



## Generic medicines: Perceptions of Physicians in Basrah, Iraq

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### Research

Please cite this paper as: Sharrad AK, Hassali MA, Shafie AA. Generic medicines: Perception of Physicians in Basrah, Iraq. AMJ 2009, 1, 8, 58-64. Doi 10.4066/AMJ.2009.82

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### Abstract

#### Background

The use of cheaper generic medicines is a strategy promoted in many countries to reduce rising health care costs. The aim of this study was to explore factors affecting generic medicine prescribing by physicians in Basrah, Iraq.

#### Methodology

A purposive sample of ten physicians practicing in Basrah was interviewed using a semi-structured interview guide.

#### Results

Analysis of the interviews identified seven major themes: medicine prescribing practice, knowledge of therapeutic equivalency of generic medicine, patients' acceptance of generic medicine, counterfeit medicine, drug information source and effect of drug advertising on medicines choice, brand substitution practice by community pharmacists, and, finally strategies to improve generic medicine usefulness. Participants identified helpful strategies to increase generic prescribing including; physician and patient education on generic medicine; persuading physicians about the safety and efficacy of generic medicines; and finally educating senior medical students on generic prescribing.

#### Conclusion

The data suggest that participants were enthusiastic about prescribing generic medicines. However physicians insist that pharmacists should not be allowed to substitute generic drugs without prior approval of doctors.

#### Key words

Generic medicines, prescribing, bioequivalence, perceptions

#### Introduction

In Iraq, the Ministry of Health (MOH) is responsible for importing medicines from companies that are previously registered with KIMADIA (the state company for importation and distribution of drugs and medical appliances). The MOH distributes imported pharmaceuticals to the public and private sectors (private pharmacies) after obtaining permission from the Drug National Quality Control Laboratories (DNQCL).

Iraqi law requires all drugs to be marketed via the KIMADIA system. For over 20 years, KIMADIA has been the sole body authorised to carry out management, planning, selection, quantification, procurement, storage and distribution of medicines and medical equipment.

In 1989, it was estimated that 70% of drugs were imported. The other 30% came from Samara Drugs Industries (SDI), a government agency.<sup>1</sup> Until 1994; the supply of medicines was dominated by the public sector. Approximately 90% of the drugs purchased using public funding was allocated to the public sector.

Currently, there is no social health insurance system exist in Iraq. There are very small, isolated health insurance programs for employees of specific companies. At present, however, there is no system for reimbursement for money spent by public on private prescriptions in the country.<sup>2</sup> Thus, ensuring the availability of high-quality drugs at affordable prices in Iraq is a public health priority.

Prescribing drugs by generic name and encouraging pharmacists to dispense prescriptions with generic medicines is one frequently suggested means for lowering the costs of healthcare.<sup>3-5</sup> Various articles have discussed the implications of generic substitution and other strategies to reduce pharmaceutical expenditure.<sup>6-9</sup> The concept of prescribing, dispensing and using generic medicines has been controversial, however.<sup>5</sup> Concern has been expressed by physicians practicing elsewhere about the efficacy of generic medication.<sup>10,11</sup> This debate has centered on issues related to bioequivalence and potential confusion that might arise when changes of medicine brands occur in some patient populations.<sup>12,7</sup> The theoretical framework for this study calls on bounded rationality theory which predicts that the quality of the decisions we make are limited by the available information and our ability to synthesize that information.<sup>13</sup>



Previous study had shown that the decision to prescribe a generic medicine as opposed to its innovator competitor is complex.<sup>11</sup> Although prescribing of generic drugs is considered good practice and is encouraged from an educational and cost-effectiveness point of view, the rate of generic medicine is still low which might be due to exposure to promotional activities by drug companies.<sup>3,5</sup>

To the best of our knowledge, no studies are currently published reporting physicians' attitudes to generic medicines in Iraq. Although a few studies have been conducted in developed countries such the United Kingdom, the United States and Australia, it is very difficult to extrapolate these results to the Iraqi context because those countries have distinct healthcare, and economic systems. Therefore, the aim of this study was to explore perceptions held by Iraqi physicians towards the use of generic medicines.

### Method

Since little research has been carried out in Iraq to identify physicians' perceptions of generic medicines, qualitative methods were used to gain understanding of this issue.<sup>14,15</sup> A qualitative approach was adopted because it allows a flexible exploration of informants' attitudes and experiences and produces a richness of data that allows the researcher to gain a deeper understanding of social phenomena.<sup>16,17</sup>

One of the challenges faced in the process of recruitment was to obtain a varied sample of informants to participate in the interviews. To address this, purposive sampling procedure was used. The advantages of purposive sampling are that it is cheaper and time-saving to implement in comparison to other sampling procedure. Semi-structured interviews were conducted with a convenient sample of physicians until we reached saturation of themes.<sup>18, 19</sup> The interview guide was developed following an extensive review of the literature on similar studies conducted elsewhere. Physicians were approached personally by the researcher at their college, hospital or private clinic. Those who agreed to participate were interviewed either at once or after all of that physician's patients in the hospital or clinic had been examined.

Ten physicians consented to be interviewed. The interviews covered the following issues: medication prescribing priorities, knowledge and confidence with generic medicine and brand substitution by community pharmacists. Follow-up questions were used when necessary to get a more in-depth explanation and to draw out more complete ideas from the participants. They were given freedom to express additional views on the subject at the end of the interview time.<sup>20</sup>

All interviews were conducted at the convenience of the participants: five at the physician's private clinic, two in a hospital and three in the College of Medicine at University of Basrah. Interviews took an average of 20-30 minutes. They were conducted by the investigator in his native language (Arabic). Interviews were documented and transcribed verbatim by qualified transcribers. Transcripts were confirmed by the researcher, corrections (if needed) were made before copies of the transcripts were sent to the respective physicians for their endorsement. The researcher manually

analysed all of the transcripts line-by-line for relevant content and themes.<sup>21,22</sup> Ten interviews were required to achieve saturation of the themes, and no new themes emerged in the last three interviews.

## Results

### Characteristics of participants

Ten physicians from various group practices were interviewed. Eight of them were practicing in the central city and the other two in rural regions in Basrah. Demographic characteristics were summarized in the Table 1.

### Themes

Thematic content analysis of the interviews identified seven major themes: medicine prescribing practices, knowledge of therapeutic equivalency of generic medicines, patients' acceptance of generic medicines, counterfeit medicines, sources of drug, and the effect of drug advertising on pharmaceutical selection, brand substitution practices by community pharmacists, and strategies to improve the usefulness of generic medicines.

#### Theme 1: Medicine prescribing practice:

Physicians were questioned about the factors they took into consideration when prescribing a medicine to their patients. The major factors identified were availability of the drug in hospitals and pharmacies, cost of the medicine, safety and quality profile of the medicine (reputation of the company supplying the drug), economic situation of the patient and severity of the disease.

*"Well, availability of drugs in pharmacies or hospitals is the most important factor for the time being" (Phy.0 1)*

*"The price of medicine is the most important factor in my mind before writing the prescription, if the price is suitable, I will favour it" (Phy.07)*

*"A company's reputation is of the highest importance; prescribing a medicine from an unknown company (possibly not good quality) can lead to financial loss for the patients in addition to therapeutic failure"(Phy0.2)*

When physicians were asked whether they prescribed generic medicine, there were mixed reactions. Some physicians were against prescribing generic medicines, whereas others were more open minded. The most commonly cited reasons for opposing generic medicine are the potential clinical problems (therapeutic failure and/or allergy).

*"I don't prescribe generic medicine because I do not have confidence in the therapeutic effect of this type of medicine" (Phy.02)*

Patient confusion also mentioned as a factor that prevents physicians from prescribing generic medicines.



*"I don't prescribe generic medicine because it can lead to patients' confusion, particularly among the elderly people" (Phy. 03)*

The physicians noted that the quality and efficacy of generic drugs deter them from prescribing generic medicines. Some physicians and their patients believe that generic medicines differ from the innovative-brand in terms of quality and safety, and this prevents them from prescribing generic medicines to their patients.

*"Patients may have worries that generic medicine could lead to deterioration of their condition rather than improving it" (Phy. 10)*

In order to prevent substitution of the medicines in the pharmacy, physicians said that they write trade names and do not use generic names in their prescriptions.

*"I write trade names to prevent the substitution in the pharmacy and to stop them from giving any medicine that does not work" (Phy.03)*

Disease severity is a factor that inhibits physicians from prescribing generic medicines. In severe cases, physicians tend to use innovative medicines.

*"In chronic cases, I don't prescribe any generic medicine" (Phy.10)*

Physicians who encourage generic medicines prescribing report that the low price of generic medicines as the most common incentive for prescribing generic medicines.

*"Cost of medicine is of the highest importance, especially to patients on low income, generic medicine is an inexpensive medicine, and therefore I prescribe generic medicine" (Phy.01)*

The availability of differently-priced alternatives for the product is a motive for prescribing generic medicines.

*"It is not fair to write a medicine for example, Daonil® and the price for this drug is about 25000 ID (USD \$ 20 for 20 tablets) while I can give him the same medication with the same efficacy with price 1200 ID (USD \$ 1 for 20 tablets)" (Phy.08)*

## **Theme 2: Knowledge of therapeutic equivalency of generic medicine**

Physicians were questioned about the bioequivalence criteria required by the World Health Organization (WHO) and/or Food and Drug Administration (FDA) and the KIMADIA and DNQCL in Iraq. We found that physicians had little or no knowledge about these requirements.

*"I don't really need this information because I don't prescribe them" (Phy.2)*

## **Theme 3: Patients acceptance of generic medicines**

All of the physicians who prescribe generic medicines felt that their patients are amenable to using these drugs. The main reason the physicians believe that their patients accept

generics is due to low socioeconomic status, meaning that these patients often cannot afford the high prices of innovative medicine.

*"Yes, the patients regularly ask me to prescribe cheap medicine and if I am satisfied with the generic medicine it is easy to convince the patient" (Phy.01)*

Some physicians thought that patients' trust in physicians is important for accepting generic medicines.

*"The physicians' confidence in generic medicine positively reflects on the patient"(Phy. 03)*

## **Theme 4: Counterfeit medicine**

All of the physicians agreed that there are a lot of counterfeit drugs in Iraq, and they hope that the NDQCL and MOH can eliminate this problem.

*"There are a lot of counterfeit medicines currently so we must reduce this problem by having a powerful control on pharmaceutical medicine allowed in Iraq" (Phy.02)*

*"I cannot make a distinction between counterfeit drugs and regular drugs. Counterfeiting is an elaborate process and this must be countered by the regulatory and quality control processes" (Phy.04)*

## **Theme 5: Drug information sources and influence of drug advertising on medicine choice**

Physicians were asked about the information sources they used in order to update themselves about medicines. The main sources were textbooks, pharmaceutical industry representatives, the Internet, leaflets, and pharmacists.

*"Textbooks, I have a book called ' MARTINDALE' where I can look for everything about the medicine" (Phy.08)*

*"BNF, Iraqi Drug Guide, pharmaceutical industry representative and the Internet" (Phy.10)*

All physicians who encourage the use of generic medicine agreed that advertising positively influenced their choice of generic drugs.

*"Sure, all companies seeking to advertise the new medicines through the medical conferences or distribute a free medical sample to the physicians"(Phy.07)*

*"Exactly, gifts from companies' give great motivation to encourage doctors to use these medicines from their companies" (Phy. 05)*

## **Theme 6: Brand substitution practices by community pharmacists**

Brand substitution refers to the substitution of a drug with another medication without permission from the prescriber. Most physicians are unhappy with the current practice of brand substitution by pharmacists.



*"This is a problem, when I prescribe innovative medicines for my patient and sometime if the patient came back with generic medicines, I don't agree with these substitutions" (Phy.03)*

The main reasons mentioned by physicians to refuse brand substitution are interfering with the physician's choice of a certain brand, inadequate training of the pharmacy staff, and fear of therapeutic failure of the substitute.

Some of the physicians generally support generic substitution, but they note that there are some cases where it is not appropriate.

*"Agreed, but not in all cases, not in low therapeutic index drugs" (Phy.04)*

*"I am in agreement, but due to the multi-source medicines in pharmacies, they must consult a doctor to change specifically in chronic diseases" (Phy.01)*

All physicians felt that if the alternative brand is of a good quality and if the decision-maker is a knowledgeable pharmacist, he should be able to do brand substitution.

#### **Theme 7: Strategies to improve generic medicine utility**

All the physicians who encourage the use of generic medicines said that a greater physician education about generic medicine could increase prescriptions for these medications and positively impact patients' perceptions on their use.

*"Increase physician education regarding safety and quality of generic medicine through conferences or presentations, this will lead to an increase in prescribing generic medicine" (Phy.01)*

*"Increase the doctors' and patients' awareness about generic medicine by the sending out on a quarterly basis a drug guide, with listings of legal drugs. This will lead to an increase usage of generic medicine" (Phy.3)*

One way to improve prescribing practices is to review the medical curriculum in Iraqi universities and add topics regarding generic medicine and cost effective prescribing and dispensing techniques. This would encourage the use of generic medicines in the future.

*"I strongly support the idea to develop curriculum for students of the Faculty of Medicine regarding generic medicines and how they should compare generic medicines with the original medicines" (Phy.07)*

#### **Discussion**

As the main prescribers of medicines in Iraqi healthcare facilities and institutions, physicians have an important role in the utilisation of generic medicines. This exploratory study offer some insights into the perceptions of physicians regarding the use of generic medicines. In this qualitative study, physicians reported that availability of the drug in Iraqi markets plays an important role in prescribing decisions. Beside therapeutic efficacy, factors such as cost of the

prescribed medications were also considered to be the most important factors in choosing a medication. In Iraq, at present, there is no health insurance and the patient must pay for physician fees and they also have to pay the cost of medications prescribed. This payment scheme for health services and prescribed medicines makes patients and physicians more sensitive to the value of services and goods rendered.

The analysis of the interviews also highlight potential barriers to using generic medicines. Two major barriers identified were the potential for confusion among patients and the physician's belief that generics are not equivalent to branded counterparts. These reasons are similar to those reported in previous studies in Australia that focused on general practitioners' beliefs about generic substitutions.<sup>23,24</sup> Beliefs about the decreased quality of generics could be dispelled by better physician education regarding drug discovery, development, and registration regulations.

None of the physicians interviewed in this study recognised the bioequivalence acceptability criteria for generic medicines as set by the World Health Organisation (WHO) and followed by NDQCL.<sup>25</sup> Their lack of knowledge could have a negative impression on the future of generic prescribing. Product quality data required before a generic product can be registered by KIMADIA and marketed to Iraqi consumers. The required quality data includes: purity, stability, Good Manufacturing Practice (GMP) and quality control.<sup>26-28</sup> these details are the same for all products, generic or innovative-brand, that seek approval for sale in Iraq.<sup>29</sup>

On the issue of patients' acceptance of generic medicines, our study found that nearly all physicians felt their patients had good acceptance rate to generic medicines.

In this study, all of the physicians were dissatisfied with the increase in counterfeit drugs in Iraq. They all depend on KIMADIA and NDQCL to solve this problem and prevent distribution and usage of these drugs. Improving facilities at the laboratories of KIMADIA and NDQCL would be a logical next step to solve this problem.

Physicians' opinions on the influence of drug advertising and incentives on their choice of medicine brands were also explored in this study. Advertising strategies used by drug companies can influence the brand of drug a physician prescribes. These qualitative results are similar to two other studies, which found that incentives from pharmaceutical companies led to increased prescribing rates of the products.<sup>30,31</sup>

The majority of physicians were dissatisfied with the practice of generic substitution by community pharmacists without previous agreement from the prescriber. Their main reason for this dissatisfaction is a lack of formal guidelines on how many times a pharmacist can change the patients' medication brand. In the long term, multiple changes in a patient's medication can lead to confusion and possible inappropriate dosing. The



physicians also expressed concern that those who perform substitutions are pharmacy staff who are not qualified to make these decisions.

Physicians who were comfortable with prescribing generic medicines suggested that to improve the use of generic medicines, physicians need to be educated about the quality and efficacy of generic medicines. Furthermore, generic medicine guidelines which include all generic medicines available in Iraq should be distributed to the physicians via KIMADIA or Association of Medical in Iraq so that the physicians feel more confident and this would lead to an increase in generic medicine prescribing. Finally, a few physicians suggested that one way to increase future acceptance and prescribing of generic medicines is to educate senior medical students about cost effective prescribing which is not currently taught in Iraqi medical curricula.

### Study Limitations

One of the limitation of qualitative methods is that the results cannot be extrapolated to the wider population.<sup>32</sup>This study was conducted in Basrah city in Iraq and the findings may not apply to physicians living in other governorates in Iraq. However, as the prescribing process for medications in Iraq is the same, it is likely that physicians from other parts of the country will have similar views on the issues explored. We were unable to include physicians from other governorates due to limited funding.

### Conclusion

Prescribing generic medicines requires a complex decision-making processes and involves the exercise of personal and professional judgment about psychosocial and economic dimensions of health. This qualitative study of perception of physicians suggests that physicians' enthusiasm for generic medicines is influenced by the high costs of medicines. Unfortunately, the prospects of more generic prescribing will require more education and further reassurance about the quality, safety and efficacy of generic medicines. A few steps have to be taken if generic medicines are to be more widely prescribed and dispensed. Firstly, the authority that regulates medicines needs to be strengthened so that it can issue strong assurance on the quality, safety and efficacy of registered medicines. This could be achieved by ensuring sufficient manpower, adequate training of staff, and strict enforcement of medicines' related registration. Secondly, the image of (KIMADIA and DNQCL) must be improved among physicians, pharmacists and patients, so that there is greater confidence in its ability to police the safety and quality of medicines. Thirdly, regulating pharmaceutical industry promotion to ensure compliance with internationally accepted codes of conduct. Fourthly setting a suitable substitution policy that gives pharmacists more freedom to switch to dispensing generic products but only after dealing with the other challenges mentioned above.

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#### **ETHICAL APPROVAL**

Pharmacists Syndicate \ Basrah branch and the Medical Association \ Basrah branch

#### **PEER REVIEW**

Not commissioned; externally peer reviewed

#### **CONFLICTS OF INTEREST**

None



Table 1 : Participants demographics (N = 10)

Descriptions	n
<b>Age range:</b> 30-40 40-50 51-60	2 7 1
<b>Gender:</b> Male Female	8 2
<b>Place of graduation:</b> Baghdad university Basrah university	3 7
<b>Number of prescriptions written per day:</b> Less than 15 More than 15	4 6
<b>Number of years practicing in Iraq:</b> Under 15 More than 15	2 8
<b>Place of work</b> Government hospital Private hospital	9 1