Usability Testing of Medication Packaging in a Pharmacy Environment

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To better understand the pharmacy medication dispensing process and its relationship with packaging and labeling, two studies were conducted: one was a contextual inquiry involving the interview of 13 experienced pharmacists and pharmacy technicians; the other was a usability test of 30 pharmacists and pharmacy technicians specifically related to a particular product family in a simulated pharmacy environment. The interviews of the contextual inquiry provided the basic understanding of the prescription’s journey from doctor to patient in the US. The usability study also provided information about a prescription’s journey and the importance of safeguards that exist in a real pharmacy environment to prevent dispensing errors.

BACKGROUND

The Institute of Medicine’s report, To Err is Human: Building a Safer Health System, recommended that the FDA develop and enforce standards for the design of drug packaging and labeling that will maximize safety in use. In December 2012, the FDA issued a draft guidance for the industry, Safety Considerations for Product Design to Minimize Medication Errors. While this guidance is distributed for comment purposes, there is clear emphasis on a systems approach to the medical product’s entire use environment, including those intermediate users who prescribe and dispense. Pharmaceutical companies should consider specific design and test activities that mitigate the risk of medication dispensing errors.

OBJECTIVES AND APPROACH

This presentation covers two aspects of packaging and labeling development: the contextual inquiry of the pharmacy process and a medication packaging usability test in a simulated US pharmacy.

1. Contextual Inquiry. The contextual inquiry consisted of interviews aimed to provide understanding of specialty and retail pharmacies to inform the design of simulated environments in future research. Specifically, these interviews were intended to provide a complete and accurate understanding of four key aspects of the pharmacy: 1) Physical environment, layout and organization of a pharmacy. 2) Interactions among staff, customers and record-keeping systems. 3) Work flow of pharmacists and technicians in filling a prescription. 4) How a pharmacy staff is made aware of new medications on the market.

Most (8/13) pharmacists and technicians who were interviewed worked in retail and specialty pharmacies, one worked in a hospital setting, and four were from pharmacies that included a compounding component. Retail pharmacies were characterized by routine interaction with customers and small, interactive staffs.

2. Pharmacist and Pharmacy Technician Usability Test. A usability test was conducted to assess whether selection errors would occur between a proposed package/product and existing on-market products. Thirty people (15 specialty pharmacists and 15 specialty pharmacy technicians) participated in the study. The specialty pharmacists and specialty pharmacy technicians were divided into pairs so that each session involved a pharmacist in one room and a pharmacy technician in the other room working to complete a number of prescription orders. Results were evaluated by participant pair. Successful task completion required the correct order to be selected and placed in a bag by the pharmacy technician and a final review by the pharmacist who stapled the bag to be placed in the patient bin. A close call was defined as a pharmacist correcting an order that was incorrectly filled by a technician.

Prescriptions including various dosage forms, strengths and package presentations within a single product family were filled. Qualitative discussions were conducted with the participants to assess if the packaging design was a factor in the close calls or errors.

CONTEXTUAL INQUIRY OF PHARMACY

1. Pharmacy Personnel. The key players in all pharmacies interviewed were one or more pharmacists and several technicians. In one small, independent pharmacy, the owner was also present and responsible for ordering inventory.

In all cases, pharmacists were legally responsible for checking that medications had been filled correctly prior to their leaving the pharmacy, at times even during the dispensing process. Pharmacists were also responsible for entering prescriptions called in by physicians (where there was no paper record). In small pharmacies, the pharmacist might also do a majority of the filling. Pharmacists were responsible for answering patients’ questions if these were about something other than what was printed on the label (which the technician could review with a patient). Lastly, pharmacists completed all work flow steps (access, dispensing and restocking) for controlled substances.

Pharmacy Technicians reported doing many of the tasks required in the pharmacy under supervision of the pharmacist such as: entering prescription information, scanning prescriptions, running insurance information, handling billing questions and filling and/or packaging prescriptions.
Technicians also typically restocked new inventory. Pharmacy technicians would be the first point of contact for the customers’ questions, but the pharmacist would answer any questions that could not be read directly from product labeling.

2. Movement in the Pharmacy. All participants described the pharmacy environment as very fluid with only one exception. Though a few had designated work stations, these stations were arranged more around tasks than users. Most described several computer terminals, each of which could be used by any staff person to complete their tasks. Some participants described a more anchored pharmacist station where the pharmacist was based and where technicians would bring and stack prescriptions that needed to be checked by the pharmacist.

3. Organization of Space. Though each pharmacy differed in layout, there were patterns among them. The layout in Figure 1 is meant to show a visual mock-up of a combination of numerous pharmacies. Most pharmacies had a fairly open floor plan; with some exceptions (notably very large mail-order pharmacies), pharmacists and technicians were working together in the same space.

Most pharmacies had refrigerators that were often in a back room or another separated location. Specialty pharmacies often had more refrigerators than retail pharmacies and usually kept these together in one place.

4. Storage of Medications. While most pharmacies alphabetized their medications by product name, the major difference centered on generic medications; in some pharmacies, generics were stored with the brand name equivalent, in others, they were stored by their own name. Some pharmacies had their own organization scheme such as grouping drugs from the same manufacturer together. Within the alphabetical setup, each product was then arranged from low to high dosage.

All pharmacies had areas of shelving dedicated to specific kinds of drugs, kept separate from the others. In all cases, these were types of treatment, such as creams and/or liquids/suspensions, and these were typically stored on a different area of the shelf from the pills and capsules, but also organized alphabetically. At least one of the pharmacists described an area of shelf that was for new medications that were waiting to be filled into the general inventory.

In order to quickly identify the correct medication, all pharmacies shelved their medications with the front of the box facing forward. For pill bottles, the label faced forward.

5. Refrigeration. In the refrigerator, medication boxes and bottles were stored as space constraints would permit. Most pharmacies laid boxes face up, short end forward, though some stacked them sideways instead of on top of each other to use space more efficiently. Because the refrigerator typically contained a fairly small number of medications, these were, in most cases, grouped by medication type. For instance, all insulin was grouped together and all nasal sprays were grouped together.

6. Medication Identifiers. Pharmacists and technicians typically looked for three key pieces of information when picking medication: the medication name, dosage and National Drug Code (NDC). Since the NDC was distinct for each specific dosage of every medication, many said that this was the most foolproof way to make sure they had the correct medication. Others, particularly those with handheld scanners, said that they would simply scan the barcode on the prescription and that on the bottle they would use to fill the prescription, and thereby confirm the match. For many, especially the pharmacies without scanners, it was crucial to match the NDC code. Even those with scanners found that verifying that the NDC codes matched was the best way to know that they had picked the correct medication from the shelf.

**PHARMACY PROCEDURE**

Most pharmacies followed a similar pattern from the point the prescription entered the pharmacy to the point it was delivered to or picked up by the customer. Pharmacists were always responsible for checking that the prescription had been entered correctly and filled correctly prior to it reaching the customer.

Most participants indicated that their pharmacy had documented Standard Operating Procedures (SOP). While not all pharmacists had a written SOP, those without a documented set of rules were the exception rather than the rule. These procedures fell along a spectrum of rigidity, from very scripted and formalized to more relaxed. Regardless of where they fell, all pharmacies had a standard way of processing prescriptions, whether this was communicated in a formal written procedure or merely by watching other staff.

Large retail chains typically had formal training and very defined procedures. Most smaller pharmacies had a standard operating procedure, but it was less formal than some of the larger pharmacies. In these cases, there might not be formal
training, but the written rules were available to staff and staff were required or expected to read through them independently or reference them as necessary.

1. Arrival in pharmacy. Prescriptions typically arrived in pharmacies in one of four ways: called in directly by a physician, sent electronically, faxed by the physician or dropped off in person. Most participants said that the number of electronic prescriptions outweighed other types of prescriptions. Most of the prescriptions that arrived in the pharmacy were entered into the pharmacy’s computer system by a pharmacy technician. This excluded phone-in prescriptions, which were received by the pharmacist.

If the prescription was missing information, the pharmacy usually needed to contact the physician to find this information. One technician explained that the first step was to consult the pharmacist, and then to reach out to the doctor’s office if necessary. Since technicians typically gathered and entered patient information, they would follow up with customers or physicians (if necessary) regarding information unrelated to the medication itself.

With a few exceptions, most participants in this study recounted not having experienced custom prescription forms.

2. Filling Process. The filling process began in many cases once the prescription was successfully entered into the computer. Once fully entered, a label was printed which contained the information entered into the computer. The label also contained the NDC code of the product chosen to fill the prescription. Most said they looked for the name and strength of the medication on the packaging as well as the NDC to match the printed label (which in turn should match the prescription). In pharmacies that had scanners, the barcode on the label and the selected medication was scanned to verify that the NDC code in the RX number and on the medication container matched. If they did not match, the computer alerted the user that something was wrong. Once a medication was selected from the shelf and matched with the label, it was counted to order. Checking that the label matched the prescription was often a component of the final check and sometimes constituted a separate step prior to the prescription actually being filled.

In some cases, the technicians double counted and marked the bottle accordingly in order to signal they had done so to the pharmacist. In some cases, the label was put on the vial at this point, though in others, the pharmacist labeled the bottle at the end of the filling process. Though there was usually limited space to put the label on a medication (particularly one that came prepackaged in a box), most said that the only rule for adding the label was not to cover “important information”—in one case specifically the NDC.

3. Final Check. After the prescription was filled, the technician left it for the pharmacist to review. Depending on how extensive a review was conducted prior to filling, the final review might cover a few elements. The key purpose of the final check was to verify that the medication in the bottle corresponded with what the doctor specified on the prescription. In the case of a refill, some said that the check they performed was more cursory, just that the medication that was used to fill the prescription matched the prescription itself (e.g. the NDC matched up with the barcode on the label). Sometimes, a visual inspection was done against a picture of the dispensed medication on the computer.

4. Customer Pick-up. In retail and specialty environments where customers were able to pick up prescriptions, the technician usually handled final payment and answered questions the customer had about how to take the medication. Most technicians said that they would only answer questions relating to material printed on the packaging or label, and that all other questions would have to be deferred to the pharmacist. The pharmacist was also responsible for administering any training or instruction for a new drug delivery device, though they said that in most cases, customers received training from their physician prior to receiving the medication.

5. Distractions. In pharmacies large enough to delegate roles to one individual, there was less interaction because phone calls and customers were funneled through a specific person. In smaller environments, interaction was typically very direct and very frequent. Pharmacists and technicians had to balance the normal filling process with customer interactions, with questions for one another and with potential calls from or to physicians. These disruptions could come at unpredictable times.

A number of participants also said that if they were in the middle of a task (like counting medication or checking a medication), they would ask the source of the interruption to wait until they completed the task at hand. All said that there were certain tasks they could not interrupt and that in these cases, they would have no problem asking a customer to wait a few minutes or put a phone call on hold. If a task had to be interrupted, participants said they would get it to a point where they could interrupt and easily pick it up again and arrange it in a certain way or make some other note to themselves of where they had to pick up the task.

6. New Medications. Most pharmacists said they receive updates about new medication types, though not usually regularly or predictably. Pharmacists might receive monthly updates about new medications, and might share this with other pharmacists in their pharmacy. Sometimes, updates about new medications came from drug representatives, though this was not the most common way of receiving these notifications. Technicians sometimes heard about these updates from the pharmacists, but most participants said that they would learn about new medications once a prescription entered the pharmacy. If they did not recognize the prescribed medication, they would ask the pharmacist. The pharmacist might know more about this medication or might look up the medication in case a customer had a question about it.

In cases where a pharmacist was not familiar with a new medication, all participants said they would look it up online. Most said they would not have to reach out to a manufacturer, except in rare cases where a customer asked about medication ingredients. Otherwise, most pharmacists said they would rely on the internet to answer questions to which they did not know the answer.

**USABILITY TEST METHODOLOGY**

This human factors usability study had the following objectives:

- Assess the ability of specialty pharmacists and pharmacy technicians to successfully fill prescriptions across a

range of presentations including the presentations of proposed packaging.

- Assess qualitatively whether there were sufficient differences between the proposed package designs and current designs to ensure accurate product identification and selection in a specialty pharmacy setting.

Users, User Need and Context

For purposes of this usability test, the carton-labeling user was defined as that population of professionals who fill prescriptions, particularly specialty pharmacists and pharmacist technicians. This study tested the pharmacy packaging selection process and verifying this through inspection. The labels were designed to make them distinctive from one another to minimize dispensing errors.

Studies have reported approximately 99% accuracy for all dispensing error types and about 99.9 percent accuracy for critical dispensing errors. Again, this test did not have sufficient samples or a sufficiently realistic pharmacy simulation to compare results quantitatively to field results.

Methodology

The test was conducted as a “lab-based” study where the research facility simulated use and environmental conditions. Each user completed a series of tasks designed to mimic the process of filling a pharmacy prescription. It should be noted that this protocol represented a worse case scenario than would be expected in real life Specialty Pharmacy. There was no data entry into a computer system, no barcode scanning, and no NDC check. Furthermore, no training was provided. Half of the participants were provided with a printout about the introduction of a new product amongst other papers on their desk. The printout was not the top paper.

A more realistic scenario would include some baseline training of the products and locations, emails from Pharmacy with new product introductions, flash alerts on computer screens upon logging into the system for the day, or an area in the pharmacy with new and important information. In addition, prescription verification was typically done prior to the Pharmacy technician selecting the product as well as barcoding verification. In some pharmacies, images on the computer screen were matched to the product to ensure the correct product was selected. Pediatric prescriptions had additional verification and notification steps.

Eight packages with varying numbers of doses, sizes of doses and delivery types of a single drug were included in the study. As the study examined potential dispensing errors due to the introduction of a new package to an existing product family line dispensing errors due to drug mix-up were not tested. There were a number of distinct package features intended to limit dispensing errors, such as package size, package primary and secondary colors, inverted fonts for dose, increased font size for dose on side panel, artistic style, NDC codes and package opening format (side or top opening).

Each 60-minute session started with a brief introduction to the study and test setting. Participants then completed a number of tasks to demonstrate their ability to fill medication orders using prescription order forms, handwritten prescriptions, or phone orders. Participants were asked to complete tasks in a simulated environment as if they were in a real-life work setting. For practical considerations, fatigue or stress of the participants were purposely not included in the study. Because of this, these results should not be extrapolated to a full work day.

1. Interview. Prior to each set of tasks, the participants were asked questions about their experiences (e.g. products they fill in their current/past jobs, number of prescriptions filled each day, size of pharmacy, pharmacy experience (retail, specialty) and number of years working) and to confirm answers provided during the recruitment period.

2. Warm-up Activity. Participants then described the process they typically went through to fill a prescription order. Moderators used this information as a point of comparison as they then explained the room set up and the process required for filling a prescription in the test environment.

3. Task Completion. Next, participants were handed a number of prescription orders and asked to retrieve the correct medication product from a simulated pharmacy shelf. Should a participant have a question, they could use the phone to call a supervisor (pharmacist in the case of pharmacy technicians), the prescribing physician, or patient in order to obtain more information if this is what they would do in their real life work place. The pharmacist and technician were allowed to interact with each other via phone or in person if they wished. An interesting aspect of this study was the use of incoming phone calls and verbal distractions to simulate real-life pharmacy distractions. Another methodological point of interest was the ability of participants to call a simulated doctor on the phone to ask questions regarding the prescription.

4. Primary Tasks.

Prescription Filling, Technician: Trials were composed of eight prescription filling tasks, each requiring the pharmacy technician to select the correct package among several available choices arranged in a refrigerator shelf as found in specialty pharmacies.

Prescription Checking, Pharmacist: The output of the pharmacy technician was passed to the other test room where a pharmacist checked the filled prescriptions before placing them in a bag to be sent to the “patient.”

Prescription Filling, Pharmacist: In order to simulate situations where a pharmacist may need to complete an end-to-end prescription filling task, pharmacists were asked to complete trials in isolation, without the use or participation of a pharmacy technician. These prescriptions were given over the phone. Due to time constraints, not all pharmacists performed this task.

5. Participants. Participants were recruited through an independent recruiting firm using a provided screener. The overall screening criterion was for an even mix of male and females representing a range of experience. 13 males and 17 females participated with an overall average of 12 years of pharmacy experience, ranging from 1—37 years. The average number of years of experience was similar between pharmacists and technicians.

Data were gathered through direct observation and video capture of the participant interacting with the package and the participant’s headshot.

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RESULTS

The most common contributing factors associated with the failures were partially due to unfamiliarity with the multiple new packages (new ones introduced with the new product) or differences between delivery methods of the drug.

The pharmacists and pharmacy technicians worked in pairs to fill the prescriptions. A total of 117 trials (prescriptions) were filled. The key criterion for success was a sealed bag containing an accurate selection of the correct package(s) or the pharmacist setting an incorrectly filled order aside for further review. Based on the key criterion of success, the success rate was 113/117 (97%).

Below is a summary of the failures which the pharmacist did not correct:

- Error #1. The technician filled order for a multiple-dose carton with an equivalent number of doses in several standard packages.
- Error #2. The technician filled order for doses of one delivery type with the equivalent number of doses of another delivery type.
- Error #3. The technician filled order for a package with a given number of doses with a package for a smaller number of doses.
- Error #4. The technician filled the order of a given number of doses of one delivery type with a package of the same number of doses of another delivery type.

Per the errors listed above, 14/15 (93%) pharmacists sent the correct dose equivalent to the patient or correctly returned an order to the technician. This rate of prescriptions filled with the correct dose equivalent across all trials was 116/117 (99%).

Six of 15 participant pairs had close calls, defined as a pharmacist correcting a prescription that was incorrectly filled by a technician. 17 trials were considered close calls with 2 Pharmacy Technicians involved in nearly half 8/17 (47%). More than half of the Pharmacy Technicians had no close calls 8/15 (53%) Three close call errors made with the multiple-dose packages were at least partially due to participants being unaware (53%) Three close call errors made with the multiple-dose packages were at least partially due to participants being unaware (53%).

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Four of the six participants who had close calls misread the prescription forms. Technicians tended to focus on matching the dose amount in milligrams indicated on the prescription with the milligram amount on the medication package, sometimes overlooking whether the prescription indicated a particular package size, an adult versus pediatric patient, or a dosage type.

Post-task interviews confirmed that these mistakes were not caused directly by the package features. Most suggested that the errors were due to lack of training and errors in the pharmacy dispensing process which is beyond the control of the manufacturer of the drug. In no case did the participant suggest changes to the package labeling. Therefore it was unlikely that further modifications to the design/artwork would decrease the instance of errors.

CONCLUSION

The prescription filling process follows similar steps from pharmacy to pharmacy, although there is variability in who performs which steps and how many people are involved in filling a single prescription. Nevertheless, unless a pharmacist is entering and filling the prescription from beginning to end, multiple people are always involved in order to check that there are no mistakes. Along the way, there are aids and shortcuts to help make the process smoother and reduce errors (e.g. scanning a barcode and a medication to automatically compare NDC and using colors to help visually reinforce priority and urgency). In pharmacies that do not have these aids in place, however, the same information is verified.

The human factors study found that the differential amongst the packages were adequate. The changes introduced with the proposed packages were found to be reasonably safe and effective for the intended users, uses, and use environments. Most commonly, the contributing factors associated with the failures were unfamiliarity with some of the packages or dosage types. These mistakes were not caused directly by the package design/artwork itself, therefore it is unlikely that further modifications to the design/artwork would further minimize the residual failure risk. It is important to note that there are multiple safeguards in the pharmacy dispensing setting that work to prevent dispensing errors, such as use of bar code scanning, comparisons of NDC codes, and other quality assurance practices. Thus, findings must be put in context: pharmacies have numerous procedural checks in place to ensure accurate prescription dispensing processes that go beyond just package design and visual inspection. In addition, each specialty pharmacy provides some level of training to their staff and familiarity with the products and packages they dispense.

Based on this research, future simulated use studies involving pharmacies should consider the following:

- Entering the prescription into the computer is a key in the filling process and should be included among tasks.
- Labels showing the NDC code should be provided to pharmacists and technicians since this would have been generated prior to the prescription being filled.
- Consider providing barcode scanners for some patients, though there are pharmacies that do not use them.
- Consider testing pharmacists and technicians in the same room at the same time since they typically work in close physical proximity to each other and provide both help and distractions to each other.
- Consider introducing technicians to new products in some way consistent with the processes in pharmacies (e.g. being asked for it by a customer or being told by the pharmacist that a customer had ordered the new medication) while being cautious not to introduce bias.

Disclosure

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