

Prescribing Generic drugs: Insights into Doctors' Knowledge, Attitudes, and Practices in a Rural Tertiary care Teaching Hospital in Northern India

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ABSTRACT

Introduction: The assessment of knowledge of prescribers and their attitude and practice towards generic drugs would help to identify the misunderstandings regarding generics and identify the hindrances which prescribers face in prescribing generic medicines.

Objectives: To assess the Knowledge, Attitude, and Practice (KAP) of doctors towards prescribing generic medicines.

Materials and Methods: A questionnaire based cross-sectional study to assess the KAP of generic medicines among prescribers working in a tertiary-care teaching hospital, Government Medical College and Associated Hospital, Jalaun (India). A questionnaire containing 34 questions was designed to assess the Knowledge, Attitude and Practices of doctors about generic medicines and the factors considered before prescribing the drugs.

Results: More than half (54.36%) of the participants were aware that generic name and generic drugs were not the same and about three fourth of the study participants (78.64%) agreed that generic medicines are usually intended to be interchangeable with an branded drug which was statistically significant; 59.22% of participants regarded generics as safe as branded drugs ($p=0.008$). 62.13% doctors were of the opinion that generic medicines are as effective as branded drugs ($p=0.005$); 72.61% of participants prescribe generic drugs ($p=0.0001$); Most of the prescribers (76.69%) were not influenced by medical representatives ($p=0.001$) while 55.33% believed that changing the patient from brand name to generic drug ($p=0.1266$) may change the results of the therapy.

Conclusion: Although most of doctors prescribed generic drugs yet some lacunae exist regarding knowledge and attitude about generic drugs. Most of the doctors were concerned regarding safety and efficacy of generic drugs. Doctors also wanted government to come up with guidelines regarding prescribing generic drugs and wider implementation of Jan Aushadhi covering all hospitals.

Key words: Generic drugs, Knowledge ,Attitude, Practice (KAP) study , Generic medicines

INTRODUCTION

Health, defined by World Health Organization (WHO) is "a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity."¹ Drugs play an important role in protecting, maintaining, and restoring people's health. However, growing healthcare costs continue to be a major issue for all nations worldwide, especially for developing countries like India. It has been estimated that about 63 million people are pushed below the poverty line (BPL) due to a rise in healthcare costs². The cost incurred on drugs make up a big component of health care costs and it has been a priority to provide generic medicines to make health care affordable without compromising on the quality.

A Generic drug is "A drug product that is comparable to a brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use."³ However a Generic Name or Non-proprietary name is a name assigned by a competent scientific body like in the United States, by the United States Adopted Names (USAN) Council or the British Approved Name (BAN) for a pharmaceutical substance, as defined in the British Pharmacopoeia. WHO has issued a specific guideline called "Guidance on the use of International

Nonproprietary Names (INNs) for Pharmaceutical Substances” which facilitates the identification of pharmaceutical substances or active pharmaceutical ingredients and each INN is unique and recognized worldwide.⁴ A Generic drug is marketed after the expiry of the patent/brand drug. On the other hand, a patent/brand drug is originally discovered and developed by a pharmaceutical company and needs to undergo extensive clinical trials for safety and efficacy before the drug is approved by the country's regulatory authority. Since a Generic drug doesn't have to undergo exhaustive and expensive clinical trials before being approved for marketing, generic drugs are much cheaper than brand drugs and prescribing generic drugs may substantially reduce the overall cost of healthcare. Substituting brand-name drugs with cheaper generic drugs has been shown to decrease expenditure on health care by 10-90%.⁵

Although generic drugs are much cheaper than branded Drugs yet due to the absence of a standard drug regulatory mechanism and inadequate compliance to Good Manufacturing Practice (GMP), doctors may favor branded drugs over generic drugs.⁷ Doctors rely on the reputation of the pharmaceutical companies in deciding which drug to give. The reason for doing this study was the misconception among prescribers about generic names and generic drugs, how these are different from brand drugs, the quality and approval process of generic drugs, and the safety profile and efficacy of generic drugs. Therefore, understanding prescribers' perceptions about generic drugs may help to recognize hurdles in prescribing. Hence, with this background the study was conducted to assess the Knowledge, attitude, and practices (KAP) of doctors towards the use of generic drugs.

MATERIAL AND METHODS

Study site

The study was planned and conducted in the Department of Pharmacology at Government Medical College and Associated Hospital, Jalaun (Orai), a 470-bed tertiary care teaching hospital, located in the Bundelkhand area of Uttar Pradesh.

Study design

This was a questionnaire-based cross-sectional study conducted with aim to assess the Knowledge, Attitude and Practice of generic medicines among prescribers in this hospital. The duration of the study was two months from 1st October 2024 to 30th November 2024.

Inclusion criteria

All doctors working in the medical college were included in the study after obtaining an informed consent.

Exclusion criteria

All those who didn't consent or those who didn't return the questioner were excluded

Data Collection

The questionnaire was distributed among the 139 doctors who were practicing in the hospital at the time of study. They were explained the objectives of the study and informed verbal consent was obtained before the start of data collection process. A total of 103 completed self-administered questionnaires were obtained which were included in the study.

Study Tool

The study questionnaire consisting of 28 questions (9 questions on knowledge of generic medicines, 11 questions regarding participants' attitude towards generic medicines and 8 questions pertaining to practice of generic medicines) was designed using information from similar studies regarding knowledge of participants for generic medicines, attitude towards generic medicines and practice of generic medicines, and the factors that influence the prescription of medicines³In addition 6 questions were added in questionnaire about various issues related with the use of generic medicines Pilot study was conducted by administering the questionnaire to 15 doctors who were from the medical college.

The doctors were requested to complete the questionnaire and return it within 5 working days to the Department of Pharmacology, GMC, Jalaun (Orai). Any clarification needed in understanding the questionnaire was provided.

Statistical Analysis

The data was entered and was analyzed using Statistical Package for Social Science (version 23.0; SPSS. Results were expressed in terms of frequency percentages. A *p*-Value of <0.05 was considered to be statistically significant.

RESULTS

Table -1- Distribution of study participants based on demographic details.

	Characteristics	Frequency (%)
Gender	Male	71(68.9)
	Female	32(31.1)
Age (years)	< 30	45(43.6)
	30-40	36(34.9)

	40-50	9(8.7)
	50-60	8(7.7)
	>60	5(4.8)
Qualification	MBBS	53(51.4)
	MD	38(36.8)
	PG Diploma	12(11.6)

Of the total participants, 68.9% were male and 31.1% were female. The majority (43.6%) were under 30 years of age, followed by 34.9% in the 30–40 years age group. Participants aged 40–50 years comprised 8.7%, those aged 50–60 years made up 7.7%, and 4.8% were over 60 years old. In terms of educational qualifications, 51.4% held an MBBS degree, 36.8% were MD-qualified, and 11.6% had completed a postgraduate diploma

Table 2: Distribution of study participants according to knowledge regarding use of generic medicines.

S.No	Questions	Yes (%)	No (%)	P- value
1	Do you believe that a generic name and generic drug are the same.	47(45.63)	56(54.36)	0.2098
2	Are Generic drug generally meant to be used interchangeably with a Patent drug?	81(78.64)	22(21.35)	0.0001
3	Can generic drugs be marketed only after the patent on the original drug has expired	56(54.36)	47(45.63)	0.2113
4	Do generic drugs contain the same active ingredient(s), dosage, route of administration, and treatment duration as patented drugs for the same condition?	64(62.13)	39(37.86)	0.0005
5	Does Generic drug manufacturer require to conduct the preclinical and clinical trials again for patent drug?	73(70.87)	30(29.12)	0.0001
6	Do you think generic drugs help reduce overall healthcare costs?	79(76.69)	24(23.30)	0.0001
7	Do Generic drug manufacturer require to carry out bioequivalence studies to prove equivalence amongst the generic drug and the patent drug?	73(70.88)	30(29.12)	0.0001
8	Are you aware that the Indian Medical Council Act (Professional conduct, Etiquette and Ethics) Regulations, 2002 encourage every doctor to prescribe drugs with generic names whenever possible.	64(62.14)	39(37.86)	0.0005
9	Are you familiar with the Government of India scheme called <i>Jan Aushadhi</i> which aims to set up generic drug stores nationwide.	71(68.94)	32(31.06)	0.0001

In the present study, 54.36% of participants correctly identified that the generic name and a generic drug are not the same ($p = 0.2098$). A significant majority (78.64%) of doctors acknowledged that generic medicines are generally considered to be interchangeable with branded (patented) drugs ($p = 0.0001$). Additionally, 54.36% of respondents were aware that generic drugs can only be marketed after the expiration of the patent period of the innovator drug ($p = 0.2113$).

Moreover, 62.13% of doctors recognized that generic drugs contain the same active ingredient(s), and are administered at the same dose(s), through the same route(s), and for the same duration to treat the same conditions as their patented counterparts ($p = 0.0005$). A substantial proportion (70.87%) understood that generic drug manufacturers are not required to redo the preclinical and clinical trials conducted for the original patented drug ($p = 0.0001$). Furthermore, 76.69% agreed that generic drugs serve as a vital tool in reducing overall healthcare expenditure ($p = 0.0001$).

Awareness regarding the necessity of conducting bioequivalence studies for generic drug approval was reported by 70.88% of doctors which was found to be statistically significant ($p = 0.0001$). The majority of the doctors i.e. 62.14% were aware that the Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulations, 2002, recommend that physicians prescribe medications by their generic names whenever possible ($p = 0.0005$). More than half 68.94% of the practitioners were familiar with the Government of India scheme called *Jan Aushadhi* which aims to set up generic drug stores nationwide.

Table 3: Distribution of study participants according to Attitude regarding the use of Generic medicines.

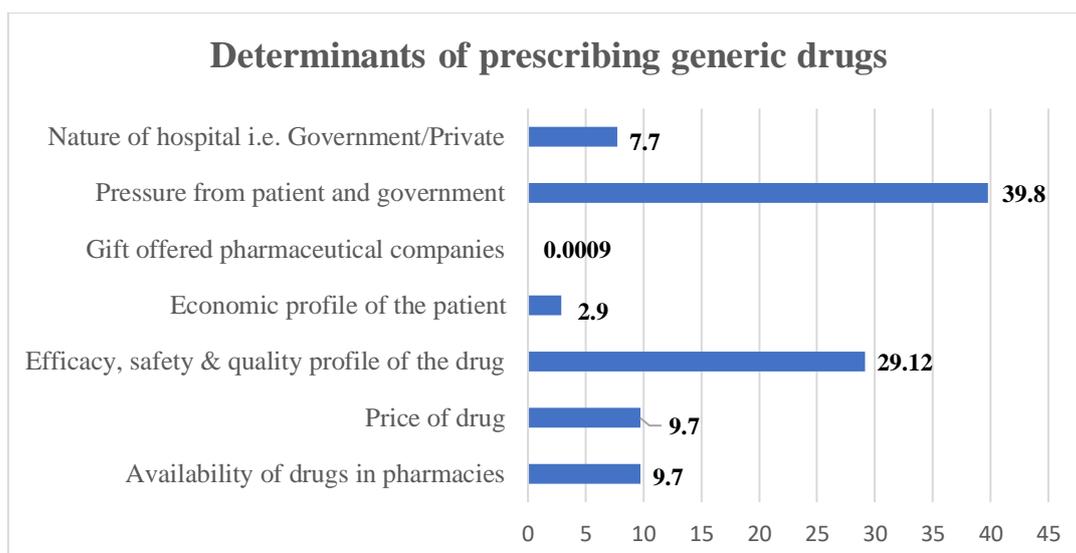
S.No.	Questions	Yes (%)	No (%)	P value
1	Are Generics of only reputed pharmaceutical companies safe and effective?	57(55.33)	46(44.66)	0.1066
2	Are Generics not as safe as branded drugs?	42(40.77)	61(59.22)	0.008
3	Are Generics not as effective as brand-name drugs?	39(37.86)	64(62.13)	0.0005
4	Are Generics intended for only low-income patients?	44(42.71)	59(57.28)	0.0368
5	Do generic medications take longer to produce therapeutic effects?	53(51.46)	50(48.54)	0.6769
6	Brand-name drugs are made in superior manufacturing facilities as compared to generic medicines	63(61.16)	38(36.89)	0.0005
7	Do you think generics are cheaper because they are of lower quality?	58(56.31)	45(43.78)	0.0706
8	Do Brand Name Drugs produce lesser side effects than generic drugs?	61(59.22)	42(40.77)	0.0083
9	Should there be training programs to improve awareness of generic drugs amongst prescribers and patients?	75(72.81)	28(27.18)	0.0001
10	Do you think that every hospital should have a dedicated generic drug store?	77(74.75)	36(34.95)	0.0001
11	Should patients have the freedom to choose generic drugs over branded ones	56(54.36)	47(45.63)	0.2113

The survey responses reveal varied attitudes toward generic drugs among participants. A statistically significant portion of respondents disagreed with common misconceptions that generics are less safe ($p = 0.008$) or less effective ($p = 0.0005$) than brand-name drugs and also rejected the idea that generics are meant only for poor patients ($p = 0.0368$). However, a notable proportion of participants believed that generics are produced in substandard manufacturing facilities compared to branded drugs ($p = 0.0005$) and that brand-name drugs cause fewer side effects ($p = 0.0083$). Despite some persistent doubts, there was strong support for initiatives to increase awareness: a significant majority agreed on the need for training programs for both doctors and patients ($p = 0.0001$) and supported the establishment of generic drug stores in hospitals ($p = 0.0001$). These findings suggest a need for educational interventions to address misconceptions and promote confidence in the use of generic medications.

Table 4: Distribution of study participants according to the use of Generic medicines.

S.No.	Questions	Yes (%)	No (%)	P value
1	Do you prescribe generic drugs?	75(72.81)	28(27.18)	0.0001
2	Do you review any articles comparing the safety and efficacy of generic and branded drugs before prescribing?	73(70.88)	30(29.12)	0.0001
3	In your opinion, can replacing a brand-name drug with a generic alter the effectiveness of the treatment?	57(55.33)	46(44.66)	0.1266
4	Do medical representatives influence your prescription habits?	24(23.30)	79(76.69)	0.0001
5	Are you comfortable if pharmacist change branded drugs prescribed by you with generic drugs?	42(40.77)	61(59.22)	0.0083
6	Do you think branded drugs name are easy to remember and recall?	51(50.51)	52(50.48)	0.1938
7	I am in favor of replacing brand-name drugs with generics in all applicable cases.	48(46.60)	55(53.40)	0.331
8	I am in favor of generic drugs substitution but not in all cases.	73(70.87)	30(29.12)	0.0001

Figure:1 Determinants of the Practice of Prescribing Generic Drugs



DISCUSSION

In the present study, although good percentages of doctors have considerable knowledge about generic medicines, yet some gaps do exist which is similar to study conducted in generic medicines among general practitioners of Karachi, Pakistan⁸. Majority of them did not know the difference between generic drug and generic name which is similar to a study done in Australian Hospital⁹. Very often generic prescribing is misconceived as prescribing by a drug's generic name or non-proprietary name. All generic drugs have a brand name as well as a nonproprietary name but all drugs having a non-proprietary name (generic name) may not be available generic drugs. A knowledge gap was observed regarding the marketing of generic drugs following the expiration of brand-name drug patents. In the present study, the majority of participants demonstrated awareness that generic medicines are considered to be interchangeable with branded drugs, based on bioequivalence data provided by the United States Food and Drug Administration¹⁰. Previous studies have confirmed that generic medicines perform equivalently to their branded counterparts¹¹. Notably, a significant portion of the study population (76.69%) believes that generic drugs play an important role in reducing overall healthcare expenditure. The average cost of branded drugs in India is found to be 70% less than generic medicines¹². To overcome the problem of unavailability of generic drugs government of India started Jan Aushadhi project in 2008, the purpose of which was to provide low-priced generic drugs¹³. 68.95% of participants are aware of Jan Aushadhi which is similar to another study conducted in India¹⁴.

The Drug Price Competition and Patent Term Restoration Act (Also known as the Hatch-Waxman Act) is a 1984 United States federal law which allowed generic drug manufacturers to skip various phases of clinical trials and needed to demonstrate bioequivalence with the original product¹⁵. This resulted not only in decreasing cost of medicines but also made manufacturing of generics easier. 70.88% of participants knew that generic drug manufacturers need not repeat the preclinical and clinical studies required for patent drug. Although generic drug manufacturers are not required to conduct the preclinical and clinical studies again, yet most of the participating doctors believe that generic medicines are equally safe and effective as branded drugs is supported by findings from a study in South India.¹⁶ The regulatory body makes sure that generic drug manufacturer compliance to the Good Manufacturing Practices (GMP) guidelines as laid down by regulatory body^{17, 18}.

About 42.71% of doctors thought that generics were meant only for the poor patients and another 61.16% were of the view that generics are manufactured in substandard facilities. The issue of substandard generics has been raised time and again and remains important hindrance in prescribing generic drugs¹⁹. Nearly half of the participants thought that generics took more time to show its therapeutic effects in the body. Majority of the participants thought that branded drugs produce lesser side effects which are similar to a study conducted in 2001²⁰. Nearly three fourth of the doctors agreed that there should be a generic store in every hospital and for the need of training program regarding awareness of generic drugs. However, significant number of treating doctors thought that patient should not have liberty to choose generic drugs over branded drugs.

Most of the participants believe that bioequivalence studies should be conducted by all manufacturing companies for all batches being produced by them and quality testing of generic medicines should be made more vigorous which is similar to the finding of another study¹⁴. 59.22% participants also believe that prices of generics should be much lower than generic drugs. 78.64% doctors also felt that government should come out with guidelines to prescribe generic drugs which would reduce confusion among prescribers. Majority of doctors also agreed that Doctor should have right to choose generic drug of specific pharmaceutical company according to doctor experience of efficacy

and safety of that product be used. In our study, we have found that most of the doctors prescribe generic medicines and their prescriptions are not influenced by medical representatives. Majority of them were not comfortable if pharmacist changed branded drugs prescribed by them with generic drugs and switching a patient to generic may alter the outcome of the therapy which is contrary to finding of a study in south india¹⁶.

The primary limitation of this study is its short duration and relatively small sample size, which restricts the generalizability of the findings. Additionally, the study focused solely on the knowledge, attitudes, and practices of doctors, excluding other key stakeholders in healthcare—namely, patients and pharmacists—whose perspectives are equally important for a comprehensive understanding.

CONCLUSION

Although most of doctors prescribe generic drugs yet some lacunae exist regarding knowledge and attitude about generic drugs. Most of prescribers faced problem in prescribing generic name for Fixed Dose Combination having more than two drugs such as cough syrups and multivitamin tablets. Most doctors agreed that they should have the autonomy to choose a generic drug from a specific pharmaceutical company based on their clinical experience with the product's efficacy and safety. This preference aligns with findings that physicians prioritize a medicine's efficacy, safety, and quality profile when prescribing drugs. There should mention of Branded or Generic drug on each strip in atleast two languages so that both doctor and patients aware about medicines they use

Regular training programs should be conducted to enhance awareness about generic drugs among both doctors and patients. Additionally, including bioequivalence study data on each drug strip would help build doctor's confidence in prescribing generic medications. It is also important to acknowledge that not all drugs can be manufactured as generics due to existing patent protections. Therefore, clear guidelines should be established for the appropriate prescribing of both branded and generic drugs. The issue of generic drug unavailability can be addressed by establishing generic medicine outlets in all hospitals and by expanding the implementation of the Jan Aushadhi project.

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Conflicts of interest- None

Permissions –Nil

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