

## RESEARCH ARTICLE

# A STUDY ON THE KNOWLEDGE, ATTITUDE, AND PRACTICE OF GENERIC MEDICINES AMONG THE DOCTORS IN A TERTIARY CARE TEACHING HOSPITAL IN SOUTH INDIA

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**Background:** The assessment of doctor's perceptions and understanding about generic medicines may help in recognizing possible barriers to greater generic medicine usage.

**Aims & Objective:** The primary objective of this study was to explore the knowledge, attitude, and practice (KAP) of doctors toward generic medicines.

**Materials and Methods:** A cross-sectional study was carried out using a pretested questionnaire in a tertiary-care teaching hospital of Perambalur district of Tamil Nadu (India). The questionnaire was designed to assess the KAP about generic medicines. The doctors working in this institute during the study period were included. All data were analyzed with the Statistical Package for Social Science (SPSS, version 16.0).  $p$ -Values of  $<0.05$  were considered to indicate statistical significance.

**Results:** It was known to 76.7% doctors that a generic medicine contains the same active substance(s) as the innovator medicine, and it is used at the same dose(s) to treat the same disease(s) as the innovator medicine ( $p = 0.000$ ). Among doctors, 79.5% were aware that generic drug manufacturers need to conduct bioequivalence studies to show equivalence between the generic medicine and the innovator medicine ( $p = 0.0000$ ); 75.3% doctors did not agree that generics are not as safe as innovator drugs ( $p = 0.0000$ ). Moreover, 64.4% doctor did not agree that generics are not as effective as brand-name drugs ( $p = 0.0123$ ); 71.2% doctors do not think that switching a patient from a brand-name to generic drug may change the outcome of the therapy ( $p = 0.0002$ ). Sixty-three percent doctors said that they prescribe generic drugs ( $p = 0.0243$ ).

**Conclusion:** Good percentage of doctors had knowledge about generic medicines. They showed good attitude about the safety, efficacy and quality of generic medicines, and majority of them said that they prescribe generic drugs. But there was a meaningful proportion who expressed concerns about generic drugs. These beliefs could represent a significant hurdle to larger generic drug use and could lead to increased health-care expenses.

## INTRODUCTION

The rising health-care expenses remain a serious concern for the health-care system worldwide. As reported by the WHO, in many developing countries out-of-pocket expenses may go up to as high as 80% of total health-care expenditures.<sup>[1]</sup> The cost incurred on medicine is one of the major concerning components of that expenditure. Hence, the need of the hour is to keep health-care costs nominal without hampering the access to quality care.<sup>[2]</sup> As we aim to cater high-quality health-care system to the masses with limited available resources, increased usage of generic medicines can improve affordability of the health care without compromising the quality.<sup>[3]</sup>

As we know that new drug development is a lengthy and costly process. New drugs are granted patents as a reward for the breakthrough of the innovator company, which allows them a period of marketing exclusivity. Once the patent ends, other companies are permitted to manufacture and market the generic version of that innovative medicine, if they can show bioequivalence. The reason of proving bioequivalence is to show equivalence between the generic and the innovative medicine, to accomplish bridging of the preclinical and clinical testing carried out on the innovative medicine. Bioequivalence is proved if the rate and extent of absorption of generic medicine is not significantly different from that of the innovative medicine.<sup>[4]</sup> Once generic version of the innovator

medicine is launched, the price of that medicine decreases substantially, which gives greater access to the larger number of patients.<sup>[5]</sup> The generic medicines, being bioequivalent to their innovator version, are regarded as safe, efficacious, and cost-effective.<sup>[6]</sup>

The prescription written by the doctors has a significant ramification on the usage of generic medicines, particularly in developing countries where patients or relatives leave no stone unturned to buy precisely what is prescribed.<sup>[6]</sup> However, doctor's viewpoint about generic medicines may pose a decisive hurdle to large-scale usage, culminating in increased health-care expenses. Physicians may favor branded medicines on various accounts. Many doctors may believe that generic medicines are not as effective and safe as their brand-name counterparts. Moreover, generic medicines in the past have been denounced for being below standard mainly due to poor adherence with Good Manufacturing Practice (GMP) guidelines.<sup>[7]</sup> Many doctors may not be familiar with the rigorous regulations imposed by the regulatory body for proving bioequivalence before a generic medicine is granted approval.<sup>[8]</sup> Therefore, understanding doctor's perceptions and an understanding about generic medicines may help in recognizing possible barriers to greater generic medicine usage.<sup>[9]</sup> Hence, the primary objective of this study was to explore the knowledge, attitude, and practice (KAP) of doctors toward generic medicines.

## MATERIALS AND METHODS

### Setting

The study was conducted at a tertiary-care teaching hospital of Perambalur district of Tamil Nadu (India). The human institutional ethics committee of this college approved this study. The study duration was 1 month.

### Study Design

It was a cross-sectional questionnaire-based study conducted in January 2014. The study participants consisted of all the doctors working at the hospital during the study period. The questionnaire designed for this study comprised 20 questions related to the KAP of generic medicine and about demographic details of the participants. The questionnaire consisted of eight questions pertaining to knowledge of generic medicine, seven questions eliciting participants' attitude toward generic medicine, and

five questions related to practice of generic medicine. Pilot testing of questionnaire was done randomly on 10 doctors of the institute.

### Sample Size

The sample size calculation for this questionnaire study was based on four factors: (1) population size, (2) margin of error, and (3) confidence interval, and (4) expected frequency value or response distribution.

The total number of doctors working in the hospital at the time of study (population size) was 135. Margin of error was 5% and confidence level was 95%. The expected frequency value of 50% was used as it produces largest sample size. The sample size was calculated with the help of [www.surveysystem.com](http://www.surveysystem.com) and [www.raosoft.com](http://www.raosoft.com) websites. Putting the values of the factors mentioned earlier, the approximate sample size came out to be 100. Simple random sampling was followed while distributing the questionnaire to the doctors.

### Data Collection

A total of 100 self-administered questionnaires (see Appendix) were randomly distributed among the doctors. One day was given for returning the anonymously filled forms.

### Statistical Analysis

All data were analyzed with the Statistical Package for Social Science (version 16.0; SPSS). One-sample *t*-test between percent was used to compare the responses. *p*-Values of <0.05 were considered to indicate statistical significance.

## RESULTS

### Demographic Characteristics

The demographic details of the participants have been summarized in Table 1.

	Factors	Frequency (%)
Gender	Female	25 (34.2)
	Male	48 (65.8)
Age (years)	Mean age	39.89 ± 13.54
	Less than 30	17 (23.3)
	30–40	34 (46.6)
	41–50	5 (6.8)
	51–60	6 (8.2)
	More than 60	11 (15.1)
Qualification	MBBS	23 (31.5)
	MBBS, MD	44 (60.3)
	MBBS, PG diploma	6 (8.2)

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

Question	Yes	No	p-Value
Generic drug are usually intended to be interchangeable with an innovator drug.	46 (63.0)	27 (37.0)	0.0243
Generic drugs can be only marketed after the expiry date of the patent of innovator.	42 (57.5)	31 (42.5)	0.1990
A generic medicine contains the same active substance(s) as the innovator medicine, and it is used at the same dose(s) to treat the same disease(s) as the innovator medicine.	56 (76.7)	17 (23.3)	0.0000
Generic drug manufacturer need to repeat the preclinical and clinical studies required for originator medicines.	40 (54.8)	33 (45.2)	0.4126
Generic drugs are an important tool for reducing overall health expenditure.	66 (90.4)	7 (9.6)	0.0000
Generic drug manufacturers need to conduct bioequivalence studies to demonstrate equivalence between the generic medicine and the innovator medicine.	58 (79.5)	15 (20.5)	0.0000
Indian Medical Council Act (Professional conduct, Etiquette and Ethics) Regulations, 2002 states that every physician should, as far as possible, prescribe drugs with generic names.	58 (79.5)	15 (20.5)	0.0000
Are you aware of regarding the scheme of Government of India called <i>Jan Aushadhi</i> whose purpose is to set up generic drug stores around the country?	33 (45.2)	40 (54.8)	0.4126

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

Question	Yes	No	p-Value
Generics are not as safe as innovator drugs.	18 (24.7)	55 (75.3)	0.0000
Generics are not as effective as brand-name drugs?	26 (35.6)	47 (64.4)	0.0123
Generics take longer to act in the body	16 (21.9)	57 (78.1)	0.0000
Brand-name drugs are made in modern manufacturing facilities, and generics are often made in substandard facilities.	30 (41.1)	43 (58.9)	0.1266
Generic drugs cost less because they are inferior to brand-name drugs.	23 (31.5)	50 (68.5)	0.0011
Do you think that there should be a training program to increase the awareness regarding generic drugs among doctors and patients?	65 (89.0)	8 (11.0)	0.0000
Do you think that there should be a generic medicine store in every hospital?	61 (83.6)	12 (16.4)	0.0000

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

Question	Yes	No	p-Value
Do you prescribe generic drugs?	46 (63.0)	27 (37.0)	0.0243
Have you anytime read any article on comparison of safety and efficacy of generic versus branded medicine?	28 (38.4)	43 (58.9)	0.0736
Do you think that switching a patient from a brand name to generics may change the outcome of the therapy?	21 (28.8)	52 (71.2)	0.0002

**Table 5:** Statement best expressing the opinion regarding generic substitution for brand-name drugs

Question	Frequency (%)
I support substitution in all cases where generic is available.	23 (31.5)
I support generic substitution but not in all cases.	42 (57.5)

**Table 6:** The most important factor taken into consideration while prescribing a medicine to the patient

Factors	Frequency (%)
Availability of drugs in pharmacies	3 (4.1)
Price of medicine	11 (15.1)
Efficacy, safety & quality profile of the medicine	57 (78.1)
Economic profile of the patient	2 (2.7)

## Response Rate

A total of 100 questionnaires were distributed among the health-care professionals and 73 responded (response rate 73%).

## Knowledge

Sixty-three percent doctors agreed that generic drugs are usually intended to be interchangeable with an innovator drug ( $p = 0.0243$ ); 57.5% doctors were aware that generic drugs can be only marketed after the expiry date of the patent of innovator ( $p = 0.1990$ ); 76.7% doctors knew that a generic medicine contains the same active substance(s) as the innovator medicine, and it is used at the same dose(s) to treat the same disease(s) as the innovator medicine ( $p = 0.000$ ). Among study participants, 54.8% knew that generic drug manufacturer need not repeat the preclinical and clinical studies required for originator medicines ( $p = 0.4126$ ); 79.5% doctors were aware that generic drug manufacturers need to conduct bioequivalence studies to show equivalence between the generic medicine and the innovator medicine ( $p = 0.0000$ ). An equal percentage of doctors were aware that Indian Medical Council Act (Professional conduct, Etiquette and Ethics) Regulations 2002 states that drugs with generic names should be prescribed by every physician ( $p = 0.0000$ ). Among the participants, 90.4% agreed that generic drugs are an important tool for reducing overall health expenditure ( $p = 0.0000$ ); 45.2% participants told that they were aware regarding the *Jan Aushadhi* scheme ( $p = 0.4126$ ). Knowledge-related questions and their responses are summarized in Table 2.

## Attitude

Majority of doctors (75.3%) were of the view that generic drugs were as safe as the innovator drug ( $p = 0.0000$ ). Moreover, 64.4% doctors felt that the generic drugs are as effective as brand-name drugs ( $p = 0.0123$ ). Among doctors, 78.1% did not agree that

generic drugs take longer to act in the body ( $p = 0.0000$ ); 58.9% doctors did not agree that brand-name drugs are made in modern manufacturing facilities and generics are mostly manufactured in below-standard facilities ( $p = 0.1266$ ). Another 68.5% doctors did not agree that generic drugs cost less because they are inferior to brand-name drugs ( $p = 0.0011$ ). Eighty-nine percent doctors agreed that there should be training program to increase the awareness regarding generic drugs among doctors and patients ( $p = 0.0000$ ); 83.6% doctors said that there should be a generic medicine store in every hospital ( $p = 0.0000$ ). Attitude-related questions and their responses are summarized in Table 3.

### Practice

A majority (71.2%) of doctors did not think that switching a patient from a brand-name to a generic medicine may change the outcome of the therapy ( $p = 0.0002$ ). Among the participants, 57.5% said that they support generic substitution but not in all cases whereas 31.5% supported substitution on all cases where generic drugs are available. Only 11.0% said that they do not agree with the practice of generic substitution. Sixty-three percent doctors said that they prescribe generic drugs ( $p = 0.0243$ ). However, 58.9% doctors reported not to have read any article on comparison of safety and efficacy of generic versus branded medicine ( $p = 0.0736$ ). Practice-related questions and their responses are summarized in Tables 4, 5, and 6.

## DISCUSSION

According to the present analysis, good percentage of doctors had knowledge about generic medicines and they had good attitude about the efficacy, safety, and quality of generic medicines; majority of them said that they prescribe generic drugs. A similar study by Jamshed et al.<sup>[3]</sup> identified gaps in knowledge but good perceptions and attitude about generic medicines among general practitioners of Karachi, Pakistan.

In our study, most of the participating doctors were aware that generic drugs need to have the same active component and dose as the innovator medicine and they can be only marketed after the expiry date of the patent of the innovator. By scrutiny of bioequivalence dossier, the regulatory body ascertains that the generic medicine will function in the same way as its respective innovator or reference medicine.<sup>[4]</sup> Significantly high numbers of doctors in this study were aware that generic drug manufacturers need to conduct bioequivalence studies to show equivalence

between the generic and the innovator medicine.

The regulatory guidelines state that generic drugs must be therapeutically equivalent with brand-name drugs. Significantly high numbers of participants in this study know that generic drugs are usually intended to be interchangeable with an innovator drug and they do not think that switching a patient from a brand-name to generic drug may change the outcome of the therapy. Various studies have reported that physiologically generic medicines function equivalently to their innovator counterparts.<sup>[4]</sup> An assessment of bioequivalence data submitted to the US Food and Drug Administration, which compared single-dose clinical bioequivalence studies of orally administered generic medicine products approved from 1996 to 2007, showed that the generic medicines did not differ substantially from their innovator counterparts.<sup>[10]</sup> Likewise, with reference to clinical efficacy, Kesselheim et al.<sup>[11]</sup> reported a comprehensive systematic review and meta-analysis that favored the use of generic drugs in treating cardiovascular disease. In another study they reported that, for antiepileptic drugs, the available data do not advocate a relation between loss of seizure control and generic switch.<sup>[12]</sup> Moreover, various studies have reported that starting the therapy with generic medicines or switching to generic medicines is not related with poorer efficacy or safety.<sup>[13,14]</sup>

Significantly high number of doctors agreed that generic drugs are an important tool for reducing overall health expenditure. Indeed, lower price is the major boon for generic drugs. In Indian context, the cost of generic drugs has been found to be up to 91% less than that of the innovator medicine.<sup>[5]</sup> Hence, widespread use of generic drugs has the potential to reduce the price of other brand-name drugs by creating more competition. But the fact that generic drugs need not have to go through the large and costly clinical trials that are required for approval of innovator medicines, ultimately leading to lower price of generics, may raise doubt about their efficacy, safety, and quality.<sup>[15]</sup> But in this study, majority of physicians were found to be comfortable with the efficacy and safety of generic medications in spite of knowing that generic drug manufacturer need not repeat the preclinical and clinical studies required for originator medicines. As a matter of fact there are no ample proofs that generic drugs are less safe or less effective than their brand-name counterparts. Moreover, when a generic-drug product is granted approval, it has fulfilled strict regulations required by the regulatory body with respect to identity, strength,

quality, purity, and potency. The regulatory body appraises the manufacturer's compliance to the GMP guidelines before the drug is marketed, and the manufacturer need to give detailed information about the facilities it uses for production, packaging, labeling, among others, of the generic drug.<sup>[15,16]</sup> In this study, majority of doctors did not agree that generic drugs are made in substandard manufacturing facility. Majority of the doctors were found to have a greater trust in generic drugs and they prescribed them to a greater degree.

Owing to the inaccessibility of drugs in the public hospitals, bulk of expenses incurred on medicine by general public are out of pocket, and thus, the availability and affordability of medicines becomes a major concern in a developing country like India. To tackle this problem, the Indian government started a project in November 2008 with plan to expand it in all 612 districts in India, when it opened the first not-for-profit medicine shop selling only generic drugs at Amritsar, Punjab. The name of the project was *Jan Aushadhi* (a Hindi term meaning 'people's drug'). Under this project the public-sector drug companies supply essential low-priced generic drugs on demand to the *Jan Aushadhi* stores. If executed as desired, this could be a model for the entire developing world. But only 45.2% participants in our study told that they were aware regarding the scheme.<sup>[17]</sup>

The major limitation of this study is the small sample size. Hence, findings of this study cannot be generalized. Another limitation is that we have only analyzed the doctor's perception and understanding about generic medicines. It would be appropriate to also know the opinion and level of understanding of pharmacist and patients about generic medicines.

## CONCLUSION

Although good percentage of doctors had good knowledge and attitude about generic medicines and majority of them said that they prescribe generic drugs but there was a meaningful proportion who expressed concerns about them. These beliefs could represent a significant hurdle to larger generic use and could lead to increased health-care expenses. Above all, it was observed in this study that the efficacy, safety, and quality profile of the medicine was the most important factor considered by physicians when they prescribe drugs (Table 6). Hence, the doctor must be knowledgeable about the efficacy, safety, and quality criteria's of generic medicines so

that they are confident while prescribing generic drugs.<sup>[3]</sup> Assumptions about the decreased quality of generics could be eliminated by continuing medical education of physicians about drug discovery, development, and regulations.<sup>[18,19]</sup> Particularly, the endeavor should be to educate the physicians early in their career about the relevance and advantages of prescribing generic drug.<sup>[18,20]</sup> Moreover, generic medicine guidelines should be disseminated to the physicians so that they feel more assured about its usage, ultimately leading to an increase in prescribing generic medicine.<sup>[21]</sup> It is expected that bestowing knowledge about generic medicine to the physician will expedite the transfer of awareness to the patients.

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