Redesigning Prescription Labels for Alzheimer's Patients:

A Human Factors Approach

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Introduction

The progressive cognitive decline associated with Alzheimer's disease presents profound challenges in medication management, representing a critical intersection of neurological impairment and patient safety. According to the Alzheimer's Association (n.d.), approximately 6.2 million Americans currently experience Alzheimer's-related cognitive deterioration, and medication administration has emerged as a particularly vulnerable domain of patient care. This decline affects patients' ability to correctly interpret and act on prescription labels, leading to increased risks of medication errors, which can compromise treatment efficacy and endanger patient safety (University of Michigan Health, 2022).

Existing prescription labeling systems fundamentally fail to address the complex cognitive processing limitations inherent in neurodegenerative conditions like Alzheimer's. Patients with Alzheimer's disease experience progressive deterioration in working memory, visual information processing, and the ability to comprehend complex instructions. These limitations directly affect their ability to identify medications, interpret dosages, and correctly time their administration (Exponent, 2021). The cognitive load required by traditional labels, which often rely on small font sizes, technical drug names, and detailed phrasing, creates significant barriers for users and increases the likelihood of errors (FDA, 2016).

Current labeling practices are shaped by the requirements of the Code of Federal Regulations (CFR) Title 21, which mandates the inclusion of essential information, such as patient and prescriber details, dosage instructions, warnings, and refill information, to ensure safety and compliance (FDA, 2017). While these regulations are necessary to

maintain consistency and legal accountability, they inadvertently contribute to cognitive overload for patients with Alzheimer's, as the dense and unstructured presentation of information is difficult to navigate and comprehend (FDA, 2022).

To address these challenges, this study proposes a redesigned prescription label that incorporates human-centered design principles and is presented as a sleeve. The sleeve format allows all legally required information to remain present, as mandated by CFR Title 21, while prioritizing accessibility and usability for the patient. The redesigned portion of the label, located on the outer sleeve, features large, high-contrast fonts, clear purpose statements (e.g., "Blood Pressure"), and simplified dosage instructions (e.g., "1 Morning"). These design elements align with human factors principles, including the reduction of cognitive load and enhancement of visual clarity (Rey-Galindo et al., 2023).

The inner portion of the sleeve retains the detailed information required by labeling guidelines, including the drug's manufacturer name, appearance description, time-of-day icons, and generic versus brand names, ensuring full compliance with CFR requirements. By organizing this information hierarchically and placing the most actionable details on the outer sleeve, the design minimizes the cognitive burden on users while still meeting regulatory standards (FDA, 2017; Exponent, 2021).

This study aims to empirically evaluate the redesigned label through task-based usability testing, focusing on error reduction, comprehension, and user confidence. The redesigned label is intended to serve as a supportive cognitive interface that transforms medication labeling from a source of potential patient risk into a tool for enhanced safety and efficacy. By addressing the intersection of cognitive impairment and patient safety through human-centered design, this investigation seeks to establish a framework for

medication labeling that is both legally compliant and user-friendly for individuals with Alzheimer's disease.

Human Factors Principles Contribution

The design prioritized minimizing cognitive load by simplifying the language on the labels. Instructions like "Take one tablet every 8 hours" were replaced with clearer, more actionable phrases such as "1 Morning" or "1 Night." Additionally, purpose labels like "Blood Pressure" replaced technical drug names, reducing the need for users to interpret or recall complex terms. This approach ensured that essential information was immediately understandable and easy to process.

Enhanced visual accessibility was another critical consideration. The redesigned labels featured large fonts to improve readability and black text on a white background to ensure high contrast under varying lighting conditions. By avoiding clutter and presenting essential information in a simplified layout, the labels accommodated users with visual impairments or age-related challenges.

To support safer medication use, the labels incorporated features aimed at preventing errors. Clear purpose statements reduced confusion when managing multiple prescriptions, while simplified timing instructions such as "1 Morning" reduced the likelihood of misinterpreting dosage instructions. Consistent formatting across all labels allowed users to quickly and confidently locate the necessary information.

The design also emphasized intuitive information processing by organizing details hierarchically. Critical information such as the medication purpose and dosage appeared at the top, with less essential details placed below. Familiar symbols and

straightforward phrasing further supported intuitive recognition, ensuring that users could easily understand the labels even in cases of cognitive decline.

Finally, user-centered design principles ensured the labels were practical and effective. Feedback from individuals with and without cognitive impairments highlighted challenges with traditional prescription labels, such as difficulty locating or interpreting instructions. These insights informed the redesign, making it a practical solution tailored to the needs of its intended users.

Methods

This study employed a comparative experimental design to evaluate the usability of traditional prescription labels against a redesigned label optimized for accessibility and error reduction. The redesigned label featured human-centered design principles, including large, high-contrast fonts for improved readability, clear purpose statements (e.g., “Blood Pressure”) to reduce cognitive load, and simplified dosage instructions (e.g., “1 Morning”) to facilitate understanding. The study aimed to assess how effectively each label design supported accurate medication identification, interpretation, and usage across diverse cognitive abilities.

To mimic real-world medication management scenarios while maintaining ethical and practical considerations, participants engaged in a task requiring them to sort medications into a weekly pill organizer. This scenario was chosen as it represents a common practice among prescription medication users, particularly those managing multiple medications or complex dosing schedules. By simulating the organization of medications for an entire week, the study created a realistic context in which

participants interacted with multiple bottles simultaneously, reflecting the challenges faced in everyday medication management.

The simulated setup incorporated multiple steps, allowing for a comprehensive evaluation of the labels. Participants were required to:

1. Identify medications: Match bottles to specific scenarios provided by the facilitator.
2. Interpret instructions: Understand the purpose, dosage, and timing information provided on the labels.
3. Act on instructions: Accurately sort the medications into the appropriate compartments of the weekly organizer.

These steps aligned with the Hierarchical Task Analysis (HTA) framework, enabling detailed observation of each participant's performance and the identification of specific points of difficulty or error.

The study included two participants, selected to represent distinct user profiles:

1. Participant A: An individual with mild cognitive impairment. This participant exemplified the challenges faced by users with reduced working memory, impaired information processing, and difficulty interpreting complex instructions.
2. Participant B: An individual without cognitive impairment. This participant served as a baseline for comparison, demonstrating how users with typical cognitive functioning interacted with the labels.

Traditional Label:

A standard prescription label can have anywhere from 20-25 cognitive load units, The inclusion of many of these units is not arbitrary; it is mandated under the Code of

Federal Regulations Title 21 (CFR Title 21), which outlines the legal requirements for prescription labels in the United States. The regulations ensure that prescription labels provide sufficient information to promote safe and effective medication use, including but not limited to:

1. Pharmacy and Prescriber Information
    a. Pharmacy name and address, contact information, prescribing doctor's name and address
2. Patient Information
    a. Name, RX Number
3. Medication Information
    a. Brand name of medication, generic name if applicable
    b. Appearance Description e.g., "Oblong blue tablet"
    c. Manufacturers name
4. Dosage and Administration Instructions
    a. Specific dosage amount, frequency
    b. Time of day Icons like a sun and a moon
    c. Administration route e.g., "orally"
5. Warnings and Additional Instructions
    a. Usage warnings e.g., "take with food"
    b. Storage instructions
6. Refill information
    a. Number of refills
    b. Expiration date

Redesigned Label:

The redesigned prescription label, with its large black font on a white background, significantly improves readability by ensuring high contrast and reducing visual strain, especially for individuals with impaired vision or cognitive challenges. Clear purpose statements like “Blood Pressure” eliminate the need to recall or decipher complex drug names, making it easier for users to identify the medication’s purpose. Simplified dosage instructions such as “1 Morning” replace technical and detailed phrasing with concise, actionable language, reducing the cognitive effort required to interpret the instructions. These features collectively enhance accessibility, minimize confusion, and support safer medication management.

HTA

Mock pill bottles were used to simulate real-world conditions for both designs. Participants performed three tasks with each label design:

1. Identify Medication:
    - Locate the label on the bottle.
    - Determine if it matches the intended medication based on a provided scenario.
2. Understand Instructions:
    - Interpret the dosage and timing instructions on the label.
3. Act on Instructions:
    - Simulate taking the correct dose at the specified time.

For each label design, the process of completing these tasks was analyzed using Hierarchical Task Analysis (HTA):

- Identify medication: Locate and read the label.
- Understand instructions: Interpret and comprehend dosage/timing.
- Act on instructions: Simulate the action of taking medication.

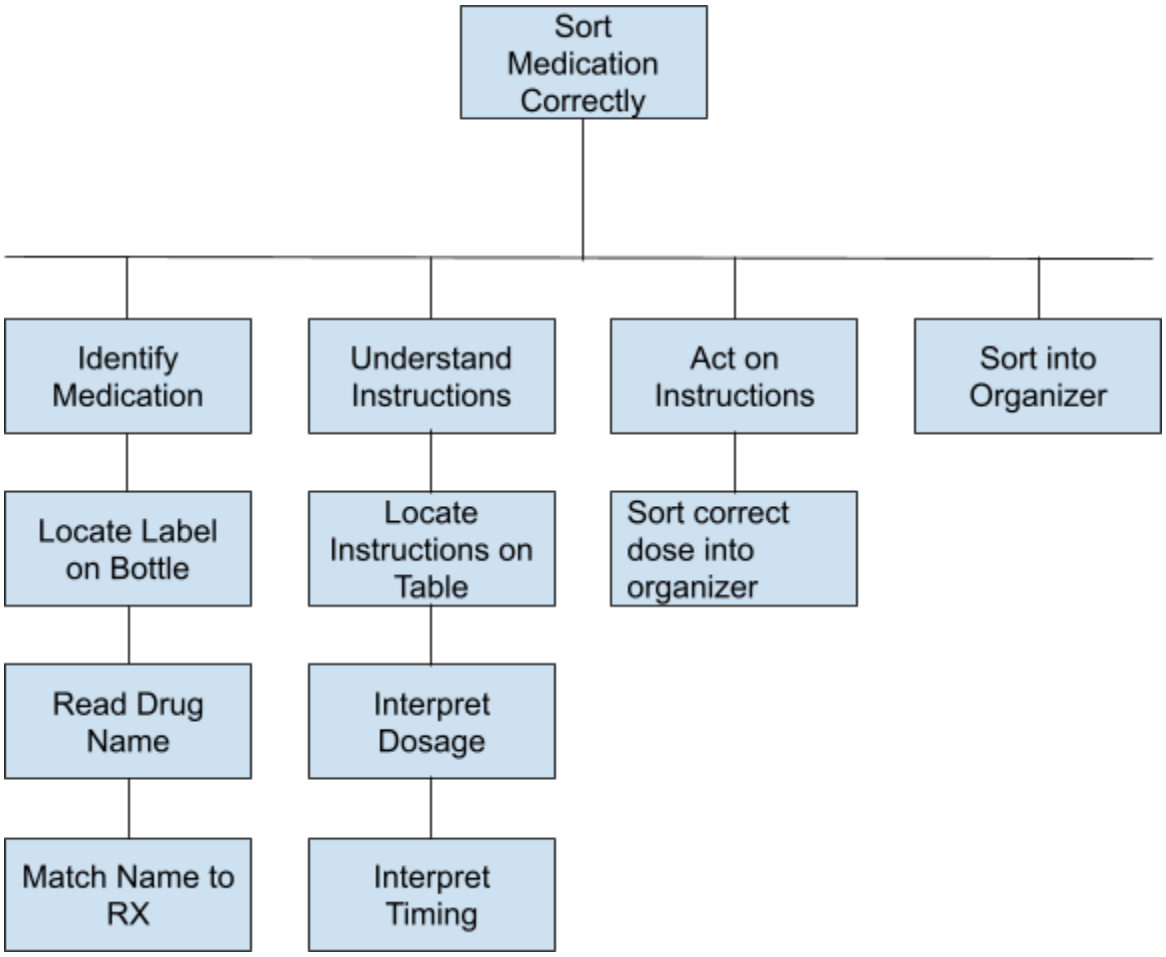
Data Collection

- Task Accuracy: Assessed whether participants completed tasks correctly.
- Error Rate: Recorded instances of incorrect identification, interpretation, or actions.

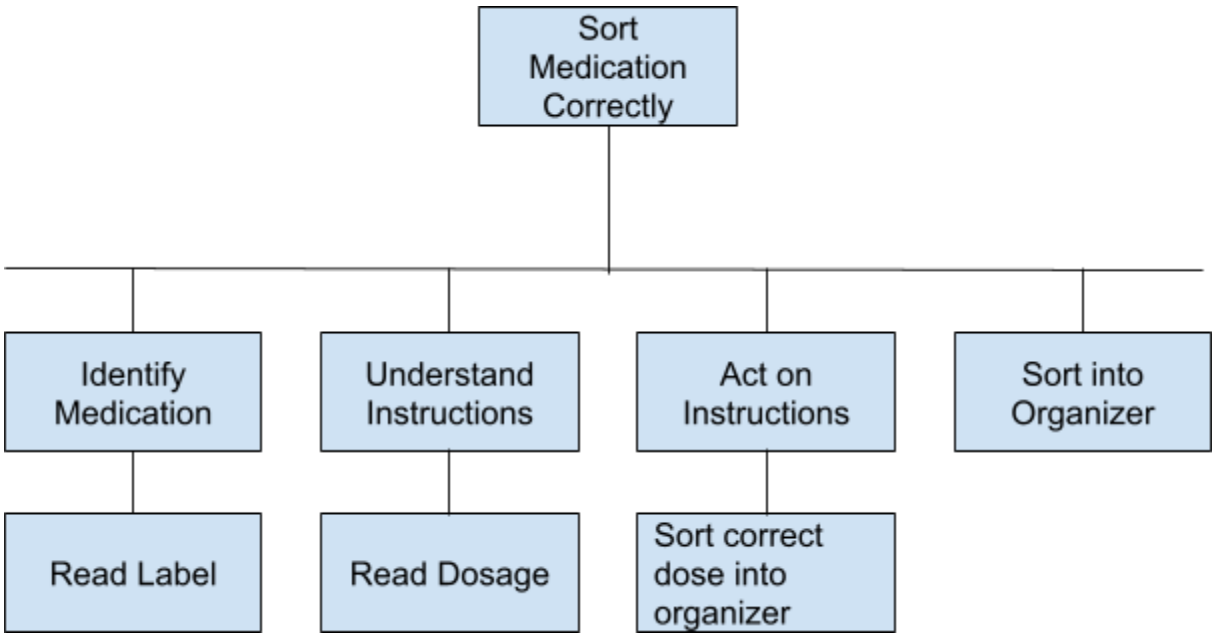
The following metrics were used to compare the two designs:

- Task Success Rate: Percentage of tasks completed correctly.
- Error Frequency: Number of errors in identification, interpretation, or execution.

Goal: Sort medication correctly (Traditional Label)



Goal: Sort medication correctly (Redesigned Label)



Results

The study used a task-based scoring approach to evaluate performance and usability for both the traditional and redesigned prescription labels. Participants began with a baseline score of zero, with each error resulting in a deduction of one point. Errors included observable mistakes such as misinterpreting dosage instructions, needing to reread the label to clarify information, or asking the facilitator for assistance. This scoring system, applied across all steps and subtasks in the Hierarchical Task Analysis (HTA), provided a structured way to assess the cognitive and usability challenges associated with each label design.

For the traditional label, there were twelve opportunities to lose points, corresponding to the complexity of the Hierarchical Task Analysis (HTA) and its subtasks. The traditional design's dense layout, small font, and complex phrasing significantly increased the likelihood of errors, especially for users with cognitive impairments. The participant with mild cognitive impairment experienced considerable challenges, recording four errors, two instances of rereading the label for clarification, and one instance of asking the facilitator for help. These mistakes highlight the substantial cognitive load imposed by the traditional label, which requires users to hold multiple pieces of information—such as the drug name, dosage, and timing—in working memory. The complexity of the phrasing and the effort required to decode critical information exacerbated the participant's difficulties, illustrating how traditional labels fail to accommodate users with reduced cognitive processing capabilities.

The participant without cognitive impairment encountered fewer challenges, completing all tasks with zero errors, zero rereads, and no requests for assistance.

However, this does not imply that the traditional label is free of usability issues; the non-impaired participant still needed to dedicate cognitive effort to decipher and act on the instructions, even if these challenges did not manifest as observable errors. The lack of mistakes for this participant highlights the resilience of typical cognitive abilities but does not negate the inefficiencies inherent in the design.

In contrast, the redesigned label had only eight opportunities for errors due to its simplified structure and reduced cognitive demands. By streamlining the steps and subtasks in the HTA, the redesigned label inherently reduced the number of opportunities for users to make mistakes. The participant with cognitive impairment experienced a marked improvement, recording zero errors and only one instance of rereading the label for clarification, with no requests for assistance. This demonstrates how the simplified instructions, such as “1 Morning,” replaced complex phrasing like “Take one tablet every eight hours,” significantly reducing the cognitive load and eliminating potential sources of confusion. The clear purpose statements, such as “Blood Pressure,” removed the need to decode the drug name, a frequent source of errors in the traditional label, and provided an intuitive interface for identifying the medication’s purpose.

The participant without cognitive impairment also performed perfectly with the redesigned label, maintaining zero errors, zero rereads, and no requests for help. This consistency across participants with and without impairments underscores the effectiveness of the redesigned label in supporting diverse cognitive abilities. By prioritizing clarity and usability, the redesign not only minimized the cognitive effort required to complete the tasks but also improved overall user confidence and efficiency.

These results emphasize the importance of reducing complexity in critical information interfaces. The reduced number of steps and subtasks in the redesigned label directly contributed to fewer opportunities for errors, reflecting a fundamental principle of human factors engineering: the elimination of unnecessary complexity enhances usability and safety. Furthermore, the improved performance of the cognitively impaired participant demonstrates how a human-centered design approach, informed by an understanding of cognitive limitations, can transform medication labeling into a supportive tool rather than a potential source of risk. The traditional label's challenges and the redesigned label's success together highlight the critical role of cognitive load management, visual accessibility, and intuitive organization in creating safer, more effective interfaces.

Traditional Label Total score = -7

Participant	Errors	Reread Label	Asked For Help	Score
Impaired	4	2	1	-7
Not Impaired	0	0	0	0

Redesigned Label Total score = -1

Participant	Errors	Reread Label	Asked For Help	Score
Impaired	0	1	0	-1
Not Impaired	0	0	0	0

This scoring approach aligns with key principles of Human-Computer Interaction (HCI) and human factors. First, it reflects the principle of error tolerance, which

emphasizes designs that minimize the risk of user errors and make tasks easier to recover from. By reducing the number of steps in the redesigned label, the design inherently decreased the cognitive load and opportunities for mistakes. Second, the approach adheres to the concept of cognitive load management by externalizing information that would otherwise need to be held in working memory. This externalization is especially critical for users with cognitive impairments, who may struggle with processing and retaining complex instructions.

Additionally, the redesigned label applies the principle of simplicity and clarity to improve task performance. The fewer points of potential failure reflect a design that aligns with users' natural limitations in attention, memory, and perception. The traditional label's complexity required users to continuously interpret, verify, and act on fragmented information, increasing cognitive strain and reducing task efficiency. In contrast, the redesigned label structured information hierarchically, ensuring that the most actionable details, such as timing and purpose, were immediately visible and easy to comprehend.

The scoring method also illustrates the impact of usability heuristics, such as consistency and standards and visibility of system status. The redesigned label's consistent layout and prominent display of critical information reduced ambiguity, while the traditional label's inconsistency in font size, phrasing, and placement created additional challenges. By making the most relevant information immediately visible, the redesigned label supported the user's ability to focus on what mattered most, reducing errors and enhancing comprehension.

This approach demonstrates how systematic scoring and task analysis can evaluate usability while driving better design outcomes. The fewer opportunities for error in the redesigned label highlight its intuitive and human-centered design, making it more accessible and safer for all users. By leveraging HCI principles and human factors concepts, the redesign addresses the inherent limitations of the traditional label, ultimately supporting more effective medication management.

Future Evaluation

To evaluate the redesigned prescription label, I would use a combination of surveys, rating scales, and open-ended questionnaires. These tools would allow for both quantitative and qualitative feedback, providing a comprehensive understanding of the label's usability and effectiveness.

Participants would begin by completing a structured survey featuring Likert-scale questions to rate various aspects of the label, such as clarity, readability, ease of use, and overall satisfaction. For example, participants might rate how easy it was to identify the medication's purpose or understand the dosage instructions, using a scale from 1 (very difficult) to 5 (very easy). This standardized approach would quantify user perceptions and help identify trends or areas needing improvement.

To complement the survey, participants would answer open-ended questions in a follow-up questionnaire. These questions would invite participants to reflect on their experience with the label, such as describing any difficulties they encountered or features they found particularly helpful. For example, a question might ask, "What changes, if any, would you suggest to make the label easier to understand?" This

qualitative data would provide deeper insights into user behavior and preferences, capturing nuances that a rating scale alone might miss.

Additionally, a task-specific usability rating scale could be used after participants complete specific tasks, such as sorting medications into a weekly pill organizer. Participants would rate the label's effectiveness in guiding them through the task, focusing on elements like error prevention, confidence in following the instructions, and perceived mental effort.

For healthcare providers and caregivers, the evaluation would include a tailored questionnaire to gather their perspectives on the label's impact on safety, error reduction, and ease of use for patients. This stakeholder feedback would ensure the label is evaluated in the broader context of medication management.

By combining these methods, the evaluation would provide a holistic view of the redesigned label's performance, balancing measurable outcomes with user experiences and expert opinions. This multi-faceted approach ensures that the label's usability and safety are rigorously assessed and that future iterations address any remaining challenges.

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