Usefulness of package inserts: Do we really read them!

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Abstract

Introduction: Package inserts (PI) are the required informational leaflets which come along with drug package containing all the necessary and relevant information about the drug. It helps in providing appropriate guidance to doctors, paramedical staff and patients according to their needs. The study was planned to analyze the knowledge, attitude and practice behavior of all stakeholders and find out the deficit in current PI and targets of improvement in PI, for overall benefit of society.

Materials and Method: A questionnaire based study was undertaken in 103 doctors, 108 paramedics (nurses and pharmacists) and 102 patients coming to the outpatient departments of the hospital.

Results: Knowledge of package inserts and their importance is well known among doctors (88.35%) and paramedics (81.48%) in contrast to patients (39.22%). Doctors are the maximum users of the internet for seeking new information. Doctors (78.25%) followed by paramedics (50.93%) felt PI should be mandatory compared to patients (15.69%). Suggestions regarding improving contents of package inserts were language modifications i.e. including local language which was advocated by patients mostly, increased font size and pictorial representation where ever possible (administration instructions and storage). Other suggestions from paramedics were information about packaging and storage, regular updating of PI.

Conclusions: Though mandatory, PI is largely ignored by both manufacturers and stakeholders. If utilized properly it can be an effective tool in educating everyone regarding dos - don't and necessary information of the drugs thus aiding in avoiding adverse effects and promoting correct utilization of medicines.

Keywords: Knowledge, Attitude, Practice, Package inserts

Introduction

Package inserts (PI) are the obligatory informational leaflets provided inside the drug package.[1] It contains all the relevant, updated and unbiased information about the drug which can be used as guide for prescribing and better storage by doctors and paramedical staff.[2] Also it gives knowledge to the ultimate stakeholders i.e. patients about the storage and safer use of the drugs thus lowering distance between prescribers and patients.[3] Therefore, these are the authentic source of new drug information.[4]

In India, regulatory body for Package inserts is Central Drug Standard Control Organization, Ministry of Health & Family Welfare (Government of India). Section 6.2 and 6.3 of Schedule D of Drug and cosmetics act (1940) and rule (1945) provides the guidelines for the contents of package inserts.[5] According to section 6.2, it should be in English and include the information regarding drug indications, posology, method of administration, contraindications, special warning and precautions, drug interactions, contraindications in pregnancy and lactation, effect on ability to drive and use machines, undesirable effect and antidote for over dosing of the medicine. While Section 6.3 makes the following information mandatory regarding pharmaceutical information on list of excipients, incompatibilities, shelf life as packaged, after dilution or reconstitution or after first opening of the container, special precautions for storage, nature and specification of container and instructions for use / handling.

Many information sources are available in today's technology driven era. There is easy accessibility, comprehensiveness and compactness of necessary data. But in abundance of information, the reliability of source can remain doubtful. So it becomes essential to extract the correct and necessary part according to the need of the stakeholder and the particular pharmaceutical product and brand information which may vary brand to brand. Although, textbooks and journals are the most reliable but the constraints like availability at need, recent additions, cost and bulkiness, often make them unfavorable with medicos and for patients/ paramedics, it's totally inaccessible. In many countries, the PI is considered an important source of drug information for healthcare providers.[6] So, PI is a medium that can provide benefit to all its stakeholders.

WHO spends millions of dollars just to make the world aware about antibiotic resistance and to stop adverse drug events. But, a large quotient of problem lies with fact that there is misuse of medicines in absence of reliable knowledge.[7] Doctors have various sources of information but the other stakeholders don't have adequate resources to educate them which may be largely due to unbalanced ratios of patient-doctor/patient-paramedics or doctors-paramedics or financial burden or time limitations. The importance of reviewing package inserts and labels prior to taking

drugs can minimize the risk associated with medication errors and misuse.[6] Hence, PI which states all information in comprehensive manner is the one of the means by which misuse and adverse drug events can be prevented.[8] Most of the time the user of PI is either the prescriber or paramedics and it is seldom used by the patients/ general public. However, to prevent these short comings the need of the hour is to increase PI use by these stakeholders/patients. The usefulness of PI can be evaluated by the knowledge and attitude of the stakeholders intended to be aided. Hence in the light of information available, a study was planned with the aim to obtain base-line data on the extent of reading PI by various stakeholders and possible factors that might affect knowledge, attitude and practice towards the PI provided with the drugs and to find out discrepancy in existing PI with targets of improvement for overall benefit of the society.

Materials and Method

Three months duration prospective, cross sectional, observational questionnaire based study was undertaken at Indira Gandhi Government Medical College and Hospital, Nagpur, Maharashtra after approval from institutional ethics committee. 313 subjects were included in the study. The 1st group included 103 doctors, 2nd group had 108 paramedics (nurses and pharmacists) and 3rd group included 102 patients coming to the outpatient departments of the hospital.

The inclusion criteria were participant of either gender above the age of 18 years who gave written informed consent and had fair knowledge of English language. The exclusion criteria were participants not willing to give written informed consent, who are unable to read English, seriously ill patients coming to the hospital, including those in the emergency department, bedridden, unconscious or disoriented patients.

A pre-validated questionnaire in English having both open-ended and closed-ended 15 questions related to various aspects of knowledge, attitude and practice was given to the stakeholders and collected after providing sufficient time to the stakeholders.

Statistical Analysis was done at the end of the study, all the data were pooled and expressed as counts and percentages.

Results

A set of questionnaire was given to 313 participants to access knowledge, attitude and practice towards package inserts.

Table 1 shows the sources of drug information used by the participants while prescribing or using a drug. The maximum use of the internet was reported by the doctors as the source of drug information to prescribe or use the drug. 88.35% doctors, 81.48% paramedical and 39.22% non-medicals had the knowledge of package inserts and knew their importance.

Table 1: The different sources of drug information used by the participants while prescribing or using a drug

Sr. No.	Option	Doctors	Paramedicals	Non-medicals
1	Textbook/ Journals/ Articles	65 (63.11%)	35 (32.41%)	0
2	Drug promotional literature via Medical Representative	22 (21.36%)	37 (34.26%)	0
3	Package Insert	21(20.39%)	18(16.67%)	68 (66.67%)
4	Medical dictionaries	10 (9.71%)	16(14.81%)	17 (16.67%)
5	Conferences/ Lectures	30 (29.13%)	0	0
6	Internet	71 (68.93%)	55 (50.93%)	22 (21.57%)
7	Any other- Doctor	0	0	51 (50%)

78.25% doctors, 50.93% paramedics and 15.69% patients supported the view that providing package insert should be mandatory and 16.67% paramedical & 33.33% non-medicals did not felt the need of package insert.

29.12% doctors, 35.18% paramedics and 16.66% of the patients consented of getting the package insert of drug with the medicine always, whereas 70.88% doctors, 64.82% paramedics and 33.34% patients received PI occasionally and 50% patients never received package inserts. 37.86% of doctors, 35.18% of paramedical and 16.66% of public always feel reading PI is a time consuming business. Table 2 shows the type of the information read in the package insert.

Table 2: Material read in Package insert

	Options	Doctors	Paramedicals	Non-medicals
1	General information of drug	60 (58.23%)	89 (82.41%)	16 (15.69%)
2	Indications/contraindications	65 (63.11%)	90 (83.33%)	0
3	Dose and schedule	73(70.87%)	72 (66.67%)	102 (100%)
4	Side effects	78(75.73%)	71 (65.74%)	50 (49.02)
5	Storage conditions	54(52.43)	74(68.52%)	18 (17.65%)
6	Special warnings and precautions	80(77.67%)	72 (66.67%)	51 (50%)
7	Drug interactions	47(45.63%)	53 (49.07%)	17 (16.67%)
8	Method of administration	67(65.05%)	58 (53.70%)	17(16.67%)
9	Treatment in case of overdosing	48(46.60%)	52 (48.15%)	34 (33.33%)
10	Shelf life after dilution/ reconstitution after first opening of container	42(40.78%)	25(23.15%)	18 (17.65%)

57.28% doctors are of the opinion that PI is regularly updated by the pharmaceutical companies, so does 66.66% paramedical and 34.31% patients. About 36.90% doctors found the information provided in PI adequate, while 63.10% were not satisfied. 50% of the paramedical were satisfied with the completeness of the information. Only 16.66% patients felt the information in PI as inadequate while the remaining public was satisfied with the information. The various resources used by stakeholder to obtain missing information are depicted in Table 3.

Table 3: Sources for obtaining missing information

Sr No.	Doctors	Paramedicals	Non – medicals
1	Textbooks and internet (51.46%)	Ask to doctors (51.85%)	Ask to their doctors (33.33%)
2	Textbooks only (20.39%)	Internet only (21.30%)	Ask to doctors and also refer the internet (28.43%)
3	Internet and journals (17.48%)	Various drug indexes and pharmacopoeia (15.74%)	Ask only to chemist/ pharmacist (25.49%)
4	Internet only (13.59%)	Textbooks only (17.59%)	Refer the pharmacist/chemist and internet (20.59%)
5	Textbook, internet, approach their seniors and teachers (8.74%)	Ask their colleagues (10.19%)	Search on internet only (17.64%)

Suggestions regarding contents of package inserts included language modifications i.e. 75.18% doctors feels comfortable with PI to be in English, 24.82% felt it should be in local language along with English and 12.62% were of the opinion that language should be easily understandable to the consumers. Among paramedical 27.78% also felt it comfortable in English, while 72.22% wants it in Hindi and local language along with English. Among the patients, 47.05% wants PI should be in English and regional language. Rest wants PI should be in English, Hindi and their regional language.

Font size of PI is major issue - 72.81% doctors, 77.77% paramedical and 55.88% patients found it difficult to read and feel that it should be bigger. 60.19% doctors, 50% paramedical and 64.70% patients feel that the pictorial representation has a better interface than the textual information for PI. Pictures regarding administration instructions and storage have been recommended by 16.50% doctors, 7.4% paramedical and 25.49% general population. Other suggestions from paramedics were information about packaging and storage (19.44%), regular updating of PI (7.4%) and dose preparation methods for emergency injectable (2.77%).

Discussion

Although package insert is a mandatory document, but its availability and usage is still largely ignored by both manufacturers and stakeholders particularly in the government setup.[9] Moreover, not many studies have been done to evaluate the knowledge, attitude and practice of package inserts in medics, paramedics and general public. Hence, keeping in mind the paucity of data, this study was conducted to evaluate the same about package inserts among various users.

In our study, 6.67% paramedics and 33.33% non-medicals did not felt the need of package inserts which suggests that still in our country awareness regarding package inserts is not there. This is in contrast to a study where 88% of respondents read PI or asked somebody to read PI for them.[10] The regular

dispensing of drugs without proper guidance cause multiple setbacks at each step from storage to compliance, unwanted interactions to side effects or adverse effects.[8] Therefore, there is a need to teach the paramedics and non-medicals about the importance of the PI.[11] However, the use of internet is gaining upper hand as the source of drug information in India. This may be due to the technology revolution going on and many people becoming techno friendly in urban parts. There are parts where most people are neither techno friendly or familiar with English/ Hindi but as per schedule D it's compulsory to make package insert in English only.[12] However, The Department of Chemicals of India has instructed the manufacturers to print labels in Hindi as well.[8] But it is not possible to print label in all local languages as the drug is launched in entire Indian market and India is a country with many languages. Therefore, to avoid language barriers comprehension can be improved pictorially as was suggested by the doctors, paramedics and non-medics in our study and other study.[8] Simple changes like bigger font size, language adding pictures, highlighting important remarks can bring into notice many things that were previously ignored.[4] The regulatory authorities and pharmaceutical companies can improve the content and quality of package inserts for the benefit of the society.[9] Therefore, the PI must be optimized, tested by the experts for delivering the necessary information accurately prior to its approval.

The rules which were made more than 7 decades ago have not been strictly followed or amended. Execution of the strict rules by the pharmaceutical companies must be ensured by the government.[11] Lack of perseverance from government agencies and deliberate slackness of pharmaceutical companies when compounded with general unawareness of stakeholders is major deficit in knowledge which has varying consequences.

PI reaches to wide masses and it can be used as informative and educational tool for the benefit of society. There is an unequivocal need that PI should be patient friendly so as to avoid at-least medication related errors.[13] This can be achieved by doing KAP studies in the users and the end users and finally implementing or imbibing the changes recommended in PI by them as is done in foreign countries.[14] Substantial regulatory efforts have been made in other countries to improve the information content of PI.[15] The regulatory bodies should make strict rules for ensuring that pharmaceutical companies comply with the implementation of the better concepts for avoidance of the adverse effects.[16]

Conclusion

The PI is still inadequate in providing accurate, effective information to the doctors, paramedics and patients. Many surveys are required to achieve the aim of PI i.e. relevant, recent and unbiased information. For this a collective effort by the regulatory bodies, users and the pharmaceutical companies is required. This can be small step in the direction of providing effective healthcare services with minimal adverse effects.

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