

## Awareness about generic drug prescription amongst practitioners: a knowledge attitude practice survey at rural set up

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### ABSTRACT

**Background:** to evaluate the knowledge, attitude and practices regarding generic drugs prescription and the factors influencing it amongst practitioners at a rural set up.

**Methods:** All the practitioners in the town, at both government and private settings were interviewed individually and the data was collected with the help of a self-administered, pre-validated and semi-structured questionnaire. Data were analysed to describe all variables and test any significant difference between the practitioners at government and private set-up.

**Results:** The study included 97 practitioners from different affiliations with a response rate of 87.63%. Our survey showed that most of the practitioners (74.36%) were in favour of generic drugs substitution owing to their knowledge about generics. Majority of the practitioners (69.10%) were aware that both the brand and generic drugs are bioequivalent and that there exists significant price difference between them, yet, concerns regarding the manufacturing standards of the latter, prevented them from practicing generic substitution. Practitioners did not report a significant pressure from patients to prescribe either brand or generic drugs. Most practitioners (76.92%) had a positive attitude towards the government's role in assuring the quality of generic drugs by improving manufacturing standards of these drugs.

**Conclusions:** Although the practitioners were strongly in favour of generic substitution, concern regarding their quality standards is discouraging them from doing the same. The government can play a major role by improving the standard operating procedures for manufacturing the generic drugs thereby assuring the practitioners about their quality.

**Keywords:** Generic drugs, Generic substitution, Practitioners, Quality standards

## INTRODUCTION

FDA defines generic drug as ‘a chemical equivalent designed from a branded drug whose patent has expired’. It is observed that India and majority of the developing countries are branded generics markets, where doctors prescribe the brand name of the drug instead of the generic name and different pharmaceutical companies sell the same generic drug with different brand names and at different prices. The use of generic drugs can significantly reduce health-care expenditure without compromising the quality or the therapeutic efficacy of the prescribed medicine hence, many countries have tried to increase the usage of generic-only drugs.<sup>1,2</sup> However, they could not be very successful because of apprehension that ‘generic-only drugs might be of substandard quality’.<sup>3</sup>

The process of adoption of generic drugs into medical practice is multifaceted; pivotal role played by the practitioners. Although there is increasing local and international encouragement for practitioners to prescribe generic products, some practitioners are not in favour of prescribing generic drugs.<sup>4</sup>

Worldwide, few studies have evaluated the knowledge, attitude and perceptions of practitioners regarding the prescriptions of generic drugs. As there is paucity of such data in our country, the present study was conducted in order to evaluate the level of awareness in the form of knowledge, attitude and practices regarding the generic medicines amongst the practitioners in a rural setup.

## METHODS

This was a knowledge attitude practice (KAP) questionnaire based survey, conducted among the practitioners of our hospital, a rural tertiary care teaching hospital and also the private practitioners practicing in the town outside the government hospital. Study was carried out after the approval from the institutional ethics committee at our institute (Approval letter no: 100 Dated: 24/12/2012). Informed consent was obtained from each participant.

For the purpose of the study, a newly designed KAP-based questionnaire was used. The initial draft was framed and circulated to the members of the research team and modifications were carried out as per the suggestions. Upon receiving the responses from the healthcare professionals, its reliability was tested by using the Cronbach alpha value.

Every physician was interviewed personally and given 30 minutes to fill the questionnaire. Any clarification or explanation needed in understanding the questionnaire was provided. In order to preclude any potential bias the identity of the responder was kept confidential except for the category of participants (whether Government hospital practitioner or Private practitioner). Initially Pre-

KAP questionnaire was briefed to all the participants and informed about the purpose of the study. It comprised of 28 questions: 10 assessing the knowledge and 9 assessing the attitude and practice each. Each correct answer and each positive response was given a score of ‘1’ whereas the negative response or wrong answers was given a score of ‘0’. The maximum possible score was 28. The KAP survey questionnaire was analysed question wise and their percentage value was calculated. Data was analysed using descriptive statistics and appropriate statistical tests. Statistical analysis was done using ‘graphpad prism, version 6.00’ for windows, graphPad software. In case of unanswered questions, the participant was excluded from the study.

## RESULTS

The present study involved a cohort of 38 government and 56 private practitioners, out of whom, 35 government and 50 private practitioners completed the questionnaire (overall response rate, 90.42%). The Cronbach alpha value for reliability assessment of the questionnaire was 0.8.

**Table 1: Demographic details of the participants.**

	Frequency (%)	
	Government	Private
<b>Age (in years)</b>		
<30	22.86	0
31-40	40	54
41-50	34.28	34
>50	2.86	12
Professional status	35	50
<b>No. of years in practice (years)</b>		
<10	54.29	62
11-20	28.57	32
21-30	17.14	6
<b>No. of prescriptions written per day</b>		
<25	14.28	14
25-50	25.71	46
51-75	25.71	18
>75	34.28	22
<b>Educational qualification</b>		
Primary care practitioners (MBBS, BAMS, BHMS, BDS)	6 (17.14)	12 (24)
Medical specialists (MD/MS/Dip )	29 (82.86)	38 (76)

The demographic data (Table1) showed that majority of the practitioners were in their early forties with less than 10 years of experience. The government practitioners dealt with more patients than the private practitioners. Most of the practitioners were medical specialists in both the setups.

**Table 2: KAP score of the respondents.**

KAP parameters	Government hospital practitioner (n=35) mean±S.D.	Private practitioner (n=50) mean±S.D.
Knowledge	6.97±1.31	7.8±1.15**
Attitude	7.91±1.02	8.1±0.88
Practice	5.6±1.72***	2±1.04

\*\* p value < 0.01 when knowledge of private practitioners is compared with that of government practitioners,  
 \*\*\* p value < 0.001 when practice of government practitioners is compared with that of private practitioners by z test.

**Table 3: Comparison of KAP parameters.**

Professional status	Mean±S.D.		
	Knowledge	Attitude	Practice
Government hospital practitioner (n=35)	6.97±1.30###	7.91±1.02 <sup>a***</sup>	5.6±1.72
Private practitioner (n=50)	7.8±1.15###	8.1±0.88 <sup>***</sup>	2±1.04

a p value < 0.05 when knowledge is compared with attitude  
 ### p value < 0.001 when knowledge is compared with practice  
 \*\*\* p value < 0.001 when attitude is compared with practice (ANOVA followed by Tukey's multiple comparison test)

The mean KAP score of the respondents was classified based on their profession. As shown in (Table 2 and 3), the knowledge of the private practitioners about generics is significantly higher than that of the government ones. However, the practice of generic drugs by the government practitioners is significantly more than the private practitioners. Also there is highly significant difference between the knowledge and practice, and attitude and practice of both the government as well as private practitioners.

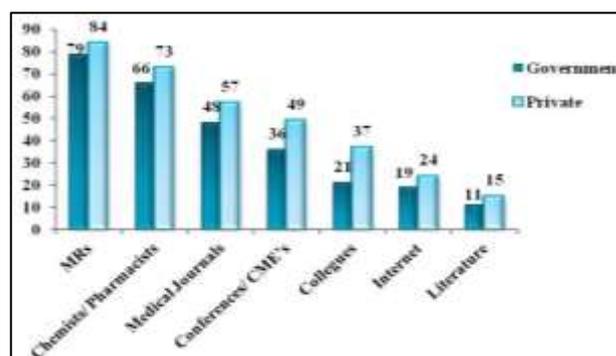
**Table 5: Proportions of practitioners who have visits from generic and brand name companies' representatives.**

	Brand name drug companies' representatives		Generic name drug companies' representatives		Amongst all the practitioners	
	Government	Private	Government	Private	Generic	Brand
Weekly	7	5	0	0	0	12
Monthly	23	39	2	0	2	62
Once in six months	4	6	1	4	5	10
Never	1	0	32	46	78	1

As shown in (Table 4), although not statistically significant, a negative correlation was observed between the knowledge-attitude, knowledge-practice and attitude-practice of the private practitioners, and also among the knowledge-practice of the government practitioners. The positive correlation between the knowledge-attitude and attitude-practice of the government practitioners was also not statistically significant.

**Table 4: Correlation between the KAP parameters of the government and private practitioners.**

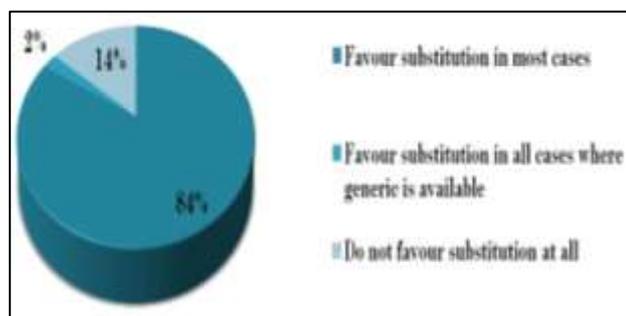
Variables	Correlation coefficient (p value)	
	Government hospital practitioner	Private practitioner
Knowledge-attitude	0.041 (0.815)	-0.179 (0.21)
Knowledge-practice	-0.17 (0.327)	-0.218 (0.125)
Attitude-practice	0.047 (0.79)	-0.263 (0.062)



**Figure 1: Source of information (in %).**

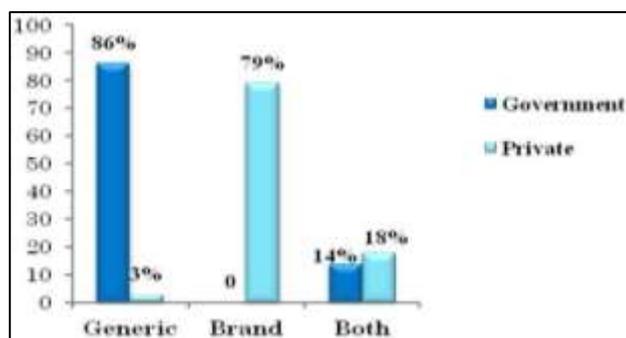
Majority of the practitioners gained the information about the generic alternatives to brand drugs from the medical representatives (MRs) and chemists/pharmacists (Figure 1). Medical literature was the least sought source. Most of the practitioners had monthly visits by the MRs of the brand-drug companies but a majority of them were never visited by the MRs of generic drug companies (Table 5).

Majority (84%) of the practitioners favour generic drug substitution in most of the cases whenever a generic alternative is available (Figure 2). Only 2% favour the substitution in all the cases. It was observed that, though majority of the practitioners were not only well-informed about the generic drugs and their benefits but was also in favour of its substitution, yet in actual practice, the prescription rate of these drugs was low.



**Figure 2: Proportions of practitioners who favour generic drug substitution.**

When asked about their prescribing habits, as shown in Figure 3, it was observed that majority of the government and very few of the private practitioners prescribed generic drugs exclusively.



**Figure 3: Drugs prescribed frequently.**

## DISCUSSION

The response rate of practitioners in our survey is 85.8% which is comparable with other studies. The study conducted by Alghasham AA observed similar response rate (85.5%) in contrast to that observed by Chua GN et al (27%).<sup>5,6</sup> Most practitioners in the present study were in their early to mid-forties. They were mainly practicing clinicians for an average period of less than 10 years and saw around 60-80 patients of all age groups per day. Primary care practitioners constitute the majority of practitioners in our country. Therefore, their contribution in cost savings would be substantial if they switch to generic prescriptions.

Majority of practitioners supported generic substitution in "most" of the cases which is in consistence with the

studies conducted thus-far. Sharrad AK et al assessed the perceptions of physicians regarding the generic medicines in Iraq.<sup>7</sup> They observed that physicians are enthusiastic about generic substitution in order to reduce the healthcare expenditure, however, they insisted on prior approval of the doctors to be obtained by the pharmacists. Similarly, the Slovene general practitioners were willing to implement generic substitution if they were provided data from additional clinical trials of generics.<sup>8</sup> However, a study conducted in Spain showed that "doctors' personal preferences" and "authorities' pressure" were the major factors influencing their prescribing.<sup>9</sup>

In the present study, many clinicians raised concerns regarding the quality of generic drugs in terms of safety and efficacy, thus considering them ineffective for use in critically ill patients. This was especially true about drugs with narrow therapeutic index. It is not surprising that few practitioners do not support generics-substitution at all. It was observed over the time, that the process of generic substitution underwent a rough ride. The popularity of generic drugs took a sharp downturn in 1989 when a scandal, involving unethical and illegal practices by some generic drug companies, shook the generic drug industry.<sup>10</sup> Generic substitution in conditions where drugs with narrow therapeutic index are essential is still debatable. Hence the regulatory bodies should emphasize greater tightness in bioequivalence before the generic formulations with narrow-therapeutic index are approved.<sup>11,12</sup>

Ideally the practitioners should seek information about drugs from reliable sources. The best source of information would, thus, be the National drug formulary of India, the essential drugs list and the pharmacopoeias. Most of the information, in our study, was derived from the medical representatives of the drug manufacturing companies followed by the pharmacists and chemists. Lot of information regarding the generic drugs was sought for by the practitioners, after a program flashed on the television pertaining to the medical malpractices, a few years ago. This compelled many of the practitioners in our study, in particular, to gather maximum information regarding the generic drugs. However the practitioners' widespread knowledge and a positive or favourable attitude towards these drugs alone are not sufficient to escalate their prescribing.

It was observed in the present study that there is a weak positive and a negative correlation observed between the variables in government and private practitioners respectively. This suggests that adequate knowledge do not necessarily improve the attitude and practice of generic drug prescribing thus underscoring the fact that there are numerous factors which hinders the practitioners from prescribing these drugs.

Majority of the respondents thought that manufacturing standards for generic medicines were not as stringent as for branded products. They also expressed a lack of

confidence in the equivalence of generic medicines to the innovator brands drugs. In order to alleviate the fear and reservations regarding the generic drugs, the practitioners need to be educated and reassured by these drug manufacturers as well as the regulatory authority with regards to the bioequivalence, quality and safety standards.<sup>13</sup>

The practitioners, in our study, observed that over few years, in most of the cases, patient's socio-economic status is no longer a criterion for the treatment strategy. Patients' changing attitude towards their treatment and the demand for better ("costly") medicines compels the clinicians to prescribe the brand drugs in increasing frequency. There is need for patient education to improve utilization of generic medicines. Patients should also be informed of the reasons for generic substitution and assured about the quality and therapeutic equivalence of generic products. This is possible only when the prescriber himself is assured of these aspects. Irrespective of these doubts, few private practitioners made an effort to promote generic drugs by referring the patients suffering from tuberculosis and HIV-AIDS to the government hospital for anti-tuberculosis therapy (ATT) and anti-retroviral therapy (ART) respectively.

Many practitioners were of the opinion that the government should curtail the cost of the brand drugs rather than promoting the generic drugs. Few practitioners in our study commented that the inconsistent availability of generic drugs is a major problem even at government setup, rendering them to depend upon the brand drugs. Concerns regarding the cost of the generic medicines were also raised. The maximum retail price (MRP) is higher than the retailer rate, thus though the generic drugs are cheaper than the corresponding brand drug, it is not so much beneficial to the patients.<sup>13</sup>

In order to combat this issue and for 'ensuring availability of quality medicines at affordable prices to all' the government of India has launched the 'jan aushadhi' campaign under which the first 'jan aushadhi' store was opened in Punjab in 2008.<sup>14</sup> Since then many such stores are functional in various states all over the country. Recently a 'jan aushadhi' store was opened in Vidarbha region of Maharashtra state and likewise many generic drug stores have also been set up thereafter. The drug controller general of India (DCGI) is set to push generic drugs solely for the benefit of the public. The central government has taken major initiative in promotion of the generic drugs in that it is directing all the states/ union territory governments to instruct their respective drug licensing authorities to grant/ renew licenses to manufacture for sale or for distribution of drugs in proper/generic names only.<sup>15</sup> Quality assurance of drugs, both brand and generic, should continue after approval through post-marketing surveillance and efficient Pharmacovigilance program. All these factors may definitely influence the practitioners to improve the generic drugs prescription.

## CONCLUSION

This survey may, nevertheless, serve as a preliminary study as the population evaluated was small and from a rural setup. The factors favouring generic prescription include the practitioners' knowledge about generic drugs' effectiveness and price differences, a positive attitude among practitioners towards generic drugs, and the government's role in supporting generic prescription. Practitioners face multiple challenges and competing forces to prescribe brand drugs. These include the influence of the brand name drug companies, brand loyalty, non-availability of generic alternatives to all the brand-name drugs and restricted use of drugs with a narrow therapeutic index especially in critically-ill patients. Also the lack of confidence regarding the manufacturing and quality standards of these drugs has led to the practice of labelling them as ineffective and of inferior quality. The success of generic substitution is indeed the result of mutual and active interaction between the practitioners, pharmacists and the patients. .

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