

Comprehension of Prescription Drug Information: Overview of A Research Program

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Abstract

Both patients and healthcare professionals must understand information about prescription drugs to help them use medications in a safe and effective manner. However drug information materials can be difficult to understand – they can be long, detailed, technical, and complex. Comprehension problems can increase the chances that ineffective treatment or medication errors will occur. This paper presents an overview of a large-scale research program on how people understand drug information, especially benefits and risks. It describes basic cognitive principles used to evaluate drug information and shows ways to make it easier to understand and use. Two key concepts underlie this work, *cognitive accessibility* and *alternative representations*. They are described and illustrated with sample experiments on comprehension of pharmacy leaflets, TV ads, medication schedules, and side effects.

Basic Problem

Both patients and healthcare professionals must understand information about prescription drugs to help them use medications in a safe and effective manner. However information for a given drug can be difficult to understand – it can be long, detailed, technical, and complex. For example, the “professional labeling” for a prescription drug, the key document in approval by the Food and Drug Administration (FDA), has multiple pages of detailed information such as indications and usage, dosage and administration, warnings, precautions, contraindications, adverse reactions, use in special populations, clinical pharmacology, and drug interactions.

Drug information documents designed for patients such as pharmacy leaflets (also known as consumer medical information, or CMI) are generally shorter, less detailed, and less technical. Nevertheless they are often difficult to understand, remember, and use as well.

Inadequate comprehension by both professionals and patients can increase the chances that ineffective treatment or medication errors will occur. Especially important is information about the potential benefits and risks of drugs.

For example, a physician must determine whether the benefits of a drug outweigh its risks for a specific patient in order to make an appropriate prescribing decision. Patients must know something about possible side effects, so they can make an informed decision about treatment, monitor for possible side effects, and take appropriate action if any occur (such as seeking immediate medical attention vs. just waiting for them to resolve).

To what extent do people understand both the benefits and risks of prescription drugs? Our research shows that they understand benefits much better than risks. Various factors may contribute to this discrepancy, such as the nature of risk information itself (its complex and technical nature) or possible emotional reactions (fear of negative health outcomes). However this research examines the “cognitive accessibility” of drug information – the ease with which people can find, understand, remember, and use it [1]. The ultimate goal is to use the information in an accurate, safe, and effective manner. Without good comprehension of the information this goal can be difficult at best.

Of particular interest is how information about drug benefits vs. risks is provided. Are they in “fair balance?” That is, are they provided in equally accessible ways? Therefore we examine various aspects of existing drug information materials (Original Displays) that can facilitate or inhibit cognitive accessibility. When we find problems, we redesign part or all of the materials to increase cognitive accessibility (Enhanced Displays). Then we test comprehension of both displays in laboratory experiments. We use the “alternative representations” approach [2] in this work, retaining the same information in both displays but providing it in different ways, as described more fully below.

Some basic cognitive principles underlie this research. They are described briefly below and are illustrated by an experiment on comprehension of pharmacy leaflets. The key concepts of *cognitive accessibility and alternative representations* are also described, with sample experiments on comprehension of TV ads, medication schedules, and side effects. Although the research program

studies both professionals and patients and over-the-counter (OTC) drugs as well as prescription (Rx) drugs, the focus of this paper is on patient comprehension of Rx drugs.

Research Approach

Sources of Drug Information

We examine a wide variety of information sources for drugs. Consumer-oriented materials include pharmacy leaflets, patient package inserts, Medication Guides (required for drugs with serious risks) and direct-to-consumer (DTC) advertising including TV ads, magazine ads, and product websites. Other materials are intended for healthcare professionals such as the professional labeling (often reprinted in the *Physicians Desk Reference*), compendium manuals such as *Drug Facts and Comparisons* and *USP Drug Information*, and various drug safety alerts such as the *Dear Healthcare Professional* letter. We examine the same types of information across all these sources, especially benefits vs. risks.

Research Phases

Cognitive Analysis Phase. First we analyze existing information (Original Display) for a given drug in terms of basic cognitive principles such as information load, chunking, coding, location, and form of representation, as described below. For example, we generate quantitative measures for various cognitive factors in a pharmacy leaflet, then calculate the cognitive accessibility of the entire document as well as for specific content such as benefits and risks.

Enhanced Display Phase. Next we redesign the information to enhance its cognitive accessibility as needed, based on cognitive principles (Enhanced Display). For example we might display a given section in an alternative format, reorder some information, or introduce contrasting fonts to demarcate various sections. However we do not change the information itself – we just make it more cognitively accessible.

Cognitive Experiment Phase. Finally we perform experiments to test the effects of the Original Display vs. the Enhanced Display on various cognitive processes including attention, comprehension, memory, problem solving, and decision making. Typically we use a Study-Test paradigm, where people study a document or video, then participate in standard or novel experiment paradigms such as search-and-find, free report, and scenario tasks. Sometimes we use multiple tasks to assess types of knowledge for important content domains, such as risks.

Research Participants

Participants vary widely in age (18-80), education (6th grade education through postdoctoral training), health status (healthy nonpatients vs. patients with a specific health condition), knowledge about medical and pharmaceutical information (laypersons vs. professionals), economic levels, and work experience. For example, some are literate young adults with only a layperson's knowledge about health treatments and no serious health conditions while others are community-dwelling adults who are currently taking a specific drug to treat a diagnosed health condition. Patients with specific health conditions should be especially motivated to understand the benefits and risks of the drug they are currently taking. However we find that the same general patterns of results occur when testing patients on their own drug vs. an unrelated one and for patients vs. nonpatients.

Professionals in this research include physicians, pharmacists, and others who possess considerable knowledge about prescription drugs. As expected they perform better overall, yet still show the same general patterns – better on some types of information than others, with similar types of errors. Despite their knowledge and expertise, they are still affected by the same cognitive accessibility factors.

Basic Cognitive Principles

To examine the cognitive accessibility of any drug information source, we begin by observing the extent to which it uses well-known cognitive principles in an effective manner. For example, people generally have more difficulty processing passive sentences than active ones [3], so we count the percentage of sentences in passive vs. active voice; a high score indicates lower cognitive accessibility. Although there are sometimes disagreements about why a given phenomenon occurs, the findings are robust and have stood the test of time – in some cases for over a half century. Below are just a few of the basic cognitive phenomena and principles used in this research. They are described here briefly, with more details and background information provided elsewhere [4].

Experimental vs. Naturalistic Materials

Many basic cognitive phenomena and principles are very robust – they are highly replicable, have stood the test of time (sometimes for over a half century), and occur across many experiment conditions. Investigators typically use highly restricted test materials to examine these classic phenomena such as numbers, words, objects, or simple sentences. Some use more complex materials such as

descriptive paragraphs or narratives, but they are still generated in the lab and are tightly controlled to test specific factors or theoretical constructs.

In contrast, the drug information research reported here begins with very complex materials that are already being used in the real world (Original Displays). It evaluates their accessibility using cognitive principles and tests them as-is in the laboratory, even though they are not as tightly controlled as standard laboratory materials. Subsequent experiments isolate specific sections or features of the Original Displays and vary them systematically with Enhanced Displays to test cognitive principles.

Information Load and Cognitive Load

Too much information can overload people so that they do not “get” much of it or even stop trying to do so. This is especially so if it is technical in nature, such as information about prescription drugs. How much is “too much” information? It is tempting to try to answer this question in terms of *information load*, such as the number of words or pages in a print or spoken communication. However it is not information load *per se* that is important, but instead *cognitive load*.

Cognitive load as used here refers to mental effort, such as the number of mental operations required for a task and their difficulty (for applications to instructional design see [5]). A heavy cognitive load can make information harder to understand, remember, and use. We can lighten cognitive load by using cognitive principles to enhance the accessibility of the information. Thus a longer document (heavy information load) with high cognitive accessibility indicators can be easier to process than a shorter one with low cognitive accessibility.

Clusters, Categories, and Organization

Clustering involves keeping like-information together. When people see word lists with items from several semantic categories (such as vegetables, professions, furniture) but in random order, they tend to recall items from the same category together even though they occurred randomly throughout the list [6]. In general, people do better with information already organized into semantic categories; for a review of some classic findings, see [7].

Chunking

Chunking involves separating a packet of information from nearby information, either in space (visual information) or time (auditory) [8]. Chunking of information can improve memory and other cognitive functions. For example, a list of digits such as 854326197 will be harder to remember than the same digits chunked as 854-326-197.

Coding

Once a given packet of information has been formed and chunked, it is often helpful to give it a brief descriptive name. Naming helps people encode the information, understand it, store it, and retrieve it later. Linguistic codes can be especially useful if used in an effective manner. For example, “side effects” is a good name for unwanted events such as dizziness and nausea, rather than “problems” which could refer to problems with side effects, dosing, existing health conditions, or the concomitant use of other drugs.

An appropriate code can depend on the knowledge and experience of the user. For example, a section might be called “side effects” in a patient leaflet and “adverse events” in a professional document. A bad code – or none at all – can mean that users miss the information when viewing it and/or lose it shortly thereafter.

Location (Order Effects)

When given a list of items, people generally recall the items at the beginning and ends of the list best and have trouble with ones in the middle. This classic “serial position effect” is a very robust phenomenon and has been replicated many times (for example, see [9]). Although information in the middle of a series is usually not retained well, this effect can be ameliorated or reversed by enhancing it in some way, such as presenting it in a different color [10].

Linguistic Complexity

Many options for linguistic expression have cognitive consequences. In general, sentences that are more grammatically complex, have more propositions (idea units), and more unfamiliar words are harder to understand and remember. We analyze various linguistic parameters of written and spoken language about prescription drugs. Some of these measures are difficult and time-consuming to obtain such as propositional analyses [11], so we also include very simple measures that are easy to obtain, correlate with more sophisticated measures, and can serve as a quick proxy for comprehensibility [12].

Experiment 1 – Basic Cognitive Processes: Pharmacy Leaflets

Some of our research on pharmacy leaflets [13] illustrates the effects of several basic cognitive principles on comprehension and memory for drug information. Participants were community-dwelling adult patients already taking a specific drug for hormone replacement (Premarin) or heart conditions (Zestril). They studied the leaflet for their own drug, then participated in multiple

experiments to test all types of information in the leaflet, such as indications (what the drug is used for), precautions, dosage and administration, side effects, and pictograms. The leaflets were generally good in overall design, legibility, and readability.

One of the experiments in this study examined patient knowledge of possible side effects for one of the drugs. The basic Premarin leaflet contained 36 side effects. Most were given in the “side effects” section but some were in the “precautions” section. When asked to report side effects provided throughout the entire leaflet, most participants were unable to report any from the precautions section as shown in Figure 1. Furthermore, performance on items located at the beginning, middle, and end of the side effects section showed the classic serial position effect. Additional testing of information in the “precautions” sections showed that patients did not understand this term well. Thus clustering, chunking, coding, and serial order practices in the leaflet design affected participants’ knowledge of the drug’s side effects.

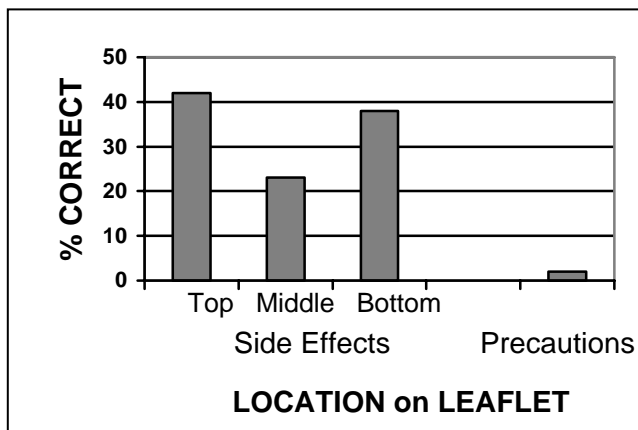


Figure 1 – Knowledge of side effects as a function of their location in a pharmacy leaflet, both for different sections and within the same section.

On a random basis, half the patients were not allowed to see their leaflets during testing (Display-Absent Condition) while the rest were allowed to consult it at any time during the testing phase (Display-Present Condition). The same pattern of results occurred in both conditions, so they were not simply memory effects. Thus leaflet features also affected the ability to search-and-find information when asked for it and to understand it.

These results hold implications for the design of drug information documents. For example, the location of all information must be considered. If there is a well chunked and coded section (such as “side effects”), put all that information in the chunk. If a subset is especially

important, locate it at the top of the section. If it must be located elsewhere (such as a boxed warning or precautions section), repeat it in its own section as well. All of these practices can facilitate comprehension, memory, and the ability to find the information again later.

Cognitive Accessibility

Cognitive accessibility is the ease with which people can find, understand, remember, and use information [1]. In the prescription drug setting, the ultimate goals for both healthcare providers and patients are behavioral. Physicians must prescribe appropriate drugs and doses for specific patients and evaluate outcomes accurately, including adverse events. Patients must take a given drug in a safe and effective manner and take appropriate action if side effects occur. Both want to achieve as positive a health outcome as possible. However without sufficient understanding of drug information, such outcomes can be compromised or even prevented.

Analysis of drug information materials provides cognitive accessibility *indicators*, as described above. However it is not until we test materials directly for comprehension, memory, problem solving, and/or other cognitive processes that we have direct evidence about their cognitive accessibility. Nevertheless as findings accumulate, we can make highly accurate predictions about the cognitive consequences of specific materials just from the accessibility indicators themselves.

Cognitive Accessibility of Rx Drug TV Ads

Direct-to-consumer (DTC) advertising of prescription drugs began in earnest in 1997, after a brief previous trial and considerable debate about possible advantages and disadvantages. Previously, drug advertising appeared only in medical journals and other professional materials. Prescription drug promotion now appears in TV ads, magazines, radio, and on the internet (e.g., drug company websites). A major concern is whether consumers understand the potential risks as well as benefits from these materials. In order to study this problem, we developed a large-scale research program on DTC advertising across media (TV, magazines, internet). Below is a sample study on TV ads.

Materials: TV Ads

We have collected drug TV ads since the year 2000 by recording several hours of television a day then extracting whatever ads appeared. Thus we have not selected them for any particular health condition or other factors. We

identify the benefit and risk portions of each ad, perform cognitive accessibility analyses of them, compute cognitive accessibility indices, then compare each ad's treatment of benefits vs. risks. We extract information about many factors, such as the amount and duration of information for benefits vs. risks and language complexity. An example of one type of measure is presented below.

Readability Analysis

We transcribe all spoken information during an ad, both from characters who appear on the screen and from any unseen narrator. We then isolate the language used for benefits vs. risks. To evaluate the comprehensibility of the spoken information, we perform a propositional analyses (e.g., count the number of basic idea units in each sentence), grammatical complexity analyses, and various semantic analyses.

We also compute a readability index. "Readability" is not the same thing as "comprehensibility." Readability indices are generally based on just two factors – word familiarity (frequency of usage in the language) and sentence length (number of words per sentence). They are very simple measures, but easy to compute and are correlated with more sophisticated measures, so we use them as a quick proxy for comprehensibility [12]. A readability score basically shows what reading grade level a person would need to understand some linguistic information. Ordinarily it is used for written language, but can also be applied to spoken language.

In one study [14], we obtained readability scores for 29 Rx drug TV ads, using the Flesch-Kincaid readability index [15]. The drugs were used to treat a variety of indications such as treatment for respiratory allergies, insomnia, arthritis, asthma, migraine, foot fungus, cholesterol reduction, weight loss, birth control, eye irritation, social anxiety disorder, gastric conditions, chemotherapy reactions, flu, and depression.

The average readability scores were higher for side effects than for benefits, as shown in Figure 2. This means that an individual would need only about a 6th grade reading level to understand the benefits in these ads, but a 9th grade level for side effects – three grade levels higher. Most individual drug ads showed this same pattern, with the most extreme case requiring eight additional grade levels to understand its side effects relative to benefits.

Experiment 2 – Cognitive Accessibility of Benefits vs. Risks in TV Ads

To what extent do people understand and remember information about both benefits and risks in Rx drug TV

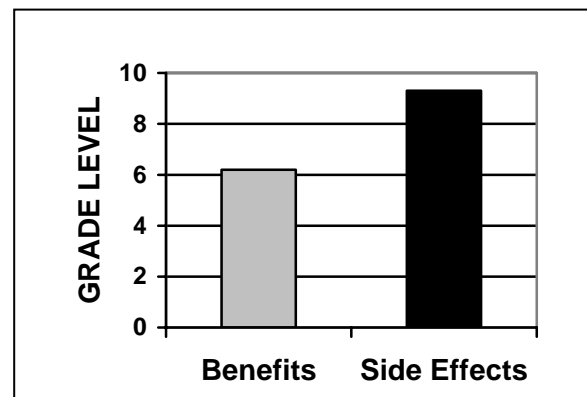


Figure 2 – Readability grade levels of benefits vs. side effects in 29 prescription drug TV ads.

ads? To study this question, we conduct laboratory experiments where people view one or more ad then participate in a battery of cognitive experiments. One type of experiment simply asks them to report the benefits and side effects in the ad. Results from one experiment [17] with three drugs (Paxil, Nasonex, Orthotricyclen) are shown in Figure 3. These results are consistent across many experiments – people are about 80% correct on benefits and only about 20% correct on side effects.

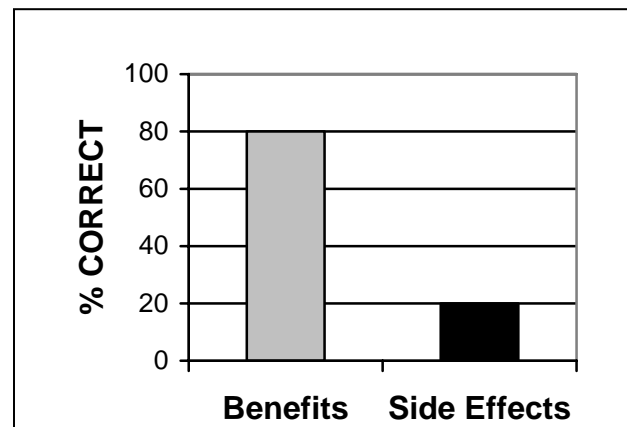


Figure 3 – Percentage correct benefits vs. side effects in an experiment on three prescription drug TV ads.

There are inevitable confounds in experiments using naturalistic materials such as the Original Displays of drug information. For example, existing drug ads generally have more side effects than benefits, so the results shown in Figure 3 could be based at least in part on differences in information load. However performance was comparable when the number of side effects was only three for a given drug (well within the limits of short-term memory) or as many as nine (at or beyond the limits of short-term memory). Therefore different treatment of benefits vs. risks in the ads contributed to the effect. One of the factors

involved was the readability of spoken text, although are others [14, 16].

To study the effects of cognitive accessibility in a more controlled and systematic manner, we also produce our own TV ads for hypothetical drugs. These ads (Enhanced Displays) enable us to control for confounding factors such as the number of benefits vs. risks and test systematically for the effects of other factors.

Alternative Representations

All information can be represented in alternative ways, such as text, lists, and matrices. Each form of representation has cognitive consequences – it can affect cognitive processes such as attention, memory, comprehension, problem solving, and decision making. External representations in hardcopy, electronic, or other means can help shape the mental representation that people develop for a given set of information.

The alternative representations approach [2] takes a given set of information, displays it in alternative formats, then tests for effects on various cognitive processes. No one representation is generally “best.” Instead each type may work better for some tasks than others (e.g., search-and-find tasks vs. comprehension tasks) or may facilitate or impede processing of some aspects of the information. Therefore when people have difficulty understanding and using information, the problem may not stem entirely from the nature of the information itself or characteristics of the individual (such as education or motivation). Instead the way the information is displayed may be at least partly responsible, as shown next for medication schedules.

Experiment 3 – Alternative Representations of Medication Schedules

Some patients take multiple prescription drugs, a situation known as polypharmacy. This practice is especially prevalent among older adults. Taking as many as a dozen drugs is not uncommon and some take even more. With so many drugs, medication errors become more likely. For example, patients may forget to take some pills, take too many, or fail to follow restrictions such as taking some with food. Patient medication errors can impede treatment, cause complications, and can lead to hospitalization, increased healthcare expenditures, and even death.

Why do people have difficulty taking their medications? Often the blame is placed on the patients themselves – perhaps they lack knowledge, education, motivation, or

sufficient financial resources, or have cognitive deficits. However the way medication instructions are provided may be at least part of the problem.

Materials

Figure 4 shows a medication schedule written by a physician and given to a patient with several health conditions [2]. It is displayed in the commonly used List Format, with the name of each drug and its instructions written on separate lines. This patient had trouble remembering what pills to take, when to take them, and whether he had already taken them.

<u>List</u>	
Inderal	– 1 tablet 3 times a day
Lanoxin	– 1 tablet every a.m.
Carafate	– 1 tablet before meals and at bedtime
Zantac	– 1 tablet every 12 hours (twice a day)
Quinaglute	– 1 tablet 4 times a day
Coumadin	– 1 tablet a day

Figure 4 – Medication schedule for an actual patient. It is displayed in the List Format, exactly as written by his physician.

The same medication schedule is reconfigured into the Matrix Format in Figure 5, with the name of the drug along the side, time zones along the top, and checkmarks to indicate when to take each pill. When given the Matrix Format (with the permission of the physician), this patient made no further medication errors.

<u>Matix</u>		Break-fast	Lunch	Dinner	Bed-time
Lanoxin		✓			
Inderal		✓	✓	✓	
Quinaglute		✓	✓	✓	✓
Carafate		✓	✓	✓	✓
Zantac			✓		✓
Coumadin					✓

Figure 5 – Matrix representations for the same medication schedule shown in Figure 4.

The Matrix solved the compliance problem for this patient in the setting of his everyday life. To examine these alternative representations for medication schedules more systematically, a laboratory experiment was performed [2].

Procedure

During the Study Phase, nonpatient young adults studied the medication schedule shown above. On a random basis, half saw the List Format and half saw the Matrix. They were told that they would see some medication instructions from a doctor to a patient who had been seriously ill, to envision themselves as this patient, and to study the instructions carefully so that they would be able to follow the doctor's orders perfectly.

During the test phase, participants were again asked to envision themselves as the patient taking the medications they had just studied and answered a series of questions. Some of the questions were factual in nature, such as "How many Quinaglute should you take per day?" Others were inferential and required participants to go beyond the explicit information given such as the scenario question, "If you leave home in the afternoon and will not be back until breakfast time the next day, how many Inderal should you take along?"

Participants were assigned randomly to one of two test conditions. For participants in the Display-Absent condition, the study displays were removed, so they had to rely entirely on memory to answer the questions. For those in the Display-Present condition, they kept the same display they had studied and could refer to it throughout the test phase. Thus the experiment used a 2x2 design, with representation (List, Matrix) and test condition (Display-Absent, Display-Present) as the factors and different participants in each of the four resulting groups.

Results and Discussion

Participants who viewed the Matrix performed better than those who viewed the List, as shown in Figure 5. This effect was pronounced for inferential questions, which were more difficult than factual questions. Not surprisingly, performance was worse when participants could not consult the displays during the test phase (Display-Absent), since they had to rely entirely on memory to answer the questions. These participants had no memory load at all – they just had to comprehend and find the information before them. Nevertheless those who used the List performed worse than the Matrix group even when the display was right in front of them, suggesting that this format can impede search and comprehension as well as memory.

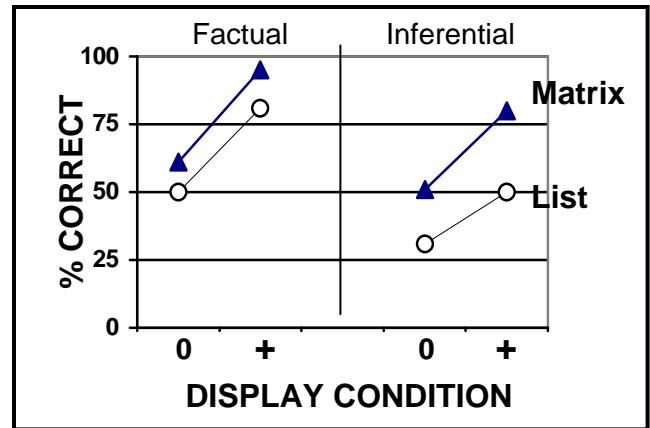


Figure 5 – Performance of participants who used the List or Matrix format, when the display was Absent (0) or Present (+) during testing, for factual vs. inferential test questions.

Curiously, having the List present during testing sometimes provided no benefit. Figure 6 shows results for an inferential question involving a real-world scenario (how many pills to take on a trip given time of departure from home and return later). Although not significant, the downward slope of the list line (from Display-Absent to Display-Present) suggests that being able to view the List may have made matters worse. The possibility that some types of displays are better read and ignored later must be confirmed in future testing with more scenario questions.

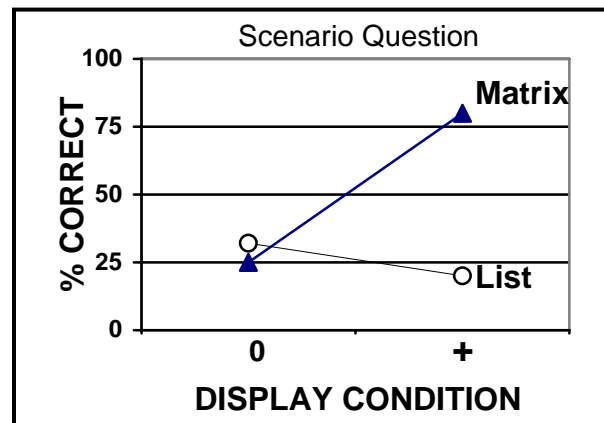


Figure 6 – Performance of participants in the same conditions as shown in Figure 5, for a real-world scenario question.

“Best” Representation. Overall the Matrix was superior to the List for the medication schedule. However the List was still useful in answering factual questions and may be satisfactory for other tasks not tested here, such as remembering the names of the drugs. Thus when we ask which form of representation is “best,” we must also ask

“best for what?” The relative success of representational formats may vary depending on the nature of the cognitive task and/or action to be performed. This principle is central to the alternative representations approach [2].

Alternative Representations of Side Effects

The overall format used to display side effects can affect how easily people can understand them, remember them, and know what actions to take if they occur. Below are some alternative representations for the same set of side effects for a hypothetical drug. The example is used to illustrate just some of the possible ways to display side effects. Results from laboratory experiments on these and other alternative displays are provided in [17].

Paragraph Format

A typical way to represent side effects is in paragraph form, which is widely used in both patient and professional information sources. Even within this traditional format, there are alternative versions, as shown in Figure 7. The Plain Paragraph just strings out the side effects, without categorizing them in any way. It also introduces them with the neutral term “include” that provides no information about their severity or likelihood of occurrence.

The Categorized Paragraph chunks and codes side effects using the severity terms “dangerous,” “worrisome,” and “mild.” They could also be categorized by frequency terms such as “more common,” “less common,” and “rare.” (Note: the use of the severity and frequency terms in this example is not a recommendation that they “should” be used; for research on how people perceive these and other terms, see [18, 19]). Although the Categorized Paragraph adds descriptor terms and syntactic structures to cluster subsets of side effects together, it still looks like the Plain Paragraph. It does not provide distinctive visual cues for the semantic categories it provides. Additional enhancements could do so, such as underlining the descriptor terms.

<u>Plain Paragraph</u>
Possible side effects include chest pain, slurred speech, seizure, anxiety, joint pain, weakness, dry mouth, headache, and nausea.
<u>Categorized Paragraph</u>
Possible dangerous side effects include chest pain, slurred speech, and seizure. Some are worrisome such as anxiety, joint pain, and weakness while others are generally mild such as dry mouth, headache, and nausea.

Figure 7 – Alternative versions of the Paragraph Format for representing the same side effects.

List Format

The same set of side effects is also shown in the List Format (Figure 8). The Plain List makes it easier to see about how many side effects there are overall. This is useful information for comparing side effect profiles across drugs and for knowing about how many to watch for during the course of treatment. It may also facilitate remembering which side effects are possible.

The Chunked List goes beyond just categorizing the side effects by severity (as in the Categorized Paragraph), since it also separates the severity groups with blankspace. This particular version also makes the descriptor terms more visually distinctive (different font style, larger font size, bolded, underlined).

<u>Plain List</u>	<u>Chunked List</u>
--chest pain --slurred speech --seizure --anxiety --joint pain --weakness --dry mouth --headache --nausea	<u>Dangerous</u> --chest pain --slurred speech --seizure <u>Worrisome</u> --anxiety --joint pain --weakness <u>Mild</u> --dry mouth --headache --nausea

Figure 8 – Alternative versions of the Paragraph Format for representing the same side effects.

Line Format

Linear order diagrams show how items vary along a single dimension such as severity or frequency. One type of linear diagram is the simple Line Format as shown in Figure 9. It emphasizes various aspects of the information including the similarities and differences in severity among items; the relative number of items in each chunk; and the degree of severity for each set chunk. It also can reduce the number of category names needed to just the high and low anchor points.

<u>Line</u>		
Mild		Dangerous
dry mouth	anxiety	chest pain
headache	joint pain	tingling
nausea	weakness	seizure

Figure 9 – Line Format for representing the severity (or frequency) of side effects.

Arrow Format

The Arrow Format also provides linear order, as shown in Figure 10. The arrow emphasizes the increasing magnitude of severity and directs attention to the most severe side effects. Other optional enhancements include larger bold characters for the most severe items and smaller italicized characters for the mild ones (such enhancements can be used in other formats as well). The anchor points can be either linguistic as shown for the Line Format in Figure 9, or pictorial as shown for the Arrow.

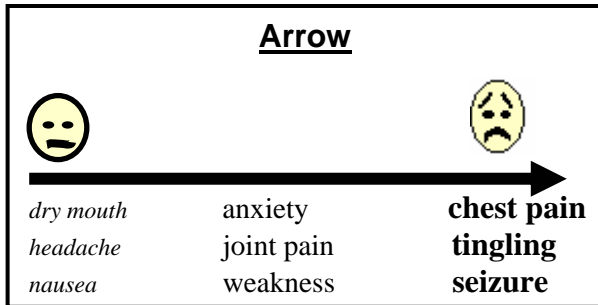


Figure 10 – Arrow Format for representing the severity (or frequency) of side effects.

Pictograms can add interest and might help people with lower literacy levels. However, comprehension testing is essential before using them. Even well known symbols can be misinterpreted. For example, when we showed a standard pictogram with a pregnant woman and a question mark intended to mean “Are you pregnant...?” participants gave multiple interpretations including, “She’s wondering whether to tell her boyfriend” [13].

Matrix Format

Two major dimensions underlie side effects – severity and frequency of occurrence. The Matrix Format displays both types of information, as shown in Figure 11. For simplicity, only two semantic categories are displayed for each dimension. Note that the descriptor terms for each dimension are just examples; for cautions about using specific severity and frequency terms, see [18].) An advantage of the Matrix is that it can show empty cells – in this case, showing that dangerous side effects are rare.

Matrix		
	Dangerous	Mild
Common		dry mouth
Rare	chest pain tingling seizure	headache nausea

Figure 11 – Matrix Format for representing both severity and frequency of side effects.

Other Formats

We have developed and tested other types of formats for representing side effects, in addition to those shown here. All have advantages over the Plain Paragraph, although some are better than others. The percentage increase in performance from Original to Enhanced Displays can be dramatic – from 80% to 800% in some cases [17].

General Discussion and Implications

Cognitive Accessibility

Experiments using Original Displays of drug information show that poor cognitive accessibility of information is a major contributor to poor comprehension. Also, performance on risks is significantly worse across a wide range of materials and cognitive tasks. The problem is not simply that people find risks “scary,” since when we repeat experiments with the same risks using Enhanced Displays, performance improves, often dramatically.

Cognitive accessibility must be considered for all types of drug information, especially risks. Otherwise materials may meet regulatory and legal criteria for “providing” risk information, yet fail to communicate it. Therefore this work reveals an important principle:

Information can be physically present
yet functionally absent.

Alternative Representations

An unlimited number of alternative representations can be generated. However “fixing” one problem with a new design may make something else worse. Therefore it is important to design new representations based on cognitive principles and evaluate them in comprehension testing.

Participants

The basic results reported here for laypersons occur across a wide range of demographic factors, including age and education level [13]. Although younger and more educated people may have higher overall performance scores on some tasks, they still show the *same pattern* of results – poor performance on risks but significant improvement with Enhanced Displays.

Healthcare professionals should do better overall than laypersons in these types of experiments, and they do. Nevertheless they still show the *same pattern* of results – poor performance on risks relative to benefits but improvement with Enhanced Displays. Despite their substantial knowledge about prescription drugs they are still human, with the same basic cognitive processes as others. They too can be overloaded, have trouble using

documents with low cognitive accessibility, and can miss or misunderstand some of the information.

Health Outcomes

Relying on information sources with poor cognitive accessibility can decrease the effectiveness of drug treatment and increase the probability of medical error. For example, a physician may not find or remember a specific drug-drug interaction in the *Physicians Desk Reference* and prescribe a drug that interacts negatively with one a patient is already taking. Although electronic prescribing technology can reduce this type of error, it does not eliminate it. The way information is provided in any medium can contribute to errors.

Patients also need to understand risks as well as benefits. It can affect their compliance with instructions and their knowledge of what to do if side effects occur. Therefore enhancing the cognitive accessibility of risks is also critical for laypersons to achieve good health outcomes.

Interdisciplinary Research

Although based primarily on cognitive principles and methods, this research is interdisciplinary in nature. It uses concepts and perspectives from linguistics, cognitive science, computer science, medicine, pharmacy, and public policy. For example, issues common to cognitive science and artificial intelligence include representation, the nature of expertise, and the design and use of intelligent systems. This work also provides a testbed for studying cross-discipline concepts in the context of a real-world setting.

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