A survey exploring the knowledge and perceptions of senior medical students in Nepal toward generic medicines

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Abstract
Background: The accurate knowledge of generic medicine issues among future prescribers will enhance the prescribing of cost-effective medicines. This study aimed to explore the knowledge and perception of senior medical students about the generic medicines.
Methodology: A cross-sectional study was conducted among 237 senior medical students (final year students and interns) using a validated self-administered questionnaire. The collected data were analyzed using Statistical Package for the Social Sciences version 20 for windows and comparison of difference was done using linear by linear association. A p value of less than 0.05 was taken as statistically significant.
Results: The average age (standard deviation) of the respondents was 23.54 (1.39) years. Almost 5% of respondents correctly answered the question regarding the regulatory limits for bioequivalence. Almost two-thirds of respondents correctly agreed that generic medicine is bioequivalent to a brand-name medicine, and 79.3% and 72.5% of respondents correctly agreed that the medicine should be present in the same dosage form and same dose, respectively, as the brand-name medicines. However, almost half of the respondents had impression that brand-name medicines are required to meet higher safety standard than generic medicines. Almost 90% of respondents felt that advertisement by the drug companies would influence the use of brand-name medicine and they need more information about generic medicine.
Conclusion: This study highlights the negative perception and knowledge deficit among the respondents. The students’ responses to almost all the statements were almost similar to the respondents’ academic year (final year students and interns), gender and nationality.

Keywords
Generic medicines, generic prescribing, generic substitution, medical students

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Introduction
Reducing constantly increasing medicine and health care costs is a challenge all over the world. In Southeast Asian countries like Nepal and India, government bodies fix the ceiling and retail price of essential medicines and try to check the raising medicine cost.¹,² Recently, the Department of Drug Administration (DDA), drug controlling authority of government of Nepal, has fixed the maximum retail price of few medicines by reducing their market price.¹,³ However, the implementation of the cost has become challenge and doubtful.³

Promotion of the use of generic medicine could be a better strategy to control the escalating medicine than the strategy of controlling retail price of medicines. The World Health Organization (WHO) defines a generic medicine as “a pharmaceutical product, usually 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.”⁴ Generic medicine is cheaper but is identical to its

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corresponding innovator medicine in terms of quality, efficacy, safety, therapeutic use, dosage form, strength and route of administration, and quality. The presence of more generic medicines in pharmaceutical market also makes the market competitive, which ultimately plays an important role in lowering the prices of other medicines including generic equivalents. Hence, promotion of generic medicines could help to reduce the escalating health care (especially medicine) cost significantly and ultimately improve medicine accessibility.

The generic medicine prescribing and generic substitution require changing existing prescribing behavior which is difficult and contentious issue even in developed countries. Several countries around the world have their own policies to promote generic medicine. Knowledge and perception of prescribers plays a very vital role in promotion of generic medicine prescribing and use. Hence, the medical students could be informed and educated about the benefits of generic prescribing at medical school. The authors of this article think that the students with good knowledge about generic medicine would practice and advocate for generic prescriptions/generic substitution.

As a future doctor/prescriber and health policy makers, the medical doctors have very important role in implementation and promotion of generic medicine. Studies conducted among Australian medical students had shown knowledge deficits about the generic medicines. Knowledge and perceptions about generic medicines among medical students has not been previously studied in Nepal. Hence, the study was carried out to (1) explore the knowledge and perception of final year medical students and interns about the generic medicine and generic prescribing and (2) compare differences of scores in knowledge and perceptions (if any) among different subgroups of respondents.

**Methodology**

**Study design and procedure**

The present cross-sectional study was conducted from 22 August to 30 September 2015 using a validated questionnaire. All the senior undergraduate medical students (final year students and interns (students undergoing residential rotational internship)) of Manipal College of Medical Sciences (MCOMS) willing to participate in the study were included in the study. The MCOMS is an international private medical school in Nepal and admits students mainly from Nepal, India, Sri Lanka and Maldives to the undergraduate medical course (MBBS). The course is of five-and-a-half years’ duration including 1-year compulsory residential rotating internship. The questionnaires were distributed to the respondents and they were asked to return back after filling the questionnaire by themselves.

**Study tool**

The validated questionnaire from previous study was used to collect information. Three faculty members of the department checked the validity of the questionnaire and their feedback and comments were modified in the final version of the tool to be clearer to the respondents. The respondents’ agreement with a set of statements was noted using the normal 5-point Likert scale (Strongly agree, Agree, Neutral, Disagree and Strongly disagree with the statements). The questionnaire consisted of three parts. The first part obtained demographic data of the respondents, for example, age, gender, nationality and year of medical study (e.g. final year or internship). The second part of the questionnaire, which included a multiple-choice question and six statements, measured respondents’ knowledge toward generic medicine. The multiple-choice question regarding the regulatory limits for bioequivalence was provided with six options out of which one was correct. The third part of the questionnaire included six statements and measured perception toward issues pertaining generic medicine utilization. The questionnaire was tested among 10 third-year students of the institution. The data of the pilot study were not included in the final analysis. Cronbach’s alpha was calculated to be 0.712, indicating a good level of internal consistency.

**Ethical considerations**

The study was approved by the Institutional Review Committee (IRC), MCOMS, Pokhara vide notification MEMG/IRC/GA (i). The respondents were invited for voluntary participation (could withdraw from the study at any time without giving any reason) in the study. They were informed about the objectives of the study, its importance and benefits were explained. They were explained that the participation was voluntary and the participants were assured about the confidentiality of the data. A written informed consent was obtained from all respondents prior administration of the questionnaire.

**Data analysis**

The collected data were entered into and analyzed using SPSS (Statistical Package for the Social Sciences) version 20 for windows. Comparison of difference according to gender, year of medical study (e.g. final year or internship) and nationality was done using linear by linear association. The data were skewed and the expected frequencies in some cell/s in most of the cross tables (chi-square test) were less than 5 (some were having expected frequency less than 1) so linear by linear association. For this study data, a p value of less than 0.05 was taken as statistically significant.

**Results**

Of 272 senior medical students (final year students and interns), 237 responded to the study with response rate of 87.1%. More number of respondents were female, of Nepalese nationality, and of age 23 years (Table 1). The average age (standard deviation (SD)) of the respondents was 23.54 (1.39) years. Table 1 shows the demographic characteristics of the final year students and interns.
they do not know the correct answer, while others (31.2%)
respondents (71 final year students and 81 interns) said that
answered the question correctly. Almost two-thirds of
the concept of bioequivalence among the respondents.
The statement was given to ensure a common understanding
the first question:

Table 1. Respondents' demographic characteristics.

| Characteristics | Final year students, n = 120 (%) | Interns, n = 117 (%) | Total, n = 237 (%) |
|-----------------|----------------------------------|----------------------|-------------------|
| Gender          | Female                           | 52 (43.3)            | 68 (58.1)         | 120 (50.6) |
|                 | Male                             | 68 (56.7)            | 49 (41.9)         | 117 (49.4) |
| Age in years    | 21                               | 9 (7.5)              | 0 (0.0)           | 9 (3.8)   |
|                 | 22                               | 36 (30.0)            | 6 (5.1)           | 42 (17.7) |
|                 | 23                               | 42 (35.0)            | 31 (26.5)         | 73 (30.8) |
|                 | 24                               | 18 (15.0)            | 46 (39.3)         | 64 (27.0) |
|                 | 25                               | 12 (10.0)            | 22 (18.8)         | 34 (14.4) |
|                 | 26                               | 2 (1.7)              | 8 (6.8)           | 10 (4.2)  |
|                 | >26                              | 1 (0.8)              | 4 (3.4)           | 5 (2.1)   |
| Nationality     | Nepalese                         | 63 (52.5)            | 78 (66.7)         | 141 (59.5) |
|                 | Indian                           | 41 (34.2)            | 37 (31.6)         | 78 (32.9) |
|                 | Sri Lankan                       | 16 (13.3)            | 2 (1.7)           | 18 (7.6)  |

The first question of the questionnaire was “The regulate-
atory limits applied are that 90% confidence intervals for
the log ratios (generic product: brand name product) of the
areas under the plasma drug concentration versus time
curves and the maximum plasma drug concentrations must
fall between,” six options (mentioned in Table 2) were
given, with the correct answer being 80%–125%. The
respondents were asked to check one of the options. The
following explanatory statement was printed prior to
the first question:

In pharmacology, the term bioavailability refers to the rate (how
fast) and the extent (how much) to which an active ingredient is
absorbed and becomes available at the site of drug action. Most
of the drug regulatory agency around the world considers a
generic product to be bioequivalent if its bioavailability is
within an allowable range compared with the currently marketed
brand product.

The statement was given to ensure a common understanding
of the concept of bioequivalence among the respondents.
Eleven (4.6%), 9 final year students and 2 interns only,
answered the question correctly. Almost two-thirds of
respondents (71 final year students and 81 interns) said that
they do not know the correct answer, while others (31.2%)
answered the question incorrectly (Table 2). Linear by linear
association showed that there was no significant difference
in the knowledge according to the respondents’ year of medi-
study (e.g. final year or internship), gender and nationality.

Responses to other individual statements measuring
knowledge toward generic medicines and perceptions toward
issues pertaining generic medicine utilization are presented in
Tables 3 and 4.

Almost two-thirds (64.1%) of respondents correctly
agreed that a generic medicine is bioequivalent to a brand-
name medicine. They also correctly agreed that the medicine
should be present in the same dosage form (79.3%) and in
the same dose (72.5%) as the brand-name medicine. In con-
trary to the above impression, 110 (46.4%) respondents had
impression that the brand-name medicines are required to
meet higher safety standards than generic medicines and
only 28.3% correctly disagreed that brand-name medicines
are required to meet higher safety standard than generic
medicine (Table 3). Almost 17% of respondents have a
wrong impression that the generic medicine causes more
side effects compared to brand-name medicines while 25%
of respondents were neutral to the question. Similarly, 39
respondents (16.5%) thought that generic medicines are less
effective compared to brand-name medicines.

More than 88% of respondents felt that they need more
information on the issue pertaining to safety and efficacy of
generic medicines (Table 4). A similar proportion of respond-
ents believed that advertisement by the drug companies
would influence the use of brand-name medicines. Almost
one-half of respondents perceive that their future prescribing
habits would be affected by the hospital budget for drug
procurement.

There was no significant difference in the knowledge and
perception according to the respondents’ gender, nationality
and year of medical study (Tables 3 and 4).

Discussion

Generic medicines are encouraged by most policy makers
around the world to make the medicine affordable and more
accessible and to decrease the cost of the health care system.6,7
Medical prescribers are one of the most important stakeholders
that have influential role in promotion and the use of generic
medicines. Medical prescribers having good knowledge
regarding generic medicines could be confident in prescribing
and substituting generic medicines. In contrary, the lack of
knowledge about generic medicine could generate negative
attitude in them.8 As a future medical prescribers and health
policy makers, the medical students should know about the
generic medicines and bioequivalence from the very beginning
of medical course. Unfortunately, this study on overall knowl-
edge and perception about generic medicine among senior
medical student showed that the respondents’ knowledge was
not optimum and there are scopes of improvement.
### Table 3. Knowledge of senior medical students about generic medicines and its association with gender, academic year (final year students and interns) and nationality.

| Questionnaire statements/questions | Response to the statements | Linear by linear association (p values) |
|------------------------------------|-----------------------------|---------------------------------------|
|                                    | SA, n (%) A, n (%) N, n (%) D, n (%) SD, n (%) | Academic year Gender Nationality |
| A generic medicine is bioequivalent to a brand-name medicine | 42 (17.7) 110 (46.4) 39 (16.5) 36 (15.2) 10 (4.2) | 0.821 0.407 0.312 |
| A generic medicine must be in the same dosage form as the brand-name medicine | 73 (30.8) 115 (48.5) 23 (9.7) 24 (10.1) 2 (0.8) | 0.216 0.677 0.049 |
| A generic medicine must contain the same dose as the brand-name medicines | 72 (30.4) 100 (42.2) 26 (11.0) 35 (14.8) 4 (1.7) | 0.925 0.171 0.976 |
| Generic medicines are less effective compared to brand-name medicines | 13 (5.5) 26 (11.0) 55 (23.2) 100 (42.2) 43 (18.1) | 0.535 0.824 0.815 |
| Generic medicines produce more side effects compared to brand-name medicines | 7 (3.0) 32 (13.5) 62 (26.2) 103 (43.5) 33 (13.9) | 0.378 0.821 0.931 |
| Brand-name medicines are required to meet higher safety standards than generic medicines | 24 (10.1) 86 (36.3) 60 (25.3) 49 (20.7) 18 (7.6) | 0.798 0.427 0.074 |

SA: strongly agree; A: agree; N: neutral; D: disagree; SD: strongly disagree.

### Table 4. Perception of senior medical students about generic medicines and its association with gender, academic year (final year students and interns) and nationality.

| Questionnaire statements/questions | Response to the statements | Linear by linear association (p values) |
|------------------------------------|-----------------------------|---------------------------------------|
|                                    | SA, n (%) A, n (%) N, n (%) D, n (%) SD, n (%) | Academic year Gender Nationality |
| I believe we need a standard guideline to medical prescribers on brand-name medicine substitution process | 113 (47.7) 112 (47.3) 10 (4.2) 0 (0.0) | 0.001 0.979 0.371 |
| In my opinion, quality use of generic medicines among patients can be achieved if medical prescribers work together | 98 (41.4) 118 (49.8) 18 (7.6) 2 (0.8) 1 (0.4) | 0.855 0.086 0.070 |
| I think patient should be given enough information about generic medicines in order to make sure they really understand about the medicines they take | 96 (40.5) 109 (46.0) 26 (11.0) 5 (2.1) 1 (0.4) | 0.751 0.166 0.453 |
| I believe advertisement by the drug companies will influence use of brand-name medicines | 74 (31.2) 120 (50.6) 36 (15.2) 6 (2.5) 1 (18.1) | 0.435 0.692 0.229 |
| I need more information on the issues pertaining to the safety and efficacy of generic medicines | 86 (36.3) 124 (52.3) 24 (10.1) 3 (1.3) 0 (0.0) | 0.405 0.613 0.051 |
| Hospital budget for drug procurement will affect my future choice of medicines | 31 (13.1) 87 (36.7) 75 (31.6) 30 (12.7) 14 (5.9) | 0.393 0.393 0.005 |

SA: strongly agree; A: agree; N: neutral; D: disagree; SD: strongly disagree.

Majority of the respondents were unable to select the correct bioequivalence limits allowed for approval of generic medicines. That a higher proportion of respondents did not attempt to select a range medical students, this might be due to lack of understanding of the complex concepts of bioequivalence testing. This concept is also not included in their medical curriculum and briefly the concept is mentioned in Pharmacology in the first year of the course.10

In our study, almost 65% of respondents believed that a generic medicine was bioequivalent to the corresponding brand-name medicine while in studies from Australia more than 85% of medical students8 and 86.1% pharmacy graduates11 believed the same. Similarly, in this study
almost more than 70% of respondents thought that a
generic medicine must be in same dose and dosage form
(e.g. tablet, capsule) as the corresponding brand-name
medicine which is higher than the knowledge of medical
students but less than the pharmacy graduates in
Australia.

Almost 50% of the respondents of our study thought
that brand-name medicines are required to meet higher
safety standards than generic medicines. However, all the
medicines marketed in Nepal, generic or brand-name
medicines, have to meet the same quality standards.
Generic medicines in Australia are also required to meet
the same quality standards as brand-name medicines,
but 81.3% of pharmacy graduates in Australia were under
impression that generic medicines need to meet lower
safety standards than brand-name medicines. Generic
substitution is not allowed in public and/or private sector
facilities in Nepal. Furthermore, 17% of the respondents
thought generic medicines are less effective and produce
more side effects compared to brand-name medicines
while almost one-quarter had neutral opinion (neither
agreeing nor disagreeing) to the statements. Less positive
attitude toward safety and efficacy of generic medicine
and no provision for generic substitution may hinder the
use of generic medicines.

More than 80% of respondents either agreed or strongly
agreed that they would like to have more information per-
taining to the safety and efficacy of generic medicines while
the percentage was 54.4 among pre-registrants pharmacy
graduates in Australia. The perception among our respond-
ents might be due to deficiency of knowledge about generic
medicine or might be a hawthorn effect (general tendency to
show willingness to acquire more information when it is
offered).

Almost 82% of respondents thought that they would be
influenced for brand-name medicine prescribing by phar-
maceutical company advertisement. Pharmaceutical compa-

Strength and limitations of the study
The high response rate and good sample size could be con-
sidered as strength of the study. The respondents were
requested to complete the questionnaire independently with-
out consultation with others, but discussion between the
respondents could not be entirely ruled out. This might be
considered as limitation of the study.

Conclusion
The students’ responses to almost all the statements (ques-
tions) were similar (no statistically significant difference) to
the respondents’ academic year (final year students vs
interns), gender and nationality. It was found that the
respondents’ and all the subgroups of respondents’ overall
knowledge about the generic medicine was deficient. The
perception of the respondents’ toward generic medicine was
also not positive. Hence, the issue needs to be addressed by
educators and the state (through Ministry of Health and
Population and DDA, Nepal) before promoting the use of
generic medicines and brand-name medicine substitution in
the country.

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