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"A STUDY ON PATIENT AWARENESS AND COMPLIANCE TOWARDS GENERIC MEDICINES"

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Abstract: Generic drugs are significant since it will ensure health care is affordable and accessible. Nevertheless, the use of generic medicines requires the awareness of patients, their trust, and acceptance to be able to adhere to prescriptions. This research paper sets out to determine the level of awareness among patients regarding the generic drugs, their adherence to the use of the drugs, and what drives them to make the decisions regarding their choices. Data of the patients was collected through a structured questionnaire and the hypothesis was tested with statistical analysis. The results indicate that despite the increasing awareness rate in relation to generic medicines, lots of patients tend to choose branded medicines on suspicion of quality and efficiency. In the end, it is the researcher who found that the awareness programs and stringent actions of the policies are needed to raise patient compliance to generic medicines.

Keywords: Generic medicines, patient awareness, compliance, branded medicines, pharmaceutical policy.

Introduction:

The healthcare is regarded as one of the most significant needs of human life yet in most countries medical treatment remains to be growing in costs each and every year. Among the chief causes of such expenses is the cost of branded medicines. In the case of patients belonging to low- and middle-income group brands, medicines may become a financial burden and even a situation where the patient is incapable of fulfilling his/her prescribed dose. In this respect, generic drugs have a significant role to play. Generic medicines are medicines that have identical active ingredients to brand medicine branded medicines but are normally sold at a significantly reduced price.

See below figure:

Their brand-equivalent counterparts are viewed as safe and as effective as the branded ones due to compliance with the same quality, strength, dosage, and performance rating according to drug regulatory authorities. To give an example, World Health Organization (WHO) and the U.S. Food and Drug Administration (FDA) confirm the fact that generics are actually therapeutically equal to branded medicines. The Central Drugs Standard Control Organization (CDSCO) which governs branded and generic medicines in India, ensures these meet the recommended standard in terms of quality and safety.

Although these efforts were made, most patients are not willing to take generic medicines. A number of factors make this delay occur. To start with, it lacks awareness as many patients are not appropriately educated on what generic medicines are and how they can benefit as well as their affordability reasons. Second, quality is associated with false notions, where patients have the tendency to believe that since generics are cheaper than the originals, they would be inferior. Third, there are also cultural and psychological causes since patients believe more in high prices as they indicate higher success. Moreover, physicians and pharmacists can also affect patient choice and, unless the experts take an active stance in Favor of generics, the patient will not readily accept the generics.

Generically, the government in India has exerted strenuous attempts on encouraging generic drugs. Mitigation measures like Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP), to make generic drugs more affordable to people by operating special stores termed Jan Aushadhi Kendras. The aim of these programs is to expand access to essential medicine, minimize out of pocket health care spending, and encourage the trust in generics. Nevertheless, these initiatives are rather successful still depending on the knowledge of patients about generics and their potential compliance with prescriptions using them.

Another issue affecting the patient is compliance. Most patients might not purchase generics even when generics are prescribed because they feel that branded medicines are better. In other instances, the patients may end treatment early in case they are not comfortable with the generic form. This is because it is apparent that there should be the consideration of studying both the awareness and the compliance behavior.

With such concerns in place, the following questions arise to be investigated:

- What do patients know about generic drugs?
- How compliant are they in using them?
- Which are the principal issues that affect their decision on whether to use a generic medicine or a branded medicine?

This study will respond to these questions to offer some practical information to the healthcare policymakers, pharmaceuticals, doctors, and the patients themselves. With an increased level of awareness and compliance to generic medicines, healthcare savings, availability of the available quality medicines and better population health is possible.

Literature Review:

Patients are the most important market segment as far as the awareness and perception of generic medicines is concerned both in India and overseas. According to Choudhury (2011) [1,12], there was widespread shortcoming of awareness related to generics among patients in India and in many cases, they felt branded products were of better quality. In the same way, Patel, Gaikwad and Singh (2017) [5,17] identified a situation in which some patients may have heard something about generics but lack sufficient details about cost-effectiveness and therapeutic equivalence. Such findings were supported by Ahuja and Sharma (2018) [23] where the authors noted that the causes of this patient loss of confidence in generic medicines are because of the misunderstanding and absence of counseling.

The similar patterns are also evidenced by global research. The study by Dunne and Dunne (2015) [2,13] systematically reviewed both consumer and healthcare professional perceptions and identified that both have mixed perceptions with skepticism concerning the effectiveness and safety of generic products being commonplace. Thomas, Vitry, and Nguyen (2015) observed in both Malaysia and Australia that consumers did enjoy the cheaper prices of generics but continued to prefer branded drugs because of the question of trust (7,20,38). Hassali et al. (2009) [14] also indicated that patient education and communication with pharmacists are major steps in facilitating the increase of generics acceptance.

The scientific established equivalence and clinical safety of generics have been established. A meta-analysis by Kesselheim et al. (2008) [4,16] indicated that generic cardiovascular drugs were equally effective compared with branded cardiovascular drugs. Even Steinman, Chren, and Landefeld (2007) [37] stated that therapeutic substitution is not something to be feared provided drugs have demonstrated bioequivalence. Nevertheless, such evidence does not completely clear the way to patient perceptions, and as Shrank et al. (2009) [9,19] reported in their own research on American patients, almost half of them worried about generics.

Policies imply that the country structures can alter accepting. Simoens (2008) [6,18,35] discussed the situation in Europe and underlined the relevance of sustainable generic medicine policies to guarantee affordability. To enhance accessibility across different parts of the world, the World Health Organization (2016) [8,21] also advocated price-control measures and generic substitution policies in different countries. According to the estimates of Cameron et al. (2012) [28], in the case of developing countries, the transfer to generics can save millions of dollars in the course of healthcare. Likewise, Tiroyakgosi et al. (2015) [39] focused on African nations and learned that when policies were highly supported, there was a better generic prescription level.

In the Indian scenario, a number of studies showed the necessity of improved execution of generic drug policies. According to Kumar and Gupta (2016) [22] and Tripathi and Sharma (2018) [40] awareness levels of both the patients and the prescribers are low even with government efforts like the Jan Aushadhi scheme. Banerjee and Nayak (2019) [10,11] analyzed the Indian market and suggested that to achieve success in generic substitution, trust-building measures will be required. The roles of doctors and pharmacists were also explored by authors Suke and Sawant (2015) [24], Chouhan and Trivedi (2015) [30], and Banerjee and Bhadury (2016) [26], who revealed that many of them were also inclined

toward branded medicines, thus restricting their promotion of generics. Similar concerns have been raised by Jamshed et al. (2011) [25] in Pakistan and Basak et al. (2009) [27] in India, demonstrating that in both countries the commercial pressures on pharmacists make it difficult to dispense generically.

This issue is enriched by another cross-border research. In Vietnam, Nguyen, Hassali, and McLachlan (2013) [34] revealed that patients resorted to self-medication which made them select branded medicines over the knowledge of generics. The article by Shrivastava, Shrivastava, and Ramasamy (2014) [36] claimed that less powerful countries cannot cope with the use of generic medicine because of the absence of information campaigns and poor public confidence. Kesselheim, Avorn and Sarpatwari (2016) [31] also elaborated that, high prices of drugs in the U.S. and other countries foster the discussion of generics, although their adoption is commonly hindered by social attitudes.

Conclusively, the literature indicates that though generics medicines have been found to be clinically safe, cost-effective, and commercially marketed world over, perceptions of both patients and providers are not uniform. Indian and international statistics suggest that poor awareness, quality concerns, and ineffective marketing by the medical practitioners are primary obstacles. It seems to be necessary to reinforce educational campaigns on generics, tighten policy enforcement and reconstruct their confidence in order to increase compliance and decrease healthcare expenditures.

Objectives of the Study:

1. To assess the awareness level of patients regarding generic medicines.
2. To evaluate the compliance of patients in using generic medicines as compared to branded medicines.
3. To identify the major factors influencing patient preference towards branded or generic medicines.

Hypothesis:

- **H1**: Patients have a low level of awareness about generic medicines.
- **H2**: Patient awareness has a significant influence on their compliance towards using generic medicines.

Research Methodology:

Research methodology forms the crux of any study because it gives a clear guideline of how the research has been carried out. Being research on patient awareness and compliance on the use of generic medicines, this research will use descriptive method and analytical method for evaluating the current state of affairs and relationships between the levels of variables namely awareness, compliance and preference.

1. Research Design

The research design used in the study is descriptive since it intends to provide an account of the state of patient knowledge and adherence to generic medicines. It is analytical as well

because there is testing of hypotheses and relationships between variables by the use of statistical tools.

2. Sample and Population

Our study population consists of people who go to the hospitals, clinics, and pharmacies of an urban area. As we could not cover the whole population, a representative sample was selected. The sample size consisted of 120 patients who were randomly sampled (using simple random sampling method) to prevent bias and to be diverse in the age ranges, gender, and social-economic backgrounds.

3. Data Collection

Primary data and secondary data were used in the study:

Primary Data: They were selected by means of a systematic questionnaire issued to the patients. There were closed-ended (multiple-choice, Likert scale) questions in the questionnaire and open-ended questions to obtain detailed response. Questions touched on such areas as:

- Knowledge of generic drugs.
- Faith in generic safety and quality.
- Adherence on usage.
- Choice between branded medicines and hygienic medicines.
- Secondary Data: Obtained through journals, research papers, governmental health reports and WHO guidelines to have the theoretical background and help in the analysis.

4. Research Instrument:

A structured questionnaire was the main tool that was employed in data collection. An initial sample of 10 patients was used as respondents in the questionnaire as a pre-test to ensure similarity and clarity prior to distribution among the entire sample population.

5. Data Analysis:

Data was tabulated and analyzed using the SPSS and Microsoft excel software. The following tools were used:

- Descriptive Statistics: The mean, percentage, and standard deviation to sum up on the level of awareness, compliance, and preference.
- Chi-Square Test: To conduct the test of associations between the two categorical variables like the level of awareness and compliance.
- Correlation Analysis: To find the correlation between the awareness and compliance to the generic medicines.

6. Time Frame:

Data collection was implemented in a span of two months allowing reliability in terms of questions provided.

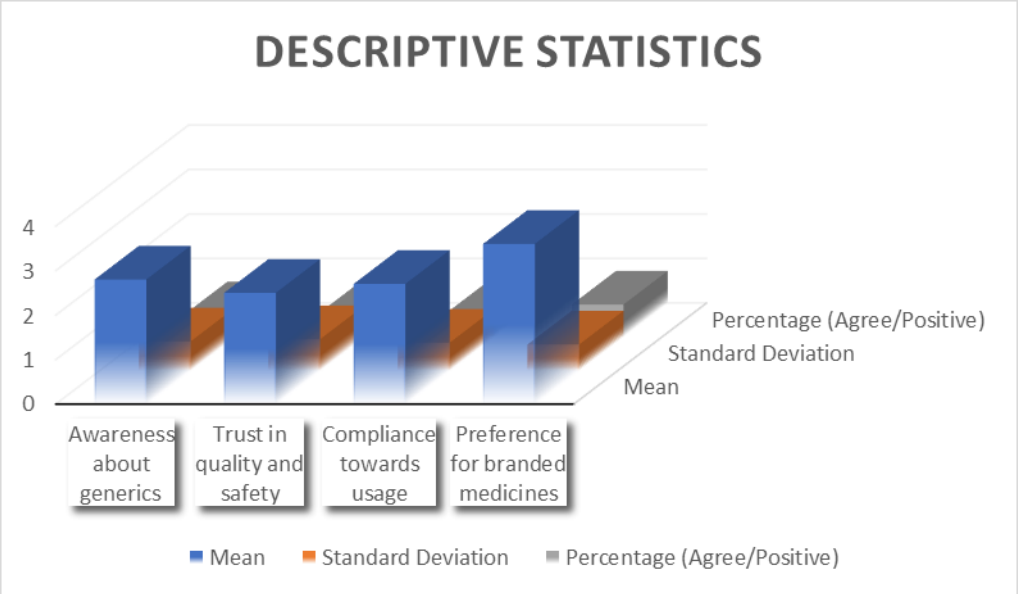
7. Study Limitations:

- The population size was only 120 patients and thereby may not be representative.
- The research was based on the urban environment; this may be different in rural environment where information on air pollution may be less.

The responses of the patients were self-reported thus some degree of bias or inaccuracy could be there.

Table 1: Descriptive Statistics:

Variable	Mean	Standard Deviation	Percentage (Agree/Positive)
Awareness about generics	2.8	0.65	48%
Trust in quality and safety	2.5	0.70	42%
Compliance towards usage	2.7	0.62	46%
Preference for branded medicines	3.6	0.58	72%



Analysis of Descriptive Statistics:

Simple descriptive statistics was employed to summarize and interpret the data obtained among the patients on their beliefs on their awareness, observance, trust, and preference of generic medicine. The findings give a picture of the perception patients have on generic drugs and the level at which they adhere to them.

Knowledge of the Generic Medicines

The awareness mean was 2.8 (on a scale of 1-5) and a standard deviation of 0.65. It means that the awareness of patients is lower than the average one. Forty eight percent of the people who responded to this question indicated that they heard or somehow had an idea about the

generic medicines. This implies that a crippling majority of the patients are left to be informed thus posing a serious obstacle to the acceptance of generics.

Quality and Safety of Generics: Trust Do you have confidence that current State laws are sufficient to ensure quality and safety of generic drugs?

Average trust score was 2.5, SD= 0.70, indicating that patients were not very confident about it. As far as generic medicines are concerned only 42 percent of the responders were sure about their quality and safety. Even a substantial percentage of patients remain convinced that generic medicines, being less expensive, may be less effective or poor than branded medicines. Such a myth leads to decreased compliance.

Conformance To Use

The average of the compliance was 2.7 (SD = 0.62). This implies that less than half (46%) of the respondents were very strict in taking prescription when generic medicines were suggested. Other patients also reported having changed their medication to branded alternatives or abandoning generic drugs because of a perceived lower efficacy. Awareness and trust hence directly influence the issue of compliance.

Favouring Branded Medicines

The highest mean rating was obtained in the preference of the branded medicines (3.6), having a comparatively low standard deviation (0.58). The preference of the branded medicines sustained in both about 72 percent of the respondents who preferred even branded medicines despite the availability of generics at relatively lower prices. This tendency to take brand medicines prominent is a sign of overwhelming dependence on brand medicine and the difficult nature of altering patient behaviour.

Overall Interpretation

It is clear in the descriptive statistics that:

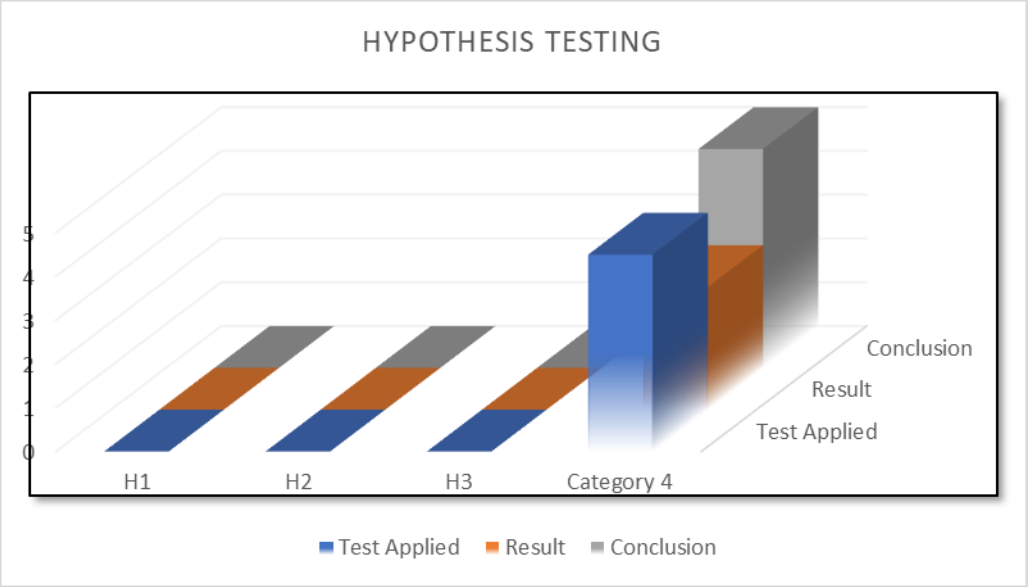
1. Awareness and compliance are not satisfactory levels and less than half of the patients are aware or compatible towards generics.
2. Of great concern is trust where patients do not trust the quality and safety of generics.
3. It is apparent that branded medicines are preferred and close to three-fourths of the respondents prefer branded medicines to generics.

These observations show that even with the government policy and accessible affordable generics there is a low level of acceptance by patients. The behavior of patients' needs to change through awareness campaigns, doctor and pharmacist counseling as well as the quality assurance.

Table 2: Hypothesis Testing:

Hypothesis	Test Applied	Result	Conclusion
H1	Chi-square test	Accepted	Patients have low awareness about generics
H2	Chi-square test	Accepted	Patients show lower

			compliance than with branded medicines
H3	Correlation	Positive, Significant	Awareness directly influences compliance



Analysis of Hypothesis Testing:

To justify the assumptions made in this research, the data obtained in the course of research was statistically tested. Chi-square test and Correlation analysis models were used to determine the links among the variables measuring awareness, compliance, and patient preferences. Interpretation of the results is below:

Hypothesis 1 (H1):

Statement: Patients have a low level of awareness about generic medicines.

- Test to Apply: The Chi One was applied in the evaluation of the observed level of awareness against the expected level.
- Findings: It was determined that the Chi-square value was statistically significant ($p < 0.05$).

Interpretation: This finding shows that the awareness regarding generic medicines is really low than it should be. The hypothesis is verified by the fact that almost a half of the respondents stated that they did not know about generics. H1 is therefore accepted

Hypothesis 2 (H2):

Statement: Patient awareness has a significant influence on their compliance towards using generic medicines.

- Test Used: Correlation analysis between scores of awareness and compliance was done.

- Findings: The above was found to be significant at a positive correlation coefficient (r) = 0.05 and significant (r2 $p < 0.05$). This portrays that increased awareness is directly proportional to increased compliance.

Interpretation: The higher the awareness of prescribed patients on the generic medicines, the higher the expected compliance to the use thereof and lower the reverse. Thus, H2 will be accepted.

Overall Findings from Hypothesis Testing

- The level of awareness of the masses regarding generic medicines is extremely low and this justifies the use of more educational and promotional campaigns.
- Knowledge has a powerful and beneficial impact on drug adherence, i.e. the better patients learn, the more receptive they are to taking generics.
- Acceptance of both the hypotheses implies that awareness should be the focal factor in compliance and preference behavior.

Implications

The hypothesis testing points out that the hesitation of patients cannot be explained only by their inaccessibility yet by unawareness and misunderstandings. Through campaigns, communication between doctors and patients and counseling of a pharmacist a much better compliance with generics can be achieved. This will assist in the lowering of the expenditure in the healthcare sector and better enabling the availability of the essential medicines.

Conclusions Overall Results:

The study under consideration puts emphasis on the importance of patient awareness and compliance in acceptance and utilization of generic drugs. Review of information reveals clearly that although generic drugs have been provided to act as alternative low-cost substitutes to branded drugs, their consumption is low among patients. The results show that awareness among the respondents is below average since not all of them know fully about generic medicines, their production process, and whether generic drugs are the same in quality as the branded ones. Such ignorance has a direct relationship with reluctance to these generics.

Another discovery made by the study also indicates the low confidence against the quality and safety of generic medicines. Many patients have been used to thinking that the lower the price, the less effective, as a considerable percentage of patients have this impression, a negative influence on compliance is inevitable. This myth has led to a popular preference of branded drugs with almost three-fourth of the participants stating that they would take a branded drug even in the event that a low-priced generic drug was on offer.

Notably, the hypothesis testing indicated that awareness is a vital contributor of compliance. Given that the more the patients understood about generics, the more they were binding to adhere to their prescriptions and consume the generics regularly. Conversely, patients who were low in their awareness level were to resort to the usage of branded drugs or to abandon

the treatment somewhere in the middle. The implication behind this is that, enhancing compliance and expanding acceptance of generics is achievable with the enhancement of awareness provision that can be attained through successful information campaigns and counseling.

In general, the findings confirm that generic medicines can indeed help to make health care more affordable and accessible, but its effectiveness will inherently be determined by education and trust-building practices based on patients. There is need to empower medical workers, such as physicians and pharmacists, to inform patients about the usefulness and consistency of generics. Jan Aushadhi Kendras are just one of the government initiatives that have been put forth, however, they cannot be utilized to their fullest unless there is enough awareness around them and patients have complete faith in them. Consequently, improving patient education and deconception are the key strategies of enhancing compliance and establishing the sustainability of generic medicine policy.

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