

RESEARCH ARTICLE

Evaluation of knowledge, attitude, and practice of generic drugs among intern doctors at a tertiary care teaching hospital

Kirtida R Tandel¹, Sunil N Bhadiyadara¹, Sameer M Zaiwala²

¹Department of Pharmacology, GMERS Medical College, Valsad, Gujarat, India, ²Consultant Radiologist, Sky Imaging Center, Vevji, Maharashtra, India

Correspondence to: Sunil N Bhadiyadara, E-mail: drsunny8289@gmail.com

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ABSTRACT

Background: The increasing health-care expenses are a major concern for the health-care providing system in the world. As stated by the World Health Organization, in the majority of developing countries out of pocket expenses may go as high as 80% of total health-care expenditures. In developing countries like India, the generic medicines are not widely prescribed due to lack of knowledge and awareness regarding generic medicines in both prescribers and in patients. Understanding of prescriber's attitude and perceptions regarding the quality, efficacy, and safety of generic medicines may help to identify important barriers for better generic prescribing. **Aims and Objectives:** The aim of the study was to assess the knowledge, attitude, and practice of generic medicines among intern doctors at a tertiary care teaching hospital. **Materials and Methods:** A prospective, cross-sectional study was conducted among intern doctors at a tertiary care teaching hospital using a questionnaire, consisting of questions related to knowledge, attitude, and practice regarding generic medicines. Data were analyzed by MS Excel. **Results:** A total of 105 (88%) interns responded to the questionnaire. Around 60% of interns agreed with that generic medicine can be used in place of innovator (patented) medicine. Among all the interns, 52.4% were aware of that generic medicine contains the same active ingredient as their counterpart innovator medicine. More than half of interns (55.2 %) were aware of Jan Aushadhi scheme launched by the Government of India. Around 69.5% of interns disagreed with that generic medicines cost less because they are inferior to innovator medicines. Majority of interns (88.6%) were of the opinion that there should be some training session to raise the knowledge and awareness about generic medicines. Around half of the interns (50.5%) had never switch a patient on innovator medicine to generic medicine. Only 1% was not in favor of supporting generic drug prescribing. **Conclusion:** Knowledge of intern doctors regarding concept and regulations about generic drugs is adequate. Although they prescribe a good number of generic drugs, concerns regarding quality, efficacy, safety, availability, and awareness are present among them. Hence, mass awareness programs and training sessions are required to address these concerns which may alter their prescribing behavior and can encourage for more use of generic medicines.

KEY WORDS: Generic Medicine; Innovator Medicine; Knowledge; Attitude; Practice

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INTRODUCTION

As defined by the World Health Organization (WHO), generic medicine is "a pharmaceutical product, usually intended to be interchangeable with an patent (innovator) product which is manufactured without a license from the innovator company and marketed after the expiry of the patent or

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other exclusive rights".^[1] Before registration, similar to all other drugs including original patent medicines, a generic medicine must go through a stringent registration process and stringent requirements to confirm its efficacy and safety which meets all the required standards.^[2,3] As the concept of bioequivalence is a necessary requirement for the approval of generic medicines,^[4] bioequivalence study is performed to reflect clinical equivalence of the generic medicine with its counterpart innovator medicines, and so repeating of the preclinical and clinical trial is not required.^[5] Generic drugs are approved under the guidelines of Central Drugs Standard Control Organization in India, which needs submission of prescribing and administrative information, drug quality, clinical, and nonclinical research reports.^[6]

The increasing health-care expenses are a major concern for the health-care providing system around the whole world. As stated by the WHO, in most of developing countries out of pocket expenses may go as high as 80% of total health care expenditures.^[7] As we want to provide a high quality of health care to the masses with limited resources availability, more uses of generic drugs can improve the health-care affordability without compromising of the quality.^[8] In the United Kingdom, generic drugs prescribing already accounts for 83% of total prescriptions dispensed.^[9,10] Generic medicines account for >70% of total prescriptions in the United States.^[11] However, in most of the developing countries the generic medicines are not as frequently prescribed due to lack of knowledge and awareness regarding generic medicines in both prescribers and in patients.

Understanding of prescribers' attitude and perceptions regarding the quality, efficacy, and safety of generic medicines may help to identify important barriers for better generic prescribing. In addition, identifying prescriber's behavior with negative perceptions regarding generic prescribing may help to insurers and policymaker agencies to target educational interventions or more restrictive policies. Hence, this study was planned to evaluate knowledge, attitude, and practice of generic medicines in intern doctors at a tertiary care teaching hospital and to identify factors which hinder or encourage the prescription of generic medicines.

MATERIALS AND METHODS

Study Site

This study was conducted among intern doctors at a tertiary care teaching hospital located at Valsad, India. The study was initiated after obtaining approval from the Institutional Human Ethics Committee.

Study Design

This was a prospective, cross-sectional, and questionnaire-based observational study. The questionnaire of study

comprised four sections: Section A of it included demographic details of the participants, Section B contains 10 questions pertaining to knowledge, Section C of 10 questions eliciting participants' attitude, and Section D of 5 questions, of which 4 were structured and 1 was open, regarding to practice of generic drugs. Prior written informed consent was taken from all the participants who willing to participate in the study.

Inclusion Criteria and Data Collection

Intern doctors working in various departments of the hospital were included in the study. Appropriate instructions were given regarding the filling of the questionnaire. A pilot study was conducted among 10 intern doctors. There were a total of 120 questionnaires randomly distributed to the intern doctors. 1 day was given for returning the filled questionnaires.

Data Analysis

Data were analyzed with the use of MS Excel. Responses were analyzed for frequency and percentage analysis.

Response Rate

A total of 120 questionnaires were distributed among the intern doctors and 105 responded (response rate is 87.5%).

RESULTS

Demographic Characteristics

The participants' demographic characteristics have been summarized in Table 1.

In this study, 70 (67%) females and 35 (33%) males were participated. The majority (54%) were of 23 years old.

Knowledge

Around 60% of interns agreed with that generic medicine can be used in place of innovator (patented) medicine. 61.9% interns did not know that generic medicines can only be marketed after the expiry of the patent of innovator medicines, 28.6% had no idea, and only 9.5% knew about patency. Among all the interns, 52.4% were aware of that generic medicine contains the same active ingredient as their counterpart innovator medicine, while 50.5% were aware of that generic medicine can be used at the same dose to treat

Table 1: Demographic details of the participants (n=105)

Characteristics	Factors	Frequency (%)
Gender	Male	35 (33)
	Female	70 (67)
Age (years)	22	48 (46)
	23	57 (54)

the same condition as the innovator medicine. Only 28.6% of interns aware of that generic medicine manufacturer need not to repeat the preclinical and clinical studies needed for the innovator medicine. Most of the interns (74.3%) believed the fact that generic medicine manufacturers need to conduct bioavailability and bioequivalence studies to reflect the equivalence between generic and innovator medicine, while 14.3% were of the opposite view. Most of them (66.7%) knew that innovator drugs are costlier than their generic substitute. About 43.8% interns knew that there is a law made by the Medical Council of India states that as far as possible, every physician should prescribe a drug with generic names only. More than half of interns (55.2 %) were aware of Jan Aushadhi scheme launched by the government of India for setting up generic medical stores across the whole country. Some (23.8%) of interns were aware of that patients or pharmacists are not legally empowered to sell or purchase generic medicines over prescribed innovator medicines. Knowledge-related questions and their responses are summarized in Table 2.

Attitude

Most of the interns (84.8%) were of the view that generic medicines are as safe as innovator medicines. Moreover, 55.2% of interns believed that generic drugs are as effective as innovator drugs. 38.1% of interns did not agree with that generic medicines have a longer duration of action as compared to innovator medicines. 47.6% of participants denied that innovator drugs are made by modern manufacturing facilities and generic drugs are often made by substandard manufacturing facilities. Around 69.5% of interns disagreed with that generic medicines are cheap because they are inferior to innovator (patented) medicines. Majority of interns (88.6%) were of the opinion that there should be some training session to raise the knowledge

and awareness about generic medicines among doctors and patients. Most of the interns (86.7%) felt that there should be a generic drug store in all the government hospitals. More than half of interns (57.1%) agreed with that there should be a strict law and regulation which bounds prescribers to compulsory use of generic medicines. 54.3% of participants agreed with that health insurance agencies should give preference to generic medicines over innovator medicines while reimbursement of insurance. Most of them (86.6%) opined that patients should be legally given freedom to select generic or innovator medicine. Attitude-related questions and their responses are summarized in Table 3.

Practice

Around 44.8% of interns had prescribed innovator medicines, while 40% of interns did not prescribe innovator medicines when generic medicines are available. Of this 40%, around 19% had mentioned the reason for unavailability of innovator medicines, 7% had mentioned the reason regarding unaware about the brand names of innovator medicines, 5% had mentioned the reason of cost-effectiveness with generic medicines, and of 44.8%, around half (47%) had mentioned the reason of less efficacy of generic drugs. Around half of the interns (50.5%) had never switch a patient on innovator medicine to generic medicine. Only 33.3% of interns had read an article about the comparison of efficacy and safety of generic versus innovator medicines. Majority of participants (77.1%) supported prescribing of generic medicines but not in all cases, while 21.9% supported prescribing generic medicines in all cases where generics are available. Only 1% was not in favor of supporting generic drug prescribing. While taking the opinion from all interns regarding the ways to improve generic prescribing, majority (16.2%) suggested that there was a need of some training session regarding generic medicines for prescribers as well as for patients,

Table 2: Generic medicine knowledge-related questions and frequency (%) of responses (*n*=105)

Questions	Yes <i>n</i> (%)	No <i>n</i> (%)	Don't know <i>n</i> (%)
Can generic drug be used in place of innovator (patented) drug?	63 (60)	8 (7.6)	34 (32.4)
Can generic drugs only be marketed after the expiry date of innovator (patented) drug?	10 (9.5)	65 (61.9)	30 (28.6)
Does a generic drug contain the same active substance (s) as the innovator (patented) drug?	55 (52.4)	18 (17.1)	32 (30.5)
Is a generic drug can be used at the same dose (s) to treat the same disease (s) as the innovator (patented) drug?	53 (50.5)	40 (38.1)	12 (11.4)
Does a generic drug manufacturer need to repeat the preclinical studies and clinical trials for generic drugs?	62 (59.0)	30 (28.6)	13 (12.4)
Does generic drug manufacturer need to conduct bioavailability and bioequivalence studies to demonstrate equivalence between generic and innovator (patented) drug?	78 (74.3)	15 (14.3)	12 (11.4)
Are generic drugs costlier than innovator (patented) drug?	8 (7.6)	70 (66.7)	27 (25.7)
Is there any law in India which states that every physician should, as far as possible, prescribe drugs with generic names?	46 (43.8)	32 (30.5)	27 (25.7)
Are you aware of the scheme of Government of India called Aushadhi whose purpose is to set up generic drug stores around the country?	58 (55.2)	22 (21.0)	25 (23.8)
Is patient or pharmacist legally empowered to purchase or sell generic drugs in place of prescribed innovator (patented) drug?	73 (69.5)	25 (23.8)	7 (6.7)

followed by availability of generic medicines at all the government hospitals (12.4%), strict laws and regulations for prescribing of generic drugs (9.5%), improvement in quality of generic medicines as of innovator medicines (2.9%), and least considered that patients' (1.9%), and pharmacists' (1.9%) freedom to select among generic or innovator medicines. Practice-related questions and their responses are summarized in Tables 4-6.

DISCUSSION

Cost of the prescriptions is a serious concern, and it accounts for major health-care expenditure which attributes to most of the health-care systems worldwide.^[12] Since physicians have an important role in prescribing of medicine, they can reduce the cost of prescriptions by prescribing generic medicines whenever possible. As interns are budding physicians, we have conducted this study among them to assess the knowledge, attitude, and practice toward generic medicines. Similar studies were conducted on physicians, medical teaching faculties, pharmacists, medical students, and postgraduates that showed similar results as in our study.^[13-17]

In this study, most of the participants know that generic medicines are a substitute of innovator medicines, which was in accordance with the finding of previous studies.^[15-19] However, only some of them were aware of that it can be prescribed after the expiry of the patent of innovator drug until it is protected by patent law and doctor can only prescribe innovator drug which was similar to the previous study.^[16] Most of the interns know that generic medicine contains the same active substance and can be used at the same dose for the same disease as their counterpart the innovator medicine which was similar to the finding of previous studies.^[15-17,20] From scrutiny of bioequivalence dossier, the regulatory body confirms that the generic drug will function in the same way as its counterpart innovator drug.^[16] There are mixed reports regarding generic bioequivalence. After the expiry of patent protection of bupropion (Wellbutrin [GSK]), many reports were submitted regarding the loss of its antidepressant effect or finding new or worsening of adverse effects to US food and drug administration in patients who had changed from the brand to generic product.^[21] Many generic products of bupropion were found not to be bioequivalent to the brand version of bupropion.^[22] On the contrary, many studies had reported that generic medicines are as effective as their

Table 3: Generic medicine attitude-related questions and frequency of responses (n=105)

Questions	Agree n (%)	Disagree n (%)	Neutral n (%)
Generic drugs are not as safe as innovator (patented) drug	8 (7.6)	89 (84.8)	8 (7.6)
Generic drugs are not as effective as innovator (patented) drug	32 (30.5)	58 (55.2)	15 (14.3)
Generic drugs have longer duration of action in comparison to innovator (patented) drug	12 (11.4)	40 (38.1)	53 (50.5)
Innovator (patented) drug is made in modern manufacturing facilities, and generic drugs are often made in substandard manufacturing facilities	22 (21.0)	50 (47.6)	33 (31.4)
Generic drugs cost less because they are inferior to innovator (patented) drug	20 (19.1)	73 (69.5)	12 (11.4)
Give your opinion about there should be a training program to increase the awareness regarding generic drugs among doctors and patients	93 (88.6)	10 (9.5)	2 (1.9)
Do you think that there should be a generic medicine store at every government hospital?	91 (86.7)	12 (11.4)	2 (1.9)
What is your opinion about "there should be a law which bounds doctor to compulsory prescribe generic drugs?"	60 (57.1)	17 (16.2)	28 (26.7)
Do you think that medical insurance company should give preference to generic drugs over innovator (patented) drugs while reimbursement of insurance?	57 (54.3)	15 (14.3)	33 (31.4)
What is your opinion about patients should be legally given freedom to choose generic or innovator (patented) drug?	91 (86.6)	7 (6.7)	7 (6.7)

Table 4: Generic medicine practice-related questions and frequency of responses (n=105)

Questions	Yes n (%)	No n (%)	NA/No response n (%)
Do you prescribe innovator (patented) drug when generic drug available? Reason/s	47 (44.8) Efficacy: 22	42 (40.0) Economic: 2, Unawareness of brand names: 3, Unavailability: 8	16 (15.2)
Have you ever switch a patient on innovator (patented) drug to available generic drugs?	52 (49.5) Availability: 3, Duration of action: 3	53 (50.5)	0 (0)
Have you ever read any article on a comparison of safety and efficacy of generic versus innovator (patented) drugs?	35 (33.3)	70 (66.7)	0 (0)

Table 5: Statement expressing the opinion about prescribing generic drugs over innovator (patented) drugs

Questions	Frequency (%)
I support prescribing generic drugs in all cases where generic is available	23 (21.9)
I support prescribing generic drugs but not in all cases	81 (77.1)
I do not support prescribing generic drugs	1 (1.0)

Table 6: The ways to improve prescribing generic medicine over innovator (patented) medicine

Questions	Frequency (%)
Availability of generic drugs in government hospitals	13 (12.4)
Improvement in quality of generic drugs as innovator drugs	3 (2.9)
Patients' freedom to choose among generic or innovator drug	2 (1.9)
Awareness program about generic drugs for patients and medical practitioners	17 (16.2)
Rules and regulations for prescribing of generic drugs	10 (9.5)
Pharmacists' freedom to choose among generic or innovator drug	2 (1.9)
No response	58 (55.2)

branded versions. A meta-analysis of 47 studies comparing the effectiveness of nine classes of cardiovascular medicines reported no evidence of inferiority of generic product including anticoagulants and antiarrhythmic drugs.^[23] Previous study conducted in Turkey^[24] stated that 82% of hospital prescribers were unsure regarding bioequivalence of generic drugs. In our study, around 75% of the participants know that generic drug manufacturers need to conduct bioavailability and bioequivalence study which was in accordance with the finding of previous studies.^[15,17,18] However, many of them were not aware of the fact that generic manufacturers need not to repeat the preclinical studies and clinical trials for generic medicines which were similar to the finding of previous studies.^[15-18] Lack of such information regarding generic medicines creates doubts about the quality, efficacy, and safety of generic products. Strengthened efforts are needed in this regard to improve knowledge and awareness regarding generic medicines.

Health-care expenditure is increasing in the majority of the health-care systems worldwide, and the cost of prescribed drugs is a serious concern.^[12] Nearly one-third of the global population finds difficulties in accessing medicines due to high costs and this is rising to 50% in the developing countries.^[25] The WHO states that 3.2% of Indians will fall beneath the poverty line due to high medication charges. Every year around 39 million Indian peoples are pushed toward poverty due to illness.^[26] Total health-care expenditure

is rising in India as per capita total health-care expenditure was \$80 in 2001^[27] and \$141 in 2011.^[28] Hence, promotion of generic drug prescribing can help to minimize the cost of health-care system. Many developing countries including India have made use of compulsory licensing or government use orders to supply of more affordable generic medicines in recent years. Many states such as Gujarat, Rajasthan, Maharashtra, Madhya Pradesh, Uttar Pradesh, Punjab, and Kerala have already taken initiative to easy availability of generic medicines for the public by opening a number of generic medicine stores under the government scheme - Jan Aushadhi (a Hindi term meaning "people's drug")^[26] Regulatory agencies should conduct various program on a mass scale to increase awareness about generic medicine, even with the help of media for mass participation of community. In this study, around 55% of interns were aware of such initiative which was similar to the finding of a study by Rohini *et al.*^[17] and contrary to the finding of a study by Bhattacharjee *et al.*^[16] Very few interns were aware about that patient or pharmacist are not legally empowered to purchase or sell generic drugs in place of prescribed innovator drugs and gave an opinion that patients or pharmacists should be empowered to choose generic or innovator medicines.

India is one of the leading generic medicines producing country. By prescribing generic medicines, there would be easy access of medicines to all the socioeconomic class, but the practice of generic drugs prescribing, dispensing, and substitution in the developing countries has been controversial among health-care providers due to issues of quality, efficacy, and safety. These controversies are due to intercountry differences in health-care policies and regulations and also due to differences in individualized knowledge and attitudes regarding generic drugs.^[29] Previous studies have stated that starting the treatment with generic drugs or switching to generic drugs is not related to poorer efficacy or safety.^[30,31] In our study, most of the interns believed that generic medicines are as safe and effective as innovator medicines which were similar to the finding of previous studies.^[15-18,20] Only a few of them believe that generic medicines take a longer time to act which was similar to the finding of previous studies.^[15-18] When a generic medicine is granted approval, it has to fulfill stringent regulations needed by the regulatory authority in regard to quality, identity, strength, efficacy and potency. The regulatory authority appraises the manufacturer's compliance with the good manufacturing practice guidelines before the drug is marketed, and the manufacturer should give complete information regarding the facilities used for production, packaging, and labeling of the generic medicine.^[32,33] In our study, most of the interns did not agree with that generic medicines are often made in substandard facilities, and many of them believed that although generic medicines are cheaper, they are not inferior to innovator medicines which were similar to findings of other studies.^[15-17]

Doctors' and patients' knowledge and awareness regarding generic drugs are prerequisites for more use and acceptance

of generic drugs. Prescribers should prescribe more generic drugs because it is evident that patients generally follow their prescriber's choice and therefore refuse for generic product substitutions. Most of the interns agree that there should be some training program for doctors and patients to increase the awareness of generic drugs which was in accordance with the finding of previous studies.^[15-18] Different sources such as internet, newsletters, medical journals, medical books, and medical representatives can be used by drug manufacturers and regulatory authorities for promotion and increase awareness regarding generic drugs in the community. Most of the interns agreed with that there should be generic medicine stores at every government hospital which was in accordance with the finding of previous studies.^[15-18]

If the health insurance agencies reimburse only generic medicines, the patient will ask the prescriber to prescribe only generic medicines. In the US, among all the drugs reimbursed under health insurance, most of them are generics; around eight out of 10 prescriptions are of generic medicines.^[34] Intercontinental Marketing Services Institute for Healthcare Informatics had conducted generic medicine savings study in 2012 stated that 192.8 billion dollars saved in 2011.^[35] Majority of participants in this study agreed with that health insurance agencies should give preference to generic medicines over innovator medicines while reimbursement of insurance to promote generic prescribing. It would be beneficial for both patients as well as for insurance agencies. In our study, the majority of interns gave the opinion that legally patients should be given freedom to choose generic or innovator drugs which were similar to the findings of the study.^[16]

In this study, around 40% of interns had prescribed generic medicines whenever available and around half of the interns had never switch a patient on innovator medicine to an available generic counterpart. Majority of interns had never read an article about comparing safety and efficacy of generic medicines versus innovator medicines which was similar to the finding of previous studies.^[15,16,18] Most of the participants gave the opinion that they support prescribing generic medicines but not in all cases which were in accordance with the finding of previous studies.^[15-18] Hence, there is a great need for awareness programs to promote more generic prescribing. Providing a free sample of generic medicines, gift vouchers, advertisement, and educating the patient regarding cost benefits of generic medicines will result in increased generic prescribing.^[21]

There were many strategies used previously to improve generic prescribing. Previous studies reported that financial incentives for general practitioners, medical students', and patient's education and information about regulations and quality of generic medicines have a promising role in improving generic prescribing.^[36] In this study, participants gave their different opinion about the ways to improve

generic prescribing such as there should be some awareness program for prescribers as well as for patients regarding generic medicines; generic medicines should be available at every government hospitals; there should be strict rules and regulations for prescribing of generic medicines; quality of generic medicines should be same as of innovator medicines; and some policy should be there which gives freedom to patients or pharmacists to choose among generic or innovator medicine.

The major limitation of our study is the small sample size. Hence, the findings of this study may not be generalized. We have only analyzed the intern doctors' perception and understanding regarding generic medicines. It would be appropriate to know the opinion and level of understanding of other health-care providers as well as patients regarding generic medicines.

CONCLUSION

Knowledge of intern doctors regarding concept and regulations about generic drugs is adequate. Although they prescribe many generic drugs, concerns regarding quality, efficacy, safety, and awareness are present among them. Some interventions are required to address these concerns which may alter their prescribing behavior and can encourage for usage of generic medicines such as educating and motivating the prescribers, practice comparison feedback, continued medical education, at least by compulsory usage of generic medicines in serious conditions and increasing the availability of generic medicines.^[12,26] Health regulatory authorities should promote generic prescribing through educational interventions such as educational campaigns in hospitals, clinics, pharmacies, and also through the mass media, internet, and television programs. Regulatory authorities must reform some policy regarding labeling of the medicines which can specify either it is branded one or generic so that patients can insist on generic prescribing and get the cost benefits. Further study is required on how interventions for health-care professionals and public can reduce negative perceptions and attitudes regarding quality, efficacy, and safety of generic medicines to increase the awareness and acceptance of generic medicines.

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