



The Role of Health Literacy in FDA's New Patient Medication Information

Vanessa Boudewyns, PhD

Lauren McCormack, PhD, MSPH

Bridget Kelly, PhD, MPH

Julia Kish-Doto, PhD, MS

Amie O'Donoghue, PhD

Murewa Oguntimein, MHS, CHES

Health Literacy Research Conference, Washington, DC, October, 2013

Background

- Millions of people in the United States use prescription drugs to maintain their health (*FDA, 2010*)
- High levels of consumer misunderstandings about medications result in **poor medication adherence** and **preventable medical errors** (*IOM, 2006*)



Patients with **low health literacy** are at a disadvantage in understanding medical information

Low Health Literacy: Challenges & Recommendations

Challenges	Recommendations
<ul style="list-style-type: none"> ▪ Recalling medical instructions 	<ul style="list-style-type: none"> ▪ Present text in shorter sentences
<ul style="list-style-type: none"> ▪ Interpreting prescription medication warning labels correctly 	<ul style="list-style-type: none"> ▪ Offer more organized, or “chunked,” text
<ul style="list-style-type: none"> ▪ Comprehending dosing instructions 	<ul style="list-style-type: none"> ▪ Use less complex terminology
<ul style="list-style-type: none"> ▪ Incomplete or contradictory information 	<ul style="list-style-type: none"> ▪ Include section headings, graphics, and other design elements
<p><i>(McCarthy et al., 2012; Davis et al., 2006; Baker, 1999)</i></p>	<p><i>(Aikin, 1998; Lorch & Lorch, 1996; Trevena et al., 2006; Vigilante & Wogalter, 1997)</i></p>

Study Goals with Respect to Health Literacy

Investigate the impact of Health Literacy on:

- ❖ Comprehension of information of PMI*
- ❖ Ease of understanding of PMI*

To achieve this goal, we:

- Conducted a randomized experiment to compare 5 versions of PMI* prototypes
- Examined if mode of material administration, contextual information, or format influenced outcomes

**Patient Medication Information*

MedGuide: Page 1 of 4

PROTOTYPE 4 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.

Bubbles With Context

Drug Approved by FDA: 2005
Last Revised: May 2009

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.

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 increased 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 weight loss. 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. 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.
- 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.

Draft Prototype 2A_Warnings

Over-The-Counter (OTC) With Context

Drug Approved by FDA: 2005
Last Revised: May 2009

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.

Tell your doctor before using Rheutopia 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 increased when used with Rheutopia.

Stop using Rheutopia and call 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 weight loss. 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. 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.
- 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.

Draft Prototype 3A_Warnings

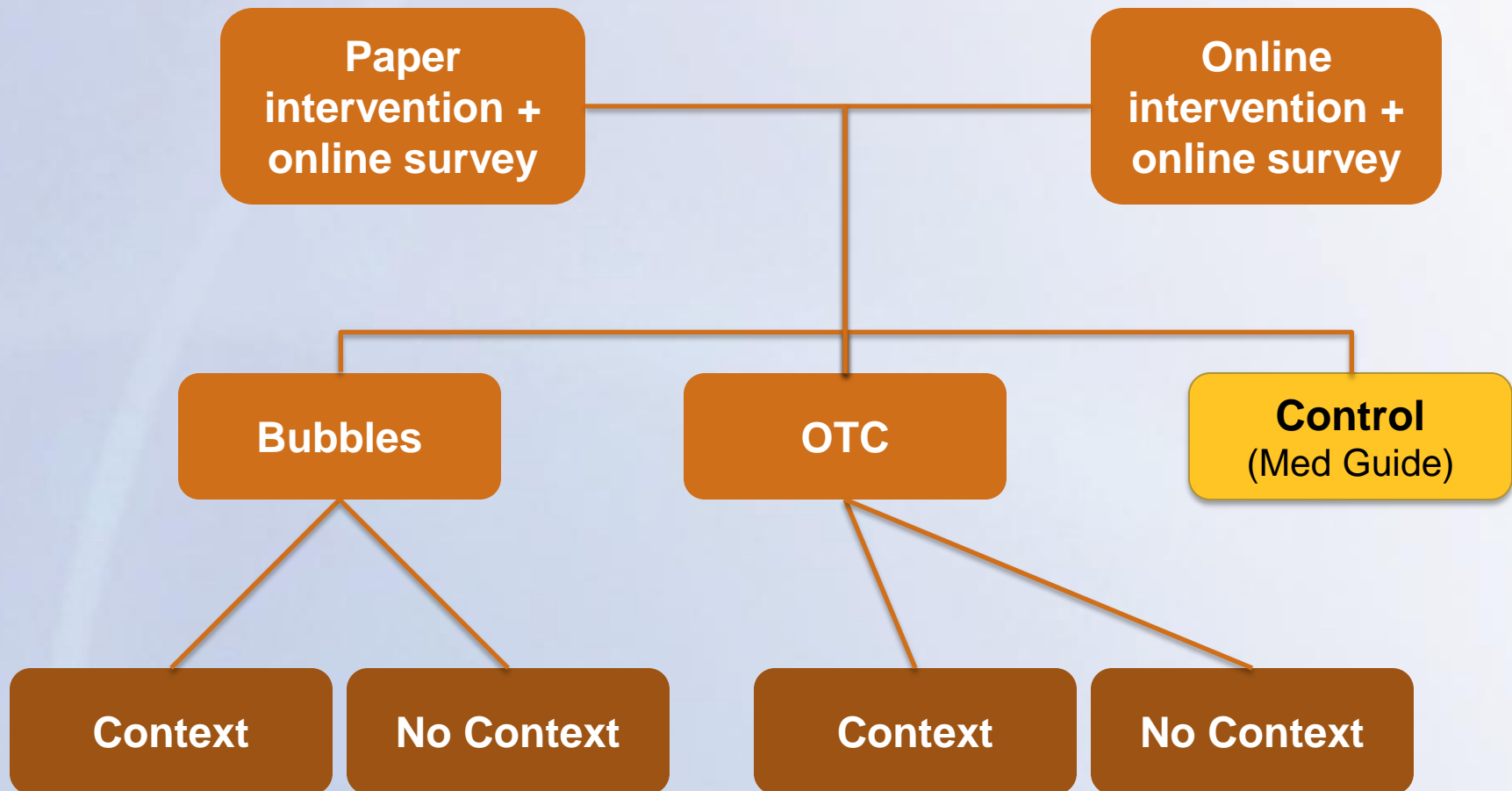
Context Snapshot

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). 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 weight loss. 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. 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.

Experimental Design



Methods

Respondents

- Diagnosed with Rheumatoid Arthritis (RA) or related chronic conditions
- Two sample sources:
 - GfK's Internet panel (KnowledgePanel ®)
 - Survey Sampling International (SSI) (a partner panel)
- Final sample: ***N* = 1,397**

Procedure

- Data collection began November 26, 2012 (lasted approx. 6.5 weeks)
- Overall response rate = 58%
- Web survey with 31 items
 - Median time to complete survey = 27 minutes

Measures

Outcome Variables

❖ **Comprehension (5 separate items)**

Open-ended

(1) Uses for Rheutopia

Closed-ended

(2) Uses of Rheutopia

(3) Contraindications

(4) Warnings/Side Effects

(5) “Application” measure (average of 5 questions)

❖ **Ease of understanding (2 items averaged together)**

Additional Variables

❖ **Illness severity** (1 item)

❖ **Illness knowledge** (1 item)

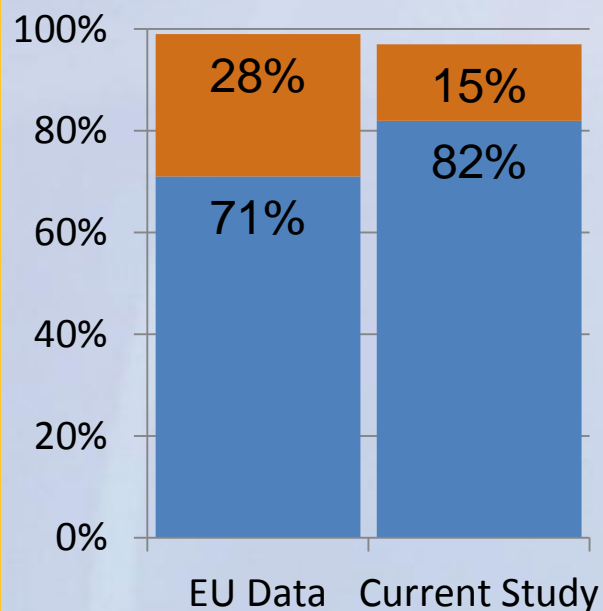
❖ **Health literacy** (3 items averaged together)

❖ **Demographics** (age, education, income)

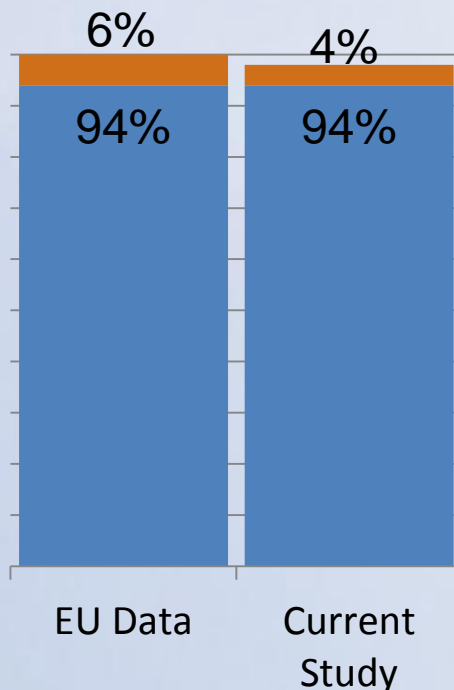
Health Literacy Items ($M = 3.4$, $SD = 0.6$)

How easy would you say it is to...

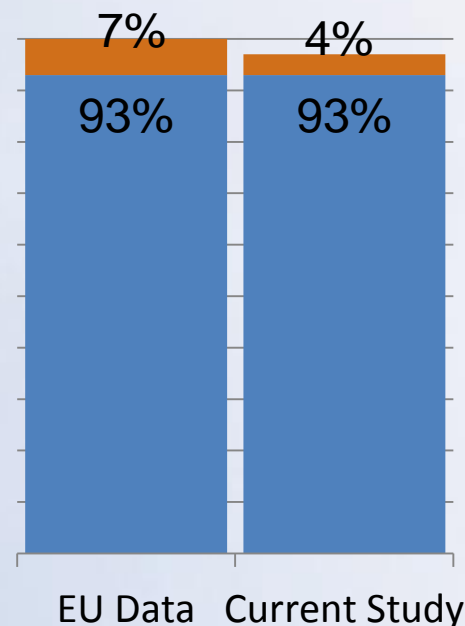
...understand the information that come with your medicine?



...follow instructions from your doctor or pharmacist?



...understand your doctor's or pharmacist's instructions on how to take a prescribed medicine?



■ Difficult
■ Easy

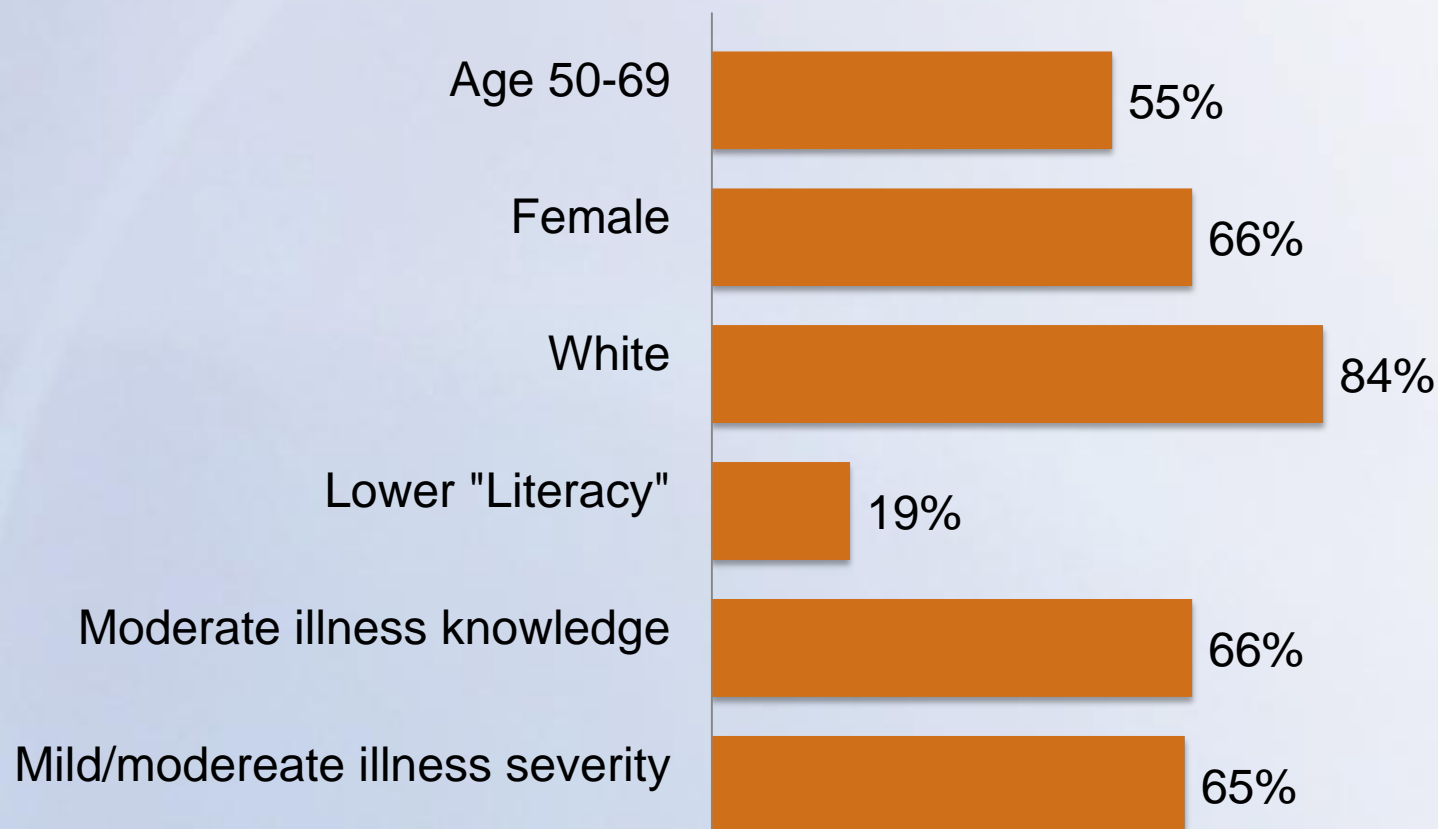
EU Data = Data from European Health Literacy Project 2009-2012

Analyses

Statistical Analysis & Dependent Variables (DV)	Independent Variables	Covariates
<p>Multivariate Analysis of Variance (MANOVA) for multiple related DV:</p> <ul style="list-style-type: none"> ▪ Comprehension <p>Multiple Linear Regression for single continuous DV:</p> <ul style="list-style-type: none"> ▪ Ease of understanding 	<ul style="list-style-type: none"> ▪ Mode ▪ Format ▪ Context ▪ Health Literacy 	<ul style="list-style-type: none"> ▪ Illness severity ▪ Illness knowledge ▪ Education ▪ Income ▪ Age

- All two-way interactions among variables were included
- Restricted significance level to $p < .01$
- All analyses were conducted using weighted data

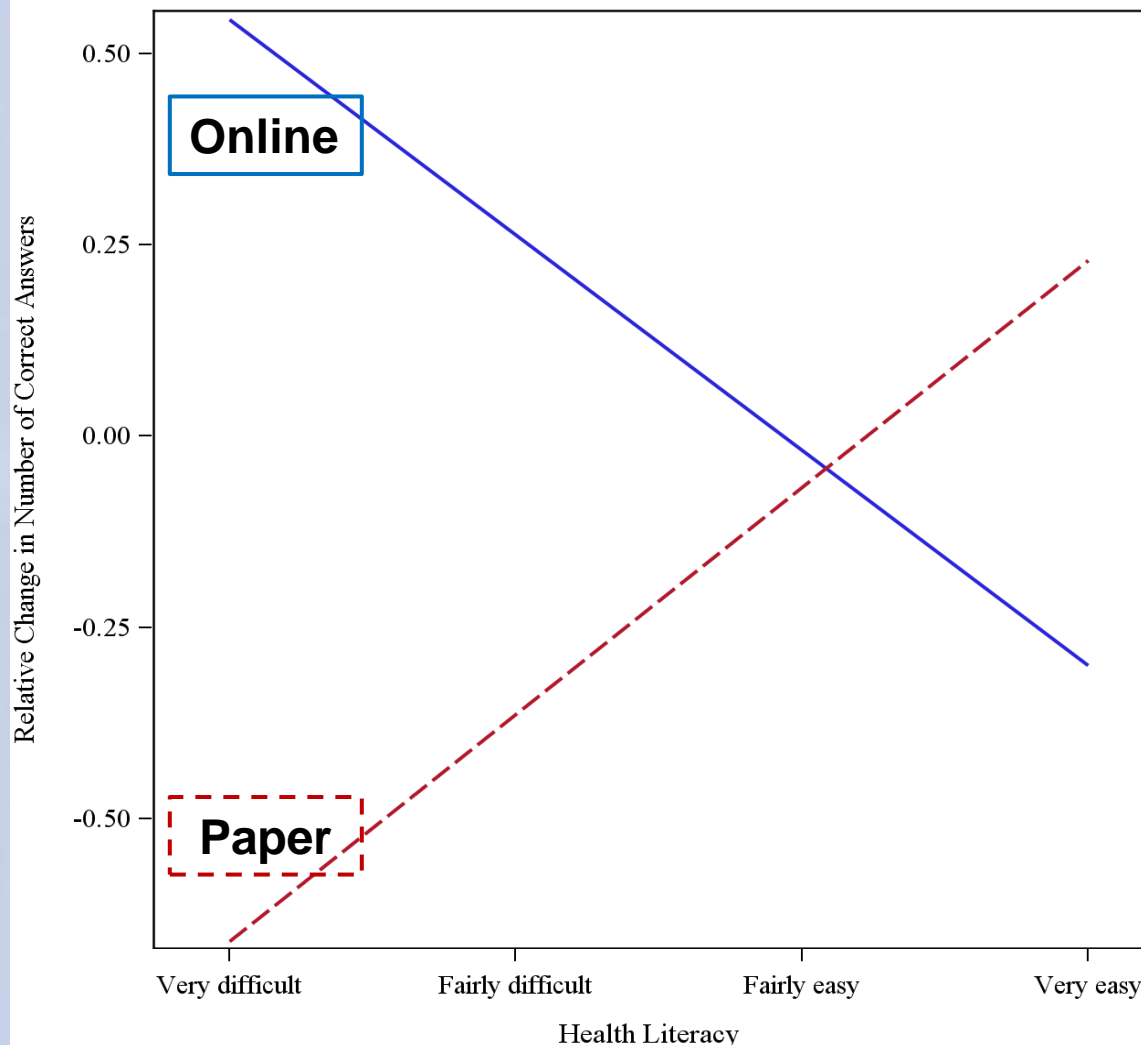
Sample Descriptives



Preliminary Findings

Variable	Comprehension	Ease of Understanding
Health Literacy		**Higher HL > Lower HL
Context	No Context > Context**	
Context x HL		
Mode	Paper > Online **	
Mode x HL	Significant*	
Illness Knowledge	Higher knowledge > Lower knowledge**	
Format	Bubbles > Med Guide** OTC > Med Guide**	
** Indicates findings significant at $p<.001$.		

Mode x Health Literacy Interaction



Mode x Health Literacy
(Wilk's Lambda = 0.98, $p < 0.001$)

- For people with **lower health literacy**, the online formats aided comprehension better than paper formats.
- For people with **higher health literacy**, paper formats aided comprehension better than online formats.

Study Limitations

- GfK had to supplement the KnowledgePanel® with opt-in panelists to achieve the target
- Could not measure literacy directly
- Self-reported measure of health literacy was not well distributed, and had ceiling effects

A male doctor with short brown hair, wearing a white lab coat over a light blue shirt and a patterned tie, is looking at a small white pill bottle he is holding in his right hand. He is also holding a black clipboard in his left hand. The background is a blurred clinical setting.

Conclusions to Date

- People with higher health literacy reported greater ease of understanding but not actual comprehension
- Paper formats resulted in better unaided recall of Rheutopia's uses than online formats
- Bubbles and OTC appear to result in better comprehension than Med Guide

Questions

The background of the slide is a collage of crumpled, colorful paper scraps in shades of red, green, blue, yellow, and white. Each scrap features a large, bold, black question mark, creating a visual theme of inquiry and questions.

Contacts

Vanessa Boudewyns, PhD

RTI International

vboudewyns@rti.org

Lauren McCormack, PhD

RTI International

lmac@rti.org