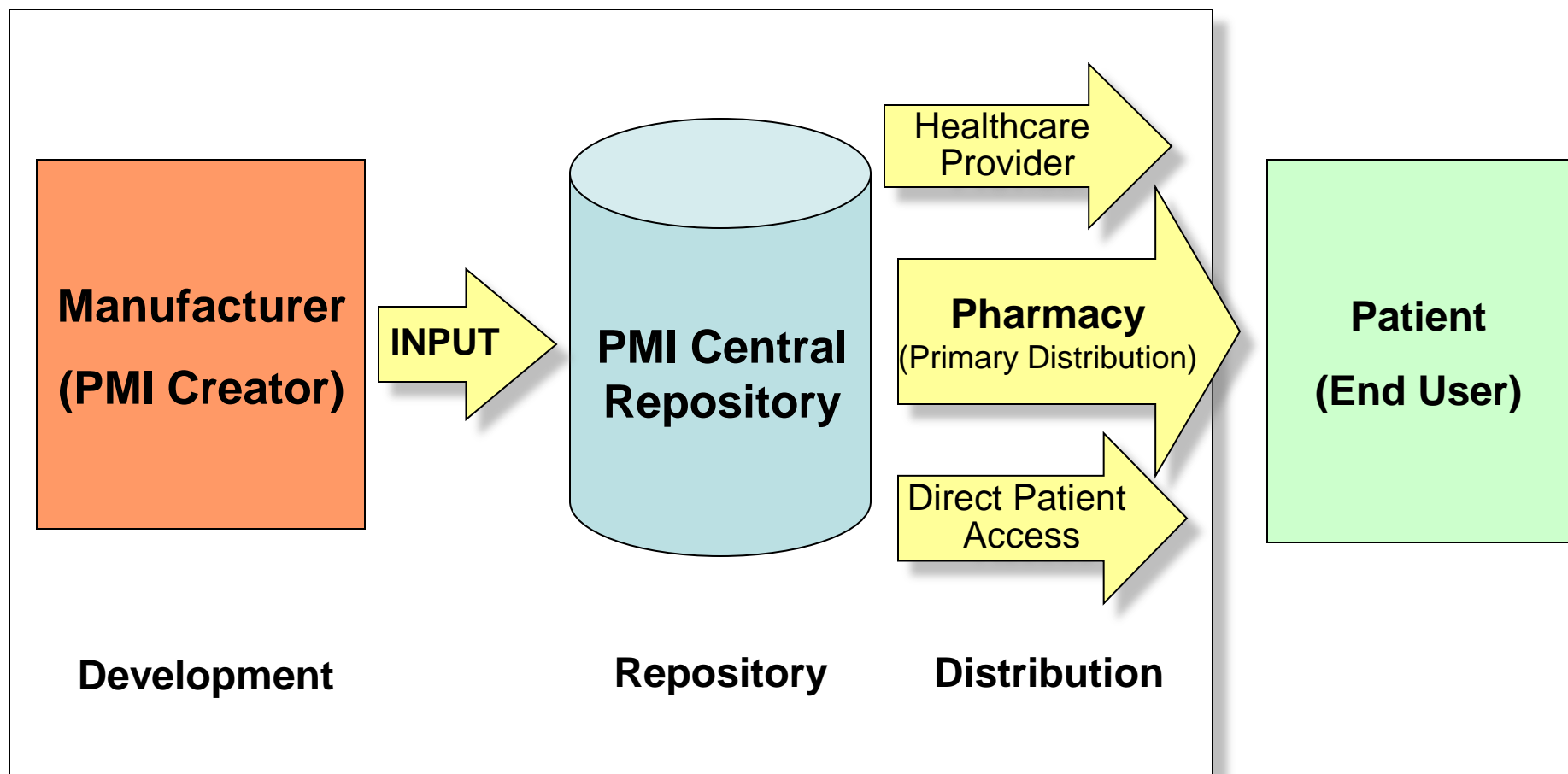
- In pharmacy in paper and electronic formats
- Online via email or other electronic method (QR code)
- Sent to patient in electronic health record

Quality Surveillance

Potential methods may include:

- Review and approval by FDA
- Content based on approved Prescribing Information
- Consumer focused comprehension testing

PMI Framework



Next Steps

- Regulation development
- Central repository development
- Stakeholder outreach and input

Exploring the Promise of Patient Medication Information

Engelberg Center for Health Care Reform
The Brookings Institution
Washington, DC
July 1, 2014



An Evaluation of Two Novel CMI Formats

“Consumers Better Understand and Prefer Simplified Written Drug Information”

Julie L. Aker, MT(ASCP)
President & CEO

Concentrics Research

Presented to The Brookings Institute
Washington, DC

1 July 2014

Acknowledgements

- GSK
 - Julie Papay, Pharm.D.
 - Tom Cantu, Pharm.D.
 - Dan Keravich, RPh., MSc., MBA
- Concentrics
 - Melissa Beck
 - Sara Travis
 - Project Management Team
 - Staff interviewers and Site team

Objectives and Methodology

Objectives

- Obtain consumer input to guide creation and adaptation of a more patient-friendly PMI
- Evaluate
 - Patient preferences on formatting
 - Patient motivation to read
 - Ability to navigate
 - Ability to understand

Methodology & Sample

- One-on-one in-depth interviews
- English-speaking adults, aged 18 years or older
- Consumers assigned to 1 of 3 drugs and rotated into one of six groups
- Interviews started immediately after participants were provided with a copy of the prototype

“New” Format

- Summary information at the top of the page
 - What it is
 - What it does
 - How to take it
 - Possible side effects
- Four major headings of information with a corresponding simple icon:
 - Important Warnings
 - Get Medical Help
 - Ask a Doctor
 - Follow Directions

**Patient Information: What You Need to Know about Taking
ORTHO TRI-CYCLEN™ (norgestimate/ethinyl estradiol)**

Drug Name: ORTHO TRI-CYCLEN tablets
















WHAT is it? • Birth control medication. It is also called the “pill.”

WHAT does it do? • When taken as directed, it prevents pregnancy 99% of the time.

HOW do I take it? • This medicine is taken by mouth.
• Take every day and at the same time each day.
• Follow the instructions in your dose pack.

Possible side effects

- **Common:** Nausea, vomiting, bleeding between menstrual periods, weight gain, breast tenderness, and difficulty wearing contact lenses. These side effects may subside within the first three months of use.
- **Rare:** A spotty darkening of your skin, usually on your face.

IMPORTANT WARNINGS 	<ul style="list-style-type: none"> • Blood clots can occur very rarely, which can lead to heart attack or stroke. • Some medicines can make the pill less effective. Ask your doctor because you will need to use <u>another form of birth control</u> if you are taking these drugs: <ul style="list-style-type: none"> ◦ Antibiotics (such as rifampin, giref/delva) ◦ Some drugs used for epilepsy (such as phenobarbital, phenytoin, carbamazepine, oxcarbazepine, primidone, topiramate) ◦ Some drugs for HIV (such as ritonavir), modafinil, St. John's wort. • ORTHO TRI-CYCLEN does not protect you from getting sexually transmitted diseases.
GET MEDICAL HELP 	<p>Seek medical help (go to the Emergency Room OR call your doctor right away) if you have:</p> <ul style="list-style-type: none"> • Sharp chest pain, are coughing up blood, suddenly feel short of breath, or if you have pain in your calf.  You may have a blood clot. • Crushing chest pain or heaviness in your chest.  You may be having a heart attack. • Sudden severe headache or vomiting, dizziness or fainting, changes in your vision or speech, weakness, or numbness in your arm or leg.  You may be having a stroke. • Sudden loss of your vision.  You may have a clot in your eye. • Severe pain or tenderness in your stomach area.  You may have a ruptured liver tumor or pancreatitis.
ASK A DOCTOR 	<p>While using ORTHO TRI-CYCLEN, ask your doctor if you have:</p> <ul style="list-style-type: none"> • Missed two periods in a row.  You may be pregnant. Talk to your doctor immediately to find out if you are pregnant. Stop taking your pills if you are pregnant. • Unusual vaginal bleeding.  You may have cancer or be pregnant. • Breast lumps.  You may have breast cancer or breast Stereocystic disease. • Skin or eyes that turn yellow (jaundice). Can occur with fever, feeling tired, losing your appetite, dark-colored urine, or light-colored bowel movements.  You may have liver problems. • Fluid retention.  You may have high blood pressure. • Difficulty sleeping, weakness, lack of energy or feeling tired, or a change in your mood.  You may have severe depression.
FOLLOW DIRECTIONS 	<ul style="list-style-type: none"> • Take ORTHO TRI-CYCLEN every day and at the same time each day. If you miss pills you may get pregnant. • If you miss a dose of ORTHO TRI-CYCLEN, follow the instructions in your dose pack. If you are not sure what to do about pills you have missed: <ul style="list-style-type: none"> • Use another form of birth control (such as condoms, spermicide, or contraceptive sponge) anytime you have sex. • Keep taking one pill every day until you can talk to your doctor. <p>If you have vomiting or diarrhea your pills may not work as well. Use another form of birth control (such as condoms, spermicide, or contraceptive sponge) until you check with your doctor.</p>

For more information, visit <http://www.ortho-mcneil.com/ortho-mcneil/>

“Bubble” Format

- Included six categories of information that were outlined by a soft edged box:



- Presented information in chunked bubbles
- Presented by FDA as a possible prototype for further research

ORTHO TRI-CYCLEN™ [or-the try-ty-klen] (also known as norgestimate/ethinyl estradiol)

Uses

- ORTHO TRI-CYCLEN is birth control that you take by mouth each day to prevent pregnancy. It is also called the “pill”.
- When taken as directed, it prevents pregnancy 99% of the time.
- You must take ORTHO TRI-CYCLEN at the same time each day and as directed for it to work.

Important Warning:

- Very rarely, ORTHO TRI-CYCLEN can cause blood clots that may lead to heart attack or stroke.
- Some medicines can make the pill less effective. Ask your doctor because you will need to use another form of birth control if you are taking these drugs:
 - Antibiotics (such as rifampin, rifabutin)
 - Some drugs used for epilepsy (such as phenytoin, phenylethylamine, carbamazepine, oxcarbazepine, primidone, topiramate)
 - Some drugs for HIV (such as ritonavir), modafinil, St. John’s wort
- ORTHO TRI-CYCLEN does not protect you from getting sexually transmitted diseases.

Tell Your Doctor

Before using ORTHO TRI-CYCLEN, tell your doctor if you have:

- Breast nodules, breast fibrocystic disease, an abnormal breast X-ray or mammogram
- Diabetes
- High cholesterol or triglycerides
- High blood pressure
- A tendency to form blood clots
- Migraine headaches or other headaches or epilepsy
- Major depression
- Gallbladder, heart, or kidney disease
- History of scanty or irregular menstrual periods

Call Your Doctor Right Away if you have:

- Missed two periods in a row. You may be pregnant. Talk to your doctor immediately to find out if you are pregnant. Stop taking your pills if you are pregnant.
- Sharp chest pain, coughing up blood, suddenly feel short of breath, or if you have pain in your calf. You may have a blood clot.
- Crushing chest pain or heaviness in your chest. You may be having a heart attack.
- Sudden severe headache or vomiting, dizziness or fainting, changes in your vision or speech, weakness, or numbness in your arm or leg. You may be having a stroke.
- Sudden loss of your vision. You may have a clot in your eye.
- Breast lumps. You may have breast cancer or breast fibrocystic disease.
- Severe pain or tenderness in your stomach area. You may have a ruptured liver tumor or pancreatitis.
- Difficulty sleeping, weakness, lack of energy, fatigue, or change in mood. You may have severe depression.
- Skin or eye: that turn yellow (jaundice). This can occur with fever, feeling tired, losing your appetite, dark-colored urine, or light-colored bowel movement. You may have liver problems.
- Unusual vaginal bleeding. You may have cancer or you may be pregnant.
- Fluid retention. You may have high blood pressure.

Common Side Effects:

- Nausea, vomiting, bleeding between menstrual periods, weight gain, breast tenderness, and difficulty wearing contact lenses. These side effects may subside within the first three months of use.
- A spotty darkening of your skin, usually on your face.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

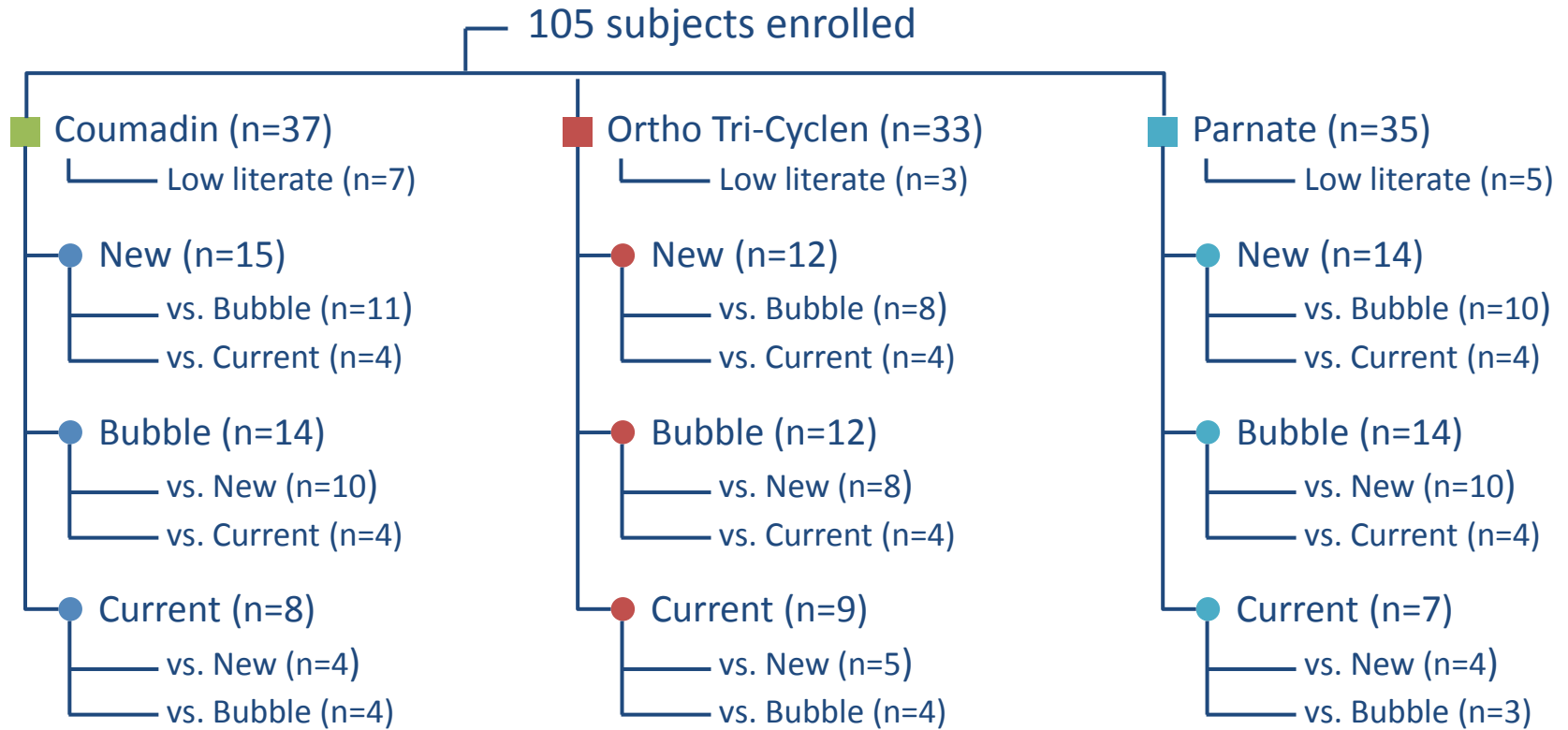
Directions for Use

Follow the detailed instructions that are included with your dose pack.

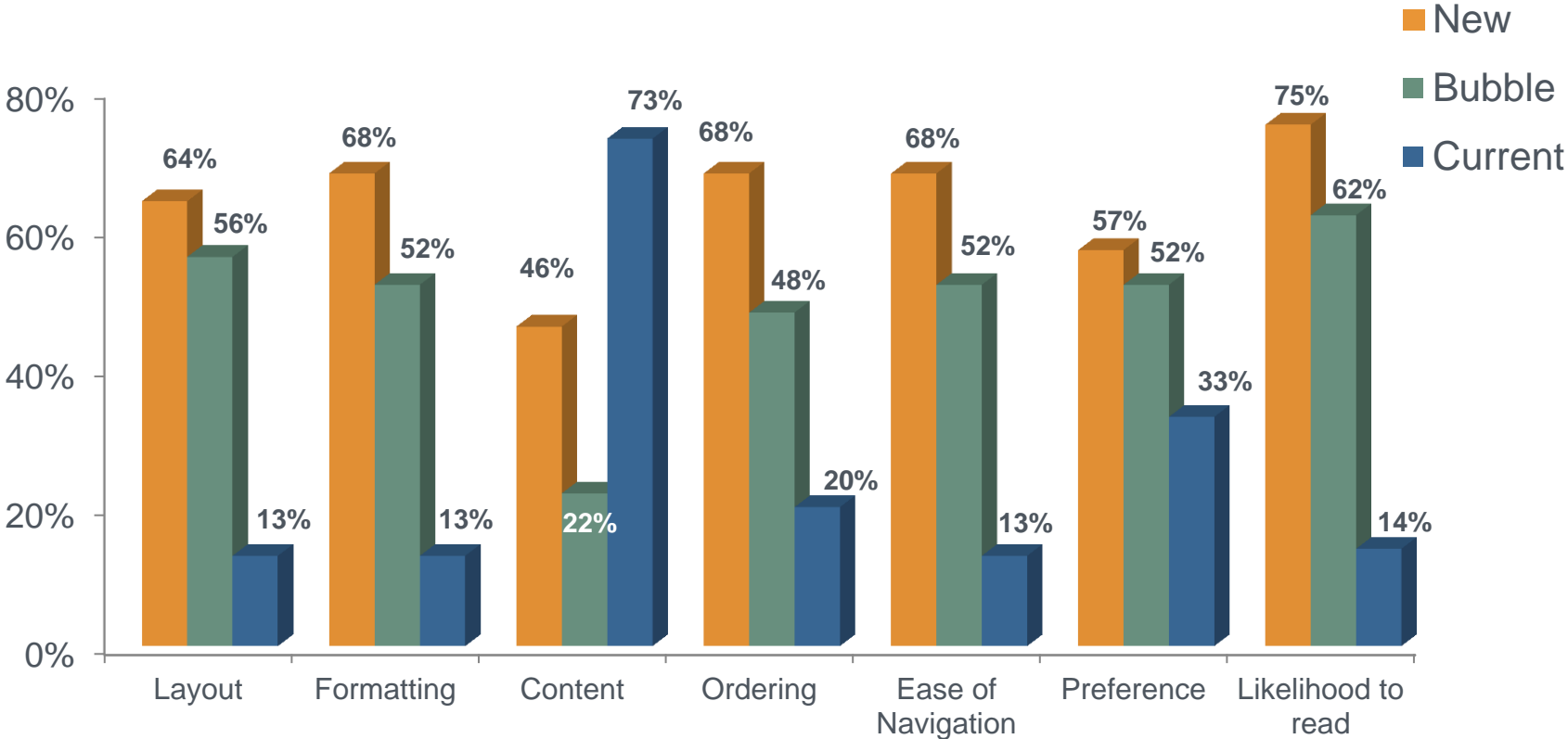
Current CMI

The “Current” CMI for each medication was obtained from a large pharmacy chain store and was provided to participants without further modification.

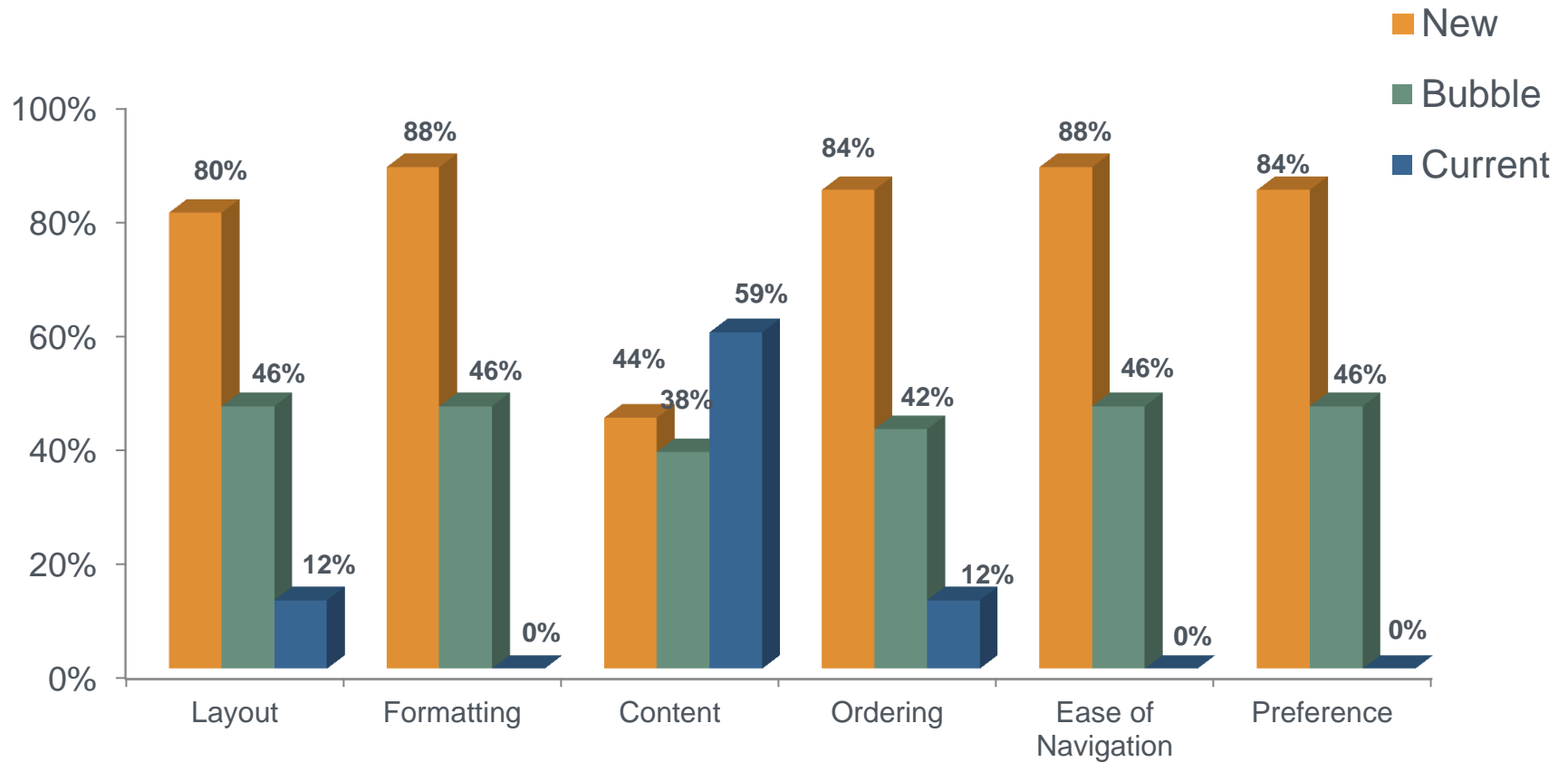
PMI Distribution



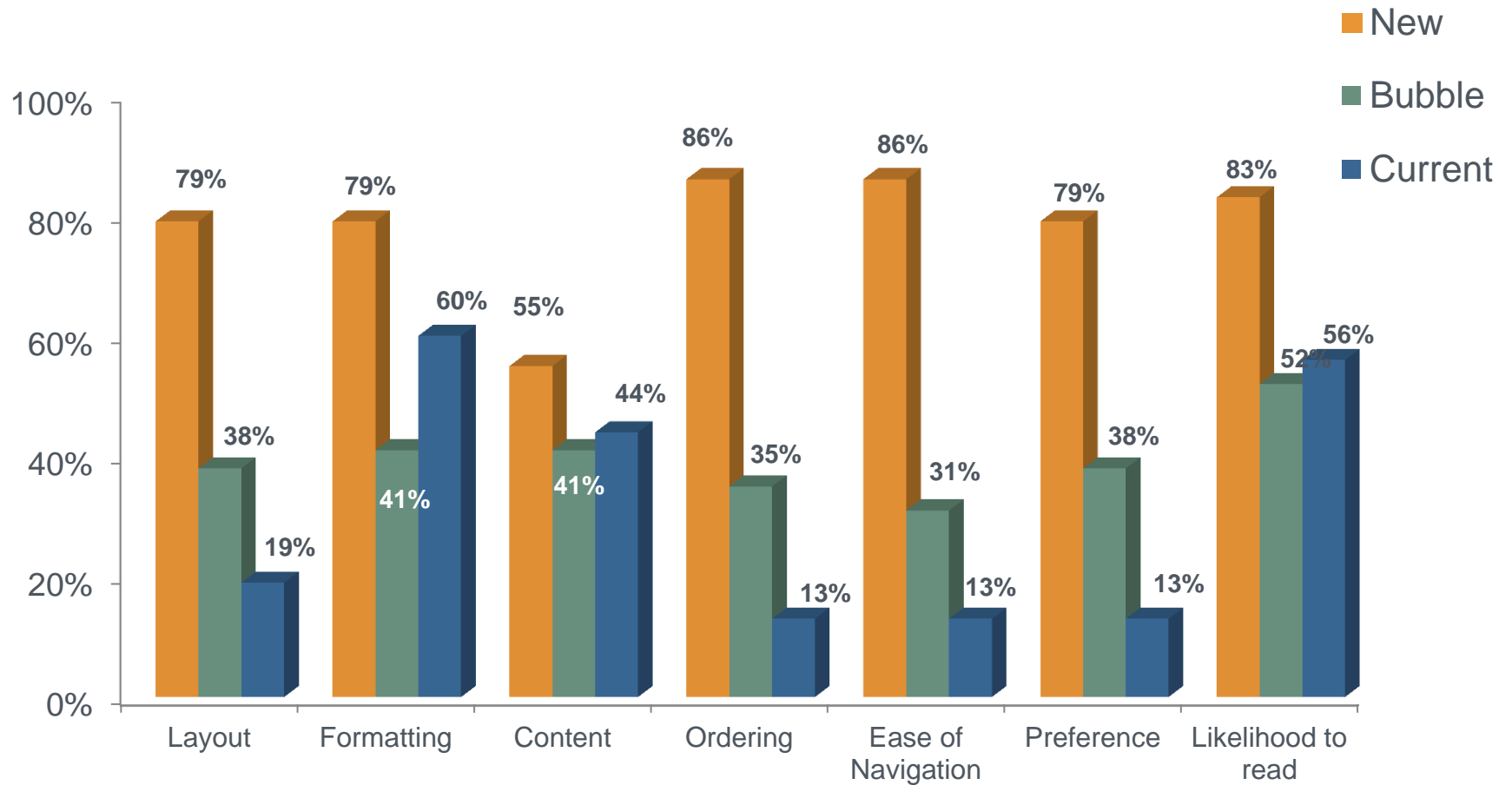
Coumadin



Ortho Tri-Cyclen



Parnate



Do simple pictures/icons help?

How would you rate the use of pictures (or icons)?

Ortho Tri-Cyclen

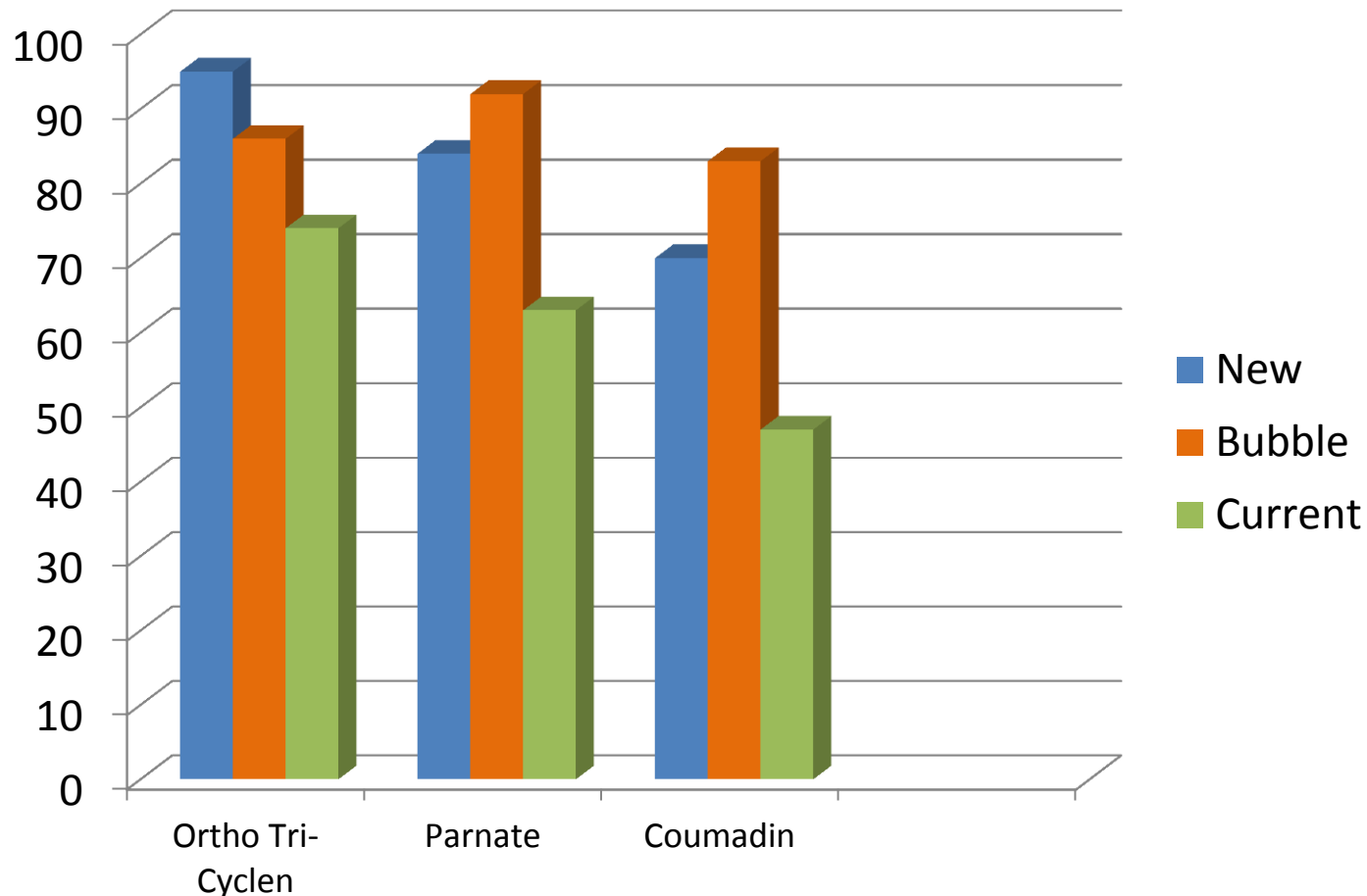
Parnate

Coumadin

Total Responding:	25		28		30	
	n	%	n	%	n	%
The pictures <i>made it</i> easier to find information	19	76.0%	22	78.6%	27	90.0%
The pictures made <i>no difference</i> in finding information	5	20.0%	5	17.9%	3	10.0%
The pictures made it <i>more difficult</i> to find information	1	4.0%	1	3.6%	--	--

Ability to Understand

Participants correctly answered more questions with New and Bubble PMI than current CMI



Asked up to 10 questions relating to specific sections on the PMI.

Key Findings

- Participants prefer PMI presented in a table format with icons.
- Format strongly influences consumers' propensity to read PMI.
 - A visually inviting format may motivate consumers to read and understand PMI.
- Participants preferred simple, clear statements in lay terminology.

Patient Information: What You Need to Know about Taking ORTHO TRI-CYCLEN™ (norgestimate/ethinyl estradiol)





Drug Name: ORTHO TRI-CYCLEN tablets

WHAT is it? • Birth control medication. It is also called the "pill".

WHAT does it do? • When taken as directed, it prevents pregnancy 99% of the time.

HOW do I take it? • This medicine is taken by mouth.
• Take every day and at the same time each day.
• Follow the instructions in your dose pack.

Possible side effects • **Common:** Nausea, vomiting, bleeding between menstrual periods, weight gain, breast tenderness, and difficulty wearing contact lenses. These side effects may subside within the first three months of use.
• **Rare:** A spotty darkening of your skin, usually on your face.

IMPORTANT WARNINGS 	<ul style="list-style-type: none"> • Blood clots can occur very rarely, which can lead to heart attack or stroke. • Some medicines can make the pill less effective. Ask your doctor because you will need to use <u>another form of birth control</u> if you are taking these drugs: <ul style="list-style-type: none"> ◦ Antibiotics (such as rifampin, griseofulvin) ◦ Some drugs used for epilepsy (such as phenobarbital, phenytoin, carbamazepine, oxcarbazepine, primidone, topiramate) ◦ Some drugs for HIV (such as zalcitabine, didanosine, St. John's wort) • ORTHO TRI-CYCLEN does not protect you from getting sexually transmitted diseases.
GET MEDICAL HELP 	<p>Seek medical help (go to the Emergency Room OR call your doctor right away) if you have:</p> <ul style="list-style-type: none"> • Sharp chest pain, are coughing up blood, suddenly feel short of breath, or if you have pain in your calf. → You may have a blood clot. • Crushing chest pain or heaviness in your chest. → You may be having a heart attack. • Sudden severe headache or vomiting, dizziness or fainting, changes in your vision or speech, weakness, or numbness in your arm or leg. → You may be having a stroke. • Sudden loss of your vision. → You may have a clot in your eye. • Severe pain or tenderness in your stomach area. → You may have a ruptured liver tumor or pancreatitis.
ASK A DOCTOR 	<p><u>While using ORTHO TRI-CYCLEN, ask your doctor if you have:</u></p> <ul style="list-style-type: none"> • Missed two periods in a row. → You may be pregnant. Talk to your doctor immediately to find out if you are pregnant. Stop taking your pills if you are pregnant. • Unusual vaginal bleeding. → You may have cancer or be pregnant. • Breast lumps. → You may have breast cancer or breast fibrocystic disease. • Skin or eyes that turn yellow (jaundice). Can occur with fever, feeling tired, losing your appetite, dark-colored urine, or light-colored bowel movements. → You may have liver problems. • Fluid retention. → You may have high blood pressure. • Difficulty sleeping, weakness, lack of energy or feeling tired, or a change in your mood. → You may have severe depression.
FOLLOW DIRECTIONS 	<ul style="list-style-type: none"> • Take ORTHO TRI-CYCLEN every day and at the same time each day. If you miss pills you may get pregnant. • If you miss a dose of ORTHO TRI-CYCLEN, follow the instructions in your dose pack. If you are not sure what to do about pills you have missed: <ul style="list-style-type: none"> • Use another form of birth control (such as condoms, spermicide, or contraceptive sponge) anytime you have sex. • Keep taking one pill every day until you can talk to your doctor. <p><i>If you have vomiting or diarrhea your pills may not work as well. Use another form of birth control (such as condoms, spermicide, or contraceptive sponge) until you check with your doctor.</i></p>

For more information, visit <http://www.ortho-mcneil.com/ortho-mcneil/>

Key Findings – Need for Flexibility

- Elements of patient-friendly PMI should consider the target population for the drug (e.g., age, gender, medical conditions, etc.), key warnings with directions on actions to take, ordering of information, and prominence of information.
- While certain format and design attributes scored better in either the “New” or “Bubble” prototypes, it is clear that some degree of flexibility may be required, based on the unique warnings with each drug.
- Thus, the ability for some customization of PMI should be permitted so that key information can be appropriately highlighted.



SUMMARY

Creating Engaging PMI: The Next Chapter

- These studies demonstrate the importance and value of obtaining consumer feedback to adopt more patient friendly PMI.
- When PMI is presented in a simplified format with clear directives, patients can efficiently find information and understand the actions to take.
- These data have been shared with FDA; evidence continues to be generated & dialogue continues with FDA as they evaluate all data.



THANK YOU!

Contact Information:

Julie L. Aker
President & CEO
Concentrics Research

julie.aker@concentricsresearch.com

1.973.737.7107

Exploring the Promise of Patient Medication Information

Engelberg Center for Health Care Reform
The Brookings Institution
Washington, DC
July 1, 2014



Improvements in Patient Labeling

July 1, 2014

Michael S. Wolf, PhD MPH

Professor, Medicine and Learning Sciences
Associate Division Chief - Research
Division of General Internal Medicine
Feinberg School of Medicine
Northwestern University

Overview

- Objective: Share process and results from a new approach to developing and testing patient labeling
- Partnership between Merck and health literacy experts
 - External Health Literacy Leaders (Northwestern & Emory Universities)
 - Michael Wolf, PhD, MPH
 - Ruth Parker, MD
 - Kara Jacobson, MPH
 - Cross Divisional Working Team at Merck (established in 2011)
 - Health Literacy Strategy
 - Office of CMO (Chief Medical Officer)
 - Legal
 - Regulatory
 - Labeling
 - Marketing
 - Market Research

Patient Labeling Pilot

- Purpose
 - Demonstrate increased patient understanding and use by optimizing development and testing of PPI for a type of skin cancer
- Partnership
 - Merck identified an opportunity to engage leaders in the field of health literacy to leverage their expertise to improve patient labeling and create internal best practices
 - Academia recognized an opportunity to put best practices into use in patient labels used by many patients

Patient Labeling Pilot

- Merck's past approach to patient labeling testing
 - Merck included a range of education levels in PPI testing; however, few respondents presented with limited health literacy
 - These individuals are harder to locate and less likely to participate in research.
 - Ensuring the comprehension of the research task and quality of their responses required application of best practices from the field of health literacy
 - Directionally, limited health literacy respondents had lower comprehension scores than those with adequate health literacy

Process Overview: Patient Labeling Development and Testing

PPI sent to
Nationally
Recognized
Health Literacy
Experts

- Nationally recognized experts applied health literacy principles to patient labeling
- Patient Label draft approved by sponsor with minimal changes

Externally
Conducted Focus
Groups

- Two focus conducted in Chicago and Atlanta
- Patient Label revised and sent to sponsor

Merck Internal
Research

- Qualitative research with limited and adequate health literacy respondents
(Phase 1 (n=100) & Phase 2 (n=30))
- Labeling revised after each phase with patient input

Draft Patient Label

TRADENAME®
(generic)

For Treatment of a Type of Skin Cancer

What You Need to Know about Your Medicine

Before you take this medicine, read this patient information.

- Keep this information. You may have questions about this medicine later.
- If you have questions, talk to your doctor or pharmacist.
- Every time you get a refill, look at the patient information. There may be new information.



What is TRADENAME?

TRADENAME is a medicine for a type of skin cancer. People take TRADENAME when their cancer gets worse, does not go away, or comes back after they have taken other medicines.

Should I take TRADENAME?

Pregnancy

- TRADENAME can hurt your baby.
- If you are pregnant or trying to get pregnant, tell your doctor right away. You might need to stop taking TRADENAME.

Breastfeeding

- We don't know if TRADENAME stays in your breast milk and gets passed to your baby.
- If you are breastfeeding, ask your doctor what to do. You might need to stop breastfeeding.

If you have any of these conditions, tell your doctor:

- a blood clot in your lung (called a Pulmonary Embolus or PE)
- a blood clot in a vein or blood vessel (called Deep Vein Thrombosis or DVT)
- high blood sugar (hyperglycemia) or diabetes
- liver disease
- nausea, vomiting or diarrhea
- any allergies

1

Other medicines

Tell your doctor about all of the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Other medicines can affect the way TRADENAME works.

- If you take valproic acid, a medicine for seizures, tell your doctor. Your doctor will decide if you should keep taking this seizure medicine.
- If you take a blood thinner, like Coumadin® (warfarin), your doctor may want to do blood tests more often.

How do I take TRADENAME?

- Most people take 4 capsules at the same time every day.
- Ask your doctor how many capsules you should take and when to take them.
- The recommended dose is 400 mg one time a day. Each capsule is 100 mg.
- If you take the recommended dose, you will take 4 capsules all at once.

When you take TRADENAME...

- Eat some food.
- Drink 8 glasses of water every day (at least 8 ounces each). This will keep you hydrated, especially when you are having nausea, vomiting or diarrhea.
- Do not chew or break open the capsule.
- If you can't swallow the capsule whole, tell your doctor. You may need a different medicine.

What if my TRADENAME breaks or gets crushed?

- If you open or crush a capsule, do not touch the capsule or powder. If the powder gets on your skin or in your eyes, wash your skin or eyes with lots of water right away. Then, call your doctor.
- Use a paper towel to clean up the capsule or powder. Then, put the medicine and paper towel in a sealed plastic bag (so that it doesn't hurt the environment) and throw it away in the trash.

What if I forget to take TRADENAME?

- If you miss a dose, take it as soon as you remember. If you do not remember until it is almost time for your next dose just skip the missed dose, and take the next dose at your regular time. Do not take two doses of TRADENAME at the same time.
- If you are not sure what to do, call your doctor.
- If you do take too much, call your doctor, poison center, or emergency room right away.

2

Draft Patient Label

Watch out for serious side effects

Be on the lookout for these serious side effects, and tell your doctor right away if you have any of the following symptoms:

Signs of a blood clot in your legs- "Deep Vein Thrombosis" or "DVT"

- Your leg swells up or feels warm
- Your leg hurts when you stand or walk
- Your leg hurts or feels very tender
- Your skin turns red or a strange color

Signs of a blood clot in your lungs- "Pulmonary Embolus" or "PE"

- You have sudden sharp chest pain
- Your heart is beating very fast
- You feel short of breath
- You feel like you might pass out
- You cough up blood
- You feel very anxious
- You start sweating

Signs of being dehydrated

- If you can't eat or drink like you usually do because you feel sick, vomit, or have diarrhea, call your doctor.

Signs of changes in your blood

Your doctor will check your blood. Here is a list of some side effects that might mean you have a change in your blood counts. Ask your doctor when you need to have your blood checked.

- You feel more tired than usual
- You look pale
- You have bleeding or your skin is bruising easily
- You feel short of breath

Common side effects

- Diarrhea
- No bowel movement
- Nausea
- Vomiting
- Not hungry
- Losing weight
- Dry mouth
- Losing hair
- Change in the way things taste
- Muscle aches
- Itchy skin
- Feeling tired
- Feeling dizzy
- Swelling in the foot, ankle and leg
- Cold
- Cough
- Chills
- Fever
- Headaches

If you have any side effect that bothers you or that does not go away, tell your doctor.

There may be other side effects to TRADENAME that are not listed. For information, ask your doctor or pharmacist. You can also report side effects to FDA at 1-800-FDA-1088.

3

What if I have diabetes?

If you are taking TRADENAME and have high blood sugar (hyperglycemia) or diabetes:

- Your doctor may need to change your diet or diabetes medicine to help control your blood sugar.
- Check your blood sugar as often as your doctor tells you to. If your blood sugar is higher than normal, call your doctor.
- If you can't eat or drink like you usually do because you feel sick, vomit, or have diarrhea, call your doctor.

Where should I keep TRADENAME?

- Don't let your medicine get really cold or really hot. Keep it at room temperature, which is 68° to 77° Fahrenheit (F) or 20° to 25° Celsius (C).
- Keep TRADENAME (and all medicines) out of the reach of children.

What else do I need to know?

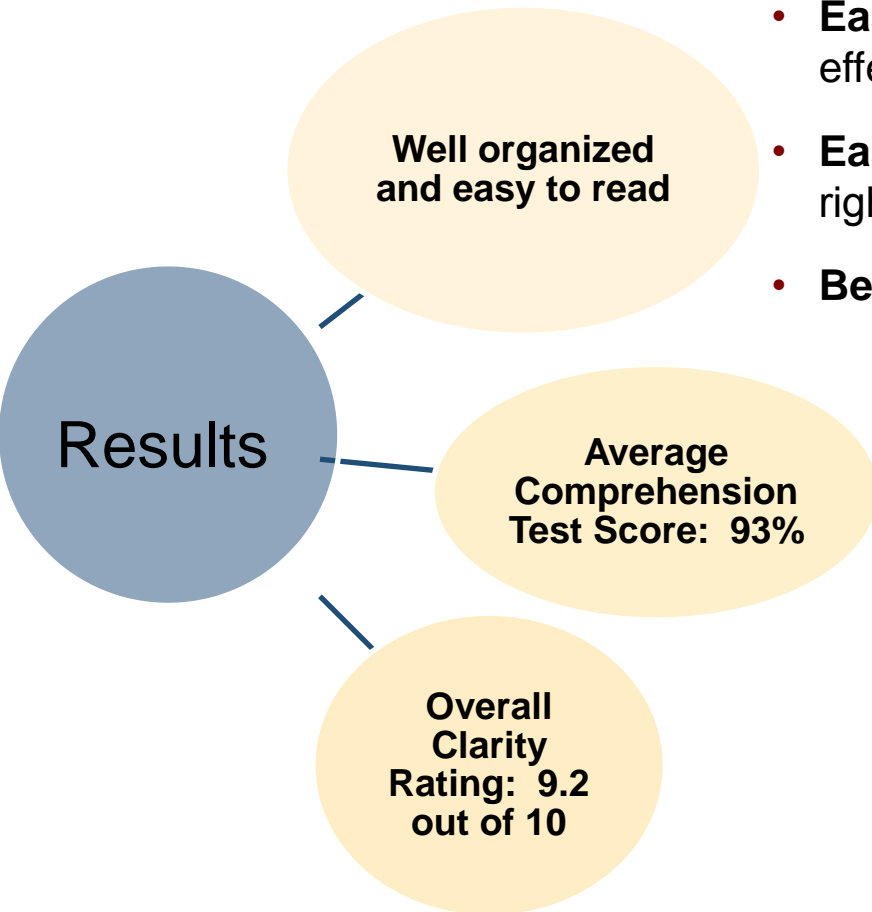
Medicines are sometimes prescribed for conditions that are not mentioned here.

What if I have questions?

- Call your doctor or pharmacist.
- Call Merck, the company that makes TRADENAME, at 1-800-622-4477.

4

Final Results: Comprehension Strong, Patient Labeling Well Received



- **Easy to understand:** What it treats, potential side effects, and how to store it
- **Easy to read:** Clear sections, font size, and “just right” amount of information
- **Better than others:** Less wordy and less confusing

• Strong comprehension by respondents with both adequate and limited health literacy

Limited Health Literacy	Adequate Health Literacy
91%	95%

Key Learnings

- Patient Labeling Research:
 - Must include a broad range of respondents across all health literacy levels
 - Must be an iterative process that incorporates patient feedback at each step
- Partnership between academia and industry is key to developing patient centric communications
- It is possible to achieve patient labeling that is well understood by individuals of all health literacy levels

Exploring the Promise of Patient Medication Information

Engelberg Center for Health Care Reform
The Brookings Institution
Washington, DC
July 1, 2014



Experimental Study of Patient Information Prototypes



Murewa Oguntimein, M.H.S., CHES.

Social Science Analyst, Division of Medical Policy Programs
Office of Medical Policy Initiatives
Center for Drug Evaluation and Research

Exploring the Promise of Patient
Medication Information

The Brookings Institution
July 1, 2014

Overview

- Purpose of Study
- Prototype Description
- Review of Study Phases and Results
- Conclusion

Purpose of Study

- Evaluation of PMI prototypes
 - Assess comprehension and readability in individuals with and without chronic health conditions
 - Examine the impact on outcomes including perceived risk, comprehension, and behavioral intentions

Prototype Development Process

- Reviewed:
 - Scientific literature
 - Current labeling practices and guidance
 - Stakeholder feedback
- Recommendations:
 - Use less complex terminology
 - Present text in shorter sentences
 - Offer more organized or “chunked” text
 - Include section headings, bullets, and other design elements

Rheutopia

- Fictitious drug
- Description of Rheutopia
 - Multiple indications
 - Several serious risks (includes boxed warning)
 - Administered by injection

Rheutopia [Roo-TOH-pee-ah] (also known as arixalate)

Uses

- Rheumatoid arthritis in adults. Rheutopia reduces painful and swollen joints, slows joint damage, and improves mobility and the ability to do physical activities.
- Polyarticular juvenile rheumatoid arthritis in children at least 4 years old who did not have good results from other medicines. Rheutopia reduces pain, improves mobility, and decreases the number of painful joints.
- Ankylosing spondylitis. Rheutopia reduces back pain, swelling, and improves mobility.
- Plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy (using ultraviolet light). Rheutopia improves or clears up areas of skin with psoriasis.

Important Warning: Serious Infections

- Rheutopia affects the immune system. It can lower your ability to fight infections. Do not use Rheutopia if you have an active infection.
- People taking Rheutopia have gotten serious infections including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some people have died from these infections.

Before using Rheutopia

Tell Your Doctor if you:

- have an infection, are being treated for an infection, or think you have an infection (such as a cold, flu or skin infection).
- have TB or have been near someone who has TB.
- have any nervous system or heart problems.
- have lived in or traveled to other countries.
- have recently been vaccinated or are scheduled to receive a vaccination (including a flu shot).
- are taking the medicine Kineret (anakinra).

Stop using Rheutopia

Call Your Doctor right away if you develop:

- Fever, cough, flu-like symptoms, skin infection (red, warm, painful skin or open sores).
- Numbness, tingling, weakness, vision problems, or dizziness.
- Chills, swollen lymph nodes, night sweats, fever, or weight loss.
- Bruising, bleeding, and pale skin.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms.

Common Side Effects

- Redness, rash, swelling, itching or bruising where the shot was given.
- Headache
- Runny nose

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use

- Rheutopia is an injection (shot). Do not use Rheutopia until your doctor has shown you how to give a shot.
- Store Rheutopia in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheutopia. Do not use Rheutopia more often than prescribed.

Drug Approved by FDA: 2005
Last Revised: May 2009

Rheuptopia [Roo-TOH-pee-ah] (also known as arixalate)

Uses

- Rheumatoid arthritis in adults. Rheuptopia reduces painful and swollen joints, slows joint damage, and improves mobility and the ability to do physical activities.
- Polyarticular juvenile rheumatoid arthritis in children at least 4 years old who did not have good results from other medicines. Rheuptopia reduces pain, improves mobility, and decreases the number of painful joints.
- Ankylosing spondylitis. Rheuptopia reduces back pain, swelling, and improves mobility.
- Plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy (using ultraviolet light). Rheuptopia improves or clears up areas of skin with psoriasis.

Important Warning: Serious Infections

- Rheuptopia affects the immune system. It can lower your ability to fight infections. Do not use Rheuptopia if you have an active infection.
- People taking Rheuptopia have gotten serious infections including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some people have died from these infections.

Before using Rheuptopia, tell your doctor if you:

- have an infection, are being treated for an infection, or think you have an infection (such as a cold, flu or skin infection).
- have TB or have been near someone who has TB.
- have any nervous system or heart problems.
- have recently been vaccinated or are scheduled to receive a vaccination (including a flu shot).
- have lived in or traveled to other countries.
- are taking the medicine Kineret (anakinra)

Stop using Rheuptopia and call your doctor right away if you develop:

- Fever, cough, flu-like symptoms, a skin infection (red, warm, painful skin or open sores).
- Numbness, tingling, weakness, vision problems, or dizziness.
- Chills, swollen lymph nodes, night sweats, fever, or weight loss.
- Bruising, bleeding, and pale skin.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms.

Common side effects

- Redness, rash, swelling, itching or bruising where the shot was given.
- Headache
- Runny nose

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for use

- Rheuptopia is an injection (shot). Do not use Rheuptopia until your doctor has shown you how to give a shot.
- Store Rheuptopia in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheuptopia. Do not use Rheuptopia more often than prescribed.

Medication Guide

**RHEUTOPIA® (ROO-TOH-PEE-AH)
(arixalate)**

Read this information that comes with RHEUTOPIA before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment with RHEUTOPIA.

What is the most important information I should know about RHEUTOPIA?

Serious infections can happen in people who receive RHEUTOPIA. These infections include TB (tuberculosis), and infections caused by viruses, fungi or bacteria. Some people have died from these infections. RHEUTOPIA is a medicine that affects your immune system. RHEUTOPIA can lower the ability of your immune system to fight infections. RHEUTOPIA can make you more likely to get infections or make worse any infection that you have.

Before starting RHEUTOPIA, tell your doctor if you:

- think you have an infection
- are being treated for an infection
- have signs of an infection, such as a fever, cough, or flu-like symptoms
- have any open cuts or sores on your body
- have warm, red, or painful skin
- get a lot of infections or have infections that keep coming back
- have TB, or have been in close contact with someone who has TB.
- have lived in an area where TB is common. If you do not know if you have lived in an area where TB is common, ask your doctor.
- were born in, lived in, or traveled to countries where there is a higher risk for getting TB. Ask your doctor if you are not sure.
- take the medicine Kineret (anakinra) or other medicines that suppress the immune system. You may have a higher chance for serious infections and a low white blood cell count when taking RHEUTOPIA with Kineret or other medicines that can suppress your immune system

Your doctor will examine you for TB and perform a test to see if you have TB before starting RHEUTOPIA. If your doctor feels that you are at risk for TB, you may be treated with a medicine for TB before you begin treatment with RHEUTOPIA and during treatment with RHEUTOPIA. If your doctor prescribes any medicine for the treatment of TB, you should start taking it before starting RHEUTOPIA. Take the full course of TB medicine prescribed. Even if your TB test is negative your doctor should carefully monitor you for TB infections while you take RHEUTOPIA. People who have a negative TB test before receiving RHEUTOPIA can develop active TB.

Call your doctor right away if you get an infection or any of the following symptoms:

- a fever
- flu-like symptoms
- feel very tired
- have any open cuts or sores on your body
- weight loss
- warm, red, or painful skin
- a cough that does not go away

What is RHEUTOPIA?

RHEUTOPIA is a medicine called a Tumor Necrosis Factor (TNF) blocker. RHEUTOPIA is used to treat:

- **moderate to severe rheumatoid arthritis (RA)** in adults. RHEUTOPIA can be used alone or with methotrexate or with certain other medicines.
- **Moderate to severe polyarticular juvenile rheumatoid arthritis (JRA)** in children who have not responded well to other treatments.

1

Its who
tions or
make

it
orse while

uch as

TOPIA

er chance

on
uppress

macist

ding.
eding

ten who
her and
555.

plete

ur doctor

You can
an

If you

2

a dose as soon
This will put you

TOPIA?"

r.
e a higher

m include:
and dizziness.

fight
away, bruising

toms include

rest discomf
cheeks or
TOPIA.

bove

If you have
a few days or

By. These are
more

o FDA at 1-800-

iginal container

it, even after it
e expiration

ixed.

3

Do
to

d like
on

23-

um

4

Study Phases

Phase 1

- **Formative research**
- Explore preferences across different versions of the PMI prototypes for: Format, Font, Order of information and Context

Phase 2

- **Pretest and Main Experimental Study**
- Obtain an empirically based comparison of several PMI prototypes to determine whether any one version resulted in better comprehension of the information, increased perceived risk, or increased ease of understanding

Phase 1: Formative Research

Purpose:

- To explore preferences across different versions of the PMI prototypes:
 - Format: OTC or Bubbles
 - Font: Arial or Times New Roman
 - Order of Information: Directions first or Warning first
 - Context: With context or No context

Phase 1: Formative Research Design

- One-On-One interviews
- English-speaking adults (n=90)
- Three population segments:
 - Target medical condition diagnosis
 - Chronic condition requiring a non-pill medication (e.g., injectable, inhaler)
 - General population
- Recruitment
 - Recruited through local rheumatology clinics and focus group facilities
 - Over sampled lower literacy individuals

Phase 1: Results

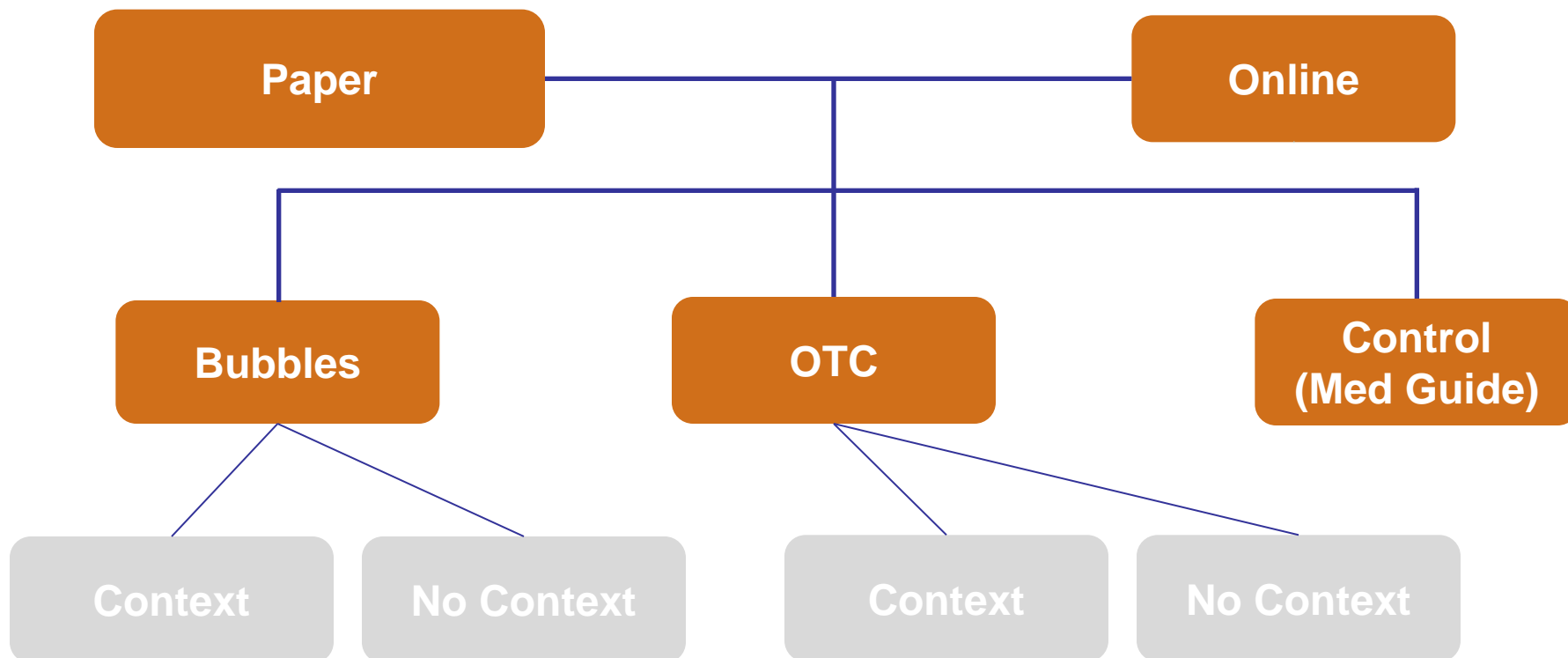
- The prototypes were preferred by most participants over the current patient information they receive.
- Participants preferred the Bubbles format over the OTC format
- Participants preferred Arial font over the Times New Roman font
- Findings for Order and Context preference were mixed

Phase 2: Main Experiment

Purpose:

- To obtain a large scale quantitative comparison of the PMI prototypes (Bubbles and OTC) to the Medication Guide prototype.
- To determine if any one PMI prototype resulted in:
 - Better comprehension of the information
 - Increased application of the information

Phase 2: Experimental Design



Phase 2: Results

Variable	Comprehension	Application
Format	***Bubbles > Med Guide ***OTC > Med Guide	NS
Mode	**Print > Online	NS
Health literacy	*Higher > Lower	**Higher > Lower
Illness knowledge	*Higher > Lower	NS
Age	*60-69 yrs. > Under 50 yrs. <i>Other age differences NS</i>	**60-69 yrs. > Under 50 yrs. <i>Other age differences NS</i>
Race/Ethnicity	*Non-Hispanic White> Non-Hispanic Black <i>Other race/ethnicity differences NS</i>	**Non-Hispanic White> Non-Hispanic Black <i>Other race/ethnicity differences NS</i>
Gender	NS	NS
Education	NS	NS

* Indicates a finding significant at p<.05; ** Indicates findings significant at p<.01;
*** Indicates findings significant at p<.001.

Conclusion

- Preference for Bubbles and OTC prototype over currently available patient information.
- Bubbles and OTC prototypes resulted in better comprehension than Medication Guide.

Acknowledgements

FDA would like to acknowledge the entire RTI staff for their work and support throughout this project.

Contact Information

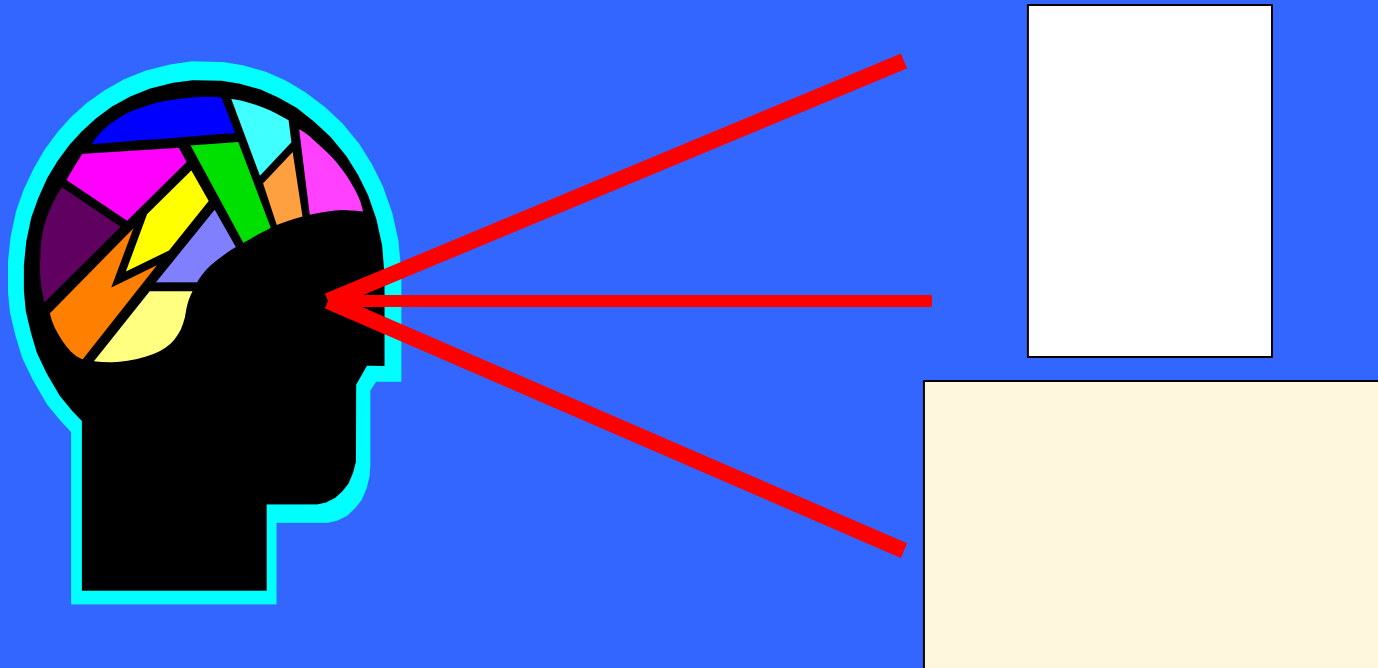
- Please email any questions concerning PMI to the Office of Medical Policy Initiatives at PMI@fda.hhs.gov

Exploring the Promise of Patient Medication Information

Engelberg Center for Health Care Reform
The Brookings Institution
Washington, DC
July 1, 2014

Enhanced Designs for PMI:

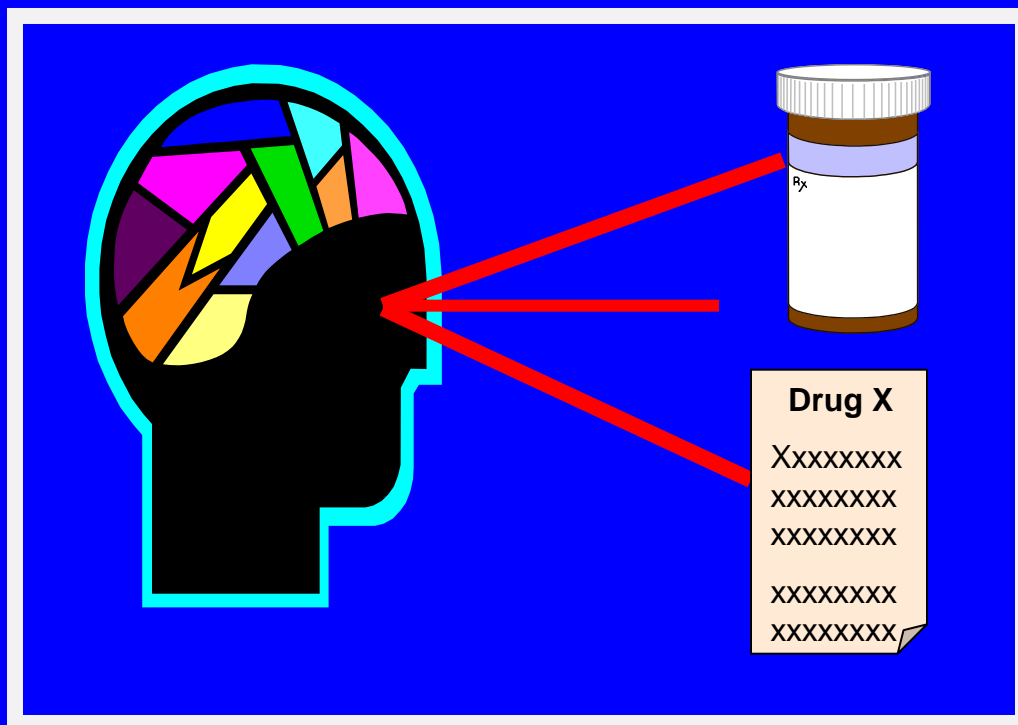
Improving Attention, Comprehension, and Memory



Ruth S. Day / Duke University

Brookings Institution / July 1, 2014

Medical Cognition Laboratory



Rx

© RuthDay

**Comprehension, memory, and use
of drug information.**

Basic Approach

```
graph TD; A[Basic Approach] --> B[Cognitive Analyses]; A --> C[Enhanced Displays]; A --> D[Cognitive Experiments];
```

**Cognitive
Analyses**

**Enhanced
Displays**

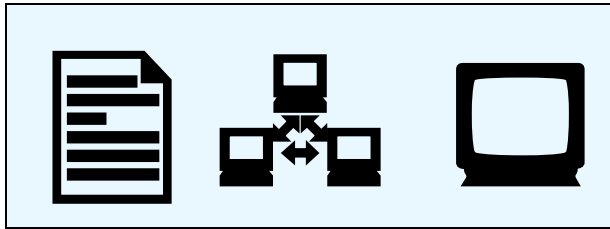
**Cognitive
Experiments**

Basic Approach

**Cognitive
Analyses**

**Enhanced
Displays**

**Cognitive
Experiments**

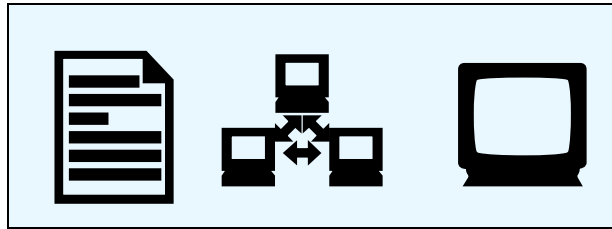


--Obtain quantitative
measures

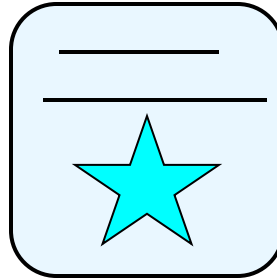
--Calculate
“cognitive accessibility”

Basic Approach

Cognitive Analyses



Enhanced Displays



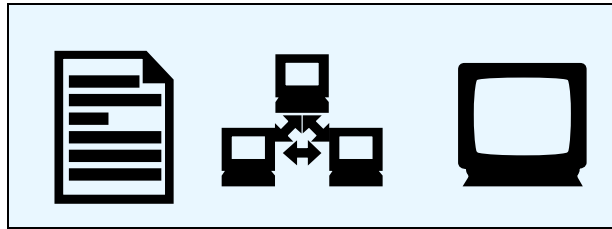
Cognitive Experiments

- Obtain quantitative measures
- Calculate “cognitive accessibility”

- Same info
- Based on cognitive principles

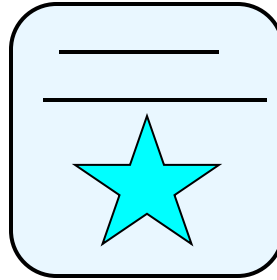
Basic Approach

Cognitive Analyses



- Obtain quantitative measures
- Calculate “cognitive accessibility”

Enhanced Displays



- Same info
- Based on cognitive principles

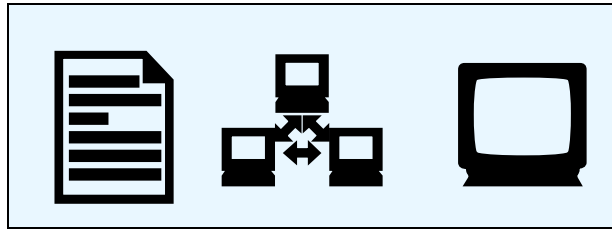
Cognitive Experiments

Test effects on:

- Attention
- Comprehension
- Memory
- Problem Solving
- Decision Making
- Behavior

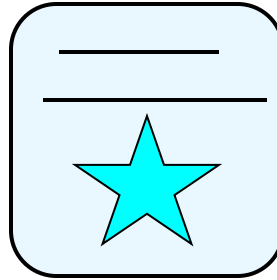
Basic Approach

Cognitive Analyses



- Obtain quantitative measures
- Calculate “cognitive accessibility”

Enhanced Displays



- Same info
- Based on cognitive principles

Cognitive Experiments

Test effects on:

- Attention
- Comprehension
- Memory
- Problem Solving
- Decision Making
- Behavior

Health Outcomes

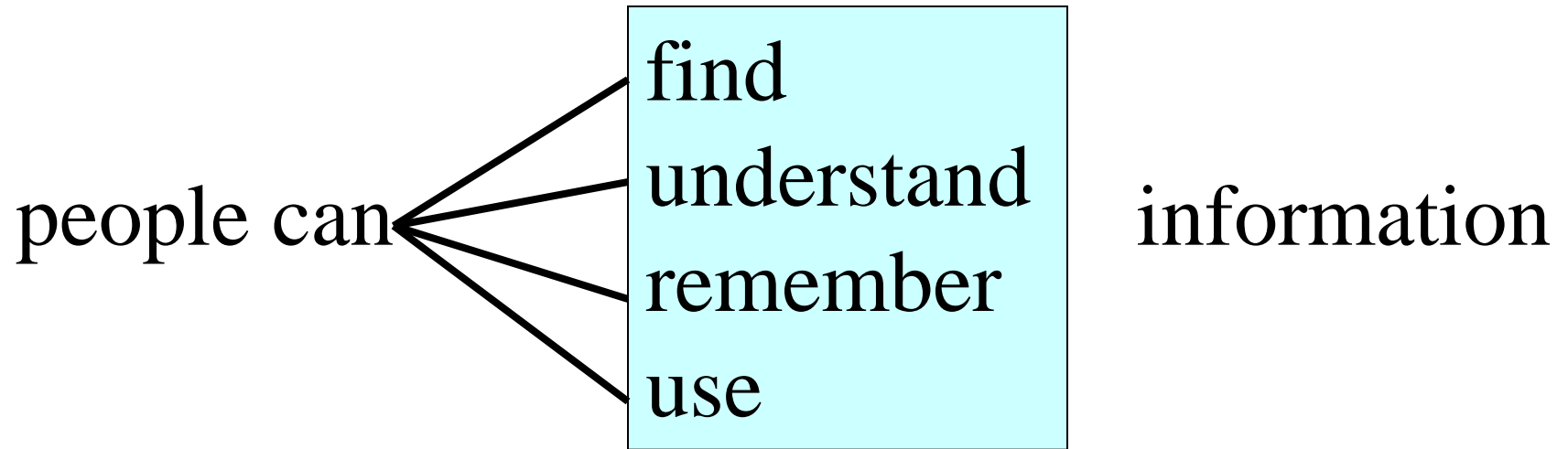
Cognitive Accessibility

Cognitive Accessibility

The ease with which

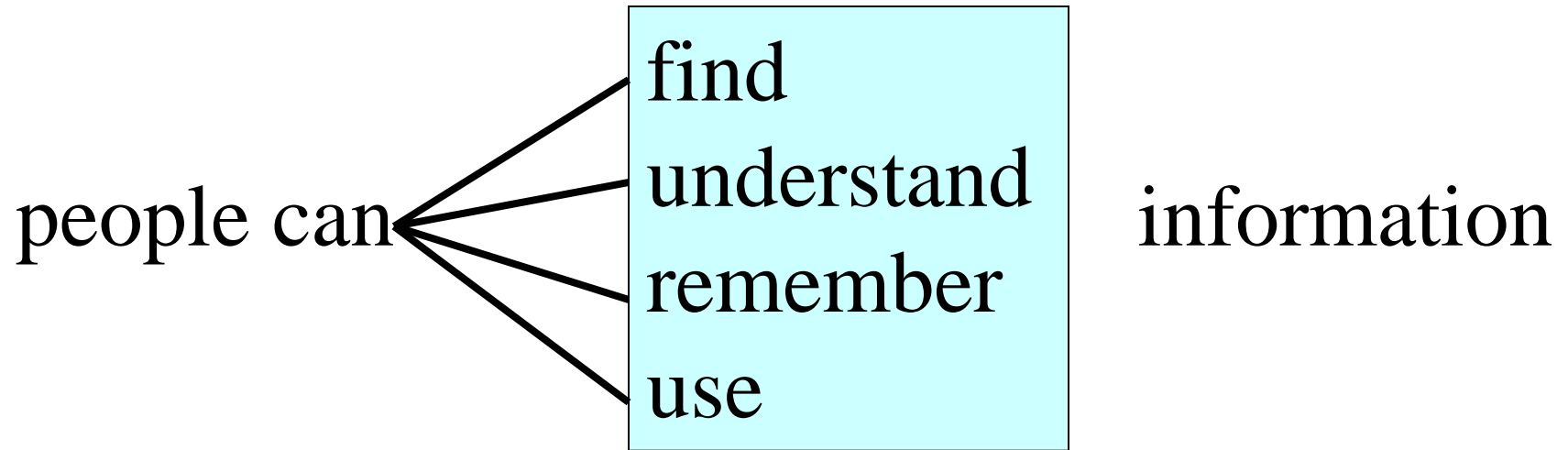
Cognitive Accessibility

The ease with which



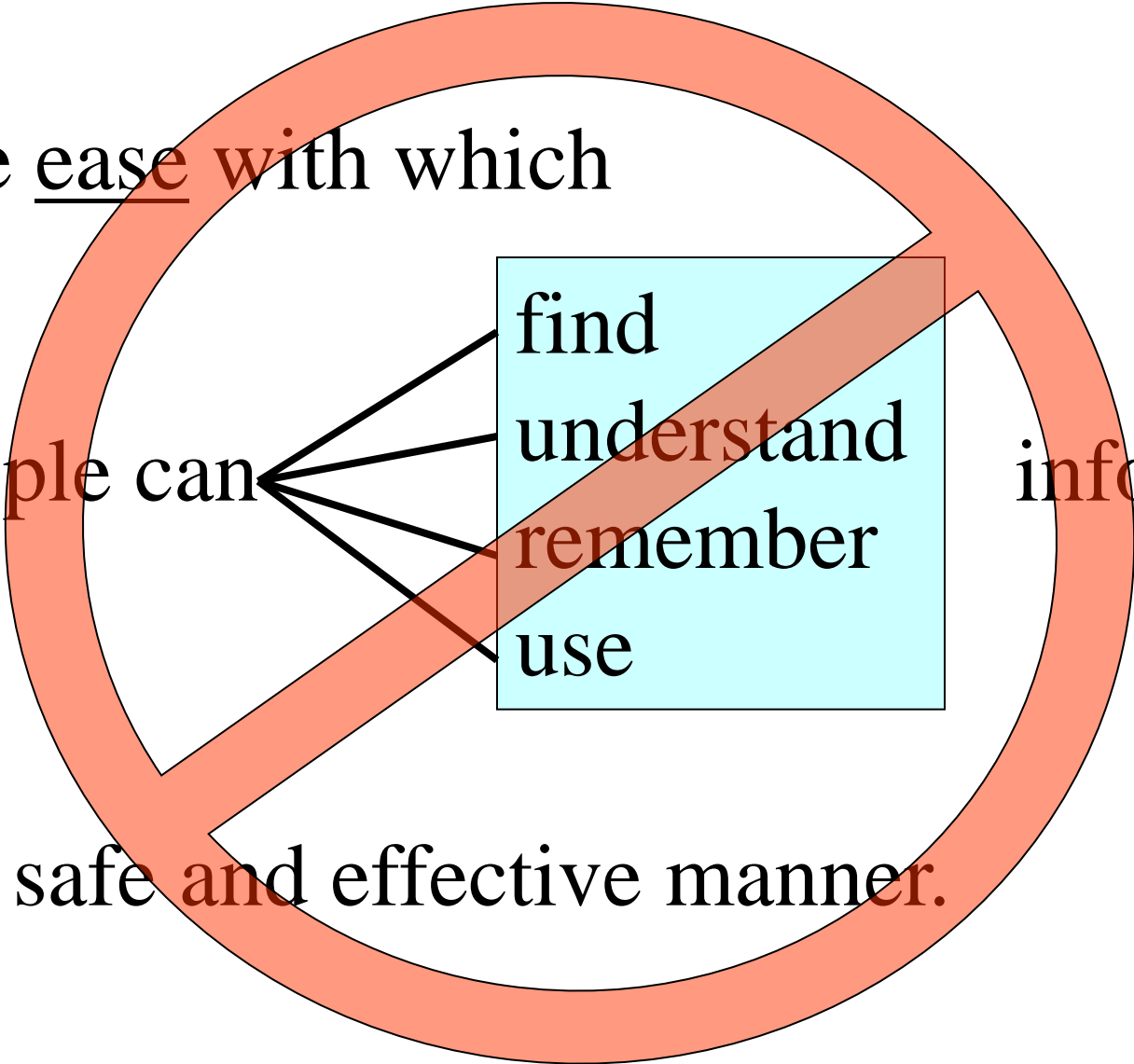
Cognitive Accessibility

The ease with which



in a safe and effective manner.

Cognitive IN-Accessibility

The ease with which
people can 
information
in a safe and effective manner.

Current Study

Patient Medication Information

PMI

PMI Versions

1 Page

PMI Versions

```
graph TD; A[PMI Versions] --- B[1 Page]; A --- C[FDA Prototype (Bubble)]; A --- D[ ];
```

1 Page

FDA
Prototype
("Bubble")

PMI Versions

```
graph TD; A[PMI Versions] --> B[FDA Prototype (Bubble)]; A --> C[Enhanced-1]; A --> D[Enhanced-2];
```

1 Page

**FDA
Prototype**
("Bubble")

Enhanced-1

Enhanced-2

PMI Versions

```
graph TD; PMI[PMI Versions] --- FDA[FDA Prototype (Bubble)]; PMI --- E1[Enhanced-1]; PMI --- E2[Enhanced-2]; E1 --- E[Enhanced]; E2 --- E;
```

1 Page

**FDA
Prototype**
("Bubble")

Enhanced-1

Enhanced-2

Enhanced

- Same info
- Plus cognitive enhancements

Patients

Number: >1,400

Patients

Number: >1,400

Wide Demographics

Age: 19-97

Gender: 48%-52% (*male-female*)

Education: 1st grade – postgrad degree

Occupations:

--unskilled, skilled, clerical, sales, managerial,
professional, retired, unemployed

Geographic Area: 38 states

Patients



42%

Phone

58%

Web

Number: >1,400

Wide Demographics

Age: 19-97

Gender: 48%-52% (*male-female*)

Education: 1st grade – postgrad degree

Occupations:

--unskilled, skilled, clerical, sales, managerial,
professional, retired, unemployed

Geographic Area: 38 states

Patients



42%

Phone

58%

Web

Number: >1,400

Wide Demographics

Age: 19-97

Gender: 48%-52% (*male-female*)

Education: 1st grade – postgrad degree

Occupations:

--unskilled, skilled, clerical, sales, managerial, professional, retired, unemployed

Geographic Area: 38 states



Basic Methods

Basic Methods

time



Study

Test

Basic Methods

time



Study

Test

OR

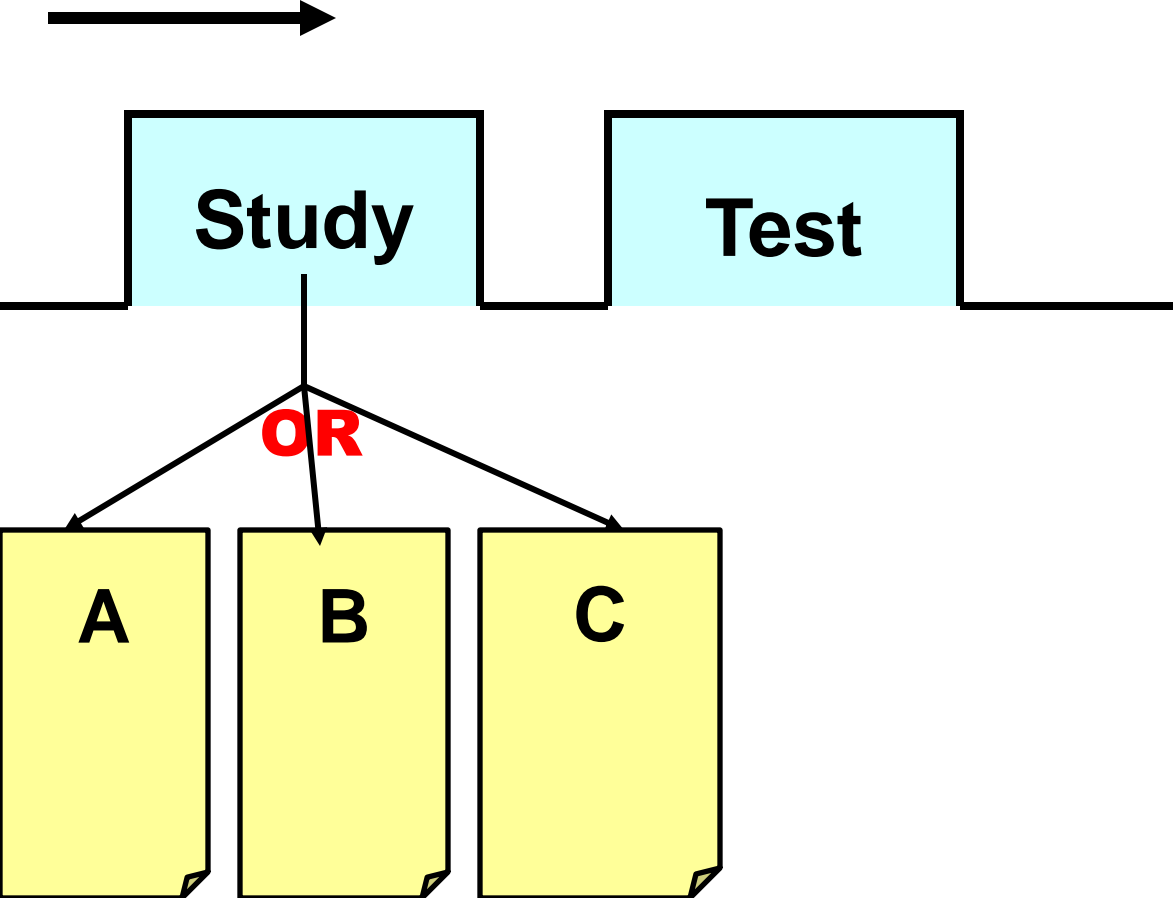
A

B

C

Basic Methods

time



Random assignment
of formats to patients

Basic Methods

time



Study

Test

**All
Content**

--benefits

--risks

--directions

--etc

Basic Methods

time



Study

Test

**All
Content**

- benefits
- risks
- directions
- etc

**Multiple
Tasks**

- attention
- comprehension
- memory

PMI versions



Prototype “Bubble”

Drug Name

Uses

Call Your Doctor

Important Warning:

Tell your Doctor

Common Side Effects

Directions for Use

Drug Name

Uses

Call Your Doctor

Important Warning:

Tell your Doctor

Common Side Effects

Directions for Use

Enhanced

Scope of the Study

Scope of the Study

**Primary + coded data
= > 2,000,000 cells**

Therefore....

Sample Results

Study Time

Study Time

```
graph TD; A["Study Time"] --> B["Fixed Time"]; A --> C["Own Time"];
```

**Fixed
Time**

**Own
Time**

Study Time

**Fixed
Time**

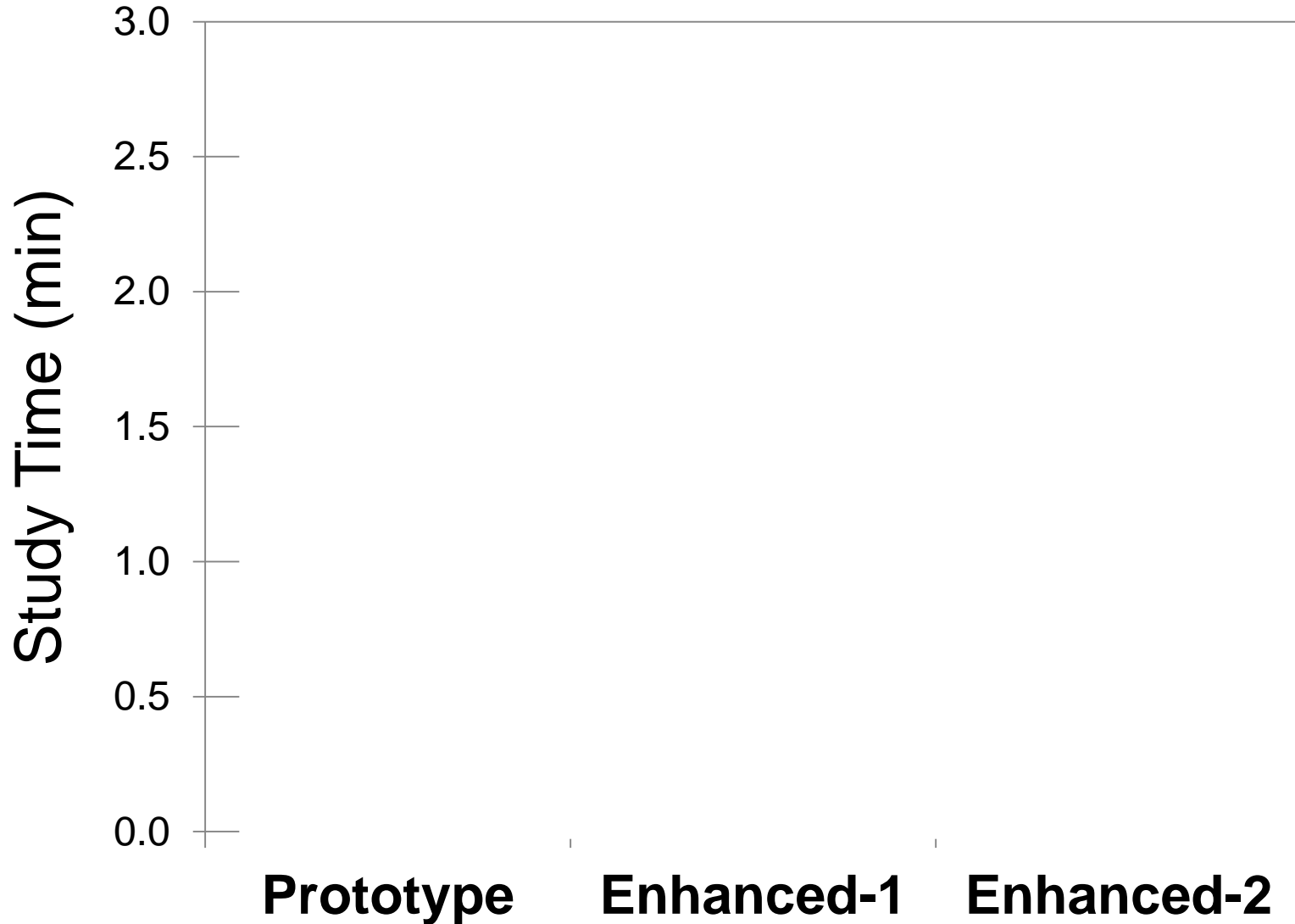
**Own
Time**

**How long did they take
to read the PMI?**



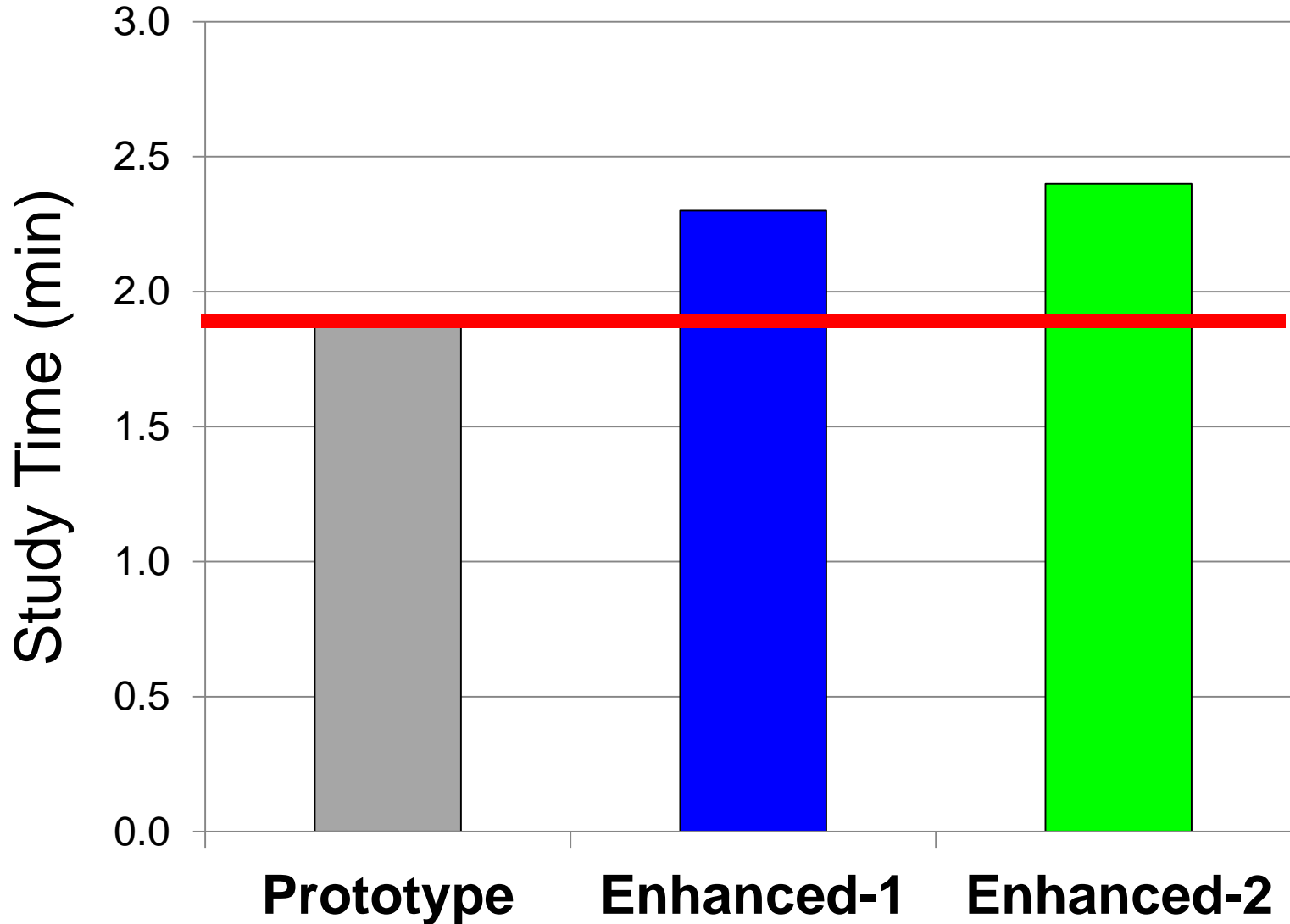
Study Time

Own Time Condition

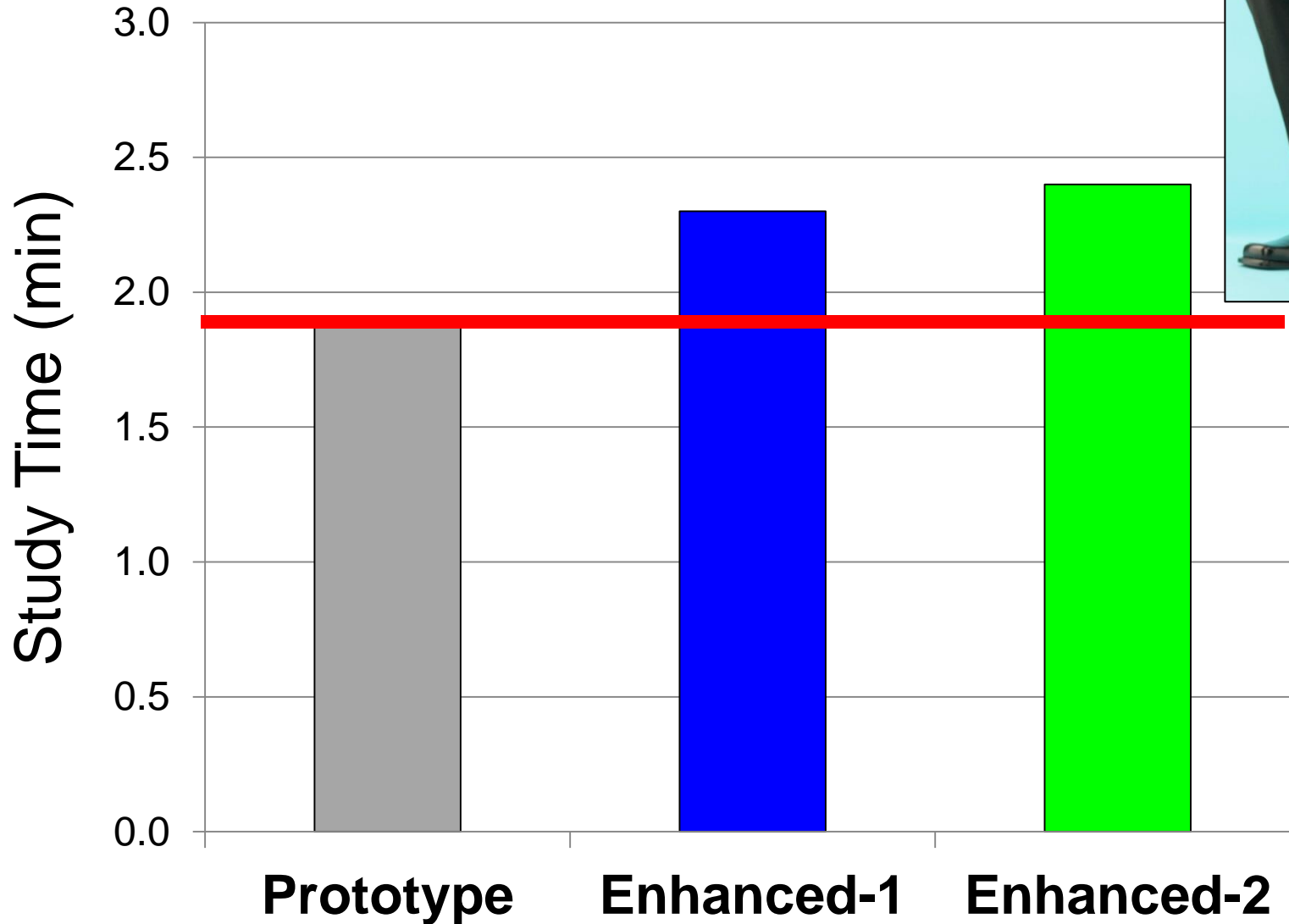


Study Time

Own Time Condition



Study Time Own Time Condition



Medication Name

Medication Name

“What is the name of this medicine?”

Medication Name

“What is the name of this medicine?”

Enhanced > Prototype

Medication Name

“What is the name of this medicine?”

Enhanced > Prototype

Sample Errors

atenolol

linsinporil

linsiporil

lipasporin

lipersel

lipisoril

Lipitrol

lipopril

Liprocil

Listensapril

Lysoprin

lystisol

Side Effects

Side Effects

Multiple cognitive tasks

- attention
- recall
- recognition
- action
- likelihood

Side Effects

Multiple cognitive tasks

- attention
- recall
- recognition
- action
- likelihood

Levels of knowledge

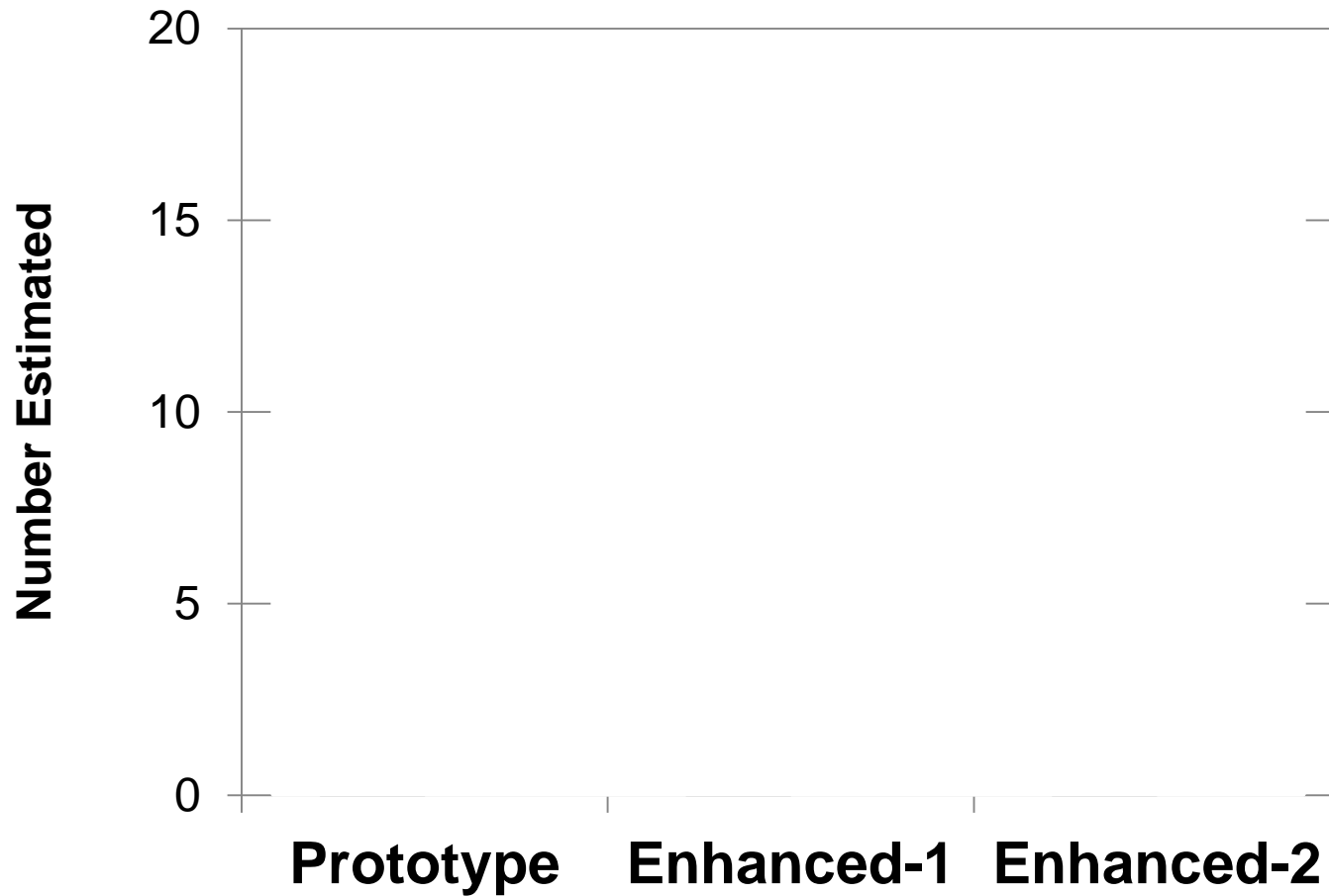
- surface
- moderate
- deep

Side Effects

“About how many side effects?”

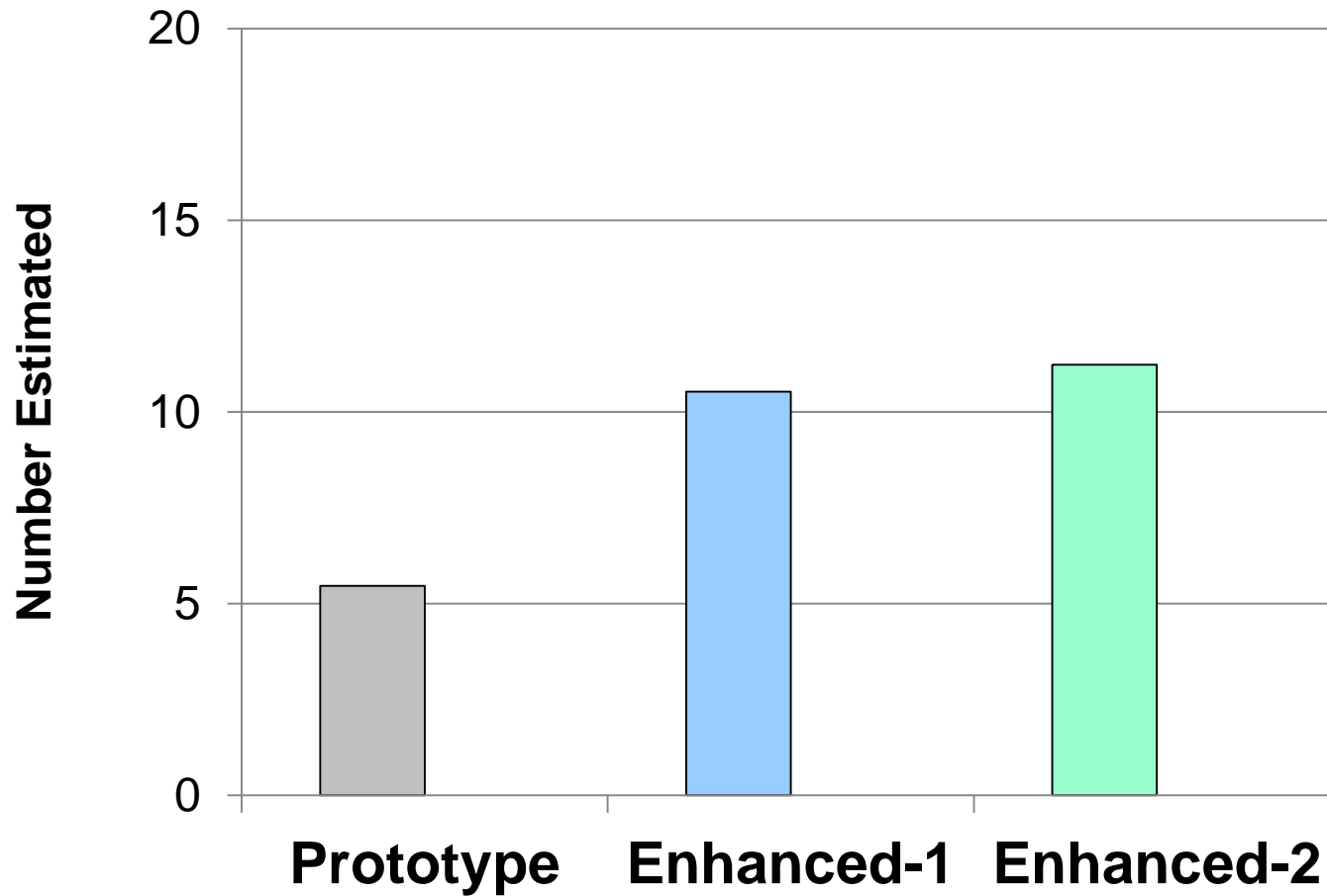
Side Effects

“About how many side effects?”



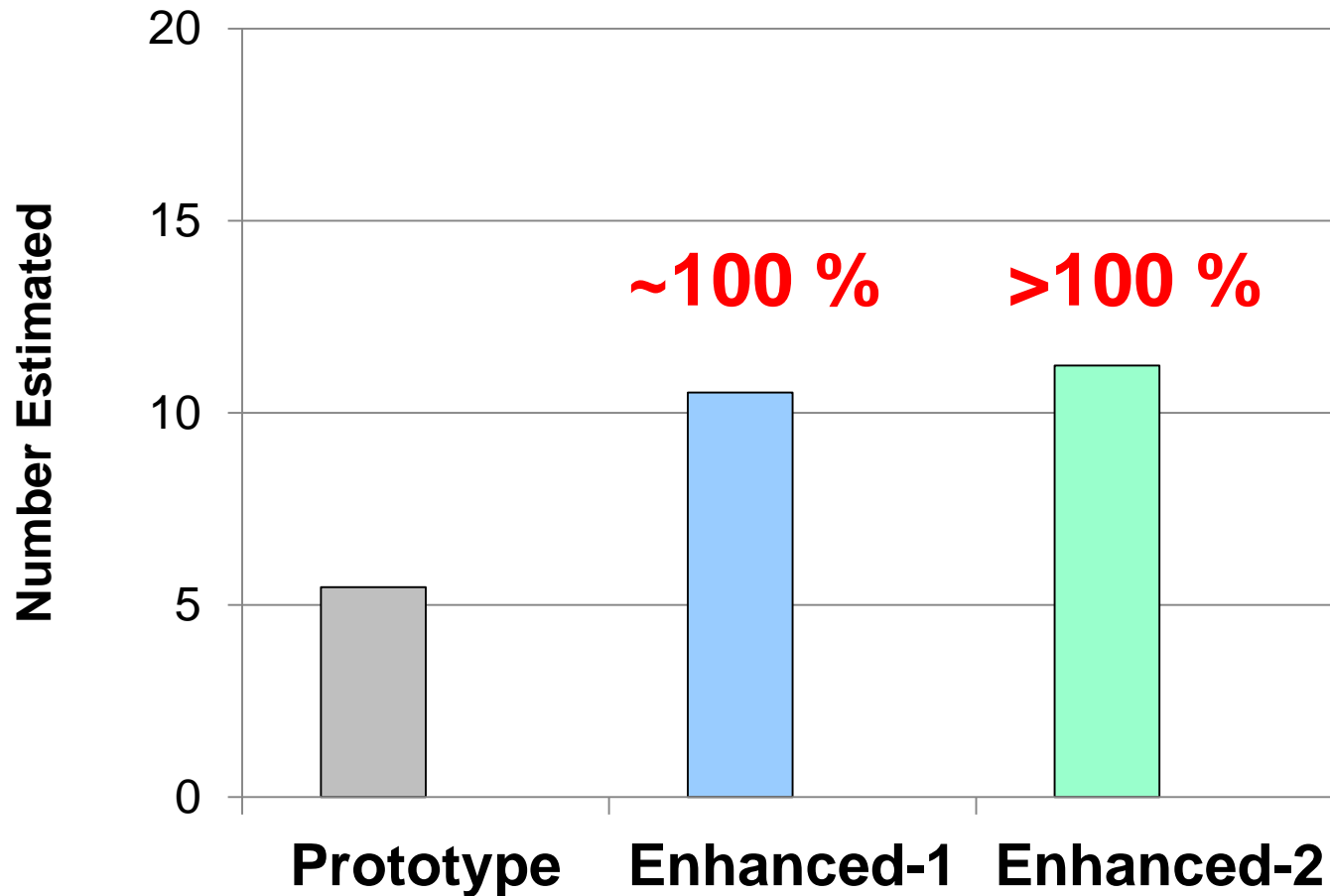
Side Effects

“About how many side effects?”



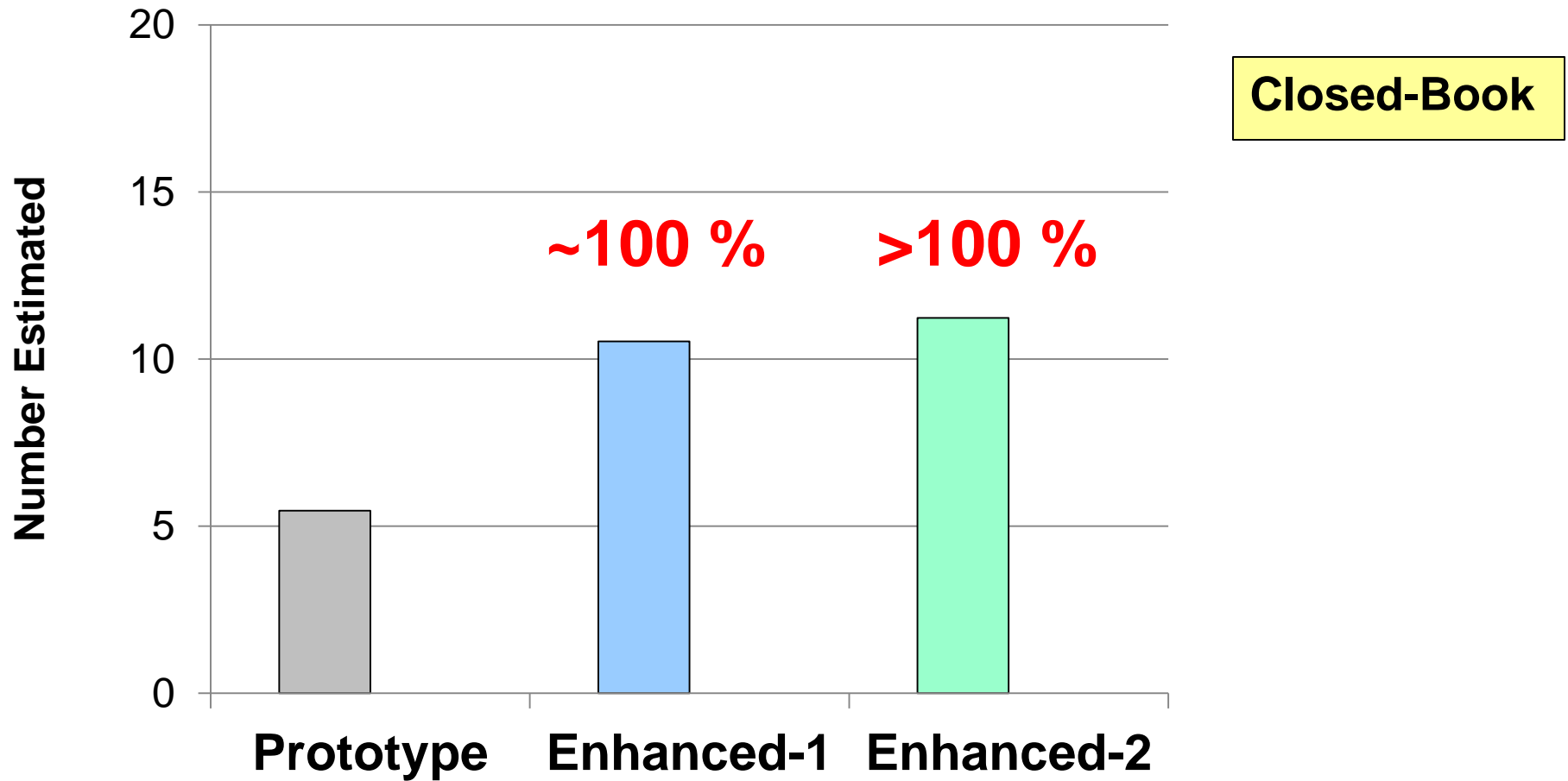
Side Effects

“About how many side effects?”



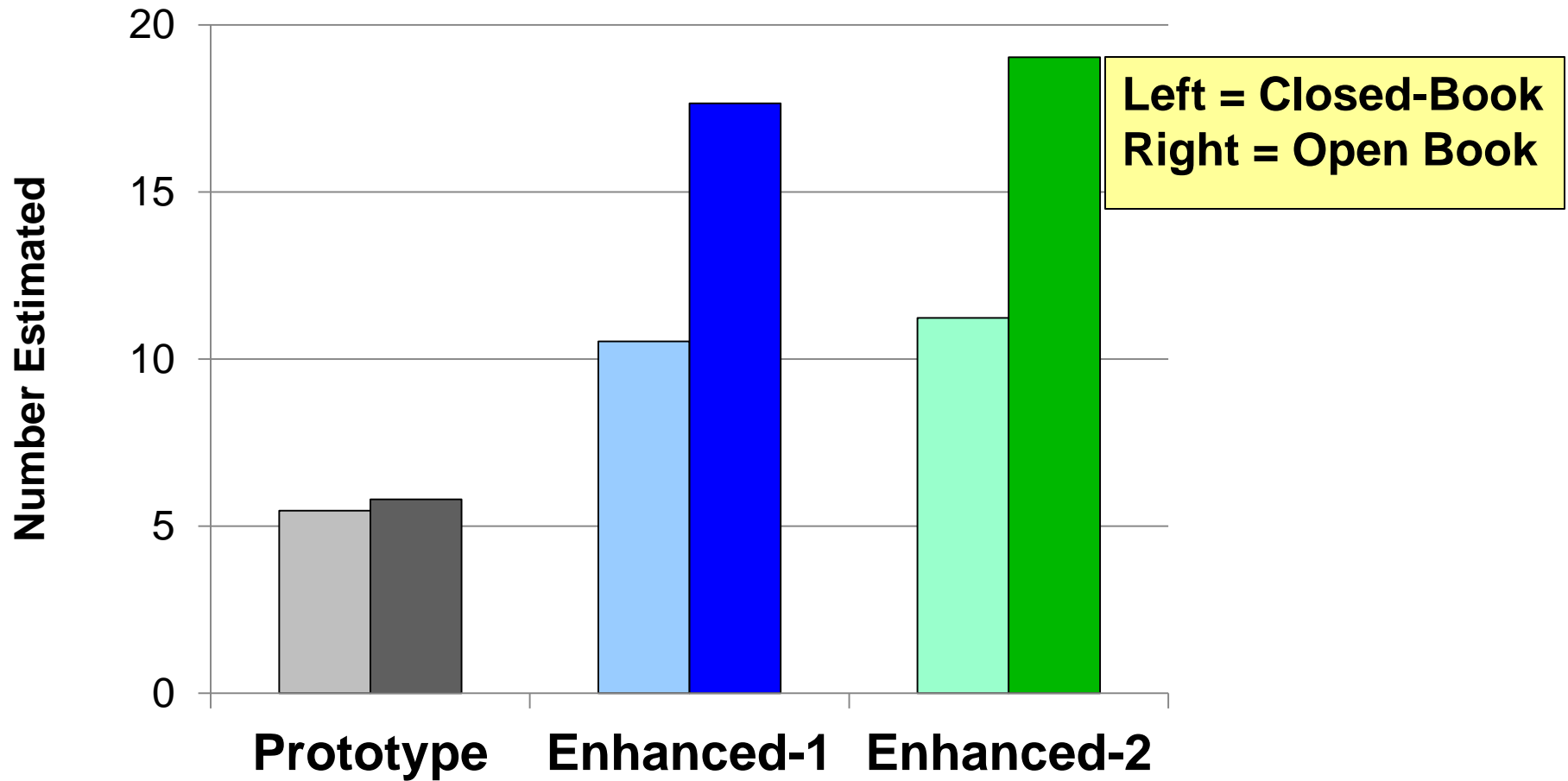
Side Effects

“About how many side effects?”



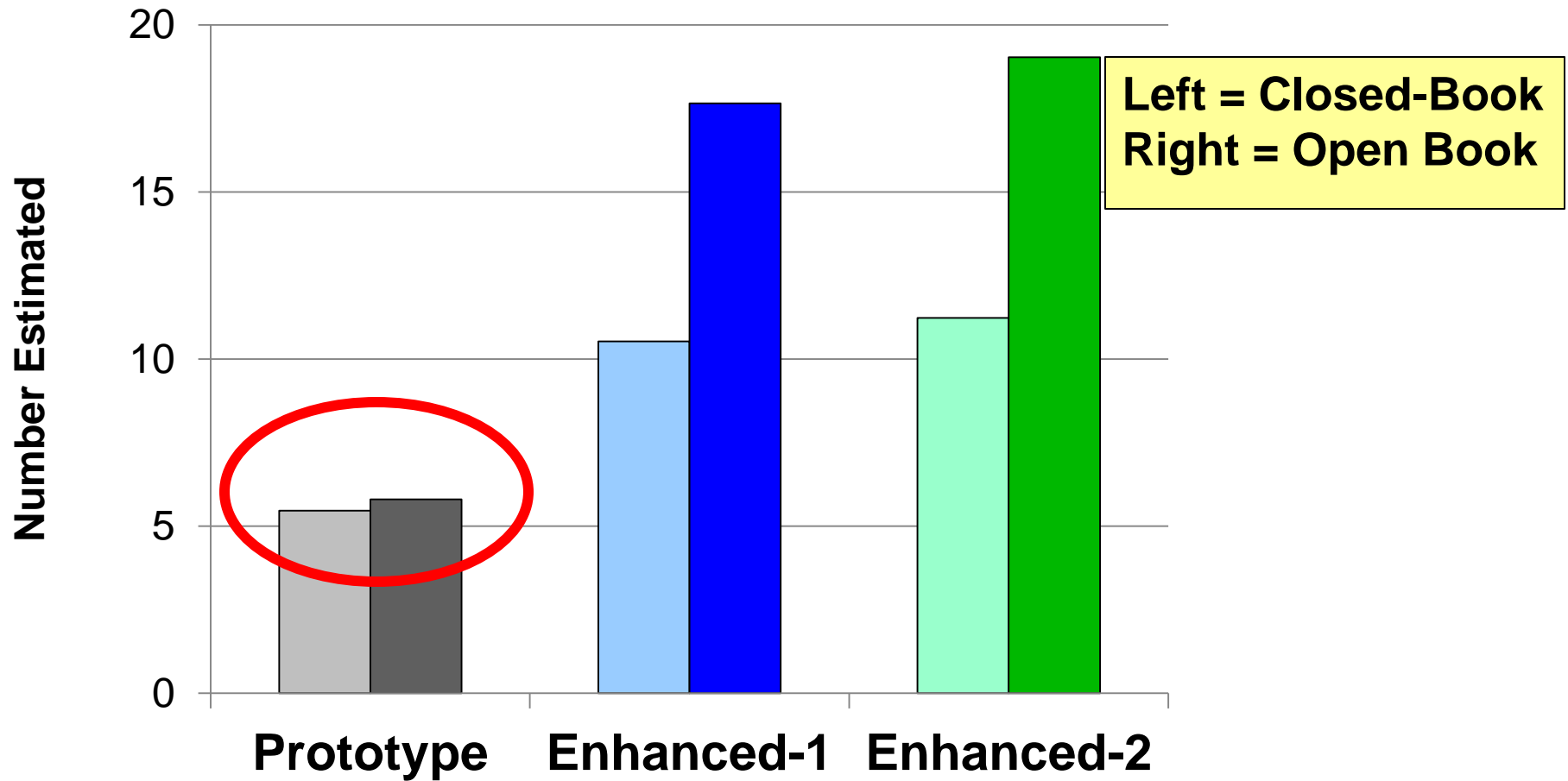
Side Effects

“About how many side effects?”



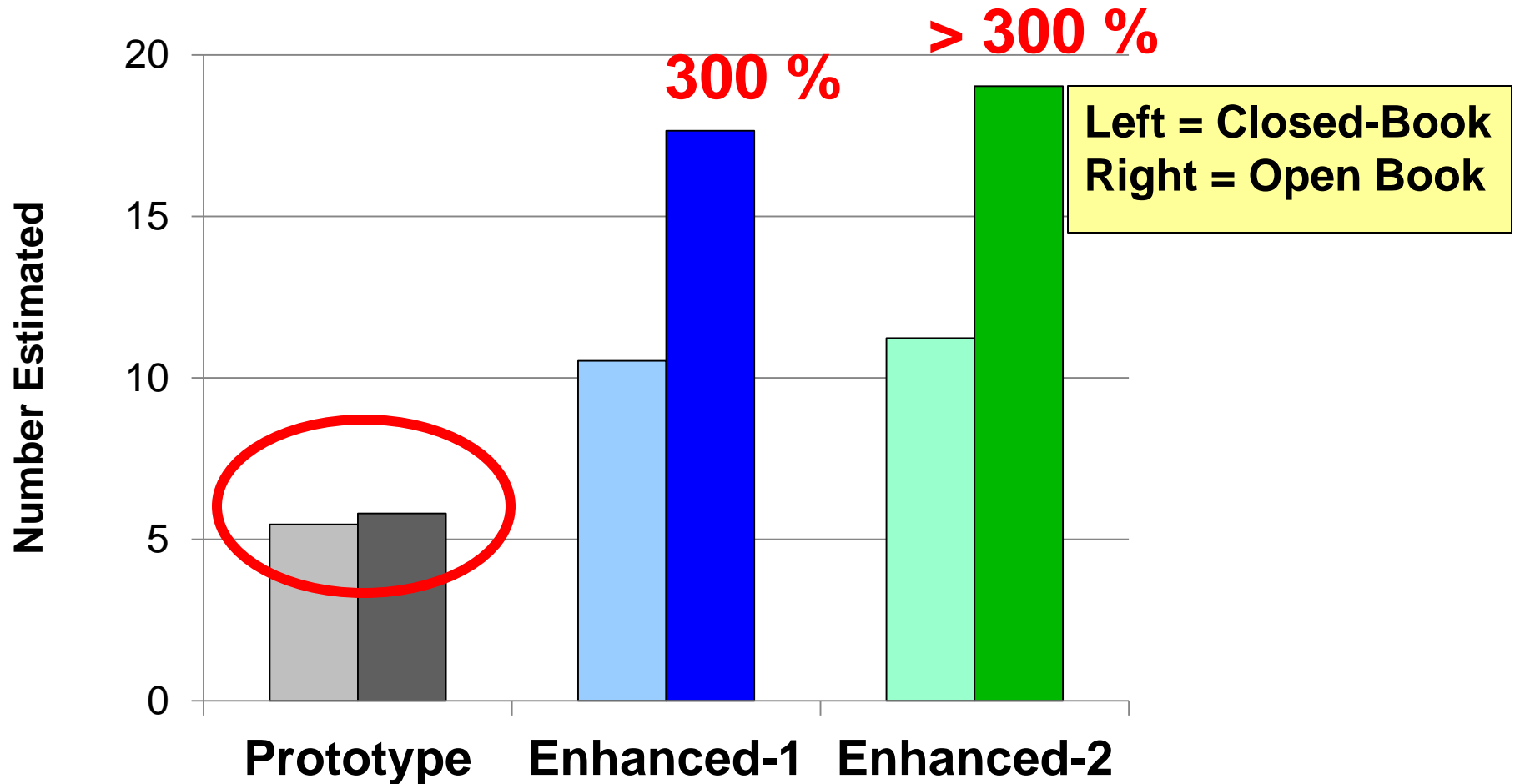
Side Effects

“About how many side effects?”



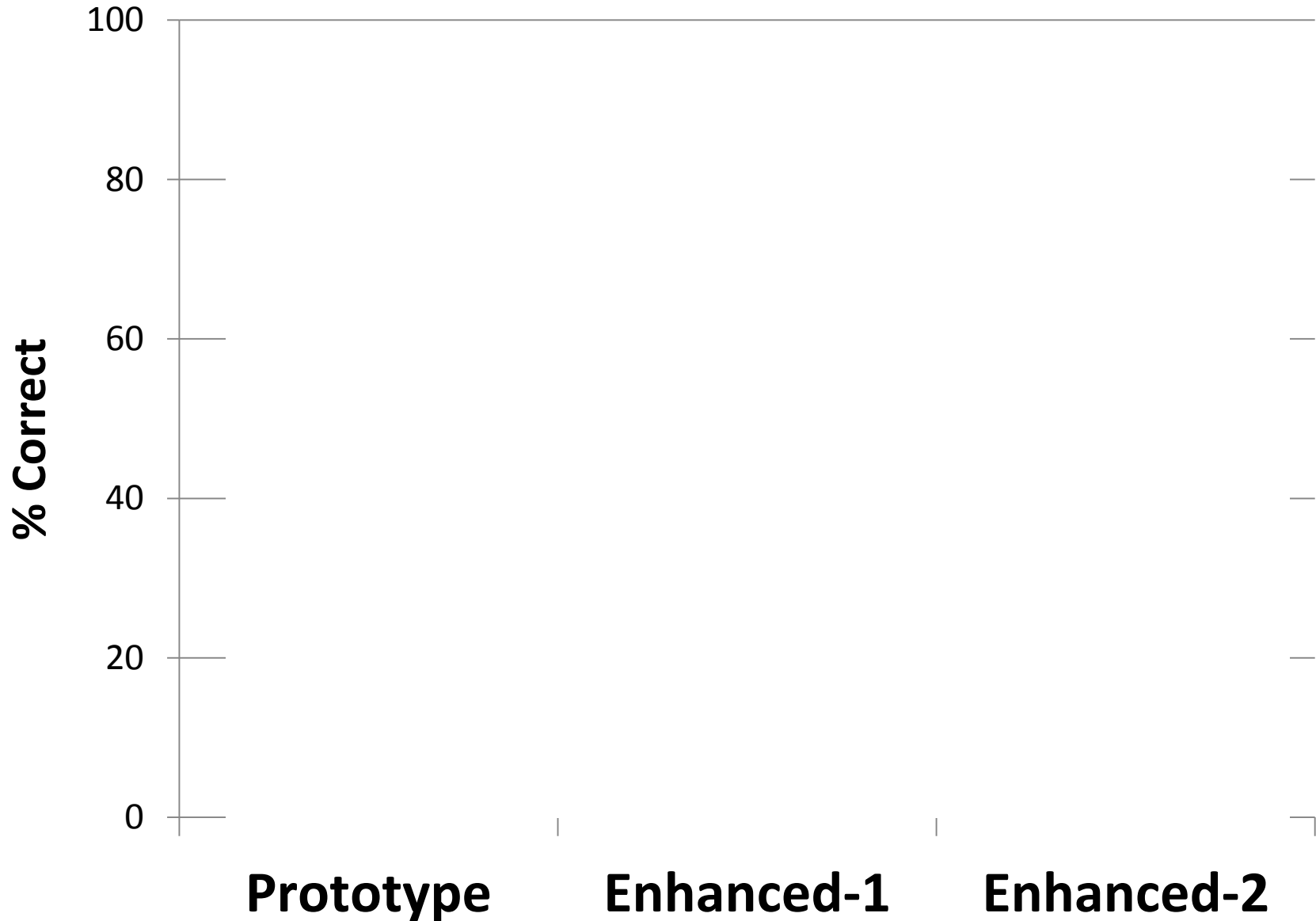
Side Effects

“About how many side effects?”

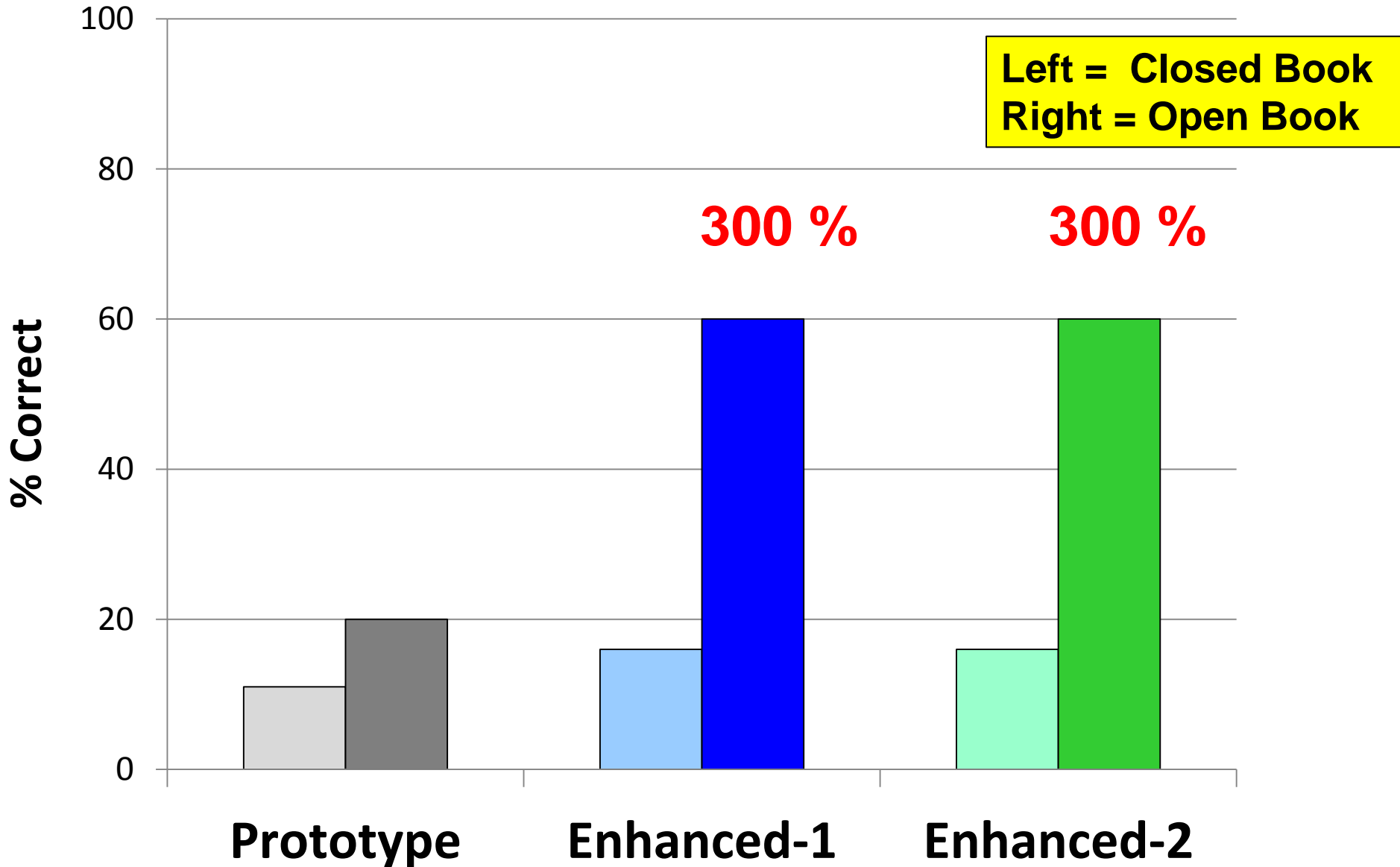


“What are the side effects?”

“What are the side effects?”



“What are the side effects?”



**Related
Study**

Eye Tracking

Eye Tracking

As people read,

--where do they look?

--how long do they spend in specific regions?

--how many times do they re-visit?

--what paths do they take?

Eye Tracking

As people read,

--where do they look?

--how long do they spend in specific regions?

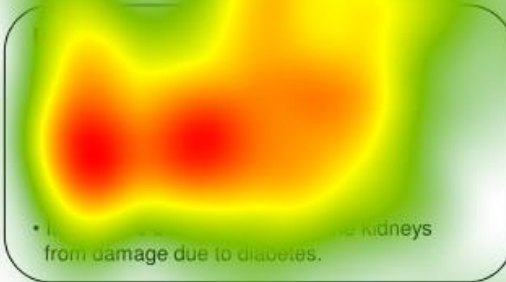
--how many times do they re-visit?

--what paths do they take?

**Do eye movements predict
comprehension & memory?**

Heat Map

First 10-sec



• It is not recommended for people with kidney disease or kidney damage from damage due to diabetes.

Important Warning: Pregnancy

Lisinopril can cause serious (possibly fatal) harm to an unborn baby, so ask your doctor about reliable birth control. Tell your doctor right away if you are planning pregnancy or think you may be pregnant.

Tell your Doctor

Before using lisinopril, tell your doctor if you:

- are allergic to it, any of its inactive ingredients or other ACE inhibitors (such as benazepril), or have any other allergies.
- have had any of the following allergic reactions: swelling of the face, lips, tongue, or throat.
- have a high level of potassium in the blood, severe dehydration, kidney disease, blood vessel diseases (such as lupus).
- are considering breast feeding.
- are taking other drugs that may interact with lisinopril (such as aliskiren or lithium), drugs that increase potassium levels (including birth control products that contain drospirenone), or medicines that could increase blood pressure or worsen heart failure (such as cough-and-cold products, diet aids, or NSAIDs such as ibuprofen or naproxen).

lisinopril"] (also known as: Prinivil, Zestril)

Call Your Doctor

Call your doctor right away if you develop:

- Symptoms of serious but rare allergic reaction such as rash, itching or swelling especially of face, tongue, or throat, severe dizziness, trouble breathing. Get medical help right away.
- Fainting, changes in amount of urine.
- Slow heartbeat, muscle weakness. These are signs of high potassium levels.
- Fever, chills, persistent sore throat. These are signs of infection.
- Dark urine, severe stomach/abdominal pain, persistent nausea/vomiting, yellowing eyes or skin. These are signs of liver problems.

Tell your doctor if you have:

- Prolonged diarrhea or vomiting. These conditions can cause dehydration which can lower blood pressure and worsen dizziness.

Common Side Effects

- Dizziness, light headedness, unusual tiredness, headache, dry cough
- If any of these persist or worsen, tell your doctor or pharmacist promptly.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use

- Take lisinopril by mouth with or without food as directed by your doctor.
- Your doctor will tell you how often to take lisinopril. Take it regularly to get the most benefit. Do not take lisinopril more than prescribed.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Store lisinopril at room temperature, away from light and moisture.

Lisinopril ["Lye-SIN-oh-priil"] (also known as: Prinivil, Zestril)

Uses

- Lisinopril is used to reduce high blood pressure to help prevent strokes, heart attacks and kidney problems.
- It is also used to treat heart failure and after a heart attack to improve survival.
- It may also be used to protect the kidneys from damage.

Important Information: Pregnancy

Lisinopril is not recommended for use during pregnancy.

Tell your doctor

Before taking Lisinopril, tell your doctor if you:

- are taking other medications (including birth control pills),
- have had any previous allergic reactions (swelling of the face, lips, tongue, or throat).
- have a high level of potassium in the blood, severe dehydration, kidney disease, blood vessel diseases (such as lupus).
- are considering breast feeding.
- are taking other drugs that may interact with lisinopril (such as aliskiren or lithium), drugs that increase potassium levels (including birth control products that contain drospirenone), or medicines that could increase blood pressure or worsen heart failure (such as cough-and-cold products, diet aids, or NSAIDs such as ibuprofen or naproxen).

Call Your Doctor

Call your doctor right away if you develop:

- Symptoms of serious but rare allergic reaction such as rash, itching or swelling especially of face, tongue, or throat, severe dizziness, trouble breathing. Get medical help right away.
- Fainting, changes in amount of urine.
- Slow heartbeat, muscle weakness. These are signs of high potassium levels.
- Fever, chills, persistent sore throat. These are signs of infection.
- Dark urine, severe stomach/abdominal pain, persistent nausea/vomiting, yellowing eyes or skin. These are signs of liver problems.

Tell your doctor if you have:

- Prolonged diarrhea or vomiting. These conditions can cause dehydration which can lower blood pressure and worsen dizziness.

Common Side Effects

- Dizziness, light headedness, unusual tiredness, headache, dry cough
- If any of these persist or worsen, tell your doctor or pharmacist promptly.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use

- Take lisinopril by mouth with or without food as directed by your doctor.
- Your doctor will tell you how often to take lisinopril. Take it regularly to get the most benefit. Do not take lisinopril more than prescribed.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Store lisinopril at room temperature, away from light and moisture.

Lisinopril ["Lye-SIN-oh-pril"] (also known as: Prinivil, Zestril)

Uses

- Lisinopril is used to reduce high blood pressure to help prevent strokes, heart attacks and kidney problems.
- It is also used to treat heart failure and after a heart attack to improve survival.
- It may also be used to protect the kidneys from damage due to diabetes.

Important Warning: Pregnancy

Lisinopril can cause serious (possibly fatal) harm to an unborn baby, so ask your doctor about reliable birth control. Tell your doctor right away if you are planning pregnancy or think you may be pregnant.

Tell your Doctor

Before you start taking this medicine, tell your doctor if you:

- are taking any other medicines, especially blood thinners (such as aspirin, clopidogrel, or warfarin), blood thinners (such as heparin or low molecular weight heparin), blood thinners (such as dabigatran, rivaroxaban, or apixiban), or blood thinners (such as enoxaparin or fondaparinux).
- are currently breastfeeding.
- are taking any other drugs that may interact with lisinopril (such as ACE inhibitors, ARBs, diuretics, drugs that affect potassium levels, potassium supplements (including birth control products that contain drospirenone), or medicines that could increase blood pressure or worsen heart failure (such as cough-and-cold products, diet aids, or NSAIDs such as ibuprofen or naproxen).

Call Your Doctor

Call your doctor right away if you develop:

- Symptoms of serious but rare allergic reaction such as rash, itching or swelling especially of face, tongue, or throat, severe dizziness, trouble breathing. Get medical help right away.
- Fainting, changes in amount of urine.
- Slow heartbeat, muscle weakness. These are signs of high potassium levels.
- Fever, chills, persistent sore throat. These are signs of infection.
- Dark urine, severe stomach/abdominal pain, persistent nausea/vomiting, yellowing eyes or skin. These are signs of liver problems.

Tell your doctor if you have:

- Prolonged diarrhea or vomiting. These conditions can cause dehydration which can lower blood pressure and worsen dizziness.

Common Side Effects

- Dizziness, light headedness, unusual tiredness, headache, dry cough
- If any of these persist or worsen, tell your doctor or pharmacist promptly.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use

- Take lisinopril by mouth with or without food as directed by your doctor.
- Your doctor will tell you how often to take lisinopril. Take it regularly to get the most benefit. Do not take lisinopril more than prescribed.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Store lisinopril at room temperature, away from light and moisture.

Lisinopril ["Lye-SIN-oh-priil"] (also known as: Prinivil, Zestril)

Uses

- Lisinopril is used to reduce high blood pressure to help prevent strokes, heart attacks and kidney problems.
- It is also used to treat heart failure and after a heart attack to improve survival.
- It may also be used to protect the kidneys from damage due to diabetes.

Important Warning: Pregnancy

Lisinopril can cause serious (possibly fatal) harm to an unborn baby, so ask your doctor about reliable birth control. Tell your doctor right away if you are planning pregnancy or think you may be pregnant.

Tell your Doctor

Before taking lisinopril, tell your doctor if you:

- are allergic to it, any of its inactive ingredients or other ACE inhibitors (such as benazepril), or if you have other allergies.

• Tell your doctor if you have had an allergic reaction such as rash, itching or swelling especially of the face, tongue, or throat, severe dizziness, or trouble breathing.

• Tell your doctor if you are taking or have recently taken any other ACE inhibitors (such as lisinopril, enalapril, or ramipril).

• Tell your doctor if you are taking or have recently taken any other medications that may interact with lisinopril, such as potassium supplements, potassium-sparing diuretics (such as spironolactone), or NSAIDs such as aspirin or naproxen.

Call Your Doctor

Call your doctor right away if you develop:

- Symptoms of serious but rare allergic reaction such as rash, itching or swelling especially of face, tongue, or throat, severe dizziness, trouble breathing. Get medical help right away.
- Fainting, changes in amount of urine.
- Slow heartbeat, muscle weakness. These are signs of high potassium levels.
- Fever, chills, persistent sore throat. These are signs of infection.
- Dark urine, severe stomach/abdominal pain, persistent nausea/vomiting, yellowing eyes or skin. These are signs of liver problems.

Tell your doctor if you have:

- Prolonged diarrhea or vomiting. These conditions can cause dehydration which can lower blood pressure and worsen dizziness.

Common Side Effects

- Dizziness, light headedness, unusual tiredness, headache, dry cough
- If any of these persist or worsen, tell your doctor or pharmacist promptly.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use

- Take lisinopril by mouth with or without food as directed by your doctor.
- Your doctor will tell you how often to take lisinopril. Take it regularly to get the most benefit. Do not take lisinopril more than prescribed.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Store lisinopril at room temperature, away from light and moisture.

Lisinopril ["Lye-SIN-oh-pril"] (also known as: Prinivil, Zestril)

Uses

- Lisinopril is used to reduce high blood pressure to help prevent strokes, heart attacks and kidney problems.
- It is also used to treat heart failure and after a heart attack to improve survival.
- It may also be used to protect the kidneys from damage due to diabetes.

Important Warning: Pregnancy

Lisinopril can cause serious (possibly fatal) harm to an unborn baby, so ask your doctor about reliable birth control. Tell your doctor right away if you are planning pregnancy or think you may be pregnant.

Tell your Doctor

Before using lisinopril, tell your doctor if you:

- are allergic to it, any of its inactive ingredients or other ACE inhibitors (such as benazepril), or have any other allergies.
- have had any of the following allergic reactions: swelling of the face, lips, tongue, or throat.
- have a history of low blood counts (such as low hemoglobin or low red blood cells).
- are considering breastfeeding.
- are taking or plan to take other medications, especially NSAIDs such as ibuprofen or naproxen.

Call Your Doctor

Call your doctor right away if you develop:

- Symptoms of a severe but rare allergic reaction such as hives, difficulty breathing, or swelling of the face, lips, tongue, or throat. Call your doctor right away.
- Fainting or dizziness.
- Slow heart rate, muscle weakness. These are signs of low potassium.
- Fever, chills, persistent sore throat. These are signs of infection.
- Dark urine, severe stomach/abdominal pain, persistent nausea/vomiting, yellowing eyes or skin. These are signs of liver problems.

Tell your doctor if you have:

- Prolonged diarrhea or vomiting. These conditions can cause dehydration which can lower blood pressure and worsen dizziness.

Common Side Effects

- Dizziness, light headedness, unsteadiness, headache, dry cough
- If any of these persist or worsen, tell your doctor or pharmacist promptly.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use

- Take lisinopril by mouth with or without food as directed by your doctor.
- Your doctor will tell you how often to take lisinopril. Take it regularly to get the most benefit. Do not take lisinopril more than prescribed.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Store lisinopril at room temperature, away from light and moisture.

Lisinopril ["Lye-SIN-oh-pril"] (also known as: Prinivil, Zestril)

Uses

- Lisinopril is used to reduce high blood pressure to help prevent strokes, heart attacks and kidney problems.
- It is also used to treat heart failure and after a heart attack to improve survival.
- It may also be used to protect the kidneys from damage due to diabetes.

Important Warning: Pregnancy

Lisinopril can cause serious (possibly fatal) harm to an unborn baby, so ask your doctor about reliable birth control. Tell your doctor right away if you are planning pregnancy or think you may be pregnant.

Tell your Doctor

Before using lisinopril, tell your doctor if you:

- are allergic to it, any of its inactive ingredients or other ACE inhibitors (such as benazepril), or have any other allergies.
- have had any of the following allergic reactions: swelling of the face, lips, tongue, or throat.
- have a high level of potassium in the blood, severe dehydration, kidney disease, blood vessel diseases (such as lupus).
- are breastfeeding.

Tell your doctor about all the drugs that may interact with lisinopril (such as spironolactone, furosemide, lithium), and about all the medicines you are taking (including over-the-counter medicines) that could affect your blood pressure. Tell your doctor about all the medicines you are taking, such as

Call Your Doctor

Call your doctor right away if you develop:

- Symptoms such as dizziness, lightheadedness, fainting, or trouble breathing. Get medical help right away.
- Fainting or dizziness in an upright position.
- Slow heart rate or other symptoms of low blood pressure.
- Fever, sore throat, or difficulty swallowing. These are signs of a possible infection.
- Diarrhea, vomiting, stomach/abdominal pain, pale stools, or yellowing eyes or skin. These are signs of liver problems.

Tell your doctor if you have:

- Prolonged diarrhea or vomiting. These conditions can cause dehydration which can lower blood pressure and worsen dizziness.

Common Side Effects

- Dizziness, lightheadedness, unusual tiredness, headache, dry cough
- If any of these persist or worsen, tell your doctor or pharmacist promptly.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use

- Take lisinopril by mouth with or without food as directed by your doctor.
- Your doctor will tell you how often to take lisinopril. Take it regularly to get the most benefit. Do not take lisinopril more than prescribed.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Store lisinopril at room temperature, away from light and moisture.

Lisinopril ["Lye-SIN-oh-pril"] (also known as: Prinivil, Zestril)

Uses

- Lisinopril is used to reduce high blood pressure to help prevent strokes, heart attacks and kidney problems.
- It is also used to treat heart failure and after a heart attack to improve survival.
- It may also be used to protect the kidneys from damage due to diabetes.

Important Warning: Pregnancy

Lisinopril can cause serious (possibly fatal) harm to an unborn baby, so ask your doctor about reliable birth control. Tell your doctor right away if you are planning pregnancy or think you may be pregnant.

Tell your Doctor

Before using lisinopril, tell your doctor if you:

- are allergic to it, any of its inactive ingredients or other ACE inhibitors (such as benazepril), or have any other allergies.
- have had any of the following allergic reactions: swelling of the face, lips, tongue, or throat.
- have a high level of potassium in the blood, severe dehydration, kidney disease, blood vessel diseases (such as lupus).
- are considering breast feeding.
- are taking other drugs that may interact with lisinopril (such as aliskiren or lithium), drugs that increase potassium levels (including birth control products that contain drospirenone), or medicines that could increase blood pressure or weight (such as fallow deer antlers cough suppressants and NSAIDs such as ibuprofen).

Call Your Doctor

Call your doctor right away if you develop:

- Symptoms of serious but rare allergic reaction such as rash, itching, especially of face, tongue, or throat, dizziness, trouble breathing, or swelling right away.
- Fainting or lightheadedness.

These are symptoms of low blood pressure. These are symptoms of low blood pressure.

• If you experience any of these symptoms, call your doctor right away.

• Tell your doctor if you are pregnant or planning to get pregnant.

• Tell your doctor if you are taking any other medicines.

Common Side Effects

- Dizziness, lightheadedness, unusual weakness, headache, or fainting.
- If all these symptoms worsen, tell your doctor or pharmacist promptly.
- Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use

- Take lisinopril **without food** as directed.
- You may take lisinopril with or without food. Tell your doctor if you are taking any other medicines.
- If you are taking lisinopril, take it as soon as you remember your next dose at your regularly scheduled time.
- Store lisinopril at room temperature, away from light and moisture.

Lisinopril ["Lye-SIN-oh-pril"] (also known as: Prinivil, Zestril)

Uses

- Lisinopril is used to treat high blood pressure, strokes, heart attack, and kidney problems.
- It is also used to treat heart failure and after a heart attack to improve survival.
- It may also be used to protect the kidneys from damage due to diabetes.

Important Warning: Pregnancy

Lisinopril can cause serious (possibly fatal) harm to an unborn baby, so ask your doctor about reliable birth control. Tell your doctor right away if you are planning pregnancy or think you may be pregnant.

Tell your Doctor

Before using lisinopril, tell your doctor if you:

- are allergic to it, any of its inactive ingredients or other ACE inhibitors (such as benazepril), or have any other allergies.
- have had any of the following allergic reactions: swelling of the face, lips, tongue, or throat.
- have a high level of potassium in the blood, severe dehydration, kidney disease, blood vessel diseases (such as lupus).
- are considering breast feeding.
- are taking other drugs that may interact with lisinopril (such as aliskiren or lithium), drugs that increase potassium levels (including birth control products that contain drospirenone), or medicines that could increase blood pressure or worsen heart failure (such as cough-and-cold products, diet aids, or NSAIDs such as ibuprofen or naproxen).

Call Your Doctor

Call your doctor right away if you develop:

- Symptoms of serious but rare allergic reaction such as rash, itching or swelling especially of face, tongue, or throat, severe dizziness, trouble breathing. Get medical help right away.
- Changes in amount of urine.
- Signs of low potassium, muscle weakness. These are signs of low potassium levels.
- Fever, chills, persistent sore throat. These are signs of infection.
- Dizziness, lightheadedness, fainting, palpitations, or irregular heartbeats or changes in heart rate.
- Swelling of the face, lips, tongue, or throat.
- Changes in vision or conditions of the eyes.
- Changes in blood pressure or conditions of the blood.

Common Side Effects

- Dizziness, lightheadedness, unusual tiredness, or weakness.
- Stomach pain, constipation, or diarrhea. If these symptoms persist, tell your doctor.
- Cough, which may be dry or with mucus. Tell your doctor if you have a persistent cough. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use

- Take lisinopril by mouth with or without food as directed by your doctor.
- Your doctor will tell you how often to take lisinopril. Take it regularly to get the most benefit. Do not take lisinopril more than prescribed.
- If you forget to take a dose, take it as soon as you remember. Do not take your next dose at your regularly scheduled time.
- Store at room temperature, away from light and moisture.

Lisinopril ["Lye-SIN-oh-priil"] (also known as: Prinivil, Zestril)

Uses

- Lisinopril is used to treat high blood pressure and heart failure.
- It is also used to treat heart failure and high blood pressure after a heart attack.
- It is used to protect the kidneys from damage.

Important Warning: Pregnancy

Lisinopril can cause serious (possibly fatal) harm to an unborn baby, so ask your doctor about reliable birth control. Tell your doctor right away if you are planning pregnancy or think you may be pregnant.

Tell your Doctor

Before using lisinopril, tell your doctor if you:

- are allergic to it, any of its inactive ingredients or other ACE inhibitors (such as benazepril), or have any other allergies.
- have had any of the following allergic reactions: swelling of the face, lips, tongue, or throat.
- have a high level of potassium in the blood, severe dehydration, kidney disease, blood vessel diseases (such as lupus).
- are considering breast feeding.
- are taking other drugs that may interact with lisinopril (such as aliskiren or lithium), drugs that increase potassium levels (including birth control products that contain drospirenone), or medicines that could increase blood pressure or worsen heart failure (such as cough-and-cold products, diet aids, or NSAIDs such as ibuprofen or naproxen).

Call Your Doctor

Call your doctor right away if you develop:

- a serious but rare allergic reaction such as hives, rash, or swelling especially of the face, lips, tongue, or throat. Call your doctor right away.
- muscle weakness. These are signs of low potassium levels.
- dizziness or lightheadedness. These are signs of low blood pressure.
- stomach pain, stomach cramps, or abdominal pain, persistent nausea/vomiting, yellowing eyes or skin. These are signs of liver problems.

Tell your doctor if you have:

- Prolonged diarrhea or vomiting. These conditions can cause dehydration which can lower blood pressure and cause dizziness.

• Dizziness, lightheadedness, or feeling tiredness, especially when you stand up.

• Weakness or muscle pain. Tell your doctor if you have these symptoms.

• Swelling of the face, lips, tongue, or throat.

Directions for Use

- Take this medicine by mouth with or without food as directed by your doctor.
- You should not take this medicine if you are allergic to it or if you are taking other medicines such as ACE inhibitors or potassium supplements.
- Store this medicine at room temperature, away from light and moisture.

Prototype

Drug Name

Uses

Call Your Doctor

Important Warning:

Tell your Doctor

Common Side Effects

Directions for Use

- Linear (vertical)
- Go all the way through
- Stop or repeat

Enhanced Design

Drug Name

Uses

Important Warning:

Tell your Doctor

Call Your Doctor

Common Side Effects

Directions for Use

- Linear (vertical)
- Go all the way through
- Stop or repeat

Enhanced Design

First
1-sec



Enhanced Design

First 1-sec

- Distinctive features
direct eye gaze
immediately



Enhanced Design

Then

- Flexible gaze
- Systematic gaze
- Get an overview
- Then focus
- More time on important information



Enhanced Design

Then

- Flexible gaze
- Systematic gaze
- Get an overview
- Then focus
- More time on important information
- Compare regions
- Optimize re-visits
- Search
- Form a mental image?!***
- Can improve cognition



Delivery of PMI

Printed vs. Electronic

*“If your doctor prescribed a medication for you in the future,
how would you like to get information about it?”*

Options

“If your doctor prescribed a medication for you in the future, how would you like to get information about it?”

Get a leaflet printed on paper,
given with the medicine at the pharmacy

Get an internet link to the leaflet,
given at the pharmacy

Do an internet search
on your own

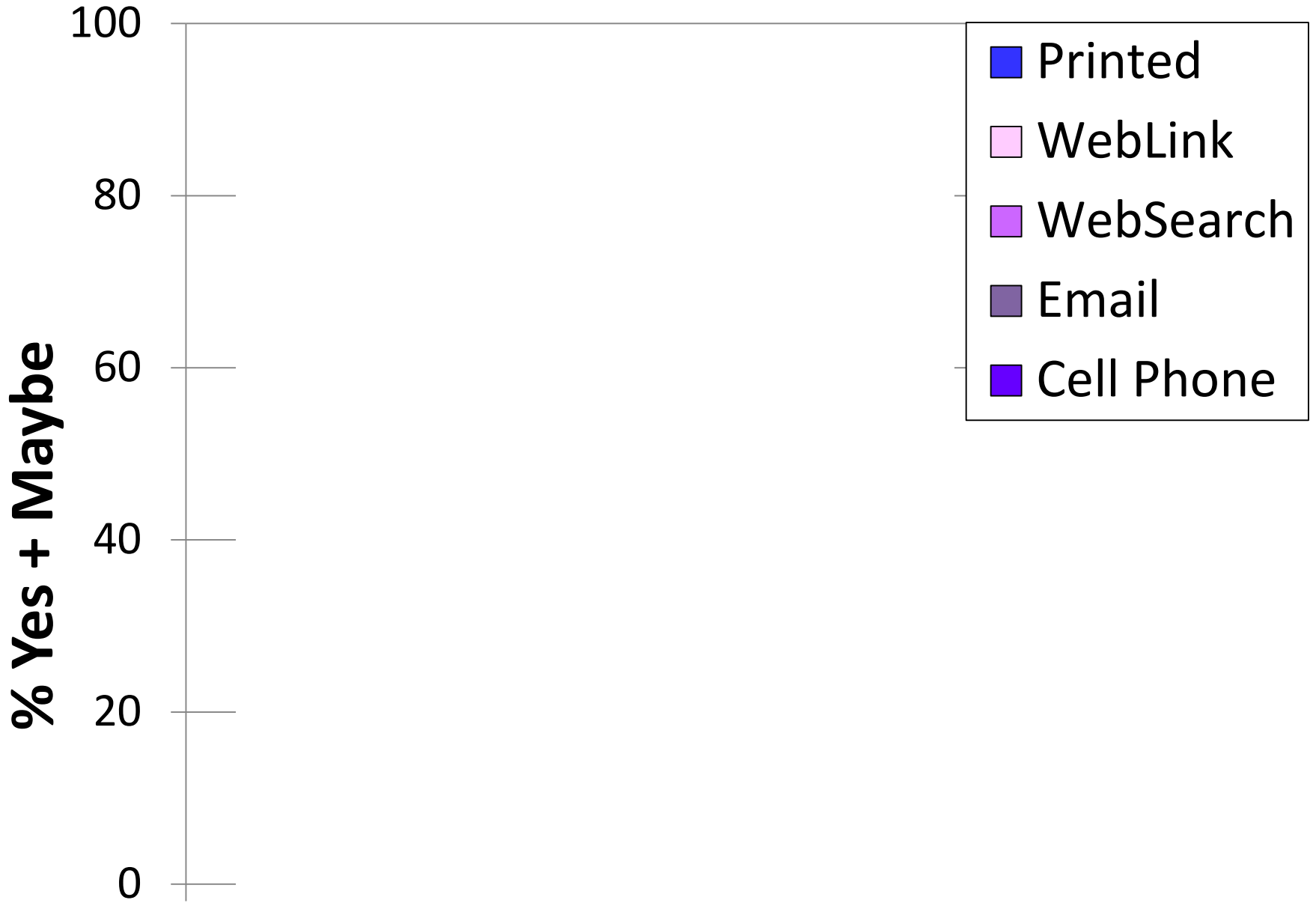
Have the leaflet sent to you by email,
from the pharmacy

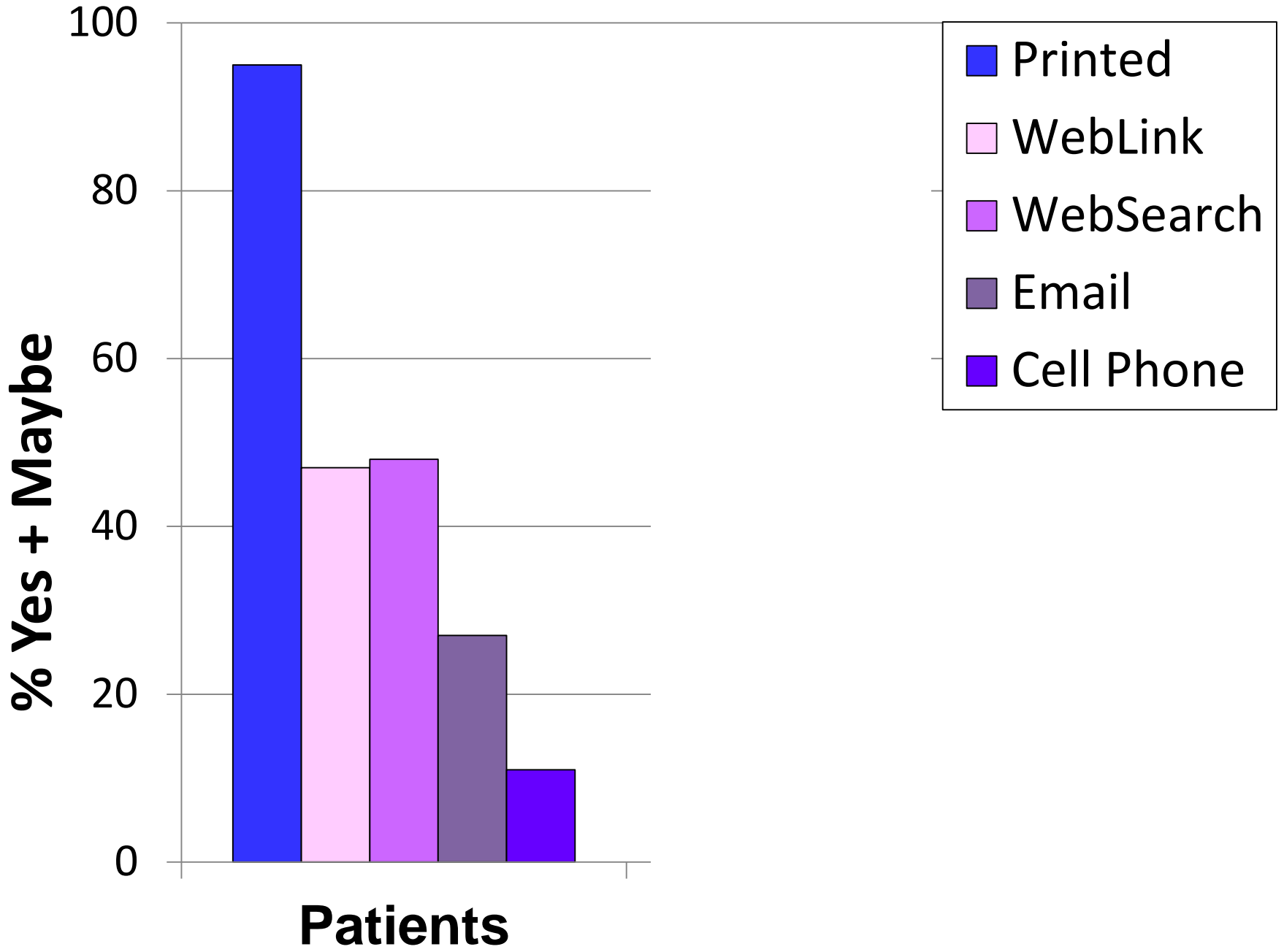
Have the leaflet sent to your cell phone,
from the pharmacy.

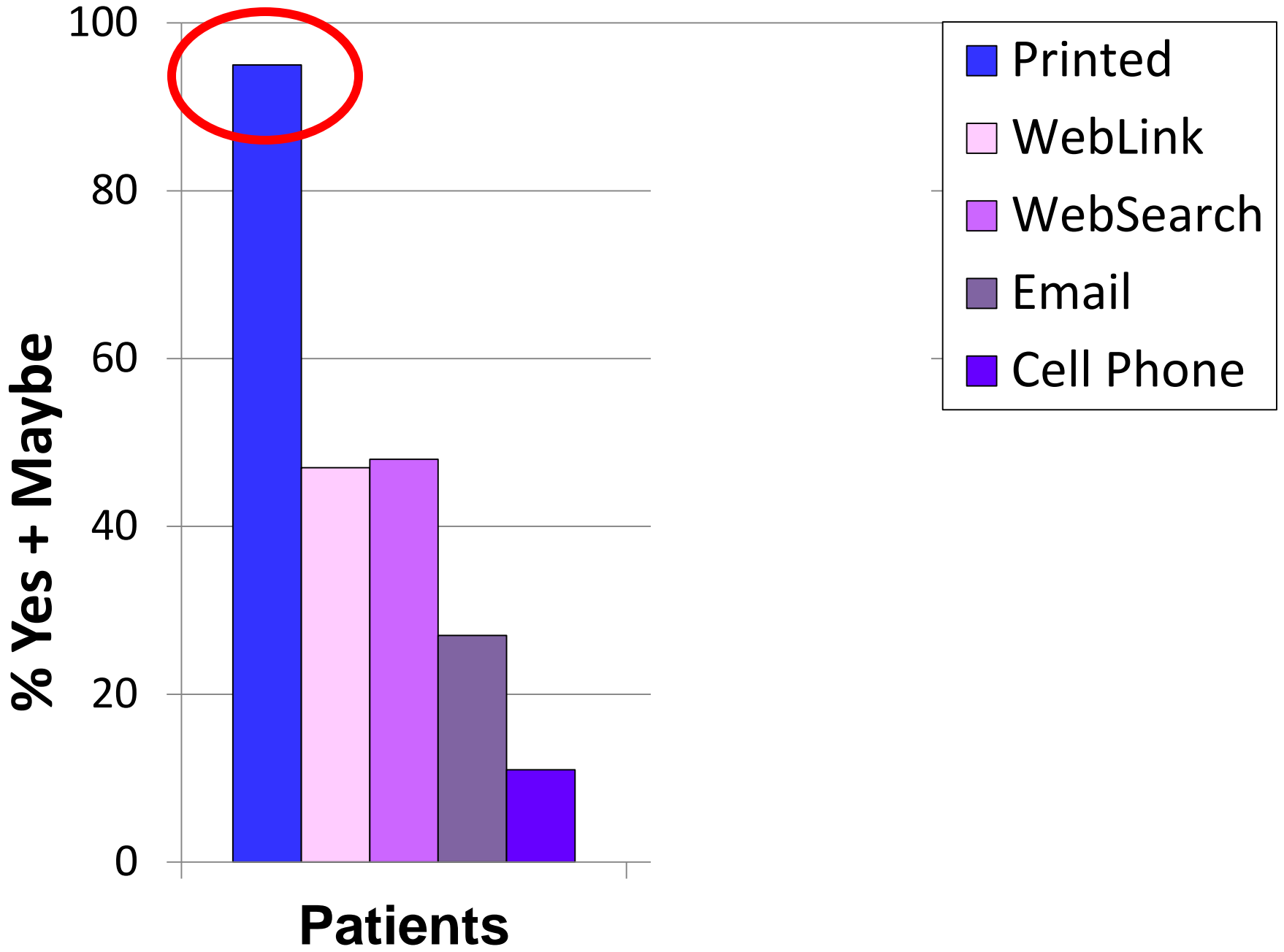
Options

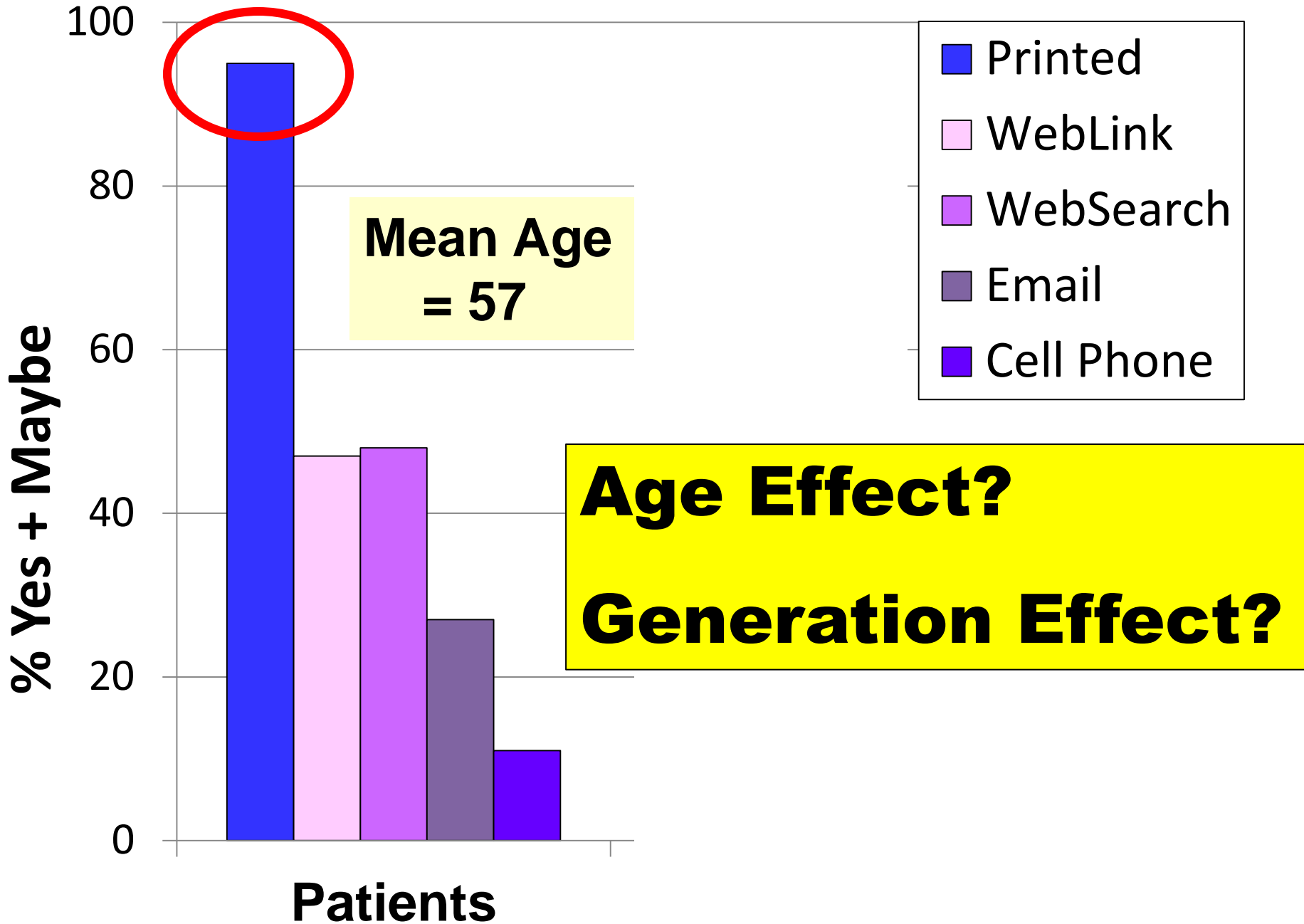
“If your doctor prescribed a medication for you in the future, how would you like to get information about it?”

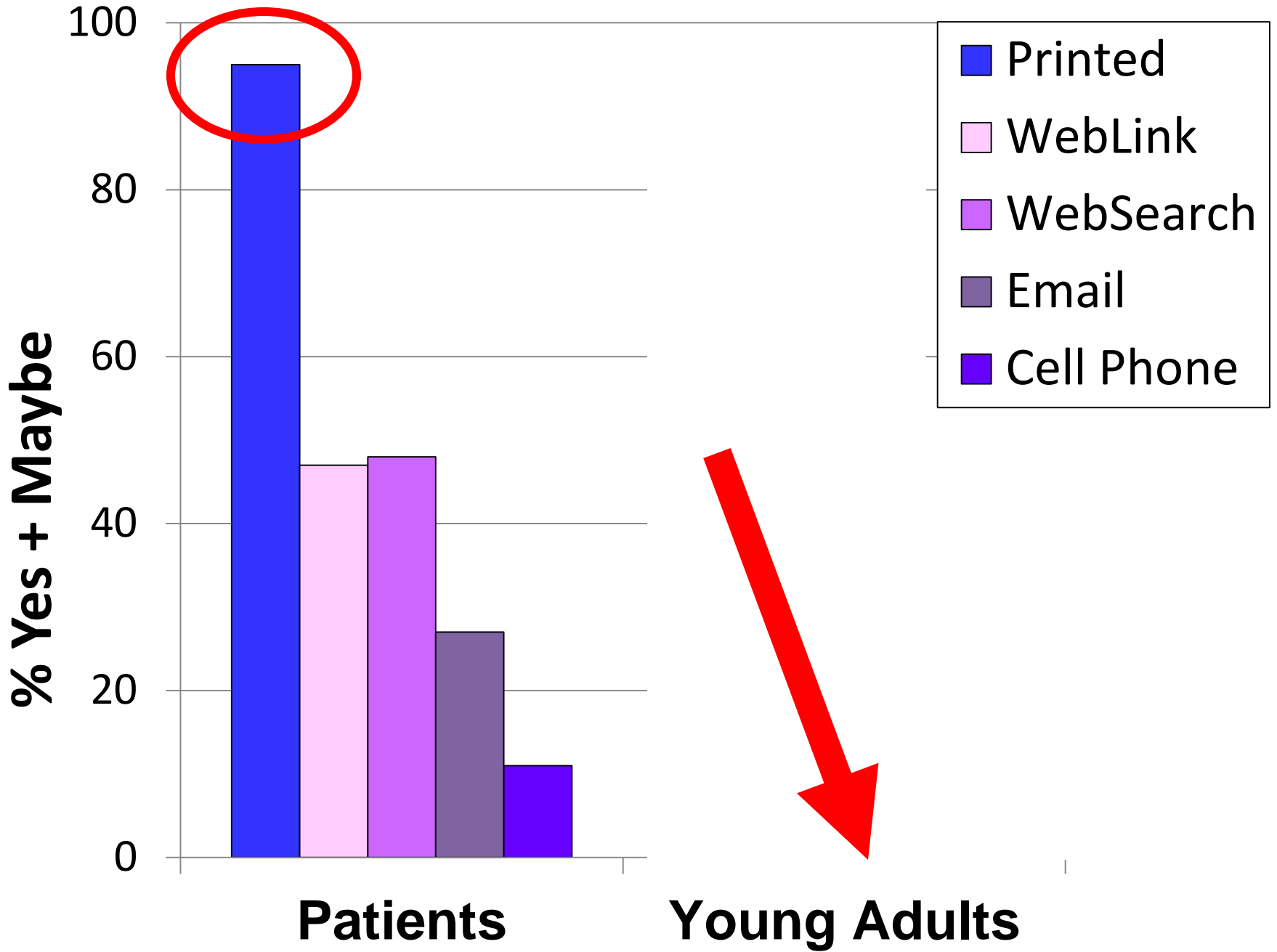
Printed	Get a leaflet printed on paper, given with the medicine at the pharmacy
WebLink	Get an internet link to the leaflet, given at the pharmacy
WebSearch	Do an internet search on your own
Email	Have the leaflet sent to you by email, from the pharmacy
Cell Phone	Have the leaflet sent to your cell phone, from the pharmacy.

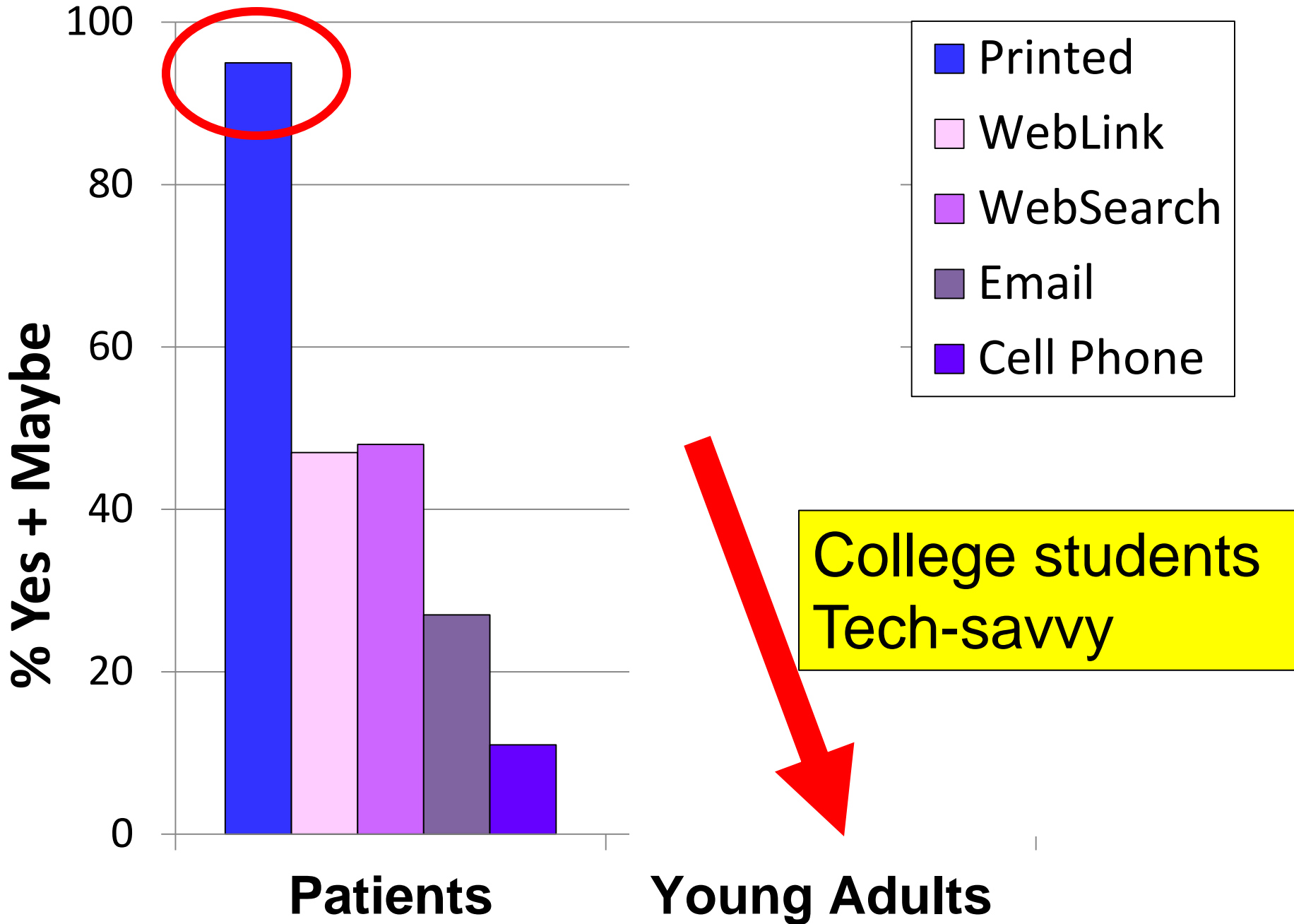


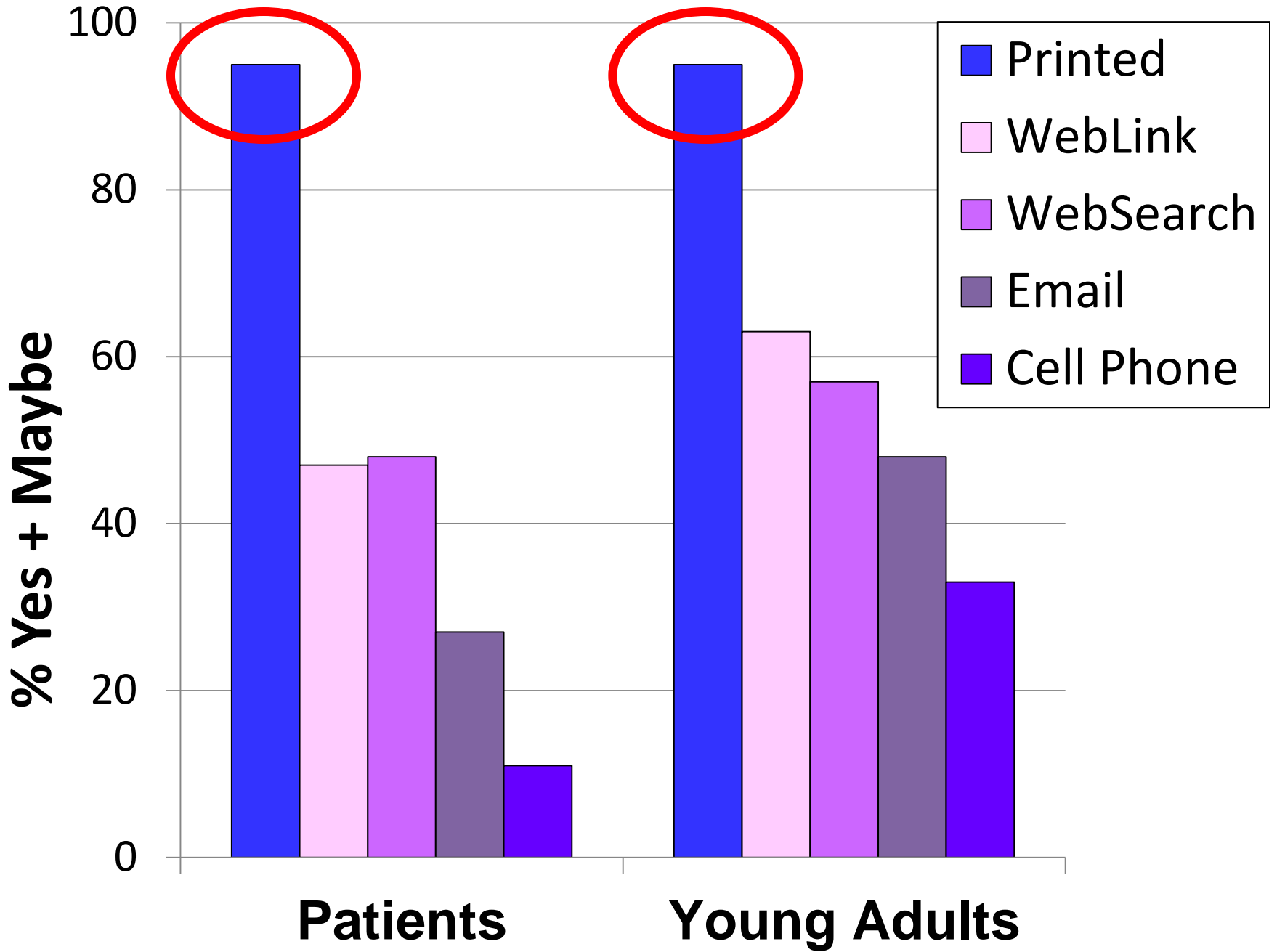












Conclusions

Prototypes

Developed with great care. Have many positive features.

<p>Prototype 1</p> <p>Rheumatoid Arthritis</p> <p>Active ingredient</p> <ul style="list-style-type: none"> • axialate <p>Uses</p> <ul style="list-style-type: none"> • rheumatoid arthritis (adults and children older than 4) • ankylosing spondylitis • plaque psoriasis in adults <p>Warnings</p> <p>Important warnings about Rheumatoid Arthritis</p> <ul style="list-style-type: none"> • You can get an infection that can cause death. <p>Ask your doctor before use if you</p> <ul style="list-style-type: none"> • have any signs of infection (fever, cough, flu-like symptoms) • have a skin infection (warm, red, painful skin or open sores) • have tested positive for tuberculosis (TB) or know someone who has TB • have gone outside the country • have a problem with your heart • are taking Kinerelex (anakinra) • have recently been vaccinated or are scheduled to be vaccinated <p>Stop use and call your doctor right away if you</p> <ul style="list-style-type: none"> • have weakness or • have an infection (fever, cough, flu-like symptoms) • have a skin infection (warm, red or painful skin) • have a skin rash • have numbness (can't feel your skin) or tingling skin • have changes in your vision • took more Rheumatoid Arthritis than you were told to take <p>You may report side effects to FDA at 1-800-FDA-1088.</p> <p>When using this medicine you may get</p> <ul style="list-style-type: none"> • redness where the shot was given • a stuffy or runny nose • headaches <p>There can be side effects of Rheumatoid Arthritis. Tell your doctor about any side effect that does not go away or gets worse.</p> <p>Directions</p> <ul style="list-style-type: none"> • Rheumatoid Arthritis is given by injection (shot). Do not use until your doctor tells you when and how to take this drug. • Do not miss any doses. If you do forget to take your Rheumatoid Arthritis, give yourself a shot as soon as you remember. Then take your next shot on time. • Store Rheumatoid Arthritis in the refrigerator (between 36°-46°F). • The medicine comes in a glass syringe. Do not drop or crush. <p>Questions</p> <ul style="list-style-type: none"> • For more information on Rheumatoid Arthritis visit www.fda.merck-information.org • Call [manufacturer] toll-free 1-800- from a.m. to p.m. (ET) Monday to Friday <p>Inactive ingredients</p> <p>Single-use prefilled syringe: sucrose, sodium chloride, L-arginine hydrochloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic anhydrous, Vitak, mannitol, sucrose, tromethamine.</p>	<p>PROTOTYPE 2</p> <p>Rheumatoid Arthritis (axialate) solution and powder for solution for subcutaneous injection</p> <p>Important Warning about Rheumatoid Arthritis</p> <ul style="list-style-type: none"> • Lymph node cancer: You may have a higher chance of getting cancer of the lymph nodes. • Blood clots: Your body may not make enough blood cells to fight infection or to help stop bleeding. Symptoms include bruising, fatigue, and pale skin. 	<p>PROTOTYPE 3</p> <p>Drug Information for: Axialate (as Rheumatoid Arthritis)</p> <p>Important Warning</p> <ul style="list-style-type: none"> • People who take Rheumatoid Arthritis have gotten serious infections, including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some 	<p>PROTOTYPE 4</p> <p>RHEUMATOID[®] (RHO-TOH-PEE-AH) (axialate)</p> <p>Read the information that comes with RHEUMATOID before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment with RHEUMATOID.</p> <p>What is the most important information I should know about RHEUMATOID?</p> <p>Serious infections can happen in people who receive RHEUMATOID. These infections include TB (tuberculosis), and infections caused by viruses, fungi or bacteria. Some people have died from these infections. RHEUMATOID is a medicine that affects your immune system. RHEUMATOID can lower the ability of your immune system to fight infections. RHEUMATOID can make you more likely to get infections or make worse any infection that you have.</p> <p>Before starting RHEUMATOID, tell your doctor if you:</p> <ul style="list-style-type: none"> • think you have an infection • are being treated for an infection • got a lot of infections or have infections that keep coming back • have any open cuts or sores on your body • have warm, red, or painful skin • have TB, or have been in close contact with someone who has TB. • have had in an area where TB is common. If you do not know if you have lived in an area where TB is common, ask your doctor. • were born in, lived in, or traveled to countries where there is a higher risk for getting TB. <p>Ask your doctor if you are not sure.</p> <p>You may have a higher chance for serious infections and a low white blood cell count when taking RHEUMATOID with Kinerelex[®] or other medicines that suppress the immune system.</p> <p>Your doctor will examine you for TB and perform a test to see if you have TB before starting RHEUMATOID. If your doctor feels that you are at risk for TB, you may be treated with a medicine for TB before you begin treatment with RHEUMATOID and during treatment with RHEUMATOID. If your doctor prescribes any medicine for the treatment of TB, you should start taking it before starting RHEUMATOID. Take the full course of TB medicine without stopping. If you test negative your doctor should carefully monitor you for TB infections while you take RHEUMATOID. People who have a negative TB test before receiving RHEUMATOID can develop active TB.</p> <p>Call your doctor right away if you get an infection or any of the following symptoms:</p> <ul style="list-style-type: none"> • a fever • a sore throat • weight loss • a cough that does not go away • flu-like symptoms • have any open cuts or sores on your body • warm, red, or painful skin <p>What is RHEUMATOID?</p> <p>RHEUMATOID is a medicine called a Tumor Necrosis Factor (TNF) blocker. RHEUMATOID is used to treat:</p> <ul style="list-style-type: none"> • moderate to severe rheumatoid arthritis (RA) in adults. RHEUMATOID can be used alone or with methotrexate or with certain other medicines. • moderate to severe polyarticular juvenile rheumatoid arthritis (PJRA) in children who have not responded well to other treatments.
--	--	--	--

Important Warning: Serious Infections

Rheumatoid Arthritis (RA) is given by injection (shot). Do not use until your doctor tells you when and how to take this drug. Do not miss any doses. If you do forget to take your Rheumatoid Arthritis, give yourself a shot as soon as you remember. Then take your next shot on time. Store Rheumatoid Arthritis in the refrigerator (between 36°-46°F). The medicine comes in a glass syringe. Do not drop or crush.

Call [manufacturer] at 1-800-123-4567

To report any side effect or concern (manufacturer) or phone 8 and Web address or FDA at 1-800-FDA-1088

Rheumatoid Arthritis was approved by the FDA on 11/20/2002

Revised: 5/20/03

back pain, swelling, and improves mobility.

- Moderate to severe chronic plaque psoriasis in adults who may benefit from taking medication (manufacturer) or phone 8 and Web address or FDA at 1-800-FDA-1088

Rheumatoid Arthritis improves or clears up areas of skin with psoriasis.

What Are The Risks?

Tell your doctor right away if you get any of the following symptoms:

- Serious Infections: See the Important Warning in the box at the top of the page. You should not use Rheumatoid Arthritis if you have an active infection. Symptoms of infection include fever, cough, flu-like symptoms, skin problems (red, warm, painful skin) or open sores.

Immune reactions with a lupus-like syndrome: Symptoms include chest discomfort or pain, shortness of breath, joint pain or a rash on your chest or arms.

Injection site reactions: You may get redness, rash, swelling, itching or bruising where the shot was given. If these symptoms get worse or don't go away in a couple days, tell your doctor.

Other common side effects may include infection, headache, or runny nose. Tell your doctor about any side effect that bothers you or that does not go away.

You may report side effects to FDA at 1-800-FDA-1088.

Read the information that comes with RHEUMATOID before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment with RHEUMATOID.

What is the most important information I should know about RHEUMATOID?

Serious infections can happen in people who receive RHEUMATOID. These infections include TB (tuberculosis), and infections caused by viruses, fungi or bacteria. Some people have died from these infections. RHEUMATOID is a medicine that affects your immune system. RHEUMATOID can lower the ability of your immune system to fight infections. RHEUMATOID can make you more likely to get infections or make worse any infection that you have.

Before starting RHEUMATOID, tell your doctor if you:

- think you have an infection
- are being treated for an infection
- got a lot of infections or have infections that keep coming back
- have any open cuts or sores on your body
- have warm, red, or painful skin
- have TB, or have been in close contact with someone who has TB.
- have had in an area where TB is common. If you do not know if you have lived in an area where TB is common, ask your doctor.
- were born in, lived in, or traveled to countries where there is a higher risk for getting TB.

Ask your doctor if you are not sure.

You may have a higher chance for serious infections and a low white blood cell count when taking RHEUMATOID with Kinerelex[®] or other medicines that suppress the immune system.

Your doctor will examine you for TB and perform a test to see if you have TB before starting RHEUMATOID. If your doctor feels that you are at risk for TB, you may be treated with a medicine for TB before you begin treatment with RHEUMATOID and during treatment with RHEUMATOID. If your doctor prescribes any medicine for the treatment of TB, you should start taking it before starting RHEUMATOID. Take the full course of TB medicine without stopping. If you test negative your doctor should carefully monitor you for TB infections while you take RHEUMATOID. People who have a negative TB test before receiving RHEUMATOID can develop active TB.

Call your doctor right away if you get an infection or any of the following symptoms:

- a fever
- a sore throat
- weight loss
- a cough that does not go away
- flu-like symptoms
- have any open cuts or sores on your body
- warm, red, or painful skin

What is RHEUMATOID?

RHEUMATOID is a medicine called a Tumor Necrosis Factor (TNF) blocker. RHEUMATOID is used to treat:

- moderate to severe rheumatoid arthritis (RA) in adults. RHEUMATOID can be used alone or with methotrexate or with certain other medicines.
- moderate to severe polyarticular juvenile rheumatoid arthritis (PJRA) in children who have not responded well to other treatments.

Rheumatoid Arthritis (RHO-TOH-PEE-AH) (also known as axialate)

Drug Approved by FDA, 2002
Last Revised: May 2003

Uses

- Rheumatoid arthritis in adults. Rheumatoid Arthritis reduces painful and swollen joints, slows joint damage, and improves mobility and the ability to do physical activities.
- Polyarticular juvenile rheumatoid arthritis in children at least 4 years old who did not have good results from other medicines. Rheumatoid Arthritis reduces pain, improves mobility, and decreases the number of painful joints.
- Ankylosing spondylitis. Rheumatoid Arthritis reduces back pain, swelling, and improves mobility.
- Plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy using ultraviolet light. Rheumatoid Arthritis improves or clears up areas of skin with psoriasis.

Important Warning: Serious Infections

Rheumatoid Arthritis is given by injection (shot). Do not use until your doctor tells you when and how to take this drug. Do not miss any doses. If you do forget to take your Rheumatoid Arthritis, give yourself a shot as soon as you remember. Then take your next shot on time. Store Rheumatoid Arthritis in the refrigerator (between 36°-46°F). The medicine comes in a glass syringe. Do not drop or crush.

Call [manufacturer] toll-free 1-800- from a.m. to p.m. (ET) Monday to Friday

Inactive ingredients

Single-use prefilled syringe: sucrose, sodium chloride, L-arginine hydrochloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic anhydrous, Vitak, mannitol, sucrose, tromethamine.

Call Your Doctor

Stop using Rheumatoid Arthritis and tell your doctor right away if you develop:

- Fever, cough, flu-like symptoms, skin infection (red, warm, painful skin or open sores). These can be symptoms of a serious infection.
- Numbness, tingling, weakness, vision problems, or dizziness. Symptoms of nervous system diseases, like multiple sclerosis, may develop or get worse.
- Chills, swollen lymph nodes, night sweats, fever, or sudden weight gain. You may have a higher chance of getting lymph node cancer.
- Bruising, bleeding, and pale skin. Your body may not make enough blood cells to fight infection or to help stop bleeding.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain. You may have a higher chance of heart failure that may develop or get worse.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms. These may be symptoms of an immune reaction with lupus-like syndrome.

Common Side Effects

- Redness, rash, swelling, itching or bruising where the shot was given.
- Headache
- Runny nose

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use

- Rheumatoid Arthritis is an injection (shot). Do not use Rheumatoid Arthritis until your doctor has shown you how to give it a shot.
- Store Rheumatoid Arthritis in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheumatoid Arthritis. Do not use Rheumatoid Arthritis more often than prescribed.

Directions for Use

- Rheumatoid Arthritis is an injection (shot). Do not use until your doctor tells you when and how to take this drug. Do not miss any doses. If you do forget to take your Rheumatoid Arthritis, give yourself a shot as soon as you remember. Then take your next shot on time. Store Rheumatoid Arthritis in the refrigerator (between 36°-46°F). The medicine comes in a glass syringe. Do not drop or crush.

Call Your Doctor

Stop using Rheumatoid Arthritis and tell your doctor right away if you develop:

- Fever, cough, flu-like symptoms, a skin infection (red, warm, painful skin or open sores)
- Numbness, tingling, weakness, vision problems, or dizziness.
- Chills, swollen lymph nodes, night sweats, fever, or weight loss.
- Bruising, bleeding, and pale skin.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms.

Common Side Effects

- Redness, rash, swelling, itching or bruising where the shot was given.
- Headache
- Runny nose

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for use

- Rheumatoid Arthritis is an injection (shot). Do not use until your doctor has shown you how to give a shot.
- Store Rheumatoid Arthritis in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheumatoid Arthritis. Do not use Rheumatoid Arthritis more often than prescribed.

Dist. Prototype 2A, 3/18/03

Rheumatoid Arthritis (RHO-TOH-PEE-AH) (also known as axialate)

Drug Approved by FDA, 2002
Last Revised: May 2003

Uses

- Rheumatoid arthritis in adults. Rheumatoid Arthritis reduces painful and swollen joints, slows joint damage, and improves mobility and the ability to do physical activities.
- Polyarticular juvenile rheumatoid arthritis in children at least 4 years old who did not have good results from other medicines. Rheumatoid Arthritis reduces pain, improves mobility, and decreases the number of painful joints.
- Ankylosing spondylitis. Rheumatoid Arthritis reduces back pain, swelling, and improves mobility.
- Plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy using ultraviolet light. Rheumatoid Arthritis improves or clears up areas of skin with psoriasis.

Important Warning: Serious Infections

Rheumatoid Arthritis is given by injection (shot). Do not use until your doctor tells you when and how to take this drug. Do not miss any doses. If you do forget to take your Rheumatoid Arthritis, give yourself a shot as soon as you remember. Then take your next shot on time. Store Rheumatoid Arthritis in the refrigerator (between 36°-46°F). The medicine comes in a glass syringe. Do not drop or crush.

Call [manufacturer] toll-free 1-800- from a.m. to p.m. (ET) Monday to Friday

Inactive ingredients

Single-use prefilled syringe: sucrose, sodium chloride, L-arginine hydrochloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic anhydrous, Vitak, mannitol, sucrose, tromethamine.

Call Your Doctor

Stop using Rheumatoid Arthritis and tell your doctor right away if you develop:

- Fever, cough, flu-like symptoms, skin infection (red, warm, painful skin or open sores). These can be symptoms of a serious infection.
- Numbness, tingling, weakness, vision problems, or dizziness.
- Chills, swollen lymph nodes, night sweats, fever, or weight loss.
- Bruising, bleeding, and pale skin.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms.

Common Side Effects

- Redness, rash, swelling, itching or bruising where the shot was given.
- Headache
- Runny nose

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use

- Rheumatoid Arthritis is an injection (shot). Do not use until your doctor tells you when and how to take this drug. Do not miss any doses. If you do forget to take your Rheumatoid Arthritis, give yourself a shot as soon as you remember. Then take your next dose at your regularly scheduled time.
- Store Rheumatoid Arthritis in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheumatoid Arthritis. Do not use Rheumatoid Arthritis more often than prescribed.

Call Your Doctor

Stop using Rheumatoid Arthritis and tell your doctor right away if you develop:

- Fever, cough, flu-like symptoms, a skin infection (red, warm, painful skin or open sores)
- Numbness, tingling, weakness, vision problems, or dizziness.
- Chills, swollen lymph nodes, night sweats, fever, or weight loss.
- Bruising, bleeding, and pale skin.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms.

Common Side Effects

- Redness, rash, swelling, itching or bruising where the shot was given.
- Headache
- Runny nose

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for use

- Rheumatoid Arthritis is an injection (shot). Do not use until your doctor has shown you how to give a shot.
- Store Rheumatoid Arthritis in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheumatoid Arthritis. Do not use Rheumatoid Arthritis more often than prescribed.

Dist. Prototype 1A, 3/18/03

Rheumatoid Arthritis (RHO-TOH-PEE-AH) (also known as axialate)

Drug Approved by FDA, 2002
Last Revised: May 2003

Uses

- Rheumatoid arthritis in adults. Rheumatoid Arthritis reduces painful and swollen joints, slows joint damage, and improves mobility and the ability to do physical activities.
- Polyarticular juvenile rheumatoid arthritis in children at least 4 years old who did not have good results from other medicines. Rheumatoid Arthritis reduces pain, improves mobility, and decreases the number of painful joints.
- Ankylosing spondylitis. Rheumatoid Arthritis reduces back pain, swelling, and improves mobility.
- Plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy using ultraviolet light. Rheumatoid Arthritis improves or clears up areas of skin with psoriasis.

Important Warning: Serious Infections

Rheumatoid Arthritis is given by injection (shot). Do not use until your doctor tells you when and how to take this drug. Do not miss any doses. If you do forget to take your Rheumatoid Arthritis, give yourself a shot as soon as you remember. Then take your next shot on time. Store Rheumatoid Arthritis in the refrigerator (between 36°-46°F). The medicine comes in a glass syringe. Do not drop or crush.

Call [manufacturer] toll-free 1-800- from a.m. to p.m. (ET) Monday to Friday

Inactive ingredients

Single-use prefilled syringe: sucrose, sodium chloride, L-arginine hydrochloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic anhydrous, Vitak, mannitol, sucrose, tromethamine.

Call Your Doctor

Stop using Rheumatoid Arthritis and tell your doctor right away if you develop:

- Fever, cough, flu-like symptoms, skin infection (red, warm, painful skin or open sores). These can be symptoms of a serious infection.
- Numbness, tingling, weakness, vision problems, or dizziness.
- Chills, swollen lymph nodes, night sweats, fever, or weight loss.
- Bruising, bleeding, and pale skin.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms.

Common Side Effects

- Redness, rash, swelling, itching or bruising where the shot was given.
- Headache
- Runny nose

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use

- Rheumatoid Arthritis is an injection (shot). Do not use until your doctor tells you when and how to take this drug. Do not miss any doses. If you do forget to take your Rheumatoid Arthritis, give yourself a shot as soon as you remember. Then take your next dose at your regularly scheduled time.
- Store Rheumatoid Arthritis in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheumatoid Arthritis. Do not use Rheumatoid Arthritis more often than prescribed.

Call Your Doctor

Stop using Rheumatoid Arthritis and tell your doctor right away if you develop:

- Fever, cough, flu-like symptoms, a skin infection (red, warm, painful skin or open sores)
- Numbness, tingling, weakness, vision problems, or dizziness.
- Chills, swollen lymph nodes, night sweats, fever, or weight loss.
- Bruising, bleeding, and pale skin.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms.

Common Side Effects

- Redness, rash, swelling, itching or bruising where the shot was given.
- Headache
- Runny nose

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for use

- Rheumatoid Arthritis is an injection (shot). Do not use until your doctor has shown you how to give a shot.
- Store Rheumatoid Arthritis in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheumatoid Arthritis. Do not use Rheumatoid Arthritis more often than prescribed.

Dist. Prototype 3A, 3/18/03

Prototypes

**Developed with great care.
Have many positive features.
But some drawbacks, too.
--i.e., cognitive accessibility**

Prototype 1 **Rheutopia**

Active ingredient

- **axixalate**

Uses

- rheumatoid arthritis (adults and children older than 4)
- ankylosing spondylitis
- plaque psoriasis in adults

Warnings

Important warnings about Rheutopia

- You can get an infection that can cause death.

Ask your doctor before use if you

- have any signs of infection (fever, cough, flu-like symptoms)
- have a skin infection (warm, red, painful skin or open sores)
- have tested positive for tuberculosis (TB) or know someone who has TB
- have gone outside the country
- have a problem with your heart
- are taking Kineret (anakinra)
- have recently been vaccinated or are scheduled to be vaccinated

Stop use and call your doctor right away if you

- have an infection (fever, cough, flu-like symptoms)
- have a skin infection (warm, red or painful skin)
- have a skin rash
- have numbness (can't feel your skin) or tingling skin
- have changes in your vision

Side effects

- feel faint or light
- easily bruise or get short of breath
- get swollen (ed)
- have chest pain

When using this medicine you may get

- redness where the shot was given
- a stuffy or runny nose
- headaches

There can be side effects of Rheutopia. Tell your doctor about any side effect you get or gets worse.

Directions

- Rheutopia is given by injection (shot). Do not use until your doctor tells you to take this drug.
- Do not miss any doses. If you do forget to take your Rheutopia, give you as you remember. Then take your next shot on time.
- Store Rheutopia in the refrigerator (between 36° - 46° F).
- The medicine comes in a glass syringe. Do not drop or crush.

Questions

- For more information on Rheutopia visit www.fda.gov/medwatch
- Call (manufacturer) toll-free 1-800- from a.m. to p.m. (ET).

Inactive ingredients

Single-use prefilled syringe: sucrose, sodium chloride, L-arginine hydrochloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic anhydrous. Vial: mannitol, sucrose, tromethamine.

PROTOTYPE 2

Rheutopia (axixalate) solution and powder for solution for subcutaneous injection

Important Warning about Rheutopia

- Lymph node cancer: You may have a higher chance of getting cancer of the lymph nodes.
- Blood problems: Your body may not make enough blood cells to fight infection or to help stop bleeding. Symptoms include bruising, fatigue, and pale skin.

PROTOTYPE 3

Rheutopia (axixalate) solution and powder for solution for subcutaneous injection

Drug Information for: Axixalate (marked as Rheutopia)

Important Warning

- People who take Rheutopia have gotten serious infections, including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some

PROTOTYPE 4

RHEUTOPIA® (Roo-TOH-PEE-ah) (axixalate)

Read this information that comes with RHEUTOPIA before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment with RHEUTOPIA.

What is the most important information I should know about RHEUTOPIA?

Serious infections can happen in people who receive RHEUTOPIA. These infections include TB (tuberculosis), and infections caused by viruses, fungi or bacteria. Some people have died from these infections. RHEUTOPIA is a medicine that affects your immune system. RHEUTOPIA can lower the ability of your immune system to fight infections. RHEUTOPIA can make you more likely to get infections or make worse any infection that you have.

Before starting RHEUTOPIA, tell your doctor if you:

- think you have an infection
- are being treated for an infection
- have signs of an infection, such as a fever, cough, or flu-like symptoms
- have any open cuts or sores on your body
- have warm, red, or painful skin
- get a lot of infections or have infections that keep coming back
- have TB, or have been in close contact with someone who has TB.
- have lived in an area where TB is common. If you do not know if you have lived in an area where TB is common, ask your doctor.
- were born in, lived in, or traveled to countries where there is a higher risk for getting TB. Ask your doctor if you are not sure.
- take the medicine Kineret (anakinra) or other medicines that suppress the immune system. You may have a higher chance for serious infections and a low white blood cell count when taking RHEUTOPIA with Kineret or other medicines that suppress your immune system.

Your doctor will examine you for TB and perform a test to see if you have TB before starting RHEUTOPIA. If your doctor feels that you are at risk for TB, you may be treated with a medicine for TB before you begin treatment with RHEUTOPIA and during treatment with RHEUTOPIA. If your doctor prescribes any medicine for the treatment of TB, you should start taking it before starting RHEUTOPIA. Take the full course of TB medicine prescribed. Even if you feel better, your doctor should carefully monitor you for TB infections while you take RHEUTOPIA. People who have a negative TB test before receiving RHEUTOPIA can develop active TB.

Call your doctor right away if you get an infection or any of the following symptoms:

- a fever
- feel very tired
- weight loss
- a cough that does not go away
- flu-like symptoms
- have any open cuts or sores on your body
- warm, red, or painful skin

What is RHEUTOPIA?

RHEUTOPIA is a medicine called a Tumor Necrosis Factor (TNF) blocker. RHEUTOPIA is used to treat:

- moderate to severe rheumatoid arthritis (RA) in adults. RHEUTOPIA can be used alone or with methotrexate or with certain other medicines.
- moderate to severe polyarticular juvenile rheumatoid arthritis (PJRA) in children who have not responded well to other treatments.

Rheutopia (Roo-TOH-pee-ah) (also known as axixalate)

Uses

- Rheumatoid arthritis in adults. Rheutopia reduces pain and swollen joints, slows joint damage, and improves mobility and the ability to do physical activities.
- Polyarticular juvenile rheumatoid arthritis in children at least 4 years old who did not have good results from other medicines. Rheutopia reduces pain, improves mobility, and decreases the number of painful joints.
- Ankylosing spondylitis. Rheutopia reduces back pain, swelling, and improves mobility.
- Plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy using ultraviolet light. Rheutopia improves or clears up areas of skin with psoriasis.

Important Warning: Serious Infections

Rheutopia affects the immune system. It can lower your ability to fight infections. Do not use Rheutopia if you have an active infection.

People taking Rheutopia have gotten serious infections including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some people have died from these infections.

Tell Your Doctor

Before using Rheutopia, tell your doctor if you:

- have an infection, are being treated for an infection, or think you have an infection (such as a cold, flu or skin infection).
- have TB or have been near someone who has TB. You may be tested and treated for TB.
- have any nervous system or heart problems.
- have lived in or traveled to other countries.
- There is more risk for getting TB or other infections in certain countries.
- have been recently been vaccinated or are scheduled to receive a vaccination (including a flu shot). You should not get a vaccination while taking Rheutopia.
- are taking the medicine Kineret (anakinra). The risk of serious infections increases when used with Rheutopia.

Call Your Doctor

Stop using Rheutopia and tell your doctor right away if you develop:

- Fever, cough, flu-like symptoms, skin infection (red, warm, painful skin or open sores). These can be symptoms of a serious infection.
- Numbness, tingling, weakness, vision problems, or dizziness. Symptoms of nervous system diseases, like multiple sclerosis, may develop or get worse.
- Chills, swollen lymph nodes, night sweats, fever, or sudden weight loss. These are symptoms of heart failure that may develop or get worse.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms. These may be symptoms of an immune reaction with lupus-like syndrome.

Common Side Effects

- Redness, rash, swelling, itching or bruising where the shot was given.
- Headache
- Runny nose

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use

- Rheutopia is an injection (shot). Do not use Rheutopia until your doctor has shown you how to give a shot.
- Store Rheutopia in the refrigerator. Do not shake or freeze.

Directions for Use

- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheutopia. Do not use Rheutopia more often than prescribed.

Rheutopia (Roo-TOH-pee-ah) (also known as axixalate)

Uses

- Rheumatoid arthritis in adults. Rheutopia reduces painful and swollen joints, slows joint damage, and improves mobility and the ability to do physical activities.
- Polyarticular juvenile rheumatoid arthritis in children at least 4 years old who did not have good results from other medicines. Rheutopia reduces pain, improves mobility, and decreases the number of painful joints.
- Ankylosing spondylitis. Rheutopia reduces back pain, swelling, and improves mobility.
- Plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy using ultraviolet light. Rheutopia improves or clears up areas of skin with psoriasis.

Important Warning: Serious Infections

Rheutopia affects the immune system. It can lower your ability to fight infections. Do not use Rheutopia if you have an active infection. People taking Rheutopia have gotten serious infections including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some people have died from these infections.

Tell Your Doctor

Before using Rheutopia, tell your doctor if you:

- have an infection, are being treated for an infection, or think you have an infection (such as a cold, flu or skin infection).
- have TB or have been near someone who has TB.
- have any nervous system or heart problems.
- have lived in or traveled to other countries.
- have recently been vaccinated or are scheduled to receive a vaccination (including a flu shot).
- are taking the medicine Kineret (anakinra).

Call Your Doctor

Stop using Rheutopia and tell your doctor right away if you develop:

- Fever, cough, flu-like symptoms, a skin infection (red, warm, painful skin or open sores).
- Numbness, tingling, weakness, vision problems, or dizziness.
- Chills, swollen lymph nodes, night sweats, fever, or weight loss.
- Bruising, bleeding, and pale skin.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms.

Common Side Effects

- Redness, rash, swelling, itching or bruising where the shot was given.
- Headache
- Runny nose

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use

- Rheutopia is an injection (shot). Do not use Rheutopia until your doctor has shown you how to give a shot.
- Store Rheutopia in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheutopia. Do not use Rheutopia more often than prescribed.

Rheutopia (Roo-TOH-pee-ah) (also known as axixalate)

Uses

- Rheumatoid arthritis in adults. Rheutopia reduces painful and swollen joints, slows joint damage, and improves mobility and the ability to do physical activities.
- Polyarticular juvenile rheumatoid arthritis in children at least 4 years old who did not have good results from other medicines. Rheutopia reduces pain, improves mobility, and decreases the number of painful joints.
- Ankylosing spondylitis. Rheutopia reduces back pain, swelling, and improves mobility.
- Plaque psoriasis in adults who may benefit from taking medicine or receiving phototherapy using ultraviolet light. Rheutopia improves or clears up areas of skin with psoriasis.

Important Warning: Serious Infections

Rheutopia affects the immune system. It can lower your ability to fight infections. Do not use Rheutopia if you have an active infection. People taking Rheutopia have gotten serious infections including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria. Some people have died from these infections.

Tell your doctor before using if you

- have an infection, are being treated for an infection, or think you have an infection (such as a cold, flu or skin infection).
- have TB or have been near someone who has TB.
- have any nervous system or heart problems.
- have lived in or traveled to other countries.
- have recently been vaccinated or are scheduled to receive a vaccination (including a flu shot).
- are taking the medicine Kineret (anakinra).

Stop use and call your doctor right away if you develop

- Fever, cough, flu-like symptoms, a skin infection (red, warm, painful skin or open sores).
- Numbness, tingling, weakness, vision problems, or dizziness.
- Chills, swollen lymph nodes, night sweats, fever, or weight loss.
- Bruising, bleeding, and pale skin.
- Shortness of breath, swelling of ankles or feet, or sudden weight gain.
- Chest discomfort or pain, shortness of breath, joint pain or a rash on your cheeks or arms.

Common side effects

- redness, rash, swelling, itching, or bruising where the shot was given.
- headache
- runny nose

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for use

- Rheutopia is an injection (shot). Do not use Rheutopia until your doctor has shown you how to give a shot.
- Store Rheutopia in the refrigerator. Do not shake or freeze.
- If you forget to take a dose, take it as soon as you remember. Take your next dose at your regularly scheduled time.
- Your doctor will tell you how often to use Rheutopia. Do not use Rheutopia more often than prescribed.

Enhanced Designs

Now is a good time to consider:

- Key cognitive principles
- Overall spatial design
 - how it can direct attention and facilitate cognition
- Distinctive designs for specific content
- The role of mental images
 - in supporting cognition

Enhanced Designs

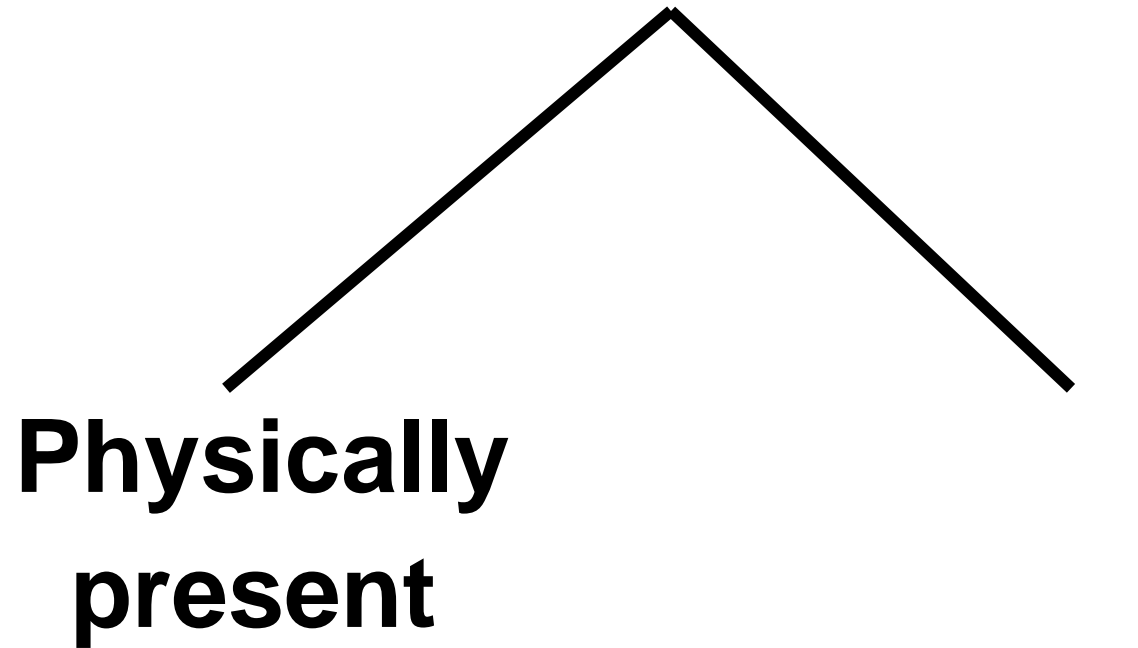
Now is a good time to consider:

- Key cognitive principles
- Overall spatial design
 - how it can direct attention and facilitate cognition
- Distinctive designs for specific content
- The role of mental images
 - in supporting cognition

The evidence presented here

--invites this consideration.

INFORMATION



**Physically
present**

INFORMATION

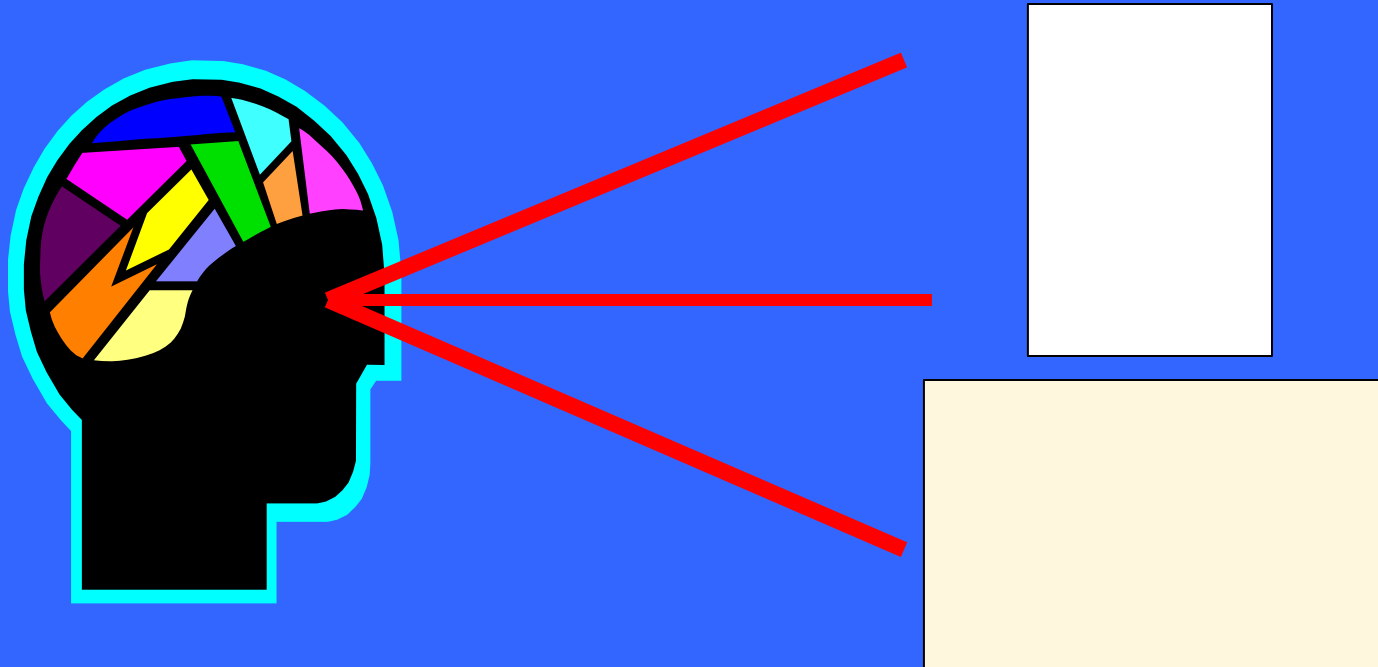
```
graph TD; INFORMATION --> Physically_present[Physically present]; INFORMATION --> Functionally_absent[Functionally absent];
```

**Physically
present**

**Functionally
absent**

Enhanced Designs for PMI:

Improving Attention, Comprehension, and Memory



Ruth S. Day / Duke University

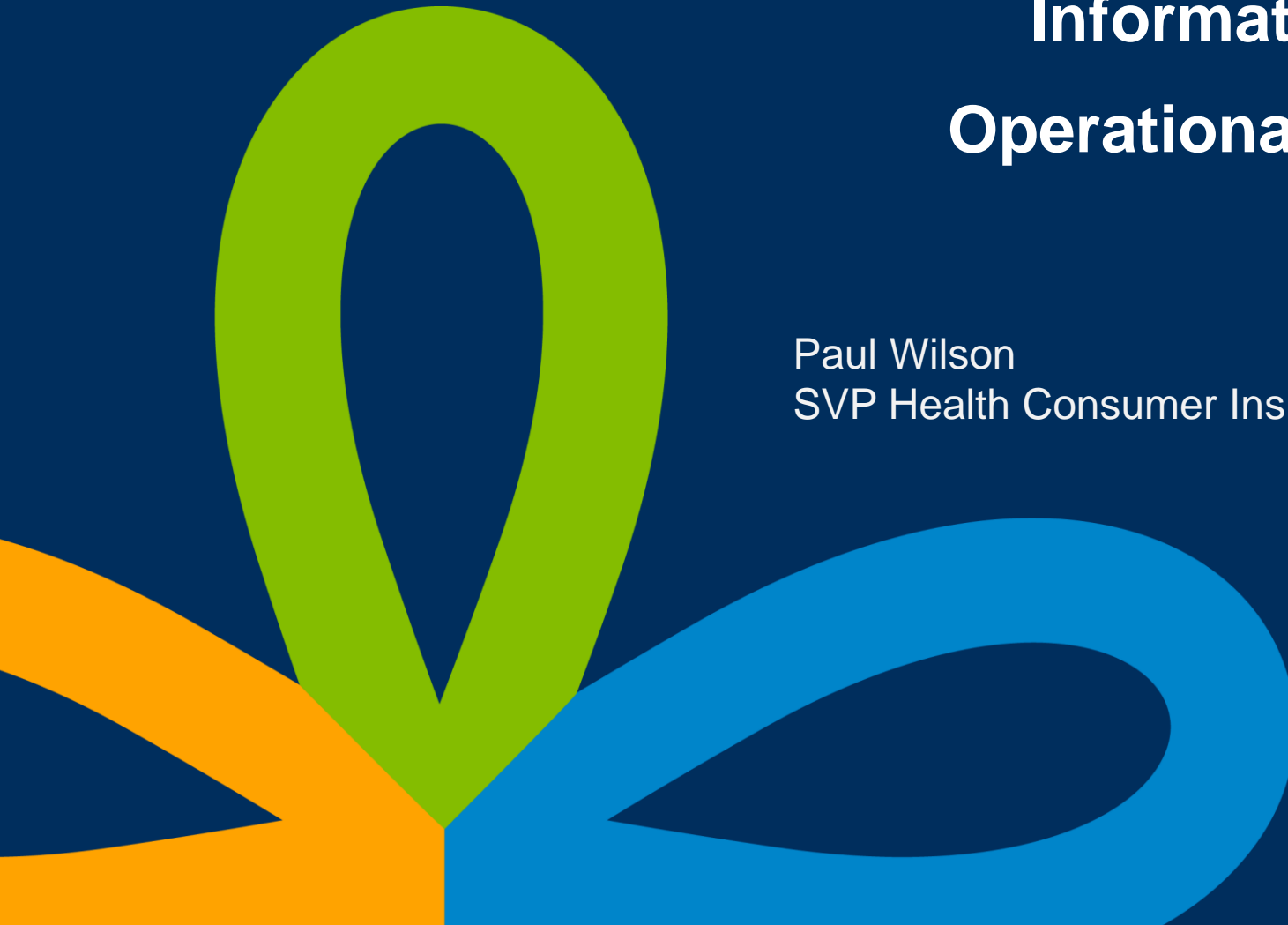
Brookings Institution / July 1, 2014

Exploring the Promise of Patient Medication Information

Engelberg Center for Health Care Reform
The Brookings Institution
Washington, DC
July 1, 2014

Patient Medication Information Operational Pilot

Paul Wilson
SVP Health Consumer Insights and Analytics

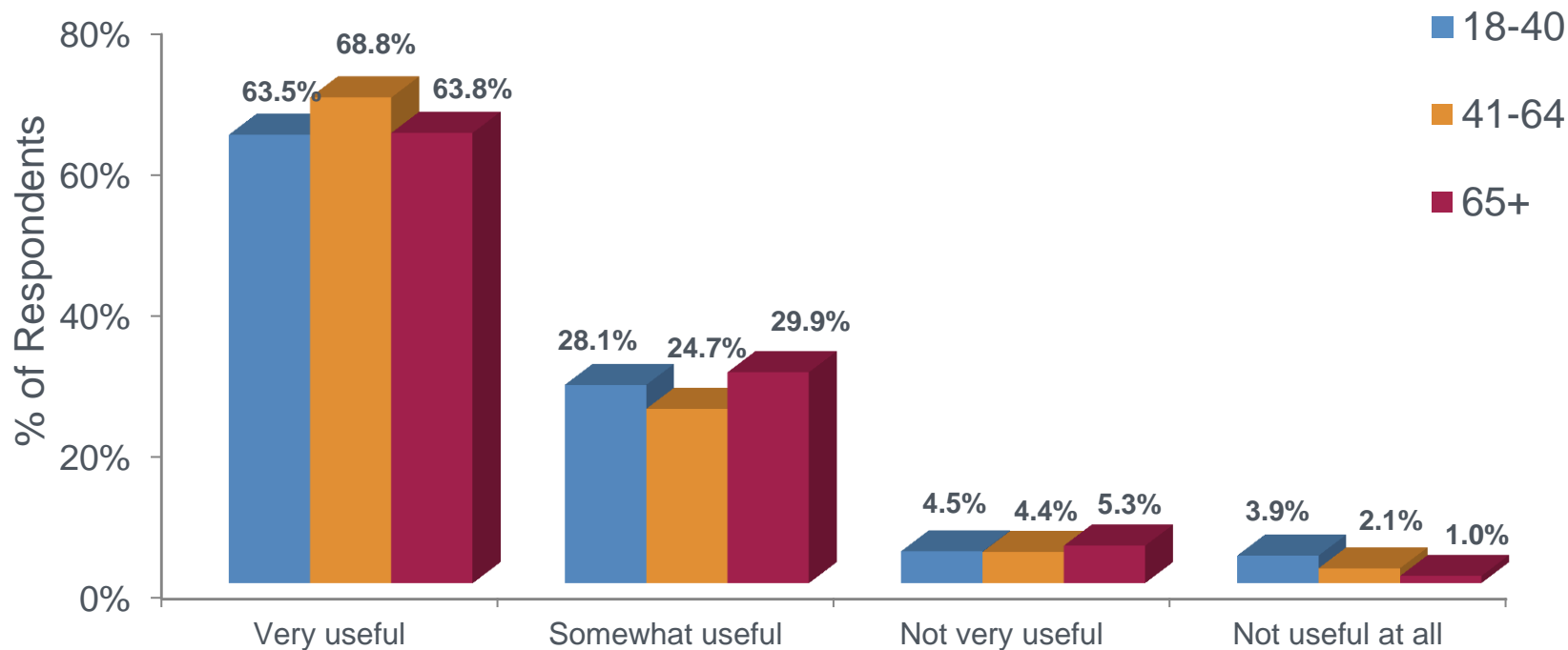


PMI Operational Pilot Survey Background

- Adheris Health in conjunction with a large retail chain ran a test of the PMI for 3 chronic brands
- PMI content developed by Pfizer (Celebrex), GSK (Ventolin HFA) and Janssen (Prezista)
- Test ran in California and Michigan between 8/6/12 and 9/30/12
- Follow up survey asked 3,200 health consumers
 - if they received new PMI
 - what they did with the PMI
 - if they found the information useful, and
 - how they would like to receive newly-formatted PMI in the future

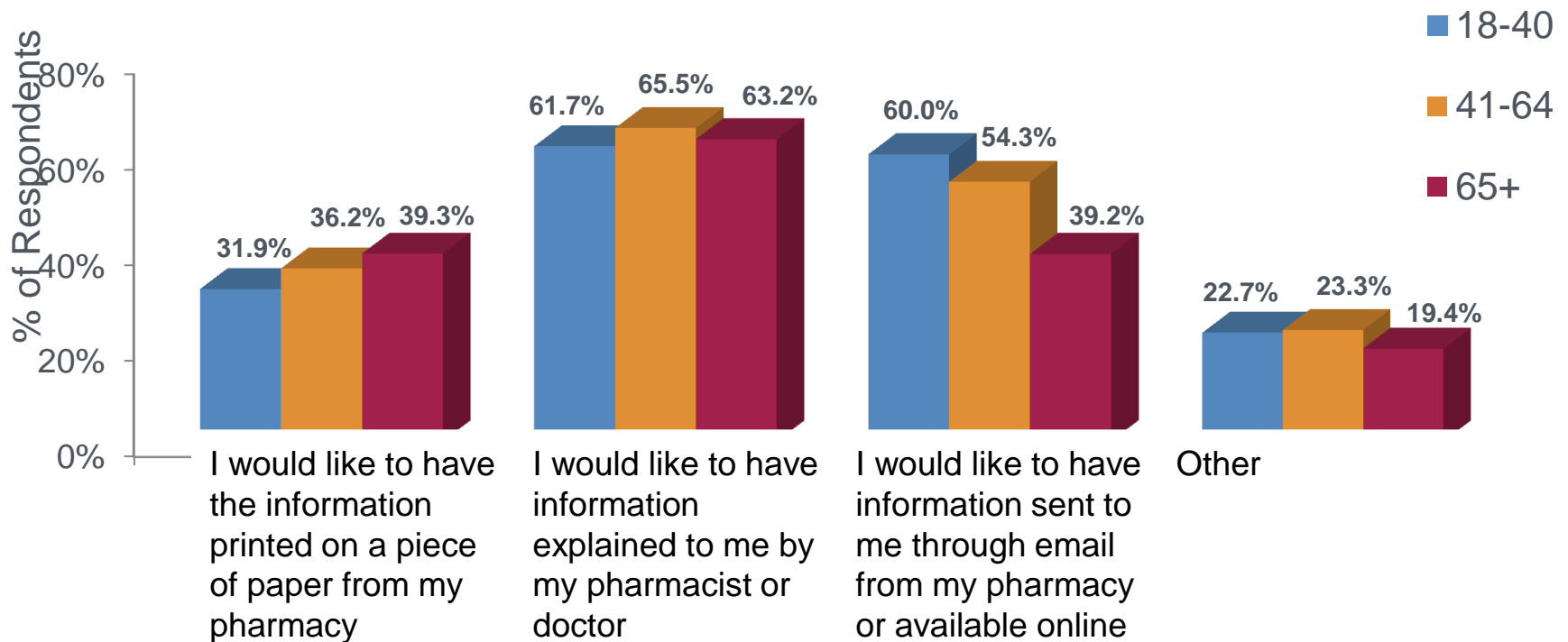
After reading the written medication information provided to you with your [medication] prescription, how useful did you find the information?

Most patients found the information was very useful



In the future, how would you prefer to receive the information about medicines that you obtain from your pharmacy? (You may choose more than one)

Younger patients prefer electronic delivery of the information more than older patients



Key Findings

- The pilot executed successfully
- Over 90% of patients recalled receiving the PMI; less than 5% reported they did not receive it
- Two-thirds of all patients read the information
- New patients are more likely to keep the information than experienced patients
- Over 90% of patients felt the information was very or somewhat useful
- Over a third of patients preferred written, verbal or digital communication
- Patients aged 65+ preferred written or verbal information but almost 40% preferred electronic delivery either by email or link to a web-site

Exploring the Promise of Patient Medication Information

Engelberg Center for Health Care Reform
The Brookings Institution
Washington, DC
July 1, 2014

Building a PMI Central Repository

Gregory Daniel
The Brookings Institution

The challenge:

Ensuring that patients, consumers, caregivers, providers, and other health care professionals have consistent live access to Patient Medication Information

Testing the repository:

- Brookings is currently working with pharmacies and electronic health record vendors to explore access to and use of the NLM repository
- Stakeholder groups are asked for their feedback on potential applications of the PMI document within their systems and processes
- A link to prototype PMI for Rheutopia is provided for testing purposes

Stakeholder feedback:

- In general, stakeholders are supportive of the PMI effort and look forward to exploring how best to use the documents
- The repository should support multiple modes of access
 - Live, single-document retrieval
 - Full PMI library download
 - Active “pushing” through links
- The repository needs to be consistently up-to-date
 - Mechanisms for communicating updates to stakeholder groups
 - “Last updated on” language on website
 - Email alerts for new or updated documents

Exploring the Promise of Patient Medication Information

Engelberg Center for Health Care Reform
The Brookings Institution
Washington, DC
July 1, 2014