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# Does educational intervention improve doctors' knowledge and perceptions of generic medicines and their generic prescribing rate? A study from Malaysia

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**Abstract**

**Objectives:** To investigate the impact of an educational intervention on doctors' knowledge and perceptions towards generic medicines and their generic (international non-proprietary name) prescribing practice.

**Methods:** This is a single-cohort pre-/post-intervention pilot study. The study was conducted in a tertiary care hospital in Perak, Malaysia. All doctors from the internal medicine department were invited to participate in the educational intervention. The intervention consisted of an interactive lecture, an educational booklet and a drug list. Doctors' knowledge and perceptions were assessed by using a validated questionnaire, while the international non-proprietary name prescribing practice was assessed by screening the prescription before and after the intervention.

**Results:** The intervention was effective in improving doctors' knowledge towards bioequivalence, similarity of generic medicines and safety standards required for generic medicine registration ($p = 0.034$, $p = 0.034$ and $p = 0.022$, respectively). In terms of perceptions towards generic medicines, no significant changes were noted ($p > 0.05$). Similarly, no impact on international non-proprietary name prescribing practice was observed after the intervention ($p > 0.05$).

**Conclusion:** Doctors had inadequate knowledge and misconceptions about generic medicines before the intervention. Moreover, international non-proprietary name prescribing was not a common practice. However, the educational intervention was only effective in improving doctors' knowledge of generic medicines.

**Keywords**

Education, generic medicine, generic prescribing, doctor, Malaysia

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## Introduction

Healthcare expenditure was escalating throughout the years.[1,2] Moreover, pharmaceutical expenditure had been reported as the second main driver for healthcare cost escalation after healthcare professional wages.[3] A similar scenario was observed in Malaysian healthcare system.[4] In this ever challenging scenario of healthcare provision, utilization of generic medicines is identified as one of the effective mechanisms to curb the escalating pharmaceutical cost.[5–8] Indeed, wide use of generic medicines led to substantial cost savings.[8–10] In fact, in Malaysia, generic medicines are approximately 30%–90% cheaper than original brand medicines.[11]

In view of the cost-saving benefits of generic medicines, various policies were formulated to improve the use of

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generic medicines in Malaysia. For example, generic medicines policy was launched initially in the year 2007 and updated in 2012 to encourage generic manufacturing, generic prescribing, generic dispensing, generic substitution and generic use in Malaysia.[12,13] Recently, in order to transform the country to be a developed nation by the year 2020, a national blue print of Economic Transformation Programme (ETP) was formulated and local generic pharmaceutical industries had been given key priority for boosting the country economic transformation.[14,15]

Despite the government's continuous effort in encouraging the use of generic medicines, the Malaysian pharmaceutical prescription market was still dominated by original brand medicines.[4] An important factor – among other factors – that contributed to this domination is the concerns and negative perceptions held by different healthcare stakeholders, including medical doctors and patients, towards generic medicines. In fact, medical doctors can play an essential role in improving the country's generic utilization rate by prescribing generic medicines. However, there are several factors that could influence doctors' willingness to prescribe generic medicines, including physician-related factors (e.g. knowledge and perceptions of generic medicines), patient-related factors (e.g. socioeconomic condition, type of disease), medicine-related factors (e.g. price of medicine, class of the medicine) and policy-related factors (e.g. health-financing plans, insurance schemes).[16] Similarly, patients' acceptance of generic medicines is an important factor given that they are the end users of these pharmaceutical products.[17] In fact, patients' socioeconomic characteristics, the type of medical condition and its level of seriousness or severity, the type of the medicine, recommendations by healthcare professionals, price difference (i.e. cost saving), previous experience of generic medicines and knowledge/information about generic medicines were considered to be the important factors that affect patients' decision to use a generic medicine or a brand medicine.[17,18] Moreover, in Malaysia, the patients have a limited opportunity to choose their brands of medicines because dispensing of prescription medicines still follows a traditional 'dispensing doctors' system in which doctors dispense medicines as a part of their professional practice.[19] This is because the 1952 Poison Act in Malaysia granted the right for registered medical doctors to prescribe and dispense medicines in their clinics.[20] In fact, the influence of doctors on patients' acceptance of generic medicines was reported by previous studies.[21–24] Therefore, doctors' adequate knowledge of generic medicines is a prerequisite for acceptance of generic medicines.[25–27] Hence, interventions must be formulated to improve doctors' knowledge, perceptions about generic medicines and prescribing practice using generic names. However, in the literature, there is paucity of data regarding the impact of educational interventions on doctors' knowledge, perceptions and prescribing practice regarding generic medicines.[28] Hence, the objective of this study was to investigate the impact of an educational intervention on doctors' knowledge and perceptions towards generic medicines and their generic (international non-proprietary name, INN) prescribing practice.

## Methodology

### Design and setting

This is a single-cohort pre-/post-intervention pilot study. The study was conducted in a tertiary care hospital in Perak, Malaysia. The hospital has 24 wards and 548 beds.[29]

### Subjects and sampling

The subjects of this study were all doctors from the internal medicine department. The internal medicine department was chosen because it is the biggest spender in the hospital's pharmaceutical expenditure.

### Intervention

The intervention consisted of an interactive lecture, educational booklet and drug list. The description of the intervention is as follows.

*Interactive lecture.* A 45-min lecture was presented by a trained senior pharmacist. The lecture material was prepared in collaboration with the experts from Universiti Sains Malaysia. The lecture covered several topics including regulatory approval requirements of generic medicines, bioequivalence concept, myth and facts about generic medicines and proper prescribing habit using generic name. In the lecture, active participation of the participants was encouraged.

*Educational Booklet.* A booklet titled 'Understanding Generic Medicines: What Health care Professionals Should Know'[30] was given to all participants who attend the lecture. The booklet consisted of information about the registration of generic medicine, and issues related to quality, safety and efficacy of generic medicines.

*A drug list using INN (generic name).* A summary list of drugs available in the hospital was prepared by Drug Information Service (DIS) Unit at the Pharmacy Department of the hospital. The drug list was prepared in which the trade names of the medicines were arranged according to alphabetical order. The drug list was given to all participants as a quick reference for the generic names.

### Data collection tool

*Knowledge and perceptions of doctors about generic medicines.* The original questionnaire was developed and validated by Chua et al.;[31] written permission was obtained from the original authors. The questionnaire comprised three sections. The first section focused on doctors'

demographic data. The second section consisted of two parts. The first part was a question asking doctors to identify Malaysia's bioequivalence standards for generic products. The second part consisted of six statements and aimed to assess their knowledge about generic medicines. The third section consisted of six statements investigating doctors' perceptions on issues pertaining to generic medicine utilization in the hospital. The responses were framed as a 5-point Likert scale (1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree and 5 = strongly agree). The pre- and post-test used the same questionnaire.

### Data collection

*Knowledge and perceptions of doctors about generic medicines.* All doctors from the internal medicine department were sent an invitation letter by researchers 2 weeks before the lecture, and a reminder card was sent 2 days before the session. On the day of the lecture, all doctors were reminded by phones. Before the session, all doctors were required to complete one pre-test questionnaire. After completing the pre-test questionnaire, they were given an educational booklet. The information session started after all the participants completed the pre-test questionnaire. The information session lasted for 45 min, and doctors were given the opportunity to ask questions and discuss the information at the end of the session. At the end of the session, doctors were asked to complete the post-test questionnaire. Certificate of attendance was given as an appreciation for their participation in this educational programme.

*Generic (INN) prescribing practice of doctors.* Pre-intervention data were collected in December 2013, and post-intervention data were collected between January 2014 and February 2014. Carbon copies of prescriptions were collected daily. Then, prescriptions were screened by pharmacists. Each prescription was screened whether it was written in generic name or brand/trade name.

### Data analysis

Descriptive statistics were used to describe the demographic characteristics. Wilcoxon signed-rank test, McNemar's test and Chi-Square test were used whenever applicable. We compared pre- and post-intervention to the null hypothesis of no change. All analyses were performed using SPSS version 16. The significance level was set at $p < 0.05$.

### Ethics approval

Ethics approval for this study was granted by the Malaysia Medical Research and Ethics Committee (NMRR 13-35-14876). Written consent was obtained from each participant prior to the study. In addition, the participants were assured of the confidentiality of their responses and their right to withdraw from the study at any time.

**Table 1.** Doctors' demographic characteristics.

| Demographic characteristics | Frequency | % |
|---|---|---|
| Gender | | |
| Male | 11 | 36.7 |
| Female | 19 | 63.3 |
| Age | | |
| 22–30 | 25 | 83.3 |
| 30–40 | 4 | 13.3 |
| 51–60 | 1 | 3.3 |
| Country of graduation | | |
| Malaysia | 16 | 53.3 |
| India | 2 | 6.7 |
| United Kingdom | 2 | 6.7 |
| Indonesia | 7 | 23.3 |
| Others | 3 | 10.0 |
| Number of prescriptions written per day | | |
| <10 | 13 | 43.3 |
| 11–20 | 13 | 43.3 |
| 21–39 | 3 | 10.0 |
| >40 | 1 | 3.3 |
| Status of prescriber | | |
| House officer | 19 | 63.3 |
| Medical officer | 9 | 30.0 |
| Specialist | 2 | 6.7 |

House officers are provisionally registered doctors who are undergoing 2-year compulsory training after graduation from basic medical degree.

## Results

### Demographic characteristics

All doctors from the internal medicine department (i.e. 38 doctors) were invited to the lecture, but only 30 of them attended the lecture, giving a response rate of 78.95%. Majority of the respondents were female (n = 19, 63.3%), and most participants (n = 26, 86.6%) wrote ≤20 prescription per day as shown in Table 1.

### Impact of the educational intervention on knowledge about regulatory bioequivalence standard for generic drug products in Malaysia

One-third (n = 10, 33.3%) of the participants correctly identified the National Pharmaceutical Control Bureau's (NPCB) bioequivalence standards for generic drug products before the educational lecture. After the intervention, most of the participants (n = 26, 86.7%) correctly identified the NPCB bioequivalence standards for generic drug products in Malaysia (Table 2). McNemar's test showed a statistically significant difference in the proportion of doctors pre- and post-intervention, $p < 0.001$.

### *Impact of the educational intervention on doctors' knowledge of generic medicines*

When the doctors were asked 'A generic medicine is bioequivalent to a brand name medicine', there was a significant increase in terms of agreement from pre-intervention (Median (inter-quartile range (IQR))=4 (3–4)) to post-intervention (Median (IQR)=4 (4–4.25)) ($Z=-2.121$, $p=0.034$, $r=-0.27$). When the doctors were asked 'A generic medicine must be in the same dosage form (e.g. tablet, capsule) as the brand name medicine', there was a significant increase in terms of agreement from pre-intervention (Median (IQR)=4 (3–4)) to post-intervention (Median (IQR)=4 (4–5)) ($Z=-2.122$, $p=0.034$, $r=-0.27$).

In addition, when the doctors were asked 'Brand name medicines are required to meet higher safety standards than generic medicines', there was a significant decrease in terms of agreement from pre-intervention (Median (IQR)=3.5 (3–4)) to post-intervention (Median (IQR)=3 (2–4)) ($Z=-2.283$, $p=0.022$, $r=-0.29$). Further details regarding impact of intervention on doctors' knowledge towards generic medicines was shown in Table 3.

**Table 2.** Impact of the educational intervention on knowledge about regulatory bioequivalence standard for generic drug products in Malaysia.

| Knowledge about National Pharmaceutical Control Bureau's bioequivalence standard for generic drug products in Malaysia | Pre-intervention, n (%) | Post-intervention, n (%) |
|---|---|---|
| Correct definition | 10 (33.3) | 26 (86.7) |
| Incorrect definition | 20 (66.7) | 4 (13.3) |
| Total | 30 (100.0) | 30 (100.0) |

### *Impact of the educational intervention on doctors' perception to issues pertaining to generic medicine utilization in the hospital*

No statistically significant changes were noted (Table 4).

### *Impact of the educational intervention on doctors' INN prescribing practice*

Table 5 presents the comparison of prescriptions after the implementation of the intervention. In this study, 585 and 503 prescriptions were screened for pre- and post-interventional analysis, respectively. The percentage of prescription written in generic name slightly dropped from 13.0% to 12.7% (from 76 to 64 prescriptions) after the intervention. There was no statistically significant difference between the percentage of prescription written in generic name before and after the intervention (13.0% vs 12.7%, respectively; $\chi^2(1)=0.002$, $p=0.968$).

## Discussion

The majority of the doctors (66.7%) who participated in this survey were not aware of the NPCB bioequivalence standards for generic drug products in Malaysia. However, our finding is better than the finding reported by Chua et al.[31] in which only 4.6% of the doctors correctly identified the bioequivalence standard. Possible reasons for this are time difference and study setting. The target group in our study was doctors practising in a public hospital, while Chua et al. targeted general practitioners in private sector. Doctors who practise in public hospitals might have a better understanding of generic medicines than those who practise in the private sector, since generic medicines are more widely used in the public sector. Therefore, doctors can gain confidence

**Table 3.** Impact of the educational intervention on doctors' knowledge of generic medicines (n = 30).

| Number | Item description | Median (IQR)[a] | | p value[b] |
|---|---|---|---|---|
| | | Pre-intervention | Post-intervention | |
| 1. | A generic medicine is bioequivalent to a brand name medicine | 4 (3–4) | 4 (4–4.25) | **0.034** |
| 2. | A generic medicine must be in the same dosage form (e.g. tablet, capsule) as the brand name medicine | 4 (3–4) | 4 (4–5) | **0.034** |
| 3. | A generic medicine must contain the same dose as the brand name medicines | 4 (4–4.25) | 4 (4–5) | 0.197 |
| 4. | Generic medicines are less effective compared to brand name medicines | 3 (2–3.25) | 2 (1–3) | 0.123 |
| 5. | Generic medicines produce more side effects compared to brand name medicines | 3 (2–3) | 2 (2–3) | 0.115 |
| 6. | Brand name medicines are required to meet higher safety standards than generic medicines | 3.5 (3–4) | 3 (2–4) | **0.022** |

IQR: inter-quartile range.

[a]Median reflects answers on a 5-point Likert scale (1 = strongly disagree; 5 = strongly agree).

[b]The p values are based on Wilcoxon signed-rank test assessing effectiveness of intervention (the significance level was set at $p<0.05$).

**Table 4.** Impact of the educational intervention on doctors' perception to issues pertaining to generic medicine utilization in the hospital (n = 30).

| Number | Item description | Median (IQR)[a] | | p value[b] |
|---|---|---|---|---|
| | | Pre-intervention | Post-intervention | |
| 1 | I believe we need a standard guideline to both prescribers and pharmacist on brand substitution process | 4 (4–4.25) | 4 (4–5) | 0.317 |
| 2 | In my opinion, quality use of generic medicines among patients can be achieved if both prescribers and pharmacist work together | 4 (4–5) | 4 (4–5) | 0.157 |
| 3 | I think patient should be given an enough information about generic medicines in order to make sure they really understand about the medicines they take | 4 (4–5) | 4 (4–5) | 0.480 |
| 4 | I believe advertisement by the drug companies will influence my future prescribing pattern | 4 (3–4) | 4 (3–4) | 0.625 |
| 5 | I need more information on the issues pertaining to the safety and efficacy of generic medicines | 4 (4–5) | 4 (4–5) | 0.346 |
| 6 | Hospital budget for drug procurement factor will affect my choice of medicines | 4 (4–5) | 4 (4–5) | 0.366 |

IQR: inter-quartile range.
[a]Median reflects answers on a 5-point Likert scale (1 = strongly disagree; 5 = strongly agree)
[b]The p values are based on Wilcoxon signed-rank test assessing effectiveness of intervention (the significance level was set at $p < 0.05$).

**Table 5.** Impact of the educational intervention on doctors' INN prescribing practice.

| Number of prescriptions written in generic name | n (%) | |
|---|---|---|
| | Pre-intervention | Post-intervention |
| Yes | 76 (13.0) | 64 (12.7) |
| No | 509 (87.0) | 439 (87.3) |
| Total | 585 (100.0) | 503 (100.0) |

INN: international non-proprietary name.

through past positive experience in using generic medicines.[32–39] Although the percentage of doctors who correctly identified the bioequivalence standard (before the intervention) was higher compared to the previous local study,[31] the number of doctors who had correct knowledge about regulatory approval limits for generic medicines is still low. This is consistent with other studies.[40,41] However, the intervention had significantly improved doctors' knowledge about NPCB bioequivalence standards and the concept of bioequivalence for generic drug products. Therefore, by having a good understanding about the standards, doctors can gain confidence in Malaysia's generic regulatory approval system in assuring generic medicines' efficacy and safety. This is important as scepticism about generic medicines' bioequivalence remains one of the main barriers in doctors' acceptance of generic medicines.[25,41,42]

In this study, before the intervention, doctors did not have adequate knowledge on the medicine registration requirements and standards. However, the intervention improved their knowledge on this aspect. In fact, prior to registration, both generic medicines and original brand medicines are required to pass through the same rigorous registration process and meet the same requirements to ensure their quality, safety and efficacy, and that it meets all the required standards.[17,43] In Malaysia, both generic and original brand medicines have to comply with the same standards and requirements of quality, efficacy and safety set by the Malaysia Drug Control Authority. In terms of quality, both parties have to follow Good Manufacturing Practice (GMP) requirements, the content of the Common Technical Document for regulatory submission, which is adopted from competent, regulatory agencies in the European Union, the United States and the International Conference on Harmonization (ICH).[16,44] Therefore, it is important that drug regulatory authorities communicate with doctors and inform them about the registration system requirements that must be met before approval is granted.[43]

In this study, regarding doctors' perceptions on issues pertaining to generic medicine utilization in hospitals, the intervention was unable to produce any significant results. In fact, perception can be affected by several factors such as demographic, socio-psychological, culture, education level, past experience, skill and motivation.[45,46] Moreover, in our study, INN prescribing is not a common practice even after the educational intervention as only 12.7% of the prescriptions were written in INN. The situation in Malaysia is similar to the findings reported in several countries including Bahrain (10.2%), India (36.5%), Belgium (2.8%) and the United States (2%–22%).[47–53] On the other hand, INN prescribing is a common practice in some countries such as the United Kingdom (83%) and Thailand (73.9%).[54,55] In Malaysia, although INN prescribing is encouraged in Malaysia generic medicine policy,[13,56] there

is a gap between formulation and implementation of this policy.[16,57] In fact, several factors and possible reasons might be accounted for this low rate of INN. Some physicians have difficulty to remember some generic names and consider brand names are easier and more memorable.[38,58,59] Therefore, it is important to empower physicians with technology and decision-support systems to help them prescribe generically (such as generic prescribing programmes). In addition, prescribing monitoring and feedback on physicians' prescribing pattern could be useful.[43] Another factor is that junior doctors might follow senior doctors' prescribing style of using trade names. Therefore, it is important to introduce and encourage INN prescribing at early stages in medical schools. On the other hand, physicians can be reluctant to prescribe by INN because of the influence from pharmaceutical industry.[60]

In our study, the educational intervention could not change the INN prescribing practice. The duration of exposure might not be enough to change the doctors' prescribing practice in terms of using INN. In fact, effectiveness of educational intervention decays with time.[61,62] Hence, reinforcement sessions might be needed to be conducted in order to achieve its optimal effect. In addition, one of the factors that could help change the prescribing practice is the collaboration and frequent communication with pharmacists about medicines.[43]

## Limitation

The study had some limitations. The sample size was small as the study was pilot in nature. The study was, however, able to provide preliminary findings and useful insights to stimulate the future research in this under-researched area. Moreover, the long-term impact of the educational intervention was not assessed. Also, there were no reinforcement educational sessions. Therefore, a larger controlled trial is warranted to further explore the variables assessed during this trial. Furthermore, future studies can investigate the impact of other interventions (e.g. prescribing monitoring and feedback).

## Conclusion

In this study, before the intervention, doctors had inadequate knowledge and misconceptions about generic medicines. Moreover, INN prescribing was not a common practice. However, the educational intervention was effective in improving doctors' knowledge of generic medicines. Nevertheless, no impact was observed on doctors' perceptions and INN prescribing practice after the intervention.

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