

# Knowledge, Attitude and Practices Regarding Counterfeit Drugs among Nurses of Madina Teaching Hospital Faisalabad

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## ABSTRACT

**Objective:** To assess the knowledge, attitude and practices among nurses regarding counterfeit drugs. **Methodology:** Cross sectional study. The study was conducted in Madina Teaching Hospital which is attached to the University Medical and Dental College Faisalabad. Total number of nurses was 60 and all were included in the study. Only nurses were chosen because of their direct involvement in administering the drug/injection during duty hours and also they are the first to notice any adverse effects of drugs. Data was collected through pretested restrictive form of questionnaire. Written permission from ethical review committee and informed consent from the participants was taken before conducting the survey. All questionnaires were edited before entering in the computer. Once the data had been cleaned as thoroughly as possible, the distribution of each variable was re-examined as a final check. Non-sampling errors like selection bias, non-coverage, non-contact and non-response were tried to minimize.

**Results:** Out of the 59 nurses who responded from a

total of 60, 57 (96.6%) had heard of incidences regarding counterfeit drugs (see table I). 59 (100%) considered them substandard in quality, 33 (55.9%) thought they were expired drugs, while 9 (15.3%) said that they were made from herbs (see table II). However a majority of 94.9% understood that they were harmful drugs. 100% nurses said they examined the packaging meticulously and checked the expiry date before administrating the drug (see table III). 98.3% sent any such drugs for laboratory testing (see table IV). 100% nurses immediately stopped the use of such drug (see table V). 34 out of the 59 nurses (57.6%) had seen adverse drug reaction in multiple patients. 89.8% said they kept records of such drugs and all of the participants (100%) reported such incidents to the authorities (see table VI). **Conclusion:** Majority of the nurses were aware of the counterfeit drugs problem and its effects on the patients. Over all, most of them understood that counterfeit drugs were harmful to the health of the patients and this study further helped to clear their concepts. **Key Words:** Counterfeit drugs, Counterfeiting, World Health Organization.

## INTRODUCTION

The scandal at the Punjab Institute of Cardiology (PIC) Lahore regarding spurious drug caused the death of over 100 cardiac patients. According to the report issued by the British Medicines and Healthcare Regulatory Agency (MHRA) each Isotab 20mg tablet, manufactured by a pharmaceutical company, was contaminated

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with 50mg pyrimethamine.<sup>1</sup> Counterfeit drugs are substandard in quality and therefore ineffective and even harmful to the patients. The World Health Organization (WHO) states that: "Counterfeiting occurs both with branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients."<sup>2</sup> Although any drug can be counterfeited, it is more common with steroids, hormones, cholesterol lowering drugs, anti-malarial, anti-tuberculosis drugs and anti-HIV drugs. The major contributors of these drugs are the developing countries of Africa and Asia,

including Pakistan, where there is a lack of drug regulatory authorities and law enforcing agencies. Accurate estimate of the extent of this ill practice is difficult to obtain but according to WHO, 10% of the world's drug trade is formed by counterfeit drugs.<sup>3</sup> As a consequence of the recent PIC tragedy mentioned earlier, many countries including Sri-lanka and Afghanistan have questioned the low quality of medicinal drugs manufactured in Pakistan which has not only defamed the country but also inflicted heavy losses to the pharmaceutical companies. The use of sub-standard drugs endangers the lives of the patients resulting in increased morbidity and mortality. Plasmodium falciparum strains resistant to artesunate have been discovered in South East Asia due to use of substandard and fake artesunate containing sub-therapeutic quantities of artemisinin and artesunate which was inadequate to kill the plasmodium specie<sup>4</sup>. The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) is a global collaborative effort under WHO formed in 2006, to combat the growing problem of counterfeit drugs worldwide by enhancing regulatory measures to reduce the production, sale, and trade of sub-standard pharmaceutical products<sup>5</sup>. Strengthening drug regulatory authorities to improvise laws relating to quality manufacture, developing drug testing laboratories at the Provincial and the Federal levels and emphasizing on quality production can also play a vital role in reducing counterfeiting. The knowledge, attitude and practices among health care workers (HCW) is of paramount importance because timely awareness among them would save many precious lives.

#### MATERIALS & METHODS

The study design was cross sectional. It was conducted in 2012 during the months of June to August. All the nurses working in Madina Teaching Hospital Faisalabad constituted the study population. Total number of nurses was 60 and all were included in the study. Only nurses were chosen because of their direct involvement in administering the drug/injection during duty hours and also because they are the first to notice any adverse effects of drugs. After acquiring the written permission data was collected through

restrictive form of questionnaire. This pretested questionnaire was then distributed among nurses and later on collected from them. Informed consent was taken from the participants before conducting the survey. As in this study respondent were genuinely concerned about the topic of study, the response rate was 99%. Data processing error such as coding, copying, data entering, programming and calculations were taken into account and any mistakes found were corrected. All the questionnaires were edited before entering in the computer. If there was any misinformation, the respondent was re-connected and information was corrected or completed. Once the data had been cleaned as thoroughly as possible, the distribution of each variable was re-examined as a final check and any corrections needed were made. The researcher tried to minimize non-sampling errors like selection bias, non-coverage, non-contact and non-response as much as possible.

#### RESULTS:

**Table I: Number of responses from nurses in yes, no and don't know (DNK) and percentages (%) regarding specific attributes. (Total number of respondents: 59)**

Attributes	Yes	No	DNK
Knowledge of counterfeit drugs	57 (96.6%)	0 (0.0%)	2 (3.4%)
Heard about any incidence regarding counterfeiting	57 (96.6%)	01 (1.7%)	01 (1.7%)
Existence of issue of counterfeit drugs in Pakistan	59 (100%)	0 (0.0%)	0 (0.0%)

**Table II: Number of responses from nurses regarding understanding of counterfeit drugs in yes, no and don't know (DNK) and percentages (%). (Total number of respondents: 59)**

Attributes	Yes	No	DNK
Genuine drug	06 (10.2%)	52 (88.1%)	01 (1.7%)
Substandard	59 (100%)	0 (0.0%)	0 (0.0%)
Constituents of counterfeit drugs are dangerous to health	58 (98.3%)	01 (1.7%)	0 (0.0%)
Harmful drug	56 (94.9%)	02 (3.4%)	01 (1.7%)
Expired drug	33 (55.9%)	05 (8.5%)	21 (35.6%)
Made up of herbs	09 (15.3%)	08 (13.5%)	42 (71.2%)

**Table III: Number of responses from nurses in yes, no and don't know (DNK) and percentages (%) regarding specific attributes. (Total number of respondents: 59)**

Attributes	Yes	No	DNK
Record of expired/damaged drugs	52 (88.1%)	06 (10.2%)	01 (1.7%)
Meticulously observing the packaging and date of expiry before administrating the drugs	59 (100%)	0 (0.0%)	0 (0.0%)

**Table IV: Number of responses from nurses in yes, no and don't know (DNK) and percentages (%) regarding specific attributes. (Total number of respondents: 59)**

Attributes	Yes	No	DNK
Sending the drugs for laboratory examination	58 (98.3%)	0 (0.0%)	01 (1.7%)
Use of drugs before the arrival of drug testing laboratory results	01 (1.7%)	58 (98.3%)	0 (0.0%)

**Table V: Number of responses from nurses in yes, no and don't know (DNK) and percentages (%) regarding specific attributes. (Total number of respondents: 59)**

Attributes	Yes	No	DNK
Ever seen the adverse effects of drug	58 (98.3%)	01 (1.7%)	0 (0.0%)
Sending such drug for laboratory testing	58 (98.3%)	01 (1.7%)	0 (0.0%)
Stopping the use of drug immediately	59 (100%)	0 (0.0%)	0 (0.0%)

**Table VI: Number of responses from nurses in yes, no and don't know (DNK) and percentages (%) regarding specific attributes. (Total number of respondents: 59)**

Attributes	Yes	No	DNK
Observing adverse effect of drug in multiple patients	34 (57.6%)	25 (42.4%)	0 (0.0%)
Reporting of adverse effects of drug to the authorities	59 (100%)	0 (0.0%)	0 (0.0%)
Record keeping of adverse effects of drugs	53 (89.8%)	06 (10.2%)	0 (0.0%)

## DISCUSSION:

Counterfeit drugs are a global public health problem causing death, disability and injury affecting adults and children. No country is free of this problem, which plagues developing and developed countries alike. Counterfeiting affects finished products and also active pharmaceutical ingredients, medical devices, diagnostic kits and other types of health-care-related items. Counterfeiting is a forgery; a copy or imitation, made without authority or right, and with a view to deceive or defraud, by the act of passing the copy or thing forged for that which is original or genuine. When the word counterfeit is used in the adjective form with the noun drug, a counterfeit

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drug is an imitation of something else with intent to deceive.

The WHO in conjunction with the pharmaceutical industry and drug regulators has developed the following definition of a counterfeit drug:

“a medicine, which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.<sup>2</sup> In comparison the definition from Pakistan's Manual of Drug Laws is "a drug, the label or outer packing of which is an imitation of, resembles or so resembles as to be calculated to deceive the label or outer packing of a drug manufacturer" conforms more closely to the WHO definition.

With regard to infectious diseases, the primary source of the burden of disease in the developing and least developed countries, counterfeit drugs lead to the selection of drug resistant pathogens, increased morbidity, mortality and a significant economic burden on developing regions of the world. In many countries there is no drug regulatory authority at all and in those where one exists, it is either inadequate to regulate drugs generally and/or does not have the power to apply measures to suppress the factors that lead to counterfeiting. Counterfeit goods are an unrecognized public health problem particularly in the area of injury morbidity and mortality and represent 5-7% of all products worldwide.<sup>6</sup>

Fourteen different artesunate tablets, representative of what can be purchased from informal sources in southeast Asia, were investigated with different techniques. The expected active pharmaceutical ingredient was detected in only five formulations via both nuclear magnetic resonance (NMR) and mass spectrometry (MS) methods.<sup>7</sup>

The illegal production, sale and distribution of fake drugs is a huge market evaluated to several billion of dollars and represents more than 50% of the pharmaceutical market in several African countries and resulted in many deaths.<sup>8</sup> Counterfeit or substandard (poor quality) drugs

pose threats to society; not only to the individual in terms of the health side effects experienced, but also to the public in terms of trade relations, economic implications, and the effects on global pandemics.<sup>9</sup>

Poverty, high cost of medicines, lack of an official supply chain, legislative lacunae, easy accessibility to computerized printing technology, ineffective law enforcement machinery, and light penalties provide the counterfeiters with an enormous economic incentive without much risk.<sup>10</sup> Governments in rich countries should not tolerate the export of substandard pharmaceutical products to poor countries, while developing country governments should improve their ability to detect substandard medicines.<sup>11</sup> The report by the WHO presents the recommendations of an international group of experts convened by the this organization to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms.<sup>12</sup> Semi-quantitative thin-layer chromatography and disintegration testing were used to measure the concentration of active ingredients against internationally acceptable standards. 12% of all samples tested from Delhi failed either one or both tests, and were substandard. 5% of all samples tested from Chennai failed either one or both tests, and were substandard.<sup>13</sup>

Since our ancestors began trading several millennia ago, counterfeit and substandard medicines have been a recurring problem, with history punctuated by crises in the supply of anti-microbials, such as fake cinchona bark in the 1600s and fake quinine in the 1800s.<sup>14</sup> The IMPACT (International Medical Products Anti-Counterfeiting Taskforce) initiative, launched in 2006 by WHO and other stakeholders worldwide (health authorities, healthcare professionals, patients, customs, police, industry), is aimed at developing precise legislative, regulatory and technical measures, and at increasing global awareness of this threat to public health.<sup>15</sup> Technologic advances have worsened the counterfeit drug problem. Because drug counterfeiting is a worldwide concern, worldwide action is needed to combat the problem.<sup>16</sup>

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It is estimated that 5% of all world trade in branded goods is counterfeit, leading to huge financial losses for the pharmaceutical industry. But much more important, from a public health point of view, is that history has shown that such products may lead to a great health risk.<sup>17</sup> "Counterfeit Drugs Kill" is the slogan the World Health Organization (WHO) uses in its anti-counterfeiting campaign. International organizations, governments of developed and developing countries, and the pharmaceutical industry created the IMPACT initiative to take on the thriving illegal industry that makes profits by selling fake drugs.<sup>18</sup> Although the practice of drug counterfeiting is unlikely to ever completely disappear, it may be controlled if governments and all relevant parties combine forces to identify and disrupt the counterfeit chain.<sup>19</sup>

Several of the currently used methods of detection are described and these include near-infrared spectroscopy, Raman spectroscopy, isotopic characterization, tensiography, chromatographic and mass spectrometric approaches. Finally, anti-counterfeiting measures such as the use of holograms, tracers and taggants and electronic tracking are summarized.<sup>20</sup> Analysis of the contents of counterfeit phosphodiesterase type 5 inhibitor (PDE5i) medications for erectile dysfunction (ED). Millions of counterfeit PDE5i are seized yearly shows inconsistent doses of active pharmaceutical ingredients (from 0% to > 200% of labeled dose), contaminants (including talcum powder, commercial paint and printer ink) and alternative ingredients that are potentially hazardous.<sup>21</sup>

## CONCLUSION

Majority of the nurses working in Madina Teaching Hospital were aware of the problems of the counterfeit drugs. It was also observed during the study that many nurses had seen patients suffering from adverse reaction of different drugs which could be the result of counterfeiting. This research might be a small step towards increasing awareness among healthcare workers regarding counterfeiting.

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