

## GENERIC DRUG: PRESCRIBER'S PERSPECTIVE

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Received: 20 Jun 2020, Revised and Accepted: 28 Jul 2020

### ABSTRACT

**Objective:** Knowledge of doctors and their understanding of generic drugs could facilitate in recognizing potential barriers to larger generic medicine prescriptions. Hence, the primary objective of this study was focused to explore knowledge, attitude, and practice (KAP) of doctors toward generic medicines.

**Methods:** It is a cross-sectional questionnaire-based study. The study participants are the doctors working in the hospital during the study period (2016–2017). The questionnaire designed for this study comprised of thirty-five questions related to the knowledge, attitude, and practice (KAP) of generic medicine and about demographic details of the participants.

**Results:** A total of 86 questionnaires were distributed among the health care professionals and the response rate is 37%. The majority of doctors who participated in this survey perceived that generic medicine is effective, safe and need to have the same active component, dose and bioequivalent as the brand name medicines. Most of the doctors (72%) were of the view that generic drugs were manufactured in poor quality than branded medicines. More than three-quarters of doctors (78%) prescribed generic drugs.

**Conclusion:** Majority of the participants had an honest angle about the efficaciousness and safety of generic and though they sometimes prescribe generic medicine, however a high range of doctors (72%) were of the opinion that generic was of poorer quality than brand medicine. To have a better understanding of the generic drug, the doctor must be well informed about the generics during their academic career resulting in savings to healthcare budgets.

**Keywords:** Generic drugs, Questionnaires, Knowledge, Attitude, Practice

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DOI: <http://dx.doi.org/10.22159/ijpps.2020v12i9.38804>. Journal homepage: <https://innovareacademics.in/journals/index.php/ijpps>.

### INTRODUCTION

Healthcare expenditure is increasing steadily worldwide and prescription drug spending is increasing and out-of-pocket expenses are 80% of total health-care expenditures [1]. In developing countries, out-of-pocket payment is as high as 80% of healthcare spending and a similar scenario are observed in the Indian healthcare system. Between 1986 and 2004, the average real expenditure per hospital admission increased three times in both government and private hospitals. Most healthcare expenses are paid out of pocket by patients and their families, rather than through medical insurance. This has led over 35% of Indian households to incur Catastrophic Health Expenditure (CHE) and hence poses a burden of affordability of medicine [2, 3]. Generic medicine utilization is often encouraged to curb the cost of medicine as the generic product are usually lower in price than innovator brands leading to substantial savings of health care expenditure [4-6].

Although the generic medicines are bioequivalent of their innovator products and are produced according to good manufacturing practices (GMP), physicians are apprehensive regarding the quality and reliability of generic drugs as compared to their brand innovator and resist prescribing them [7, 8].

Therefore, understanding doctor's perceptions and an understanding of generic medicines may help in recognizing possible barriers to greater generic medicine usage. Hence, the primary objective of this study was focused to explore knowledge, attitude, and practice (KAP) of doctors toward generic medicines.

### MATERIALS AND METHODS

#### Methods

The study was conducted in a tertiary-care teaching hospital in North-East India after obtaining due permission from the institutional ethics committee (NEIGR/IEC/2015/0039).

#### Study design

It is a cross-sectional questionnaire-based study. The study participants were all the doctors working in the hospital during the study period. The questionnaire designed for this study was comprised of 35 questions related to the knowledge, attitude, and practice (KAP) of generic medicine and about demographic details of the participants. The questionnaire consisted of four sections. The first section focused on doctors' demographic data. The second section was a set of twelve statements and aimed to assess their knowledge about generic medicines. The third section comprised fourteen statements investigating doctors' attitude on issues about generic medicine utilization in the hospital. The fourth section consisted of nine questions related to the practice of generic medicine.

#### Data collection

All doctors from the study hospital were informed about the study utilizing an invitation letter by researchers one week before the study, and a reminder card was sent one day before the session. On the day of the data collection, structured and pre-validated questionnaires were distributed to the doctors who gave consent for participating in the study. For pre-validation, questions were subjected to cognitive testing with five physicians who were shown the questions and allowed to provide responses and their feedback regarding their understanding of the questions. Accordingly, necessary amendments were made to the questions before the main study. The responses of these physicians were included in the analysis. The study participants had to fill up the questionnaire anonymously within 60 min and return the same to the researcher.

#### Statistical analyses

Descriptive statistics, including frequency calculations, percentages and means, were used to analyze demographics of the participants

and respective answers on different categories of the questionnaires.

## RESULTS

Response rate-A total of 86 questionnaires was distributed among the health care professionals and 32 responded (response rate 37%).

Demographic characteristics-The demographic details of the participants have been summarized in table 1.

### Knowledge

Seventy-eight percent (78%) doctors agreed that generic medicine is bioequivalent to a brand name medicine. Seventy-two percent (72%) and seventy-five percent (75%) doctors were aware that generic medicines are the same dosage form and contain the same dose as the brand name medicines, respectively. Eighty-four (84%) doctors did not agree that generics are less effective and produce

more side effects than brand name medicines. Sixty-six percent (66%) doctors disagreed that brand name drugs meet higher safety standard, but seventy-two percent (72%) doctors were not satisfied with the quality of generic drugs. Seventy-two percent (72%) doctors were unaware that generic drugs can be only marketed after the expiry date of the patent of original drugs. Among study participants, fifty (50%) doctors knew that generic drug manufacturers need not repeat the preclinical and clinical studies of original drugs but eighty-one percent (81%) doctors were aware that generic drug manufacturers need to conduct bioequivalence studies to show the equivalence of generic and original drugs.

Among the participants, fifty-six (56%) doctors told that they were aware regarding the JanAushadhi scheme and eighty-four (84%) doctors were aware of the Indian Medical Council (IMC) act to prescribe drugs with generic names.

Knowledge related questionnaires and their responses are summarized in table 2.

**Table 1: Demographic details of the participants (n = 32)**

Factors		Frequency (%)
Gender	Male	56
	Female	44
Age(years)	20-30	66
	30-40	34
	Mean	31.32+/-04.22
Qualification	MBBS	66
	MD	28
	DM	06

**Table 2: Knowledge-related questions and frequency (%) of responses**

S. No.	Questions	Yes (%)	No (%)
1	A generic medicine is bioequivalent to a brand name medicine	78	13
2	A generic medicine must be in the same dosage form as the brand name medicine	72	28
3	A generic medicine must contain the same dose as the brand name medicines	75	22
4	Generic medicines are less effective compared to brand name medicines	13	84
5	Generic medicines produce more side effects compared to brand name medicines	13	84
6	Brand name medicines meet higher safety standards than generic medicines	31	66
7	Generic drugs can be only marketed after the expiry date of the patent of original drug	19	72
8	Generic drug manufacturer need to repeat the preclinical and clinical studies required for original drug	50	44
9	Generic drug manufacturers need to conduct bioequivalence studies to demonstrate equivalence between the generic medicine and the original drug	81	13
10	Are you aware of the scheme of Government of India called <i>Jan Aushadhi</i> ?	44	56
11	Are you aware about the Indian Medical Council (IMC) Act to prescribe drugs with Generic names	84	16
12	Are you satisfied with the quality control measure of generic medicines by the Regulatory authority	25	72

### Attitude

Majority of doctors (69%) were of the view that generic drugs were as safe as branded drugs and eighty-four percent (84%) doctors felt that there is a huge price difference so that they prescribe cheaper generic substitutes. Seventy-five percent (75%) doctors did not agree that generic drugs cost less because they are inferior to brand name drugs and sixty-six percent (66%) doctors agreed that both generic and branded drugs have the same quality in general.

Another sixty-two percent (62%) doctors disagreed that brand names are easy to remember, eighty-seven (87%) doctors felt that both prescriber and pharmacist if work together, there is more use of generic drugs in society and ninety-four percent(94%) participants felt that there should be a standard guideline to prescribe generic medicines. Only 91% of doctors mentioned they give enough information to the patients about generic medicines and their price differences. It is observed that 72% of participants felt that they need more information related to safety and efficacy of generic medicines, and 38% of doctors felt that advertisement by the drug companies will influence their future prescribing pattern.

Majority of doctors (91%) agreed that there should be a training program to increase the awareness regarding generic drug use

among doctors and patients and there should be a general medicine store in every hospital. Only 38% of doctors are satisfied with the marketing permission process granted to generic medicines and not satisfied with the quality control measures of it.

Attitude related questionnaires and their responses are summarized in table 3.

### Practice

Majority of doctors (78%) prescribed generic drugs to their patients and 63% of them prescribed as much as 1 to 3 generics per prescription. Doctors prescribe generic medicine for their patients and themselves in 69% and 63% cases, respectively. As many as 47% of doctors discussed with their patients regarding generic drugs and 84% of them felt that the patient's socioeconomic condition influenced their prescription, as shown in table 4.

Seventeen (53%) out of the total respondent of doctors did not think that switching all patients from branded drugs to generic may change the outcome of the therapy, but only 38% of participants thought switching brand name drugs with narrow therapeutic range to generic may change the outcome of the patient. Most of the doctors (38%) got information regarding the availability of generic drugs from the Internet, followed by Journal (12.5%), Drug

compendium (12.5%) and Medical representatives (12.5%) etc. Majority of doctors (81%) never received any free sample of generic medicines but received (81%) free samples of branded drugs.66%

participants stated that representatives of generic drug manufacturers never visited them but 59% of doctors were visited weekly by Representative of brand name drugs manufacturers.

**Table 3: Attitude-related questions and frequency (%) of responses**

S. No.	Questions	Disagree (%)	Neutral (%)	Agree (%)
1	Generics are as safe as branded drugs	13	19	69
2	The price difference between generic and brand name drugs is often so great that I feel I must prescribe generic substitutes	0	16	84
3	Generic drugs cost less because they are inferior to Brand name drugs	75	6	16
4	Generic medicines are generally of the same quality as brand-name drugs	19	16	66
5	It is easier to remember brand names, rather than generic drug names	62	16	22
6	Quality use of generic medicines among patients can be achieved if both prescribers and pharmacist work together	0	13	87
7	We need a standard guideline to prescribe generic medicines	0	6	94
8	Patient should be given enough information about generic medicines in order to make sure they really understand about the medicines they take	0	9	91
9	Advertisement by the drug companies will influence my future prescribing pattern	22	38	38
10	Need more information on the issues pertaining to the safety and efficacy of generic medicines	0	25	72
11	There should be a training program to increase awareness regarding generic drugs among doctors and patients	0	9	91
12	There should be a generic medicine store in every hospital	0	9	91
13	Satisfied with the marketing permission process granted to generic medicine	34	28	38
14	Satisfied with the quality control measures of generic medicines	38	28	31

**Table 4: Practice-related questions and frequency (%) of responses**

S. No.	Questions	Yes (%)	No (%)
1	Do you prescribe generic drugs to your patients?	78	19
2	Have you ever taken Generic Medicine?	63	34
3	Have you ever prescribed generic medicine to your family members?	69	28
4	Have you ever talked to your patient regarding Generic drugs?	47	50
5	Do you think that switching all patients from a brand name to generics may change the outcome of the therapy?	41	53
6	Do you think switching brand name drugs with narrow therapeutic range to generic may change the outcome of the therapy of patient?	38	56
7	Does the socioeconomic condition of your patient influence your prescription?	84	09
8	Have you ever received free samples of Generic drugs?	16	81
9	Have you ever received free samples of Brand name drugs?	81	16

## DISCUSSION

The response rate achieved in this study, too, was 37%, which is quite similar to the earlier study by Kumar *et al.* [9]. It is more challenging to obtain high response rate, especially from doctors practicing not only in private healthcare sectors but also in Government hospitals. Moreover, Kellerman and Herold reported that nonresponse bias may be of less concern to physicians because they are considered to be consistent in opinion and view regarding knowledge, attitude and practice [10, 11].

The majority of doctors who participated in this survey perceived that generic medicine is effective, safe and needs to have the same active component, dose and bioequivalent as the brand name medicines. It is quite similar to the earlier study by Jamshed *et al.* as stated correct knowledge about generic medicine being a "Copy of the brand name medicine" [11, 12].

In the present study, the majority of doctors (81%) were aware of bioequivalence studies, which are required by generic drug manufacturers during generic product approval system. Our finding is better than the finding reported by Chua *et al.* and Hassali *et al.* where 4.6% and 33.3% doctors respectively were aware of the bioequivalence standards for generic products [12, 13].

Most of the respondents in our study were unaware about some regulatory requirements (like generic marketed after the expiry of the patent of the originator or no need to repeat preclinical and clinical study for the generic product) imposed on generic drugs as stated in earlier studies [14]. A large number of doctors (72%) were

of the view that generic was manufactured to the poorer quality than brand name medicines. According to the present analysis, close to three-quarters of the participants had a good attitude about the efficacy and safety of generic medicines, and the majority of doctors actively prescribe generic medicines similar to the earlier study [15, 16]. Moreover, various studies have reported that generic medicines neither differ substantially from their innovator counterparts nor related to poor efficacy or safety and even favored the use of generic drugs in treating various diseases [17, 18].

In our survey, the majority of doctors were aware of the huge price difference between generic and brand name products, and they give enough information to the patient about generic medicines with their price differences. They also prescribe cheaper generic substitutes, considering the patient socioeconomic condition. It was earlier reported that the cost of generic medicines is up to 91% less than that of the brand name drugs [19-22].

The rising health care expenses remain a serious concern for the health care system worldwide, especially in developing countries like India where availability and affordability of medicine are a major concern. To tackle this problem, the Indian Government started a project "Jan Ausadhi" to supply essential low priced generic medicine on-demand to Jan Ausadhi stores. Only half of the participants in our study were aware of regarding Jan Ausadhi Scheme. The expansion of the generic market should have a positive impact on patients' access to cheaper drugs [22-25].

Though most of the participating doctors received a free sample of branded drugs and half of the participants were visited weekly by

the representative of brand name medicine manufacturers in our study, but a few of doctors (38%) felt that advertisement by the drug company will influence their future prescribing pattern which is contradictory to earlier studies where they stated the presence of heavy and successful promotional activities from branded product industry may negatively influence generic prescribing [26-28].

More than three-quarters of doctors (78%) prescribed generic drugs and they (84%) were aware of the Indian Medical Council (IMC) Act to prescribe drugs in generic names in the present study. Our result is far better than the previous studies in Bahrain (10.2%), Belgium (2.8%), Malaysia (12.7%) and USA (2-22%) but is quite similar to the earlier studies in the UK (83%) and Thailand (73.9%) [29, 30]. This may be due to the introduction and encouraging generic prescribing at the early stage of medical school and the Indian Medical Council (IMC) Act to prescribe drugs in generic names. Even in Europe, several measures and interventions have been taken to enhance prescribing in generic medicines [30-32].

Although majority of the doctors surveyed had good knowledge and attitude about generic medicines and a meaningful proportion of doctors actively prescribed generic drugs, still more information about generic drugs are needed by them especially on quality to increase generic medicine prescription rates [33, 34]. Participating doctors also agreed that it was important to establish a greater collaboration between them and the pharmacists, in order to improve generic utilization among consumers. They also expressed the need for standard guidelines on generic substitution policy.

#### LIMITATION

A possible limitation of this study could be the small sample size, thus findings of this study can hardly be generalized. A further potential limitation may be the manner of participant selection as all doctors participating had a university affiliation and working in the tertiary medical teaching hospital. Other limitation may be such as the age of the participants as most of our participants are young fresh medical graduates (age range 20-40yrs and 2/3 doctors have less than 10 y of experience after their medical graduation). Lastly, we have only analyzed the doctor's view, perception, knowledge, attitude, and practice about generic medicine prescribing. It would be appropriate also to know the opinion, belief, and level of understanding of pharmacists and patients about generic medicines and analysis of prescriptions.

#### CONCLUSION

Although majority of the doctors surveyed had good knowledge and attitude about generic medicines and a meaningful proportion of doctors actively prescribed generic drugs, still more information about generic drugs are needed by them especially on quality to increase generic medicine prescription rates. In order to have a better understanding of generic, the doctor must be well informed about the generic during their academic career resulting in savings to healthcare budgets. They also expressed the need for standard guidelines on generic substitution policy.

#### FUNDING

Nil

#### AUTHORS CONTRIBUTIONS

Dr. Chayna Sarkar, Dr. Biswadeep Das, Dr. JoonmoniLahon, Dr. Julie Wahlang, DrBanylla shisha Nongkynrih: Design and executed the study.

Dr. JoonmoniLahon, DrBanylla shisha Nongkynrih, Dr. DK Brahma: Validated the questionnaire and Data Analysis

Dr. Chayna Sarkar, Dr. Biswadeep Das, Dr. Julie Wahlang: Manuscript preparation

#### CONFLICTS OF INTERESTS

Declared none

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