Original research

Role of Health Professionals in Quality Monitoring of Pharmaceutical Products

Findings of Cross-sectional Survey in Sudan 2009-2010

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Abstract

Background: In 2010, a team of experts from different institutes in Sudan conducted a study to understand the role of health professionals in the field related to the quality of medicines. Also, the study aimed (1) to understand the cause-effect relationships around substandard medicines in Khartoum (Sudan) that influence the practice of health professionals; and (2) to analyse the knowledge, attitude and practice of pharmacists and doctors when they face quality-related problems. This study principally relied on feedback from doctors and pharmacists, with special focus on their observations, concerns and comments regarding medicines that they have concerns about the quality and/or effectiveness of. **Methods**: A cross-sectional survey was conducted targeting 82 pharmacists and 95 doctors practicing in Khartoum. Data were collected using self- and non-self-administered questionnaires designed for this purpose. **Results**: From the results, it is clear that awareness about the impact of this problem and its effects varies among health professionals. The educational background and experience seem to play an important role in these differences. The results emphasised the role of health professionals as an important source of information about the quality of medicines. **Conclusions**: Building strong relationships with health professionals and strengthening the communication and feedback systems with them are essential mechanisms to improve knowledge about quality-related problems. Quality monitoring programs of medicines will not be effective without the active involvement of health professionals from the healthcare field.

Introduction:

Partnership models for detecting, analysing and resolving the problem of substandard medicines has become fundamental and vital concept (1, 2). The extent to which the key players, including communities, professionals and policy-makers from different sectors, are involved in the implementation of a PMS system, makes it easier to achieve successful collaboration in managing and reducing the existence of substandard medicines in the country (3). In countries like Sudan, this concept is essential, as there are several contributing and limiting factors that can affect the situation. For example, the huge area of Sudan, the weak economic situation and the great differences and diversities in cultures and beliefs among the public and even health workers. All of these factors limit the ability of the authorities to respond to this problem alone. Without a doubt, healthcare professionals (pharmacists, doctors and others) are the main individuals with important roles in improving the detection of substandard medicines. Since this category is well oriented and educated about this problem, they should be an integral part of any solution. At the same time, any possible involvement of these professionals should consider their knowledge, attitude and practice towards the issue of substandard medicines. This is important because how doctors and pharmacists act towards, and deal with, substandard medicines, is the corner-stone of any solution that could help to improve the situation. Despite the fact that medicines inspection function in Sudan has greatly improved in the last few years, the unexpected failure of most inspectors to identify significantly substandard products has put into question the training programs and/or inspection protocols. The main concern is whether these systems are adequate to build-up a sufficient capacity of the inspectors to gain the skills required (4). In addition, the relationship of the authorities and its officials with health professionals is also very limited, which leads to many missed opportunities with regard to improving the detection of quality problems in the field.

In 2010, a team of experts from different institutes in Sudan conducted a study to understand the role of health professionals in monitoring the quality of medicines. Besides that, the study aimed at (1) understanding the perspective of these professionals about cause-effect relationships around substandard medicines and illustrate the influence of this problem on the practice of health professionals; and (2)

analysing the knowledge, attitude and practice of pharmacists and doctors when they are facing quality-related problems, and how they usually deal with that.

Prior to this study, the research team decided to evaluate the quality of medicines which were circulating in the pharmaceutical market in Khartoum. Due to a number of reasons, this was not easy, and it was difficult to select the targeted medicines on which the study would focus. This methodology principally relied on feedback from doctors and pharmacists, with special focus on their observations, concerns and comments regarding medicines that they have concerns about the quality and/or effectiveness of. Based on the feedback received from the health professionals, the study team conducted a random check in order to verify the existence of substandard medicines in the study area according to the feedback and surveillance of complaints emanating from health professionals.

Methods

Study geographical area:

Sudan is one of the largest countries in the region and this vast area usually represents enormous challenge for medicines regularity authority. Khartoum city is the capital and the main city in the country; it comprises about 13.5% of the total population in Sudan (5). Patients' frequency in Khartoum cities is the highest among all cities in the country (6). Due to all of these facts, Khartoum city was selected as the study site for this research.

Study population:

Statistically, the private sector represents the major targeted sector for the provision of health services in Sudan. Studies have shown that the main factor behind this is the poor efficiency of the healthcare services in the public sector as well as in the NGOs sector (7). For that reason, the study focused on the private sector in Khartoum city and considered the representation of the following categories: (1) Doctors practicing in private clinics, and (2) Pharmacists practicing in private retail pharmacies.

Sample size:

Out of the 328 retail pharmacies located in Khartoum city, a sample of 82 pharmacies was targeted in this study. Out of the 420 private clinics located in Khartoum city, 95 clinics were targeted in this study.

Study tools:

The opinions of doctors and pharmacists were collected using two different types of questionnaires, including a non-self-administered questionnaire designed for pharmacists. This consisted of 23 questions that aimed to evaluate the knowledge, attitude and practice of pharmacists towards low quality medicines. In addition to that, there was a self-administered questionnaire designed for doctors, which consisted of 20 questions that aimed to evaluate the knowledge, attitude and practice of pharmacists towards low quality medicines.

Results:

Structure of the response:

The response rate among pharmacists was relatively higher than doctors; 100% of the targeted pharmacies responded to the questionnaire, while only 78% of the doctors agreed to respond to the questionnaires sent to them. The experience of the respondents from the pharmacy sector varied, but the majority (40%) had more than 5 years of experience in the field. Regarding the doctors, around 56% of the respondents were specialists and 25% were registrars, while general practitioners represented the rest of the sample (19%).

The existence of the problem of substandard medicines:

About 85% of pharmacists believed that there are substandard medicines circulating in the market, compared to less than 70% of doctors. One of the logical reasons behind this difference is the fact that pharmacists usually deal directly with medicines and receive direct feedback from the patients about this topic, unlike doctors.

Level of the problem:

The figure below reflects the response of surveyed health professionals about their estimation of substandard medicines as a public health problem and the level of this effect.

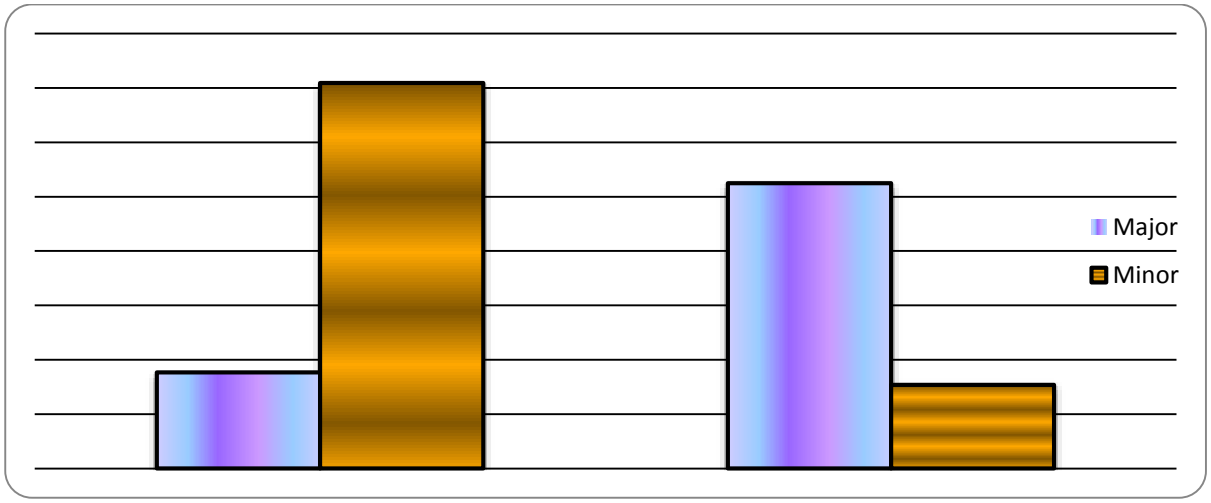

Figure 1: Professionals' evaluation - Level of the problem

They were asked to classify the problem as either "major" (i.e. it exists extensively and widely) or "minor" (i.e. not a major public health risk). The great difference and variation in the results between pharmacists and doctors seems to be due to differences in the definition of major and minor. The way in which the data were actually collected can have an obvious effect on the way in which each respondent defines its meaning. This is one of the known problems with "self-" versus "non-self-"administered data collection tools. In self-administered questionnaires applied to "doctors", the meaning will depend solely on the perception of the information provider rather than the standard definition in the study.

Effectiveness problems:

The aim of this part of the questionnaire was to assess, based on professionals' opinion, whether medicines with suspected quality problems were usually associated with ineffectiveness and/or therapeutic failure problems that may face them. This may come as a result of direct observation from them and/or based on patient monitoring and/or complaints made by the patients. All of the surveyed pharmacies located within the major household areas in the city received a continuous flow of

patients' complaints to pharmacist about ineffective medicines, compared to 90% of pharmacies located close to major clinics or hospitals. The pharmacists were divided between two opinions about the possible reasons for these complaints. While 68% of them considered the majority of these complaints to be due to problems related to the patients and the way in which they used medicines, the rest (32%) thought that the major reasons for these problems were related to the quality of medicines. Those who referred the problem to factors related to the patients mentioned the following issues: (1) Factors related to the administration method and its impact on effectiveness; (2) Factors related to the selection of the right medicine for specific cases (rational prescribing or rational dispensing); and (3) Factors related to subject-to-subject variability and different responses to the same drug.

The majority of pharmacies (88%) received complaints from patients reporting treatment failures (symptoms not fully relieved). Also, 40% of the pharmacies received reports from patients about the alternative products that they used which were not effective (interchangeability problems). On the other hand, only 35% of pharmacies received complaints about the side effects of medicines. These results, when combined with other data and findings, support the significant importance of feedback from the patients. Patients in this sense proved to be an important source of information and one of the channels by which to detect substandard medicines.

Unlike pharmacists, 45% of the doctors believed that the quality of medicine itself is a major factor in cases in which there is a therapeutic failure. This figure is critical, as these doctors assumed that they had prescribed the right medicines for the right cases and that the administration of medicines was also perfect. If this is the case, then the quality of medicines will be the determinant factor for these reports of therapeutic failure. In total, 15% of the doctors reported continuous observations of therapeutic failure of specific products for almost all of the patients using those products, although the majority of doctors (60%) experienced this observation at some point. Among other reasons, 45% of the doctors referred the problem to factors related to the quality of the product itself and suggested that it was not related directly to the patients. On the other hand, 21% of the doctors believed that in the majority of the observed cases of therapeutic failure, the problems were related to subjects' variability and not directly related to medicines and its quality.

Medicines significantly reported:

The following figure shows the most important generics which pharmacists complained about (either in terms of quality, efficacy problems or complaints from patients).

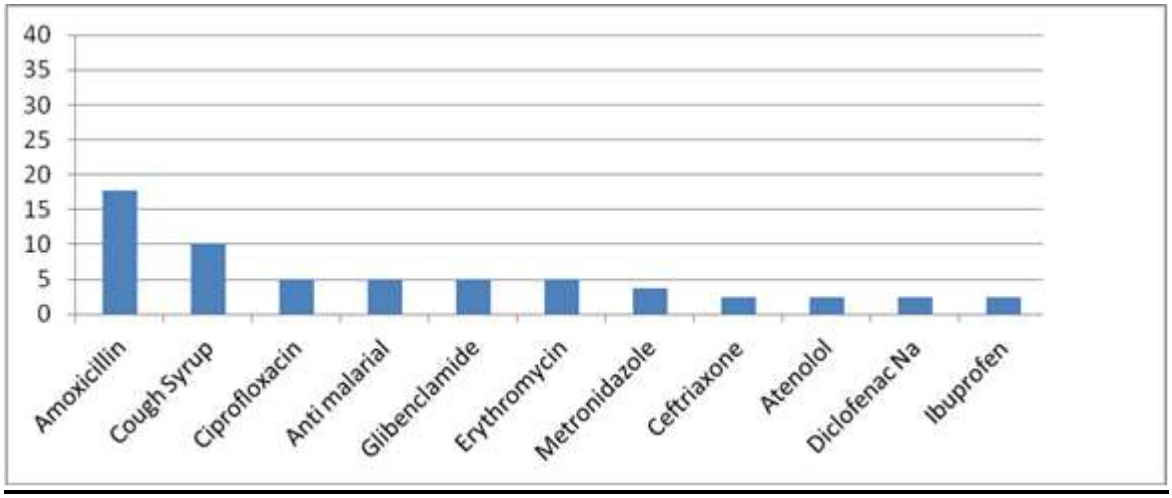

Figure 2: Medicines with top complaints from pharmacists

In general, anti-infective medicines represented the main therapeutic group of the reported cases (44% of pharmacists received reports under this heading). The table below shows the top five groups reported.

Groups	% n=81
Anti-infectives	44.3
Respiratory tract	15.2
NSAIDs	7.6
Cardiovascular system	5.1
Endocrine	5.1

Most of the reported cases were medicines that were locally produced in Sudan (23%), while 10% were manufactured in India and a similar proportion was manufactured in some European countries.

Similar to the experience of pharmacists, anti-infective medicines represented the main therapeutic group in the cases reported (25% of cases). The table below shows the top five groups reported.

Pharmacological Groups	% n=74
Anti-infectives	25.3
Cardiovascular system	5.5
Endocrine	5.5
Central Nervous system	2.2
Anti-Malarial	2.2

Alterations of patient medications:

This part of the results illustrates some indicators that described the practice and attitude of health professionals when they make the decision to shift their patients from one product to another and the shape that these decisions take. The generics reported in these shifting decisions were generally similar to those mentioned in pharmacists' responses about quality concerns (Ciprofloxacin, Amoxicillin and other antibiotics).

Shifting attitudes - Pharmacists:

Most of the pharmacists (85%) experienced at least one occasion when they took the decision to shift a patient from one product to another. Most of these decisions (54%) were taken to shift the treatment to a drug from the same generic category, but a different product. On the other hand, 14% of the decisions were taken to shift the patients to another generic but within the same therapeutic group; the rest of the cases shifted the patients to a completely different therapeutic group. From another aspect, 46% of the decisions included the substitution of locally produced products for imported products. This is an important finding as pharmacists stated different attitudes about their trust in the local products in comparison to products from low income countries (46% reported a preference for local products over products manufactured in low income countries). Despite that, in 40% of the decisions, the shifts occurred among products that were manufactured in low income countries.

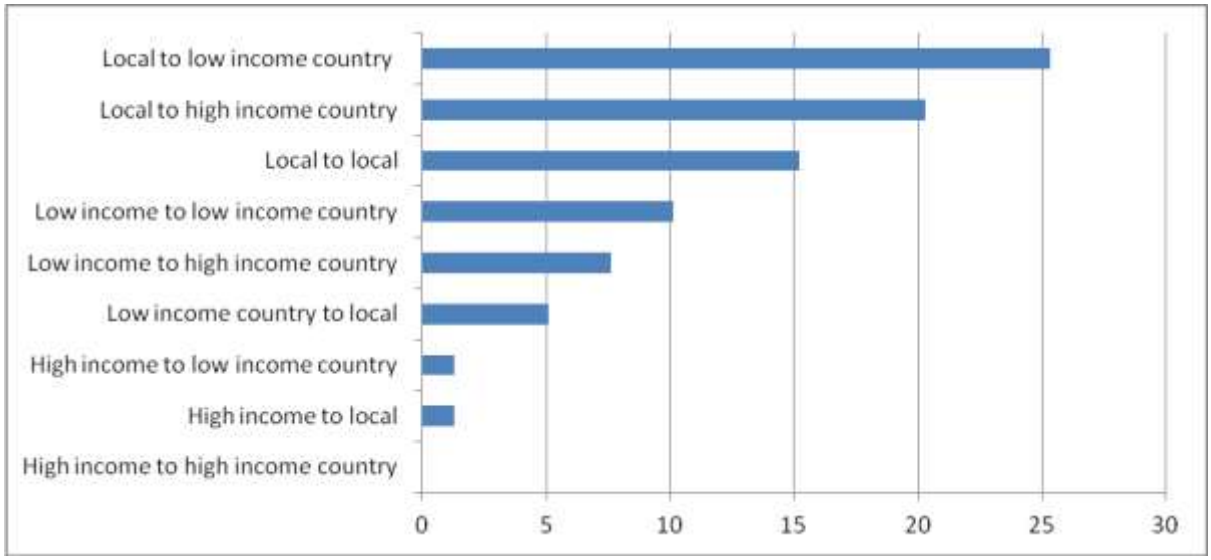

Figure 4: Pharmacists shifting attitude related to countries of origin

The following summery shows top five generics of "Product A – shifting the patient from":

Generic Name	% (n=71)
Amoxicillin	27.8
Ciprofloxacin	12.7
Glibenclamide	11.4
Diclofenac	5.1
Amox-clav	3.8

The following summery shows top five generics of "Product B – shifting the patient to":

Generic Name	% n=71
Ciprofloxacin	15.2
Glibenclamide	11.4
Amox-clav	8.9
Azithromycin	8.9
Erythromycin	7.6

The following summery shows top five origins of “Product A”:

Origin	% n=71
Sudan	59.5
India	12.7
Some Arab countries	3.8
Some countries in Europe	3.8
Jordan	2.5

The following summery shows top five origins of “Product B”:

Origin	% n=71
Europe	27.8
Jordan	22.8
Sudan	20.3
Egypt	3.8
India	3.8

Shifting attitudes - Doctors:

Unlike the feedback obtained from the pharmacists, 86% of doctors took the decision to shift their patients from one product to another, but within the same generics. In the rest of the cases, the alternative products were from different generics. It was noted that 84% of the doctors’ decisions were to shift their patients from products manufactured in low income countries to products manufactured in high income countries.

The following summary shows top five generics of “Product A & B– *similar data*”:

Generic name	% n=36
Ceftriaxone	5.5
Ciprofloxacin	3.3
Amox-clav	2.2
Azithromycin	2.2
Other Antibiotics	3.3

The following summary shows top three origins of “Product A”:

Origin	% n=36
India	7.7
Sudan	5.5
Arab countries	3.3

The following summary shows top five origins of “Product B”:

Origin	% n=36
Europe	13.2
Other Arab countries	6.6
India	1.1

All of these data reflect the debate about products’ substitution, interchangeability and equivalence. The issue of generics substitution is currently a burning issue on the agenda of the global pharmaceutical sector as it has a critical impact on the shape of the global markets as far as it was 20 years ago (8).

Trust in local products as alternatives:

This component of the questionnaire addresses the concerns usually raised in developing countries about the quality of locally manufactured products, especially when compared with the imported products. Using a few questions, the information providers were asked to evaluate their trust and opinion regarding the local production in Sudan and whether or not they would use this as an alternative if it was available on the market. The results showed that 80% of the pharmacists trusted the local products versus only 55% of the surveyed doctors, who used it as an alternative. In more depth analysis, it was found that the degree of trust was related to the experience of the information provider. Experienced professionals trust local production more than younger professionals (regardless of whether the respondents were pharmacists or doctors).

Price as indicator of quality:

“Products of high price usually has better quality than product with low price”. This aphorism is not uncommon among health professionals; it usually appears when the professionals prefer one product over others just according to this rule. The feedback

from pharmacists and doctors regarding this subject indicated different perspectives; pharmacists were divided equally in their approaches, as some were objectors, with some agreeing totally while others agreed with some reservations. On other hand, 45% of the doctors believed that the saying is generally true “but not always”.

Relations with regularity bodies:

The role of pharmacy or health regularity bodies is important and vital in the linkage between the professional practitioners and the products they use in their work. This is important because the feedback from practitioners about the products’ efficacy, safety and quality should be communicated with the relevant authority. Only a small proportion of health professionals surveyed (only 15% of pharmacists and 10% of doctors) have ever reported any complaints or issues to any regularity body regarding medicines-related problems. Upon analysing the responses of those who have ever communicated with the authorities, regarding the response to their reports, we found that the majority of the reporters received “no response”. Many of the information providers state that this is probably due to: (1) Inefficient complaints receiving and management systems; (2) Poor documentation systems within the authorities; and (3) Weak decision making procedures.

Linkage between quality and source of origin:

This part of the questionnaires discussed the possible relationship between the country of origin and quality of medicines from particular countries. The information providers were asked to evaluate and comment on products originating from different sources. This included Sudan, other low income countries, high income countries and products manufactured by multinational industries; this classification of countries was based on World Bank classifications (9). They were asked to classify products generally as either being of “good quality” or of “low quality” from specific origins. Overall, 67% and 48% of pharmacists and doctors, respectively, believed that products manufactured in low income countries were generally worse than those from high income countries and products from multinational companies. In general, 64% and 35% of pharmacists and doctors, respectively, believed that locally manufactured products are good quality. With in-depth analysis, 46% of pharmacists and 30% of doctors were found to consider local products to be of better quality than those produced specifically in low income countries (they prefer local products over

these products). This again reflects the trust of health professionals in the local production of pharmaceuticals.

Problems related to physical appearance:

Observing changes of the physical appearance of pharmaceutical products is not uncommon among pharmacists in Sudan. A total of 99% of pharmacists experienced this problem at least once during their practice, and across the sample, all categories of pharmacists experienced it equally. Amoxicillin & Multivitamin products (especially capsules for both generics) were those in which the problem was notified the most frequently.

Most of the pharmacists noticed distinct physical changes among all dosage forms, whether this was in the dosage unit and/or the inner packages and/or outer packages. From the results, it was very difficult to judge whether the problem was mainly due to inappropriate storage conditions or related to poor manufacturing specifications. In general, capsules as the dosage form (soft gelatine & hard gelatine) represent the major source of complaints under this heading.

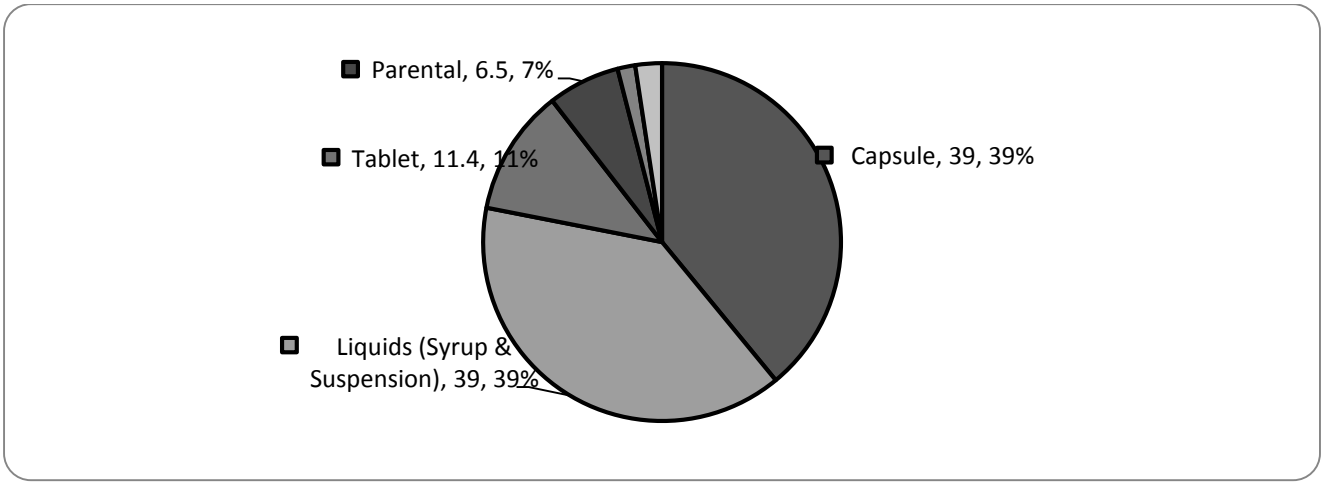

Figure 6: Classification of physical appearance problems

Doctors' awareness & knowledge about substandard medicines:

Some questions were posed to doctors for specific purposes; one of the questions was designed to evaluate the knowledge of doctors about the negative impacts of substandard medicines. Here, 40% of the doctors mentioned that the immediate effect of substandard medicines could lead to the patient's death. Similar results to this were also shown in another survey performed by a press newsletter in India about this area (10). In general, these results indicated the need for more educational interventions about substandard medicines which should be further developed and implemented. This should aim to increase awareness about the impact of the problem of substandard medicines and how to deal with it (11).

Insistence on prescribing particular trade products:

Overall, 63% of doctors, particularly specialists, reported that they insist on prescribing certain trade products to their patients. Most of them referred this to their successful experience with these products relative to others available on the market. On the other hand, only 14% of doctors referred this to the price considerations as a factor that may influence their decision to select certain reasonably affordable products over others.

Availability versus quality:

"Available low quality drug is better than the drug is not available at all"

According to the results, 30% of the doctors agreed with the above concept in which if there were no available alternatives, they may prescribe low quality products to save the patients. This result was significant and at the same time is debatable, as many theories considered that low quality medicines should not be used under any circumstances (12). This could be evaluated only under the personal experiences of doctors in Sudan. In the context of Sudan, there is a relatively small number of registered medicines (13). This obviously affects the decisions of the doctors because of the small number of options available. One third of the doctors will choose the unique drug drugs regardless of their quality.

Discussion:

It is valid that the conceptual beliefs of medical professionals related to substandard medicines affects the curative process in any medical field to a great extent (whether in the public or private sectors). Health professional beliefs could be of potential importance as it has been driven by years of experience and repeated practical knowledge. However, this could also be a possible drawback on the health provision process when these pre-judgments are not supported by evidence (14). This survey will help us, as public health experts, to recognise the conceptual understanding of the health professionals in the study area (and other similar settings) regarding the issue of substandard medicines circulating in the private markets, and to link these thoughts to that which has really taken place in practice. The results of this survey showed major issues regarding the professionals' ideas and how they deal with substandard medicines. It was obvious that there are different concepts regarding these issues among the doctors surveyed and other significantly different concepts among the pharmacists. One of the possible reasons for this could be the basic educational background that allows pharmacists to deal with medicines objectively regarding their quality despite the source of origin, price or any other associated factors other than evidence-based quality problems (15). This reflects the need to develop educational programs to address the problems of counterfeit and substandard products in the curricula of pharmacy and medicine schools as part of essential medicines concept. On the other hand, the judgment of doctors regarding the quality of any product used for the patients will always be concluded with a slightly subjective evaluation which could be generated from their experiences in the field. As an example, the use of substandard narrow-spectrum antibiotics causes practitioners to believe that the product is ineffective, and leads them to unnecessarily prescribe new/more expensive broad-spectrum antibiotics, which places additional financial pressures on the healthcare system and the patient as well (16). Another example with a similar scenario can be applied for life saving drugs with a narrow therapeutic index which are considered and taken seriously for patients with ischemic heart diseases and other life threatening diseases (17, 18).

From the results, it is clear that awareness of the impact of this problem and its effects varies among health professionals. The educational background and

experience seem to play an important role in these differences. The message that may be conveyed from medical professionals to the public about the quality of medicines can sometimes be extremely misleading information and affect the overall handling of the issue. The concepts that link the quality of medicines to their prices and/or their origins are relevant in this case. It has been argued that increasing the awareness among the public about the existence of poor quality drugs may cause patients to worry excessively about whether the medicines they are taking are authentic and effective. This has been seen in many countries in which national awareness raising activities have been widely implemented. On the other hand, a lack of vigilance, monitoring and reporting of quality may generate a lack of trust among both consumers and professionals. Still, the question of this matter will persist regarding opinions around the issue of substandard medications, bringing this to public attention as an essential first step towards reinforcing current methods of surveillance, with consideration to what extent this will affect the patient's trust in the health system in general.

Conclusion:

Based on the results obtained, it is clear that the complaints received by the pharmacists from the patients were most likely due to factors related to the individual patients. Among the complaints received by pharmacists, the most important issue raised by the patients was that the medicines administered were not effective or, sometimes, the symptoms were not relieved after using the medicines. Although this was a subjective issue, this finding was still significant since some of these medicines were for chronic use e.g. antihypertensive and anti-diabetic medicines. Quality monitoring programs will not be effective without the active involvement of health professionals form the healthcare field. This involvement will strengthen the outcomes of these programs and, at the same time, it will help the implementing bodies to improve outcomes in the future. Building strong relations with health professionals and strengthening the communication and feedback systems with them are essential mechanisms to improve knowledge about quality-related problems. It seems that the development of educational programs targeting health professionals regarding the management of low quality medicines including substandard and counterfeit products is also an important aspect of this intervention.

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