

A Disconnect in the Process and Understanding of Prescription Medications

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In a country where about 70% of the population takes some form of prescription medication, issues and topics relating to the world of pharmaceuticals should be common knowledge (Mayo Clinic). Today, issues relating to high medication costs, the influences of big business, and drug regulations impact millions of patients who are prescribed medication (Wu). In addition to these issues, many patients could be susceptible to the potential risks and effects of medications due to the lack of a more complete understanding of their prescription drugs (Prescription Labels – Consumer Reports Health). In an attempt to mitigate this misunderstanding, prescription medications come with industry-developed and FDA-approved materials, such as medication guides, which are designed to be read by a patient prior to using the medication. Moreover, these medication guides provide instructions surrounding the specific dosing administration to decrease the chances of serious side effects associated with using the medication, present the potential health risks that could contribute to one's decision to take the medication, or highlight the benefit this medication has towards the patient's well-being, and the necessity for proper compliance (Wolf et al., "A Critical Review").

While previous studies have determined the readability and suitability of medication guides as well as explored the communication between physicians and patients, few have connected the two in regard to the overall effect they have on a patient's understanding of their prescribed medication (Britten et al.; Wolf et al., "Usability of FDA-Approved Medication Guides"). Pharmaceutical representatives often play a substantial role in influencing a physician's understanding of a medication, but it is questionable whether enough information is then conveyed to the patient regarding the medication they are being prescribed (Lexchin 664). Without a general knowledge of the medications they are taking, patients are unaware of the effects and potential risks the medication may impose. While it may be true, defining patients as being "unaware" does not directly associate to the literal sense of them being incognizant of the medication they are taking. This idea of patients being "unaware" relates more to the idea of them being incognizant of why they are being prescribed certain medicine. With a doctor being potentially manipulated by a pharmaceutical representative to push a certain medication, along with a patient's possible aversion to medicine that is not discussed, the medication the patient is prescribed may not be the most beneficial for their particular illness or case (Lexchin 666; Britten et al. 1497).

My study, discussed in this article, was conducted to see if patients understand their prescribed medication and the effects of using them, through

communication with their physician and the use of patient information leaflets (Medication Guides) that come with the medication. This research was of particular interest to me as I am studying to become a physician and majoring in biochemistry at a small liberal arts college.

Literature Review

Prior research has identified a multitude of topics that are relevant to prescription medication literature and the physician-patient interaction. Research analyzing pharmaceutical text types has established how language and the use of language varies across different texts within the field of pharmacology. This research identifies the keywords and lexical bundles most frequently used in four types of pharmaceutical texts: patient information leaflets, summaries of product characteristics, clinical trial protocols, and chapters from pharmacology academic textbooks (Grabowski 24). Analysis of these texts found that keywords and phrases became more simplified within the patient information leaflets and summaries of product characteristics (27). Simplification of these text types may have been for the purposes of the patient's understanding of their prescription, in the case of the patient information leaflets, as well as for physicians and pharmacists to be able to properly understand and issue medications, in the case of the summaries of product characteristics (24). Summaries of product characteristics are included with prescription medications and are a description of the product, including its "pharmacological, chemical, pharmaceutical and toxicological properties as well as of the clinical use to which they can be put" (24). Patient information leaflets can be defined as the pamphlet that comes with each medication providing information on how to take the drug along with other important information associated with the patient, also known as a package insert (27). Regardless of the simplification of these patient information leaflets, other studies have shown that patients still have difficulty understanding these information guides due to their complexity and formatting (Prescription Labels – Consumer Reports Health).

The complexity and formatting are critical to study as prior research has explored the readability of this literature and the levels of literacy required of the patients for comprehension. For example, in a study done by Wolf et al., 185 medication guides were analyzed and given both a Lexile score and a suitability score. Lexile scores are utilized as a measurement of the difficulty and complexity of written passages, while a suitability score is determined by the Suitability Assessment of Materials (SAM) instrument, which is most commonly used to evaluate the appropriateness of written healthcare information. Out of the 185 medication guides studied, only seven met the recommended lexical score that is associated with a reading difficulty of $\leq 8^{\text{th}}$ grade and only one was determined to be suitable according to the SAM analysis (Wolf et al., "Usability of FDA-Approved Medication Guides" 1717).

Along with this lack of understanding of their prescription information, many patients express a sense of dislike for taking medicine or medication in general (Britten et al. 1496). Most patients feel less inclined to convey their concerns or opinions of medications because they think it will infringe on the social interaction with their physician (1502). This becomes an issue that drastically affects a patient's feeling toward their medication because they may be prescribed a medication that they do not want to take but were worried about addressing their opinions to the physician. A patient may feel less inclined to have a shot or an injection and may rather wish to take an oral medication such as a pill, but without proper communication with the physician the preference of the patient may not be taken into account. Even when a patient expresses their opinions or preferences on medication, the extent to which it manipulates the prescription the physician writes is questionable (1502).

Other research has focused directly on the interactions between physicians and detailers, and the issues that arise from them. Detailers are employees of pharmaceutical companies who inform and persuade physicians to prescribe the company's products, also known as pharmaceutical representatives (Lexchin 664). The primary issue regarding detailers is that they have a major conflict of interest. This is the result of their necessity to sell products for their company but to also provide the doctor with information and products that will actually enhance the health of the physician's patients (664). When a detailer's company is asking their employee to promote a specific medication, that is most likely the medication that is given to the doctors, and eventually prescribed to the patients. This process directly manipulates a physician's prescribing habits, which may lead to a physician prescribing a drug that may not be the most specific and beneficial for a patient's particular case (671). If a physician is being continually implored by the detailer to prescribe a medication that treats the general symptoms of an illness and the patient needs a prescription medication for specific symptoms of that illness, the physician may feel inclined to prescribe the medication that treats the general symptoms because it has been so heavily promoted by the detailer. This leaves the patient at a disadvantage.

The readability of medication guides and the variability of the physician-patient interaction indicate that there is a need to improve the patient's understanding of their prescription medications. Therefore, the aim of this study is to examine both medication guides and the physician-patient interaction through participant surveys and think-aloud protocols.

Methodology

Research Design

Through the research conducted in this study, two main questions were addressed: How are communication and literature about prescription medication

conveyed from doctors to patients? How aware are patients of the justification for their prescription medications and the effects of them?

Data for this study was gathered via the distribution of a survey and through think-aloud protocol sessions. The surveys were distributed to twenty individuals and consisted of the following questions: 1) What is your opinion of prescription medications in general (Like or Dislike)? Why? 2) Have you understood the purpose of your past prescription medications? 3) Were you aware of the risks of your past prescription medications while taking them? 4) Have you ever refused to take a medication due to its risks? 5) Did the physician, or nurse via the physician's orders, explain the reasoning behind why they were prescribing that medication? 6) Does the physician usually ask for your opinion regarding your openness to take certain kinds of prescription medications and do you think your opinion is considered by the physician?

For the think-aloud protocol sessions, three groups of four individuals were gathered to discuss their views and opinions of a package insert (Medication Guide) for Advair HFA, "an oral inhalation medication for treatment of asthma in patients aged 12 years and older" (Center for Drug Evaluation and Research). This specific medication guide was chosen because Advair is a commonly prescribed medication for asthma, a lung disease that affects approximately 25 million people in the United States alone (Centers for Disease Control and Prevention). Furthermore, this medication guide was selected as the age range of the participants in this study corresponded well with the age of patients that are afflicted with asthma and therefore prescribed this medication. In these think-aloud protocol sessions, the participants were asked the following questions: 1) Are you familiar with medication guides? 2) How often do you read the medication guide that comes with your prescribed medication? 3) Did you read this entire medication guide? 4) Did it make sense? If so, why? If not, what aspects were confusing? 5) Is the language and terminology understandable? 6) Does the formatting make it easier to read? 7) Are the potential risks and effects of this drug clear and understandable? 8) At what point do you think the risks outweigh the benefit of the medication?

While there is an inherent limitation due to the small sample size of participants, this was intentional as the focus of the study is based on audience experience. Both the surveys and the think-aloud protocol sessions were conducted in March 2017. All participants of the study were 18- to 22-year-old individuals varying in gender and ethnicity, and studying at a small liberal arts college. This study was conducted under existing IRB approval in accordance with institutional policy. A letter of consent was administered prior to the participation of any individual in the surveys and the think-aloud protocol sessions. In all forms of data collection, consent was for the purposes of being able to use and analyze the information and data found during the research. While participants of the study remained anonymous during data collection, participants consented to the use of their

biographical information, which is noted in the data. Subjects' participation was voluntary and individuals could choose to withdraw from the study at any time.

Data Analysis Procedures

Analysis of the data gathered in the surveys was based strictly on audience experience and the commonalities observed in the participant responses to their views and understanding of prescription medications, as well as their recollection of interactions with their physician. In addition, analysis of the data gathered in the think-aloud protocol sessions was rooted in Rhetorical Genre Theory. Rhetorical genre studies support the examination of a genre by analyzing the scene and situation in which the genre is used, the features of the genre, and how those features mediate the participant's interactions with the genre (Bawarshi et al. 193). Within this study, the genre analyzed was medication guides, and specifically the medication guide for Advair HFA. The scene and situation of this genre was analyzed in the think-aloud protocol sessions through questions about how the participants used the guide. Features of this genre were explored through the think-aloud protocol sessions which analyzed the structure, language, and complexity of this medication guide. In addition, these think-aloud protocols were performed in order to identify how participants interact with and respond to the medication guide due to its distinct features.

Results

The survey and think-aloud protocol session data indicate that both the physician-patient interaction and the way in which patients engage the medication guide contribute to an insufficient understanding of patients' prescribed medication. This incomplete understanding is a result of four issues in particular: skimming the medication guide, difficult terminology in the guide, varying awareness of the risk and effects, and differing levels of communication with the physician.

Obtaining Information: Skimming the Medication Guide

"Every time I'm prescribed a new medication or a change occurs."
-- *Research Participant, on how often they read the medication guide that comes with their prescribed medication*

With the medication guide being an essential aspect to understanding one's prescription medication, it is necessary to determine if individuals read them as common practice. Although the excerpt above provides an example of an individual who regularly reads these package inserts, there were varying answers in response to this question. According to the think-aloud protocols, approximately 58% of the participants said they read these medication guides occasionally or as they see fit, while the remaining 42% of participants

responded by saying they never read them. Furthermore, when asked if they read the entire medication guide that was given to them during the study, more than 90% of the participants responded by saying they skimmed through it.

This decision to skim is most likely due to the length and the amount of information within the guide. When analyzing the genre of medication guides, I found that length was a common theme across the majority of these text types. Often times these medication guides are about 10 pages in length and are full of information, which may cause the reader to feel the need to skim through the guide rather than read it thoroughly.

In addition, patients may feel encouraged to skim through these medication guides due to their typical structure and formatting. In a think-aloud protocol session, participants made several remarks about the formatting, such as “The formatting is good” and “Bullet points are nice, and short, simple phrases make it easy to read and understand.” Through analysis of the genre of medication guides as a whole, along with the responses from the study, it is justifiable to state that these guides have a primary purpose of informing the patient and are formatted and structured in such a way that makes it easy for the patient to understand. Brief statements in the active voice allow the patient to quickly identify the most important information: “Use 2 inhalations of ADVAIR HFA 2 times each day” (Center for Drug Evaluation and Research). These commonalities in the text were also identified by Grabowski, who determined that keywords and phrases became more simplified within the medication guides, most likely for purposes of aiding the patient in their ability to understand the material (27). Together, these results show that the length and formatting often encourage patients to skim, not read, the medication guide.

Specialized Terminology: Issues in Understanding Medication Guides

“Partially, it used words/phrases I did not know such as the acronyms and the pharmaceutical terminology.”

-- *Research Participant, on if they found the language and terminology understandable*

Despite the fact that the majority of these medication guides are relatively understandable, specialized terminology is a predominant issue that is interfering with patients’ understanding of the information. More than 60% of the participants in the study responded negatively to the language and terminology being understandable by referring to the acronyms and other specialized terminology that was used in the text. For individuals in the study, the pharmacological and chemical content may have been difficult to read because the majority, if not all, of the individuals participating in the research lack the knowledge necessary to be able to properly interpret this kind of terminology. Similar evidence was found in prior research which stated, that patients have difficulty understanding these information guides due to their complex terminology (Prescription Labels –

Consumer Reports Health). This type of terminology is exemplified in the medication guide that was reviewed in the study: “ADVAIR HFA combines the inhaled corticosteroid (ICS) medicine fluticasone propionate and the LABA medicine salmeterol” (Center for Drug Evaluation and Research). For example, this excerpt’s utilization of words such as “fluticasone propionate,” “LABA,” and “salmeterol” leaves most readers baffled. In addition, analysis of the genre shows that the majority of these medication guides contain this specialized terminology, which suggests that they are somewhat exclusive to members of pharmaceutical or medical discourse communities. This results in an overlying issue of a large majority of individuals who read these guides being unable to interpret certain aspects of the text that are potentially important.

Risks and Effects: Critical Aspects of Prescription Medications

In terms of the medication in general, one of the most crucial aspects to consider are the potential risks and effects of the drug. With that being said, it is no surprise that medication guides place so much importance on conveying these risks in a clear and concise manner. Through analysis of these medication guides, it was evident that the most important aspect was the part that discussed the side effects or risks that may come with taking the drug and information on what to do in case of emergency. For example, this section consisted of many bolded words, bullet points, and simple phrases that direct the reader’s attention. When looking at the medication guide during the think-aloud protocols, every participant stated that the potential risks and effects of the drug were clear and understandable.

However, despite the clarity of the risks and effects of the drug in the medication guide, there were many mixed responses from individuals regarding their awareness of the risks of their own prescription medications. For example, one participant responded, “yes, but I wasn’t told about them; I experienced the effects as they were happening but didn’t really care because the medication was a benefit to my health.” Another participant responded by saying, “common side effects, yes; other harmful risks/serious side effects, no.” These responses point to two possible issues: the first reverts to the earlier discussion regarding the patient’s inclination to skim the medication guide, and the second associates with a lack of communication with the physician. These excerpts demonstrate that it is likely that neither individual read the medication guide thoroughly, but the amount of communication with the physician did vary between the two. While the first response proposes that the individual did not have a conversation regarding the risks and effects of the prescribed medication with the physician, the second response conveys the idea that a discussion was had but it still left the patient without knowledge of the more serious risks and effects.

Regardless of the individual’s awareness of the risks and effects of their prescribed medication, data from the study shows that 70% of the participants have never refused to take a medication due to its risks. Many individuals may

feel that the medication will benefit them, and therefore they begin to disregard any risks or effects conveyed to them through the medication guide or by the physician. This data correlates to the responses found in the group discussions when participants were asked at what point they thought the risks conveyed in the medication guide, or in general, outweighed the benefit of the medication. One individual stated: "In general, if it is fatal, life-threatening, or may cause other serious problems. I am usually willing to try medication but if it may affect my daily life then no." Another participant responded by saying, "When the risks are fatal or extensively debilitating."

In addition to most individuals never refusing to take a medication due to its risks, from the data it is evident that the majority of people only begin to feel concerned about the risks and effects of medication if they are potentially life-threatening or inhibiting their daily life. With a large amount of the data pointing to the idea of individuals feeling relatively unconcerned by the common risks and effects addressed by these medication guides, it is necessary to look at the genre as a whole. Through analysis of various medication guides, which all addressed both the common and serious risks and side effects of their respective medications, the reasoning behind the pharmaceutical company's need to address them is questionable. Do they address these serious risks and effects for liability purposes, or have these effects been seen in research trials that were conducted prior to the medication being put on the market for patients?

Discussing Medications: Communication with the Physician

After concluding the surveys, it was evident that 80% of the participants understood the reasoning behind why they were prescribed a medication due to the physician's explanation during consultation. This relates back to the earlier discussion surrounding skimming the medication guides. For example, when I asked a group how often they read the medication guide, multiple individuals responded by saying, as I paraphrase, *I usually never do because I trust the medication the doctor prescribes*. This feeling of "trust" that is cited by the patient is most likely the result of the physician effectively communicating with the patient. With proper communication from the physician that would normally include not only the reasoning behind the prescription, but also brief information on the medication, the patient may feel at ease regarding the medication they are being prescribed leading them to feel less inclined to read the medication guide.

Nevertheless, effective communication with the physician was uncommon. Similar to the data found in this study, prior research determined that even when a patient expresses their opinions or preferences on medication, the extent to which it manipulates the prescription the physician writes is questionable (Britten et al. 1502). As found in the participant surveys, 70% of individuals felt that their opinion regarding their openness to take certain kinds of prescription medications is neither communicated with the physician nor taken into account if it is in fact communicated. For example, one individual responded by saying, "No, I often

feel like my opinion is not considered.” Another responded, “No, I don’t think my opinion is taken into account.” While these responses may be much different with improved communication between the physician and patient, prior research has identified that patients feel less inclined to convey their concerns or opinions of medications because they think it will infringe on the social interaction with their physician (1502). This presents a predominant issue within physician-patient interaction that must be improved and maintained so that both the physician and patient convey their opinions effectively. Improved communication with the physician may eliminate potential confusion and dissatisfaction that the patient would otherwise have to overcome.

Conclusion

While general information about a prescribed medication is given to the patient via the physician and/or pharmaceutical literature, due to a common lack of communication and understanding regarding one’s prescribed medication, findings show that physicians and pharmaceutical literature must improve in terms of providing the patient with a more complete understanding of the medications they are prescribed. In the US alone, an estimated 54 million people over the age of 12 have misused prescription medications at some point in their lifetime (National Institute on Drug Abuse). Nevertheless, with a more holistic understanding of a medication’s risks and effects these current issues surrounding high rates of prescription drug misuse may be better combated. Although specific inferences and assumptions can be made from the data collected through the research, it is difficult to justify more broad and general inferences, resulting from the data, due to some of the limitations of the research. That being said, the predominant limitation of this research was the sample size. For example, the survey participants responded to a biographical question regarding their ethnicity prior to answering questions concerning their experience communicating with their physician about prescription medications. With a larger sample size, differences and correlations between the way different ethnic groups communicate with their physicians may have been identified, but with the smaller sample size associated with this study it is unjustifiable to make these inferences.

Furthermore, limitations in sample size also result in difficulties with opposing prior research through data collected in the study. For instance, prior research has found that many patients express a sense of dislike for taking medicine or medication in general, but the data found in this research suggests otherwise (Britten et al. 1496). From the data collected in the research, the vast majority responded positively regarding their opinion of prescription medication, while only a few expressed a similar opinion found in the prior research. With the sample size being entirely represented by college students ranging in age from 18-22, it may be inferred that the younger generation views prescription medications in a different light than those of past generations. However, because the sample size

is so concentrated, it becomes difficult to justify this assumption without expanding the research.

In regard to further research expanding on the topics addressed in this study, there is a multitude of information that can be discussed and focused on. One area of particular interest is further analyzing the risks and effects section of medication guides to determine how these pharmaceutical companies decide to address them in the text. Further research into this topic may be able to identify if the risks and effects listed in these guides are addressed because they were consistently evident in the clinical trials of the medication or because they are intended to eliminate any liability the pharmaceutical company may incur if a patient experiences an unforeseen risk or side effect. Another topic for further research may be trying to identify ways in which the information a patient receives on a medication can be more standardized, rather than each patient receiving varying amounts of information and thus resulting in differing levels of understanding, which was evident in this research. Standardizing the way in which doctors and pharmaceutical texts convey information to patients may lead to individuals having a more complete understanding of their prescribed medication.

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