

Research Article



Cross Sectional, Observational Study to Assess Prescription Practices of Physicians with Respect to Use of Generic Medicines

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ABSTRACT

In India, 70% people spend 10-20 % of their total income on healthcare alone. The generic drugs are cheaper and provide an opportunity for patients to reducing their out of pocket expenditure in healthcare. So a study was done to assess prescription practice of physician by generic name and physician's knowledge, attitude and perception towards the same. An observational study was conducted at a tertiary health care center. Prescriptions of physicians and pediatrician were assessed for use of generic medicine in their respective OPDs. Then the knowledge, attitude and perception of physicians about use of generic medicine were assessed with help of questionnaire. Study Duration was three month. The data was analyzed by using conventional statistical methods. Total 600 prescriptions were studied of which 300 from Medicine and 300 from Pediatric OPD. It was found that in medicine OPD generic name of all medicines was written in only 14 (4.66%) prescriptions whereas in pediatric OPD it was 130 (43.33%). Responder rate of 75% was achieved. The total percentage of correct responses regarding knowledge of generic medicines was seen in 48% respondents. On further analysis it was observed that only 10% physician had very good knowledge about generics. Almost 40% physicians had inclinations for prescribing generics. 40 (66.67%) physicians were doubtful about efficacy of generics; whereas 67% physicians had average perception regarding use of generics. 38.33% of the respondents expressed their concern towards lack of quality check in locally manufactured products. In order to increase use of generics, doctors need to be educated and reassured about generic products approval system with regards to efficacy, bioequivalence, quality and safety during their professional career. Although the gap in knowledge of generic medicines among physicians is evident, in general conducive perceptions and attitudes were observed.

Keywords: Attitude, Cross sectional, Generic Medicine, Knowledge, Perception, Physician, Prescription practice.

INTRODUCTION

In India, 70% people spend 10 – 20 % of their total income on healthcare alone. Cost of medicines constitutes a large percentage of the total medical costs of an individual.¹ As per survey done in year 2011 WHO says 3.2% Indians will fall below the poverty line because of high medical bills. 39 million Indians are pushed to poverty because of ill health every year. Around 30% in rural India didn't go for any treatment because of financial constrains. About 47% rural and 31% urban hospitalizations are financed by loans and sale of assets.² Over 95% of the Indian population is not covered by medical insurance such medical expenditure continues to haunt the common man. As we strive to provide high-quality health care in a time of limited resources, increased use of generic medications, when clinically appropriate, can reduce costs without reducing quality.³ Thus use of generic drugs steadily increasing internationally as a result of economic pressure on drug budgets.⁴ Generics provide the opportunity for major savings in healthcare expenditure since they are usually substantially lower in price than innovator brands.⁵

Health care costs are the second most frequent reason for rural indebtedness. A major component of health care costs is medicines.⁶ Previous studies had shown that in India the cost of medicines is anything between 50 to 80

percent of the total cost of treatment. Currently, many of the patients seeking care in Public Health Facilities (PHF) have to buy medicines from retail shops and these medicines are very costly for a variety of reasons. So Government of India announced 12th Five Year Plan, in which a provision will be made for 'free medicines for all in Public Health Facilities under the National Rural Health Mission (NRHM) for facilities up to the District Hospital in those districts which are/ would not be covered under the National Urban Health Mission (NUHM) and in the District Hospitals and other tertiary care centers under the NUHM.⁷

At present Nagaur and Chittorgarh districts of Rajasthan are running these kinds of Jan Aushadhi stores and dispensing quality generic drugs at affordable cost on 24 × 7 basis by govt. agencies. Also in Tamilnadu since 1995 all patients visiting public health facilities get all medicine free. This has been possible because the Tamilnadu Medical Service Corporation (TNMSC) procures generic medicines in bulk directly from manufacturers through transparent bidding process. Govt. of Kerala has adopted the TNMSC model. The govt. of Bihar and Rajasthan are in process of doing so.⁷

While doing study on generic drugs it is important to know some true facts about them. A generic drug (generic



drugs, short: generics) is a drug defined as "a drug product that is comparable to brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use."⁸ It has also been defined as a term referring to any drug marketed under its chemical name without advertising.⁹ Generic drugs are usually sold for significantly lower prices than their branded equivalents. One reason for the relatively low price of generic medicines is that competition increases among producers when drugs no longer are protected by patents. So companies are able to maintain profitability at a lower price.¹⁰

The adoption of generic drugs in medical practices is a complex phenomenon and physicians play a key role in controlling this phenomenon. Understanding physician's perceptions about the quality and efficacy of generics may help identify potential barriers to greater generic medication use. Additionally, identifying physician characteristics associated with negative perceptions about generics may help insurers and policymakers to target educational interventions or more restrictive policies.¹¹ So there is a need to do similar research in developing countries where low cost generic medicine is the most important viable option for the majority of the population.

Keeping in view this background this study aims to assess prescription practice of physician with respect to use of generic medicine and their knowledge, attitude and perception towards the same in treatment of disease conditions.

MATERIALS AND METHODS

The study was conducted in compliance with protocol, ICH GCP guidelines, ICMR, Schedule 'Y' and Indian regulatory requirements. This was an observational, cross sectional questionnaire based study conducted at tertiary

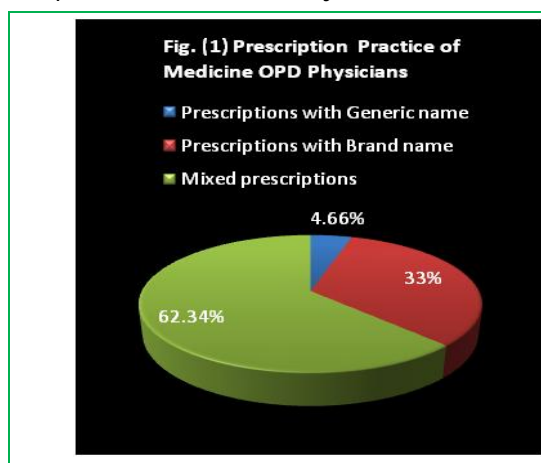
health care center in Mumbai. Approval from Institutional Review Board was taken prior to initiation of the study. After approval from IRB a permission from HOD of medicine and pediatric was obtained to conduct study in their departments. In First week of study randomly every fifth prescription from OPD units of medicine and pediatric departments of KEM Hospital were selected and studied for use of generic medicines assuming that none, partial or complete prescription was written by generic name. In next week study instrument i.e. questionnaire was distributed amongst physicians of medicine and pediatric OPD units of Seth G.S. Medical College & KEM Hospital Mumbai to assess their Knowledge, Attitude and Perception regarding use of Generic Medicine. Questionnaire was distributed on site during working hours amongst those physicians satisfying selection criteria and willing to give free, written, informed consent. Participants were asked to respond on the same day. Out of 80 physicians 60 filled the questionnaire and remaining 20 did not return the questionnaire in spite of reminding them repeatedly.

RESULTS

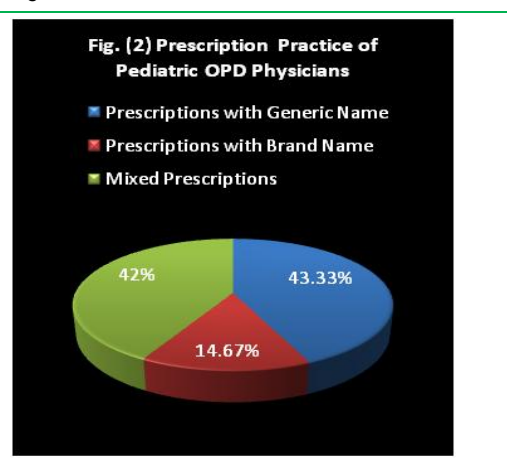
Results of Prescription Analysis

To assess prescription practices of physicians by generic name we had collected total 600 prescriptions written by 60 different physicians (10 prescriptions per physician) of medicine and pediatric OPD units. Of which 300 prescriptions were from medicine OPD and another 300 from pediatric OPD unit.

In medicine OPD we found that only 14 (4.66%) prescriptions were written by generic name of medicines. Whereas in around 99 (33%) prescriptions were written by brand names of medicines. Remaining 187 (62.34%) prescriptions were mixed in which some medicines were written with brand name and some with generic name. [See figure 1]



In pediatric OPD we found that 130 (43.33%) prescriptions were written by generic name of medicines and 44 (14.67%) prescriptions were written by brand names of medicines. Remaining 126 (42%) prescriptions were mixed in which some medicines were written with brand name and some with generic name. [See figure 2]



When we calculated number of prescriptions in which at least one generic name was written we found 67.33% prescription in medicine OPD and 88.66% prescriptions in pediatric OPD. This indicates that at least single generic name written in approximately seven prescriptions per physician in medicine OPD. Whereas there were almost

nine prescriptions per physician in pediatric OPD in which at least one generic name written.

Results of questionnaire analysis

Total 80 questionnaires were randomly distributed amongst physicians from medicine and pediatric departments; out of those 60 responded and filled the questionnaire. Response rate was 75%. Out of 60 respondents 30 were from medicine and 30 from pediatric department of hospital. In study 35 (58.33%) were male & 25 (41.67%) respondents were female. The majority of respondents (n=42) were in the age range of 21-30 (70%). Out of 60 respondents 10 were involved in private practice (16.67%).

Knowledge of Generic Medicines

When the respondents were asked about the basic information regarding generic medicines, only 19 (31.67%) respondents answered 'yes' that generic medicines are the copy of the brand name medicines. When the respondents were questioned about the manufacturing of generic medicines 52.54% (n=31) respondents answered 'yes' that 'generic medicines are

manufactured after patent expiry or innovator'. In terms of safety, 86.67% (n=52) of respondents incorrectly understood that generic medicines are less safe than brand name medicines. Whereas only 14 (23.33%) answered 'yes' that generic medicine manufactured by local company are safe. In terms of quality, 45 (75%) respondents answered 'no' that 'brand name medicines are of better quality than generic medicines'. The total percentage of correct responses regarding knowledge of generic medicines was seen in 48% (n=29) of the respondents. Other question's responses were indicated in Table (1) as correct and incorrect answers.

Attitude towards Generic Medicines

Around three-quarters of the respondents expressed their wish to prescribe low cost medicines in their practice (n=41; 68.33%); whereas 46.67% (n=28) of the respondents showed their hesitancy to prescribe low cost brands in some therapeutic categories. In the case of lack of quality check in locally manufactured products 38.33% (n=23) of the respondents expressed their concern towards lack of quality check in locally manufactured products.

Table 1: Knowledge of Generic Medicines among Physicians

Que. No.	Questions	Correct Responses (n)	Incorrect Responses (n)
1	Generic medicines are therapeutically equivalent to brand name medicines	40	20
2	Generic medicines must be in the same dosage form (such as tablet, capsule) as brand name medicines	41	19
3	Generic medicines are available in the market of India	59	0
4	Brand name medicines are required to meet higher safety standards than generic medicine	21	35
5	Can generic medicine combined and given?	44	12

Table 2: Attitude of Physicians towards Generic Medicines

Que. No.	Questions & Response options	Strongly disagree	Disagree	Neither disagree nor agree	Agree	Strongly agree
1	Therapeutic failures is a serious problems with some locally manufactured medicines	4	15	14	21	6
2	Socioeconomic condition of patient influence the prescription	6	12	3	18	21
3	I am comfortable to prescribe products from all local manufacturers	5	13	14	21	6
4	I feel that my personal experience with medicines influence my prescribing decisions	4	11	11	18	16
5	I feel that patient's demand of medicine influence my prescription	21	19	7	1	12
6	I feel that medical representative is a good source of information for me	28	8	14	8	2
7	I am comfortable if brands in prescription is changed by pharmacist	15	23	5	5	12



Table 3: Perception of Physicians towards Generic Medicines

Que. No.	Questions & Response options	Never	Seldom	Some of the time	Most of the time	All of the time
1	Generics are of low quality than brands	20	18	13	9	0
2	I believe that all the local companies in India are not following GMP guidelines.	7	24	18	10	0
3	I view few local companies as reputable generic medicine manufacturers	0	12	22	22	3
4	I believe that doctors should be educated more about prices of medicines	2	6	6	7	39
5	I believe that doctors should be given incentives to write generic names	24	4	9	5	18
6	I think that confidence should be built in the patient about the low-cost brand	3	6	7	11	33

Table 4: Grading of physicians as per their scoring of KAP

Sr. No.	No. of Physicians →	As per Knowledge Scoring		As per their Perception Scoring		As per their Attitude Scoring	
	Grade (%) ↓	Medicine	Pediatric	Medicine	Pediatric	Medicine	Pediatric
1	Very Good (above 85)	4	2	0	2	0	0
2	Good (75-85)	13	11	3	7	11	13
3	Average (60-75)	3	13	19	21	11	14
4	Poor (< 60)	10	4	8	0	8	3

Almost 67% (n=40) were disagree that pharmaceutical companies' premium offers (gifts) influence their prescribing behavior. The remaining responses were coated in table 2.

Perception about Generic Medicines

When physicians were asked about the affordability of generic medicines 95% (n=57) of respondents agreed that generic medicines are more affordable than brand name medicines. All physicians were believe that locally manufactured medicines are of the same effectiveness as brand name medicines but 66.67% (n=40) were doubtful about this. Similarly, when respondents were questioned about the side effects, only 31.67% (n=19) answered that generic medicines never produce more side effects than brand name medicines. Interestingly, in terms of quality, more than two third (92%) of the respondents viewed that multinational products were of better quality than local company products. The 63.33% (n=38) of respondents believed that their prescribing decision is never influenced by medical representatives. 27 (45%) said that it is not easy to remember brand name medicines. Remaining outcomes present in Table 3.

Results by Scoring of Physicians Knowledge, Attitude and Perception regarding use of Generics

For assessment of Knowledge about Generic Medicine we allotted score '1' for each correct answer and '0' for

incorrect. For assessment of Attitude of physicians about use of Generic Medicine in practice we allotted score Maximum of '5' for best desirable response and further descending scores to poor or undesirable response minimum up to '1'. For assessment of Perception of physicians about use of Generic Medicine in practice we allotted score maximum of '5' for best desirable response and further descending scores to poor or undesirable response minimum up to '1'. After assessing and scoring on basis of their score of Knowledge, Attitude and perception following results obtained. (Table 4)

DISCUSSION

It was mentioned in Indian guidelines of prescription practices as per the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, every physician should, as far as possible, prescribe drugs with generic names;¹¹ but not a single study was found in literature under this heading. So we did prescription assessment at tertiary care centre for use of generic drugs by physician. This study has a great importance in view of health economy of country. WHO says 3.2% Indians will fall below the poverty line because of high medical bills. 39 million Indians are pushed to poverty because of ill health every year. Around 30% in rural India didn't go for any treatment because of financial constrains.² However, physician knowledge, attitude and perceptions about



generic medications may represent an important barrier to greater generic use.

Our findings from medicine OPD showed that only 4.66% (n=14) prescriptions were written by generic name of medicines. Whereas in pediatric OPD we found that 43.33% (n=130) prescriptions were written by generic name of medicines. When we calculated number of prescriptions in which at least one generic name was written we found 67.33% prescription in medicine OPD and 88.66% prescriptions in pediatric OPD. This indicates that at least single generic name written in approximately seven prescriptions out of ten per physician in medicine OPD. Whereas in pediatric OPD almost nine (out of ten) prescriptions per physician were with at least one generic name. The difference of prescription practice between two OPDs is significant and KAP of those physicians may justify this difference.

However, there are many contradictions observed in the physicians' responses: on the one hand, they seemed to be positive about generics and the implementation of an INN system, and on the other hand when it comes to the actual prescribing, they chose the branded products. These findings could be explained by the lack of physicians' information on generics during their education and clinical practice as well as the insufficient regulatory framework of the generic market in the country. In this study knowledge of physicians in terms of safety is very good and most of them were positive (86.67%) about safe use of generic drug in their practice. But they were doubtful about generic medicine prepared by local company so only 23.33% said that the generic medicines manufactured by local company are safe.

Our study was also a first of its kind in India to explore the understanding of knowledge, perception, and attitude of physicians towards generic medicine utilization including factors which affect generic prescribing. In this study, we assessed general knowledge, attitude and perceptions about generic medications to better understand barriers to generic use for commonly used medications. Previous studies in USA have evaluated physician perceptions about specific classes of drugs that have narrow therapeutic windows, such as antiepileptic and anticoagulants.^{12,13} One of the general survey in US by William HS et al., conclude that proportion of physicians expressed negative perceptions about generic medications, representing a potential barrier to generic use.³

By definition, a generic drug is equivalent to its innovator drug in terms of active ingredients, dose, dosage form and bioequivalence. In our study while testing knowledge about generics, 50% respondent had good knowledge about definition and manufacturing of generic medicines. 52.54% of the respondents knew that 'generic medicines are manufactured after patent expiry or innovator'.

Knowledge of physicians in terms of quality is also good 75% of them believe that generic medicines were as equally effective as brand name medicines and they were

of better quality. The total percentage of correct responses regarding knowledge of generic medicines was seen in 48% of the respondents and their scoring shows physician having average knowledge about use of generic medicine.

When we assessed physician's perception the majority (95%) of respondents were agreed that generic locally manufactured medicines are more affordable and of the same effectiveness when compared to brand medicines. Interestingly, in terms of quality, more than two third (91.67%) of the respondents viewed that multinational products of better quality than local company products. This is further confirmed by our findings which showed that the large majority of physicians reported concerns for quality check in locally manufactured medicines. This concern for quality was also supported in a recent US study.³ A system is needed to ensure the quality of generics. The Government of India should be prompted to develop trust for local manufacturers. This could be done by conducting bioequivalence studies in some of the specific therapeutic classes and disseminate information about the similarity of both generic and brand medicines. This finding was similar to those reported from other countries where physicians had poor knowledge on the bioequivalence acceptability criteria for generic medicines as set by their respective drug regulatory bodies.^{14, 15}

The majority of respondents believed that their prescribing decision is never influenced by medical representatives (n=38; 63.33%). In both qualitative^[16] and quantitative phases doctors admitted that the persuasion of medical representatives affected their prescribing patterns and prescribing decision. Interestingly, a large body of evidence suggested that medical representatives are a good source of information and pharmaceutical industries and their representatives do have direct and indirect effect on prescribing outcomes.^[17] On the contrary, a study conducted on GPs in the UK denied any undue impact of drug representatives on their prescribing¹⁸ which is similar to our study.

Almost 39 (61.67%) physicians were viewed that all the time doctors should be educated about prices of generics. More than the half physician's perceived that generics are not only for poor people. Furthermore the government can play a positive role by means of communication messages, pamphlets and flyers about generic medicines. This could be put in line with persuasive communication theory. It is the theory that endeavors to explicate how behavior is affected by communication and attitude processes. The aim of persuasive communication is to influence the doctor and to change the attitude. Thus, the essential intent of persuasive communication is attitude change.

Some of the previously published studies suggested that GPs consider commercial sources of drug information more powerful than non-commercial information sources.¹⁹ We propose a system where non-commercial



sources of information for doctors should be promoted. Journals, product monographs, non-commercially sponsored CME programs could be useful to seek information. A 24x7 Drug Information Center (DIC) at a national level which expect to foster dissemination of unbiased information will pave the way for rational prescribing. One of the convincing findings in this study was the doctor's expectations to be educated more about the prices of medicines. This is in concordance with the previous studies done in USA and Ireland in which physician's understanding of the cost is an important determinant in prescribing, awareness about the cost of medicines, as well as the need of interventional strategies and educational activities are prerequisites to make doctors cost-effective prescribers.²⁰

Considering how little we know about what interventions influence physician prescribing behavior, any such approach should be studied rigorously to build an evidence base for interventions to encourage rational prescribing.

Limitations of our Study

We identified some limitations in the study which should be taken into account. The major limitation of our study is that the study finding could not be applied to wider medical community as the study was restricted to physicians practicing in hospital setup. Another thing we would like to mention here while scoring physicians knowledge, attitude and practice regarding use of generic drugs we assumed all positive thoughts regarding generics this view may differ from researcher to researcher and may introduce bias in results.

Our Recommendations from this study for Promotion of use of generics

- 1) Doctors need to be educated and reassured about generic products approval system with regards to efficacy, bioequivalence, quality and safety during their academic and professional career. This will be done by conducting several BA/BE studies with Generic vs. Branded drugs and results should be communicated.
- 2) Generic medicine awareness campaign should be carried out to improve use of economical medicines by giving confidence to patients regarding their safety and efficacy.
- 3) There is need for regulations to prescribe medicine by generic name and systematic efforts should be taken so that every prescriber follow those regulations.
- 4) There is a need to make easy availability of generic medicines throughout the country and their marketing should be done through dedicated outlets like Janaushdhi stores.
- 5) Pharmacist should be authorized to substitute costly branded drugs with cheaper generics on patient's demand.

- 6) Promotion of generic drugs is possible by non-commercial sources of information for doctors like Journals, product monographs, non-commercially sponsored CME programs & newsletters of professional bodies.
- 7) Furthermore the government can play a positive role in promotion by means of communication messages, pamphlets and flyers about generic medicines usage and availability.
- 8) A system is needed to ensure the quality of generics. The Government of India should be prompted to develop trust for local manufacturers. This could be done by conducting bioequivalence studies in some of the specific therapeutic classes and disseminate information about the similarity of both generic and brand medicines.
- 9) Medical Practitioner Associations and Medical Council of India in collaboration with the Government of India should distribute wall hangings for their private clinics and government set ups. These wall hangings should be inscribed with basic facts about generic medicines.
- 10) Insurance companies and trust or NGOs who are works in the interest of patient's care should encourage use of generic medicine.
- 11) The government should create a database of generic equivalents of branded medicine, paving the way for mandatory prescription of such low-cost drugs along with their costlier versions.
- 12) We also found that as there were more patient of non-communicable diseases like HTN, IHD, DM in Medicine OPD as compare to pediatric (most of the patients with communicable diseases like fever, URTI, Malaria etc.). This dynamic management may influence Doctor's decision about use of generics. More studies will be needed to confirm this statement.

CONCLUSION

Though specific guidelines given to physicians to write prescriptions with generic name very few of them were following those guidelines so there is a need to streamline this issue with help of regulations. Although the gap in knowledge of generic medicines among physicians is evident, but conducive perceptions and attitudes were observed. In order to increase use of generics, doctors need to be educated and reassured about generic products approval system with regards to efficacy, bioequivalence, quality and safety during their professional career. Socio-economic condition of the patient and the influence of medical representatives were some of the cited measures to favor generic prescribing. All these issues need to be addressed for the realization of the true benefit of generic medicines as part of the country's cost-containment strategy as well as the establishment of generic medicines policy in India.



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