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Revolutionizing the Patient Package Insert with Infographics

Mitchell Cunningham

Abstract: Communication is critical for all aspects of public health. In the pharmaceutical industry, the patient package insert is used to relay important information to patients. Unfortunately, there are intrinsic flaws with the current patient package insert that can be seen through the vast number of medical injuries patients incur. This article dissects the root problems of the patient package insert in the modern world and analyzes the utilization of infographics to combat these issues.

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In a constantly changing world, the only way to thrive is to adapt to new norms. Adaptation applies to all aspects of society: education, employment, entertainment, public health, and safety. Despite diminished attention spans being one of the major changes in today's world, there is a lack of response in the public health safety sector. For decades, the U.S. Food and Drug Administration (FDA) has administered long, detailed Patient Package Inserts (PPIs) with prescription drugs. These PPIs contain a plethora of crucial information for patients' safety, including warnings, precautions, adverse reactions, and drug interactions. Additionally, PPIs provide background information about the drug itself, which can be seen in the clinical studies, description, and clinical pharmacology sections. With people's diminishing ability to focus their attention, crucial information may be overlooked or ignored. A revolution in public communication is pertinent for maintaining safety in the realm of public health.

THE PROBLEM: COMMUNICATION

Not all communication styles are created equal, and public communication is unique in its topics and target audience. Public communication consists of a group, like the FDA, communicating with the general public¹; PPIs are an example of this modality. There are a few key characteristics that embody all public communications: large scale distribution and reception, heterogeneous audience, impersonal interactions, and an asymmetrical sender-receiver relationship.¹ Unfortunately, these commonalities make public communication difficult. In other words, public communication is distributed to the masses, who lack a unifying trait outside of geographical location, eg, the United States. It is also one-sided since there is no face-to-face interaction, and the receiver is not able to ask for clarification. The diverse target-audience makes the word choice challenging because not all members of the population have the same educational background, yet they must be able to comprehend the message to the same degree. Furthermore, the asymmetrical relationship between sender and receiver presents an additional challenge because impersonal communication makes it more difficult for the recipient to receive the correct message.

Within pharmacy, public communication can be seen in a few different areas. Firstly, the FDA can require drug studies of

prescription drugs after they are approved for marketing. The FDA can also require a risk evaluation and mitigation strategy (REMS) for potentially dangerous drugs. While REMS may be required in order to gain initial FDA approval, the FDA can also require REMS to be added to already marketed drugs to help share important safety discoveries with healthcare professionals.² Patients may also receive documentation via medication guides and PPIs based on the additional data gathered when a drug is widely used.² Secondly, and perhaps more noticeably, public communication can be seen with product labelling and patient package inserts. The pharmaceutical industry has greatly relied on these two tools to inform patients of health risks since the 1960s.³

Although the PPI is standard today, it was not unanimously accepted when it was first brought to the public. In the 1970s, the FDA considered requiring the accompaniment of a PPI with all oral contraceptive pills.⁴ Both physicians and pharmaceutical companies opposed the idea based on the notion that it would interfere with the doctor-patient relationship.⁴ Prior to 1970s, the physician normally controlled both the patient's treatment and how well the patient understood his or her treatment plan.⁴ This provided physicians with supreme power and allowed manufacturers and physicians to foster strong relationships with each other.⁴ Because of the potential lack of understanding by patients, the FDA began requiring PPIs. Charles F. Keown stated that PPIs would,

promote patient understanding and adherence to drug therapy, permit the patient to avoid adverse interactions with other drugs or foods, prepare the patient for possible side effects, and permit the patient to share in the decision to use the drug.⁵

Furthermore, historian Elizabeth Watkins stated that, "in the absence of good doctor-patient communication..., the insert would supply facts necessary to make an informed choice."⁴ These goals are accurate and desirable, but they are not always easy to achieve with PPIs alone.

Historically, PPIs have effectively relayed important information about specific drugs. Patient package inserts attempt to address adverse reactions, both serious and mild, to improve

safety of the general public. Knowledge of the existence and frequency of adverse drug events is essential in establishing drug safety.⁶ One might think PPIs are working beautifully and do not require tweaking since their major goal coincides with one of the most important aspects of public health safety. However, PPIs may not be as effective as desired.

Dr Brian Edwards and Dr Sweta Chakraborty explained that each individual's perception influences public reception and processing of risk communications.³ From this, we can understand that although creators of PPIs have the right goals in mind, their pamphlets may not convey the proper message to the general public. Moreover, patients are unable to identify the most crucial of warnings from the PPI. This is evident when observing that hospital admissions for all medication and drug related issues have increased by 117% from 1997 to 2008.³ This statistic is the greatest indication that our patient package inserts are not adapting to modern times and therefore require modification. Any modification should address the lack of user-friendliness and eliminate as much confusion as possible throughout the entire population. It must ensure that all patient groups can utilize every PPI in order to establish universal drug safety.

THE POSSIBLE SOLUTION: THE INFOGRAPHIC

Perhaps the easiest way to account for heterogeneity of the population is by utilizing infographics to convey the most crucial information to patients. Infographics are a perfect avenue for communicating to an educationally diverse population due to the use of visual aids. Visual aids can provide a more universal language in order to help people understand a foreign term or the severity of a symptom of an adverse effect. For example, a patient may not understand a warning for tachycardia, a dangerously rapid heart rate, but he or she may better comprehend a skull placed beside a vertical "up" arrow graphic in front of a heart with an embedded EKG reading. Visual aids also allow for the creation of context, as well as improvements on the passive voice frequently seen in PPIs that can be difficult to understand.

Infographics are the ideal solution to our society's decreasing attention span because they exploit visual processing, which is the most dominant capacity of the human brain.⁷ This function is integral for learning, therefore infographics can relay more information over a shorter duration of time.⁷ Furthermore, the structure of infographics allows information to be portrayed as a story, which utilizes our most evolutionarily-conserved process of understanding.⁷ The use of colors in infographics can also add to comprehension and help those that have impaired vision or memory, eg, Alzheimer's disease patients.⁸ For example, elderly patients tend to have weaker vision so utilizing red print with a yellow background greatly increases their ability to read.⁸ One could also use violets and soft yellows for medications that should be taken with food because these colors tend to increase one's appetite.⁸

Infographics do a tremendous job relaying information in an easy-to-understand format via data-visualization, but they have limitations. It is important not to include more than 5 main points of interest in an infographic, as anything more will likely

result in a lengthy infographic. As the length increases, people's declining attention spans will interfere with comprehension. Therefore, compressing all of the information from a PPI into a single infographic may result in oversimplification, which would limit a patient's understanding of his or her new medicine.

In conclusion, patient package inserts cannot be replaced by infographics, but PPIs should be accompanied by them. Infographics could drastically help with Black Box Warnings and other sections laden with medical jargon due to their incorporation of visual aids. Pictographs are a universal language across populations because they provide multiple inputs to our brain and eliminate many of the barriers of public communication. Research does not yet exist for the effectiveness of patient education infographics, but there is potential benefit of infographics in every patient population.

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