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Original Research Article

To study doctor's beliefs, barriers, awareness, and actual practices regarding use of generic medicines

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ABSTRACT

Background: Government of India is trying to popularize generic medicines, still most Registered Medical Practitioners (RMPs) doubt its quality and efficacy. We conducted a cross sectional survey to study the barriers that hinders the practice of writing generic prescriptions. The aim was to study doctor's knowledge, beliefs and actual practices regarding generic medicines. This study is a KAP survey model (Knowledge, attitude, practices) to study beliefs, barriers, awareness and actual practices regarding use of generic medicines amongst private practioners and RMPs of tertiary care Government hospital in Nanded city.

Methods: A cross sectional survey was conducted on a sample of 300 randomly selected RMPs practicing in Nanded, Maharashtra. A 26-item questionnaire was designed, validated, and data collected through personal visits. Fisher's exact test was applied to see associations between variables using Graphpad Prism 7.

Results: 234 RMPs responded to the questionnaire i.e. a response rate of 78% was achieved. 107 (45.7%) participants claimed to be actively prescribing generic medicines. 122 (52.1%) of the participants were unaware of any generic medical shop in their locality. 83 (35.5%) participants believed generics to be duplicate/ substandard. However, 16 (19.3%) of them still prescribed generics. One-third of them actually preferred its use for family.

Conclusions: RMPs do not accept the use of generic medicines for concerns about its quality and efficacy. Also, there was unawareness regarding availability of generic medicines in the locality. RMPs need to be educated about manufacture, sale and quality aspects of generic medicines in India.

Keywords: Awareness, Barriers, Beliefs, Generic medicines, Practices, RMPs

INTRODUCTION

Branded medicines generally cost about 2.6 times more than their generic equivalents.[1] In some countries, this price differential is more than 10-fold.[1] With increasing cost of healthcare, and insurance cover less than 17%, about one-fourth of the Indians get pushed into poverty because of high out of pocket (OOP) expenses for health care.[2,3] The highest budget share of OOP expenditure is by drugs i.e. almost 80% of the total.[2,3] The public sector in the country procures medicines most often as unbranded generics.[4] However, surveys have revealed very poor availability of essential medicines in public sector hospitals. Therefore, low income patients are forced to buy more expensive medicines from private sector or simply go without treatment.[5,6]

Branded medicines are strongly promoted and these promotional costs also add to their MRPs.[7] Studies also suggest that interactions with medical representatives influences prescribing and cause cognitive dissonance for prescribers.[8] The unethical practice of bribing doctors by pharmaceutical companies to create more and more prescriptions makes the essential medicines unaffordable to common man.

Most of the prescriptions have branded medicines written on them, although prescription guidelines promote generic prescriptions.[9] The reason being debated is doctors concern about quality and efficacy of generic medicines supplied by Indian manufacturers.[10-12] Food and Drug Administration states that generic medicines work just as well as branded medicines and have stringent regulations regarding its quality assurance and bioequivalence.[13] India, however have been blamed for its counterfeit and spurious drug supply in name of generics.[14] Central Drugs Standard Control Organisation report shows that extent of spurious drugs in retail pharmacy is much below projections made by various media, World Health Organisation, and other studies i.e. only 0.046%.[15]

India is known as the "Pharmacy of Third world" providing the most affordable generic medicines of assured quality, as it retains its public health safeguards in its Intellectual property rules.[16] Although Government of India is trying to popularize generic medicines, still most of doctors do not prefer it and are not sure about its quality and efficacy.[17-19] This study is a KAP survey model (Knowledge, attitude and practices), to study beliefs, barriers, awareness and actual practices regarding use of generic medicines amongst Registered Medical Practitioners (RMPs) in Nanded city.

Objectives

- To study doctors knowledge and awareness regarding generic medicines.
- To study doctors attitude and beliefs regarding generic medicines.
- To study the barriers that hinders the practice of writing generic prescriptions and factors affecting it.

METHODS

Operational definition: generic medicines

According to World Health Organisation, "A Pharmaceutical Product usually intended to be interchangeable with an innovator product, from the innovator company and marketed after the expiry date of the patent or other exclusive rights."

A cross sectional survey of KAP type was undertaken between May 2 and June 30, 2016 after approval of the Institutional Ethics Committee of Government Medical College, Nanded. A 26-item questionnaire, designed to study beliefs, barriers, awareness and actual practices of Registered Medical Practitioner's (RMPs) towards generic medicines was used as a study tool.

300 RMPs practicing allopathic/ integrated medicine in Nanded city (100 from Government and 200 from private sector) were randomly selected. Simple randomization was done with the help of lists of RMPs obtained from office of Government medical college, Nanded (List of 210 RMPs) and office of Indian Medical Association, Nanded (List of 700 RMPs). RMPs from non-allopathic background, but practicing allopathic/integrated medicine were also included in the study. However, RMPs practicing only non-allopathic medicine were excluded.

These RMPs were personally visited for data collection. Of these 249 RMPs responded to the questionnaire. However, 15 responses collected were found to have missing information and therefore discarded. Thus, a total of 234 responses were included in the study. A total response rate of 78% was achieved and RMPs practicing in Government hospital had a response rate of 100%. The response rate achieved is highly acceptable, as non-response bias is of less concern amongst doctors.[20] Respondents were provided with information sheet, and a written informed consent was taken from each for participation into research activity. Any personal data collected or accessed during the survey was kept confidential. The investigator was responsible for the privacy, confidentiality and archival of the data.

The questionnaire comprised of three sections: six items to characterize RMPs demographics, eight specific questions to assess their knowledge and awareness regarding generics, twelve statements describing their beliefs regarding generics and barriers in practice of prescribing the same using a five-point likert type scale. The first draft of questionnaire was reviewed by a panel of professionals, with experience in generic medicines and survey type research consisting of:

- Two Pharmacology Professors from Government Medical College, Nanded.
- A Pharmacology Professor from Nanded Pharmacy College.
- A Professor of Pharmaceutical Jurisprudence from Nanded Pharmacy College.

Revisions were made according to suggestions by panel over content and construct validity of questions. The revised version of questionnaire was pilot tested among twenty RMPs which were not part of the actual sample. Reliability analysis was performed and cronbach's alpha coefficient was found to be 0.768 for the third section of questionnaire.

All the data collected was entered and tabulated into Microsoft excel and analyzed by using Graphpad Prism 7. Fisher's exact test was applied to see associations between variables at a significance level of 0.05 (Confidence interval- 95%). Vancouver style has been used for reference citation and listing.

RESULTS

Demographic characteristics

Of the 234 RMPs participated in the study, 100 practiced in Govt. Hospital and 134 were private practitioners. 183

(78.2%) participants were male, and 88 (37.5%) were between 31 and 40 years old. Only 107 (45.7%) Participants claimed that they actively prescribed generic medicines. The RMPs practicing in Govt. Hospitals were found to be significantly more likely to prescribe generic medicines (P-Value: 0.0002). Further details of participant's demographic characteristics and their influences over their generic prescribing tendency are provided in Table 1.

Table 1: Demographic characteristics of participants and its influence over generic prescribing.

Characteristics		No. of RMPs (%)	Actively prescribing generic medicines?		P-Value
			Yes n (%)	No n (%)	
Total participants		234	107 (45.7%)	127 (54.3)	
Institution of practice	Government	100 (42.7%)	60 (60%)	40 (40%)	0.0002*
	Private	134 (57.3%)	47 (35.1%)	87 (64.9%)	
Gender	Male	183 (78.2%)	84 (45.9%)	99 (54.1%)	1.0000
	Female	51 (21.8%)	23 (45.1%)	28 (54.9%)	
Age (years)	≤30	83 (35.5%)	39 (47%)	44 (53%)	0.2183
	31-40	88 (37.5%)	41 (46.6%)	47 (53.4%)	
	41-50	35 (15%)	11 (31.4%)	24 (68.6%)	
	>50	28 (12 %)	16 (57.1%)	12 (42.9%)	
Years in practice	≤10	161 (68.8%)	74 (46%)	87 (54%)	0.6569
	11-20	39 (16.7%)	15 (38.5)	24 (61.5%)	
	21-30	22 (9.4%)	12 (54.5%)	10 (45.5%)	
	>30	12 (5.1%)	6 (50%)	6 (50%)	
Education	MBBS ± PG ± Superspeciality	195 (83.3%)	92 (47.2%)	103 (52.8%)	0.1687
	BDS ± PG	11 (4.7%)	3 (27.3%)	8 (72.7%)	
	BAMS ± PG	18 (7.6%)	10 (55.6%)	8 (44.4%)	
	BHMS ± PG	10 (4.3%)	2 (20%)	8 (80%)	

Fishers Exact Test is used
*P<0.05 is considered significant
MBBS- Bachelor of Medicine and Bachelor of Surgery, PG- Post graduate, BDS- Bachelor of Dental Surgery,
BAMS- Bachelor of Ayurveda Medicine and Surgery, BHMS- Bachelor of Homeopathic Medicine and Surgery

Table 2: Influence of RMPs knowledge and beliefs regarding generics over practice of generic prescribing.

Variable		Actively Prescribing generic medicines?		P-Value
		Yes n (%)	No n (%)	
Perception regarding generic medicines?	Duplicate/ Substandard/ lower therapeutic efficacy	16 (19.3%)	67 (80.7%)	<0.0001*
	As efficient as branded medicines	91 (60.3%)	60 (39.7%)	
Knowledge of laws and Regulations?	Yes	63 (54.8%)	52 (45.2%)	0.0085*
	No	44 (37%)	75 (63%)	
Knowledge of availability of generics in locality?	Yes	61 (54.5)	51 (45.5)	0.0125*
	No	46 (37.7)	76 (62.3)	
Prefer generics for family or personal use?	Yes	73 (65.8%)	38 (34.2%)	<0.0001*
	No	7 (10.1%)	62 (89.9%)	

Fishers Exact Test is used
*P<0.05 is considered significant

Beliefs, knowledge and attitude of RMPs regarding generics and its influence over their practice

224 (95.7%) participants claimed of having knowledge of generic medicines, and 83 (35.5%) participants believed the generic medicines to be duplicate/substandard/of lower therapeutic efficacy.

Perceptions of participants regarding quality and efficacy of generic medicines highly influenced their prescribing pattern (Table 2, P-Value: <0.0001).

It was also noted that 16 (19.3%) of participants who considered generic medicines to be substandard or of lower therapeutic efficacy were actively involved in prescribing generic medicines. Whereas, 60 (39.7%) participants considering generics to be equivalent to branded medicines did not actively prescribe it.

Question: Generic Medicines can be described as,

- The duplicate drugs marketed without any active content.
- Cheaper Substitutes of brand name drugs with same active content but in substandard amounts or of substandard quality.
- Cheaper Substitutes of brand name drugs with same active content but lower therapeutic efficacy.
- Cheaper Substitutes of brand name drugs with same active content and therapeutic efficacy.

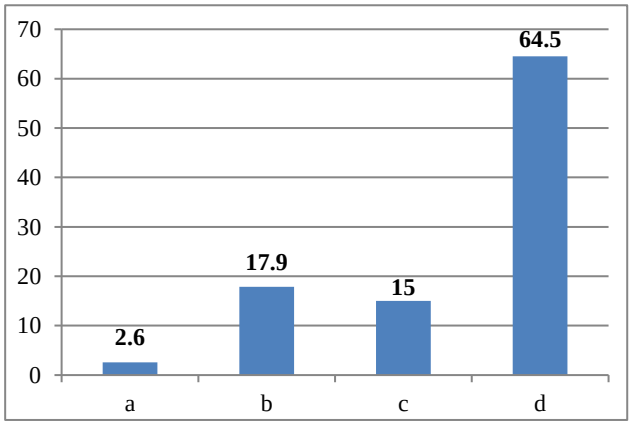

Figure 1: Response to above question in %.

115 (49.1%) participants claimed of having knowledge of laws and regulations governing manufacture, sale and quality aspects of drugs in India. However only 81 (34.7%) correctly identified the law to be Drugs and cosmetics act. The participants who didn't know such laws and regulations were significantly less likely to prescribe generic medicines (Table 2, P value- 0.0085).

122 (52.1%) participants did not know any medical shop in their locality where generic medicines are available, and knowledge of availability of generics in the locality indeed significantly influenced generic prescribing tendency. (Table 2, P-value: 0.0125). It was also noted that, about one-third (34.2%) of participants who do not prefer to prescribe generic medicines to patients actually preferred to use it for their family or personal use.

195 (83.3%) Participants reported that there is large cost difference between generic and branded medicines. Majority of participants (60.7%) blamed high marketing and Research and Development expenses incurred by company to be responsible for higher costs of branded medicines.

132 (56.4%) participants believed generic medicines to be bioequivalent to their branded counterparts. However 51 (21.8%) participants had doubts over efficacy of generic medicines, while 20 (8.5%) participants believed that generic medicines produce more side effects.

Barriers in practice of prescribing generic medicines

RMPs were asked to indicate their responses on factors influencing their prescribing tendencies (Table 4). Majority of the RMPs reported that Patients socio-economic factor (74%), Unavailability of generics (50%), and Practice/suggestions of seniors and colleagues (41.4%) influenced their prescribing patterns. Only 27.7% of the participants agreed over the influence of advertisements by pharmaceutical companies.

Table 3: RMPs perceptions regarding generic medicines (response over Llikert scaling).

Statements	Response - n (%)				
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1. Generic medicines have same active contents and in equal amounts to its branded counterparts.	66 (28.2%)	94 (40.2%)	35 (14.9%)	36 (15.4%)	3 (1.3%)
2. Manufacturing procedure and Food and Drugs Administration (FDA) standards of generic drugs are equivalent to its branded counterparts.	48 (20.5%)	90 (38.5%)	54 (23.1%)	38 (16.2%)	4 (1.7%)
3. Generic medicines are within standards of bioequivalence to its branded counterparts.	43 (18.4%)	89 (38%)	61 (26.1%)	36 (15.4%)	5 (2.1%)
4. Generic medicines have same efficacy than its branded counterparts.	38 (16.2%)	89 (38%)	56 (24%)	43 (18.4%)	8 (3.4%)
5. Generic medicines produce more side effects.	4 (1.7%)	16 (6.8%)	61 (26.1%)	115 (49.2%)	38 (16.2%)
6. It is preferable to use generics for my family or personal use.	25 (10.7%)	86 (36.7%)	54 (23.1%)	40 (17.1%)	29 (12.4%)

n= number of participants

Table 4: Factors influencing prescribing patterns of RMPs (response over likert scaling).

Statements	Response - n (%)				
	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
1. Unavailability of generic medicines influences my prescribing pattern.	29 (12.4%)	88 (37.6%)	57 (24.4%)	48 (20.5%)	12 (5.1%)
2. Practice and suggestions of my seniors and colleagues influence my prescribing pattern.	12 (5.1%)	85 (36.3%)	48 (20.5%)	65 (27.8%)	24 (10.3%)
3. Advertisements by Pharmaceutical companies influence my prescribing pattern.	13 (5.5%)	52 (22.2%)	43 (18.4%)	83 (35.5%)	43 (18.4%)
4. Bonuses/gifts offered by pharmaceutical companies influence my prescribing patterns.	8 (3.4%)	18 (7.7%)	31 (13.2%)	91 (38.9%)	86 (36.8%)
5. Patient socio-economic factor influence my prescribing pattern.	55 (23.6%)	118 (50.4%)	22 (9.4%)	23 (9.8%)	16 (6.8%)
6. Pharmacists tend to replace prescriptions for profit making.	52 (22.2%)	96 (41%)	33 (14.1%)	38 (16.3%)	15 (6.4%)

n= number of participants

While, 75.7% participants did not think that bonuses/ gifts offered by companies will influence their choice of medicine. 63.2% of the participants were skeptic over pharmacist's tendency to replace prescription for profit making.

DISCUSSION

The study aimed to explore the Knowledge, awareness, beliefs, and attitude of the RMPs towards generic medicines utilization including the factors that hinder and favor generic prescribing.

A response rate of 78% was achieved. This response rate in a physician population is one of the strengths of this study. However, Kellerman and Herold reported that non-response bias may be of less concern amongst physicians. This is because physicians are considered to be consistent in opinion regarding understanding, views, attitudes, training, and behavior.[20]

The survey results showed that more than half of the (54.3%) participant RMPs deferred from actively prescribing generic medicines. This result is not consistent with the survey amongst General practitioners of Malaysia and Australia which indicated a high generic prescribing rate, but consistent with the similar study in Pakistan, Nigeria and Saudi Arabia.[18,21-26] This may be probably due to the geographical differences in the attitude of RMPs. However, it did not even comply with the study conducted in Tamilnadu.[27] The Prescribing pattern was significantly associated with institute of practice of RMPs. The RMPs practicing in Government institution were significantly more likely to prescribe generic medicines (P value- 0.0002). This might be due to the fact that, Government practitioners are more exposed to poor patients and rational-cost effective prescribing is an integral part of its health care system. However, in contrast to other studies, no significant association was found between age, experience or education of the participants with their generic prescribing patterns in this study.[18,21-24]

35.5% of the participants believed generic medicines to be duplicate/ substandard/ of lower therapeutic efficacy. However, mixed perceptions were identified regarding quality, efficacy and bioequivalence of generic medicines amongst RMPs. Gaps were identified in the knowledge of RMPs regarding generic medicines and many had misconceptions regarding its safety, efficacy and quality. Nearly similar findings were reported in other similar studies.[18,21-24]

It was noted that, 39.7% doctors considering generic medicines to be equivalent to branded medicines did not actively prescribe it. This may be due to the influence of pharmaceutical companies or seniors and colleagues. However, the gaps like RMPs retired from practice or indulged in a non-clinical faculty were not excluded in this study, which is a limiting factor in above result. However, most of the RMPs (75.7%) disagree over the influence of bonuses and gifts by pharmaceutical companies over their prescriptions.

In contrast to above finding, the influence of socio-economic factor of patients can be appreciated from the finding that 19.3% of participants actively prescribed generic medicines even though they believed them to be of substandard quality. The confused perception of the RMPs is such that 34.2% of participants deferring from prescribing of generic medicines to patients preferred it for their own family or personal use.

Even the fact that about half (52.1%) of the participants are unaware of the availability of generic medicines in the locality may be an influencing factor. The knowledge of

participants regarding laws and regulations governing pharmaceutical industry is also found to be significantly related to practice of generic prescribing (P value-0.0085). Thus, the basic information of such laws and regulations in the curriculum of aspiring doctors may be beneficial.

63.2% of the participant RMPs were skeptic that pharmacists tend to replace prescriptions for profit making. This shows the disharmony and distrust amongst the health team. Such a disharmony always ends up with the ill effects over the patients' health and economy of health care services.

CONCLUSION

It appeared that nearly half of the RMPs do not accept the use of generic medicines in their practice. They have concerns about the quality and efficacy of such products. Also there was unawareness regarding availability of generic medicines in the locality.

RMPs need to be educated about manufacture, sale and quality aspects of generic medicines in India. Further studies need to be conducted to assess the impact of educational intervention on knowledge, perception and practice of RMPs regarding generic medicines.

Several factors influencing prescribing patterns of doctors may be checked to improve the prescribing rates of generic medicines. The influence of pharmaceutical industry may be considered a major factor. Policy to check the bribing of doctors by pharmaceutical industries through bonuses or gifts by pharmaceutical industries need to be formulated and implemented. Junior doctors tend to follow senior doctors' prescribing style of using brand names. Therefore, it is important to introduce and encourage generic prescribing at early stages in medical schools. In addition prescription monitoring may also be useful.

The current findings have important implications in designing policy to promote generic medicines in India. However, generalizability of the findings is somewhat limited.

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Appendix

Questionnaire

1. Age _____ 2. Sex_____ 3. Institution of Practice- Government/ Private/ Other

2. Designation- JR1/JR2/SR/RMO/Lecturer/Private RMP/Other

3. No. of years in practice_____ 6. Education_____

4. Do you know about generic medicines?

a. Yes

b. No

5. Generic Medicines can be described as,

a. The duplicate drugs marketed without any active content.

b. Cheaper Substitutes of brand name drugs with same active content but in substandard amounts or of substandard quality.

c. Cheaper Substitutes of brand name drugs with same active content but lower therapeutic efficacy.

d. Cheaper Substitutes of brand name drugs with same active content and therapeutic efficacy.

6. Do you actively prescribe generic medicines?

a. Yes

b. No

7. Do you know about laws and regulations governing Manufacture, sale and quality aspects of drugs in India?

a. Yes

b. No

8. Which of the following law governs manufacture, sale and quality aspects of drugs in India?

a. Pharmacy Act

b. Drugs and Cosmetics Act (D and C Act)

c. Drug Price Control Order (DPCO)

d. Don't Know

9. Do you find any cost difference between generics and branded medicines?

a. Yes large difference

b. Yes small difference

c. No

d. Don't know

10. According to you, why branded products have high cost than its generic substitutes?

a. Branded Medicines have higher quality

b. Branded medicines have better therapeutic effect

c. Due to Company's reputation

d. Due to Profit making motto of company

e. Due to High marketing and R and D expenses incurred by company

f. Can't say

11. Do you know medical shops in your locality where generic medicines are available?

a. Don't Know

b. Yes, I know one such shop

c. Yes, I know 2-5 such shops

d. Yes, I know more than 5 such shops

Make a tick mark (√) over the most appropriate answer:

Questions-	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
12. Generic medicines have same active contents and in equal amounts to its branded counterparts.					
13. Manufacturing procedure and Food and Drugs Administration (FDA) standards of generic drugs are equivalent to its branded counterparts.					
14. Generic medicines are within standards of bioequivalence to its branded counterparts.					
15. Generic medicines have same efficacy than its branded counterparts.					
16. Generic medicines produce more side effects.					
17. It is preferable to use generics for my family or personal use.					
18. Unavailability of generic medicines influences my prescribing pattern.					
19. Practice and suggestions of my seniors and colleagues influence my prescribing pattern.					
20. Advertisements by Pharmaceutical companies influence my prescribing pattern.					
21. Bonuses/gifts offered by pharmaceutical companies influence my prescribing patterns.					
22. Patient socio-economic factor influence my prescribing pattern.					
23. Pharmacists tend to replace prescriptions for profit making.					