

Knowledge and Use of Generic Drugs in Fresh Doctors and Nurses

KEYWORDS

generic drugs, perception of doctor/health care professionals, safety of generics, bioequivalence.

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ABSTRACT OBJECTIVES: With new drugs being introduced into the market at a fast pace, it is a tendency that fresh doctors and nurses would go unaware of many important facts about generic drugs METHODS: It was a cross sectional descriptive study with 206 sample. We used a 16 item questionnaire which had 5

METHODS: It was a cross sectional descriptive study with 206 sample. We used a 16 item questionnaire which had 5 options to assess the perceptions of doctors, medicos, nurses and nursing students.

RESULTS: Our study revealed that, ninety point one percent of doctors and 81.9% of nurses knew that some drugs were branded and others generic but only twenty five percent of doctors and 23.3% of nurses knew about their bioequivalence. Eighty eight point nine percent of doctors and 65% nurses believed that a cost difference existed between generic and branded drugs. Fifty four point four percent and 48.1% of doctors and nurses respectively believed that generics are as safe as their branded counterparts. Fifty three point four percent of doctors and 41.2% of nurses strongly believe that the general physicians get misguided by medical representatives about generics.

CONCLUSIONS: Our survey brings to the fore, the dismal reception of generic drugs by health care professionals and health care professionals-in the making. This is attributed to the negative perceptions through prejudices, ignorance and unauthentic information sources.

INTRODUCTION:

By definition generic drugs are those that are exactly the same as the brand-name drug, but can only be produced after the brand-name drug's patent has expired. It is comparable in efficacy, dosage, safety and quality to the brand drug. The generic drugs are similar in pharmacokinetics and dynamics and they are bioequivalent with the brand name drugs. Generic drugs are usually sold for significantly lower prices than their branded equivalents. One reason for the relatively low price of generic medicines is that competition increases among producers when drugs no longer are protected by patents. This policy allows for affordable, essential medicines. Generic drugs are inappropriate when a drug with a narrow therapeutic range is necessary. (Palo Alto Medical Foundation, 2001).

Generic drugs are looked on with suspicion by most physicians as the quality is uncertain. Generic drugs are unfamiliar to the general public. Doctors are known to prefer branded drugs as their availability is definite because of the vigorous marketing strategies. The self administered drugs, the OTC (over the counter) drugs, pharmacists-advised drugs also have an impact on drug sales. Although generic drugs are being used, they are not being prescribed to the full potential. This requires governmental policies to cater to the quality use of generics.

Historically, generic drugs originated in Venice in 1474, followed by England in 1623, and the US in 1790. These systems of legal protection emerged with the development of capitalism, as manufacturers wanted to secure 7the fruits of their investments from competition. As recently as 40 years ago, drug companies could release new products with far less testing than it requires today. The real test of a drug's safety and effectiveness came after it went to market when too many patients had bad reactions to the drug. In 1962, the FDA (Food and Drug Administration) revamped the Federal Food, Drug and Cosmetic Act, originally passed in 1938, in which it strengthened the drug testing laws wherein the companies were required to prove that a drug was both safe and effective before it reached the market place. In 1984, the US Congress approved the Drug Price Competition and Patent Term Restoration Act, known as the Hatch-Waxman Act, where it allowed for generic companies to begin work on bioequivalence studies while the competitor's drug is still on-patent. In the Indian generics industry, Ranbaxy was incorporated in 1961 and began producing generics in 1967. Its competitor Dr Reddy's which originated in 1970's also moved into generics market in 1984.

Since the 1970s, generic drugs have been substituted for branded drugs as a common prescribing pattern. Family physicians have more preference to generic drugs (Bower and Burkett, 1987). Generic drugs are on the rise in all written prescriptions including non-refill prescriptions.

In our study we decided to dissect this multifaceted problem by considering doctors' opinions on use of generic drugs and assessing their knowledge on generic drugs. This study undertook the possible hurdles that physicians feel that impact their prescription decision making. We also assessed the opinions of medical students, in this regard. Nurses' are an important member of the health care team; hence their perceptions would also influence use of prescription drugs. Nursing students' opinion would also be a considerable indicator.

With new drugs being introduced into the market at a fast pace, it is a tendency that fresh doctors and nurses would go unaware of many important facts about generic drugs. So it is very important to update one's knowledge on the various drugs used and their adverse effects, if any. This study is to assess and evaluate the fresh doctors' and

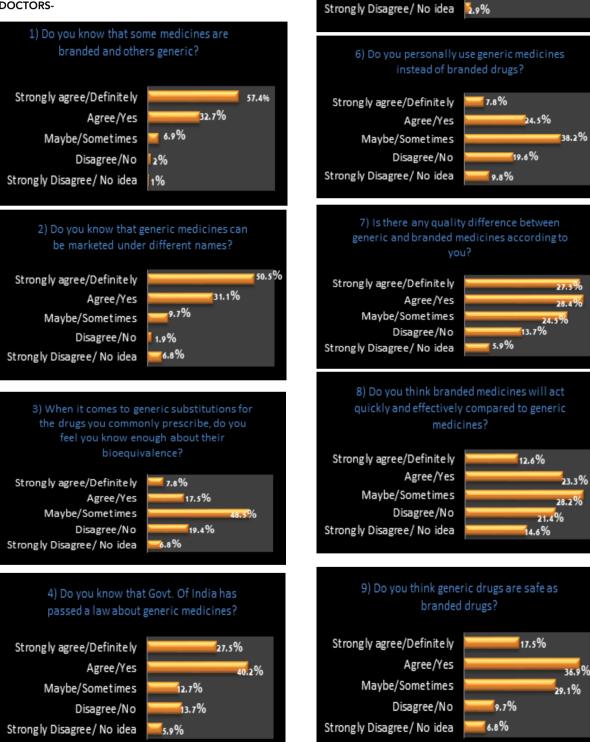
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nurses' perceptions, views and knowledge towards generic drugs. It is also to evaluate opinions and practises regarding generic drug substitutions.

MATERIALS AND METHODS:

It was a cross sectional descriptive study with 206 sample. We used a 16 item questionnaire which had 5 options to assess the perceptions of doctors, medicos, nurses and nursing students.

RESULTS: DOCTORS-



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5) Do you find any cost difference between

generic and branded medicines?

6.8%

1.9%

49.5%

18.8%

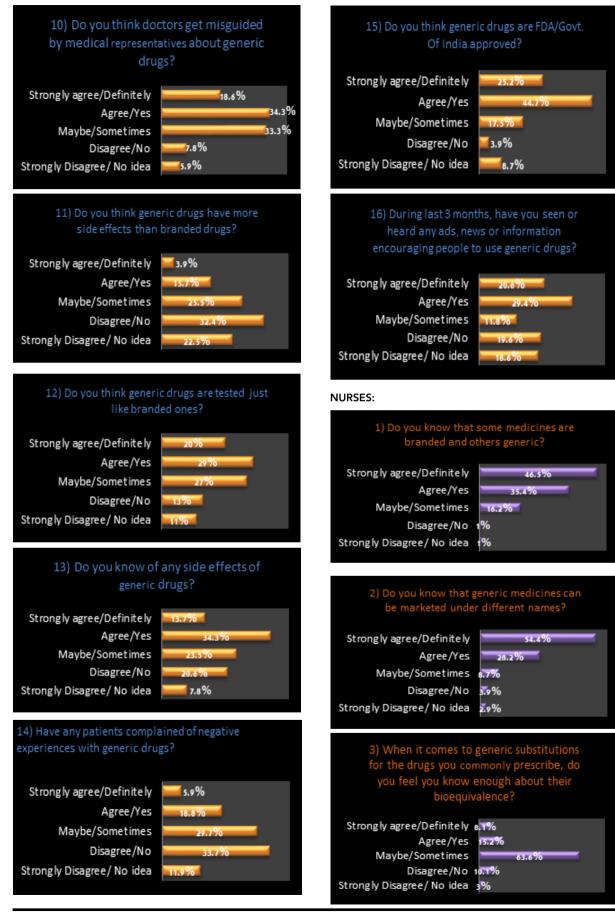
Strongly agree/Definitely

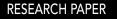
Maybe/Sometimes

Agree/Yes

Disagree/No

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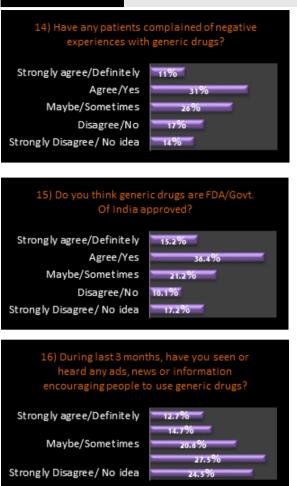


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DISCUSSION:

In our study, we have analysed the questionnaires on the awareness, the preferences and attitudinal beliefs on use of generics in prescribing. We undertook health care professionals and would-be health care professionals for this comparative attitudinal choice on this pertinent principal of prescribing. In the Indian context, the doctors are the only group of prescribers; nurses do not prescribe but they are often the final point before the drug reaches the patient and hence they are the lynch-pin in the health care delivery system.

The knowledge of use of branded drugs was known to doctors (90.1%) and nurses (81.9%) alike with only a marginal difference. The quality use of generic medicines can be promoted by also understanding the pharmacists' perceptions¹. There are discrepancies in the knowledge of pharmacy personnel. There is a mixed reaction towards the use of generic medicines varying from country, economic, drug product characteristics and pharmaceutical reimbursement system². There appears to be a marked difference in physicians of different countries about their perceptions of generic drugs³.

Both the nurses (63.6%) and the doctors (48.5%) were unsure about the bioequivalence in generic substitutions. It's alarming to know that they were unsure about the bioequivalence which tells us that they should be better educated regarding generics⁴. Once the patent for an original medication has expired, the companies producing its generics must show that it is 80%-125% bioequivalent to its

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original⁵.

The doctors (40.2%) and nurses (33.3%) are aware of the government of India's legislative requirements on generic medicines. In the Indian pharmaceutical sector, growth in the domestic and international forum constitutes a large volume. Although the Indian equivalent statistics are not available, it would be favourable to have. The US fill 8-10 prescriptions for generic drugs.

Most of the doctors (88.3%) as well as the nurses (65%) are aware of the economic differences between generic and branded medications. The assessment of laypersons on usage profile for generic drugs showed 88.8% agreed that they had lower price and hence 80% also believed that generic drugs are brought because of the lower price range. The lay people also concluded that doctors never prescribe generic drugs⁶. For developing countries specially, not withstanding other countries, the constrained healthcare resources require understanding of barriers to cost effective drug use⁷.

The frequency of use of generic drug was more vehemently disagreed by nurses (23.8%) as opposed to doctors who constituted 19.6%. On the whole the nursing (uses generic drugs-35.6%, uses generic drugs sometimes-29.7%, doesn't use generic drugs-33.7%) personnel were equivocal in the use of generic drugs. The doctor community on the other hand advocates to the use of generic drugs often but not as a usual (62.7%). It was noted that some of the doctors would not take generics themselves but also would not recommend generics for family members. Physicians reported that pharma companies dole out drug information to physicians (75%). Physicians have a negative perception about generic medicines that is a major concern as a potential barrier to generic drug use⁷. One out of 7 doctors would choose Branded medicines over Generics if given a choice⁸.

It is surprising to note that the quality difference between generic and branded was most definitely vouched for by the nurses (65.6%). The doctors (55.9%), on the other hand, were reticent on their absoluteness of the quality difference among the drugs. Among the patients of lower socioeconomic demographic group, some mistrust remains where they believe that less expensive equals lower quality⁹.

There was total agreement among the doctors (35.9%) and the nurses (32.3%) that branded drugs would be more rapid and effective than generics. The whole principle of generics could be fixated on this item and it brings us to the stark reality of the wastage of generics.

The safety of generic drugs has been equally evinced by both doctors (54.4%) and nurses (48.1%). The need for generic drugs is for its optimal effectiveness, safety, kinetics with minimised cost. The disagreement of doctors (9.7%) and nurses (12.7%) although insignificant is still an indicator of the ineffective propagation and education imparted to health care professionals.

The health care professionals (D-18.6%, N-13.4%) definitely agree that the medical representatives preclude the use of generic drugs eloquently. It is also interesting to note that while nurses disagree on the misguidance by representatives about generic drugs at 14.4%% while doctors stand at 7.8% It is the staunch ideology and strong foundation of pharmacological principles that would prevent the sway

Doctors (3.9%) are definite that generic drugs have more side effects than branded drugs while nurses opine the same at 7%. Thus, the general public too believed that generics caused more adverse reactions¹⁰. Thirty two point four percent of doctors disagree that generics have more adverse drug reactions. The whole purpose of the issue of generic drugs is "everything else being the same, they are available at a reasonable price".

The health care professionals (D-49%, N-37%) agree that generic drugs have undergone impartial testing.

The doctors (13.7%) are affirmative on the side effects of generic drugs while more nurses (18.6%) believe on the extent of adverse effects with generic drugs. There seems to be, a total disconnect in understanding generic drugs by health care professionals. The very purpose of generic drugs is defeated with such attitudes. Restructure educative programs at various stages from academic to field, is the solution to this problem.

Doctors-33.7% and Nurses-17% have not found patients with negative experience with generics. They believed that most negative experiences complained by the patients were not real but a nocebo effect ^{11, 12}.

Both doctors (69.9%) and nurses (51.6%) agree to the mandatory approval by regulatory agencies of generic drugs. The opinion of health care professionals to generic drugs although adverse is nonetheless accepted as licensed.

Despite the media and authoritative forums putting out awareness and information of generic drugs, it is disheartening to note that doctors 19.6% and nurses27.5% have not seen or heard any advocacy for generic drugs. The general public feel that use of pamphlets with appropriate information regarding generics would be handy¹³.

The doctors and nurses opinions were mirrored but, the nurses have a positive tendency towards generic drugs.

It is imperative to inculcate in nursing students, medical students and health care professional the true concept of generic drugs i.e. to have same quality and performance as branded drugs. Moreover, research show that generics work just as well as branded drugs. In fact, one studied evaluated the results of 38 published clinical trials that had compared cardiovascular branded and generic drugs that showed equiv-efficaciousness. Legislation does not allow generic drugs to have 45% difference in activity. Indeed generic drugs have been designed to have the economic advantage. Even though generic drugs are of low cost, they have the same quality as that of a branded drug. To evaluate the safety of the generic drugs, the ill-effects that are reported are monitored. The government is actively involved in making the generic drugs safer by investigating their ill-effects.

Our survey brings to the fore, the dismal reception of generic drugs by health care professionals and health care professionals-in the making. This is attributed to the negative perceptions through prejudices, ignorance and unauthentic information sources. These are surmountable barriers that limit the use of generic drugs. Solutions that can overcome this impassé are health education and appropriate regulations and policies that advocate the effective yet cheaper alternative.

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