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## A STUDY OF AWARENESS OF GENERIC DRUGS AMONGST RESIDENTS AND INTERN DOCTORS IN A TERTIARY CARE HOSPITAL IN SURAT CITY

Krima H. Patel <sup>\*1</sup> and Umang J. Patel <sup>2</sup>

Department of Pharmacology <sup>1</sup>, SMIMER Medical College, Surat - 395010, Gujarat, India.

Department of Medicine <sup>2</sup>, Nootan Medical College, Visnagar - 384315, Gujarat, India.

### Keywords:

Generic drug, Brand name, Jan Aushadhi, Awareness, Knowledge

### Correspondence to Author:

**Dr. Krima H. Patel**

Resident Doctor,  
Department of Pharmacology,  
SMIMER Medical College, Surat -  
395010, Gujarat, India.

**E-mail:** p.krima2121@gmail.com

**ABSTRACT: Introduction:** As defined by WHO generic drug is “a pharmaceutical product which is intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights. They are made with the same active substance as the non-generic drugs which are already authorized and approved for their safety, efficacy and quality before getting licensed. **Method:** A cross-sectional, prospective, questionnaire-based study was conducted on 115 residents and intern doctors. Awareness and knowledge about generic drugs was checked using pre-validated questionnaire which was followed by an educational intervention and post-questionnaire. The collected data was analyzed using MS-excel. **Result:** A total of 94 participants properly filled up the questionnaire. As per the result of pre-test many participants were not aware of the difference between generic and branded drug, but after conducting educational intervention, increase in knowledge about term generic drugs, branded drugs, safety, efficacy, availability and regulation regarding prescription of generic drug was seen. In post-test, we found that 98.94% believed that generic drugs are cheaper than branded drugs, 95.74% agreed that generic drugs are as safe as branded drugs, while 97.87% believed increasing awareness regarding generic drugs will increase acceptability of generic drugs. **Conclusion:** The major reasons for not prescribing branded drugs were lack of awareness regarding efficacy, safety, acceptability and availability of generic drugs. Periodic training program would help in clearing doubts, enhance the prescribing of generic drugs, and reduce the health expenditure and economical burden.

**INTRODUCTION:** Generic drugs are pharmaceutical products that demonstrate bioequivalence to a brand or reference drug, meaning they exhibit similar pharmacokinetic and pharmacodynamic properties within an acceptable range <sup>1</sup>.

According to the World Health Organization (WHO), a generic drug is “a pharmaceutical product which is intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights” <sup>2</sup>.

For generic approval, manufacturers are generally required to provide evidence of bioequivalence to the reference product, but not to repeat the full spectrum of preclinical and clinical trials conducted for the original drug. This regulatory pathway is distinct from that of new drugs and is designed to

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streamline approval while maintaining rigorous standards for quality, safety, and efficacy<sup>3</sup>.

Brand name is the name given by the Pharmaceutical Company or by which they market their products, thus there are many brand names. Generic names remain the same all over world and have clarity. Generic drugs are cheaper than the branded drugs because manufacturers rarely spend money on advertising and marketing.

Generic drugs are made with the same active substance as the non-generic drugs which are already authorized and approved for their safety, efficacy and quality checked before getting licensed. The National Medical Commission (NMC) issued guidance in October 2016 recommending that physicians prescribe medicines by their generic names to encourage rational prescribing practices. Generic drugs, are therefore expected to provide quality care with an affordable cost. The WHO states that nearly 80% of total health-care expenses are shared by out-of-pocket payments<sup>4</sup>. As we try to provide good-quality health-care system to the community with limited available resources, increased usage of generic drugs can improve affordability of the health care without compromising the quality<sup>5</sup>.

Indian government started a campaign named “Jan Aushadhi” in 2008 to provide generic medicines to the population at affordable cost, which renamed as “Pradhan Mantri Bhartiya Janaushadhi Pariyojana” in November, 2016<sup>6</sup>. In India, generic medicines are approved under the guidelines of Central Drug Standard Control Organization (CDSCO), which requires submission of information regarding administrative and prescribing information, product quality, clinical as well as non-clinical study reports<sup>7</sup>. Therefore we plan to evaluate awareness about generic drugs amongst this group because they are future doctors in our society.

**Aim and Objectives:** To evaluate awareness in resident and intern doctors regarding generic drugs and identify factors which discourage or encourage the prescription of generic drugs. Specific objectives include:

1. To assess baseline awareness of generic drugs among interns and resident doctors.

2. To evaluate changes in awareness and prescribing practices regarding generic drugs following an educational intervention.

## **MATERIALS AND METHODOLOGY:**

**Study Site:** The study was conducted at tertiary care hospital in Surat city.

**Study Design:** A quasi-experimental pre–post interventional questionnaire-based study was conducted to assess the knowledge and awareness of generic medicines among intern and resident doctors before and after an educational intervention. The study was conducted after obtaining approval from the Institutional Ethics Committee (IEC).

**Ethics Approval and Informed Consent:** Ethical approval for the study was obtained from the Institutional Ethics Committee (IEC approval no. SMIMER/IEC/11/10-01-2023) prior to initiation of the study. Written informed consent was obtained from all participants after explaining the purpose and procedure of the study. Participation was entirely voluntary and confidentiality of the participants’ responses was maintained.

## **Participant Recruitment and Sampling:**

Participants were recruited using a convenience sampling method from intern doctors and resident doctors working at the tertiary care teaching hospital. Potential participants were approached personally and informed about the objectives of the study. Participation was voluntary and no academic or clinical pressure was applied to encourage participation.

**Study Duration:** The study was conducted over a period of six months from January 2023 to June 2023.

**Sample Size:** A total of 115 intern and resident doctors were approached to participate in the study. Among them, 115 provided consent and completed the pre-test questionnaire. However, 21 questionnaires were excluded due to incomplete responses and therefore 94 participants were included in the final analysis and completed both the pre-test and post-test assessments.

**Inclusion Criteria:** Interns and resident doctors who gave consent to participate in this study.

**Exclusion Criteria:** Incompletely filled forms were excluded from the study and those who were not willing to give consent.

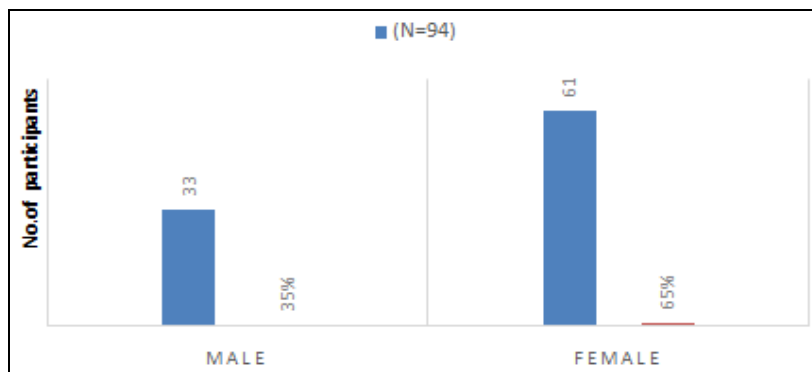
**Methodology:** A total of 16 questions was administered to participants to assess their baseline knowledge and awareness regarding generic medicines (pre-test). The questionnaire used in this study was obtained from previously published literature and used after obtaining necessary permission from the source. The questionnaire was reviewed and validated by experts from the Department of Pharmacology to ensure content validity and suitability for the study objectives. Minor modifications were made to adapt the questionnaire to the local clinical and educational context. Prior to the study, the questionnaire was pilot tested on a small group of participants to assess clarity and relevance of the questions. After completion of the pre-test questionnaire, participants attended a 2-hour educational session on generic medicines. The session was conducted by faculty members from the Department of Pharmacology. The intervention consisted primarily of a structured lecture supported by presentation slides, covering topics such as:

- Concept and definition of generic medicines.

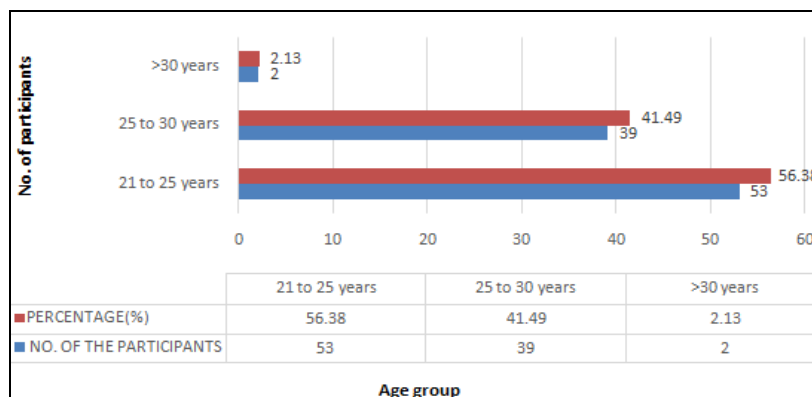
- Regulatory approval process and bioequivalence.
- Advantages and misconceptions regarding generic drugs.
- Prescribing practices and government initiatives promoting generic medicines.

Following completion of the educational session, the same questionnaire was administered immediately as a post-test to assess the change in knowledge and awareness among participants after the intervention. The collected data were entered into Microsoft Excel and analyzed using appropriate statistical software. Descriptive statistics were used to summarize the data and a paired t-test was applied to compare pre-test and post-test scores.

**RESULT:** A total of 115 participants were included in this study after written informed consent, but 21 out of them were excluded due to incompletely filled form during analysis. Out of 94 subjects, 61 (65%) females and 33(35%) males participated in the study **Fig. 1**. Most of them were aged between 21 to 25 years old **Fig. 2**. 59(61%) resident doctors and 35(39%) intern doctors responded to the questionnaire **Fig. 3**.



**FIG. 1: GENDER WISE DISTRIBUTION**



**FIG. 2: AGE WISE DISTRIBUTION**

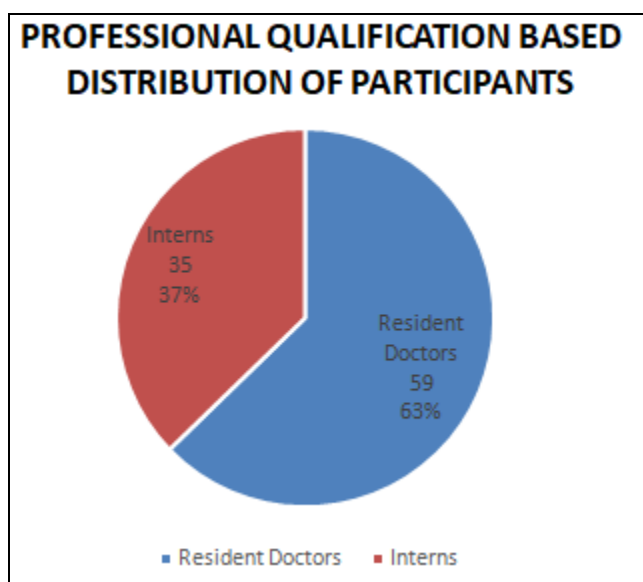


FIG. 3: DISTRIBUTION BASED ON PROFESSIONAL QUALIFICATION

TABLE 1: COMPARISON OF PRE-TEST AND POST-TEST RESPONSES TO QUESTIONNAIRE ON KNOWLEDGE REGARDING GENERIC MEDICINES (N=94)

Sr. no.	Questions	Pre-test Yes n(%)	Pre-test No n(%)	Pre-test Don't know n(%)	Pre-test Yes n(%)	Pre-test No n(%)	Pre-test Don't know n(%)
1.	Can a branded drug also be a generic drug?	63 (67.02%)	27 (28.72%)	4 (4.25%)	88 (93.61%)	6 (6.38%)	0
2.	Do generic drugs contain the same active substance and dose as branded drugs?	72 (76.60%)	19 (20.21%)	3 (3.19%)	89 (94.68%)	5 (5.31%)	0
3.	Does a generic drug manufacturer need to repeat preclinical and clinical studies for original drugs?	38 (40.42%)	41 (43.61%)	15 (15.95%)	27 (28.72%)	67 (71.27%)	0
4.	Does a generic drug manufacturer need to conduct bioequivalence studies with branded drugs?	41 (43.61%)	42 (44.68%)	11 (11.70%)	61 (64.89%)	32 (34.04%)	1 (1.06%)
5.	Are generic drugs cheaper than branded drugs ?	90 (95.74%)	4 (4.25%)	0	93 (98.93%)	1 (1.06%)	0
6.	Should generic drugs be prescribed only for poor patients ?	3 (3.19%)	91 (96.80%)	0	1 (1.06%)	93 (98.93%)	0
7.	Are prescribers in India encouraged or required(as per professional guidance) to prescribe drugs by generic name ?	32 (34.04%)	40 (42.55%)	22 (23.40%)	48 (51.06%)	45 (47.87%)	1 (1.06%)
8.	Are you aware of the purpose of "Jan Aushadhi Scheme" launched by Government of India ?	70 (74.46%)	16 (17.02%)	8 (8.51%)	92 (97.87%)	2 (2.12%)	0
9.	Are you aware of the regulatory provisions regarding pharmacist substitution of generic drugs for branded drugs in India ?	47 (50%)	26 (27.65%)	21 (22.34%)	57 (60.63%)	31 (32.97%)	6 (6.38%)
10.	Are generic drugs as safe as branded drugs ?	83 (88.29%)	6 (6.38%)	5 (5.31%)	90 (95.74%)	2 (2.12%)	2 (2.12%)
11.	Are Generic drugs equally efficacious as branded drugs ?	73 (77.65%)	15 (15.95%)	6 (6.38%)	82 (87.23%)	10 (10.63%)	2 (2.12%)
12.	Do you prescribe generic drugs in your clinical practice ?	88 (93.61%)	6 (6.38%)	0	91 (96.80%)	3 (3.19%)	0
13.	Do Generic drugs produce more Adverse Drug Reaction (ADR) than branded drugs ?	6 (6.38%)	77 (81.91%)	11 (11.70%)	7 (7.44%)	83 (88.29%)	4 (4.25%)
14.	Do you think that switching from	28	57	9	26	66	2

	branded to generic drugs may affect therapeutic outcomes?	(29.78%)	(60.64%)	(9.57%)	(27.65%)	(70.21%)	(2.12%)
15.	Will the use of generic drugs decrease healthcare expenditure ?	73	16	5	77	17	0
		(77.65%)	(17.02%)	(5.31%)	(81.91%)	(18.08%)	
16.	Do you feel that increasing awareness about generic drugs will improve their acceptability among patients?	90	4	0	92	2	0
		(95.74%)	(4.25%)		(97.87%)	(2.12%)	

In Pre-Test, total of 63(67.02%) participants believed that branded drug can be generic also, which was increased to 88(93.62%) after conducting the training session. In Pre-test, 72(76.60%) subjects responded that generic drugs contain same active substance and same dose as the branded drugs, this was increased to 89(94.68%) in post-test. In Pre-test, 41(43.62 %) of them knew that generic drug manufacturer doesn't need to repeat preclinical and clinical studies for original drugs, this was improved to 67(71.28%) in post-test. 90(95.74%) of them responded that generic drugs are cheaper than branded drugs in pre-evaluation which was increased positively to 93(98.94%) in post-evaluation **Table 1**.

In pre-test 91(96.81%) of them agreed that generic medicine should not be prescribed in poor patient only, which increased to 93(98.94%) in post-test. In pre-test 70(74.47%) participants were aware about the purpose of "Janaushadhi Scheme" launched by Government of India and 32(34.04%) knew that there is any law in India which states that prescribing generic drugs are mandatory, which improved to 92(97.87%) and 48(51.06%) in participants after training session respectively. In pre-test 26(27.66%) believed that pharmacist have no legal right to sell generic drugs in place of prescribed branded drugs before session which improved to 31(32.98%) after training session. Nearly 83(88.30%) and 73(77.66%) participants agreed that generic drugs are as safe and equally efficacious as branded drugs in pre-test, which increased to 90(95.74%) and 82(87.23%) in post-test respectively **Table 1**.

Total of 77(81.91%) subjects believed that generic drugs do not produce more Adverse Drug Reaction (ADR) than branded drugs which was improved around 83(88.30%) after an educational intervention. Although majority of them 57(60.64%) think that switching from branded drug to generic medicine may not affect the outcome of therapy but this was improved to 66(70.21%) after

session. In pre-test, 73(77.65%) of resident and intern doctors believed that use of generic drugs will decrease health expenditure which was improved to 77(81.91%) post-test. In pre-test 90(95.74%) knew that increasing awareness regarding generic drugs will increase acceptability of generic drugs which increased 92(97.87%) post-test **Table 1**.

**DISCUSSION:** Resident and intern doctors who are the future practitioners should know about the concept of generic medicines and their safety, efficacy, quality and bioequivalence from the very beginning of medical course. In our study, post-test 94.68% agreed that generic drugs contain same active substance and same dose as the branded drugs whereas another study by Gupta, R et al, found that 89.9% doctors had knowledge that composition, dose and indications of generic medicines are same as the branded counterparts (p<0.0001) <sup>7</sup>.

In our study, post-test 64.89% participants assumed that a generic drug manufacturer need to conduct bioequivalence studies between generic and branded drugs however 81% participants were aware about the same in a study conducted by Hadia RB *et al* <sup>8</sup>. In our study, pre-test 40.42% participants had no idea that preclinical and clinical trials are not needed to be repeated for generic medicine which is similar to the result of 40% of respondents were unaware that generic drug manufacturers need not repeat preclinical and clinical trials in the study by Priyadarshini, R *et al* <sup>9</sup>. In our study, post-test 98.93% participants believed that Generic drugs should not be prescribed for poor patients only where as another study done by Shivgunde *et al*. shows that 69.23% of them believed about the same <sup>10</sup>. In this study, post-test 97.87% participants were aware about the purpose of "Janaushadhi Scheme" launched by Government of India which promotes the cost – effective drugs and their prescription, whereas in a study done by Prithul Bhattacharjee *et al* all the

120(100%) doctors knew about this<sup>11</sup>. In our study, post-test 31(32.98%) believed that pharmacist have no legal right to sell generic drugs in place of prescribed branded drugs which is quite similar to the result of 20% in a study by Charan, J *et al*<sup>12</sup>.

In our study, post-test 87.23% of the participants believed that generic drugs are as efficacious as branded drugs which is similar to Priyadarsini R *et al.* study in which 84% of government physicians and only 64% of private physicians believed that generic medicines are just as effective and secure as branded medicines<sup>9</sup>. In our study, post-test 95.74% of the participants believed that generic drugs are as safe as branded drugs which was different in Zhao M, Zhang L study found that 44.17% agreed or strongly agreed that the safety of the generic medicines is similar to the originators<sup>13</sup>. In our study, post-test 88.29% believed that generic drugs do not produce more adverse drug reactions (ADR) as compare to branded drugs where as 84% believed the same in the study carried out by Hadia RB *et al*<sup>8</sup>. There is strong misconception in medical fraternity that any drug which is expensive is better than affordable generic drugs, which is quite disgraceful. Policy makers around the world try to make the generic medicines affordable and more accessible by reducing the cost of the health care system. In Indian context, the cost of generic drugs has been found to be up to 91% less than that of innovator medicine. In our study, 98.94% of the participants knew that the cost of generic medicines is less than the branded drugs which is similar to a study which suggests 83.1% UG's and 87.8% interns knew that cost of generic medicine is considerably lower than brand medicine<sup>4</sup>.

As there are many misconceptions observed regarding the generic drugs hence upgrading the knowledge and spreading awareness regarding generic medicines prescription among the health care professionals should be implemented, for this various programs and training sessions to be planned for creating awareness about generic drugs. This will promote the generic drugs prescribing habit and thus will reduce the economic burden to the society.

**Limitations:** This study has several limitations. Being a single-center study conducted among

interns and resident doctors of one institution, the findings may have limited generalizability to other settings, including clinicians and general practitioners. The use of convenience sampling may also introduce selection bias. As the study was questionnaire-based, it is subject to recall bias and relies on self-reported responses, which may not always accurately reflect actual knowledge or practice. The immediate post-test assessment following the educational intervention may have introduced testing and learning bias, potentially overestimating the effect of the intervention. Additionally, social desirability bias cannot be ruled out, as participants may have provided responses they perceived as favorable. Finally, the study did not assess long-term retention of knowledge, limiting conclusions regarding the sustained impact of the intervention.

**CONCLUSION:** The majority of interns and resident doctors were aware of generic medicines; however, gaps were identified in their knowledge regarding key aspects such as bioequivalence, regulatory requirements, efficacy, and safety. These findings highlight the need for targeted educational interventions to strengthen understanding and promote rational prescribing of generic medicines. Structured awareness programs, including workshops and continuing medical education (CME) activities, can help build confidence and encourage the adoption of generic prescribing practices among healthcare professionals. Furthermore, improving the accessibility and dissemination of guidelines and regulatory information through official websites and webinars may enhance awareness and ensure that healthcare professionals remain well-informed about generic medicines.

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**Declarations:**

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**Ethical Approval:** The study was approved by the Institutional Ethics Committee

**CONFLICT OF INTEREST:** None declared

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