



Research Article

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Medication Package inserts, concept among doctors pharmacists and laypersons- A beneficial guidance or a source of confusion

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Abstract

Increasing emphasis on the importance of the package insert we tend to designed a questionnaire to work out the perspective of physicians, pharmacists and laypersons of Karachi towards package inserts (PI) for medication data. The sample size of our study was 270 that embody ninety physicians, ninety pharmacists and ninety laypersons. The study explore the results of the survey that the majority of respondents (93.7%) are aware about the packaging Insert (PI) or showed the positive response about awareness to PI and (70.4%) aforementioned that they read the packaging insert (PI) before prescribing or taking the drugs. Out of 70.4% respondents who read the PI, (52.6%) listed "adverse effects" and (51.1%) listed "indications" as the principle section of interest, and show least interest (19.6%) in pharmacology. The quality and amount of knowledge offered within the PIs has been shown to influence patients' compliance and satisfaction, wherever as solely 18.9% consider PIs just a source of confusion.

Keywords: Package inserts, medical information, awareness, package inserts, medical guidance .

INTRODUCTION

A medication monograph is an investigative archive on the medication that depicts the properties, cases, signs and states of utilization for the medication. All substance of the bundle supplement is part into titled segments. Individuals can discover regions of interest, for example, Warnings or contraindications, and read that area only. The medical packaging inserts more often than not comprises of three areas. Segment I, contains professionals data. It contains the data required for the proper prescribing, appropriate dispensing and administration of medication. Segment II, with respect to investigative data, contains more inside and out and finish exploratory/research data, for example, toxicology and information from animal studies and human clinical trials. It supplements and develops the data contained in Section I. Section III, contains patient related data which helps the consumer comprehend what the medicine is, the way to utilize it and what the potential reactions are. It is likewise planned to serve as an aide for wellbeing experts to effortlessly recognize the data required for directing patients^[1].

The patient Packaging inserts (PPI) is critical for giving vital medication data to patients assuming control over-the-counter and also prescription only medicines. In developing areas, the PPI is viewed as an essential source of medication data for medicinal services suppliers also, in light of a constrained capacity to access recent data about medications. Further, studies have demonstrated that the PPI makes an association between health care providers and patients and improves patients' learning about drugs. The quality and amount of data accessible in the PPI has been appeared to impact patients' conformity fulfillment and trust^[2]. A research was conducted in Saudi Arabia to know about the public interest and awareness regarding packaging insert in 1998, showed that 88% respondents read the PI^[3]. Another research was conducted in India, showed that the majority (42%) said that they never read the package inserts^[2]. Another study from India, uncovered that most package inserts contained data under headings, for example, indications, contraindications, undesirable effects etc., recommended by the Drugs and Cosmetics Rules 1945. The results showed impressive change in PPIs following 1996. but, on basic assessment it was uncovered that clinically imperative data was not all around displayed and was regularly inadequate. Data as to pediatric and geriatric use was available in just 44% and 13% of the PPIs, individually. Just five of the supplements had data on the most frequent adverse medication responses connected with the medication. Likewise, data on interactions and over dose was often absent^[4].

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Further a most recent research reports that large number of people (40%) do not even read package inserts [5]. Therefore we conducted this study to access the knowledge about packaging inserts among doctors, pharmacists and laypersons and to know about the public interest and awareness about packaging inserts and to evaluate their concept about packaging inserts that either they affect health outcomes and are beneficial or just a source of confusion.

STUDY DESIGN

A cross sectional questionnaire based study was conducted in Karachi city. The questionnaire consisting of questions about knowledge of package inserts, their beneficence and deficiencies were prepared and distributed among three distinct social groups of our community including 90 doctors, 90 pharmacists and 90 layperson. Total sample size is 270. The response rate is 100%. The questions were emphasizing on concepts of doctors pharmacist and laypersons about package inserts and their ideas of how package inserts can be made easier for average person to read and comprehend and how to make it the effective source of information. Our objective of study was explained and then doctors pharmacist and laypersons are requested to fill up the questionnaire.

RESULTS AND DISCUSSION

This study was undertaken to evaluate and to compare the awareness of general practitioners (GPs), pharmacists and the general public of the Karachi city about patient information leaflets or packaging inserts (PI) and either PIs are helpful to them or just a source of confusion. We chose to sample from general public of Karachi, Doctors and pharmacists of different hospitals and not restrict the study to patients with a specific disease or using certain medications. The result of the survey showed that the majority of respondents 93.7% (Doctor 33.3%, Pharmacist 32.2%, Layman 28.1%) are aware about the packaging Insert (PI) or showed the positive response about awareness to PI. Subjects were asked about reading the PI before taking the PI. 70.4% (i.e. Doctor 21.1%, Pharmacist 26.7%, and Layman 22.6%) said that they read the packaging insert (PI) before prescribing or taking the medicine. Out of 70.4% who read the PI, 25.2% (Doctor 11.1%, Pharmacist 8.9%, Layman 5.2%) read composition, 22.6% (Doctor 8.5%, pharmacist 2.6%, Layman 11.5%) read description, 19.6% (Doctor 6.7%, Pharmacist 8.9%, Layman 4.1%) read pharmacology, 51.1% (Doctor 20.4%, Pharmacist 17.0%, Layman 13.7%) read indication, 27.4% (Doctor 9.6%, Pharmacist 13.3%, Layman 4.4%) read contraindication. 52.6% (Doctor 17.8%, Pharmacist 21.5%, Layman 13.3%) read adverse effects, 34.1% (Doctor 9.6%, Pharmacist 13.7%, Layman 10.7%) read drug interaction, 44.1% (Doctor 14.4%, Pharmacist 13.3%, Layman 16.3%) read warning, 48.5% (Doctor 13.3%, Pharmacist 17.4%, Layman 17.8%) read dosage/administration, 40.0% (Doctor 13.7%, Pharmacist 11.5%, Layman 14.8%) read storage/precautions before prescribing or taking medication. (Figure 1)

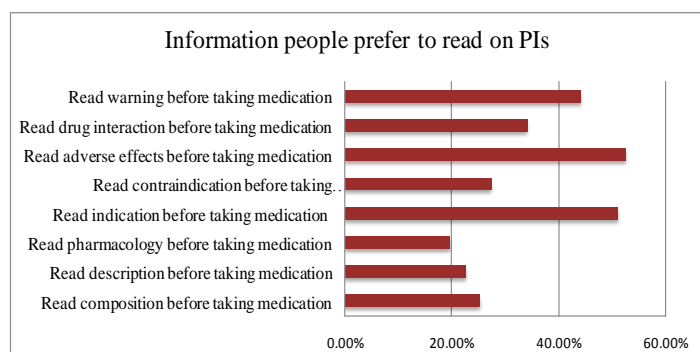


Figure 1: Information people prefer to read on PIs

All three groups perceived these leaflets to be useful and an aid to improving compliance. Doctors' estimates on what percentage of persons actually read leaflets were significantly lower than estimates by the general public. Concerning the information included in leaflets as beneficial, Doctors and pharmacists and general public rated the inclusion of a section on pharmacology, description and pharmacology of drug as being the less beneficial, whilst the section on the adverse effects, dosage/administration, storage as being more interesting or beneficial. A Previous study show that (76%) see package inserts for how long the medicine can be kept [6]. Patients must know how to store the medicines. If medicine is store properly it is less likely to deteriorate. Manifestly, medicines should not be kept beyond the shelf life. But a change in the appearance of the medicine can also warn the patient that it should no longer be used. Some precautions should also be kept in mind. For example, aspirin tablets that smell of vinegar should be discarded [7].

Health professionals are traditionally opposed to the introduction of patient package inserts or patient information leaflets (PIs), claiming that they cause adverse effects by suggestion and have an unfavorable effect on patient compliance. In our study 87.0% (i.e. 24.4% of the doctors, 31.9% of the pharmacists and 30.7% of the laypersons) agree that package inserts should be explain by pharmacist or doctors to patients. Patients need a certain amount of information to use their medicines optimally. The pharmacists and the physicians are the preferred sources of this information, though health professional do not always ensure minimal knowledge transfer [8]. Local pharmacists would give patients at least the basic information about the amount of medicine to be taken, and how often, with additionally a word of caution about possible side effects [9].

Among the respondents 75.6% (i.e. 28.5% of the doctors, 24.4% of the pharmacists and 22.6% of the lay persons) believe that packaging inserts are affecting health outcomes where as 18.9% (i.e. 4.8% of the doctors, 6.7% of the pharmacists and 7.4% of the lay persons) consider PPIs just a source of confusion. (Figure 2) A review of several studies showed that the majority of patients receiving written information express favorable attitudes, in some cases over 90%, and even to their treatment as a whole. Effects on knowledge, compliance and therapeutic outcome have been examined in more than 30 studies. It is clear that knowledge is increased considerably, compliance somewhat less, and therapeutic outcomes are smallest (in four out of seven studies). Patient information leaflets are to become a normal feature of health care. Their advantages and benefits are obvious. But they require careful preparation and the support of oral information at the point of delivery [10]. The respondents were asked about for the possible reason due to which most of the people don't like to read PPIs; 52.6% thought that people do not read it because of medical terminologies; 28.1% because of the small font size of PPIs; 45.7% because of extensive information provided. (Figure 3)

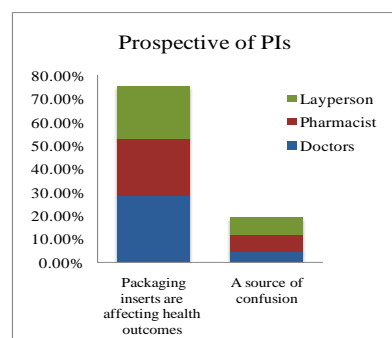


Figure 2: Prospective of PIs

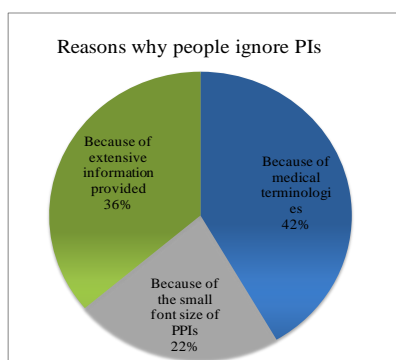


Figure 3: Reasons why people ignore PIs

Subjects were asked about how to make package inserts easier for the average person to read and comprehend; 31.5% (i.e. 13.7% of the doctors, 9.3% of the pharmacists and 8.5% of the lay persons) believed that by avoiding medical terms; 22.6% (i.e. 8.1% of the doctors, 7.0% of the pharmacists and 7.4% of the lay persons) decided by explaining medical terms while 20.7% (i.e. 4.8% of the doctors, 9.6% of the pharmacists and 6.3% of the lay persons) selected diagrammatic representation and 61.1% (i.e. 20.0% of the doctors, 18.5% of the pharmacists and 22.6% of the lay persons) preferred that by printing package inserts in native language, an average person can read and understand the information without difficulty. (Figure 4)

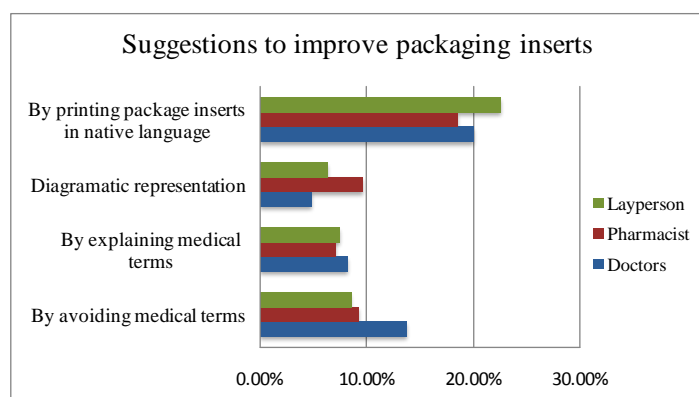


Figure 4: Suggestion to improve packaging inserts

The information must be easily understood and convincing and this will result in more effective and safer use of the drug. Font, layout, and other aspects of design are important. The style and format in which the information is finally offered should aim at conciseness, preciseness and readability [7]. Extensive investigations into the effectiveness of various kinds of illustrations, ranging from simple black and white line drawings to colored photographs, showed that simple, labeled line drawings resulted in most learning. In patient information, color might in any case be inappropriate. It is appealing to think that illustrations will always aid learning, but there is some opposing evidence that one picture is not always worth a thousand words. The possibility of using illustrations as an alternative to text on prescription labels to assist poor readers had disappointing results, and we know that, in general, symbols are often misunderstood or cannot be interpreted by those for whom they are intended in non-clinical settings. It is clear that diagrams can be useful, predominantly in showing more complex maneuvers, e.g. inserting suppositories or instilling eye-drops [10]. Several studies and a review emphasize the significance of using pictures in conjunction with written or oral instructions to augment patients' understanding of how they should take their medications, to promote intellectual capacity and adherence and to avoid misconception of picture only instructions [11].

Well-written and legible information needs further support. When printed, the size of type must be clear and large enough and be adequately spaced to be read. The layout must also help by creating a center of attention of the reader towards the information, and preserving consideration. The physical factors likely to affect the impact of written information include the format of the text, the size of the typeface, use of capitals and italics, space between lines, length of lines, justified or unjustified lines; like titles entirely in capitals are picked out less easily than lower-case and italics reduce the speed of comprehension. Packaging inserts are to become a normal feature of health care. Their advantages and benefits are obvious. But they require careful preparation and the support of oral information at the point of delivery [12].

CONCLUSION

As package inserts are one of the most often used sources of in writing pharmaceutical data, advances to make them effective and useful as possible should be explored. This particularly refers to complexities in comprehending the extensive data provided; even educated persons have shown difficulties in understanding some single-syllable medical terms. It is proposed that layman can be assisted or help by interpreting medical terminologies or by utilizing illustrations and size of type must be clear and large enough and be adequately positioned to be read.

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