Differences in Participant Recall and Preference Based on Patient Medication Information Format

by

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Abstract

Patient medication information (PMI) is currently not meeting patients' needs, especially those with low health literacy. Studies suggest that adding relevant images to otherwise textual PMI as well as video presentation may be preferred and beneficial to this cohort in terms of information recall. To investigate this, three PMI formats were created for a fictitious medication, Ellistrum. The FDA-Like PMI format was based on an FDA PMI prototype. The other two PMI formats, Picture-Enhanced and Video, were developed using recommended plain language and graphical design principles. Aside from one oversight, the three formats did not differ in content. Participants (n = 584) with below functional health literacy were recruited from Amazon Mechanical Turk, an Internet crowdsourcing market place. They were randomized to one of the three formats and then responded to survey items meant to measure their recall of the information presented. Subsequently, participants were shown all three formats and asked which they would prefer to receive from their pharmacy electronically as well as what they liked and disliked about each format. Average recall scores (± SD) were 6.6/10 (± 1.9), 7.1/10 (± 2.0), and 7.0/10 (± 2.0) for the FDA-Like, Picture-Enhanced, and Video PMI formats, respectively. Transformed ANOVA showed a statistically significant difference in recall scores across the three groups ($F(2,581) = 3.715$, $p = 0.025$), and Scheffe post-hoc test determined that this difference was between the FDA-Like and Picture-Enhanced format groups ($p = 0.039$). Among the 429 participants who indicated preference for only one format, the number who preferred the FDA-Like (n = 170, 29.1%), Picture-Enhanced (n = 153, 26.2%), and Video Format (n = 106, 18.2%) was statistically significantly different ($X^2(2) = 15.37$, $p < 0.001$). The remaining participants indicated preferring some combination of formats (n = 137, 23.5%) or having no preference (n =18, 3.1%). In conclusion, this study found that participant recall was higher when relevant images and other design elements were added to otherwise plain, textual PMI. Future studies

should further explore the benefits of incorporating pictures, video, and other design elements into PMI in terms of participant recall, comprehension, and preference.

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List of Abbreviations

ASHP	American Society of Health-System Pharmacists
CCI	Clear Communication Index
CMI	Consumer Medication Information
FDA	Food and Drug Administration
HALS	Health Activities Literacy Scale
HIT	Human Intelligence Task
IALS	International Adult Literacy Survey
MedGuide	Medication Guide
METER	Medical Term Recognition Test
mTurk	Amazon Mechanical Turk
NAAL	National Assessment of Adult Literacy
NALS	National Adult Literacy Survey
NCPIE	National Council of Patient Information and Education
NVS	Newest Vital Sign
PEMAT	Patient Education Materials Assessment Tool
PMI	Patient Medication Information
PPI	Patient Package Insert
REALM	Rapid Estimate of Adult Literacy in Medicine
SMOG	Simplified Measurement of Gobbledygook

TOFHLA	Test of Functional Health Literacy in Adults
WRAT	Wide Range Achievement Test

Chapter 1 | Introduction

This chapter serves as an introduction to and overview of this dissertation. Topics discussed include the background of the problem of low health literacy; the specific aims, research questions, and hypotheses of the study; the importance of the study; an overview of the methods employed to carry out the study; and an overview of the results. The chapter concludes with an overview of the organization of the dissertation as a whole.

Background of the Problem

Most often defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services they need to make appropriate health decisions," (Selden, Zorn, Ratzan, & Parker, 2000, p. vi) health literacy is requisite for patients to take an active role in the decision making process in their own health care. Unfortunately, low health literacy is prevalent in the United States (US). Nearly 90% of US adults may lack skills needed to properly manage their health, and 14% may have difficulty performing the simplest of health-related tasks. Older adults, those with lower levels of formal education, and minorities are more likely to have low health literacy (Kutner, Greenburg, Jin, & Paulsen, 2006).

Low health literacy is associated with poor utilization of healthcare services and poor health-related outcomes (Berkman et al., 2011). These include poorer overall health (Baker, Gazmararian, Williams, et al., 2002; Baker, Parker, Williams, Clark, & Nurss, 1997; Cho, Lee, Arozullah, & Crittenden, 2008; Michael S Wolf, Gazmararian, & Baker, 2005), poorer knowledge and outcomes related to chronic diseases and cancer (C. L. Bennett et al., 1998; DeWalt, Dilling, Rosenthal, & Pignone, 2007; Kalichman & Rompa, 2000; Paasche-Orlow et al., 2005; Schillinger et al., 2002; M. V. Williams, Baker, Honig, Lee, & Nowlan, 1998), poorer medication management and adherence (DeWalt et al., 2007; Kalichman & Rompa, 2000; Paasche-Orlow et al., 2005; M. V. Williams et al., 1998; Yin, Dreyer, Foltin, van Schaick, & Mendelsohn, 2007; Yin et al., 2010), decreased use of preventive services (I. M. Bennett, Chen, Soroui, & White, 2009; Lindau et al.,

2002; Scott, Gazmararian, Williams, & Baker, 2002), increased hospitalization (Baker, Gazmararian, Williams, et al., 2002; Baker, Parker, Williams, & Clark, 1998; Baker et al., 1997; Cho et al., 2008; DeWalt et al., 2007), and increased mortality (Baker et al., 2007; Sudore et al., 2006). The annual cost of low health literacy to the US economy was estimated to be between $106 billion to $238 billion in 2007 (Vernon, Trujillo, Rosenbaum, & DeBuono, 2007).

When it comes to effectively improving the health literacy of society, the health context is equally as important as an individual's skills. The health context includes the marketplace, individuals, and, most germane to this study, the materials that an individual interacts with regarding health (Nielsen-Bohlman, Panzer, & Kindig, 2004). In most cases, the onus is on healthcare organizations and providers to ensure that the health context meets the health literacy needs of patients. One specific health context that could be greatly improved upon in this regard is written consumer medication information (CMI).

Problem Statement

CMI, defined as "written information about prescription drugs developed by organizations or individuals other than a drug's manufacturer that is intended for distribution to consumers at the time of drug dispensing" (FDA, 2006, p. 4), is currently not meeting the health literacy needs of patients (FDA, 2006; Kimberlin & Winterstein, 2008; Winterstein, Linden, Lee, Fernandez, & Kimberlin, 2010). Not only is valuable information often missing, a large portion of CMI is written and formatted in a way that is not easily comprehensible to patients (Kimberlin & Winterstein, 2008; Raynor et al., 2006; Svarstad, Mount, & Tabak, 2004). This is problematic, given that 1) CMI is meant to serve as a reliable resource for patients when it comes to their medications and 2) the belief that well informed patients can make better health-related decisions (FDA, 2006).

The Food and Drug Administration (FDA) has acknowledged this concern and is considering regulation to replace CMI, as well as patient package inserts (PPIs) and medication guides (MedGuides), with a one-document solution called patient medication information (PMI). PPIs and MedGuides are FDA regulated drug information written by the manufacturer for the consumer

(Aker et al., 2013). The FDA has created four PMI prototypes (Prototypes 1, 2, 3, and 4) for a fictitious medication (Rheutopia) and has made a call for the development and pilot testing of novel PMI formats that are designed to meet the health literacy needs of patients (Brookings, 2010).

While the FDA PMI prototypes are basic, being white paper with black printed text, there is evidence to suggest that the addition of informative pictures or icons (Houts, Doak, Doak, & Loscalzo, 2006; Montagne, 2013; Thompson, Goldszmidt, Schwartz, & Bashook, 2010) as well as a video format (Sobel et al., 2009; Tuong, Larsen, & Armstrong, 2014) may benefit patients in terms of recalling and comprehending the information therein. This is especially true for patients with low health literacy (Austin, Matlack, Dunn, Kesler, & Brown, 1995; Delp & Jones, 1996). There is also evidence to suggest that patients, in particular those with low health literacy, may prefer these enhanced formats (Advani, Lopez, Jones, & Patel, 2013; Aker et al., 2013; Dowse & Ehlers, 1998; Tuong et al., 2014). Given this and the FDA's call, there is a significant need for the development and pilot testing of PMI formats that incorporate pictures as well as video.

Specific Aims

There were two specific aims for this study:

Specific Aim 1: Determine what affect, if any, the formatting of patient medication information (PMI) has on participants' recall of the information therein.

Specific Aim 2: Explore participants' preferences for the three PMI formats as well as the basis for those preferences.

Inclusion criteria for this study required that all participants have low or marginal health literacy, as determined by the Medical Term Recognition Test (METER). Three PMI formats were compared: 1) FDA-Like, 2) Picture-Enhanced, and 3) Video. The three formats were developed for a fictitious medication, Ellistrum. Aside from an oversight regarding the directions as to how

often the medication should be taken, the three formats contained the exact same information. Otherwise, only the formatting and presentation of the information varied.

Research Questions and Hypotheses

1. How does participant recall of information vary based on the three PMI formats: FDA-Like, Picture-Enhanced, and Video?
    a. Null Hypothesis (H_{0A}): There will be no significant difference in participants' recall based on the PMI format they receive.
    b. Alternative Hypothesis: (H_{1A}): There will be a significant difference in participants' recall based on the PMI format they receive.
2. Which of the three formats do participants prefer and why?
    a. Null Hypothesis (H_{0B}): There will be no difference in participants' preferences for the three PMI formats.
    b. Alternative Hypothesis: (H_{1B}): There will be a difference in participants' preferences for the three PMI formats.

Importance of the Study

This study can greatly inform the design and delivery of PMI and, subsequently, patient utilization thereof and education therefrom. Further, these novel formats (i.e., Picture-Enhanced and Video), if found to be superior, can easily be optimized for delivery via any digital device (e.g., desktop, laptop, tablet, smartphone). Given the FDA's recent call for investigation of new PMI presentation and distribution methods (Brookings, 2010), this study is as timely as it is innovative.

Overview of Methods

Data were collected via an electronic survey built in Qualtrics, and participants were recruited via Amazon Mechanical Turk (mTurk), a crowdsourcing Internet marketplace (Amazon.com, 2014). A link to the survey along with a brief description of the study was posted to mTurk. The first items of the survey screened potential participants to ensure they met inclusion criteria. Among other criteria, participants must have had either low or marginal health literacy, as determined by a Medical Term Recognition Test (METER) score of ≤ 20 or 21–34, respectively. Participants who

met inclusion criteria were randomized to one of the three PMI formats. After viewing the PMI format to which they were randomized, all participants responded to subsequent survey items designed to measure their recall of the information covered in the PMI. Participants were then shown all three PMI formats. Survey items following this were designed to gauge participants' preferences for the three formats as well as the basis of their preferences. Demographic information was also collected.

The three PMI formats were developed in stages. First, the FDA-Like format (Appendix A) was developed to be comparable, in terms of design, length, readability, order of information, and number bullet points, to Prototype 1 developed by the FDA (Appendix B). Graphic and information design principles were then applied to develop the Picture-Enhanced format (Appendix C). The Picture-Enhanced format was subsequently used as the basis for the Video format (available at http://bit.ly/EllistrumPMI). All three formats were for the same fictitious drug (Ellistrum) and, aside form the oversight mentioned previously, contained the exact same information. Only the formatting and method of presentation of the information varied from format to format.

Overview of Results

Five hundred eighty-four participants completed the survey with 188, 189, and 207 participants randomized to the FDA-Like, Picture-Enhanced, and Video formats, respectively. Looking at demographics, there were statistically significantly more females in the FDA-Like format group ($n = 85$) compared to the Video format group ($n = 69$; $p < 0.05$), more Hispanics/Latinos in the Video format group ($n = 27$) compared to the FDA-Like format group ($n = 12$; $p < 0.05$), more Asians in the Picture-Enhanced format group ($n = 24$) and Video group ($n = 25$) compared to the FDA-Like format group ($n = 9$; $p < 0.05$), and more multiracial participants in the FDA-Like format group ($n = 9$) compared to the other two format groups ($n = 2$; $p < 0.05$). Otherwise, demographics did not differ significantly between the three format groups, including participants' health literacy as determined by METER scores.

Participants' average recall scores (± SD) were 6.6/10 (± 1.9), 7.1/10 (± 2.0), and 7.0/10 (± 2.0) for the FDA-Like, Picture-Enhanced, and Video format groups, respectively. Because there was no correlation between participants' METER scores or age — the only two potential covariates that are continuous variables — and recall scores (i.e., the dependent variable), ANCOVA could not be performed. Therefore, ANOVA was utilized to determine if there was a statistically significant difference between participants' recall scores across the three PMI format groups. Due to negatively skewed data, a "reflect and square root" transformation was applied to participants' recall scores. ANOVA was run on the transformed data with and without outliers and, in both cases, indicated that there was a statistically significant difference in participants' recall scores between the three PMI format groups. Scheffe post hoc test indicated that this statistically significant difference in recall scores was between the FDA-Like format group (6.6 ± 1.9) and the Picture-Enhanced format group (7.1 ± 2.0; $p = 0.039$, transformed with outliers). No other statistically significant difference was found.

In terms of which of the formats participants would prefer to receive from their pharmacy via computer, the FDA-Like format received the most votes (170, 29.1%), followed by the Picture-Enhanced format (153, 26.2%), and then the Video format (106, 18.2%). Chi-square goodness of fit test indicated that, among the 429 participants who indicated preference for only one format, the number of participants who preferred the FDA-Like, Picture-Enhanced, and Video Format was statistically significantly different ($X^2(2) = 15.37$, $p < 0.001$). The remaining participants indicated they would prefer to receive some combination of formats (137, 23.5%) or that they had no preference (18, 3.1%). Looking at qualitative feedback, the top five aspects that participants indicated liking about the FDA-Like format include the *compact/condensed* design (n = 173), that it is *easy to read* (n = 117), that it is *easy to find information* within the format (n = 73), that the information is *easy to understand* (n = 65), and that the format is *familiar or similar to existing PMI formats* (n = 53). The top five aspects that participants indicated not liking about the FDA-Like format that it is *bland, plain, or boring* (n = 154), the *small font* (n = 69), that it contains *too much*

information (n = 53), the *lack of color* (n = 44), and that it is *easy to skim and miss/skip information* (n = 39).

For the Picture-Enhanced format, the top five aspects that participants indicated liking include that the information is *easy to understand* (n = 111), that it is *easy to read* (n = 87), that it incorporates *colors/is colorful* (n = 81), the incorporated *pictures in general* (n = 74), and that the incorporated *pictures reiterate/explain the text* (n = 52). The top five aspects that participants indicated disliking about the Picture-Enhanced format include that it required *too much scrolling/was too long* (n = 176), that there was *too much white space* (n = 24), that there was *no audio/video* incorporated into the format (n = 23), that it was generally *clunky/hard to navigate* (n = 21), and the incorporated *pictures in general* (n = 24). Aside from general content, the top five aspects of the Video format that participants indicated liking include that it was *easy to understand/follow* (n = 179), that they *do not have to read* the information (n = 86), that the *narration mirrors the text* (n = 39), the incorporated *pictures in general* (n = 35), and that the format is *memorable* (n = 32). The top five aspects participants indicated disliking about the Video format include that the format was *too long/time consuming* (n = 112), that the *voiceover was too slow* (n = 98), that it was *difficult to skip to a specific location/information* (n = 65), that the narrator's *voice is monotone* (n = 60), and that the format was *bland, boring, or dull* (n = 45).

Organization of the Dissertation

This dissertation is organized into five chapters. This chapter, chapter one, provides an introduction to and overview of the research project as a whole. Chapter two consists of a literature review. Chapter three outlines in detail the methods employed throughout the project. Chapter four contains the research findings, and chapter five includes conclusions, a discussion, and suggestions for future research.

This chapter provides information concerning health literacy, written patient medication information (PMI), and the use of illustrations and video to educate patients. In terms of health literacy, this chapter covers the definition of health literacy and associated terms, health literacy assessment tools for individuals and materials containing health-related content, the prevalence of low health literacy, the relationship between low health literacy and health-related outcomes, and initiatives to improve health literacy. Different forms of PMI are discussed, including the degree to which these resources meet patients' needs as well as attempted and proposed FDA regulation thereof. Lastly, studies that have explored the use of illustrations and/or video to educate patients are discussed. The information presented is based on an extensive literature review, which included primary, secondary, and tertiary resources.

Health Literacy

Definition

There are many definitions of health literacy. The most widely used definition is "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services they need to make appropriate health decisions" (Selden et al., 2000, p. vi). Developed by the National Library of Medicine, this definition appears to focus solely on an individual's innate abilities and skills, which are mediated by education and culture, in making health decisions. However, in addition to this, health literacy is also mediated by the characteristics of the health context.

Health context refers to the media, marketplace, government agencies, individuals, and materials a person interacts with regarding health. Since the impact of health literacy arises from the interaction of the individual and the health context, the health context is equally as important as an individual's skills. To clarify this, some have suggested that the definition of health literacy also include the demands of the environment of care, such as a hospital or health center, and the expectations and skills of those providing health information and services (R. E. Rudd &

Anderson, 2007). Others recommend that the definition of health literacy be expanded to include the formatting of information provided to patients and what it requires of them (Peters, Hibbard, Slovic, & Dieckmann, 2007). In *Health Literacy from A to Z: Practical Ways to Communicate Your Health Message*, author Helen Osborne suggests the following as a functional definition of health literacy: “Health literacy is a shared responsibility between patients (or anyone on the receiving end of health communication) and providers (or anyone on the giving end of health communication). Both must communicate in ways the other can understand” (p. 10).

Health literacy is related to, but more specific than general literacy, which is defined as “a set of reading, writing, basic mathematics, speech, and speech comprehension skills” (Nielsen-Bohlman et al., 2004, p. 32). Health literacy serves as the bridge between an individual’s general literacy skills and abilities and the health context. Functional literacy refers to one’s use of literacy to perform a particular task, while functional health literacy refers more specifically to one’s use of literacy to perform a health-related task.

Terms more specific than health literacy have been developed and defined that deal with literacy as applied to the realm of pharmacy. These include pharmacotherapy literacy and pharmacy health literacy. Developed by King, McCaffrey, and Bouldin (2011), pharmacotherapy literacy is defined as “an individual’s capacity to obtain, evaluate, calculate, and comprehend basic information about pharmacotherapy and pharmacy related services necessary to make appropriate medication-related decisions, regardless of the mode of content delivery (e.g. written, oral, visual images and symbols)” (p. 213). Similarly, pharmacy health literacy, as defined by the Agency for Healthcare Research and Quality (AHRQ), refers to “the degree to which individuals are able to obtain, process, and understand basic health and medication information and pharmacy services needed to make appropriate health decisions” (AHRQ, 2014).

Skills necessary for an individual to possess functional pharmacotherapy or pharmacy health literacy are the same as those necessary for the possession of functional health literacy. These

include numeracy, print literacy, oral literacy, and, at times, computer literacy. Numeracy refers to the ability to meaningfully interpret numbers, such as determining the correct dose of a medication based on a child's weight. Print literacy is the ability to read, write, and understand documents as well as locate and interpret information within texts such as patient package inserts. Oral literacy refers to the ability to speak and listen effectively, such as discussing medical treatment options with a healthcare professional (Berkman et al., 2011). Computer literacy, being the ability to operate a computer, is also often a necessary component of health literacy (Glassman, 2014). For instance, the only way for Medicare beneficiaries to evaluate all of the available Part D plans during the annual open enrollment period is to use the web-based Plan Finder tool. Use of the Plan Finder tool not only requires proficient computer literacy; proficient numeracy, print literacy and, often, oral literacy are also required for successful use of the tool. Although all of these components may be necessary for functional health literacy, depending on the health context, current health literacy assessment tools have focused predominantly on print literacy and, to a lesser extent, numeracy (Nielsen-Bohlman et al., 2004).

Health Literacy and Readability Assessment Tools

While many tools have been developed to assess the level of health literacy of patients as well as the readability of written information, existing tools often only focus on one or a couple of aspects for assessment. For instance, health literacy assessment tools for patients generally only focus on print literacy and, to a lesser extent, numeracy. Oral literacy, on the other hand, is rarely assessed (Nielsen-Bohlman et al., 2004). Similarly, tools assessing the reading level of written information predominantly focus on the average number of syllables in words and the average number of words in sentences. Although there are now validated tools to do so, factors such as word choice, tone, organization and layout, and use of illustrations are rarely assessed. Further, readability assessment tools were not developed to assess health information specifically (Osborne, 2013). Despite these limitations, health literacy and readability assessment tools are indeed useful.

In addition to comprehensive, general literacy and health literacy surveys (discussed below), several health literacy assessment tools that focus on the individual's abilities have been validated. Although there are many others, the two most commonly used health literacy assessment tools are the Test of Functional Health Literacy in Adults (TOFHLA) (R. M. Parker, Baker, Williams, & Nurss, 1995) and the Rapid Estimate of Adult Literacy in Medicine (REALM) (Davis, Long, & Jackson, 1993). More recently developed health literacy assessment tools include the Medical Term Recognition Test (METER) (Rawson et al., 2010) and the Newest Vital Sign (NVS) (Weiss et al., 2005). These tools assess individuals' health literacy skills and abilities, focusing mainly on print literacy and, in some cases, numeracy. The most commonly used instruments to measure numeracy alone include the Schwartz and Woloshin Numeracy Test (Schwartz, Woloshin, Black, & Welch, 1997) and the Wide Range Achievement Test (WRAT) math subtest (Jastak & Wilkinson, 1984), neither of which focus specifically on health contexts. Table 1 contains summary information for each of these tools. Single-item screening questions, such as "How confident are you filling out medical forms by yourself?" and "How often do you have someone help you read hospital materials?" have also been studied but appear to be less reliable in determining one's health literacy level (Chew et al., 2008; Lorraine S. Wallace, Rogers, Roskos, Holiday, & Weiss, 2006).

Table 1 – Commonly Used Health Literacy Assessment Tools

Instrument	Description	Method of Assessment	Scoring
Medical Term Recognition Test (METER) (Rawson et al., 2010)	70 item recognition test containing 40 real medical terms and 30 made-up terms Length: 2 minutes	Printed word recognition (print literacy)	Continuous score (0–40) Recommended conversion of continuous score into a categorical score: ≤ 20: low health literacy 21–34: marginal health literacy ≥ 35: functional health literacy

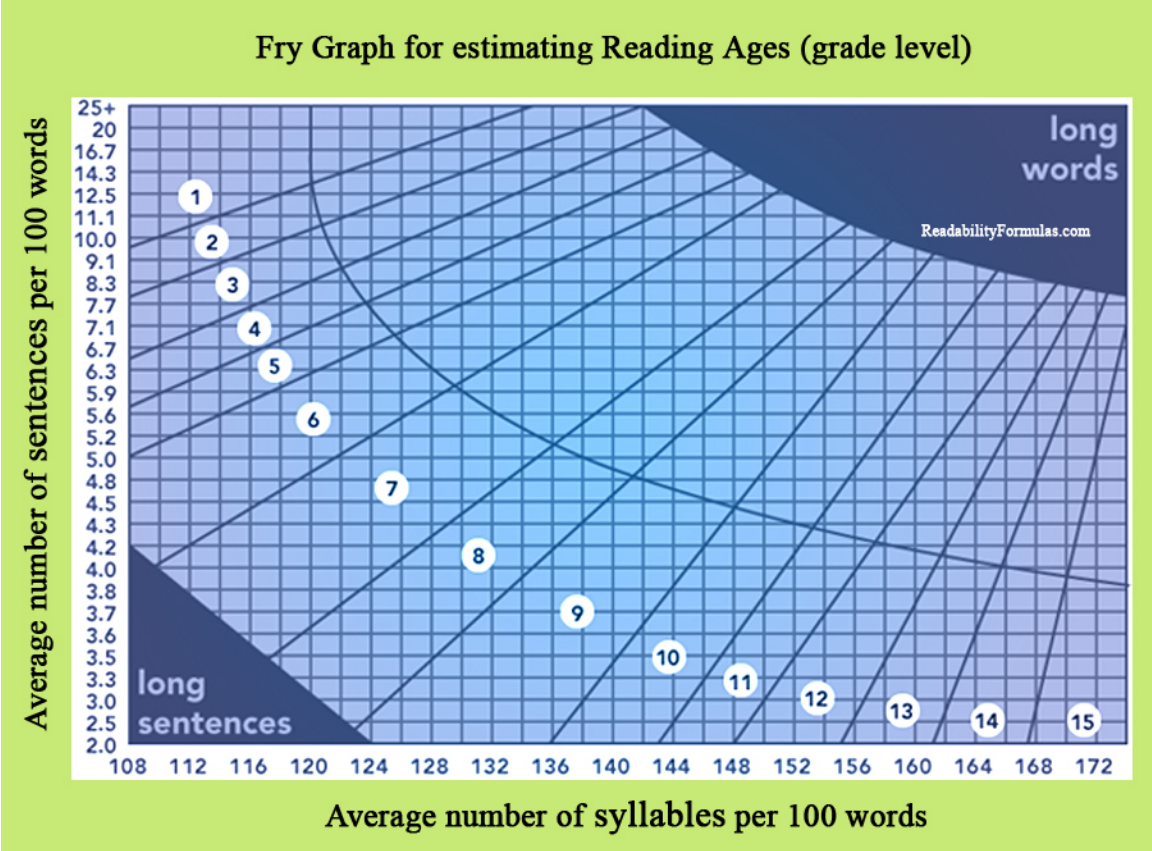
Instrument	Description	Method of Assessment	Scoring
Newest Vital Sign (NVS)†	6 questions about an ice cream nutrition label Length: 3 minutes	Document (print literacy) and quantitative skills (numeracy) test	Continuous score (0–6) Recommended conversion of continuous score into a categorical score: < 2: low literacy 2–4: possible low literacy > 4: adequate literacy
Rapid Estimate of Adult Literacy in Medicine (REALM)†	66-item measure of health literacy Length: 1–2 minutes Also available in short form as REALM-R and REALM-SF and for special populations as REALD-30 and REALM-Teen	Printed word recognition and pronunciation (print literacy)	Continuous score (0–66) Recommended conversion of continuous score into a grade level score: 0–18: <3rd grade 19–44: 4-6th grade 45–60: 7th-8th grade 61–66: >9th grade
Schwartz and Woloshin Numeracy Test †	3 word problems assessing numeracy	1. Probability 2. Converting a percentage to a proportion 3. Converting a proportion to a percentage	Percentage of correct responses
Test of Functional Health Literacy in Adults (TOFHLA)†	67-item measure of health literacy, including reading comprehension and quantitative skills Length: 20–25 minutes. Available in Spanish and English Also available in short form (S-TOFHLA) and for special populations as British version (UK-TOFHLA) and dental version (TOFHLiD); Length: 5–10 minutes	Reading comprehension via Cloze method (print literacy) and quantitative skills (numeracy) test	Continuous weighted score (0–100) Recommended conversion of continuous score into a categorical score: 0–59: inadequate 60–74: marginal 75–100: adequate

Instrument	Description	Method of Assessment	Scoring
Wide Range Achievement Test WRAT-3, Arithmetic Subtest†	55-item scale assessing numeracy skills Length: 15 minutes	Counting, reading number symbols, solving simple arithmetic problems Standard scores and percentiles compare individual performance with that of others of the same age	Continuous score (0–55)

† = Adapted from (Berkman et al., 2011).

The readability of written information can be assessed by hand with formulas or via computer software. Readability formulas that are commonly used in health care include the Simplified Measurement of Gobbledygook (SMOG), the Fry Readability Graph, the Flesch Reading Ease formula, the Flesch-Kincaid Formula, and the Gunning's Fog Index (Koo, Krass, & Aslani, 2003). The Flesch Reading Ease formula calculates higher scores for material that is easier to read. Although they do so in different ways, all of the other aforementioned formulas calculate grade-level scores for the text under assessment. The SMOG, for example, counts the total number of words with three or more syllables in three 10-sentence exerts from the beginning, middle, and end of the text, then adds three to the square root of this total. If there were 64 words with three or more syllables in the 30 sentences analyzed, the SMOG would calculate the text to be at an 11^{th} grade reading-level. The Fry formula, on the other hand, first counts the total number of syllables and sentences in three randomly selected 100-word passages from the text. The average number of syllables and sentences per 100-word passage are then plotted on the Fry Graph (Figure 1), and their intersection point determines the grade reading-level of the text (Osborne, 2013).

Figure 1 - Fry Graph for Estimating Reading-Level



Adapted from: http://www.readabilityformulas.com/graphics/frygraph2lg.jpg

Computer software can also be used to calculate the readability of text. Some word processors have built in readability assessment tools. For instance, Microsoft® Word® (Microsoft Corp, Redmond, WA) can be used to calculate the Flesch-Kincaid grade level score and the Flesch Reading Ease score for any digital document. There are also standalone software solutions. Readability Calculations (Micro Power & Light Co, Dallas, TX) is proprietary software that can be used to perform up to nine different readability formulas on digital text. Similarly, Readability Studio (Oleander Solutions, Vandalia, OH) will run a battery of readability assessment formulas on a given text and will even suggest edits to improve the reading level of the document (Badarudeen & Sabharwal, 2010; Osborne, 2013).

The Center for Disease Control's (CDC's) Clear Communication Index (CCI) (CDC, 2014) and the Agency for Healthcare Research and Quality's (AHRQ's) Patient Education Materials

Assessment Tool (PEMAT) (Shoemaker, Wolf, & Brach, 2013) are more comprehensive than the aforementioned readability formulas and include in their assessment many design and communication characteristics of the material in question. The CCI builds on and expands the Federal Plain Language Guidelines, which are described later in this dissertation. It contains 20 items that assess materials in 7 areas: 1) main message and call to action, 2) language, 3) information design, 4) state of the science, 5) behavioral recommendations, 6) numbers, and 7) risk. Based on the material being assessed, each of the 20 items that is applicable is assigned a score of either 0 or 1, which are then converted to an overall score on a scale of 100. A score of 90 or higher is considered passing (CDC, 2014). The PEMAT contains 26 items in two main domains, understandability and actionability. Items in the understandability domain focus on content, word choice and style, use of numbers, organization, layout and design, and use of visual aids. The PEMAT can be used to assess either printed material or audio/visual material. Not all of the 26 items apply to both formats. Based on the material being assessed, each applicable item is assigned either a 0 or 1. The sum of the individual item scores is converted to an overall percentage score. Higher scores indicate higher understandability or actionability (Shoemaker et al., 2013).

Prevalence of Low Health Literacy

Several large-scale surveys have examined the nation's literacy and health literacy, including the 1992 National Adult Literacy Survey (NALS) (Kirsch, Jungeblut, Jenkins, & Kolstad, 1993), the International Adult Literacy Survey (IALS) (Kirsch, 2001), and the 2003 National Assessment of Adult Literacy (NAAL) (Kutner, Greenberg, & Baer, 2005). Overall, findings from these surveys suggest that low health literacy is prevalent in the US and varies based on several demographic and socioeconomic variables. Results from smaller, less comprehensive studies echo these findings.

At the time, the 1992 NALS (Kirsch et al., 1993) was the largest and most comprehensive assessment of the US adult population's literacy. It was administered to over 26,000 US adults age 16 and older. Following the NALS, joint efforts were made to develop and conduct the first

ever comparative, international assessment of adult literacy. The result of these efforts was the IALS (Kirsch, 2001), which was administered from 1994–1998. The NALS and the IALS used the same definition for literacy: "*Using printed and written information to function in society, to achieve one's goals, and to develop one's knowledge and potential" (Kirsch et al., 1993, p. 2).* They also used the same framework to construct literacy tasks and assessed participants along the same three literacy scales: prose literacy, document literacy, and quantitative literacy. However, although some of the literacy tasks were health related, neither the NALS nor the IALS made the distinction between literacy and health literacy in their analysis.

In 2004, the Educational Testing Service (ETS) published *Literacy and Health in America*, which was based on data collected in the 1992 NALS and the IALS (R. Rudd, Kirsch, & Yamamoto, 2004). The publication's intent was to elucidate the relationship between literacy and health. In order to produce the report, researchers analyzed 191 tasks from the 1992 NALS and IALS that they deemed to be health-related. This included tasks, with related materials, on topics such as disease treatment and prevention, drugs and alcohol, safety and accident prevention, first aid, emergencies, staying healthy, and determining the correct dosage of medications. Participants' scores from these tasks were compiled to create a new Health Activities Literacy Scale (HALS) (R. Rudd et al., 2004). Scores on the HALS range from 0–500 and are divided into six levels: Below Level 1 (0–175), Level 1 (176–225), Level 2 (226–275), Level 3 (276–325), Level 4 (326–375), and Level 5 (376–500). Levels 1 through 5 were devised using the same criteria found in the NALS and IALS. Participants' scoring at Level 1 of the HALS are said to possess very limited and restricted health literacy proficiencies. Level 5 represents the highest health literacy proficiency, and Level 3 has been cited as a minimum standard for success in today's labor markets. Below Level 1 was introduced in the HALS in order to identify those who would be expected to score poorly (i.e., < 60%) on a test made up entirely of Level 1 tasks (R. Rudd et al., 2004).

Findings from the ETS's *Literacy and Health in America* indicate that low health literacy is prevalent among the US adult population. The overall average HALS score was 272 (Level 2), and nearly 1 in 5 participants possessed health literacy skills at Level 1 (12%) or Below Level 1 (7%). Based on the population in 1992, this corresponds to an estimated 36 million adults in the US performing at or below Level 1 of the HALS. Of the participants scoring Below Level 1, 51% reported being born in the US, 41% in Spanish speaking countries, and the remaining 8% in other countries. With average scores of 271 and 272 respectively, there was no significant difference between men and women on the HALS (R. Rudd et al., 2004).

HALS scores, and therefore health literacy, were also found to vary based on demographic variables, including level of education, ethnicity, and age. Adults who had not completed high school or obtained a GED had an average HALS score of 220 (Level 1). This compares to an average score of 271 (Level 2) for those who had either graduated from high school or earned their GED and an average score of 306 (Level 3) for those who continued their education beyond high school. Further, 48% of those who had not completed high school or obtained a GED scored at or below Level 1, compared to only 14% and 4% of those who had completed high school or obtained a GED and those who continued beyond high school, respectively. Looking at ethnicity, White adults had an average HALS score of 285 (Level 3), while Blacks had an average score 239 (Level 2) and Hispanics had an average score of 217 (Level 1). Only 3% of Whites scored Below Level 1, compared to 12% and 30% of Blacks and Hispanics, respectively. As for age, the average health literacy skills of younger populations are significantly higher than those of older adults. Participants age 16–45 had an average HALS score of 282–287 (Level 3) with 11–12% scoring at or below Level 1. Participants age 46–65 had an average score of 266 (Level 2) with 21% scoring at or below Level 1, and those 65 and older had an average score of 224 (Level 1) with 48% scoring at or below Level 1 (R. Rudd et al., 2004).

The 2003 National Assessment of Adult Literacy (NAAL) is the most up-to-date, comprehensive, and nationally representative measure of adult literacy in the US (Kutner et al., 2005). The NAAL

was sponsored by the National Center for Education Statistics (NCES) and administered to over 19,000 US adults age 16 and older. The NAAL includes several improvements over its progenitor, the 1992 NALS, including a newly added component that directly measured health literacy. Measurement of health literacy was accomplished through 28 tasks completed by participants in three health-related content domains: *clinical*, *prevention*, and *navigation of the health system*. The 28 health literacy tasks were developed to correspond with the NAAL's prose, document, and quantitative literacy scales. Materials used for the tasks, as well as the tasks themselves, were selected to be representative of real-world health-related information, including preventive care information, medication directions, and health insurance information.

The NAAL health literacy assessment results were reported in four levels: *Below Basic, Basic, Intermediate,* and *Proficient*. The *Below Basic* literacy level "indicates no more than the most simple and concrete literacy skills" (Kutner et al., 2006, p. 5). For example, a task that mapped to the *Below Basic* literacy level required participants to circle the date on a hospital appointment slip. The *Basic* literacy level "indicates skills necessary to perform simple and everyday literacy activities" (Kutner et al., 2006, p. 5), such as reading and understanding information in simple prose texts and documents as well as using easy-to-locate quantifiable information to solve simple, one-step problems. A task that mapped to the *Basic* literacy level required participants to use information in a one-page article about a medical condition to explain why it is difficult for people to know if they have the given condition. The *Intermediate* literacy level "indicates skills necessary to perform moderately challenging literacy activities" (Kutner et al., 2006, p. 5). This includes reading, understanding, and making simple inferences from dense prose text or documents, as well as solving problems from less familiar quantitative information in which the arithmetic operation is not easily inferred. A task that mapped to the *Intermediate* literacy level required participants to use information on a prescription drug label to determine what time the prescription medication should be taken in relation to mealtime. Lastly, the *Proficient* literacy level "indicates skills necessary to perform more complex and challenging literacy activities" (Kutner et al., 2006, p. 5), such as synthesizing information and making complex inferences from lengthy,

complex prose texts or documents as well as solving multi-step, complex quantitative problems that are not easily inferred. One task that mapped to the *Proficient* literacy level required participants to calculate how much an employee would pay in insurance costs for the year based on a table that shows how employees' monthly costs vary based on income and family size (Kutner et al., 2006).

According to the NAAL, low health literacy is prevalent among US adults and varies based on demographic characteristics. Only 12% of US adults were found to have *Proficient* health literacy. The majority of adults (53%) were found to have *Intermediate* health literacy. Twenty-two percent of US adults had *Basic* health literacy, and the remaining 14% had *Below Basic* health literacy. Women had higher health literacy on average than did men. Further, 16% of men had *Below Basic* health literacy as compared to 12% of women. Minorities, being Black, Hispanic, American Indian/Alaska Native, and Multiracial adults, had lower average health literacy than did White and Asian/Pacific Islander adults. Overall, Hispanic adults were found to have the lowest average health literacy among all ethnic groups. Looking at age, adults 65 and older were found to have lower average health literacy than any other age group. As for education, average health literacy increases for each higher level of educational attainment after graduating from high school or obtaining a GED. More specifically, of the adults who did not complete high school, 49% had *Below Basic* health literacy. This is compared to 15% of adults who ended their education with a high school diploma or GED and only 3% of adults with a bachelor's degree having *Below Basic* health literacy. Looking at income, adults below the poverty level had lower average health literacy than those above the poverty level (Kutner et al., 2006).

The NAAL also found that health literacy level varies based on self-reported overall health as well as type of health insurance coverage. As for overall health, the higher the level of participants' self-reported health, the higher the average health literacy as compared to the next lower level. Looking at health coverage, individuals with Medicare and/or Medicaid and those with no insurance coverage had lower average health literacy as compared to individuals with health

insurance coverage through their employer, through a family member's employer, through the military, or through privately purchased health insurance. In addition, 27% and 30% of those with Medicare and Medicaid, respectively, were found to have *Below Basic* health literacy.

Sources of health information utilized by individuals were also found to vary based on health literacy level. Those with *Below Basic* health literacy, as compared to all other health literacy levels, were less likely to get information from any written sources, including magazines, books, brochures, newspapers, and the Internet. Adults with *Basic* or *Below Basic* health literacy, as compared to those with *Intermediate* or *Proficient* health literacy, were more likely to receive a significant amount of health information via radio and television (Kutner et al., 2006).

Other studies that are smaller and less-comprehensive have also found low health literacy to be prevalent among the US adult population. A 1995 cross-sectional survey conducted at two urban hospitals by Williams and colleagues examined the functional health literacy of both English- and Spanish-speaking adults using the Test of Functional Health Literacy in Adults (TOFHLA). Overall, the researchers found that 691/2,659 (26%) could not understand information regarding the scheduling of a follow-up appointment, 1,106/2,659 (41.6%) could not comprehend medication administration directions specifying that the medication be taken on an empty stomach, and 1,582/2,659 (59.5%) could not comprehend a standard informed consent document. Further, 665/1,892 English-speaking adults (35%) and 473/767 Spanish-speaking adults (62%) had inadequate or marginal functional health literacy, which was more prevalent among elderly participants (age 60 and older) as compared to younger participants (M. V. Williams et al., 1995).

Gazmararian et al. (1999) found results similar to the previously cited studies. The researchers utilized the shortened form of the TOFHLA (S-TOFHLA) to assess health literacy among 3,260 new Medicare enrollees 65 years and older. Twenty-three percent of the English-speaking, and 34.2% of the Spanish-speaking, participants had inadequate health literacy and another 10.4%

and 19.7%, respectively, had marginal health literacy. Participants with inadequate health literacy often misread simple prescription instructions, information regarding blood glucose test results, and simple instructions regarding preparation for a radiographic procedure. Those with marginal health literacy performed better on these particular tasks but displayed poor comprehension of blood glucose tests, instructions to take a medication on an empty stomach, and a reading passage on Medicaid rights and responsibilities. A significant portion of those determined to have adequate health literacy in this study still had difficulty with comprehension of the Medicaid rights and responsibilities passage (17.3%) and with certain numeracy tasks, such as understanding a blood glucose range (23.5%). The researchers also found a strong relationship between age and health literacy, with the prevalence of inadequate health literacy increasing from 15.6% of participants aged 65–69 years to 58.0% of those 85 years or older. Other variables found to be associated with inadequate or marginal health literacy in this study include race/language, study location, level of education, occupation, and cognitive impairment (Gazmararian et al., 1999).

A systematic review by Paasche-Orlow, Parker, Gazmararian, Nielsen-Bohlman, and Rudd (2005) found that limited health literacy is prevalent among the US adult population and is consistently associated with level of education, ethnicity, and age. The review included 85 studies with data on 31,129 subjects. Various tools were used to assess participants' level of health literacy. Pooled analyses showed a weighted prevalence of low health literacy of 26% (95% CI, 16% to 23%). An additional 20% (95% CI, 16% to 23%) were found to have marginal health literacy. Age, ethnicity, and level of education were consistently associated with health literacy. For example, the rate of high school completion ($p = 0.02$) and the rate of Black participants ($p = 0.0003$) were significantly associated with the rate of low health literacy. Those tested in English had a lower rate of low health literacy than those tested in Spanish (26%, 95% CI, 22%–29%; $p = 0.002$ vs. 44%, 95% CI, 26%–62%). As for age, studies in which the average age was over 50 had more than two times the prevalence of low health literacy as compared to studies in which the average age was in the lowest quartile (37.9, 95% CI, 31.6–44.2 vs. 15.9; 95% CI, 7.7–24.1) (Paasche-Orlow et al., 2005).

Studies assessing health literacy generally indicate that low health literacy is prevalent and associated with several demographic variables, including age, level of education, and ethnicity. According to the NAAL, only 12% of US adults have *proficient* health literacy. This means that nearly 9 out of 10 individuals may lack the skills needed to properly manage their health. Additionally, 14% of US adults were found to have *below basic* health literacy. These individuals may have difficulty performing the simplest of health related tasks (Kutner et al., 2006). The primary importance of low health literacy and its prevalence, however, stems from its association with health-related outcomes.

General Implications of Health Literacy

Whether sick or well, health-related activities are part of daily living for most individuals, and functional health literacy is necessary to be an active participant in one's own health care. Traditionally, the primary focus of healthcare was to ensure that the care provided was medically appropriate and safely executed, with physicians making most of the decisions involved. However, in the past several decades, healthcare has been transitioning to shared decision making, in which the individual patient's goals and concerns are incorporated and addressed in the decision making process (Fowler, Levin, & Sepucha, 2011). Now more than ever, individuals are expected to be engaged as collaborators in their personal health and properly self-manage their disease states. To accomplish this, individuals must be able to meaningfully discuss treatment options with their health care providers, comprehend food and drug labels, process a staggering amount of health-related information encountered from various disparate sources, navigate the healthcare system, and properly adhere to prescribed medication regimens and other treatments, among many other tasks.

Consider a typical doctor-patient encounter. According to the 2010 National Ambulatory Medical Care Survey (NAMCS) conducted by the Centers for Disease Control (CDC), the average time spent with a physician during a patient visit was 20.8 minutes for all specialties and 19.3 minutes in general and family practice (CDC, 2013). In order for these brief face-to-face meetings to be

productive and meaningful, patients must both understand and communicate health information efficiently (Osborne, 2013). Healthcare providers expect patients to provide an accurate description of their symptoms and health histories in addition to comprehending verbal instructions (Nielsen-Bohlman et al., 2004; Schwartzberg, VanGeest, & Wang, 2005). The onus is not only on the patient, however. In these encounters, healthcare providers must also communicate in a way that the information conveyed can be processed and used effectively by the patient (Osborne, 2013).

Outside of the doctor's office, patients are often responsible for accomplishing a wide variety of health-related tasks. This may include activities such as checking their blood glucose and taking further action when necessary; self-administering prescribed medication according to a schedule based on time of day and/or in relation to mealtime; adherence to a recommended diet; or choosing the most cost-effective health and/or prescription drug insurance plan for themselves. Activities such as these, which require adequate health literacy to be performed correctly, often change over time along with an individual's daily roles and responsibilities. These changes bring about new demands in terms of health literacy. Studying adults engaged in adult education programs, Purcell-Gates, Degener, Jacobson, and Soler (2000) found that the birth of a child, a change in one's own health status or that of a family member, or a change in employment all evoke changes in individuals' literacy practices. For instance, as their own health or the health of a family member changed, participants reported increased reading associated with medications, books, and calendars (Purcell-Gates et al., 2000).

Whether specifically seeking it out or not, individuals often encounter a staggering amount of health-related information throughout the day that must be processed for potential utilization. This includes direct-to-consumer advertising, health-related information on the Internet and from friends or family, as well as health-related information obtained from healthcare entities. Again, just as healthcare providers must communicate in a way that is understandable, health information, in order to be effective, must be written or packaged such that it can be processed

and used appropriately by patients (Peters et al., 2007).

Health Literacy and Health-Related Outcomes

Although no causal relationships have been established, low health literacy has been shown to be associated with poor health-related outcomes and poor utilization of healthcare services (Berkman et al., 2011). Table 2 contains a selection of studies that have examined these associations. Because of the relationship between low health literacy and health-related outcomes, the annual cost of low health literacy to the US economy was estimated to be $106 billion to $238 billion in 2007 (Vernon et al., 2007). At the patient level, low health literacy is estimated to result in additional healthcare-related costs of $143–$7,798 per individual per year (Eichler, Wieser, & Brügger, 2009).

Table 2 - Studies Examining the Association between Low Health Literacy and Various Health-Related Outcomes

Citation	Population	Study Design	Setting	Data Collection Method	Health-Related Outcome Associations
Arnold et al. (2001)†	N = 600 pregnant women; 296 African American; 303 Caucasian; Mean age: 23	Convenience Sample	Louisiana obstetric clinics	REALM; Structured interview; Urine cotinine levels; Self-report of smoking practices	Those scoring lower on the REALM had less knowledge about the effects of smoking and less concern about the health effects of smoking on their baby than those with higher scores. REALM scores were not related to smoking practices even after controlling for race, age, and living with a smoker.
Baker et al. (2007)	N = 3,260 Medicare beneficiaries	Prospective cohort	Prudential Medicare managed care (4 locations)	S-TOFHLA; Structured interview; National Death Index	After adjusting for baseline health, socioeconomic status, and demographics, hazard ratio for all-cause mortality was 1.52 (95% CI, 1.26-1.83) for those with inadequate health literacy and 1.13 (95% CI, 0.90-1.41) for those with marginal health literacy, as compared to those with adequate health literacy. Those with inadequate health literacy had higher rates of cardiovascular death, after adjustments.

Citation	Population	Study Design	Setting	Data Collection Method	Health-Related Outcome Associations
Baker, Gazmararian, Williams, et al. (2002)†	N = 3,260 Medicare beneficiaries; 2,956 English speakers; 304 Spanish speakers	Prospective cohort	Prudential Medicare managed care (4 locations)	S-TOFHLA; Structured interview; MMSE; Geriatric Depression Scale; SF-12; Managed care organization claims	After adjusting for demographics, income, schooling, cognitive function, and social support, those with inadequate and marginal health literacy reported worse health status and were significantly more likely to have been hospitalized than those with adequate health literacy. Spanish speakers had a lower risk of admission than English speakers.
Baker, Gazmararian, Sudano, et al. (2002)†	N = 2,787 Medicare beneficiaries; 354 Blacks; 2,343 Whites; Mean age: 73	Cohort	Prudential Medicare managed care (4 locations)	S-TOFHLA; MMSE; Self-report	There was a linear relationship between health literacy and total MMSE score.
Baker et al. (1998)†	N = 979	Prospective cohort	Large public hospital emergency department in Atlanta	TOFHLA; Structured interview Grady Memorial Hospital information system	Those with inadequate literacy were significantly more likely to be hospitalized one or more times than those with marginal or adequate literacy, even after adjusting for age, gender, race, self-reported health, socioeconomic status, and health insurance.

Citation	Population	Study Design	Setting	Data Collection Method	Health-Related Outcome Associations
Baker et al. (1997)†	N = 2,659; 913 English speakers; 767 Spanish speakers	Prospective cohort	Two large public hospitals in Atlanta and Los Angeles	TOFHLA; Interview	Even after controlling for age, gender, race, and socioeconomic indicators, those with inadequate health literacy were significantly more likely to report poorer health than those with adequate health literacy. After adjustments, there was no relationship between health literacy level and ambulatory care use, but there was a relationship between inadequate health literacy and increased hospitalizations in the preceding year at the Atlanta site.
I. M. Bennett et al. (2009)	2,668 US adults aged 65 years and older	Cross-sectional	Data from the 2003 NAAL	NAAL background questionnaire; NAAL health literacy component	Increased level of health literacy correlated with self-report of good or better health. After adjustments, level of health literacy was found to mediate the ethnic and education-related disparities in self-reported health status and receipt of influenza vaccination as well as the education related disparities in receipt of mammogram and dental care.
C. L. Bennett et al. (1998)†	N = 212 low-income men; 109 Blacks; 103 Whites	Convenience sample	Prostate clinics in Shreveport, LA and Chicago, IL	REALM; Medical record review; Pathology reports	Those with health literacy levels below the sixth grade were more likely to present with Stage D cancer than those with higher literacy levels.

Citation	Population	Study Design	Setting	Data Collection Method	Health-Related Outcome Associations
Cho et al. (2008)	489 Medicare patients	Cross-sectional	Midwestern US city	S-TOFHLA; Face-to-face interviews	Health literacy was directly and positively associated with self-rated health status. Health literacy was directly and negatively associated with self-reported hospitalizations and ER visits
DeWalt et al. (2007)	150 children age 3 to 12, who had a clinical diagnosis of asthma for ≥ 3 months and recurrent wheezing episodes, along with their parents	Retrospective cohort	Three outpatient pediatric clinics at North Carolina Children's Hospital	REALM; Interview; Electronic medical records	Children with asthma, whose parents had low health literacy, had increased hospitalizations, increased ER visits, poorer asthma symptom control, and increased use of rescue inhaler.
Howard, Gazmararian, and Parker (2005)	N = 3,260 Medicare beneficiaries	Prospective cohort	Prudential Medicare managed care (4 locations)	S-TOFHLA; In-person survey; Administrative claims files	Compared to those with adequate health literacy, the probability of using an emergency room is significantly higher for those with inadequate health literacy, as are emergency room costs ($108; 95% CI: $62, $154, p < 0.0001)

Citation	Population	Study Design	Setting	Data Collection Method	Health-Related Outcome Associations
Kalichman and Rompa (2000)†	N = 339 HIV-positive adults; Mean age: 40	Convenience sample	HIV clinics; AIDS service organizations; Social service agencies	TOFHLA – reading comprehension section; Questionnaire or interview	Those with lower health literacy had lower CD4 counts, higher viral loads, were less likely to take antiretroviral medications, and reported more hospitalizations and poorer health than those with higher health literacy. After adjusting for level of education, lower health literacy was associated with poorer knowledge of one's HIV-related health status and AIDS-related disease and treatment knowledge, and more negative health-care perceptions and experiences.
Kripalani et al. (2006)	N = 152 patients with coronary heart disease	Cross-sectional, randomized trial	Inner city clinic at a large, urban, university-affiliated public hospital in Atlanta	REALM; Interview; Drug Regimen Unassisted Grading Scale; MMSE	Inadequate health literacy was significantly associated with lower medication management capacity ($p < 0.001$). Those with inadequate health literacy were up to 18 times more likely to be unable to identify all of their medications, as compared to those with adequate health literacy ($p < 0.05$).

Citation	Population	Study Design	Setting	Data Collection Method	Health-Related Outcome Associations
Lindau et al. (2002)†	N= 529 English speaking women older than 18 years; Median age: 27; 58% Black; 18% Hispanic	Prospective cohort	Ambulatory OBGYN clinic; Woman's HIV clinic	REALM; Interview; Chart review; Physician survey	Health literacy level was the only factor independently associated with knowledge related to cervical cancer screening, even after controlling for education, employment, ethnicity, insurance, and age. Those with inadequate and marginal health literacy were significantly more likely than those with adequate health literacy to state that they would seek care for an illness in an emergency department or acute care facility (11% vs. 3%) and would not seek medical care if informed of an abnormal Pap test (30% vs. 19%)
Paasche-Orlow et al. (2005)	N = 73 patients admitted with physician diagnosis of asthma exacerbation; Mean age: 41; Mostly Black, female, unemployed, and unmarried	Prospective cohort	Two inner city academic medical centers	S-TOFHLA; Interview-administered survey; Medical records	Adults with asthma and inadequate health literacy are more likely to have been hospitalized in the past 12 months and to have lower asthma related knowledge and poorer MDI technique as compared to those with adequate health literacy.

Citation	Population	Study Design	Setting	Data Collection Method	Health-Related Outcome Associations
Schillinger et al. (2002)†	N = 408 patients with Type-2 Diabetes older than 30 years	Cross-sectional	Two primary care clinics and a public hospital in San Francisco	S-TOFHLA; Diabetes care profile social support scale; Short form of the Center for Epidemiologic Studies Depression Scale; Interview; Hospital database	After adjustments, health literacy level, insurance status, and treatment regimen were all independently associated with HbA1c level. Those with inadequate health literacy were less likely to achieve tight glycemic control and were more likely to report having retinopathy, as compared to those with adequate health literacy.
Scott et al. (2002)†	N = 2,722 Medicare beneficiaries; Mean age: 71	Cohort	Prudential Medicare managed care (4 locations)	S-TOFHLA; Interview	Inadequate health literacy was independently associated with lower use of preventive health services, including receiving influenza and pneumococcal vaccinations, a mammogram, or a Pap smear, even after adjusting for demographics, level of education, income, number of physician visits, and health status.

Citation	Population	Study Design	Setting	Data Collection Method	Health-Related Outcome Associations
Sudore et al. (2006)	N = 2,512 community dwelling elderly; Mean age: 75.6	Five-year Prospective cohort	Memphis and Pittsburg	REALM; Interview; Yearly physical exams; Hospital records; Social Security Death Index; MMSE	After adjustments, those with limited health literacy had greater risk of death (hazards ratio 1.75; 95% CI 1.27, 2.41) as compared to those with adequate health literacy. A higher portion of those with limited health literacy reported having "fair" to "poor" health, and had diabetes, hypertension, obesity, high depressive symptoms, poor access to health care, poor health-related behaviors, and poor psychosocial status ($p < 0.05$).
Waldrop-Valverde et al. (2009)	N = 155 HIV positive patients	Cross-sectional	HIV care clinics in Miami	TOFHLA; Woodcock Johnson – III Tests of Achievement (Applied Problems subtest); Medication Management Test; Interview	Reading comprehension ($p < 0.05$) and numeracy ($p < 0.01$) were directly and significantly associated with Medication Management Test scores.
M. V. Williams et al. (1998)†	N = 483; 273 from emergency department with mean age: 37; 210 from asthma clinic with mean age: 47	Cohort	Urban public hospital in Atlanta	REALM; Interview; Observation of MDI technique	Reading level was the strongest predictor of asthma knowledge and MDI technique in multivariate analysis. Poor MDI technique was found in 89% of patients reading below a third-grade level vs. 48% of patients reading at a high school level.

Citation	Population	Study Design	Setting	Data Collection Method	Health-Related Outcome Associations
Michael S Wolf et al. (2005)	N = 2,923 Medicare enrollees	Cross-sectional	Medicare managed care (4 locations)	S-TOFHLA; Interview; Medical Outcomes Study 36-Item Short Form Heath Survey	Compared to those with adequate health literacy, those with inadequate health literacy had worse physical functioning, worse mental health, and more difficulties with activities of daily living and instrumental activities of daily living.
Yin et al. (2010)	N = 302 parents or caregivers of children presenting for care	Experimental	Public hospital pediatric clinic in New York City	NVS; Interview; Observation; Hollingshead's 4-Factor Index of Social Status	After adjustments, those with limited health literacy were more likely to make a dosing error (Adjusted OR 1.7; 95% CI 1.1, 2.8; p = 0.02)
Yin et al. (2007)	N = 292 parents or caregivers with a child aged between 30 days and 8 years	Cross-sectional	Urban public hospital in New York City	TOFHLA or S-TOFHLA; Interview; Hollingshead's 4-Factor Index of Social Status	After adjusting for child's age, caregiver acculturation and education, and health care experiences, inadequate/marginal health literacy was associated with lack of knowledge of weight-based dosing (OR 2.3; p = 0.03). After adjustments, lower reading comprehension was associated with self-reported use of non-standardized instruments (OR 2.4; p = 0.007) and lack of knowledge of weight-based dosing (OR 2.0; p = 0.03).

† = Adapted from: Nielsen-Bohlman et al. (2004); REALM = Rapid Estimate of Adult Literacy in Medicine; S-TOFHLA = Shortened Test of Functional Health Literacy in Adults; CI = Confidence interval; TOFHLA = Test of Functional Health Literacy in Adults; NAAL = National Assessment of Adult Literacy; MMSE = Mini Mental State Exam; SF-12 = Short Form-12 Health Survey, a measure of self-rated physical and mental health; MDI = Metered Dose Inhaler; NVS = Newest Vital Sign

Low health literacy is associated with negative aspects and poorer outcomes of nearly every facet of an individual's personal healthcare and wellness. Studies show that low health literacy is associated with worse self-reported physical and mental health status (Baker, Gazmararian, Sudano, et al., 2002; Baker, Gazmararian, Williams, et al., 2002; Baker et al., 1997; I. M. Bennett et al., 2009; Cho et al., 2008; Sudore et al., 2006; Michael S Wolf et al., 2005). Low health literacy is associated with decreased health- and disease-related knowledge (Arnold et al., 2001; Lindau et al., 2002; Paasche-Orlow et al., 2005; M. V. Williams et al., 1998). Individuals with lower health literacy display poorer use of preventive services, such as vaccines, mammograms, and Pap smears (I. M. Bennett et al., 2009; Lindau et al., 2002; Scott et al., 2002). Low health literacy is associated with poorer control and/or outcomes related to specific disease states, including asthma (DeWalt et al., 2007; Paasche-Orlow et al., 2005), diabetes (Schillinger et al., 2002), HIV/AIDS (Kalichman & Rompa, 2000), and cancer (C. L. Bennett et al., 1998), and it is associated with increased hospitalizations and utilization of emergency care services (Baker, Gazmararian, Williams, et al., 2002; Baker et al., 1998; Baker et al., 1997; Cho et al., 2008; DeWalt et al., 2007; Howard et al., 2005; Paasche-Orlow et al., 2005).

Low health literacy is associated with poorer medication management and adherence (Kalichman & Rompa, 2000; Kripalani et al., 2006; Paasche-Orlow et al., 2005; Waldrop-Valverde et al., 2009; M. V. Williams et al., 1998; Yin et al., 2007; Yin et al., 2010). Studying a convenience sample of 339 HIV-positive individuals, Kalichman and Rompa (2000) found that those with lower health literacy were less likely to take their antiretroviral medications, resulting in lower CD4 counts and higher viral loads, as compared to those with higher health literacy. Also looking at HIV-positive patients ($n = 155$), Waldrop-Valverde et al. (2009) found reading comprehension ($p < 0.05$) and numeracy ($p < 0.01$) were both directly and significantly associated with individuals' Medication Management Test scores. Kripalani et al. (2006) found that, among 152 patients with coronary heart disease, inadequate health literacy was significantly associated with lower medication management capacity ($p < 0.001$). Those with inadequate health literacy were up to 18-times more likely to be unable to identify all of their medications, as compared to those with

adequate health literacy ($p < 0.05$). Examining patients admitted to the hospital with a diagnosis of asthma exacerbation (n = 73), Paasche-Orlow et al. (2005) found that those with inadequate health literacy had poorer metered dose inhaler (MDI) technique, as compared to those with adequate health literacy. Looking at parents or caregivers of children (n = 302), Yin et al. (2010) found that those with limited health literacy were more likely to make a weight-based dosing error. In a previous study examining a similar cohort (n = 292), Yin et al. (2007) found inadequate/marginal health literacy was associated with lack of knowledge of weight-based dosing.

Lastly, and arguably most significantly, low health literacy is associated with increased mortality (Baker et al., 2007; Sudore et al., 2006). In a prospective cohort study of over 3,000 Medicare beneficiaries, Baker et al. (2007) found that the hazard ratio for all-cause mortality was 1.52 (95% CI, 1.26–1.83) for those with inadequate health literacy and 1.13 (95% CI, 0.90–1.41) for those with marginal health literacy, as compared to those with adequate health literacy. This was after adjusting for baseline health, socioeconomic status, and demographics. Further, Baker et al. (2007) found that those with inadequate health literacy had higher rates of cardiovascular-related death, after adjustments. Similarly, in a five-year prospective cohort study of 2,512 community dwelling elderly, Sudore et al. (2006) found that those with limited health literacy had greater risk of death (hazards ratio 1.75; 95% CI 1.27–2.41) as compared to those with adequate health literacy.

In summary, lower health literacy status has been shown to be associated with poorer overall health status, poorer knowledge and outcomes related to chronic diseases and cancer, poorer medication management and adherence, decreased use of preventive services, and increased hospitalizations and mortality. In addition to poorer health-related outcomes, low health literacy is also associated with significant increases in healthcare costs and is estimated to cost the US economy upwards of $200 billion annually (Vernon et al., 2007).

Initiatives to Improve Health Literacy

Given the importance of health literacy as well as its association with poor health-related outcomes and increased costs, there have been several large-scale initiatives to improve health literacy in the US. This includes initiatives led by the National Council on Patient Information and Education (NCPIE, 2015), the Institute of Medicine (IOM) (Nielsen-Bohlman et al., 2004), the Agency for Healthcare Research and Quality (AHRQ, 2014), and the Department of Health and Human Services (HHS, 2010). Recent legislation, such as the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) (Patient Protection and Affordable Care Act, 2010) and The Plain Writing Act of 2010 (Plain Writing Act, 2010), included sections meant to address health literacy. While some of these efforts focus on patients, the primary focus is on the healthcare system and providers.

Initiated in response to a recent study showing an apparent gap in communication, NCPIE's current "Talk Before You Take" campaign is aimed at both healthcare providers and patients and seeks to increase conversations between the two about prescription medications. A recent study by Ipsos Healthcare (2013) found that, of the 2,000 consumers surveyed, approximately 62% were not aware of any of their medications' safety warnings. Further, 10% of those who were surveyed and unaware of the possibility of having a severe reaction or side effect from their medication had actually experienced a serious drug reaction. The "Talk Before You Take" campaign is NCPIE's response to these findings. The initiative has four focal points, including patients talking with and asking questions of their healthcare providers about their medications' risks and benefits, patients informing their healthcare providers of all their current medications as well as any allergies and sensitivities, and patients fully reading and following the medication labels and directions (NCPIE, 2015).

The IOM, NIH, AHRQ, and HHS all have initiatives or reports aimed at improving health literacy in the US, focusing on the healthcare system. The IOM's 2004 report, *Health Literacy: A Prescription to End Confusion*, examines the extant literature applicable to health literacy and

recommends specific actions to promote a health-literate society. For instance, one recommendation in the report is for healthcare entities to “explore creative approaches to communicate health information using printed and electronic materials and media in appropriate and clear language” (Nielsen-Bohlman et al., 2004, p. 16). Another recommendation is to incorporate health literacy training into the curricula of health professions schools and continuing education programs (Nielsen-Bohlman et al., 2004). The IOM Roundtable on Health Literacy has begun identifying the attributions of a health-literate organization (Koh et al., 2012). AHRQ, working with the University of North Carolina at Chapel Hill, has developed and tested the Health Literacy Universal Precautions Toolkit. According to AHRQ, this toolkit “offers primary care practices a way to assess their services for health literacy considerations, raise awareness of the entire staff, and work on specific areas” (AHRQ, 2014). Pharmacy health literacy is one specific focus of the toolkit, which includes a pharmacy health literacy assessment tool, a training program for pharmacy staff on communication, standardized prescription medicine instructions, and various other tools (AHRQ, 2014).

In 2010, HHS developed the National Action Plan to Improve Health Literacy. The plan is based on the following two principles: “Everyone has the right to health information that helps them make informed decisions” and “health services should be delivered in ways that are understandable and beneficial to health, longevity, and quality of life.” There are seven major goals for healthcare entities laid out in the plan, including the development and dissemination of accurate, accessible, and actionable health and safety information; increasing research, practices, and interventions to improve health literacy; and increasing the dissemination and utilization of health literacy practices and interventions that are evidence-based. The plan was developed due to the realization that improving health literacy is critical to achieving specific objectives of *Healthy People, 2020 (US Department of Health Human Services Office of Disease Prevention Health Promotion, 2010).* This includes increasing the number of patients who report that they received understandable instructions from their healthcare provider on how to take care

of their illness and increasing the number of patients who report that the offices of their providers always offer help in completing forms (R. Parker & Ratzan, 2010).

Recently introduced legislation includes provisions aimed at improving health literacy. This includes the Affordable Care Act of 2010 and the Plain Writing Act of 2010. The Affordable Care Act addresses health literacy both directly and indirectly by incorporating health literacy into professional training and simplifying the enrollment procedures for Medicaid, the Children's Health Insurance Program, and the state-based insurance exchanges. The law also requires health plans and insurers to provide consumers with a summary of benefits and coverage via a standardized template, in hopes of making the health information more clear, consistent, and comparable (Koh et al., 2012). The Plain Writing Act requires that all new publicly distributed documents and forms from the federal government be written in a clear, concise, and well-organized manner. In terms of health literacy, the aim therein is to enable individuals to better understand and apply for government benefits and services for which they are eligible, including health insurance, disability support, and nutrition support (Koh et al., 2012).

There have been many public and private initiatives aimed at improving health literacy. While there is some focus on patients, the primary focus is on the health context. Viewed globally, the overall aim is to make the healthcare system, providers, and information more accessible, understandable, and useful to patients. One specific area that could be improved upon in this way is written patient medication information.

Written Patient Medication Information

Major Types of Written Patient Medication Information

Written medication information for consumers comes in several different formats, only some of which are regulated by the Food and Drug Administration (FDA). Although there are others, the three major categories of written medication information include patient package inserts (PPIs), Medication Guides (MedGuides), and Consumer Medication Information (CMI). Table 3 contains summary information for each of the three formats. All three are intended for distribution to

consumers at the time of drug dispensing. Both PPIs and MedGuides contain prescription drug information that is drafted by the drug's manufacturer and subsequently reviewed, revised as necessary, and approved by the FDA. The FDA also specifies content and formatting requirements for both PPIs and MedGuides. CMI, on the other hand, is not subject to FDA regulation. However, the FDA is currently considering implementation of new regulation that would affect CMI, MedGuides, and PPIs (Brookings, 2010).

Table 3 - Major Types of Written Patient Medication Information

Format	Description	Author	FDA Review
Patient Package Inserts (PPIs)	Leaflets written as part of labeling for certain medications (e.g., oral contraceptives and other estrogen containing products)	Pharmaceutical manufacturer	Yes
Medication Guides (MedGuides)	Leaflets written as part of labeling for certain medications (e.g., antidepressants and NSAIDs) that FDA determines pose a serious and significant public health concern		
Consumer Medication Information (CMI)	Printed information often provided voluntarily by pharmacies; usually stapled to the outside of or put into the pharmacy bag with the prescription medication	Drug information publishers	No

Adapted from: (Aker et al., 2013)

Introduced in the late 1960s, PPIs are required to be dispensed with specific medications, most notably oral contraceptives and other estrogen-containing products. MedGuides were established by the FDA in 1996 and are required to be dispensed with certain medications that, according to the FDA, pose a serious and significant public health concern. Prominent examples of medications requiring MedGuides include antidepressants, due to an increased risk of suicide, and non-steroidal anti-inflammatory medications (NSAIDs), due to an increased risk of gastrointestinal bleeding, stroke, and heart attack.

In contrast to PPIs and MedGuides, CMI as defined by the FDA is "written information about prescription drugs developed by organizations or individuals other than a drug's manufacturer that is intended for distribution to consumers at the time of drug dispensing" (FDA, 2006, p. 4).

Neither the FDA nor a drug's manufacturer reviews or approves CMI (FDA, 2006). Independent producers of CMI include First Databank, Wolters Kluwer, and the American Society for Health-System Pharmacists (ASHP), among others. Pharmacies contract with these companies to receive CMI, which they then provide to their patients. Once received, pharmacies and/or their information systems vendor often alter the CMI prior to dispensing it to the patient. This results in significant variations in the content and formatting of CMI that patients ultimately receive (Barlas, 2009). For instance, CMI from the same publisher and date of publication can vary greatly in both content and appearance from one pharmacy to the next (Kimberlin & Winterstein, 2008).

Importance of Written Patient Medication Information

In order to make informed decisions and be an active participant in their own healthcare, patients must have accurate, understandable, and actionable information at their disposal. Written medication information is an important component in filling this need. There are several other potential sources of medication information for patients, but they are not without limitations. For instance, oral communication between patients and healthcare providers concerning medications is often incomplete (Livingstone, Hayes, & Ladenheim, 1993; N. Morrow, Hargie, & Woodman, 1993; Svarstad, Bultman, & Mount, 2003; Tarn et al., 2006). Further, patients often forget or fail to understand the information they receive verbally from healthcare providers (Jansen et al., 2008; Kessels, 2003; Wilson, Robinson, Blenkinsopp, & Panton, 1992). Other sources of medication information, such as those found on the Internet, often provide inaccurate or incomplete information and are frequently written at a higher-than-average reading level (Graber, Roller, & Kaeble, 1999). In the face of these shortcomings of other sources, written medication information is meant to serve as a reliable resource that patients can refer to as needed.

Verbal communication between patients and healthcare providers concerning medications is often incomplete (Livingstone et al., 1993; N. Morrow et al., 1993; Svarstad et al., 2003; Tarn et al., 2006). An observational study by Tarn et al. (2006) found that, when 45 doctors counseled patients on a total of 243 new medications, duration of therapy and potential adverse effects were only discussed for 34% and 35% of the medications, respectively. Further, the number of tablets

to be taken daily and the frequency or timing of doses was explicitly discussed for less than 60% of the new medications (Tarn et al., 2006). There have been similar findings looking at the verbal counseling patients received from pharmacists. Svarstad et al. (2003) had trained shoppers deliver three new prescriptions to be filled at 306 pharmacies across eight states. Overall, oral drug information was given for only 63% of the prescriptions, with duration of therapy and potential adverse effects being discussed for only 46% of the prescriptions (Svarstad et al., 2003). Based on these findings, it seems that physicians expect pharmacists to cover specific counseling points with patients, which does not always occur. This creates a gap in communication between healthcare providers and patients concerning their medications.

Compounding this issue, patients often have difficulty recalling or understanding the information that they receive verbally from healthcare providers (Jansen et al., 2008; Kessels, 2003; Wilson et al., 1992). Kessels (2003) estimates that 40–80% of medical information provided verbally to patients by healthcare providers is forgotten immediately. Further, Jansen et al. (2008) found that, among 260 newly diagnosed cancer patients, as the amount of information provided increased, patients' recall decreased. They also found that patients with a poorer prognosis recalled less information.

Due to the wide range of potential sources, many of which have been shown to be incomplete, inaccurate, or difficult to read, the Internet is often limited in terms of being a useful resource for health and medication information for many patients. Berland et al. (2001) analyzed the quality of information from 25 well-recognized health websites, including WebMD, the American Cancer Society, the National Library of Medicine, and CBS Health Watch. They found that, on average, 24% of the clinical elements were not covered at all. Of the clinical elements that were covered, only 45% on average were completely accurate. Further, information on all of the sites analyzed was written at a high school level, as determined by the Fry Readability Graph (Berland et al., 2001). Similarly, Kim, Metzger, Wigle, and Choe (2011) analyzed consumer information for 10 medications found on Medline Plus, Yahoo Health, and WebMD, three well-known websites.

Overall, the information was accurate yet difficult to read, with a mean reading level of 13th grade level and 10th grade level or higher as determined by the SMOG and Fry Readability Graph, respectively (Kim et al., 2011). In a study by Graber et al. (1999), researchers first searched the Internet for patient education information on various topics, including obstetrics and gynecology, pediatrics, internal medicine, and psychiatry. They then analyzed the reading level of the information obtained using the Flesch-Kinkaid Readability Test. The average reading level was determined to be 10th grade, which is not comprehensible to the majority of patients (Graber et al., 1999). Looking specifically at the quality of medication information provided by retail pharmacy websites, including Walgreens, CVS, and Rite Aid, Ghoshal and Walji (2006) found that, for the four medications analyzed, the medication information was adherent to 77% of the criteria created by a national panel of experts. Further, the average reading level was 10th grade, as determined by the Gunning Fog Test (Ghoshal & Walji, 2006).

Written medication information is meant to serve as a reliable and readily available resource for patients. It increases patients' understanding and knowledge related to their medications, and may lead to increased adherence and satisfaction (Koo et al., 2003). Additionally, written medication information is well positioned to overcome many of the shortcomings of other information sources. This includes the incomplete nature of verbal medication information received by patients from healthcare providers, which is subsequently often forgotten or misremembered, as well as the unreliability of sources found on the Internet. However, despite these strengths, many serious inadequacies have been identified with written medication information.

Background: FDA Regulation and Guidance

The first drug to require written consumer medication information was isoproterenol inhalation products, beginning in 1968 (Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, 1996). The FDA required a PPI for these products to warn patients that excessive use could cause breathing difficulties (CFR, 1990; Woodcock, 2013). In the 1970s, the FDA began requiring PPIs for oral

contraceptives (CFR, 2009b) and other estrogen containing products (CFR, 2009a) based on new data indicating the potential for long-term side effects (FDA, 2006). Also during this time, the FDA began evaluating patient labeling for prescription medications, which resulted in further attempted regulations.

In 1979, the FDA proposed regulations requiring manufacturers to produce consumer medication information for all medications to be reviewed by the FDA before distribution (FDA, 2006). The FDA finalized those regulations in 1980, only requiring CMI for a limited number of prescription drugs. However, in 1982 the FDA revoked the regulations based in part on assurances by healthcare professional associations, pharmaceutical manufacturers, and private-sector providers of written consumer medication information that the goals therein would be met more effectively and with greater innovation without regulation. Also in 1982, the National Council on Patient Information and Education (NCPIE) was formed. With a membership of over 300 organizations, the NCPIE serves as a major coordinating body for private-sector initiatives to improve communication to consumers about their prescription medications (Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, 1996).

The distribution of written consumer medication information increased after 1982, but its quality varied greatly (FDA, 2006; Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, 1996). FDA surveys found that, in 1982, only 16% of patients reported that they received written medication information from pharmacists. By 1994, this had increased to 55% (Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, 1996). That same year, the National Association of Boards of Pharmacy (NABP) found that 64% of consumers reported receiving written medication information. The quality of the content and formatting of the CMI, however, was highly variable (FDA, 2006).

In response to these findings, the FDA proposed regulation in 1995 entitled *Prescription Drug Product Labeling: Medication Guide Requirements,* commonly known as the MedGuide proposal. In addition to requiring that manufacturers produce MedGuides for certain medications deemed by the FDA to pose a serious and significant public health concern, the proposed rule also encouraged production of written consumer medication information for all prescription drugs. To this end, the MedGuide proposal established the following goals: By 2000, 75% of new prescriptions would be accompanied with useful written patient information; By 2006, 95% of new prescriptions would be accompanied with useful written patient information. To allow systematic evaluation of the written information, "usefulness" was defined in the proposed regulation (FDA, 2006). Once again, although consumer- and patient-advocacy groups indicated strong support for the proposed rule, healthcare professional organizations, information vendors, and the pharmaceutical industry ultimately dissented (Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, 1996).

In August of 1996, Public Law 104-180 was enacted (Title VI Related Agencies and Food and Drug Administration Department of Health and Human Services, 1996). A provision was included therein that established a voluntary private-sector process through which a committee of interested stakeholders would develop a long-term action plan to achieve the goals specified in the MedGuide proposal (Brookings, 2010; Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, 1996). Further, the law prohibited the FDA from regulating the content and format of written consumer information if the goals were being met by private-sector initiatives (Brookings, 2010). The law also required the Secretary of HHS to evaluate progress and, if the 2000 or 2006 goals were not being met, gave the Secretary the authority to institute regulation to this end. Per requirements of the new law, the Secretary of HHS, with the aid of a steering committee, developed and released the *Action Plan for the Provision of Useful Prescription Medicine Information* (i.e., The Action Plan) in 1996. The purpose of The Action Plan was to improve the quality and availability of

useful consumer medication information that is voluntarily provided to consumers (Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, 1996).

The Action Plan included, among other things, guidelines for useful prescription medication information that were meant to provide direction for developers without being overly prescriptive (Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, 1996). According to The Action Plan, written consumer medication information should be: "(1) scientifically accurate, (2) unbiased in content and tone, (3) sufficiently specific and comprehensive, (4) presented in an understandable and legible format that is readily comprehensible to consumers, (5) timely and up-to-date, and (6) useful." Based on the MedGuide proposal, the Action Plan defined useful as enabling the patient to use the medication properly and appropriately, avoid harm, and receive the maximum benefit. Specific criteria, components, and formats in regards to usefulness are further delineated in the Action Plan to provide additional guidance (Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, 1996).

In 1998, the FDA contracted with the NABP to assess CMI and determine progress toward meeting the goals set forth by Public Law 104-180. After conducting a pilot study in 1999 in eight states, the NABP conducted a national study in 2001, the specific findings of which will be discussed shortly. In order to evaluate CMI, the expert panel devised the criteria in Table 4 based on the Action Plan.

Table 4 - Usefulness Criteria for Written Consumer Medication Information

Criterion	Description
1	Drug names, indications for use, and how to monitor for improvement
2	Contraindications and what to do if they apply
3	Specific directions about how to use and store the medicine, and overdose information
4	Specific precautions and warnings about the medicine
5	Symptoms of serious or frequent possible adverse reactions and what to do
6	Certain general information, including encouraging patients to communicate with healthcare professionals, and disclaimer statements
7	Information that is scientifically accurate, unbiased in tone and content, and up-to-date
8	Information in an understandable and legible format that is readily comprehensible to consumers

Adapted from FDA (2006)

Overall, the NABP's 2001 national study found that, while 89% of patients received some form of medication information, the average usefulness of the information was only about 50%. These findings indicated that the year 2000 goal that 75% of new prescriptions would be accompanied with useful written patient information was not being met. Because of this, the FDA Drug Safety and Risk Management Advisory Committee recommended that the FDA take a more active role in advising and encouraging the private sector to meet the 2006 goal. Based on this recommendation, the FDA met in 2003 with various stakeholder groups and held a public hearing to get input (FDA, 2006).

In 2006, the FDA developed and released the *Useful Written Consumer Medication Information (CMI)* guidance document. The purpose of the guidance document was to provide clarification on how the Action Plan should be interpreted and implemented, thereby providing further assistance to CMI developers (FDA, 2006). It should be noted that guidance documents released by the FDA, including this one, do not establish legally enforceable responsibilities. Instead, they describe the FDA's current thinking on a topic and provide recommendations, not requirements (FDA, 2006).

In 2008, an FDA-commissioned follow-up study incorporating both consumer and expert evaluation of CMI found that the 2006 goal of having 95% of new prescriptions accompanied with useful written patient information was not being met. The details of the study are discussed below but, overall, findings showed that while 94% of consumers received CMI with new prescriptions, only 75% of the minimum criteria for usefulness were met (Kimberlin & Winterstein, 2008). This same year, the FDA received a citizen petition, including representation from pharmacy practice, medical consumers, and medical communications companies, requesting that the FDA adopt a "one document solution" to replace CMI, PPIs, and MedGuides (Brookings, 2010). In 2009, the FDA Risk Communication Advisory Committee echoed the petition request, recommending that the FDA adopt a single standardized document to replace the aforementioned existing formats.

Evaluations of Written Consumer Medication Information

Studies specifically examining CMI in terms of formatting and content show that this information source is not meeting the health literacy needs of patients (Kimberlin & Winterstein, 2008; Raynor et al., 2006; Svarstad, Bultman, Mount, & Tabak, 2002; Svarstad et al., 2004). These studies include evaluation by experts and consumers examining aspects such as the completeness, accuracy, unbiasedness, comprehensibility, and legibility of the medication information. Given the issues of health literacy discussed previously, combined with the fact that CMI serves as a primary source of knowledge for patients when it comes to their medications, and the belief that well informed patients can make better decisions about their medications and personal health care, the inadequacy of current CMI is highly problematic.

In 2001, the FDA funded a study by Svarstad et al. (2004), coordinating with the NABP, in which both consumers and experts evaluated CMI for four medications (atenolol, atorvastatin, glyburide, and nitroglycerin). Professional shoppers were utilized to obtain the CMI from 384 randomly selected pharmacies in 44 states. This was the first study to evaluate a national sample of CMI from community pharmacies. Of the 1,536 prescriptions filled for the study, 89% (1,367) were dispensed with CMI that only met approximately 50% of the usefulness criteria (Svarstad et al., 2004).

A panel of 16 experts evaluated the CMI using rating forms in which drug-specific subcriteria were developed for the eight main criteria (see Table 4), which were based on specifications in the FDA's 1996 *Action Plan for the Provision of Useful Prescription Medicine Information*. The rating forms were created and validated in a previously conducted pilot study (Svarstad et al., 2002). Expert ratings were given on a 5-point scale, with level 5 representing the highest quality and level 1 representing the lowest. Ratings varied by criterion. Accuracy and unbiasedness received the highest ratings, with 95% of the CMI meeting level 5. Drug names and indications and specificity of directions received a level 5 rating for 32% and 19% of the CMI, respectively. Adverse drug reactions and general information, disclaimer, and encouragement to ask questions both received a level 5 rating for only 13% of the CMI. Less than 10% of the CMI met level 5 on contraindications and what to do before using the drug, precautions and how to avoid harm, and legibility/comprehensibility. The expert panelists were most critical of the lack of risk information and the legibility/comprehensibility of the CMI (Svarstad et al., 2004).

In the same study by Svarstad et al. (2004), 154 consumers also evaluated the 1,367 CMI for comprehensibility, legibility, and usefulness from their perspective. To do so, the consumers used a one-page form developed by Svarstad et al. (2002) that employed a 5-point scale, with 1 representing the lowest rating and 5 representing the highest. Line-spacing (mean rating ± SD; 2.9 ± 1.4), print size (3.0 ± 1.4), and ease of reading (3.1 ± 1.4) received the lowest ratings from consumers. Consumers rated 36% of the CMI as hard to read and gave 40% of the CMI low scores (i.e., ≤ 2) on spacing and print size. Helpfulness (3.7 ± 1.2) and completeness (3.7 ± 1.2) received the highest ratings from consumers (Svarstad et al., 2004).

Raynor et al. (2006) used the same expert rating forms created by Svarstad et al. (2002) to evaluate four CMI leaflets from the United States as well as five CMI leaflets from both Australia and the United Kingdom (UK). It should be noted that, in both Australia and the UK, legislation mandates that comprehensive, manufacturer-developed CMI leaflets be dispensed to patients.

The mean quality adherence score for the CMI from the US (68%; range 65%–77%) was much lower than that of the CMI from Australia (90%; range 83%–94%) and the UK (81%; range 73%–84%). Further, the US CMI received poor ratings (i.e., ≤ 50%) for contraindication and precaution information, often omitting warnings about preexisting allergies and drug interactions. Three of the four US CMI also received poor ratings (i.e., ≤ 60%) for legibility and comprehensibility due to lack of clear headings and bullet points, which enhance readability (Raynor et al., 2006).

In 2008, the FDA commissioned Kimberlin and Winterstein (2008) to perform a follow-up study to the 2001 study conducted by Svarstad et al. (2004). The 2008 study used a similar approach and methods to those of the 2001 study. Professional shoppers were used to obtain CMI leaflets for prescriptions filled at a national representative sample of 365 pharmacies in 41 states. Notable changes include the use of two different medications (metformin and lisinopril) as well as incorporation of criteria specified in the FDA's 2006 *Guidance: Useful Written Consumer Medication Information*. This led to alterations in the drug-specific subcriteria used on the expert rating forms. The consumer evaluation forms, however, were unaltered. Word count was obtained for each CMI leaflet, but this was not included in the quality scores. Reading difficulty of each CMI leaflet was determined by the Flesch-Kincaid Grade Level Index and was included in the quality scores. Overall, although the percent of content criteria met by the CMI leaflets was found to have increased since the 2001 study, adherence to formatting recommendations had not improved (Kimberlin & Winterstein, 2008).

Of the 365 pharmacies included in the Kimberlin and Winterstein (2008) study, 94% provided CMI for metformin (n = 342) and lisinopril (n = 343). Word count for the 685 leaflets was highly variable, ranging from 33 to 2,482. In terms of expert evaluations, 274 (75%) and 233 (64%) of the CMI for lisinopril and metformin, respectively, met the pre-specified threshold for usefulness (i.e., ≥ 60% of all subcriteria). Very low quality scores (i.e., < 40% of all subcriteria) were obtained for 14% of the lisinopril CMI and 16% of the metformin CMI. The highest mean scores were obtained for scientific accuracy, with 97.3% (± 14.0) and 97.4% (±14.3) of the lisinopril and

metformin CMI, respectively, meeting all of the subcriteria therein. Legibility/comprehensibility received the lowest mean scores, with only 43.8% (± 11.1) of the lisinopril CMI and 42.6% (± 10.8) of the metformin CMI meeting all of the subcriteria. Directions received the next lowest scores, with 53.9% (± 23.9) and 45.6% (±18.3) of the lisinopril and metformin CMI, respectively, meeting all of the subcritera for this standard (Kimberlin & Winterstein, 2008).

Consumers who participated in the 2008 study were most critical of print size, line spacing, and ease of use of the CMI being evaluated. Font size ranged from 5-point to 12-point, with only 29% of the CMI evaluated meeting the FDA guidance criterion specifying that a 10-point font or larger be used. The criterion for line spacing, which specifies that space between lines be ≥ 2.2 mm, was only met by 15% of the CMI. Utilization of bullets for the listing of key points occurred in only 7% of the leaflets, and bolded text for emphasis was used by only 6% of the CMI. Further, only 3% of the CMI indicated black box warnings with a bolded font or an actual box around the warning. Analysis of reading level found that only 10% of the lisinopril and 6% of the metformin CMI were written at ≤ 8th grade reading level as specified by the FDA guidance document. The mean reading level was above 9th grade for both medications' CMI (Kimberlin & Winterstein, 2008). A previous, less comprehensive study by Kirksey, Harper, Thompson, and Pringle (2004) found a mean reading level of 12th grade (range 8–14) for the 45 CMI leaflets analyzed using the SMOG.

In summary, studies indicate that current CMI is not meeting the health literacy needs of patients. Not only is valuable information such as precautions and how to avoid harm while taking the medication often missing, a large portion of CMI is written and formatted in a way that is not easily comprehensible to patients. This includes too small of font size and line spacing; poor use of bolding, bullets, and headings; and content that is written at too high of a reading level for the general public. As such, there is a demonstrated need for an overhauling and standardization of current CMI content and formatting so that it is more accessible and useful to patients.

Time for Change – Written Patient Medication Information

As mentioned previously, a 2008 citizen petition to the FDA called for a revamping of CMI formatting. Specifically, the petition called for a one-document solution to replace CMI as well as PPIs and MedGuides (Brookings, 2010). This new standardized format is being referred to as written patient medication information (PMI). In 2010 and 2011, the FDA worked with the Engelberg Center for Health Care Reform at Brookings to hold expert stakeholder meetings and public hearings to discuss principles for effectively communicating prescription information, optimal content and formatting of PMI, and appropriate evaluation metrics for PMI (Brookings, 2010). Also discussed was a quality management system to ensure standardized PMI development, access, and distribution. In response to the feedback provided, the FDA developed and further refined four draft PMI formats (Prototypes 1, 2, 3, and 4) (Brookings, 2010).

Currently, it appears that the FDA is seriously considering having drug manufacturers independently produce PMI. The PMI would be subject to FDA content and formatting standards, but there would seemingly be little editorial oversight otherwise. Janet Woodcock, the chief of the FDA's drugs division, stated that "information about a manufactured product is best produced and tested by that manufacturer." She also pointed out that manufacturer-produced PMI is currently used in the European Union, Canada, Japan, Australia, and New Zealand (Traynor, 2014).

The FDA's plan to have manufacturers produce PMI is not without opposition. A representative from First Databank pointed out four major flaws in this plan, including concerns of efficiency, consistency, objectivity, and timeliness (Lupinetti, 2012a, 2012b). ASHP has expressed similar concerns (Traynor, 2014). This unease stems from the fact that, if the FDA's plan were put into place, approximately 800 manufacturers would be responsible for creating more than 22,000 documents, with generic manufacturers essentially performing the exact same task as its competitors. Instead, both ASHP and First Databank recommend that the FDA contract with a third party to have PMI produced to the FDA's specifications (Lupinetti, 2012a, 2012b; Traynor, 2014).

Raising additional concerns for manufacturer-produced PMI, several studies have found that manufacturer-produced written drug information does not meet the health literacy needs of the majority of patients. Analyzing 63 PPIs, Basara and Juergens (1994) found an average reading level of 10th grade and poor design characteristics overall, including small font size and poor paper quality. Roskos, Wallace, and Weiss (2008) performed an analysis of consumer drug information for intranasal corticosteroids developed by the drugs' manufacturers. Most of the information analyzed had too small of font size (9 ± 2.2), and poor illustrations for proper patient education (Roskos et al., 2008). Similarly, manufacturer-developed consumer drug information for asthma inhalation devices was found to have an average reading difficulty level (8.2 grade ± 1.5), an average font size (9.2 ± 2.2), and poorly formatted diagrams/illustrations and instructions that make it suboptimal for patient education (Lorraine S Wallace, Roskos, & Weiss, 2006). Analyzing 40 MedGuides, Michael S. Wolf, Davis, Shrank, Neuberger, and Parker (2006) found an average reading level of 11th–12th grade and lack of summary information in the majority (90%) of the MedGuides. The researchers therefore concluded that MedGuides are not likely to be useful to patients with low health literacy (Michael S. Wolf et al., 2006).

No matter the direction the FDA decides to go in terms of PMI production, the FDA has stated that vetting and formalizing new rules could take several years. In the meantime, the FDA encourages stakeholders to initiate pilot studies evaluating PMI formatting, content, and distribution strategies. To this end, the FDA indicated that it would be interested in pursuing concurrent distribution pathways, including digital and paper-based formats (Brookings, 2010). Two novel design and presentation formats that should be evaluated in terms of meeting the health literacy needs of patients include a colored, Picture-Enhanced format and a Video format.

The Use of Illustrations in Healthcare

The utility of illustrations in enhancing recall of information, in healthcare and other disciplines, stems from the pictorial superiority effect. Specifically, the pictorial superiority effect refers to findings from a large number of studies showing that conveying information via pictures or

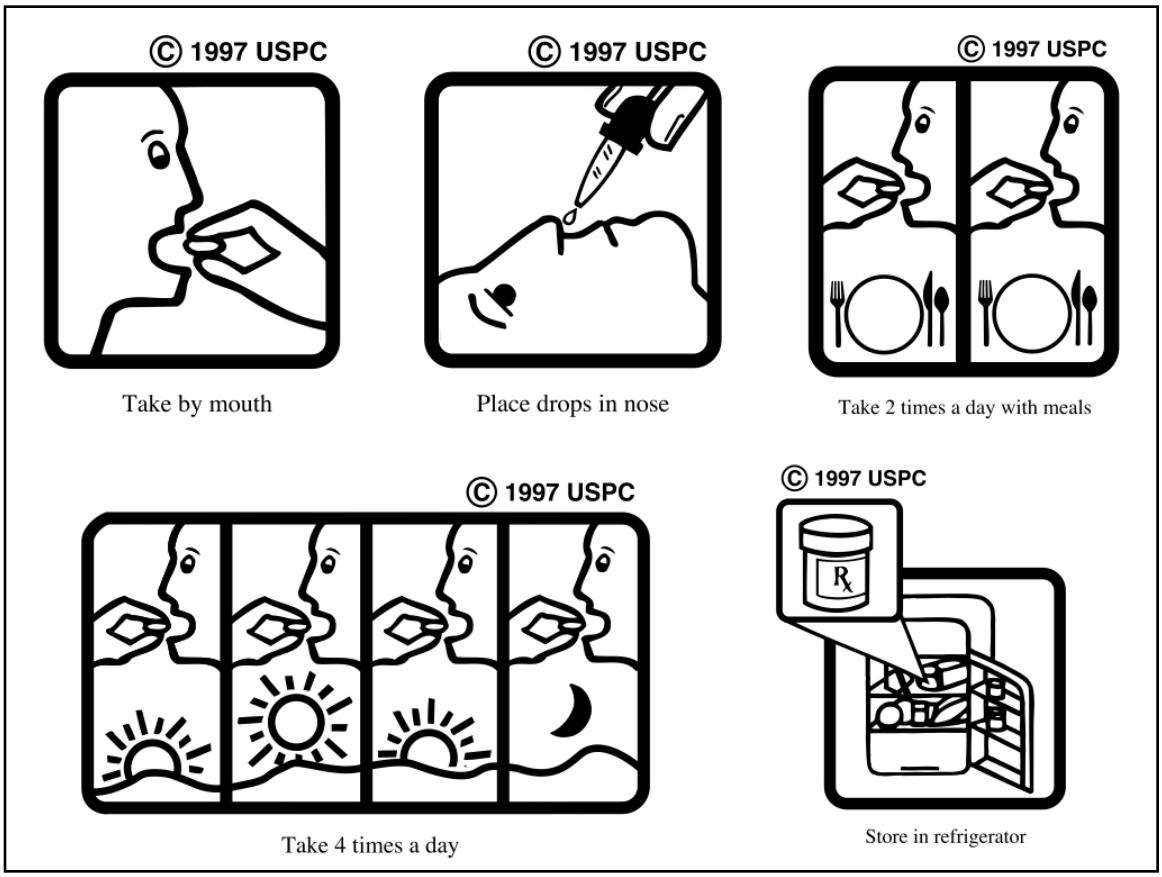
illustrations is preferred and results in greater recall of the information presented as compared to their written word counterparts (Houts et al., 2006; Montagne, 2013; Thompson et al., 2010). This includes cued and non-cued recall. For example, examining participants' (n = 20) cued recall of spoken medical instructions, Houts et al. (1998) found that participants correctly recalled 85% of the instructions that were accompanied by illustrations vs. 14% of the instructions without illustrations ($p < 0.0001$) directly after being given the instructions. A follow-up study expanded these findings, showing that illustrations presented during oral medical instructions and recall can help those with low literacy (≤ 5th grade; n = 21) with short-term recall (85% correct recall rate) and long-term recall (71% correct recall rate at 4 weeks) (Houts, Witmer, Egeth, Loscalzo, & Zabora, 2001). Studies examining non-cued recall are discussed below. Thus far, there have been no studies indicating that the pictorial superiority effect varies based on the type of illustration or picture used or the topic covered (Houts et al., 2006).

In healthcare, the addition of illustrations to written information has been shown to enhance recall, comprehension, and execution of, as well as adherence to, a variety of health related activities. Austin et al. (1995) compared patients' recall of information from written laceration wound care instructions that included illustrations versus the same written instructions alone. Looking at patients with a high school education or below (n = 71), those who received the instructions with illustrations were 1.8 times more likely to answer ≥ 5 of the 10 assessment questions correctly as compared to those who received the text-only instructions ($p = 0.038$). Delp and Jones (1996) performed a similar study that yielded similar results. Patients who were given wound care instructions with illustrations were more likely to have read the instructions (98% vs. 79%, $p < 0.001$), correctly answer all 4 wound care questions (46% vs. 6%, $p < 0.001$), and were more adherent to the daily wound care prescribed therein (77% vs. 54%, $p < 0.01$). When analysis was limited to only include patients with less than a high school education (n = 57), larger differences were seen between the two groups in terms of correctly answering all wound care questions (46% vs. 0%, $p < 0.001$) and adherence to the prescribed regimen (82% vs. 45%, $p = 0.008$) (Delp & Jones, 1996). Kools, van de Wiel, Ruiter, and Kok (2006) compared patients' recall of

instructions as well as actual performance with a peak flow meter and an inhaler chamber after receiving either text instructions alone or the same text instructions with illustrations. Overall, results showed that the illustrations had a significant positive effect on participants' recall of instructions (inhaler chamber only) and performance (both devices) (Kools et al., 2006).

The addition of well-designed pictograms, a specific type of illustration, to medication labels has proved to be beneficial to and preferred by patients, overall. According to Dowse and Ehlers (1998, p. 109), well-designed pictograms are "simple, clear, graphical symbols able to convey their intended meaning to all patients." In 1987, the United States Pharmacopoeia (USP) staff worked with advisory panels to develop standardized pictograms for pharmaceutical labeling. Twenty-nine USP pictograms were published in 1989. By 1998, there were 89 USP pictograms published, a number of which show the same instructions for different dosage forms (Dowse & Ehlers, 1998). See Figure 2 for USP pictogram examples. Pictograms are not meant to stand alone. Without explanation, they can easily be misinterpreted by patients (Hanson & Hartzema, 1995; Knapp, Raynor, Jebar, & Price, 2005). As such, they should always be accompanied by verbal or written instructions (Dowse & Ehlers, 2003). To this point, a study by Sojourner and Wogalter (1998) found that, of all participants (n = 216), those who were randomized to receive a drug information sheet that incorporated pictograms that were fully redundant of the included text had better recall of the information as compared to those who received text alone, pictures alone, or text with only some redundant pictures ($p < 0.05$).

Figure 2 - United States Pharmacopeia Pictogram Examples



Several studies have examined the utility of adding pictograms to written medication information for patients. Working with an impoverished population in South Africa with low levels of formal education (i.e., ≤ 10 years), Dowse and Ehlers (2005) assessed the effects of adding locally developed pictograms (Dowse & Ehlers, 2001) to text-only medication labels. The researchers found that, on average, patients given the medication labels that incorporated pictograms (n = 46) better understood the label's instructions (95.2% vs. 69.5%, $p < 0.01$) and were more adherent to the prescribed antibiotic regimen (89.6% vs. 71.5%, $p < 0.01$), as compared to those who received text-only labels (n = 41). Similarly, Ngoh and Shepherd (1997) found that dispensing a locally developed pictogram-based visual aid to illiterate female adults (n = 52) in West Africa significantly increased comprehension ($p < 0.05$) and adherence ($p < 0.05$) to the prescribed antibiotic regimen, as compared to those who did not receive the pictogram-based visual aid (n = 26). Mansoor and Dowse (2003) assessed the effect of incorporating pictograms onto the

medication label and patient information leaflet (PIL) for nystatin suspension among 60 low-literate participants with low formal education (i.e., ≤ 7 years) and for whom English was their second language. As compared to text-only information, the addition of pictograms was shown to improve comprehension of more complex information. Further, 93.3% of participants in the pictogram group (n = 30) achieved 100% understanding of the label incorporating pictograms. This was achieved by only 40% of the non-pictogram group (n = 30, p = 0.001). Participants also expressed an overall preference for the materials that incorporated pictograms (Mansoor & Dowse, 2003). Other studies have also noted that patients prefer and are more likely to read drug information that incorporates illustrations (Advani et al., 2013; Aker et al., 2013; Katz, Kripalani, & Weiss, 2006; Moll, 1986; Thompson et al., 2010). Bernardini, Ambrogi, Perioli, Tiralti, and Fardella (2000) surveyed 1,008 patients in pharmacies in Europe about the use of pictograms in medication package leaflets. Seventy-four percent of those surveyed found the incorporation of pictograms useful.

As compared to those receiving usual care, caregivers who received pictogram-based medication instruction sheets had increased adherence and knowledge and made fewer dosing errors when administering liquid medication to children (Yin et al., 2008). Kripalani et al. (2007) developed illustrated medication schedule cards, the use of which helped the majority of patients (94%, n = 173) remember important medication information, such as the name, purpose, and time of administration of the medication. The researchers also found that patients "with inadequate or marginal literacy skills, less than high school education, or cognitive impairment were most likely to refer to the card on a regular basis initially and at 3 months ($p < 0.05$)" (Kripalani et al., 2007). In a quasi-experimental crossover group study involving nine pharmacies, Hanson (1995) found that the use of pictogram-based medication labels led to significantly better understanding of the instructions therein by all participants ($p = 0.011$) as well as participants with low literacy ($p = 0.026$), as compared to traditional medication labels. D. G. Morrow, Hier, Menard, and Leirer (1998) found that, when a 12-hour timeline illustration was incorporated into otherwise text-only instructions, patients more quickly and more accurately answered questions dealing with the

dosing and timing of medication administration. However, in a previous study, D. G. Morrow, Leirer, and Andrassy (1996) found that text-only instructions resulted in the most accurate recall of medication schedules by participants, followed by a 24-hour timeline illustration.

Although there are not many, some studies have failed to return positive results in terms of the utility of incorporating illustrations into written health information for patients. Hämeen-Anttila, Kemppainen, Enlund, Bush Patricia, and Marja (2004) found that incorporating USP pictograms did not increase 5th and 7th graders' understanding of an "easy-to-read" medication leaflet, as compared to the same leaflet without illustrations. However, the rate of comprehension was high in the text-only group (97%), leaving little room for improvement in the pictogram + text group (95%). Looking at participants' (n = 130) interpretation of pharmacy auxiliary warning and information labels, Hwang, Tram, and Knarr (2005) found that the addition of illustrations improved performance in 5–7% of subjects, but actually worsened performance in 7–9% of subjects, as compared to text-only labels. Morrell, Park, and Poon (1990) found that, although incorporating illustrations with text on medication labels enhanced younger adults' memory, doing so appeared to impede older adults' memory of the prescription information. When it comes to health information that could be considered sexual in nature, specifically breast self-examinations, Labranche, Helweg-Larsen, Byrd, and Choquette (1997) found that incorporating illustrations can make some participants feel uncomfortable and less competent in terms of performing the procedure. Findings from these studies indicate that illustrations must be developed and tested diligently to ensure that they are indeed useful to patients.

A recent study by Aker et al. (2013) compared three CMI formats for three medications. These included an existing CMI format ("current format"), a format similar to one of the four proposed FDA prototypes ("proposed format") and a completely new format that incorporated pictures ("picture format"). Participants (n = 105) correctly answered more questions with the proposed format (70%–95%) and the picture format (83%–92%) as compared to the current format (53%–74%). They examined patients' preferences for formatting, motivation to read, and ability to

navigate the presented information. It took participants roughly twice as long on average to locate information in the current format as compared to the other two formats. Overall, participants preferred the picture format, indicating that the simple illustrations assisted them in finding important information and that they would be more motivated to read it (> 75%), as compared to the other formats (14%–62%) (Aker et al., 2013). In a similar study, Whatley, Mamdani, and Upshur (2002) randomized 196 elderly Canadians with osteoarthritis to receive for a hypothetical medication either a standard text-only PIL, a PIL with additional percentages and illustrative icons, or a PIL with additional graphs. The textual content of the three PIL formats was the same. Results showed that participants who received the standard text-only PIL were less likely to consider taking the hypothetical medication, as compared to those who received the other two formats ($p < 0.001$) (Whatley et al., 2002).

In summary, incorporating meaningful illustrations into written health- and medication-related information has been shown to benefit patients in many ways. Patients prefer and are more likely to read information that includes relevant illustrations. Incorporation of illustrations can increase recall and comprehension of textual information. In some cases, adding illustrations to written information has even been shown to increase performance and adherence to certain health activities, including medication adherence. Similarly, the use of video to convey health- and medication-related information offers several benefits related to meeting the health literacy needs of patients.

The Use of Video in Healthcare

The use of videos in the education of patients in healthcare is appealing for many reasons. Using videos in place of healthcare providers offers a less resource intensive means of delivering standardized information to patients. This frees healthcare providers to perform other necessary, more involved tasks. Once developed, a video delivers consistent education, thereby removing inconsistencies that often occur across educators. Individuals with low health literacy have been shown to be receptive to video education, which can be tailored to meet their health literacy needs (Tuong et al., 2014). The percent of online adults (i.e., adults who use the Internet) who

watch or download videos has increased greatly over the past several years, with 78% of online adults doing so today. Further, half of all online adults say they watch educational videos online (Purcell, 2013). For these reasons, videos offer unique utility in educating patients, and their use has been studied in a variety of healthcare settings.

Studies have assessed the utility of videos for patients following hospital discharge or a medical procedure. Albert, Buchsbaum, and Li (2007) assessed the use of video education on healthcare utilization, symptoms, and self-care behaviors among patients being discharged following hospital admittance for heart failure. Compared to those who received usual care alone (n = 53), patients who also received video education (n = 59) had a number of improved outcomes at 3 months, including better self-care ($p < 0.01$), greater reduction in heart failure signs and symptoms ($p < 0.04$), and decreased need for extra diuretic dosing ($p < 0.02$) (Albert et al., 2007). In a similar study, Heikel M. Mahler, Kulik, and Tarazi (1999) assessed patients' adherence to a prescribed diet and exercise regimen after coronary bypass graft surgery. Compared to those who received standard care, patients who also viewed an educational video on the topic reported higher self efficay and adherence to the regimen after one month (Heikel M. Mahler et al., 1999).

The use of video to educate and inform patients prior to a medical procedure has also been studied. Prior to ambulatory surgery, Done and Lee (1998) randomized 127 patients to either usual care alone or usual care plus a video meant to convey preanesthetic information. The video group had significantly better recall of information, as compared to the usual care group. In another study, Bytzer and Lindeberg (2007) randomized patients to either see a video on the colonoscopy procedure and cleansing (n = 72) or to usual care with no video (n = 90) before undergoing a colonoscopy. In this study however, there were no significant differences between the two groups in terms of situational anxiety, rating of pain, or tolerability of the procedure. Evaluating the use of video in preparing patients for a coronary artery bypass graft (CABG), Heikel M. Mahler and Kulik (1998) found that, as compared to those who received only usual care (n = 67), patients who viewed any of the three videos developed for the study (n = 190) "felt

significantly better prepared for the recovery period, reported higher self-efficacy for using the incentive spirometer and for speeding their recovery, performed more repetitions with their incentive spirometer… had shorter intensive care unit stays, and were released from the hospital more quickly" ($p < 0.05$, p. 39).

In the outpatient setting, educational videos have been shown to increase the understanding of disease as well as performance of self-care and preventive health behaviors. In a pilot study by Sobel et al. (2009), the viewing of a video that was developed based on health literacy "best practices," resulted in significant improvement of subjects' ($n = 130$) understanding of asthma and the importance of self-care ($p < 0.05$). Working with participants newly diagnosed with type 2 diabetes, Dyson, Beatty, and Matthews (2010) found that participants who were randomized to a video-based lifestyle education program ($n = 21$) had significant increases in knowledge at 6 months ($p < 0.0001$) as compared to those who received usual care ($n = 21$). In a sample of 328 women aged 60 and older, Wood, Duffy, Morris, and Carnes (2002) found that those randomized to receive age- and race-sensitive video-based breast health kits ($n = 206$) had greater increases in knowledge about breast cancer risk and screening ($p < 0.001$) as well as greater improvements in self exam proficiency ($p < 0.001$) as compared to those randomized to receive educational pamphlets ($n = 122$), after adjustments for age, education, and cognitive ability. To evaluate the effectiveness of an educational video at increasing knowledge and preventive health behaviors related to osteoporosis, Kulp, Rane, and Bachmann (2004) randomly assigned 195 women between 35 and 80 years of age without diagnosis of osteoporosis to either view the video before their routine gynecological office visit ($n = 98$) or to the office visit alone ($n = 97$). Participants who viewed the video performed significantly better (92% vs. 80%, $p < 0.001$) on an osteoporosis assessment questionnaire directly following the office visit. Results from a 3-month followup questionnaire indicated that "significantly more women in the intervention group started taking calcium supplements (26.5% vs. 4.9%; $P < 0.001$), started taking vitamin D supplements (20.6% vs 6.6%; $p = 0.02$), started a program of weight-bearing exercise (13.3% vs. 1.7%; $p = 0.03$), and started hormone therapy (8% vs. 1%; $p = 0.04$)" (Kulp et al., 2004, p. 116). Armstrong, Idriss, and

Kim (2011) performed a randomized controlled trial comparing the effectiveness of an online educational video and an educational pamphlet in terms of improving participant comprehension and adherence to sunscreen use as well as satisfaction with the two interventions. As compared to those who recevied the pamphlet (n = 47), participants in the video group (n = 47) had significantly greater improvement in knowledge scores ($p = 0.003$), reported greater sunscreen adherence at 12-weeks ($p < 0.001$), rated the intervention as more useful and appealing ($p < 0.001$), and referred to the video more often ($p = 0.018$). Leiner, Handal, and Williams (2004) compared patient recall of information from a vaccine information sheet produced by Centers for Disease Control (n = 96) versus an animated cartoon video covering the same information (n = 96). Results showed that recall was much better in patients who watched the video. Twenty-nine (30.2%) of the participants in the video group responded to all questions correctly, while none of the participants in the information sheet group did so (Leiner et al., 2004).

The use of videos has been shown to have an impact on risky sex-related behaviors. More specifically, video interventions have been shown to increase knowledge, adherence, and the likelihood of reporting for follow up in patients with sexually transmitted diseases (STDs). Solomon and Dejong (1988) found that, compared to usual care (n = 446), patients who also viewed a “soap opera” style educational video (n = 456) had a greater increase in knowledge ($p < 0.0001$) and were more likely to report for follow up ($p < 0.0003$). After performing a meta-analysis, Healton and Messeri (1993) found that, although there was no effect on treatment compliance, educational videos did increase patients’ knowledge and attitudes about STDs and condom use more so than programmed learning guides, didactic sessions, and usual care. Brock and Smith (2007) performed a quasi-experimental study, comparing pre- and post-intervention measures related to HIV. Results showed a significant increase in HIV disease and medication knowledge in the short term as well as a significant increase in self-reported adherence 4–6 weeks after watching a 17-minute video delivered on a personal digital assistant. In a study involving 54 participants with crack cocaine use and HIV with suboptimal medication adherence, 6 sessions of video information plus debriefing (n = 28, baseline adherence: 56.4% ± 28.5%) was

shown to be as effective as 6 sessions of motivational interviewing (MI) plus feedback and skills building (n = 26, baseline adherence: 60.2% ± 26.7%) in terms of increasing adherence at 3 months (87% ± 25.3%, n = 23; 93.3% ± 10%, n = 19, respectively; p = 0.28) and 6 months (86% ± 29.1%, n = 23; 93.9% ±13.7%, n = 19, respectively; p = 0.28) (Ingersoll et al., 2011). A study by Maneesriwongul, Prajanket, and Saengcharnchai (2012) found similar results: participants with HIV/AIDS who were randomly assigned to an educational video (n = 30) or MI (n = 30) had greater improvements post-intervention in disease knowledge ($p < 0.001$), health beliefs ($p < 0.001$), and medication adherence ($p < 0.001$) as compared to those who received usual care (n = 30). There were no significant differences in these measures between the MI and video groups. Zimmers, Privette, Lowe, and Chappa (1999) found that women randomized to view an educational video on female condom use (n = 50) were significantly more likely to use the product as compared to women who received the same information minus the video (n = 50, $p < 0.05$).

Although statistically significant improvements were not seen in all of the studies on the subject, patient education via video has also shown promise when it comes to recall, comprehension, and adherence related to medications. In a study involving 412 seniors, Alemagno, Niles, and Treiber (2004) delivered to participants interactive educational videos via a laptop computer on the use and misuse of medications. Almost all participants reported this to be an easy (96%) and useful (89%) intervention. Further, 63% of respondents stated that they learned something new from the videos (Alemagno et al., 2004). In a study by Muir et al. (2012) looking at the utility of an educational video at improving glaucoma medication adherence, subgroup analysis of patients with inadequate health literacy showed that, after 6 months, those in the video education group (n = 13) had 41 fewer days without medication as compared to those in the control group (n = 13). However, this difference was not significant ($p = 0.17$). In another study, Powell and Edgren (1995) mailed an educational video to study group subjects (n = 1993) pertaining to a prescription medication they were currently taking. Although 88% of those who received a video said it was somewhat or very useful, there was no significant improvement in medication adherence. As part of a larger trial comparing four different nicotine replacement therapies (NRTs), May et al. (2003)

used 8-minute videos to educate participants on the smoking cessation products. After 1 week of NRT use, participants (n = 411) were asked to rate the video pertaining to the particular NRT they were using in terms of how accurately the product was portrayed. The great majority (89%–100%) responded positively, indicating that brief videos are an effective way of conveying information about NRTs to smokers (May et al., 2003).

In summary, low health literacy is prevalent and associated with negative health-related outcomes, ranging from medication non-adherence to increased mortality. Aside from educating the general population, one way to address this issue is to ensure that health-related materials are written and formatted in such a way that they are both comprehensible and memorable to patients and consumers. The addition of well-designed, explanatory illustrations to written information and the presentation of information in a video format have been shown to be beneficial in these respects. One area in particular that needs to be addressed in this way is PMI, which is currently not meeting the needs of patients. The FDA has called for pilot studies investigating potential improvements of PMI formatting and distribution strategies. This study seeks to address this call.

Methods Overview

This chapter describes in detail the methods of PMI format development, participant recruitment, and the procedures for data collection and analysis. As an overview, the three PMI formats, FDA-Like, Picture Enhanced, and Video, were first developed. Participants were then recruited from Amazon Mechanical Turk (mTurk), a crowdsourcing Internet marketplace (Amazon.com, 2014). Potential participants were screened, and those meeting inclusion criteria were randomized to one of three PMI formats. Participants then responded to a Qualtrics survey measuring their recall of information covered in the PMI. Subsequently, participants were shown all three PMI formats and responded to survey items measuring their preferences for the formats. Participants who completed the entire survey were paid $3.00 for their time. A mixed methods approach was used to analyze the data collected, employing both qualitative and quantitative analyses.

Pre-Study Survey

For this project, a pre-study survey (Appendix D) was built in Qualtrics and deployed on mTurk to test procedures and determine the level of health literacy of mTurk workers. The survey included the METER, the NVS, and demographic items. Catch or screening questions (i.e., “What is 2 + 2?” and “Who is the current President of the United States) were also included to ensure that participants were responding meaningfully, as opposed to quickly clicking through to get paid. Inclusion of screening questions is recommended in the literature that has studied mTurk for use in survey-based research (Downs, Holbrook, Sheng, & Cranor, 2010; Mason & Suri, 2012; Paolacci, Chandler, & Ipeirotis, 2010). In order to qualify to participate in the pre-study survey, mTurk workers had to 1) be currently located in the US, 2) be ≥ 19 years of age, 3) speak English as their first language, and 4) have never received professional training or education in order to become a healthcare professional, such as a doctor or physician, physician's assistant, podiatrist, dentist, veterinarian, nurse, nurse practitioner, nurse midwife, or pharmacist. Five hundred participants successfully completed the survey with an average completion time of eleven minutes, seven seconds. Participants were paid $1.00 for their time, giving an average hourly

earnings of $5.40. Total time for all 500 participants to complete the survey was less than 2 hours.

Pre-study survey results suggest that the majority of mTurk workers have functional or adequate health literacy. Specifically, METER results showed that 14/500 participants had low health literacy, 43/500 had marginal health literacy, and 443/500 had functional health literacy. According to the NVS, 6/500 participants had high likelihood (i.e., > 50%) of limited health literacy, 24/500 had the possibility of limited health literacy, and 470/500 had adequate health literacy. The average age of participants was 32.9 and ranged from 19–69. The majority were white (n = 405), male (n = 288), non-Hispanic/Latino (n = 471), and had a bachelor's degree (n = 208). Yearly household income ranged from less than $10,000 (n = 42) to $150,000 or more (n = 14), with the majority falling between $20,000–$59,000 (n = 268). Findings from the pre-study survey informed the dissertation project, as described below.

Survey Development

The aim of the survey (Appendix E), which was built in Qualtrics, was two-fold. The first aim was to determine if participants' recall of information covered in the PMI differed based on the PMI format that they were presented. The second aim was to explore participants' preferences for the three PMI formats. Given this, there were two major sections of the survey after the pre-screening items, one for each aim.

Pre-Screening

Participants were recruited from Amazon Mechanical Turk, a crowdsourcing Internet marketplace (Amazon.com, 2014). mTurk was originally designed to allow individuals and businesses to recruit humans to perform tasks that current computers cannot. Examples of these tasks include data entry and de-duplication, categorization of products, and classification of images. Requestors (i.e., those looking to recruit individuals to complete a task) post tasks, referred to as Human Intelligence Tasks (HITs), to mTurk. Requestors can set mTurk worker requirements (e.g., located in the US) as well as the number of workers needed to complete a HIT. Potential workers can be anyone 18 years of age or older who has set up an mTurk worker account

(Amazon.com, 2014). Qualifying mTurk workers may select and complete a HIT for monetary compensation that is predetermined by the requestor. A study analyzing payments as hourly wages suggests that, in general, the lowest amount of money mTurk workers were willing to complete a task for (i.e., their reservation wage) was $1.38/hour (Mason & Suri, 2012). Ipeirotis (2010) estimated the effective, or average, hourly wage for HITs to be $4.80. When setting up a HIT, Amazon recommends an hourly wage of $6.00 (Amazon.com, 2014).

Recently, mTurk has been used to recruit participants for primarily survey-based research projects (Berinsky, Huber, & Lenz, 2012; Buhrmester, Kwang, & Gosling, 2011; Downs et al., 2010; Mason & Suri, 2012; Paolacci et al., 2010). Studies examining the reliability of data collected from participants via mTurk have found them to be as reliable as, and in some cases more reliable than, traditional survey data collection methods (Buhrmester et al., 2011; Mason & Suri, 2012; Paolacci et al., 2010). Further, US mTurk workers have been shown to be more demographically representative of the general US adult population than most convenience samples (Berinsky et al., 2012; Buhrmester et al., 2011). As for health-related studies, Schleider and Weisz (2015) reported similar findings when using mTurk to study family processes and youth mental health with assessments of participants in three consecutive months. Overall, mTurk is a relatively quick, reliable, and inexpensive alternative to many other recruiting methods (Berinsky et al., 2012; Buhrmester et al., 2011; Mason & Suri, 2012; Paolacci et al., 2010).

For this project, the target recruitment goal was 600 participants, 200 for each of the three PMI formats. The number of participants was decided upon based on the amount of funds available to pay participants for their time. When setting up the HIT within mTurk, requirements were set to ensure potential participants met inclusion criteria. Specifically, participants must 1) have been located in the US at the time of taking the survey and 2) not have taken the pre-study survey. Location was determined by mTurk via workers' IP addresses. The list of mTurk worker IDs who completed the pre-study survey was used to exclude these individuals from participating in the project. Additionally, participants had to 1) be ≥ 19 years of age, 2) speak English as their first

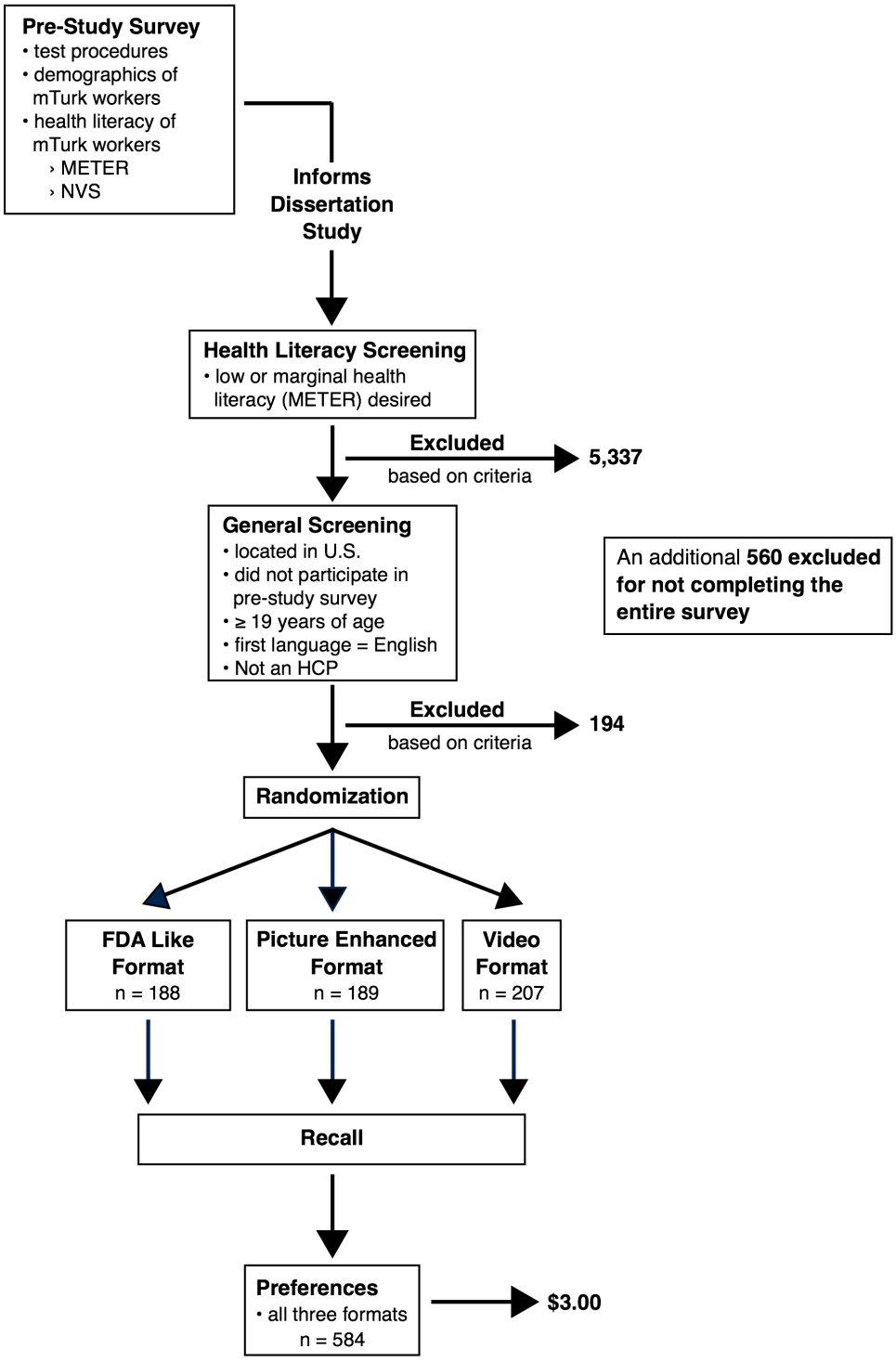
language, 3) not have any severe hearing disabilities, 4) have the ability to hear sound from their computer, and 5) have never received professional training or education in order to become a healthcare professional, such as a doctor or physician, physician's assistant, podiatrist, dentist, veterinarian, nurse, nurse practitioner, nurse midwife, or pharmacist. These were the initial screening items of the survey, and potential participants who indicated that they did not meet these requirements were not allowed to continue and did not receive any monetary compensation.

Potential participants also had to have either low or marginal health literacy, as determined by METER scores of ≤ 20 or 21–34, respectively. The METER was shown to be highly correlated with the REALM ($r = 0.74$) and has been validated as a reliable self-administered tool for measuring health literacy (Powers, Trinh, & Bosworth, 2010; Rawson et al., 2010). Originally, participants completed the METER as part of the pre-screening portion of the survey after viewing the information letter, agreeing to the terms therein, and completing the pre-screening items described above. Those that scored ≥ 35 (i.e., have functional health literacy) were excluded from completing the rest of the survey and were awarded $0.10 for their time. Those participants who met all inclusion criteria and completed the entire survey received the $0.10 plus a bonus payment of $2.90, a total of $3.00.

However, with this original setup, the survey sorted and displayed in mTurk as only paying participants $0.10, when in actuality those participants who completed the entire survey received $3.00. This presumably led to slow recruitment. Given this issue, the order of the screening items and payment were altered as follows. Participants who were screened and did not meet the inclusion criterion of having low or marginal health literacy according to the METER were no longer paid $0.10. Only participants who met all inclusion criteria and completed the entire survey were paid, and they were paid $3.00. This allowed the survey to be posted and sorted in mTurk as paying participants $3.00 as opposed to $0.10. Since participants who did not meet the inclusion criteria relating to health literacy were no longer paid $0.10, the METER was moved up

in the survey flow to be the first item after the information letter. This minimized time taken from those participants who did not qualify to take the entire survey. Figure 3 reflects this change in participant screening and payment.

Figure 3 - Project Procedures



Development of PMI Formats

FDA-Like PMI Format

FDA's Prototype 1 for the fictitious medication Rheutopia (Appendix B) was used as a template to develop the FDA-Like PMI for Ellistrum (Appendix A), another fictitious medication. This FDA-Like format served as the control to which the other two PMI formats, Picture-Enhanced and Video, were compared. In place of simply having the drug name at the top, a statement was added to the top of the FDA-Like format (i.e., "This information will help you take Ellistrum safely and effectively") in order to make the purpose of the material completely evident. This addition was made based on recommendations in plain language and patient education materials guidelines (Doak, Doak, & Root, 1996; R. Rudd, 2012; Shoemaker et al., 2013) and was included in all three formats. The FDA's Prototype 1 was not used because Rheutopia is an injectable drug. Ellistrum is an oral medication, a much more commonly encountered dosage form. A fictitious medication was used to ensure that participants had no prior knowledge of the medication covered by the PMI.

As can be seen in Appendices C and D, the FDA-Like PMI for Ellistrum is very similar to the FDA's Prototype 1 for Rheutopia. They have the same nine major headings in the same order with the same number of bullet-points under each. The word count for the Rheutopia PMI is 358, whereas the word count for the Ellistrum PMI is 313. For the Rheutopia PMI, the Flesch-Kincaid Grade Level and the Flesch Reading Ease scores were 4.6 and 75.2, respectively, as determined by Microsoft Word for Mac 2011 (Microsoft Corporation, Redmond, WA). The Flesch-Kincaid Grade Level and the Flesch Reading Ease score for Ellistrum were 5.7 and 66.7, respectively, as determined by Miscrosoft Word for Mac. According to their Flesch-Kincaid Grade Level scores, both formats are below the recommended 6^{th}–8^{th} grade reading level for consumer medication information (FDA, 2006). Scoring the PMI formats via the SMOG by hand returned an 8^{th} grade and 9^{th} grade reading level for the Rheutopia and Ellistrum PMI, respectively. These higher grade reading levels are, in part, due to the drugs' names. When the two drugs' names and active ingredients are excluded from the scoring, the SMOG returns a 7^{th} and 8^{th} grade reading level for

Rheutopia and Ellistrum, respectively. The Ellistrum FDA-Like format received scores of 72.7% and 60% for understandability and actionability, respectively, on the AHRQ's Patient Education Materials Assessment Tool (PEMAT). Higher scores on the understandability portion of the PEMAT indicate that "consumers of diverse backgrounds and varying levels of health literacy can process and explain key messages," and higher scores on the actionability portion indicate that "consumers of diverse backgrounds and varying levels of health literacy can identify what they can do based on the information presented" (Shoemaker et al., 2013). Aside from one oversight, discussed below, the Picture-Enhanced and Video PMI formats contain the exact same information, in the same order, as the FDA-Like format.

Picture-Enhanced PMI Format

The Picture-Enhanced format (Appendix C) is a thirteen-slide Apple Keynote (Apple, Cupertino, CA) presentation that was converted into a thirteen page PDF. It was developed using basic graphic design principles (CDC, 2010, 2014; Control & Prevention, 2009; FDA, 2006; Osborne, 2013; Shoemaker et al., 2013; R. Williams, 2014). Keynote was used for layout design. Headings with more than six bullet points (i.e., "Ask your doctor before use if you have…" and "Stop use and call your doctor right away…") were split into multiple slides. Dividing long lists into shorter more manageable lists is referred to as chunking and is recommended in plain language guides (Shoemaker et al., 2013). Although there are only four bullet points, the directions were also split across two slides in order to accommodate the icons developed for this section.

Overall, fifteen icons were developed for the Picture-Enhanced format. Eight of the icons correspond with the nine major headings, with the same icon being used for both active and inactive ingredients. There are four directions icons and there is one icon for the title page. The icons were developed using iDraw (Indeeo, Inc.) for Mac, with input and guidance from dissertation committee members.

Two fonts were used throughout the Picture-Enhanced format. Lucida Bright, a serif font, was used for the headings, and Helvetica, a sans serif font, was used for the body and bullet points.

Bold and italics were used to draw attention to important words that, in most cases, capture the essence of the message being conveyed. The title font size was set at 110, and the body 65. These font sizes were chosen based on the readability of the content on a mobile device, specifically an iPhone 5s. Although study participants will not be viewing the content on a mobile device, the format was designed to be easily readable on both small and large screens. The Picture-Enhanced format received PEMAT scores of 93.3% and 80% for understandability and actionability, respectively.

Video PMI Format

The Video PMI format for Ellistrum was derived from the Picture-Enhanced format, thereby making the two formats as similar as possible. First, transitions were added in Keynote between slides and from bullet point to bullet point of the Picture-Enhanced format. Video of the slideshow was then recorded, also using Keynote. The video was exported to a QuickTime (Apple, Cupertino, CA) video file, which was then imported into iMovie (Apple, Cupertino, CA). A male voiceover was recorded to a QuickTime audio file using a Blue Yeti microphone (Blue Microphones, West Village, CA) and subsequently imported into iMovie. To ensure consistency across formats, the voiceover is a verbal reading of the PMI content. iMovie was used to edit together the Keynote video and voiceover audio. This style of video is often referred to as a "voice over PowerPoint" video. The Video PMI format is three minutes and nineteen seconds long. It can be viewed at https://youtu.be/RZ2sq6H-UeM. The Video format received PEMAT scores of 91.6% and 100% for understandability and actionability, respectively.

Survey Procedures

After meeting inclusion criteria, participants were randomized to one of the three PMI formats: FDA-Like, Picture-Enhanced, or Video. Qualtrics' "Randomizer" Survey Flow feature was used to automatically randomize participants. After the survey had been posted to mTurk for ten days, it was noticed that participants who were randomized to the FDA-Like PMI format were not completing the survey. This realization occurred when the HIT was being altered to display in mTurk as paying participants $3.00 as opposed to $0.10. Upon investigation, it was determined that an HTML coding error within the Qualtrics survey was preventing the FDA-Like PMI format

from displaying. This issue was resolved and, in an attempt to have a similar number of participants randomized to each of the three formats, randomization from that point forward was performed on a 7:1:1 ratio for the FDA-Like, Picture-Enhanced, and Video PMI formats, respectively. All formats and survey items were presented in Qualtrics.

Once randomized, participants were instructed to view the PMI as though they 1) were recently prescribed Ellistrum and 2) had just received the PMI electronically (i.e., on their computer) from their pharmacy. They were then given as much time as was needed to view the PMI. Since a major focus was on participants' recall of information, the PMI was no longer displayed once the participants indicated they were done viewing it by clicking the next (">>") button. The subsequent twelve survey items measured participants' recall of information covered in the PMI (i.e., Specific Aim 1). The twelve items included fill-in-the-blank, multiple-choice, and true/false style questions. These question types have been recommended (FDA, 2006) and utilized in previous recall and comprehension studies (FDA, 2006; Jansen et al., 2008; Michael S Wolf et al., 2014; Woloshin & Schwartz, 2011). Further, the twelve survey items, which were the same across all three PMI formats, were pilot tested by five staff members of the school of pharmacy and an undergraduate student for clarity and face validity.

Several steps were required before participants' responses to the recall survey items could be scored. Due to an oversight, the directions for the dosing regimen differed between the FDA-Like format and the other two PMI formats. The FDA-Like format stated "Take two capsules by mouth two times a day, 12–hours apart." The other two formats stated "Take two capsules by mouth three times a day, 8–hours apart." Because of this difference, the three survey items pertaining to this content were not included when scoring participants' responses. This resulted in inclusion of nine recall items worth a maximum of ten points. One point was assigned for a correct response to eight of the survey items. The ninth survey item (i.e., "If you started having chest pain while taking Ellistrum, what should you do?") was worth a maximum of two points because a complete

answer required two pieces of information (i.e., 1. Stop taking the medication and 2. Call your doctor).

A plugin called Fuzzy Lookup (Microsoft, Redmond, WA) for Microsoft Excel (Microsoft, Redmond, WA) was used to address misspellings in participant responses to two fill-in-the blank items, “What is the name of the medication?” and “What is the active ingredient in the medication?” The Fuzzy Lookup plugin checks the content of cells from one table (e.g., participants’ responses) against a reference table (e.g., correct spelling) and returns a Jaccard similarity score for the compared content. A higher similarity score indicates a closer match. A similarity score of one indicates an exact match between tokens (i.e., a correct spelling), and a similarity score of zero indicates that the two tokens compared are not similar enough to be considered a match. A similarity score between 0–1 indicates that the tokens compared are considered a match, but not an exact match (Arasu et al., 2011). The default settings were used when running the plugin. Results were visually inspected to ensure face validity for those misspellings that were assigned a similarity score and therefore counted as correct. All participant responses that were assigned a similarity score of zero (i.e., incorrect) were reanalyzed by hand by two coders.

The second section of the survey addressed Specific Aim 2 of the project. After completing the first section, participants were shown all three PMI formats. They were informed that they had seen one of the three formats previously and that all three formats contained the same information. Participants were then asked to select which format(s) they would like to receive from their pharmacy via computer. Participants were able to select one, two, or all three PMI formats as well as “no preference.” Next, each of the three PMI formats was displayed individually in a random order to each participant. Participants were asked to “describe what you like…” and “describe what you do not like…” about the displayed format. A similar approach has been used in previous preference studies (Aker et al., 2013).

The survey also included demographic and catch items. The demographic items, which included age, gender, race, ethnicity, level of education, and household income, as well as the two catch items (i.e., "What is 2 + 2?" and "Who is the current President of the United States?") were the same as those used in the pre-study survey. As mentioned previously, participants who successfully completed the entire survey were compensated $3.00 for their time. Table 5 below summarizes all of the aforementioned measures and items used.

Table 5 - List of Variables Included in the Study

Variable	Meaning	Data Source	Operationalization
Health literacy (Inclusion criteria)	Capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions	Medical Recognition Test (METER), Questionnaire Q1.1 (1 item)	• ≤ 20: low health literacy • 21–34: marginal health literacy • ≥ 35: functional health literacy (excluded)
Recall (Dependent variable)	Participants' ability to recall PMI content	Questionnaire Q7.2, 7.3, 7.6–7.15 (12 items)	• 8 items were scored as correct (1) or incorrect (0) • 1 items was scored as correct (2), partially correct (1), or incorrect (0) • Scale is a sum of 9 items • 3 items were dropped due to a discrepancy between PMI formats
Preference (Dependent variable)	Participants' preferences for the 3 PMI formats	Questionnaire Q12.1 (1 item)	• Participants could indicate preference for 1, 2, or all 3 PMI formats or no preference
Qualitative Feedback (Dependent variable)	Participants' likes and dislikes for each of the 3 PMI formats	Questionnaire Q9.3, 9.4, 10.3, 10.4, 11.3, 11.4 (6 items)	• Participants responded to two open-ended questions (i.e., "What do you like…?" and "What do you dislike…?") for each of the 3 PMI formats

Statistical Analysis

Statistical analysis of recall data (i.e., Specific Aim 1) was quantitative in nature. ANOVA was used to determine if there was a statistically significant difference between participants' recall scores across the three PMI formats, and Scheffe post hoc test was used to determine the location of the statistically significant difference detected by ANOVA. ANCOVA was considered in

analysis of these data, but its assumptions were not met. Specifically, age, gender, race, ethnicity, household income, highest educational achievement, and METER scores were all considered as potential covariates. However, there was no correlation between participants' recall scores and their age and METER scores (i.e., the only two potential covariates that are also continuous variables), as determined by Pearson product-moment correlation. See Chapter 4 for more details. Although it was also considered, time spent viewing the PMI to which the participant was randomized could not be treated as a covariate due to it being a function of and collected during the intervention (Laerd Statistics, 2013). Given that ANCOVA requires a continuous covariate that is linearly associated with the dependent variable across all levels of the independent variable in order to be utilized (Laerd Statistics, 2013), ANOVA was used in its stead.

Analysis of preference data (i.e., Specific Aim 2) involved both qualitative and quantitative statistics. Descriptive statistics characterizing participants' PMI format preferences are reported, and a chi-square goodness-of-fit test was used to determine if there was a statistically significant difference in the number of participants who indicated preference for one format type over the others. In addition, the relationship between participants' PMI format preferences and the format to which they were previously randomized is also reported, and chi-square test for independence assessed the association between the PMI format to which participants were randomized and the PMI format(s) they preferred.

As for qualitative analysis of preference data, a realistic thematic analysis of the two fill-in-the-blank survey items (i.e., "Describe what you like…" and "Describe what you do not like...") for each PMI format was performed. The guidelines provided by Braun and Clarke (2006) were adapted and used to this end. First, participant responses were divided into six datasets, one dataset for each PMI format for each of the two survey items. Each dataset was individually imported into ATLAS.ti (Scientific Software Development GmbH, Berlin, Germany), a qualitative data analysis and research software program. Each participant response was treated as a quote from which codes were derived and applied. In order to become familiar with the data, the primary

researcher read over one of the datasets, noting potential codes. Subsequently, the researcher created a code list based on this initial read-through. The researcher then reread over the dataset, applying codes from the code list. Codes were further refined during this process, which was repeated for the remaining five datasets.

To increase the validity of coding, a second researcher coded a random sample of approximately 10% of each dataset. This approach has been recommended in the literature (Mackey & Gass, 2015; Mayring, 2014). The second coder applied codes from the code lists created by the primary researcher. Once completed, the two researchers met to discuss the need for additional codes. The primary researcher then collated codes into themes via an inductive approach. The Coding Analysis Toolkit (Texifter, LLC, Pittsburg, KS) was used to calculate Krippendorf's Alpha in order to determine inter-rater reliability for the portions of the datasets coded by both researchers.

Chapter 4 | Results

Chapter 4 covers the results of this project. This includes the results pertaining to participant screening and recruitment, participant demographics, participants' recall scores, and participants' preferences, likes, and dislikes regarding the three PMI formats. A summary of all results is also included at the end of the chapter. Statistical analysis of quantitative data was performed with SPSS Version 23 (IBM, Armonk, NY). ATLAS.ti was used to analyze qualitative data, and the Coding Analysis Toolkit was used to calculate Krippendorf's Alpha in order to determine inter-rater reliability for the portions of the datasets coded by both researchers. The two research questions and related hypotheses for this project were as follows:

1. How does participant recall of information vary based on the three PMI formats: FDA-Like, Picture-Enhanced, and Video?
    a. There will be no significant difference in participants' recall based on the PMI format they receive.
    b. Alternative Hypothesis: (H_{1A}): There will be a significant difference in participants' recall based on the PMI format they receive.
2. Which of the three formats do participants prefer and why?
    c. Null Hypothesis (H_{0B}): There will be no difference in participants' preferences for the three PMI formats.
    d. Alternative Hypothesis: (H_{1B}): There will be a difference in participants' preferences for the three PMI formats.

Participant Screening and Recruitment

The Qualtrics-built survey was posted to mTurk on July 20th, 2015. Between July 20th and August 3rd, 6,678 unique respondents initiated the survey. Of those, 560 were excluded for not completing the entire survey, 5,337 were excluded for having functional health literacy, defined as a METER score of 35 or greater, and 194 were excluded for not meeting additional inclusion criteria. Three more were excluded for missing a screening/catch question. Ultimately, 584

participants were included in the study and randomized to one of the three PMI formats: FDA-Like (n = 188), Picture-Enhanced (n = 189), and Video (n = 207).

As mentioned previously, an HTML code segment was inadvertently left out upon survey construction, and the FDA-Like format would not load for participants. This was realized on July 30th, at which point 240 participants had been randomized to either the Video (n = 120) or the Picture-Enhanced (n = 120) formats and had completed the survey. Upon this realization, the HIT containing the survey was temporarily removed from mTurk, and the needed HTML code segment was added. When the HIT was reposted to mTurk, the survey was set to randomize seven participants to the FDA-Like format for every one participant randomized to each of the Picture-Enhanced and Video formats. This was done in order to ensure that near equal numbers of participants were randomized to each of the three formats.

Participant Demographics

Of the 584 participants, 354 (60.6%) were male and 230 (39.4%) were female. This is consistent with the gender makeup of the pre-study survey participants, of which 57.6% were male. However, previous studies examining the demographics of mTurk workers found that the majority (i.e., 55–70%) are female (Mason 2012, Paoloacci 2010, Ipeirotis 2010, Berinsky 2012). The general US population is 50.8% female (US Census Bureau, 2014). Table 6 below provides the number of males and females randomized to the three PMI formats. There was a statistically significant difference in the number of females in the FDA-Like group (n = 85) compared to the Video group (n= 69; $p < 0.05$).

Table 6 – Participant Gender

Gender		PMI Format			Total
		FDA-Like	Picture-Enhanced	Video	
Male	Count	103_a	$113_{a, b}$	138_b	354
	% within Gender	29.1%	31.9%	39.0%	100.0%
	% within Format	54.8%	59.8%	66.7%	60.6%
Female	Count	85_a	$76_{a, b}$	69_b	230
	% within Gender	37.0%	33.0%	30.0%	100.0%
	% within Format	45.2%	40.2%	33.3%	39.4%
Total	Count	188	189	207	584
	% within Gender	32.2%	32.4%	35.4%	100.0%
	% within Format	100.0%	100.0%	100.0%	100.0%
Differing subscript letters denote a subset of PMI Format categories whose column proportions differ significantly from each other at the 0.05 level.					

The average age of all participants was 30.8 (SD 9.4). Age ranged from 19–68. This is similar to previous findings regarding mTurk worker age (Mason 2012, Paoloacci 2010, Ipeirotis 2010, Berinsky 2012). As can be seen in Table 7 below, the average age was 32.1 (SD 10.4) in the FDA-Like group, 30.2 (SD 8.8) in the Picture-Enhanced group, and 30.1 (SD 8.9) in the Video group. Age did not differ significantly between groups.

Table 7 - Participant Age

PMI Format	Mean Age	N	Std. Deviation	Minimum Age	Maximum Age
FDA-Like	32.1	188	10.4	19	68
Picture-Enhanced	30.2	189	8.8	19	68
Video	30.1	207	8.9	19	66
Total	30.8	584	9.4	19	68

As for ethnicity, 59 (10.1%) of the 584 participants were Hispanic/Latino. A previous study by Berinsky 2012 found that 6.1 percent of mTurk workers are Hispanic. Approximately 17.4% of the general US population is Hispanic/Latino (US Census Bureau, 2014). As illustrated in Table 8 below, the number of Hispanic/Latino participants differed significantly between the FDA-Like group ($n = 12$) and the Video group ($n = 27$; $p < 0.05$).

Table 8 - Participant Ethnicity

Ethnicity		PMI Format			Total
		FDA-Like	Picture-Enhanced	Video	
Hispanic/Latino	Count	12_a	$20_{a, b}$	27_b	59
	% within Ethnicity	20.3%	33.9%	45.8%	100.0%
	% within Format	6.4%	10.6%	13.0%	10.1%
Not Hispanic or Latino	Count	176_a	$169_{a, b}$	180_b	525
	% within Ethnicity	33.5%	32.2%	34.3%	100.0%
	% within Format	93.6%	89.4%	87.0%	89.9%
Total	Count	188	189	207	584
	% within Ethnicity	32.2%	32.4%	35.4%	100.0%
	% within Format	100.0%	100.0%	100.0%	100.0%
Differing subscript letters denote a subset of PMI Format categories whose column proportions differ significantly from each other at the 0.05 level.					

Looking at race, 8 (1.4%) participants were American Indian or Alaska Native, 58 (9.9%) were Asian, 75 (12.8%) were Black or African American, 2 (0.3%) were Native Hawaiian or Other Pacific Islander, 428 (73.3%) were White, and 13 (2.2%) were multiple races. Although there are slightly more Asians, the race breakdown is very similar to the general US population (US Census Bureau, 2014). Previous studies have also found an over representation of Asians on mTurk as compared to the general US population (Ipeirotis 2010). As can be seen in Table 9 below, the number of Asian and multiracial participants in the FDA-Like group differed significantly from those in the Picture-Enhanced and Video groups ($p < 0.05$). Otherwise, race was similar between the three groups.

Table 9 - Participant Race

Race		PMI Format			Total	US Population
		FDA-Like	Picture-Enhanced	Video		
American Indian or Alaska Native	Count	1_a	4_a	3_a	8	1.2%
	% within Race	12.5%	50.0%	37.5%	100.0%	
	% within Format	0.5%	2.1%	1.4%	1.4%	
Asian	Count	9_a	24_b	25_b	58	5.4%

	% within Race	15.5%	41.4%	43.1%	100.0%	
	% within Format	4.8%	12.7%	12.1%	9.9%	
Black or African American	Count	28_a	22_a	25_a	75	13.2%
	% within Race	37.3%	29.3%	33.3%	100.0%	
	% within Format	14.9%	11.6%	12.1%	12.8%	
Native Hawaiian or Other Pacific Islander	Count	1_a	0_a	1_a	2	0.2%
	% within Race	50.0%	0.0%	50.0%	100.0%	
	% within Format	0.5%	0.0%	0.5%	0.3%	
White	Count	140_a	137_a	151_a	428	77.4%
	% within Race	32.7%	32.0%	35.3%	100.0%	
	% within Format	74.5%	72.5%	72.9%	73.3%	
Multiracial	Count	9_a	2_b	2_b	13	2.5%
	% within Race	69.2%	15.4%	15.4%	100.0%	
	% within Format	4.8%	1.1%	1.0%	2.2%	
Total	Count	188	189	207	584	
	% within Race	32.2%	32.4%	35.4%	100.0%	
	% within Format	100.0%	100.0%	100.0%	100.0%	

Differing subscript letters denote a subset of PMI Format categories whose column proportions differ significantly from each other at the 0.05 level.

In terms of highest level of educational achievement, 574 (98.3%) of the participants had at least a high school diploma or equivalent. Further, 248 (48%) of the participants had at least a bachelor's degree. This is much higher than the educational achievement level of the general US population (US Census Bureau, 2014). Previous studies examining the demographics of mTurk workers also found higher average educational achievement as compared to the general population (Paoloacci 2010, Ipeirotis 2010). As can be seen in Table 10 below, the highest level of educational achievement did not differ significantly between groups.

Table 10 - Participant Educational Achievement

Highest Level of Educational Achievement		PMI Format			Total
		FDA-Like	Picture-Enhanced	Video	
No schooling completed	Count	0	0	1	1
	% within Highest Education	0.0%	0.0%	100.0%	100.0%
	% within Format	0.0%	0.0%	0.5%	0.2%
9th, 10th or 11th grade	Count	0	1	1	2
	% within Highest Education	0.0%	50.0%	50.0%	100.0%
	% within Format	0.0%	0.5%	0.5%	0.3%
12th grade, no diploma	Count	0	3	4	7
	% within Highest Education	0.0%	42.9%	57.1%	100.0%
	% within Format	0.0%	1.6%	1.9%	1.2%
High school graduate - high school diploma or the equivalent (for example: GED)	Count	28	25	27	80
	% within Highest Education	35.0%	31.3%	33.8%	100.0%
	% within Format	14.9%	13.2%	13.0%	13.7%
Some college credit, but less than 1 year	Count	32	20	25	77
	% within Highest Education	41.6%	26.0%	32.5%	100.0%
	% within Format	17.0%	10.6%	12.1%	13.2%
1 or more years of college, no degree	Count	29	33	41	103
	% within Highest Education	28.2%	32.0%	39.8%	100.0%
	% within Format	15.4%	17.5%	19.8%	17.6%
Associate degree (for example: AA, AS)	Count	21	23	22	66
	% within Highest Education	31.8%	34.8%	33.3%	100.0%
	% within Format	11.2%	12.2%	10.6%	11.3%
Bachelor's degree (for example: BA, AB, BS)	Count	64	6	71	200
	% within Highest Education	32.0%	32.5%	35.5%	100.0%

	% within Format	34.0%	34.4%	34.3%	34.2%
Master's degree (for example: MA, MS, MEng, MEd, MSW, MBA)	Count	13	13	13	39
	% within Highest Education	33.3%	33.3%	33.3%	100.0%
	% within Format	6.9%	6.9%	6.3%	6.7%
Professional degree (for example: LLB, JD, DSW, ThD)	Count	0	1	0	1
	% within Highest Education	0.0%	100.0%	0.0%	100.0%
	% within Format	0.0%	0.5%	0.0%	0.2%
Doctorate degree (for example: PhD, EdD)	Count	1	5	2	8
	% within Highest Education	12.5%	62.5%	25.0%	100.0%
	% within Format	0.5%	2.6%	1.0%	1.4%
Total	Count	188	189	207	584
	% within Highest Education	32.2%	32.4%	35.4%	100.0%
	% within Format	100.0%	100.0%	100.0%	100.0%

Looking at household income, the mean and median household income bracket for all participants was $40,000–$49,999. This is lower than the median household income of the general US population ($53,046) (US Census Bureau, 2014). Previous studies examining mTurk worker demographics found similar or lower household incomes (Paoloacci 2010, Ipeirotis 2010, Mason 2012). As can be seen in Table 10 below, income did not differ between groups.

Table 11 - Participant Household Income

Household Income		**PMI Format**			**Total**
		FDA-Like	Picture-Enhanced	Video	
Less than $10,000	Count	13	11	20	44
	% within Household Income	29.5%	25.0%	45.5%	100.0%
	% within Format	6.9%	5.8%	9.7%	7.5%
$10,000 - $19,999	Count	16	20	19	55
	% within Household Income	29.1%	36.4%	34.5%	100.0%
	% within Format	8.5%	10.6%	9.2%	9.4%

$20,000 - $29,999	Count	27	34	32	93
	% within Household Income	29.0%	36.6%	34.4%	100.0%
	% within Format	14.4%	18.0%	15.5%	15.9%
$30,000 - $39,999	Count	37	26	28	91
	% within Household Income	40.7%	28.6%	30.8%	100.0%
	% within Format	19.7%	13.8%	13.5%	15.6%
$40,000 - $49,999	Count	32	17	23	72
	% within Household Income	44.4%	23.6%	31.9%	100.0%
	% within Format	17.0%	9.0%	11.1%	12.3%
$50,000 - $59,999	Count	15	29	26	70
	% within Household Income	21.4%	41.4%	37.1%	100.0%
	% within Format	8.0%	15.3%	12.6%	12.0%
$60,000 - $69,999	Count	14	10	13	37
	% within Household Income	37.8%	27.0%	35.1%	100.0%
	% within Format	7.4%	5.3%	6.3%	6.3%
$70,000 - $79,999	Count	13	15	15	43
	% within Household Income	30.2%	34.9%	34.9%	100.0%
	% within Format	6.9%	7.9%	7.2%	7.4%
$80,000 - $89,999	Count	7	5	10	22
	% within Household Income	31.8%	22.7%	45.5%	100.0%
	% within Format	3.7%	2.6%	4.8%	3.8%
$90,000 - $99,999	Count	4	3	6	13
	% within Household Income	30.8%	23.1%	46.2%	100.0%
	% within Format	2.1%	1.6%	2.9%	2.2%
$100,00 - $149,999	Count	8	11	10	29
	% within Household Income	27.6%	37.9%	34.5%	100.0%
	% within Format	4.3%	5.8%	4.8%	5.0%
$150,000 or more	Count	2	8	5	15
	% within Household Income	13.3%	53.3%	33.3%	100.0%
	% within Format	1.1%	4.2%	2.4%	2.6%
Total	Count	188	189	207	584
	% within Household Income	32.2%	32.4%	35.4%	100.0%
	% within Format	100.0%	100.0%	100.0%	100.0%

The average METER score for all participants was 26.0 (SD 9.3) and ranged from 0–34. The mean METER score in the FDA-Like format group, the Picture-Enhanced format group, and the Video format group was 26.0 (SD 9.3), 25.3 (SD 9.5), and 26.7 (SD 9.1), respectively. Overall METER scores did not differ significantly between the three PMI format groups (p = 0.34), nor did the number of participants with low and marginal health literacy (p = 0.48), as determined by the METER.

Table 12 - METER Scores Stratified by PMI Format Allocation

PMI Format	Mean METER Score	Standard Deviation	Range	Participants with low health literacy (METER ≤ 20)	Participants with marginal health literacy (METER 21–34)
FDA-Like	26	9.3	0–34	45	143
Picture Enhanced	25.3	9.5	1–34	50	139
Video	26.7	9.1	0–34	44	163
Total	26	9.3	0–34	139	445

METER = Medical Term Recognition Test

Participant Recall Scores

As mentioned previously, Fuzzy Lookup, a plugin for Excel, was used to determine which misspelled participant responses to count as correct for two of the nine survey recall items. Misspellings that were marked as incorrect by Fuzzy Lookup were reassessed by hand by two coders. Table 13 below indicates the number of correct spellings, the number of responses that were misspelled but counted as correct due to their Fuzzy Lookup similarity score, the number of responses counted as correct by hand, and the overall total number of responses counted as correct across all three formats. The remaining two fill-in-the blank survey items (i.e., “The information gave you a warning that you should not take Ellistrum if:” and “If you started having chest pain while taking Ellistrum, what should you do?”) were scored by hand. Grammar and misspellings were ignored for responses to these two items.

Table 13 - Scoring Participant Recall of the Medication Name and Active Ingredient

Question (Answer)	Counted as Correct			
	Correct Spelling	Fuzzy Lookup	By Hand	Total
What is the name of the medication? (Ellistrum)	275	148	47	470
What is the active ingredient in the medication? (Sulfaporterzole)	109	61	21	191

The overall mean recall score for all participants was 6.9 (SD 2.0) out of 10. The mean scores for the FDA-Like format group, Picture-Enhanced format group, and the Video format group were 6.6/10 (SD 1.9), 7.1/10 (SD 2.0), and 7.0/10 (SD 2.0), respectively. Table 12 below presents these summary data, as well as the average time participants spent with the format to which they were randomized. Looking at participant responses to each of the nine recall items, chi square goodness of fit showed that there was a statistically significant difference between the number of participants who correctly recalled the active ingredient (Sulfaporterzole) in the FDA-Like group (n = 45) as compared to both the Picture-Enhanced (n = 70) and Video (n = 76) groups (p = 0.008). No other statistically significant difference was found between participant responses to the individual recall items.

Table 14 - Mean Recall Scores and Time Spent with PMI

PMI Format	n	Mean Time* ± SD; (Range) Spent with Format	Mean Recall Score† ± SD
FDA-Like	188	90 ± 87; (1–690)	6.6 ± 1.9**
Picture-Enhanced	189	110 ± 140; (1–1,453)	7.1 ± 2.0**
Video	207	226 ± 117; (1–877)	7.0 ± 2.0
Overall	584	144 ± 131 (1–1,453)	6.9 ± 2.0

*Time is in seconds | †Score is out of a total of 10 points
**Statistically significantly different ($p < 0.05$), as determined by ANOVA and Scheffe post-hoc test

Age, gender, ethnicity, race, household income, highest educational achievement, and METER scores were all considered as potential covariates for ANCOVA. Given that ANCOVA must include at least one continuous covariate that is linearly related to the dependent variable (i.e., recall scores) across all levels of the independent variable (i.e., PMI format) in order to be performed (Laerd Statistics, 2013), a bivariate Pearson correlation was performed between

participants' recall scores and participants' METER scores and age, which were the only two potential covariates that are continuous variables. Results indicated that there is no correlation between participants' recall scores and METER scores (correlation coefficient = -0.005; p = 0.899) or participants' recall scores and age (correlation coefficient = -0.005; p = 0.907). Given this, none of these potential covariates could be controlled for. Also, as mentioned previously, time spent viewing the PMI to which the participant was randomized was considered but could not be treated as a covariate due to it being a function of and collected during the intervention (Laerd Statistics, 2013). An ANOVA was therefore used for statistical analysis.

Before running an ANOVA, the assumptions of no outliers and normal distribution were tested for participants' recall scores. Nine outliers were identified via box plots. The outliers were not measurement or input errors and thus could not be excluded justifiably. It was determined through visual inspection of histograms as well as computation and interpretation of skewness and kurtosis z-scores for participants' recall scores that the data were moderately negatively skewed for both the Picture-Enhanced and Video format groups.

Due to the presence of moderately negatively skewed data, a "reflect and square root" transformation was applied. Specifically, the transformation involved taking the square root of the difference between the overall highest recall score plus one (i.e., 11) and each individual recall score (Laerd Statistics, 2013). Note that this resulted in the lowest recall scores becoming the highest and vice versa, after the transformation. Post transformation, the data were normally distributed, as determined by visual inspection of histograms as well as computation and interpretation of skewness and kurtosis z-scores. However, the nine outliers were still present.

Due to the presence of outliers, ANOVA was run on the transformed data both with and without the outliers. Both ANOVAs returned the same results: a statistically significant difference in participants' recall scores was found across the different PMI formats (with outliers included: $F(2,581) = 3.715$, $p = 0.025$; with outliers excluded: $F(2,572) = 4.582$, $p = 0.011$). A Scheffe post hoc test was then run to determine the specific location of this difference. In both cases, the

Scheffe post hoc test found that participants' recall scores were statistically significantly higher for the Picture-Enhanced format group as compared to the FDA-Like format group (p = 0.039 with outliers included; p = 0.011 with outliers excluded). No other statistically significant differences were determined by the Scheffe post hoc test with or without the outliers. Given that exclusion of outliers did not change the statistical significance of the results, Tables 15–17 below summarize these findings for the transformed ANOVA with outliers included.

Table 15 - Descriptive Statistics for Transformed Data

Format	N	Mean Recall Score	Standard Deviation	Standard Error	95% CI	Minimum	Maximum
FDA-Like	188	2.03	0.48	0.03	1.96-2.10	1.00	3.32
Picture	189	1.90	0.53	0.04	1.82-1.97	1.00	3.16
Video	207	1.92	0.51	0.03	1.85-1.99	1.00	3.16
Total	584	1.95	0.51	0.02	1.91-1.99	1.00	3.32

Picture = Picture-Enhanced; CI = Confidence Interval

Table 16 - ANOVA Results for Transformed Data

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	1.910	2	.955	3.715	.025
Within Groups	149.401	581	.257		
Total	151.311	583			

df = degrees of freedom; Sig. = significance

Table 17 - Scheffe Post Hoc Test for Transformed Data

(I) Format	(J) Format	Mean Difference (I-J)	Std. Error	Sig.	95% CI	
					Lower Bound	Upper Bound
FDA-Like	Picture	0.13316*	0.05223	0.039	0.0050	0.2613
	Video	0.10905	0.05109	0.103	-0.0163	0.2344
Picture	FDA-Like	-0.13316*	0.05223	0.039	-0.2613	-0.0050
	Video	-0.02411	0.05102	0.894	-0.1493	0.1011
Video	FDA-Like	-0.10905	0.05109	0.103	-0.2344	0.0163
	Picture	0.02411	0.05102	0.894	-0.1011	0.1493

*The mean difference is significant at the 0.05 level.
Picture = Picture-Enhanced; Std. Error = Standard Error;
Sig. = Significance; CI = Confidence Interval

Participant Preferences, Likes, and Dislikes

Participants Preferences

All 584 participants responded as to which format(s) they would prefer to receive from their pharmacy via computer. As can be seen in Table 18 below, 170 participants (29.1%) indicated that they would prefer to receive the FDA-Like format, followed by 153 participants (26.2%) indicating they would prefer to receive the Picture-Enhanced format. One hundred six participants (18.2%) indicated they would prefer to receive the Video format. Eighteen participants (3.1%) indicated they had no preference, and the remaining 137 participants (23.5%) indicated that they would prefer to receive a combination of two or all three formats. Table 18 summarizes these results, stratifying PMI preferences based on the format to which participants were randomized. There was no statistically significant association between the PMI format to which participants were randomized and PMI preference ($X^2(14) = 23.122$, $p = 0.058$), as determined by chi-square test for association. Chi-square goodness of fit test indicated that, among the 429 participants who indicated preference for only one format, the number of participants who preferred the FDA-Like, Picture-Enhanced, and Video Format was statistically significantly different ($X^2(2) = 15.37$, $p < 0.001$).

Table 18 - Participant Format Preferences

		Randomized Format (IV)			
Preferred Format(s)		**FDA-Like**	**Picture-Enhanced**	**Video**	**Total**
FDA-Like	Count	42	66	62	170
	Expected Count	54.7	55.0	60.3	170.0
	% within Format Preference	24.7%	38.8%	36.5%	100%
	% within Format (IV)	22.3%	34.9%	30.0%	29.1%
	% of Total	7.2%	11.3%	10.6%	29.1%
Picture-Enhanced	Count	58	46	49	153
	Expected Count	49.3	49.5	54.2	153.0
	% within Format Preference	37.9%	30.1%	32.0%	100%
	% within Format (IV)	30.9%	24.3%	23.7%	26.2%

	% of Total	9.9%	7.9%	8.4%	26.2%
Video	Count	35	37	34	106
	Expected Count	34.1	34.3	37.6	106.0
	% within Format Preference	33.0%	34.9%	32.1%	100%
	% within Format (IV)	18.6%	19.6%	16.4%	18.2%
	% of Total	6.0%	6.3%	5.8%	18.2%
FDA-Like and **Picture-Enhanced**	Count	19	10	16	45
	Expected Count	14.5	14.6	16.0	45.0
	% within Format Preference	42.2%	22.2%	35.6%	100%
	% within Format (IV)	10.1%	5.3%	7.7%	7.7%
	% of Total	3.3%	1.7%	2.7%	7.7%
FDA-Like and **Video**	Count	11	9	13	33
	Expected Count	10.6	10.7	11.7	33.0
	% within Format Preference	33.3%	27.3%	39.4%	100%
	% within Format (IV)	5.9%	4.8%	6.3%	5.7%
	% of Total	1.9%	1.5%	2.2%	5.7%
Picture-Enhanced and **Video**	Count	12	15	20	47
	Expected Count	15.1	15.2	16.7	47.0
	% within Format Preference	25.5%	31.9%	42.6%	100%
	% within Format (IV)	6.4%	7.9%	9.7%	8.0%
	% of Total	2.1%	2.6%	3.4%	8.0%
All three formats	Count	8	1	3	12
	Expected Count	3.9	3.9	4.3	12.0
	% within Format Preference	66.7%	8.3%	25.0%	100.0 %
	% within Format (IV)	4.3%	0.5%	1.4%	2.1%
	% of Total	1.4%	0.2%	0.5%	2.1%
No preference	Count	3	5	10	18
	Expected Count	5.8	5.8	6.4	18.0
	% within Format Preference	16.7%	27.8%	55.6%	100.0 %
	% within Format (IV)	1.6%	2.6%	4.8%	3.1%
	% of Total	0.5%	0.9%	1.7%	3.1%
Total	Count	188	189	207	584

	Expected Count	188.0	189.0	207.0	584.0
	% within Format Preference	32.2%	32.4%	35.4%	100.0 %
	% within Format (IV)	100.0%	100.0%	100.0%	100.0 %
	% of Total	32.2%	32.4%	35.4%	100.0 %

Participants Likes and Dislikes

The six datasets consisting of participants' open-ended responses as to what they liked and disliked about each of the three formats totaled 40,939 words, or approximately 82 single-spaced pages. Across the six datasets, a total of 117 codes were created, with significant code overlap between datasets, as can be seen in Tables 19–24. Multiple codes were applied to each quote (i.e., participant response), as appropriate. These codes were then placed into one of six subsequently identified themes, one of which (i.e., Audio Aspects) only applies to the Video format. The remaining five themes (i.e., 1. Visual and Organizational Aspects, 2. Comprehensibility and Memorability, 3. Navigational Aspects, 4. General Content, and 5. Other) apply to all six datasets. Overall inter-rater reliability was adequate (Krippendorff's $\alpha = 0.70$) for the approximately ten percent of the datasets that was coded by both researchers.

FDA-Like Format | Participant Likes

Looking at what participants indicated they liked about the FDA-Like format, there were 584 participant responses totaling 6,200 words, or approximately 12.4 pages. A total of 18 codes were identified and placed into the five aforementioned themes. Eleven codes pertained to the "Visual and Organizational Aspects" theme, two codes pertained to the "Comprehensibility and Memorability" theme, three codes pertained to the "Navigational Aspects" theme, one code pertained to the "Content" theme, and two codes were placed into the "Other" theme. Table 19 below contains all of the codes organized in descending order in their respective themes, along with example quotes for each code. The code applied most often under the "Visual and Organizational Aspects" theme was *Compact/condensed* (n = 173). Under the "Comprehensibility

and Memorability" theme, *Easy to understand/clear* (n = 65) was coded most often. *Easy to find information* (n = 73) was the most applied code under the "Navigational Aspects" theme. *Informative/detailed* (n = 43) was the only code under the "General Content Aspects" theme, and *Nothing/unsure* (n = 26) was the most applied code under the "Other" theme. Codes were not applied to 50 participant responses due to the responses being irrelevant, uninformative, or nonsensical. For example, no codes were applied to the participant responses, "cool" and "even contrast."

Table 19 - FDA-Like Format | Participant Likes

Code (n)	Example Quotes
Theme: Visual and Organizational Aspects	
Compact/condensed (173)	• "I like reading all of the information, and it's condensed and easy to scroll through." • "Easy to follow and has all of the information in a small area. Very efficient"
Easy to read (117)	• "Easy to read well organized" • "Easy to read and clean, professional and to the point."
Familiar/similar to existing formats (53)	• "Covers important information. Official/standard layout for medicine" • "Everything is all in one place, it is familiar"
Well organized (53)	• "All the information is laid out neatly" • "Easy to read well organized"
Information sectioned/categorized (43)	• "All information is on one page and separated into their own boxes for easy read." • "Organized in sections, separated by lines - Bullet points make it easy to look over information"
One page (43)	• "All in one page. easy and simple" • "All the information is here on one sheet that I can print out and have easy access to."
Bullets/lists (24)	• "Organized in sections, separated by lines - Bullet points make it easy to look over information" • "I like the list format."
Not distracting/cluttered (20)	• "Everything is clearly labeled without any unnecessary information cluttering the page." • "Everything seems to be displayed on one page, black and white colors are simple so no distractions for the reader"
Clear headings (19)	• "Appropriate headers, easy to find what you are looking for" • "Everything is clearly labeled without any unnecessary information cluttering the page."
Professional appearance (9)	• "Looks more professional" • "It seems formal and professional."
Holds attention/focus (1)	• "It keeps u more focused"

Theme: Comprehensibility and Memorability	
Easy to understand/clear (65)	• "All the information is clear and direct." • "Easy to read and understand."
Easy to remember (3)	• "It is compact and easy to remember" • "It is very simple and easy to read and to remember"
Theme: Navigational Aspects	
Easy to find information (73)	• "Appropriate headers, easy to find what you are looking for"
Go at own pace (18)	• "Can go at my own pace" • "I like that I am in control of how long it takes me to read it."
Theme: General Content Aspects	
Informative/detailed (43)	• "Gives all necessary info." • "Detail of information"
Theme: Other	
Nothing/unsure (26)	• "Not sure" • "Nothing"
Easy to print (7)	• "All the information is here on one sheet that I can print out and have easy access to." • "Is a short version I could print and have on my board and read it when I need."

FDA-Like Format | Participant Dislikes

As for participants indicating what they disliked about the FDA-Like format, there were 580 participant responses totaling 6,205 words, or approximately 12.4 pages. A total of 20 codes were identified, which were placed into the five themes. Twelve codes pertained to the "Visual and Organizational Aspects" theme, and two codes pertained to each of the four remaining themes. Table 20 contains all of the codes organized into their respective themes, along with example quotes for each code. Overall, the most applied codes pertaining to the "Visual and Organizational Aspects" theme was *Bland/plain/boring* (n = 154). The most applied code under the "Comprehensibility and Memorability" theme was *Difficult to understand information* (n = 26). Under the "Navigational Aspects" theme, the most frequently applied code was *Easy to skim and skip/miss information* (n = 39). *Too much information* (n = 53) was the most applied code under the "General Content Aspects" theme. The most applied code under the "Other" theme was *Nothing/unsure* (n = 125). Codes were not applied to 34 participant responses, such as "It is too shady," that were deemed to be irrelevant, nonsensical, or uninformative.

Table 20 - FDA-Like Format | Participant Dislikes

Code (n)	Example Quotes
Theme: Visual and Organizational Aspects	
Bland/plain/boring (154)	• "A little bland, more color would be perfect" • "Dull and unattractive."
Font too small (69)	• "I dislike the small text." • "I think the fonts should be larger"
Lack of color (44)	• "A little bland, more color would be perfect" • "I think a color difference maybe red for warnings would be good to draw the eyes to that information"
Important information is not highlighted (35)	• "It is hard to know what information is important and what is not." • "Not enough bolding of text to highlight very important aspects"
Lack of pictures/icons (35)	• "It's easier to understand with the pictures." • "The big downside is no graphic aids on how to take the correct dosage."
Difficult to read (33)	• "Can be hard to read." • "All the information runs together. It's harder to read it."
Crowded/cluttered (31)	• "All the information runs together. It's harder to read it." • "Everything is crammed."
Does not hold attention/focus (15)	• "Hard to hold attention (wanted to stop reading, just scanned the information)." • "I dislike the black and white because it's so plain, and it doesn't get your attention."
Organization/order of information (11)	• "Directions should come before 'uses'" • "I hate it when you have to search for the directions. That should be on top"
Lack of font bolding (5)	• "Not enough bolding of text to highlight very important aspects" • "This is really hard to read and very dry. The colors and bolding of the other formats worked better for me."
Too formal/technical (5)	• "It is too technical." • "Seems abit formal"
Blurry (2)	• "Is a bit blurry." • "Is kinda blurry"
Theme: Comprehensibility and Memorability	
Difficult to understand information (26)	• "A bit hard to digest" • "Difficult to understand"
Difficult to remember information (9)	• "It's a bit harder to remember some parts of the information when compared to watching the video format." • "Not very memorable"
Theme: Navigational Aspects	
Easy to skim and skip/miss information (39)	• "A little easy to miss something" • "Easy to skip over information."
Difficult to find information (12)	• "Hard to look for specific info." • "A bit bland and it's a little more difficult to find the information you're looking for compared to the other

	one.”
Theme: General Content Aspects	
Too much information (53)	• “A lot of information on this page” • “It seems like a bunch of information to take in at one time.”
Not enough information (5)	• “I could have used just a little bit more information.” • “Some areas are very vauge, could use a little more information”
Theme: Other	
Nothing/unsure (125)	• “I didn't dislike anything about it” • “Don't know”
Lack of audio/voiceover (6)	• “Sound” • “For drugs with ingredients I'm not familiar with, having pronunciations (like in the video) make it easier for me to communicate any issues with a doctor. I hate to have a conversation with someone, away from the information on the drug, and not remember hat it's called.”

Picture-Enhanced Format | Participant Likes

There were 583 participant responses pertaining to what they liked about the Picture-Enhanced format totaling 7,173 words, or approximately 14.3 pages. Twenty-six codes were identified across the five themes. Seventeen of the codes pertain to the “Visual and Organizational Aspects” theme, one code pertained to the “Comprehensibility and Memorability” theme, three pertained to the “Navigational Aspects” theme, one code pertained to the “General Content Aspects” theme, and four fell under the “Other” theme. Table 21 contains all of the codes generated for what participants indicated they like about the Picture-Enhanced format, as well as how many times each code was applied and sample quotes for each. The most frequently applied code under the “Visual and Organizational Aspects” theme was *Easy to read* (n = 87). *Easy to understand* (n = 111) was the only code under the “Memorability and Comprehensibility” theme, and *Informative/detailed* (n = 11) was the only theme under the “General Content Aspects” theme. *Go at own pace* (n = 50) was the most applied code under the “Navigational Aspects” theme and, under the “Other” theme, *Nothing/unsure* (n = 20) was the most frequently applied code. Codes were not applied to 59 participant responses that were deemed irrelevant, uninformative, or nonsensical. For example, no codes were applied to the participant response, “I like it.”

Table 21 - Picture Enhanced Format | Participant Likes

Code (n)	Example Quotes
Theme: Visual and Organizational Aspects	
Easy to read (87)	• "Easy to follow and read." • "Format allows for easy reading of the information"
Colors/colorful (81)	• "I like that it has colors and bold print." • "I like this the best by far, the color and images allow quick access to the information I need. It is much more readable than the black and white format."
Pictures/graphics/icons (74)	• "I like this the best by far, the color and images allow quick access to the information I need. It is much more readable than the black and white format." • "I really like the infographics. The fonts are nice as well."
Pictures reiterate/explain text (52)	• "I like that there is pictures to go with the text and that it's easy to read." • "It has pictures which help reinforce the information"
Information is sectioned/categorized (48)	• "I like the sections of the picture format and the colors and images. The font is also easy to read" • "It seperates the information into different sections, which makes it easier to take in. It allows me to take in the information at my own pace."
Attractive/inviting (41)	• "The information is presented in a friendly and easy to read manner, and I can scroll to what I want to see." • "The picture format perhaps attracts the user's attention."
Large font (38)	• "Large print and easily understandable." • "This is good for older people who may have trouble seeing the smaller print of the black and white"
Font bolding/emphasis on key words (22)	• "I like that it has colors and bold print. • "Bold letters is highlight important areas/text. Pictures. Easy to read."
Well organized/order of information (22)	• "All very organized in a neat power point layout" • "Well organized and better presentation than the black and white text. Information is more easily digested"
Brief/concise (20)	• "Brief and focuses on important points (much less overwhelming to look at that the usual information sheets provided with a drug)" • "Short and right to the point"
Powerpoint/slides (18)	• "All very organized in a neat power point layout" • "I like the powerpoint presentation feel of this. It is much faster to just look at the information I'm curious about in this display."
Pictures are easy to understand (15)	• "I like the easy to understand graphics. The graphics make it so simple to digest the information." • "The pictures are easy to read and to follow"
Header pictures (11)	• "I like the graphics next to the headlines" • "I like the large icons that indicate what the sections are about."
Pictures are inviting/engaging (10)	• "Clip art draws my eyes. Emphasizes key words." • "What I liked about the Picture Format is that the visuals make it more appealing to read, and the

	sections are all set to a certain subject, making it easier to follow along with what the information is trying to say."
Not overwhelming/intimidating (9)	• "Brief and focuses on important points (much less overwhelming to look at that the usual information sheets provided with a drug)" • "Its easy to find everything, and not overwhelming."
Not just text (3)	• "Better than a wall of text" • "Colorful and less boring than just a printed out text"
Professional in appearance (3)	• "I like the more professional look" • "It was professional and simple."
Theme: Comprehensibility and Memorability	
Easy to understand (111)	• "Clear language and easy to read text" • "Easy to follow and understand."
Theme: Navigational Aspects	
Go at own pace (50)	• "It seperates the information into different sections, which makes it easier to take in. It allows me to take in the information at my own pace." • "Can read at own pace, and can go back to re-read information."
Easy to find information (33)	• "Clear headings on every section makes it easy to quickly find answers one may have" • "If i were looking for specific information, the pictures would help me to quickly scan the document and find the section I needed (like if I were looking for directions, or side effects, etc)."
Easy to reference/refer back to (18)	• "Easy to pull up and locate again direct panel you need." • "Easy to reference for information"
Theme: General Content Aspects	
Informative/detailed (11)	• "I like that all the information you need is listed." • "Informative"
Theme: Other	
Nothing/unsure (20)	• "I do not like anything about it" • "Don't know"
No audio/video (7)	• "It's not a video" • "I like reading information better than listening to it, so it's nice to have all the information available to read, and I don't feel rushed like by watching a video, I can take my time and go back easily if I want to look at something else."
Can print (2)	• "I am able to print images to keep on file." • "This is my favorite, I can print this and keep it for my records. Its easy to read and nice to look at."
Digital/on computer (2)	• "Easy to read, I can save it to my computer." • "I like that it is on the computer, and good for the environment."

Picture-Enhanced Format | Participant Dislikes

Looking at dislikes concerning the Picture-Enhanced format, there were 579 participant responses totaling 6,066 words, or approximately 12 single-spaced pages. A total of 26 codes were identified across the five themes. Table 22 contains all of the codes organized into their respective themes, along with example quotes for each. Of the 14 codes falling under the "Visual and Organizational Aspects" theme, *Too much white space* (n = 24) was coded most often. Two codes fell under the "Comprehensibility and Memorability" theme, of which *Difficult to remember* (n = 6) was applied more frequently. Of the four codes falling under the "Navigational Aspects" theme, *Too long/too much scrolling* (n = 176) was applied the most. *Too much information* (n = 12) was the most applied code under the "General Content Aspects" theme. Four codes fell under the "Other" theme, with *Nothing/unsure* (n = 166) applied the most. Codes were not applied to 69 participant responses, such as "An academic may not like it," that were deemed to be irrelevant, uninformative, or nonsensical.

Table 22 - Picture-Enhanced Format | Participant Dislikes

Code (n)	Example Quotes
Theme: Visual and Organizational Aspects	
Too much white space (24)	• "Everything is spread out. The slides could likely be condensed a little." • "How much white space there was after the information in each box. it required unnecessary scrolling."
Pictures – general (21)	• "Graphics and minimal color" • "I do not like the pictures. I think it takes up too much room and does not get straight to the point."
Not engaging/interactive (13)	• "It could be a lot more interactive." • "It's not as engaging as a video would be."
Too plain/simple (13)	• "It is very plain" • "It's too simple of a format"
Distracting/too busy (12)	• "For me, the picture format is more distracting and makes it a little harder to focus on the important information." • "Way too many icons, colors, headings, and pictures. Much too busy."
Colors (11)	• "Graphics and minimal color" • "It doesn't have a lot of color"
Order of information (10)	• "Inactive ingredients buried at the end whereas active are up front." • "Slides seem out of order, just like the video."
Unprofessional/childish (9)	• "Does not look professional."

	• "It seems almost childish in how it presents the information."
Headings split across multiple slides (8)	• "I dislike that there are multiple slides for the same purpose i.e. 2 slides for the directions. I'd like it to be on one slide for quick reference." • "That there are two before use sections"
Font (5)	• "There was not anything I disliked other then the blue font." • "The information is spreat out too far. Maybe the font is a bit too large"
Pictures are distracting (5)	• "Graphics and formatting are often a distraction. Doesn't help me pronounce the terms or retain the information." • "Some of the pictures distract from the actual information being presented."
Powerpoint/slides (5)	• "I don't like that its in s slideshow format" • "Looks too much like powerpoing slides and doesnt look like something i would take seriously."
Pictures are confusing (4)	• "First directions box has too many pictures, looks confusing" • "The pictures don't really help - you still need to read the instructions. The images could be designed if one were illiterate."
No table of contents (3)	• "It needs a table of contents." • "It would be nice if it had a table of contents just to find the information even more quickly."
Theme: Comprehensibility and Memorability	
Difficult to remember (6)	• "Hard to remember, feels like a ton of info crammed into your face. not memorable." • "This format makes it hard to remember everything that was covered. If it had been more condensed I would be more likely to remember everything it contained."
Difficult terminology (5)	• "Don't know how to spell the terms, also don't understand some." • "They use large words I never heard of."
Theme: Navigational Aspects	
Too long/too much scrolling (176)	• "Dislike having to scroll through the pictures to find what I'm looking for. The black and white text format provides all the information 'at a glance'." • "It is a little long. Takes a long time to get through all of the information."
Clunky/hard to navigate (21)	• "A bit clunky and hard to get around" • "It takes more time to navigate than the black and white version."
Easy to inadvertently skip information (17)	• "13 pages to scroll through makes it easy to miss something or lose interest" • "It's too easy to scroll past the important information."
Difficult to reference later (3)	• "Cannot be referenced later." • "Too hard to look up information at a later time. Everything should be put on 1-2 pages for easy reference"
Theme: General Content Aspects	

Too much information (12)	• "It is a LOT of info to take in. otherwise all good." • "there is too much information presented and can be confusing"
Not enough information (10)	• "I would like to see more information about the possibilities of side effects and how many people are affected. I would also like more informationa about the drug in general like a company or FDA website" • "Doesn't give much information"
Theme: Other Aspects	
Nothing/unsure (166)	• "Couldn't find any dislikes" • "Don't know"
No audio/video (23)	• "I have to read it all. the video allows me to follow along." • "I would rather hear the information than read it."
Not easy to print (3)	• "13 slides are a lot of pages and this might lead to having a lot of print outs and if someone losses pages it would be a problem." • "Its long, not printable."
Rather not have to read (3)	• "I dislike having to read so much." • "You have to read it yourself."

Video Format | Participant Likes

There were 584 participant responses pertaining to perceived positive attributes of the Video format totaling 7,462 words, or approximately 14.9 pages. Thirty-four codes were identified across the six themes. Eight of the codes pertain to the "Visual and Organizational Aspects" theme, twelve codes fell under the "Audio Aspects" theme, two codes pertained to the "Comprehensibility and Memorability" theme, three pertained to the "Navigational Aspects" theme, two codes pertained to the "General Content Aspects" theme, and six fell under the "Other" theme. Table 23 contains all of the codes generated for what participants indicated they liked about the Video format, as well as how many times each code was applied and sample quotes for each code. The most frequently applied codes under the "Visual and Organizational Aspects" and "Audio Aspects" themes were *Pictures/icons/graphics* (n = 35) and *Don't have to read* (n = 86), respectively. *Easy to understand/follow* (n = 179) was the most frequently applied code under the "Comprehensibility and Memorability" theme, and *Difficult to skip information* (n = 12) was the most applied code under the "Navigational Aspects" theme. Under the "General Content Aspects" theme, *Informative/detailed* (n = 82) was the most applied code, and *Catches/holds attention* (n = 21) as well as *Nothing/unsure* (n = 21) were the most frequently applied codes under the "Other Aspects" theme. Codes were not applied to 39 participant

responses, such as “Great features,” that were deemed to be irrelevant, nonsensical, or uninformative.

Table 23 - Video Format | Participant Likes

Code (n)	Example Quotes
Theme: Visual and Organizational Aspects	
Pictures/icons/graphics (35)	• “I like that it has illustrations and audio to guide you along step by step so you have everything you need to know about this medicine.” • “The combination of clear graphics, text and audio makes it easy to understand”
Well organized/order of info (28)	• “Everything is organized well and there is a voice to also go along with a video to help you learn the format.” • “The flow of the information made sense and was easy to follow.”
Colors/colorful (18)	• “It catches your eye with the large fonts and colors, and it also is easier to remember by being spoken aloud in the video.” • “It is very visual and colorful. The letter are large enough to read”
Powerpoint/slides (15)	• “I like that it uses a power slide and pictures to demonstrate what they are saying.” • “The power point style.”
Large font (7)	• “Clear, text big enough to see clear” • “It catches your eye with the large fonts and colors, and it also is easier to remember by being spoken aloud in the video.”
Professional/well-designed (7)	• “The voice and slideshow are professional” • “It was very informative and basic to understand. They tell you the side effects, when to take the medicine, when not to take the medicine and even mention office hours. Overall it was a very professionally done video.”
Bullet points/lists (3)	• “I like how each information is clearly presented and the list each reason one by one” • “I like the images and bullet points”
Transitions (2)	• “I like how it slides between each bit of information and the human element of having it read to me” • “I like how the screens flowed from one to the next and the normal voice explaining each item.”
Theme: Audio Aspects	
Don’t have to read (86)	• “Sound and clear, don't have to read” • “Being able to listen besides reading gives a better understanding”
Narration mirrors text (39)	• “Clean and easy to read directions, visual as well as audio directions.” • “I like hearing the voice, it makes it more understandable while reading it. The video helps you read along.”
Provides pronunciations (31)	• “Easy to understand, provides pronounciations which could be helpful, and is super helpful if you have trouble reading or a vision problem.”

	• "I like how there is audio to help pronouce difficult words."
Speaks clearly (29)	• "Clear speaking voice, slow paced for slower readers. Colors visually pleasing" • "Easy to listen to and the speaker spoke clearly and slowly."
Good pace/speed (23)	• "It is at a reasonable pace that is digestable. I feel like I understand how I should use it better than if I had just read it." • "Informative and the information is presented at a good pace"
Speaks slowly (22)	• "Clear speaking voice, slow paced for slower readers. Colors visually pleasing" • "Easy to listen to and the speaker spoke clearly and slowly."
Good for blind/seeing impaired (12)	• "Easy to understand, provides pronounciations which could be helpful, and is super helpful if you have trouble reading or a vision problem." • "Would be good if one had problems reading or seeing. Gives a lot of information."
Good if have trouble reading/illiterate (11)	• "Easy to understand, provides pronounciations which could be helpful, and is super helpful if you have trouble reading or a vision problem." • "Would be good if one had problems reading or seeing. Gives a lot of information."
Voice/narrator – general (11)	• "I like the guy's tone of voice." • "well voiced and easy to follow along"
Good for audio/video learners (10)	• "I am more of an auditory learner so it helps to hear the words spoken aloud. This is especially helpful because I usually do not know how to pronounce a lot of the medical terms. I like that it highlighted the FDA phone number." • "It's colorful. I personally learn a lot better if I hear someone talk about it instead of reading it myself."
Speaks calmly (7)	• "Calm voice, very easy to listen to. while still being very informative. intimidating medical words seem less out of place when being spoken" • "His voice is calming, and it presents in a mannerly order."
Easy to listen to (3)	• "Easy to listen too" • "Easy to read and listen to"
Theme: Comprehensibility and Memorability	
Easy to understand/follow (179)	• "Clear easy to understand." • "Made things even more clear, plus now you know how to say the drug, which over the phone my be important."
Memorable (32)	• "It catches your eye with the large fonts and colors, and it also is easier to remember by being spoken aloud in the video." • Hhearing the info and having it presented like this made it a little easier to remember"
Theme: Navigational Aspects	
Difficult to skip information	• "Covers everything, can't miss anything"

(12)	• "Watching is helps me to go through everything in detail instead of skipping though the information"
Can re-watch if needed (3)	• "Can re watch it" • "I dont have to read the information. I only have to listen to the video. I can play it back and forth if dont understand something"
Easy to skip information when you want (2)	• "I like the video because it is easier to skip past the information that you don't want. The narrator adds an extra element to the provided information by reading the instructions to the potential consumer. It feels more personal." • "Makes you know about all the information, and since it's a video I can pause or skip as much as I like"
Theme: General Content Aspects	
Informative/detailed (82)	• "Informative" • "Gives you all of the information about this medication"
Concise/straight forward (16)	• "It is clear and to the point." • "The video format was the best by far, it was easy to follow and short and to the point."
Theme: Other Aspects	
Holds/catches attention (21)	• "Easy to follow, keeps attention" • "I like that it's easier to pay attention, and focus on what is being said. I like that some words are in bold."
Nothing/unsure (21)	• "I didnt like it at all." • "Nothing, no opinion"
Interactive/engaging (14)	• "I feel this is a very modern way to learn about medications. It's the more interactive way to learn about the drug." • "I like the video because it engages me. When I see it and hear the information being described I am engaged enough to keep watching."
Can multitask during (3)	• "Because I can listen while doing something else. It is practical" • "I liked that it was a video and I could listen it to while doing other things."
Feels personal (3)	• "I like how it spells everything out. A lot of times, the black and white version has such small print and it does not feel personable. This is great because it goes through everything in a non-threatening way. It feels a lot more like sitting with a dotor and getting the instructions. It is very clear and covers all the vital information." • "I like that it sounded like a doctor explaining it to me, it made me feel well informed and confident. I liked how it went nice and slow but not too slow."
Modern approach (1)	• "I feel this is a very modern way to learn about medications. It's the more interactive way to learn about the drug."

Video Format | Participant Dislikes

There were 580 participant responses in terms of dislikes of the Video format totaling 7,462 words, or approximately 14.9 pages. Twenty-four codes were identified across the six themes. Six of the codes pertain to the "Visual and Organizational Aspects" theme, eight codes fell under the "Audio Aspects" theme, two codes pertained to the "Comprehensibility and Memorability" theme, four pertained to the "Navigational Aspects" theme, two codes pertained to the "General Content Aspects" theme, and two fell under the "Other Aspects" theme. Table 24 contains all of the codes generated for what participants indicated they like about the Video format, as well as how many times each code was applied and sample quotes for each. Under the "Visual and Organizational Aspects" theme, *Bland, boring,* dull (n = 45) was the most frequently applied code. *Voiceover is too slow* (n = 98) was the most applied code under the "Audio Aspects" theme, and *Difficult to remember* (n = 22) was the most frequently applied code under the "Comprehensibility and Memorability" theme. *Difficult to skip to specific location/information* (n = 65) and *Covered unnecessary information* (10) were the most frequently applied themes, respectively, under the "Navigational Aspects" and "General Content Aspects" themes. Under the "Other Aspects" theme, *Too long/time consuming* (n = 112) was the most frequently applied code. Codes were not applied to 50 participant responses that were deemed irrelevant, nonsensical, or uninformative. For example, no codes were applied to the participant quote, "Everything."

Table 24 - Video Format | Participant Dislikes

Code (n)	Example Quotes
Theme: Visual and Organizational Aspects	
Bland, boring, dull (45)	• "Extremely dull and easily forgotten" • "Gets boring after awhile"
Pictures are too basic (7)	• "Images could be a bit more interesting." • "It is simple, but also a little too simple. I think increased graphics could help the users remember this drug."
Order of information (5)	• "Directions shouldnt be at the end" • "Order of information could be better formatted (ex: Active and inactive ingredients should stay together - not separated)."
Visual Transitions (4)	• "Makes me a little dizzy when switching to next section" • "Honestly, I didn't like how the information on screen would slide off to the side when moving on to a new section of information. It made me a little dizzy. Maybe it's just poor graphics on my computer or something."

Not engaging/interactive (2)	• "It is not interactive." • "It is painfully slow moving. I can read through it much quicker and understand the information. If I needed to go back and look for something, I have to click at random point on the video until I find what I need. The information was not presented in an iteresting manner to capture my attention."
Prefer to see narrator (2)	• "It was basically the same format as the slideshow with the addition of a voice. I would have preferred to see the speaker as he explained the instructions." • "You did not see the person talking"
Theme: Audio Aspects	
Voiceover is too slow (98)	• "A bit too slow" • "I don't like the pace. I felt it could have been quicker."
Voice – Monotone (60)	• "Boring monotone voice" • "I didn't like the monotone of the narrator."
Rather read vs. watch/listen (26)	• "I do not like to watch videos - I prefer to read the information." • "I like reading myself, not hearing someone else tell me"
Voice – General (21)	• "The speaker doesn't sound very articulate or intelligent, so that's kind of off-putting when learning about a medication. Also I prefer information to be given in a read-only format." • "His voice tends to drone on."
Voiceover is too fast (11)	• "It simply moves too fast for anyone to remember all the little details (spelling, technical/scientific names)." • "It moves to fast, needs to slow down alittle"
Faster to read vs. watch/listen (11)	• "It feels long. I could read the information in about half that time." • "It irritates me that I can read through the information much faster than the reader."
Voice – Accent (8)	• "He has a fairly strong accent its somewhat distracting. Also he speaks slow enough but he almost speaks too slow." • "I speaker spoke very slowly. I could have read the information much faster. It was annoying. I also detected an accent. I would suggest fining someone with a non-regional dialect."
Voiceover just repeats text (5)	• "The text simple repeated what he was saying, which is bad for mental recall." • "Does not give additional info that is not included in the slide but is saying the same things that are shown on the slides."
Theme: Comprehensibility and Memorability	
Difficult to remember (22)	• "Extremely dull and easily forgotten" • "I find it hard to remember and hard to reference."
Difficult terminology (5)	• "It was hard to process the information as it was using words that are large as well as the tone being very monotonous." • "The language is confusing."
Theme: Navigational Aspects	

Difficult to skip to specific location/information (65)	• "Have to jump around video to find specific information" • "I don't like the fact that you can't quickly glance at it to look up information and you have to watch the entire video again if you forgot something."
Difficult to reference later (21)	• "1. Too long 2. No way to keep the information 3. The voice is annoying" • "I have no copy of the information for my records. I would have to go back and listen to the video again in order to refer to the information."
Cannot go at own pace (8)	• "Can't go through at your own pace." • "I disliked that I couldn't finish it at my own time frame and that I would have to rewind it to re-listen to something"
Have to "rewind" to review information (8)	• "I disliked that I couldn't finish it at my own time frame and that I would have to rewind it to re-listen to something • "I need to rewind the video if I need to hear a specific part again."
Theme: General Content Aspects	
Covered unnecessary information (10)	• "Covered medical info I didn't need to know." • "Do you really need to list all the inactive ingredients? It would be hard to refer back to it to get the info I wanted."
Not enough information (2)	• "I think there should be more information." • "The information was the same but I would prefer to read the color visual hand out than sit through the video. I have taken enough medications in my life where I can read the information quicker than a sitting through the video. If the video had more inforation about the drug than was in the hand out received from pharmacist I would like it better."
Theme: Other Aspects	
Too long/time consuming (112)	• "I do not like how long the video is. If you forget something and want to look it up, you'd have to filter through a lot when you could easily just read it on a chart that has all the information in one glance." • "I dislike how slow and long it was."
Nothing/unsure (110)	• "Don't dislike anything." • "Didn't really have a dislike of the video."

Results Summary

In summary, 584 participants completed the survey with 188, 189, and 207 participants randomized to the FDA-Like, Picture-Enhanced, and Video formats, respectively. Looking at demographics, there were statistically significantly more females in the FDA-Like format group (n = 85) compared to the Video format group (n = 69; $p < 0.05$), more Hispanics/Latinos in the Video format group (n = 27) compared to the FDA-Like format group (n = 12; $p < 0.05$), more Asians in the Picture-Enhanced format group (n = 24) and Video format group (n = 25) compared to the

FDA-Like format group (n = 9; $p < 0.05$), and more multiracial participants in the FDA-Like format group (n = 9) compared to the other two format groups (n = 2; $p < 0.05$). Otherwise, demographics did not differ significantly between the three format groups, including participants' health literacy as determined by METER scores.

Participants' average recall scores (± SD) were 6.6 (± 1.9), 7.1 (± 2.0), and 7.0 (± 2.0) for the FDA-Like, Picture-Enhanced, and Video format groups, respectively. Because there was no correlation between participants' METER scores or age — the only two potential covariates that are continuous variables — and recall scores (i.e., the dependent variable), ANCOVA could not be performed. Therefore, ANOVA was utilized to determine if there was a statistically significant difference between participants' recall scores across the three PMI format groups. Due to negatively skewed data, a "reflect and square root" transformation was applied to participants' recall scores. ANOVA was run on the transformed data with and without outliers and, in both cases, indicated that there was a statistically significant difference in participants' recall scores between the three PMI format groups. Scheffe post hoc test indicated that this statistically significant difference in recall scores was between the FDA-Like format group (6.6 ± 1.9) and the Picture-Enhanced format group (7.1 ± 2.0; $p = 0.039$, transformed with outliers). No other statistically significant difference was found.

In terms of which of the formats participants would prefer to receive from their pharmacy via computer, the FDA-Like format received the most votes (170, 29.1%), followed by the Picture-Enhanced format (153, 26.2%), and then the Video format (106, 18.2%). Among these 429 participants who indicated preference for only one format, the number of participants who preferred the FDA-Like, Picture-Enhanced, and Video Format was statistically significantly different ($X^2(2) = 15.37$, $p < 0.001$). The remaining participants indicated they would prefer to receive some combination of formats (137, 23.5%) or that they had no preference (18, 3.1%). Looking at qualitative feedback, the top five aspects that participants indicated liking about the FDA-Like format include the *compact/condensed* design (n = 173), that it is *easy to read* (n =

117), that it is *easy to find information* within the format (n = 73), that the information is *easy to understand* (n = 65), and that the format is *familiar or similar to existing PMI formats* (n = 53). The top five aspects that participants indicated not liking about the FDA-Like format were that it is *bland, plain, or boring* (n = 154), the *small font* (n = 69), that it contains *too much information* (n = 53), the *lack of color* (n = 44), and that it is *easy to skim and miss/skip information* (n = 39).

For the Picture-Enhanced format, the top five aspects that participants indicated liking include that the information is *easy to understand* (n = 111), that it is *easy to read* (n = 87), that it incorporates *colors/is colorful* (n = 81), the incorporated *pictures* in general (n = 74), and that the incorporated *pictures reiterate/explain the text* (n = 52). The top five aspects that participants indicated disliking about the Picture-Enhanced format include that it required *too much scrolling/was too long* (n = 176), that there was *too much white space* (n = 24), that there was *no audio/video* incorporated into the format (n = 23), that it was generally *clunky/hard to navigate* (n = 21), and the incorporated *pictures in general* (n = 24). Aside from general content, the top five aspects of the Video format that participants indicated liking include that it was *easy to understand/follow* (n = 179), that they *do not have to read* the information (n = 86), that the *narration mirrors the text* (n = 39), the incorporated *pictures* in general (n = 35), and that the format is *memorable* (n = 32). The top five aspects participants indicated disliking about the Video format include that the format was *too long/time consuming* (n = 112), that the *voiceover was too slow* (n = 98), that is was *difficult to skip to a specific location/information* (n = 65), that the narrator's *voice is monotone* (n = 60), and that the format was *bland, boring, or dull* (n = 45).

This chapter serves as a discussion of this project as a whole, focusing on methods and results, implications of findings, and considerations for moving forward. First, the utility of mTurk for participant recruitment is discussed, followed by discussion of the importance of the statistical findings concerning participants' recall scores. Participants' qualitative feedback is then considered in terms of how it may be utilized to further improve the formatting of PMI. Study limitations are then discussed. Lastly, directions for future research are considered.

Participant Screening and Recruitment

mTurk worked extremely well for participant recruitment. Set up was relatively easy, cost per participant was low, participants recruited were demographically diverse, and overall data collection took relatively little time. After building the survey in Qualtrics, it was relatively easy to set up the HIT on mTurk. A blog post at http://brentcurdy.net/qualtrics-tutorials/link/ by Brent Curdy, a graduate student at Duke University, was used as a guide to complete this process and proved to be an invaluable resource to this end. The cost per participant was $4.20 (i.e., $1.20 in service fees + $3.00 payment per participant). Given that the mean time taken to complete the entire survey was 15.76 (± 7.50) minutes, participants were paid $11.42/hour, on average. Outside of participants volunteering to participate for free, it is hard to envision how a lower cost per participant could have been obtained. Also, it should be noted that paying nearly 600 participants, even at this low cost, could not have been achieved without the financial support received from the American Foundation for Pharmaceutical Education (AFPE). Participant demographics are diverse and, judging by previous studies (Berinsky et al., 2012; Buhrmester et al., 2011), more similar to the general US population as compared to what could have been achieved with a convenience sample.

Participant recruitment and data collection took a total of 15 days. This is a relatively short amount of time, considering that there were a total of 584 participants and more than 6,500 potential participants were screened. However, this process could have been much faster had the

HIT been originally posted as paying participants $3.00 instead of $0.10 with a $2.90 bonus payment. For instance, with the HIT posted in its original form, in which it indicated participants would be paid $0.10, it took approximately 10 days to screen 1,583 individuals, 112 of whom were recruited as participants. Once the HIT was modified to indicate that participants would be paid $3.00, it took approximately four hours to screen 982 participants, 100 of whom were recruited as participants. Researcher time spent on data collection was also relatively small, especially compared to the time it would have taken had in-person participants been utilized. Further, collecting data in this way allowed for the necessary screening of over 6,500 potential participants in order to recruit only those who met inclusion criteria, including having below functional health literacy. This would have been difficult to achieve outside of mTurk. And, as mentioned previously, studies examining the reliability of data collected from participants via mTurk have found them to be as reliable as, and in some cases more reliable than, traditional survey data collection methods (Buhrmester et al., 2011; Mason & Suri, 2012; Paolacci et al., 2010). This method of data collection, however, is not without its limitations, which are discussed below.

Aim 1 - PMI Format and Participant Recall

The format of the PMI was found to have an impact on participants' short-term recall. Specifically, participants' overall recall scores were statistically significantly higher in the Picture-Enhanced format group (7.1 ± 2.0) as compared to the FDA-Like format group (6.6 ± 1.9; $p = 0.039$). Given this finding, there are presumably design features of the Picture-Enhanced format not present in the FDA-Like format that played a role in participants' recall. These could include the explanatory pictures, added colors, bolding of key words, larger font, the chunking of distinct sections of information onto separate pages/slides, or a combination of these features, all of which are recommended in plain language and patient education materials' guidelines (Doak et al., 1996; R. Rudd, 2012; Shoemaker et al., 2013). Future studies could attempt to tease out the effect of these individual design features by comparing formats that differ only by a single design element (e.g., Format A and B are the same, except that Format A includes bolding of key words, and Format B does not).

Looking at the nine recall items individually, there was a statistically significant difference between the number of participants who correctly recalled the active ingredient (Sulfaporterzole) in the FDA-Like group (n = 45) as compared to both the Picture-Enhanced (n = 70) and Video (n = 76) groups (p = 0.008). Again, this difference in recall may be due to design features present in both the Picture-Enhanced and Video formats that are not incorporated in the FDA-Like format. In other words, certain formats or design features may boost recall of certain types of information (e.g., technical medical terms, in this case). Future studies, as described above, are needed to determine the extent to which this is true.

Although the difference between overall recall scores in the Picture-Enhanced format group and the FDA-Like format group is statistically significant, the clinical significance of this difference is unclear. The difference between the two mean scores is 0.5/10 (i.e., 5%). The effect size (Cohen's d) for this difference is 0.256, which is small. Does this small increase in information recall affect related actions and outcomes? In other words, does increased recall of medication information lead to safer (e.g., stopping the medication when appropriate) and/or more effective (e.g., taking the medication consistently as prescribed) use of the medication, which would presumably lead to better outcomes? This is unknown and out of the scope of this study. Existing literature has found positive correlations between medication knowledge, medication adherence, and health-related outcomes (Al-Qazaz et al., 2011; Hope, Wu, Tu, Young, & Murray, 2004). That said, a similar study by Boudewyns et al. (2015) found that, although comprehension was greater for participants who were randomized to two plain language-based PMI formats versus a MedGuide-based format, participants' application of the information in open-ended scenarios was not improved. Patient knowledge is undoubtedly a starting point for the safe and effective use of medication, and this study demonstrates that the format of medication information impacts the amount of medication knowledge gleaned from PMI by individuals with below functional health literacy, at least in the short term.

Further, it should be noted that the difference between recall scores of participants in the Video format group (7.0 ± 2.0) and the Picture-Enhanced format group (7.1 ± 2.0) is only 0.1/10 (i.e., 1%). This difference could be due to the way in which the information is consumed. The Picture-Enhanced format must be read, while the Video format is read to the consumer. Given that the Video format was essentially derived from the Picture-Enhanced format, this is essentially the only difference between the two formats. Also the Video format can make it difficult for the consumer to review the information at his own pace. This was a dislike of the Video format specifically pointed out by eight participants. Related to self-paced consumption of the information, 98 participants expressed that the voiceover to the Video format was too slow, and 11 said it was too fast. However, given this small difference, the Video format should not necessarily be discarded as a less effective format. There is ample room to improve upon both the Picture-Enhanced and Video formats. Ideas for improvement are discussed below in the "moving forward" section.

Aim 2 - PMI Format and Participant Preferences, Likes, and Dislikes

The most preferred format by participants was the FDA-Like format (n = 170, 29.1%), followed by the Picture-Enhanced format (n = 153, 26.2%), then the Video format (n = 106, 18.2%). The remaining participants either had no preference (n = 18, 3.1%) or preferred a combination of formats (n = 137, 23.5%). Among the 429 participants who indicated preference for only one format, the number of participants who preferred the FDA-Like, Picture-Enhanced, and Video Format was statistically significantly different ($X^2(2) = 15.37$, $p < 0.001$). Further, it should be noted that the majority (67.8%) of participants indicated that they would prefer to receive something other than, or in addition to, the FDA-Like format.

The FDA-Like format is most similar to what is currently offered by most retail pharmacies, and it is very similar to what the FDA is proposing as a potential standardized PMI template. However, based on this study's findings, offering different PMI formats may be preferred by the majority of patients. In addition, the FDA-Like format did not result in the highest level of information recall among the three formats tested, as discussed previously. Thus, making multiple PMI formats

available could result in increased patient satisfaction, increased patient utilization of PMI, and increased patient recall of information therein. That said, if the FDA does decide to regulate and standardize PMI, having manufacturers produce the content, this approach might not be feasible. This is further evidence for this study's timeliness in terms of the future of PMI.

Development of a New PMI Format

Design aspects and features from all three PMI formats could be combined to develop a new and improved (New) PMI format, with participants' qualitative feedback serving as a starting point to this end. For the FDA-Like format, participants liked that it was compact and only one page. Participants were most critical of this format being bland, plain, or boring and its small font. For the Picture-Enhanced format, participants most often indicated liking the incorporated colors and relevant images and disliking the physical length of the format. This feedback could be combined and utilized in the development of a New PMI format.

The New format could be designed to address participants' major dislikes while preserving the aspects participants indicated liking about the FDA-Like and Picture-Enhanced formats. For instance, the New format could be made less bland by incorporating design elements found in Picture-Enhanced format (e.g., color, larger font, font bolding, relevant images) while also maintaining a compact design and keeping page count to a minimum. If multiple pages are required, a table of contents could be added, thereby making the New format easier to navigate. Further, since the FDA is interested in digital distribution, optional narration (e.g., speaker icons that, when clicked, played the narration) could be added to the format, thereby providing pronunciation of difficult drug names, ingredients, and other medical terminology. This is a feature of the Video format that many participants indicated liking. Having optional narration would ensure that participants who would rather listen to the information than read are able to do so, and those who would rather read than listen can do so as well. It would also benefit those with any reading disabilities and those who are auditory learners. Adding narration in this way could be accomplished within a PDF or an eBook (i.e. electronic book) file format.

Currently, in order to bring these proposed PMI formats to market, contracts with retail pharmacies could be pursued. The evidence from this and future studies for the PMI formats in terms of patient preference and information recall would presumably be appealing and persuasive to retail pharmacies, especially if a strong correlation can be drawn to medication adherence. With a contract in place, the formats could be made available through the pharmacy's computer system. If multiple formats are utilized, then patients could be asked which they would prefer to receive. Their preference could be recorded on their profile, ensuring that they would receive their preferred format along with their medication in the future. If the FDA does decide to regulate and standardize PMI, then it may be possible to develop a contract with the FDA in order to provide the agreed upon, evidence-based PMI formats.

Limitations

Participant Characteristics and Generalizability

The demographics of participants in this study differed on some measures from that of the general US population. These include more males (60.6% vs. 49.2%), fewer Hispanics/Latinos (10.1% vs. 17.4%), more Asians (12.8% vs. 0.2%), higher educational level (at least a bachelor's degree: 48% vs. 29.3%), and a slightly lower median household income ($40,000–$49,999 vs. $53,046) for this study's participants as compared to the general US population (US Census Bureau, 2014). These differences are likely due to the types of persons drawn to utilizing mTurk versus those who are not. Despite these differences, participants' demographics are presumably more diverse and representative of the general US population than what would have been obtained via a convenience sample.

The demographics of participants in this study also differed from that of previous studies conducted on mTurk. Specifically, participants in this study were predominantly male (60.6%), whereas previous studies have found that the majority of mTurk workers are female (Mason 2012, Paoloacci 2010, Ipeirotis 2010, Berinsky 2012). There were also more Hispanic/Latino participants in this study (10.1%) as compared to a previous mTurk study (6.1%) (Berinsky et al., 2012). Given that these previous mTurk studies were conducted four or more years ago, one

possible explanation for these differences is that mTurk worker demographics may have shifted over time. Another possible explanation is that mTurk workers with different demographic characteristics are drawn to different types of HITs.

This study excluded minorities for whom English is a second language. There is a definite need for PMI that is designed to meet the health literacy needs of these individuals. However, this would potentially require design and language considerations that are out of this project's scope. Similarly, individuals with functional health literacy, defined as a METER score > 34, were also excluded. Therefore, the study's findings can only be generalized to individuals with below functional health literacy who also meet other inclusion criteria. Although the cohort of individuals with low health literacy have the greatest need for PMI that is written and formatted to meet their unique needs, individuals with functional health literacy may also benefit from improvements in PMI formatting. Inclusion of minorities who speak English as a second language and individuals with functional health literacy should be considered in future studies.

Fictitious Medication and Off-Site Participants

The PMI formats are for a fictitious medication, and participants were not explicitly told that they would be asked questions pertaining to the PMI content. A fictitious medication was used to ensure that participants did not have background knowledge of the medication. However, since participants were obviously not currently taking the medication, nor is there a chance they will ever actually take the medication, this approach may increase the likelihood that participants minimized the importance of the information as they reviewed it. Further, it was not explicitly expressed to participants that they would be asked questions regarding the content of the PMI. This also may have impacted the degree to which participants paid close attention to the material presented.

Since they took the survey online and in private, there was no oversight of participants. It is therefore possible that participants were in a highly distracting environment, multitasking, etc., while participating. As mentioned previously, there were catch questions to deter participants

from mindlessly clicking through the survey items. Participants were made aware of the catch question prior to initiating the survey, and this hopefully helped keep their attention on the information being presented and the task at hand. Only three respondents were excluded due to missing the catch questions. On a positive note, this approach — having participants engaged in the study from remote locations — potentially increases external validity. Participants' circumstances and environments while taking the survey online may be more representative of the circumstances and environments they would encounter when reviewing PMI for a medication that they are actually taking. Additionally, all data collected from participants was self-reported, which has inherent bias. However, as mentioned previously, studies examining the reliability of data collected from participants via mTurk have found them to be as reliable as, and in some cases more reliable than, traditional survey data collection methods (Buhrmester et al., 2011; Mason & Suri, 2012; Paolacci et al., 2010)

Another limitation inherent in using off-site participants is that there was no way to ensure that participants did not have access to the PMI when responding to survey recall items. The survey was designed so that the PMI format to which the participant was randomized was not displayed when the participant was responding to survey recall items, but participants could have easily circumvented this. With the FDA-Like and Picture-Enhanced formats, both of which were PDFs, participants could have downloaded the file to their computer for access or simply taken screenshots of the material. For all three formats, it was possible for participants to open the format in another tab in their browser, which they could have then accessed as needed. One way to control for this in future studies is to conduct the studies in-person, allowing the researcher to observe if participants access the PMI while responding to the survey recall items. However, this approach is not without its challenges. Primarily, the time required to recruit participants in-person would be much greater as compared to the time required with the methods that were used, and the diversity of participants obtained by the methods used in this study would be difficult-to-impossible to replicate with in-person recruitment.

Medical Term Recognition Test (METER) Scoring

Although the METER provided a reliable and valid means of assessing the health literacy of potential and actual participants, it seems to have an inherent limitation. The METER is a 70-item recognition test containing 40 real medical terms and 30 made-up terms. It is scored based on the number of real medical terms identified by the participant and does not take into account the number of made-up terms that the participant indicates as being real medical terms. Thus, if someone were to mark all 70 items as real medical terms, they would receive a perfect score of 40. Presumably, this could lead to artificially inflated recall scores. However, as mentioned previously, the METER is a validated tool for assessing individuals' health literacy (Rawson et al., 2010). Further, the instructions for the METER specify that participants are not to guess and should only mark items that they know to be real medical terms.

Quality of Qualitative Feedback

In terms of the qualitative feedback from participants, in-person interviews would have provided richer responses than those captured with the Internet-based survey. In-person interviews would have allowed the opportunity for participants to elaborate on or clarify the meaning of their initial comments, as prompted by the researcher. This would have indeed been helpful, as much of the feedback from participants is simple and vague. For instance, codes were not applied to 8.6% (301/3,490) of participant responses to the six qualitative feedback survey items because they were deemed to be irrelevant, nonsensical, or uninformative. However, the researcher would not have been able to include near as many participants if qualitative feedback was captured via in-person interviews, as this would be much more time intensive. In-person interviews, presumably, also would not have provided the demographic diversity of participants that was obtained via the method utilized.

Delayed Recall and Comprehension

Additional limitations include only assessing immediate recall while not assessing delayed recall or comprehension and the inadvertent content difference between the FDA-Like format and the other two formats. Immediate recall is a starting-point in terms of knowledge acquisition. If there is no immediate recall, then there can be no delayed recall. Regarding comprehension, a couple of

the survey items asked participants when the next dose should be taken based on the timing of a previous dose as well as how many capsules to take in one day. The answers to these questions were not directly stated in the PMI, and therefore involved mental energy to derive the answer from the information presented. However, as described previously, these items could not be scored due to discrepancies among the PMI formats. This is unfortunate. It is unknown if the incorporation of these questions into participants' recall scores would have shown larger or smaller differences across the three PMI formats. Moving forward, future studies could address these issues.

Moving Forward

There is ample opportunity for future research based on the findings of this project. This includes the development and testing of additional, novel PMI formats, such as the New format described above; assessment of participant comprehension and delayed recall across different PMI formats; and assessment of different PMI formats for a real medication with participants who are newly prescribed the medication. Lastly, the ultimate vision as to where this research is leading is described.

Additional novel and innovative PMI formats could be developed and tested. For instance, a New format could be developed based on participants' qualitative feedback, as described above. Other features could be added to make the format more interactive. It could be designed such that users could click on the FDA website or phone number in order to contact the FDA, as needed. Additionally, completely new PMI formats could be tested. In terms of a video format, there are many directions that could be explored. A truly animated video format could be developed and tested, or a video format with a pharmacist prominently featured could be tried. The latter approach is used by MedsOnCue (VUCA Health, Lake Mary, FL), however no studies evaluating this approach could be located.

Future studies could assess delayed recall as well as comprehension. As for delayed recall, one approach would be to use mTurk. A study similar to this one could be completed. Then, after a

set period of time (e.g., 1 week) the participants could be invited to participate in a follow-up survey, thereby assessing their recall at that time. Comprehension could be assessed by incorporating survey items that, in order to be correctly answered, require participants to extrapolate from the information explicitly provided in the PMI. In order to engage higher order thinking, upper levels of Bloom's Taxonomy (i.e., apply, analyze, evaluate, create) should be utilized when constructing comprehension survey items (Krathwohl, 2002). Measuring comprehension could be accomplished in a similar fashion as was attempted in this study (i.e., incorporate comprehension questions in with recall questions that participants respond to without having access to the PMI). Alternatively, since understanding and not recall is key, comprehension questions could be administered while the participant has access to the PMI.

Future studies assessing the impact of PMI format on recall and/or comprehension could utilize an existing medication and patients who are actually prescribed the medication. This would greatly increase the validity of the results, as it would provide a more real world example than that provided by use of a fictitious medication. Presumably, individuals who are actually prescribed and taking the medication would have a vested interest in the PMI for that medication. Individuals who are newly prescribed the medication would be best, as they would presumably have less prior knowledge than individuals who have been taking the medication previously. Either way, prior knowledge could be controlled for by administering to participants a pre-test on aspects of the medication. The results of the pre-test could then be factored out in statistical analysis, if appropriate. Participants would most likely have to be recruited from pharmacies or doctors' offices, which would likely increase the time-commitment and difficulty of carrying out the study. However, a study such as this is definitely feasible.

The ultimate vision is for effective, interactive, digital PMI to be pushed (i.e., automatically delivered) to patients via a mobile pharmacy application (app) upon the patient first filling the medication. With 64% of Americans owning a smartphone, 62% of whom have used their phone to look up health related information (Smith, 2015), this seems to be the most viable digital

distribution strategy. For those not interested in a digital format, a physical format (i.e., ink on paper) could still be offered, thereby providing dual distribution strategies. Currently, most chain pharmacies already have an existing smartphone app. App functionality varies depending on the pharmacy, but most offer dose reminders, refill pickup reminders, the ability to request refills, and also provide information about the pharmacy, such as store locations, phone number, and store hours. Some offer more advanced features. For instance, the CVS Pharmacy app offers a pill identifier and a drug interaction checker. The Walgreens app allows users to live chat via text with a pharmacy professional and offers live doctor consultations via video chat. What these apps appear to be lacking, however, is prominent, well-designed, interactive PMI that accompanies users' prescription medications. Interactivity could include allowing the patient to indicate within the app whether they have any of the conditions listed in the PMI (e.g., Do not take Ellistrum if...) that contraindicates use of the medication. This information could be pushed back to the pharmacy, thereby alerting the pharmacist. The PMI could also be made available in video and written form as well. This distribution strategy offers convenience — an individual almost always has access to their smartphone — on a platform that more and more individuals are using for health related activities.

In conclusion, this study has demonstrated that the format of PMI has a statistically significant impact on the short-term recall of information therein by individuals with low health literacy. Future studies could explore the impact of specific design aspects on recall. These could include design aspects of the PMI in this study or other design aspects not considered in this study. Studies could focus on minorities with English as a second language, as there is a definite need for effective PMI for this cohort. Studies could be expanded beyond measuring short-term recall, the outcome scope of this project, to assess delayed recall as well as comprehension. Participants' qualitative feedback in this study could be utilized in the development of a New PMI format, which could then be tested. Novel PMI could be developed and tested for an actual medication, as opposed to a fictitious medication. Ultimately, evidence-based PMI that is the result of this and

future studies could be incorporated into existing pharmacy apps, thereby providing patients with attractive, reliable PMI that meets their health literacy needs.

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Appendix A - Ellistrum FDA-Like PMI Format

This information will help you take **Ellistrum** (sulfaporterzole) safely and effectively.

Active ingredient

- sulfaporterzole

Uses

- urinary tract infections (UTIs)
- bacterial skin infections
- pneumonia

Warnings

Important warning

- Do not use Ellistrum if you are allergic to sulfaporterzole or any other sulfonamide (sulfa) medicine.

Ask your doctor before use if you have:

- a heart rhythm disorder, especially if you take medicine to treat it.
- had an allergic reaction to an antibiotic.
- liver or kidney disease.
- HIV or AIDS.
- a thyroid disorder.
- low levels of potassium in your blood (hypokalemia).
- become pregnant or plan to become pregnant while using Ellistrum.

Stop use and call your doctor right away if you:

- have changes in your vision.
- get short of breath easier than normal.
- have chest pain.
- bruise or bleed easier than normal.
- become pregnant.
- took more than your doctor recommended.
- have swelling in your face or tongue.
- have bloody diarrhea.
- have yellowing of the skin or eyes.
- have severe weakness
- have loss of control of your body movement.
- have slurred speech.

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

When using Ellistrum you may get:

- upset stomach and diarrhea
- mild itching or rash
- headache

These can be side effects of Ellistrum. Tell your doctor about any side effect that does not go away or gets worse.

Directions

- Take two capsules by mouth two times a day, 12–hours apart.
- Continue taking until all capsules are gone.
- Take each capsule with food and a cup of water.
- Swallow each capsule whole. Do not open, crush, or chew.
- Do not drink alcohol while taking Ellistrum.

Questions

- For more information on Ellistrum visit fda.more-information.gov.
- Call Star Pharmaceuticals toll-free 1-800-797-1080 from 8 a.m. to 5 p.m. (ET) Monday to Friday

Inactive ingredients

Each capsule contains: black iron oxide, colloidal silicon dioxide, croscarmellose sodium, D&C yellow no. 10, FD&C red no. 40, gelatin, magnesium stearate, microcrystalline cellulose, titanium dioxide

Appendix B - FDA Prototype 1 - Rheutopia PMI

Prototype 1 **Rheutopia**

Active ingredient

- arixalate

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
- took more Rheutopia then you were told to take
- have weakness in your arms or legs
- feel faint or light headed
- easily bruise or bleed
- get short of breath
- get swollen (fat) ankles
- have chest pain

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

When using this medicine you may get

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

These can be side effects of Rheutopia. Tell your doctor about any side effect that does not go away or gets worse.

Directions

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

Questions

- For more information on Rheutopia visit **www.fda.more-information.gov**
- 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. **Vial:** mannitol, sucrose, tromethamine.

This information will help you take

Ellistrum

(sulfaporterzole)

safely and **effectively.**

Active ingredient

- sulfaporterzole

Uses

- urinary tract infections (UTIs)
- bacterial skin infections
- pneumonia

Important warning

Do not use Ellistrum if you are **allergic** to **sulfaporterzole** or any other sulfonamide (**sulfa**) medicine.

Ask your doctor *before* use if you have:

- a **heart rhythm** disorder, especially if you take medicine to treat it.
- had an **allergic reaction** to an **antibiotic.**
- **liver** or **kidney** disease.

Ask your doctor *before* use if you have:

- **HIV** or **AIDS.**
- a **thyroid** disorder.
- **low** levels of **potassium** in your blood **(hypokalemia).**
- become **pregnant** or plan to become pregnant while using Ellistrum.

Stop use and call your doctor right away if you:

- have changes in your **vision**.
- get **short of breath** easier than normal.
- have **chest pain.**
- **bruise** or **bleed** easier than normal.
- become **pregnant.**
- **took more than** your doctor **recommended.**

Stop use and call your doctor right away if you:

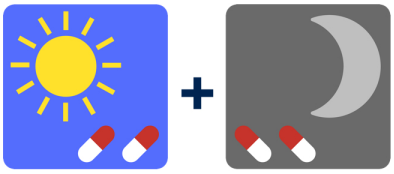
- have **swelling** in your **face** or **tongue.**
- have **bloody diarrhea.**
- have **yellowing** of your **skin** or **eyes.**
- have **severe weakness.**
- have **trouble controlling your body movement.**
- have **trouble speaking.**

When using Ellistrum you may get:

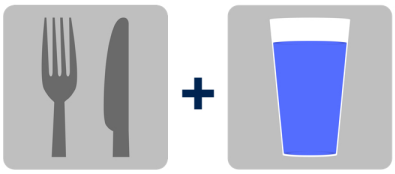
- upset stomach and diarrhea
- mild itching or rash
- headache

These can be **side effects** of Ellistrum. Tell your doctor about any side effect that does not go away or gets worse.

Directions



Take **two capsules** by mouth **two times a day**, 12-hours apart.
Take until **all capsules** are gone.



Take each dose with **food** and a cup of **water**.

Directions

Swallow each capsule whole.
Do not open, crush, or chew.

Do not drink alcohol while taking Ellistrum.

For more information on Ellistrum:

- visit **fda.more-information.gov.**
- call Star Pharmaceuticals toll free at **1-800-797-1080** from 8 a.m.–5 p.m. (ET) Monday–Friday.

Inactive ingredients

black iron oxide • colloidal silicon dioxide • croscarmellose sodium • D&C yellow no. 10 • FD&C red no. 40 • gelatin • magnesium stearate • microcrystalline cellulose • titanium dioxide

Appendix D - Pre-Study Survey

University Office of Research Compliance or the Institutional Review Board by phone (334)-844-5966 or e-mail at IRBadmin@auburn.edu or IRBChair@auburn.edu.

HAVING READ THE INFORMATION ABOVE, YOU MUST DECIDE IF YOU WANT TO PARTICIPATE IN THIS RESEARCH PROJECT. IF YOU DECIDE TO PARTICIPATE, PLEASE CLICK "Agree and continue with survey" BELOW. YOU MAY PRINT A COPY OF THIS LETTER TO KEEP.

Agree and continue with survey ○ Disagree and end survey now ○

Are you currently in the United States?

- ○ Yes
- ○ No

Is English your first language?

- ○ Yes
- ○ No

Are you 19 years of age or older?

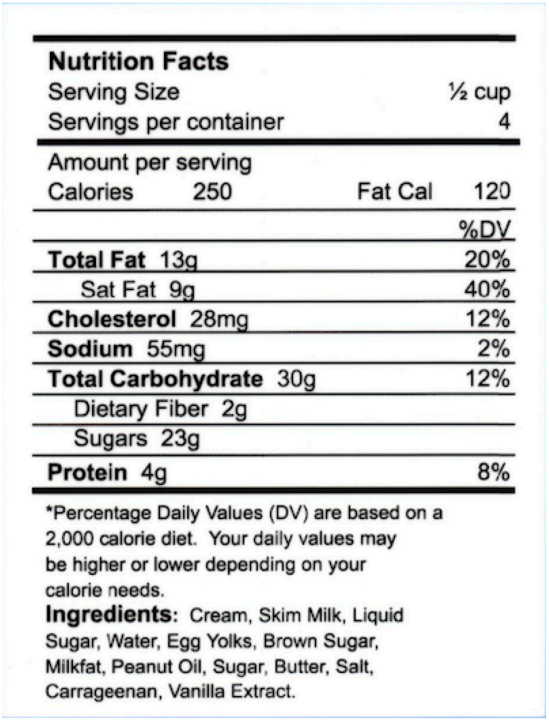
- ○ Yes
- ○ No

Have you ever received professional training or education in order to become a healthcare professional, such as a doctor or physician, physician's assistant, podiatrist, dentist, veterinarian, nurse, nurse practitioner, nurse midwife, or pharmacist?

- ○ Yes
- ○ No

NVS and METER Block

This information is on the back of a container of a pint of ice cream. Use this information to answer the following questions.



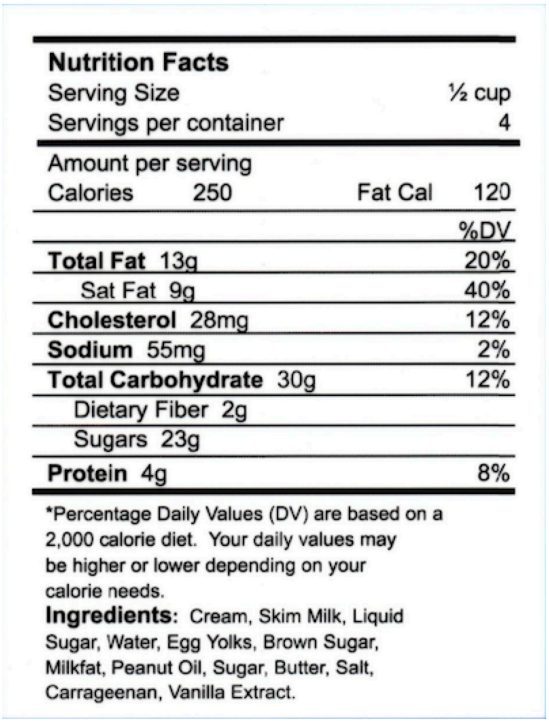
Nutrition Facts

Serving Size	½ cup
Servings per container	4
Amount per serving	
Calories 250	Fat Cal 120
	%DV
Total Fat 13g	20%
Sat Fat 9g	40%
Cholesterol 28mg	12%
Sodium 55mg	2%
Total Carbohydrate 30g	12%
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

If you eat the entire container, how many calories will you eat?

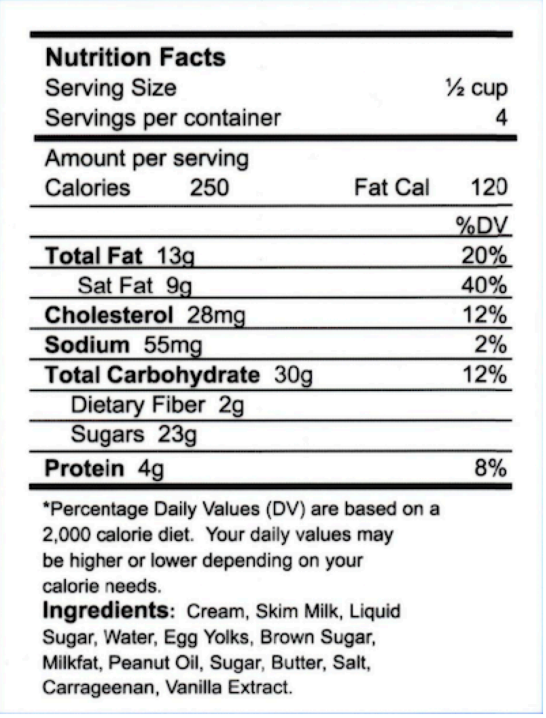


Nutrition Facts	
Serving Size	½ cup
Servings per container	4
Amount per serving	
Calories 250	Fat Cal 120
	%DV
Total Fat 13g	20%
Sat Fat 9g	40%
Cholesterol 28mg	12%
Sodium 55mg	2%
Total Carbohydrate 30g	12%
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

If you are allowed to eat 60 grams of carbohydrates as a snack, how much ice cream could you have?



Nutrition Facts

Serving Size	½ cup
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Amount per serving	
Calories 250	Fat Cal 120
	%DV
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Sat Fat 9g	40%
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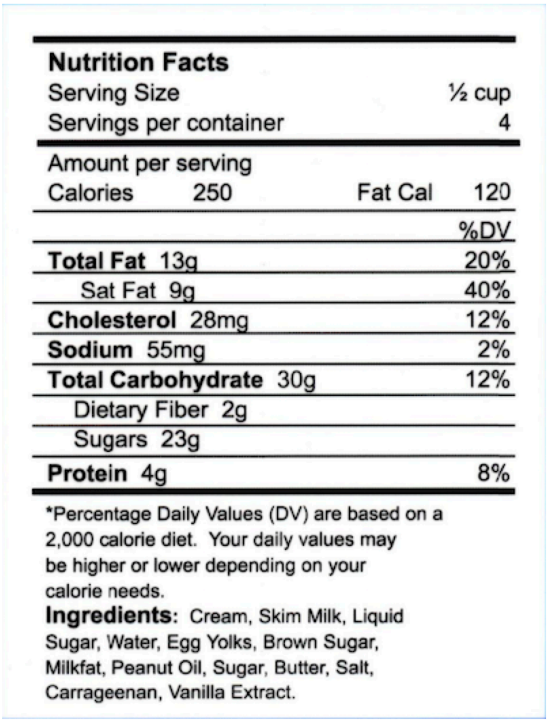
Total Carbohydrate 30g	12%
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

Your answer to the previous question was ${q://QID4/ChoiceTextEntryValue}. How much ice cream is ${q://QID4/ChoiceTextEntryValue} if you were to measure it into a bowl?

NOTE to IRB: This question only displays if the participant's answer to the previous question does not contain "cup," "cups," "container," or "containers." If and when displayed, "${q://QID4/ChoiceTextEntryValue}" will be replaced by the participant's answer to the previous question.



Nutrition Facts	
Serving Size	½ cup
Servings per container	4
Amount per serving	
Calories 250	Fat Cal 120
	%DV
Total Fat 13g	20%
Sat Fat 9g	40%
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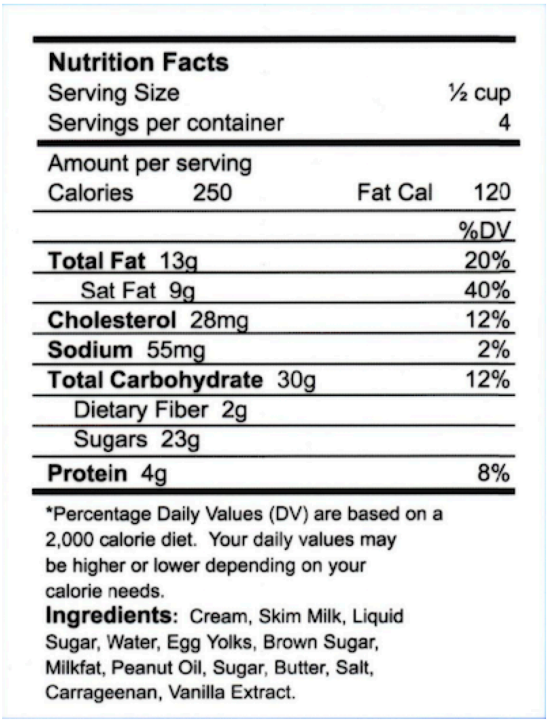
Total Carbohydrate 30g	12%
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

Your doctor advises you to reduce the amount of saturated fat in your diet. You usually have 42 grams of saturated fat each day, which includes one serving of ice cream. If you stop eating ice cream, how many grams of saturated fat would you be consuming each day?



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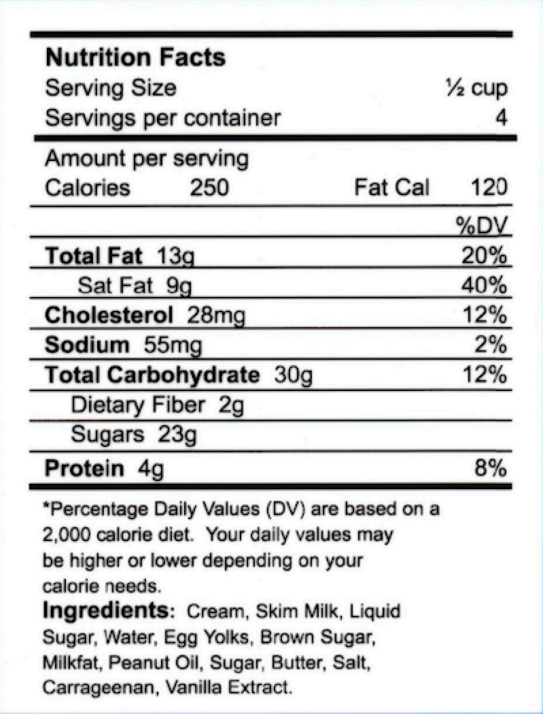
Dietary Fiber 2g	
Sugars 23g	
Protein 4g	8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

If you usually eat 2,500 calories in a day, what percentage of your daily value of calories will you be eating if you eat one serving of ice cream?



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Sugars 23g	
Protein 4g	8%

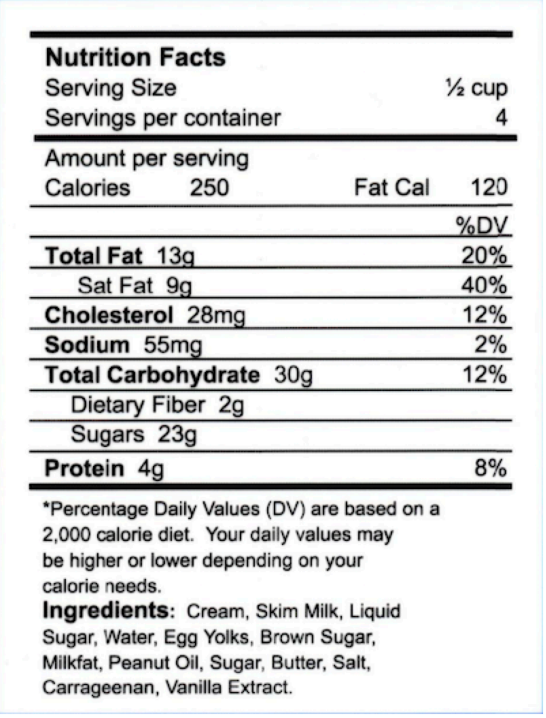
*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

For the following question, pretend that you are allergic to the following substances: penicillin, peanuts, latex gloves, and bee stings.

Is it safe for you to eat this ice cream?

- ○ Yes
- ○ No



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Protein 4g	8%

*Percentage Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Ingredients: Cream, Skim Milk, Liquid Sugar, Water, Egg Yolks, Brown Sugar, Milkfat, Peanut Oil, Sugar, Butter, Salt, Carrageenan, Vanilla Extract.

Again, for the following question, pretend that you are allergic to the following substances: penicillin, peanuts, latex gloves, and bee stings.

Why is not safe for you to eat this ice cream?

What is the sum of 2 + 2?

- 2
- 4
- 6
- 8

The following list contains some real medical words. For example, some of the words have to do with body parts or body functions, kinds of diseases, or things that can make your health better

or worse. The list also contains some items that may look or sound like medical words but that are not actually real words.

As you read through the list, check the box next to the items that you know are real words.

You should not guess. Only check the box next to an item if you are sure it's a real word.

☐ Irrity	☐ Potient	☐ Pollent	☐ Dose
☐ Arthritis	☐ Menopause	☐ Malories	☐ Hemorrhoids
☐ Obesity	☐ Diagnosis	☐ Cancer	☐ Testicle
☐ Flu	☐ Depretion	☐ Alcoheliose	☐ Eye
☐ Behaviose	☐ Jaundice	☐ Antibiotics	☐ Midlocation
☐ Syphilis	☐ Gallbladder	☐ Antiregressant	☐ Insomniate
☐ Potassium	☐ Miscarriage	☐ Colitis	☐ Bloodgatten
☐ Hormones	☐ Hepatitis	☐ Diabetes	☐ Sexually
☐ Nerves	☐ Astringe	☐ Occipitent	☐ Pelvince
☐ Pilk	☐ Nutral	☐ Nausion	☐ Vaccilly
☐ Rection	☐ Asthma	☐ Impetigo	☐ Prescription
☐ Blout	☐ Inflammatory	☐ Menstrual	☐ Germs
☐ Boweling	☐ Anemia	☐ Abghorral	☐ Gonorrhea
☐ Exercise	☐ Allargren	☐ Seizure	☐ Tumic
☐ Pustule	☐ Prognincy	☐ Appendix	☐ Fatigue
☐ Cerpes	☐ Stress	☐ Fam	☐ Osteoporosis
☐ Kidney	☐ Ellargic	☐ Infarth	☐ Constipation
☐ Emergency	☐ Inlest		

Demographic Information Block

Please enter your current age in years.

Gender:

○ Male

Female

Please specify your ethnicity.

- Hispanic or Latino
- Not Hispanic or Latino

Please specify your race. Select all that apply.

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White

What is the highest degree or level of school you have completed?

- No schooling completed
- Nursery school to 8th grade
- 9th, 10th or 11th grade
- 12th grade, no diploma
- High school graduate - high school diploma or the equivalent (for example: GED)
- Some college credit, but less than 1 year
- 1 or more years of college, no degree
- Associate degree (for example: AA, AS)
- Bachelor's degree (for example: BA, AB, BS)
- Master's degree (for example: MA, MS, MEng, MEd, MSW, MBA)
- Professional degree (for example: LLB, JD, DSW, ThD)
- Doctorate degree (for example: PhD, EdD)

Have you ever worked in the healthcare field?

- Yes
-

No

What is/was your job title when working in the healthcare field?

Who is the current President of the United States of America?

- Ronald Reagan
- Bill Clinton
- George Washington
- Herbert Hoover
- Barack Obama

What is your yearly household income?

- Less than $10,000
- $10,000 - $19,999
- $20,000 - $29,999
- $30,000 - $39,999
- $40,000 - $49,999
- $50,000 - $59,999
- $60,000 - $69,999
- $70,000 - $79,999
- $80,000 - $89,999
- $90,000 - $99,999
- $100,00 - $149,999
- $150,000 or more

Appendix E - Project Survey

AUBURN UNIVERSITY

AUBURN UNIVERSITY

HARRISON SCHOOL OF PHARMACY

DEPARTMENT OF HEALTH OUTCOMES RESEARCH AND POLICY

(NOTE: DO NOT AGREE TO PARTICIPATE UNLESS IRB APPROVAL INFORMATION WITH CURRENT DATES HAS BEEN ADDED TO THIS DOCUMENT.)

INFORMATION LETTER
for a Research Study entitled
"Comparison of Three Patient Medication Information Formats"

You are invited to participate in a research study to compare three patient medication information (PMI) formats on Amazon Mechanical Turk (mTurk). The study is being conducted by Joshua C. Hollingsworth, PharmD under the direction of Brent I. Fox, PharmD, PhD in the Auburn University Department of Health Outcomes Research and Policy. You are invited to participate because you:

- Are located in the United States,
- Are 19 years of age or older,
- Speak English as your first language,
- Do not have a severe hearing disability,
- Currently have the ability to hear sound from your computer, and
- Have never received professional training or education in order to become a healthcare professional, such as a doctor or physician, physician's assistant, dentist, podiatrist, veterinarian, nurse, nurse practitioner, nurse midwife, or pharmacist.

What will be involved if you participate? Your participation is completely voluntary. If you decide to participate in this research study, you will be asked to complete a short survey. Estimated time to complete the first portion of the survey is 1–2 minutes. If you qualify to continue, the estimated time to complete the entire survey is 20–30 minutes.

2316 Walker Building

362 Thach Concourse

Auburn, AL 36849

Telephone:

334-844-8348

Fax:

334-844-8353

pharmacy.auburn.edu

Are there any risks or discomforts? The risks associated with participating in this study are minimal. One concern is that any work performed on mTurk may be linked to your public profile page. To minimize this risk, your mTurk worker ID (i.e., the 14 character sequence of letters and numbers used to identify workers) will NOT be shared with anyone outside of the research team. Your mTurk worker ID will only be collected for the purpose of distributing compensation and will not be associated with survey responses. To further minimize this risk, you may wish to restrict what information you choose to share in your public profile.

Will you receive compensation for participating? If you qualify and complete the entire survey, you will receive $3.00 through your mTurk account. Not everyone will qualify. Estimated time to complete the entire survey is 20–30 minutes. The survey contains questions that check to ensure that you read the directions.

Are there any costs? There are no costs to participate.

If you change your mind about participating, you can withdraw at any time by closing your web browser window. Partially completed surveys will be discarded and will not be eligible for compensation. Your decision about whether or not to participate or to stop participating will not jeopardize your future relations with Auburn University, the Department of Health Outcomes Research and Policy, or the researchers.

Any data obtained in connection with this study will remain anonymous. We will protect your privacy and the data you provide by not sharing your mTurk worker ID with anyone outside of the research team and not linking your mTurk worker ID to your survey response. Further, all data will be kept on a password protected computer. Information obtained through your participation may be used to fulfill an educational requirement, published in a professional journal, and presented at a professional meeting, but information from this study will only be reported as a group, and not individually.

If you have questions about this study, please contact Joshua C. Hollingsworth at jch0010@auburn.edu or Brent I. Fox at foxbren@auburn.edu.

If you have questions about your rights as a research participant, you may contact the Auburn University Office of Research Compliance or the Institutional Review Board by phone (334)-844-5966 or e-mail at IRBadmin@auburn.edu or IRBChair@auburn.edu.

HAVING READ THE INFORMATION ABOVE, YOU MUST DECIDE IF YOU WANT TO PARTICIPATE IN THIS RESEARCH PROJECT. IF YOU DECIDE TO PARTICIPATE, PLEASE CLICK "AGREE AND CONTINUE WITH SURVEY" BELOW. YOU MAY PRINT A COPY OF THIS LETTER TO KEEP.

Investigator 7/30/2015 Date

7/30/2015

Co-Investigator Date

The Auburn University Institutional Review Board has approved this document for use from July 30, 2015 to July 4, 2018. Protocol #15-297 EX 1507

Agree and continue with survey ○

Disagree and end survey now ○

The following list contains some real medical words. For example, some of the words have to do with body parts or body functions, kinds of diseases, or things that can make your health better or worse. The list also contains some items that may look or sound like medical words but that are not actually real words.

As you read through the list, check the box next to the items that you know are real words.

You should not guess. Only check the box next to an item if you are sure it's a real word.

☐ Irrity	☐ Potient	☐ Pollent	☐ Dose
☐ Arthritis	☐ Menopause	☐ Malories	☐ Hemorrhoids
☐ Obesity	☐ Diagnosis	☐ Cancer	☐ Testicle
☐ Flu	☐ Depretion	☐ Alcoheliose	☐ Eye
☐ Behaviose	☐ Jaundice	☐ Antibiotics	☐ Midlocation
☐ Syphilis	☐ Gallbladder	☐ Antiregressant	☐ Insomniate
☐ Potassium	☐ Miscarriage	☐ Colitis	☐ Bloodgatten
☐ Hormones	☐ Hepatitis	☐ Diabetes	☐ Sexually
☐ Nerves	☐ Astringe	☐ Occipitent	☐ Pelvince
☐ Pilk	☐ Nutral	☐ Nausion	☐ Vaccilly
☐ Rection	☐ Asthma	☐ Impetigo	☐ Prescription
☐ Blout	☐ Inflammatory	☐ Menstrual	☐ Germs
☐ Boweling	☐ Anemia	☐ Abghorral	☐ Gonorrhea
☐ Exercise	☐ Allargren	☐ Seizure	☐ Tumic
☐ Pustule	☐ Prognincy	☐ Appendix	☐ Fatigue
☐ Cerpes	☐ Stress	☐ Fam	☐ Osteoporosis
☐ Kidney	☐ Ellargic	☐ Infarth	☐ Constipation
☐ Emergency	☐ Inlest		

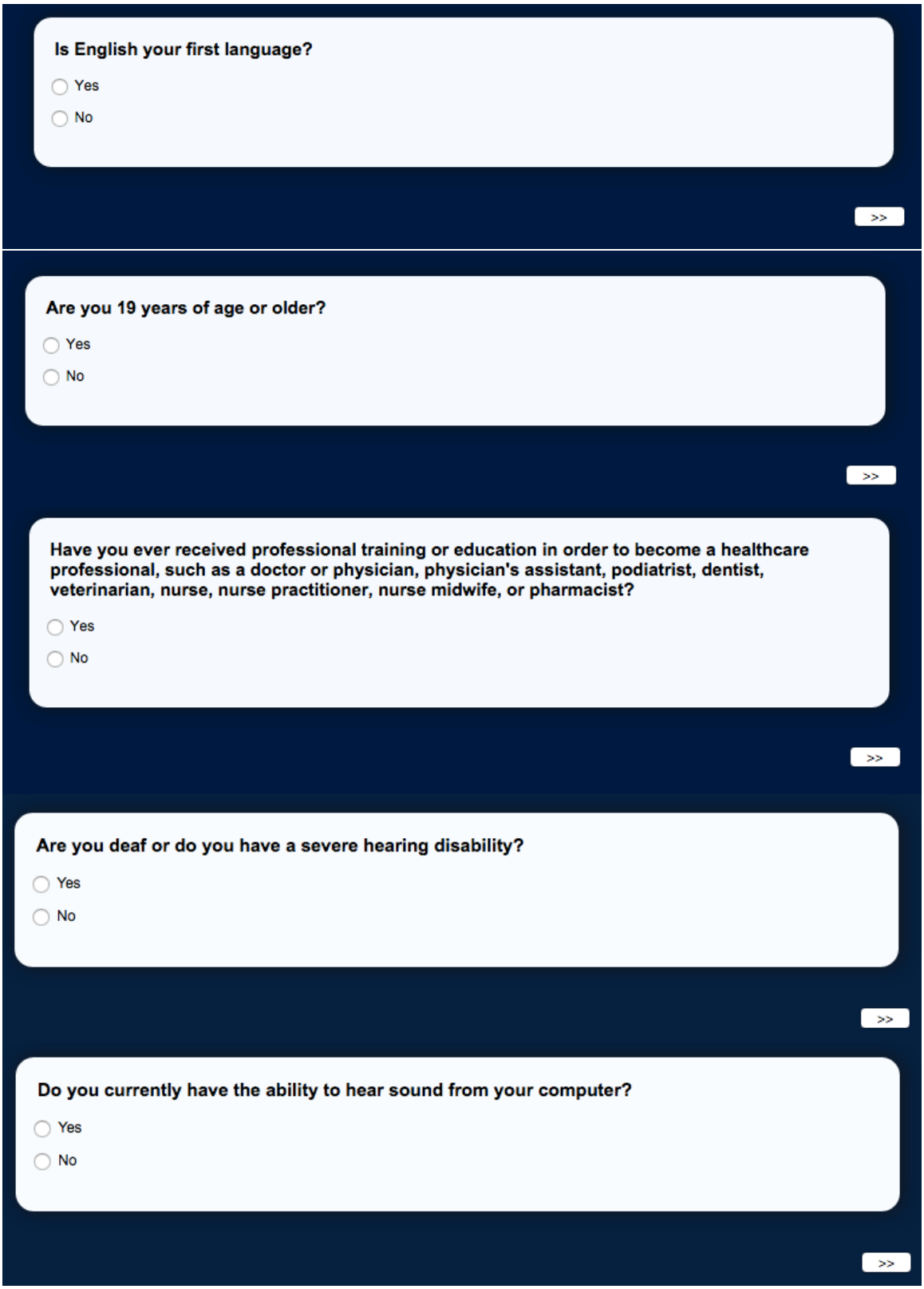
>>

Are you currently in the United States?

○ Yes

○ No

>>


Is English your first language?
Yes
No
>>
Are you 19 years of age or older?
Yes
No
>>
Have you ever received professional training or education in order to become a healthcare professional, such as a doctor or physician, physician's assistant, podiatrist, dentist, veterinarian, nurse, nurse practitioner, nurse midwife, or pharmacist?
Yes
No
>>
Are you deaf or do you have a severe hearing disability?
Yes
No
>>
Do you currently have the ability to hear sound from your computer?
Yes
No
>>

Pretend:

- You just got a prescription from your doctor for a new medication named Ellistrum.
- After you get the prescription filled at your pharmacy, your pharmacy sends you the following information on your computer.
- Note that Ellistrum is not a real drug. It is a made-up (fake) drug.
- Click ">>" below to see the information.

>>

- Below is what your pharmacy sent you.
- Read the information as if you were actually going to take the medication.
- Take as much time as you need.
- Scroll down to see all of the information.
- Click ">>" when you are done.

>>

What is the name of the medication?

What is the active ingredient in the medication?

What is 2 + 2?

- 1
- 2
- 3
- 4

>>

The information gave a warning that you should not take Ellistrum if:

Ellistrum can be used to treat:

- HIV or AIDS.
- a heart rhythm disorder.
- liver disease.
- pneumonia.
- I don't know.

If you started having chest pain while taking Ellistrum, what should you do?

How many times per day should you take Ellistrum?

Each capsule should be taken with food and a cup of water.

- True
- False
- I don't know.

It is ok to drink alcohol while taking Ellistrum.

- True
- False
- I don't know.

Each capsule should be chewed.

- True
- False
- I don't know.

You should stop taking Ellistrum when you feel better, even if you have not taken all of the capsules.

- True
- False
- I don't know.

How many Ellistrum capsules should you take per day?

If you took your first dose of Ellistrum at 8 a.m., what time should you take the next dose?

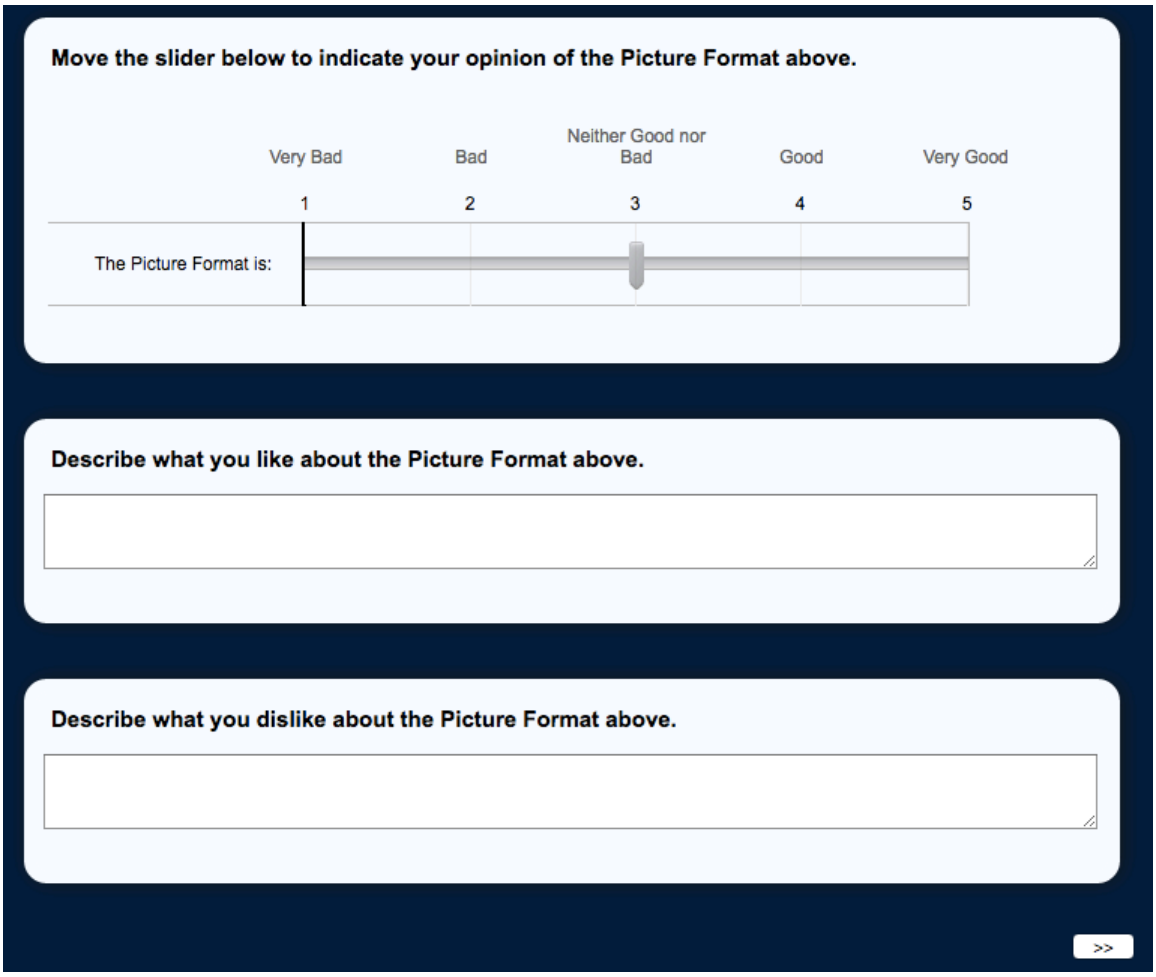
>>

- Next you will see three different formats of the information for Ellistrum.
  - You have already seen one of these formats.
- All three formats contain the exact same information.
- Please look at each format and think about:
  - Which format(s) you would like to receive from your pharmacy on your computer.
  - What you like and dislike about each format.
- If you do not have a computer of your own, pretend that you do.

>>

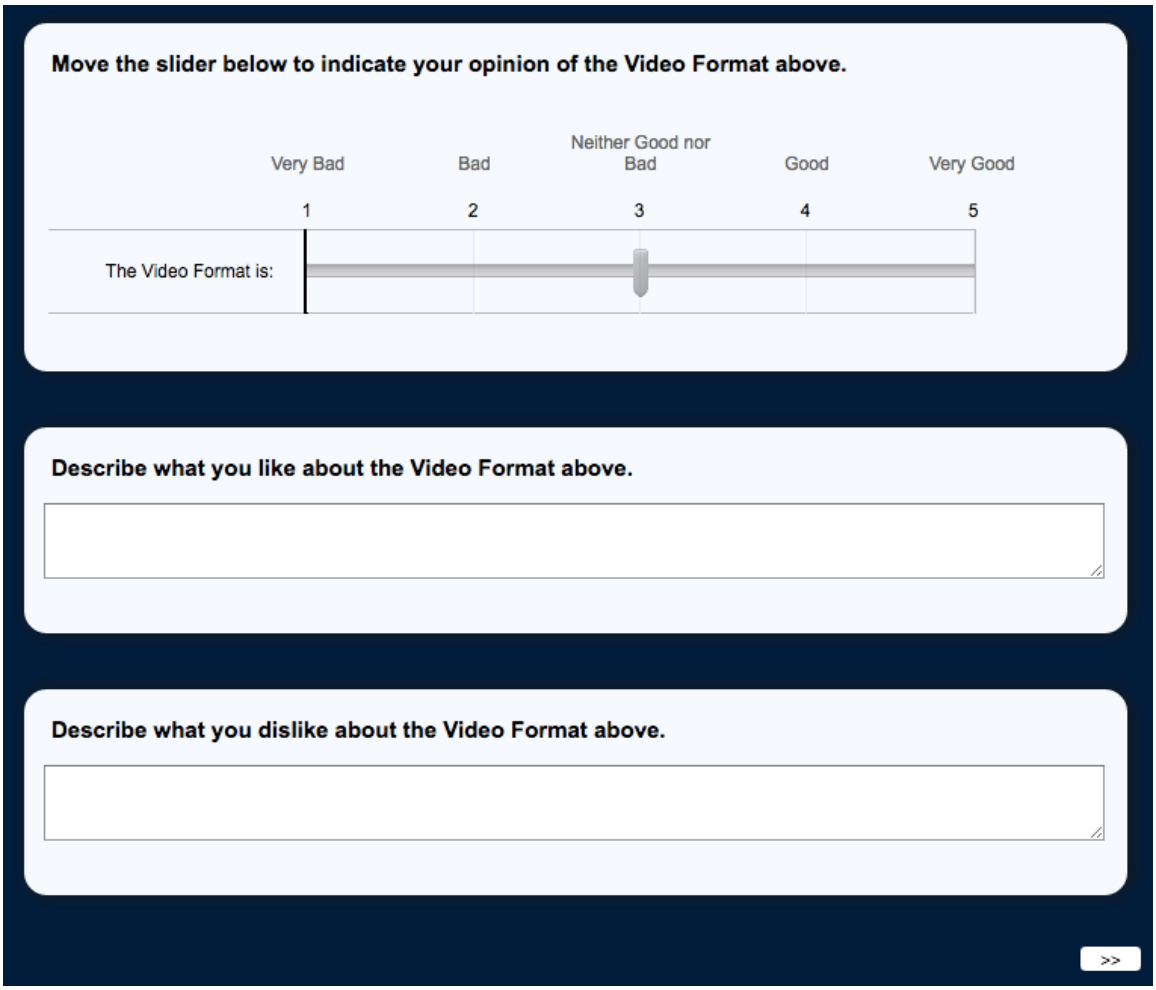
Picture Format

- Scroll down to see all of the information.

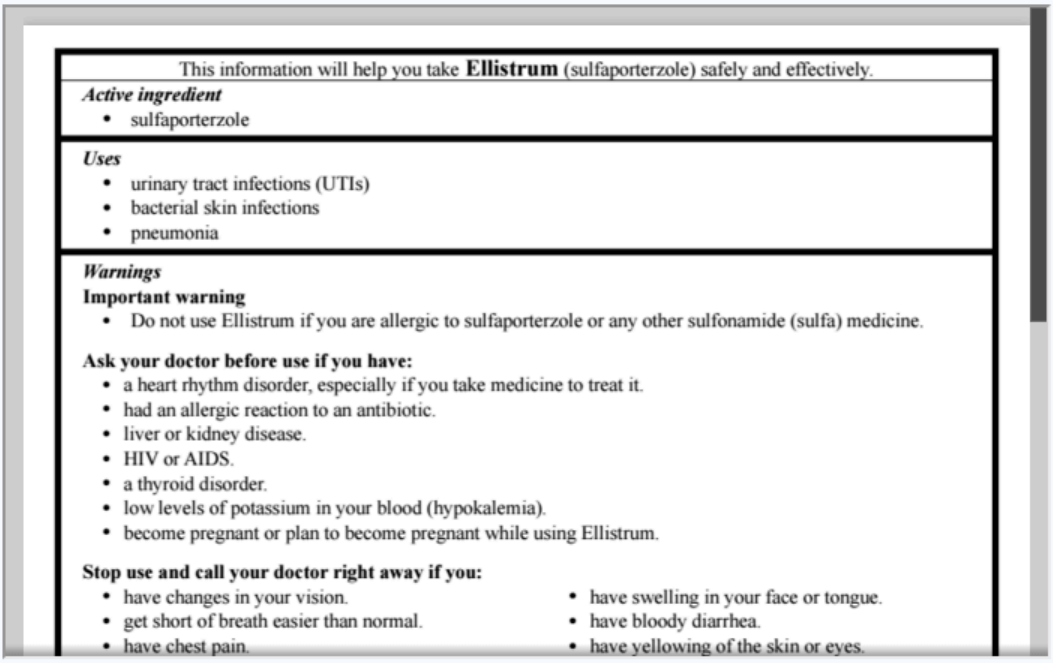

Move the slider below to indicate your opinion of the Picture Format above.
Very Bad
Bad
Neither Good nor Bad
Good
Very Good
1
2
3
4
5
The Picture Format is:
Describe what you like about the Picture Format above.
Describe what you dislike about the Picture Format above.
>>

Video Format

- **Make sure the volume is turned up on your computer.**
- **Click on the video to play.**


Move the slider below to indicate your opinion of the Video Format above.
Very Bad
Bad
Neither Good nor Bad
Good
Very Good
1
2
3
4
5
The Video Format is:
Describe what you like about the Video Format above.
Describe what you dislike about the Video Format above.
>>

Black and White Format
- **Scroll down to see all of the information.**



This information will help you take **Ellistrum** (sulfaporterzole) safely and effectively.

Active ingredient
- sulfaporterzole

Uses
- urinary tract infections (UTIs)
- bacterial skin infections
- pneumonia

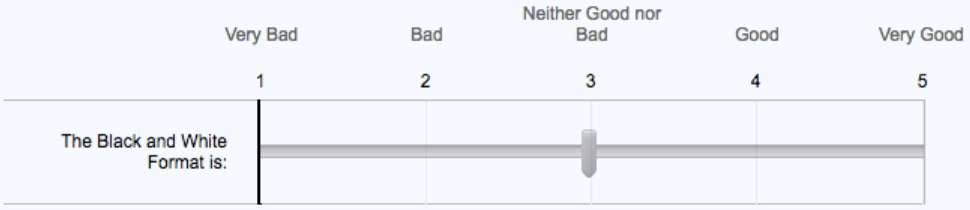
Warnings

Important warning
- Do not use Ellistrum if you are allergic to sulfaporterzole or any other sulfonamide (sulfa) medicine.

Ask your doctor before use if you have:
- a heart rhythm disorder, especially if you take medicine to treat it.
- had an allergic reaction to an antibiotic.
- liver or kidney disease.
- HIV or AIDS.
- a thyroid disorder.
- low levels of potassium in your blood (hypokalemia).
- become pregnant or plan to become pregnant while using Ellistrum.

Stop use and call your doctor right away if you:
- have changes in your vision.
- get short of breath easier than normal.
- have chest pain.
- have swelling in your face or tongue.
- have bloody diarrhea.
- have yellowing of the skin or eyes.

Move the slider below to indicate your opinion of the Black and White Format above.



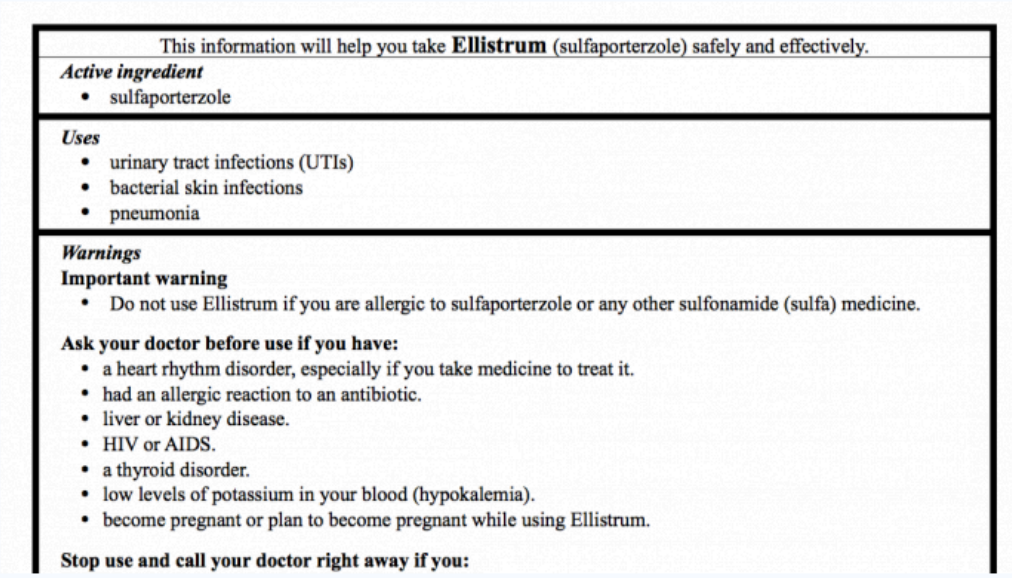
Describe what you like about the Black and White Format above?

Describe what you dislike about the Black and White Format above?

>>

If you had the option, which format(s) would you like to receive from your pharmacy on your computer? You may select one, two, or all three formats. Or you may indicate that you have no preference.

☐ **Black and White Format**



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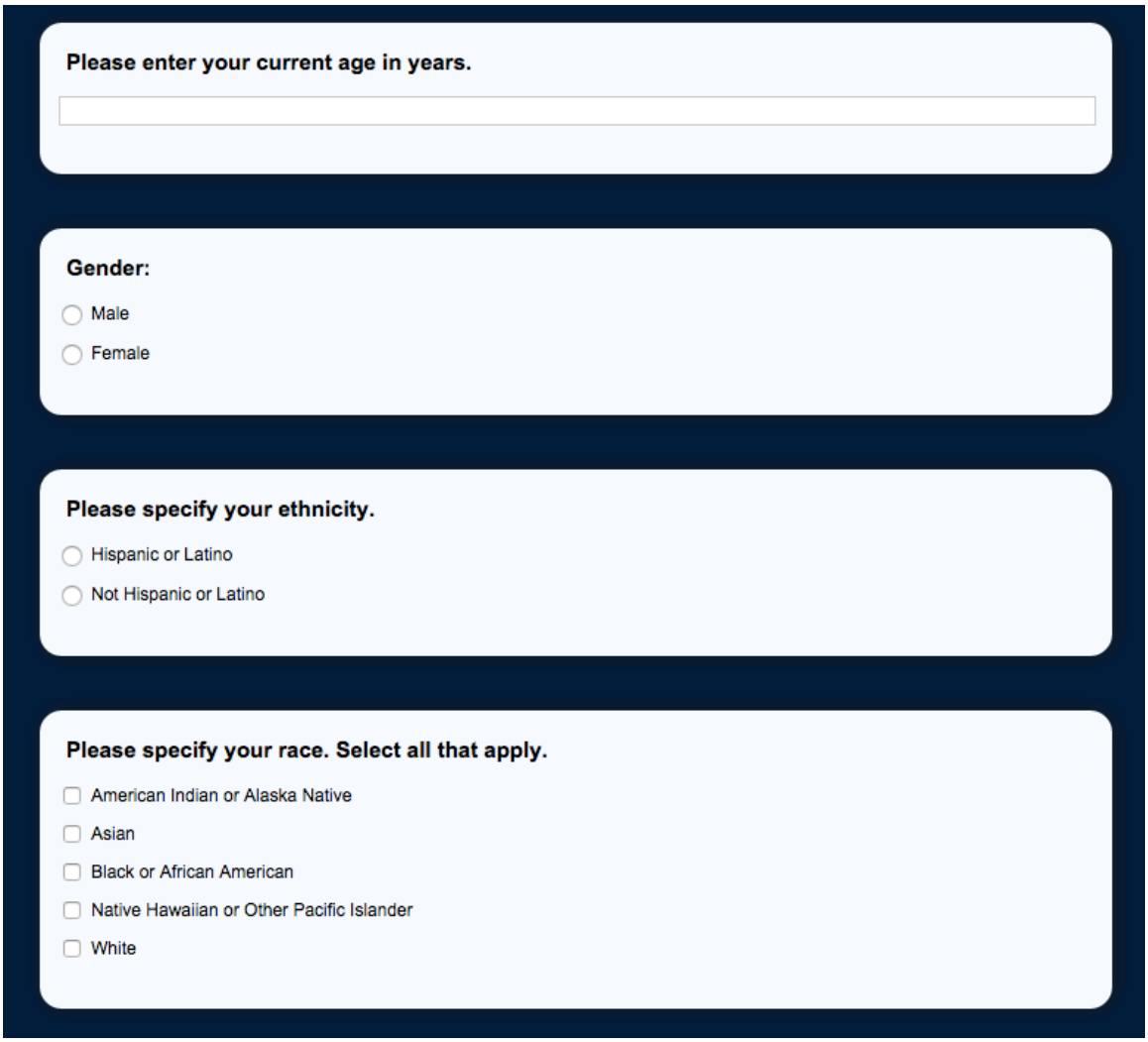
- liver or kidney disease.
- HIV or AIDS.
- a thyroid disorder.
- low levels of potassium in your blood (hypokalemia).
- become pregnant or plan to become pregnant while using Ellistrum.

Stop use and call your doctor right away if you:

☐ **Picture Format**

☐ **Video Format**

☐ **I have no preference.**


Please enter your current age in years.
Gender:
Male
Female
Please specify your ethnicity.
Hispanic or Latino
Not Hispanic or Latino
Please specify your race. Select all that apply.
American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or Other Pacific Islander
White

What is the highest degree or level of school you have completed?

- ○ No schooling completed
- ○ Nursery school to 8th grade
- ○ 9th, 10th or 11th grade
- ○ 12th grade, no diploma
- ○ High school graduate - high school diploma or the equivalent (for example: GED)
- ○ Some college credit, but less than 1 year
- ○ 1 or more years of college, no degree
- ○ Associate degree (for example: AA, AS)
- ○ Bachelor's degree (for example: BA, AB, BS)
- ○ Master's degree (for example: MA, MS, MEng, MEd, MSW, MBA)
- ○ Professional degree (for example: LLB, JD, DSW, ThD)
- ○ Doctorate degree (for example: PhD, EdD)

Have you ever worked in the healthcare field?

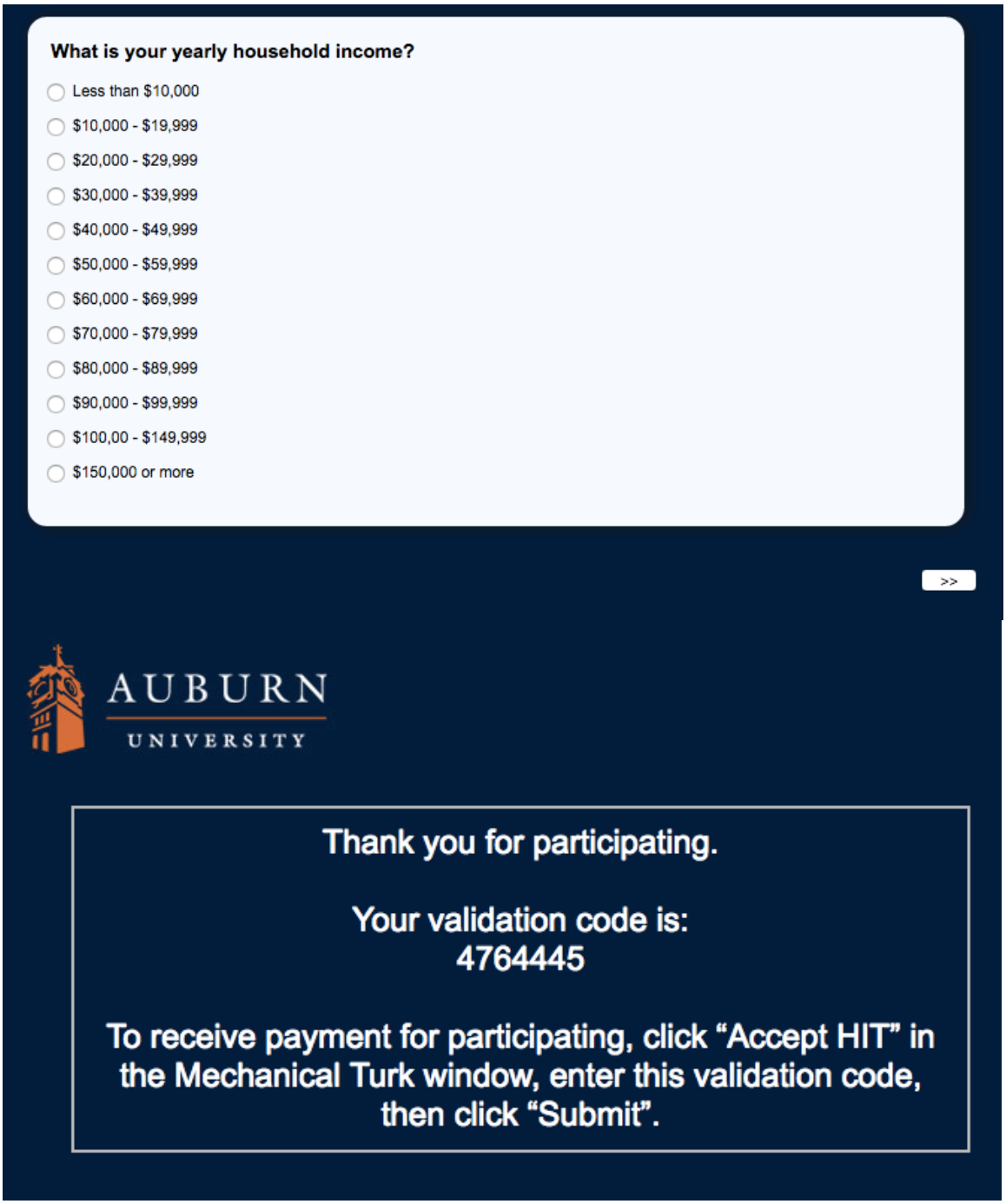
- ○ Yes
- ○ No

>>

Who is the current President of the United States of America?

- ○ Ronald Reagan
- ○ Bill Clinton
- ○ George Washington
- ○ Herbert Hoover
- ○ Barack Obama

>>


What is your yearly household income?
Less than $10,000
$10,000 - $19,999
$20,000 - $29,999
$30,000 - $39,999
$40,000 - $49,999
$50,000 - $59,999
$60,000 - $69,999
$70,000 - $79,999
$80,000 - $89,999
$90,000 - $99,999
$100,00 - $149,999
$150,000 or more
>>
AUBURN
UNIVERSITY
Thank you for participating.
Your validation code is:
4764445
To receive payment for participating, click “Accept HIT” in the Mechanical Turk window, enter this validation code, then click “Submit”.