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

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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

Manufacturer (PMI Creator) → PMI Central Repository → Pharmacy (Primary Distribution) → Patient (End User)

- Development
- Repository
- Distribution
- Healthcare Provider
- Direct Patient Access
Next Steps

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

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“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
“Bubble” Format

- Included six categories of information that were outlined by a soft edged box:
  - Uses
  - Important Warnings
  - Tell your Doctor
  - Call your Doctor right away if
  - Common side effects
  - Directions for use

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

105 subjects enrolled

- **Coumadin (n=37)**
  - Low literate (n=7)
  - New (n=15)
    - vs. Bubble (n=11)
    - vs. Current (n=4)
  - Bubble (n=14)
    - vs. New (n=10)
    - vs. Current (n=4)
  - Current (n=8)
    - vs. New (n=4)
    - vs. Bubble (n=4)

- **Ortho Tri-Cyclen (n=33)**
  - Low literate (n=3)
  - New (n=12)
    - vs. Bubble (n=8)
    - vs. Current (n=4)
  - Bubble (n=12)
    - vs. New (n=8)
    - vs. Current (n=4)
  - Current (n=9)
    - vs. New (n=5)
    - vs. Bubble (n=4)

- **Parnate (n=35)**
  - Low literate (n=5)
  - New (n=14)
    - vs. Bubble (n=10)
    - vs. Current (n=4)
  - Bubble (n=14)
    - vs. New (n=10)
    - vs. Current (n=4)
  - Current (n=7)
    - vs. New (n=4)
    - vs. Bubble (n=3)
Coumadin
Ortho Tri-Cyclen

- Layout: New 80%, Bubble 46%, Current 12%
- Formatting: New 88%, Bubble 46%, Current 0%
- Content: New 44%, Bubble 38%, Current 59%
- Ordering: New 84%, Bubble 42%, Current 12%
- Ease of Navigation: New 88%, Bubble 46%, Current 0%
- Preference: New 84%, Bubble 46%, Current 0%

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Parnate

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Do simple pictures/icons help?

<table>
<thead>
<tr>
<th>How would you rate the use of pictures (or icons)?</th>
<th>Ortho Tri-Cyclen</th>
<th>Parnate</th>
<th>Coumadin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Responding:</td>
<td>25</td>
<td>28</td>
<td>30</td>
</tr>
<tr>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>The pictures <em>made it</em> easier to find information</td>
<td>19</td>
<td>76.0%</td>
<td>22</td>
</tr>
<tr>
<td>The pictures made <em>no difference</em> in finding information</td>
<td>5</td>
<td>20.0%</td>
<td>5</td>
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<tr>
<td>The pictures made <em>more difficult</em> to find information</td>
<td>1</td>
<td>4.0%</td>
<td>1</td>
</tr>
</tbody>
</table>
Participants correctly answered more questions with New and Bubble PMI than current CMI.

As 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.
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.
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
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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 Embolism 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

Other medicines

Tell your doctor about all 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.

* NOT YET SUBMITTED TO FDA
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 or feels very tender
- Your leg hurts when you stand or walk
- 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
- You feel short of breath
- You cough up blood
- You start sweating
- Your heart is beating very fast
- You feel like you might pass out
- You feel very anxious

**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 have bleeding or your skin is bruising easily
- You look pale
- You feel short of breath

**Common side effects**
- Diarrhea
- No bowel movement
- Nausea
- Vomiting
- Not hungry
- Loosing weight
- Dry mouth
- Loosing 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.

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 59° to 86° Fahrenheit (15° to 30° Celsius).
- 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.
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

**Results**

- **Well organized and easy to read**
- **Average Comprehension Test Score**: 93%
- **Overall Clarity Rating**: 9.2 out of 10

**Limited Health Literacy** | **Adequate Health Literacy**
---|---
91% | 95%

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

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The Brookings Institution
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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.

**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.

**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.

**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.

**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).

**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 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.
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- 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 Rheutopia 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.

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- 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)
(artsikolate)

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 for 6 weeks 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
- think you have 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

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.
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

- **Paper**
  - Bubbles
    - Context
    - No Context
  - OTC
    - Context
    - No Context

- **Online**
  - Control (Med Guide)
    - No Context
### Phase 2: Results

<table>
<thead>
<tr>
<th>Variable</th>
<th>Comprehension</th>
<th>Application</th>
</tr>
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<tbody>
<tr>
<td><strong>Format</strong></td>
<td>*<strong>Bubbles &gt; Med Guide</strong></td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>***OTC &gt; Med Guide</td>
<td></td>
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<tr>
<td><strong>Mode</strong></td>
<td><strong>Print &gt; Online</strong></td>
<td>NS</td>
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<tr>
<td><strong>Health literacy</strong></td>
<td>*Higher &gt; Lower</td>
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<tr>
<td><strong>Illness knowledge</strong></td>
<td>*Higher &gt; Lower</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td>*60-69 yrs. &gt; Under 50 yrs. Other age differences NS</td>
<td>**60-69 yrs. &gt; Under 50 yrs. Other age differences NS</td>
</tr>
<tr>
<td><strong>Race/Ethnicity</strong></td>
<td>*Non-Hispanic White &gt; Non-Hispanic Black Other race/ethnicity differences NS</td>
<td>**Non-Hispanic White &gt; Non-Hispanic Black Other race/ethnicity differences NS</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td>NS</td>
<td>NS</td>
</tr>
</tbody>
</table>

* 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

Comprehension, memory, and use of drug information.

© Ruth Day
Basic Approach

Cognitive Analyses
Enhanced Displays
Cognitive Experiments
Cognitive Analyses

Enhanced Displays

Cognitive Experiments

--- Obtain quantitative measures

--- Calculate “cognitive accessibility”
Cognitive Analyses

- Obtain quantitative measures
- Calculate “cognitive accessibility”

Enhanced Displays

- Same info

Cognitive Experiments

- 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

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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

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Cognitive Accessibility
Cognitive Accessibility

The ease with which
Cognitive Accessibility

The **ease** with which

people can

find, understand, remember, use

information

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The ease with which people can find, understand, remember, and use information in a safe and effective manner.

Cognitive Accessibility

Ruth Day
The ease with which people can find, understand, remember, and use information in a safe and effective manner.
Current Study
Patient Medication Information

PMI
PMI Versions

1 Page

FDA Prototype
(“Bubble”)
PMI Versions

1 Page

- FDA Prototype ("Bubble")
- Enhanced-1
- Enhanced-2
PMI Versions

1 Page

FDA Prototype ("Bubble")

Enhanced-1

Enhanced-2

Enhanced
--Same info
--Plus cognitive enhancements
Number: >1,400
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
Number: >1,400

Wide Demographics
Age: 19-97
Gender: 48%-52% (male-female)
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Occupations: unskilled, skilled, clerical, sales, managerial, professional, retired, unemployed
Geographic Area: 38 states

Patients
42% Phone 58% Web
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Basic Methods
Basic Methods

Study

Test
Basic Methods

Study

Test

A

OR

B

C

Ruth Day
Basic Methods

Random assignment of formats to patients

Study

Test

OR

A
B
C

time
Basic Methods

Study

Test

time

All Content

--benefits
--risks
--directions
--etc
Basic Methods

Study

Test

All Content
--benefits
--risks
--directions
--etc

Multiple Tasks
--attention
--comprehension
--memory

Ruth Day
Enhanced
Scope of the Study
Primary + coded data
= > 2,000,000 cells

Therefore....
Sample Results
Study Time
Study 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 (min)

Prototype  Enhanced-1  Enhanced-2
Medication Name

“What is the name of this medicine?”
“What is the name of this medicine?”

Enhanced > Prototype
“What is the name of this medicine?”

Enhanced > Prototype

Sample Errors

- atenolol
- linsinporil
- linsiporil
- lipasporin
- lipersel
- lipisoril
- Lipitrol
- lipopril
- Liprocil
- Listensapril
- Lysoprin
- lystisol

Ruth Day
Side Effects
Side Effects

Multiple cognitive tasks
--attention
--recall
--recognition
--action
--likelihood
Multiple cognitive tasks
--attention
--recall
--recognition
--action
--likelihood

Levels of knowledge
--surface
--moderate
--deep
Side Effects

“About how many side effects?”
“About how many side effects?”
Side Effects

“About how many side effects?”

Number Estimated

Prototype | Enhanced-1 | Enhanced-2
----- | ----- | -----
5 | 10 | 15

Ruth Day
Side Effects

“About how many side effects?”

- Prototype: ~100%
- Enhanced-1: >100%
- Enhanced-2: >100%
Side Effects

"About how many side effects?"

Number Estimated

Prototype: ~100 %
Enhanced-1: >100 %
Enhanced-2: >100 %

Ruth Day
Side Effects

“About how many side effects?”

![Bar chart showing the number of estimated side effects for Prototype, Enhanced-1, and Enhanced-2. The bars for Enhanced-1 and Enhanced-2 are taller than for Prototype.]

Left = Closed-Book
Right = Open Book

Ruth Day
Side Effects

“About how many side effects?”

Number Estimated

Prototype   Enhanced-1   Enhanced-2

Left = Closed-Book
Right = Open Book

Ruth Day
Side Effects

“About how many side effects?”

Number Estimated

Prototype  Enhanced-1  Enhanced-2

300 %  > 300 %

Left = Closed-Book
Right = Open Book

Ruth Day
“What are the side effects?”
“What are the side effects?”
“What are the side effects?”

Left = Closed Book
Right = Open Book

% Correct

Prototype
Enhanced-1
Enhanced-2

300 %
300 %
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?
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

**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 or 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 breastfeeding.
- 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, Zestrel)**

**Uses**
- High blood pressure (hypertension)
- Heart failure

**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.

**Tell your Doctor**
Before you take 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).

**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.
**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 help protect the kidneys from damage due to high blood pressure.

**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.

**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.

**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**
Be sure to tell your doctor if you:
- Are taking or stop taking any over-the-counter medicines, herbal products, vitamins, or drugs that may interact with lisinopril (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).

**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 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.

**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.

**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 take lisinopril, tell your doctor if you:
- are allergic, or have any of its inactive ingredients or other inhibitors (such as benazepril), or any other allergies.
- have kidney or liver disease.
- have had a blood allergy (including birth control that contains hormone). Before you start any new medicine, tell your doctor or pharmacist.
- have diabetes, gout, lupus, or have had an allergic reaction to NSAIDs such as aspirin or naproxen.

**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.

**Call Your Doctor**
**Call your doctor right away if you develop:**
- Symptoms of a serious but rare allergic reaction such as swelling of the mouth, tongue, throat or face, hives, trouble breathing or swelling of the hands, arms, feet or legs. Go to the nearest hospital.
- Fainting or feeling very weak.
- Slow heartbeat, muscle cramps, loss of appetite, rash that does not go away. 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.

**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,
- Nausea, vomiting, diarrhea, or stomach pain.
- Fast or slow heartbeat, weakness or cold feeling in body,
- Flu-like symptoms such as fever, sweating, muscle pain, and pain in the upper body or neck
- Weak and/or rapid heartbeat
- Nausea or vomiting

**Common Side Effects**
- Dizziness, light headedness, unusually fast, weak, or weak and rapid heartbeat, 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 breast feeding.
- are taking drugs that may interact with lisinopril (such as potassium, or lithium).

**Call Your Doctor**
Call your doctor right away if you develop:
- Swelling of the face, lips, tongue, or throat. These are signs of an allergic reaction.
- Dizziness, fainting, rash, 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.

**Common Side Effects**
- Dizziness, fainting, rash, unusual tiredness, headache, dry cough.
- If any of these persist or worsen, tell your doctor or pharmacist promptly.

**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 treat high blood pressure to help prevent strokes, heart attack, and kidney failure.
- It is also used to treat heart failure and after a heart attack to help 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 (such as potassium-sparing diuretics), or medicines for blood pressure or arthritis (such as cough medicines, or NSAIDs such as aspirin, or naprosyn).

**Common Side Effects**
- Dizziness, light headedness, unusual tiredness, headache.
- 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 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.
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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.
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**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 water retention such as 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, swelling, especially of face, tongue, or throat.
- Trouble breathing.
These are not all the side effects that may occur. Other side effects may occur that usually do not need medical attention. However, if they continue or are bothersome, tell your doctor.

**Common Effects**
- Dizziness, heartburn, unusual tiredness, headache.
- If any of these symptoms get worse, 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 with or without food as directed by your doctor.
- You may take lisinopril morning or evening; take it at the same time each day.
- If you miss a dose, take it as soon as you remember it. If it is almost time for your next dose, take it later. Do not try to catch up by taking more than your scheduled dose.
- Store lisinopril at room temperature, away from light and moisture.
Lisinopril [“Lye-SIN-oh-pril”] (also known as: Prinivil, Zestril)

**Uses**
- To treat high blood pressure and reduce the risks of stroke and heart attacks.
- 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.
- Swelling in arms or legs.
- Headache, muscle weakness. These are signs of low potassium levels.
- Fever, chills, persistent sore throat. These are signs of an infection.
- Dizziness, pale skin, fast or irregular heartbeat, shortness of breath, or feeling light-headed.

**Contacts**
- Family members, relatives.
- Physicians or health care provider.
- Call your doctor for more information.

**Report Adverse Effects**
You may report adverse effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**Directions for Use**
- Take by mouth with or without food as prescribed 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 regular time.
- Store at room temperature, away from light and moisture.

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

**Uses**
- Lisinopril helps to lower blood pressure and improve heart function, which helps to lower the risk of heart attack and stroke.
- It is used to treat high blood pressure and heart failure.
- It is used to treat conditions such as kidney disease.

**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 severe rash or allergic reaction (including swelling of the face, lips, tongue, or throat).
- Difficulty breathing or swelling especially of the face, lips, tongue, or throat.
- Headache, dizziness, or light-headedness may occur.
- Muscle weakness. These are signs of low potassium levels.
- Coughing at night. These are signs of fluid buildup in your lungs.
- Stomach 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.

**Directions for Use**
- Take by mouth with or without food as directed by your doctor.
- You may take this medicine at any time of the day.

- Store at room temperature, away from light and moisture.
Prototype

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

--Linear (vertical)
--Go all the way through
--Stop or repeat
First 1-sec Enhanced Design

Ruth Day
Enhanced Design

First 1-sec

--Distinctive features
direct eye gaze immediately
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
“If your doctor prescribed a medication for you in the future, how would you like to get information about it?”
‘If your doctor prescribed a medication for you in the future, how would you like to get information about it?’

<table>
<thead>
<tr>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Get a leaflet printed on paper, given with the medicine at the pharmacy</td>
</tr>
<tr>
<td>Get an internet link to the leaflet, given at the pharmacy</td>
</tr>
<tr>
<td>Do an internet search on your own</td>
</tr>
<tr>
<td>Have the leaflet sent to you by email, from the pharmacy</td>
</tr>
<tr>
<td>Have the leaflet sent to your cell phone, from the pharmacy</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Options</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printed</td>
<td>Get a leaflet printed on paper, given with the medicine at the pharmacy</td>
</tr>
<tr>
<td>WebLink</td>
<td>Get an internet link to the leaflet, given at the pharmacy</td>
</tr>
<tr>
<td>WebSearch</td>
<td>Do an internet search on your own</td>
</tr>
<tr>
<td>Email</td>
<td>Have the leaflet sent to you by email, from the pharmacy</td>
</tr>
<tr>
<td>Cell Phone</td>
<td>Have the leaflet sent to your cell phone, from the pharmacy.</td>
</tr>
</tbody>
</table>
Mean Age = 57

Age Effect?
Generation Effect?
College students Tech-savvy
Conclusions
Developed with great care. Have many positive features.
Developed with great care. Have many positive features.

But some drawbacks, too. --i.e., cognitive accessibility
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
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
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
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.
The solution: A central online repository

- Patients
- Caregivers
- Providers
- Pharmacies
- Third-party vendors
- EHR systems
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

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