



Evaluation of knowledge and attitude towards counterfeit drugs among the doctors in a tertiary care hospital

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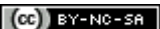
ABSTRACT

Background: Counterfeit drugs represent an enormous public health challenge such as life threatening issues as well as financial loss on health care providing system. **Methods:** This was a cross sectional questionnaire based study was conducted among Doctors in Sri Venkateshwara Medical College Hospital & Research Centre, for a period of 3 months after Institutional Ethics Committee approval. Written informed consent obtained. 146 Doctors of both the gender were recruited by simple random sampling with an exclusion of 57 due to incomplete questionnaire forms. 13 predesigned and validated questions focused on knowledge (5) and attitude (8) was answered. The response was evaluated for a total score of 18, pertaining to knowledge 10 points and 8 for attitude. **Results:** Demographic profile of the 146 entrants, showed 84 were male over 62 female. The mean age group was 33.27 ± 9.59 with an average experience of 7.32 ± 9.173 . The overall score was 11.25 ± 3.187 , which was shared by Knowledge and attitude 5.07 ± 1.995 , 6.18 ± 1.943 respectively. **Conclusion:** Observations of this study enlighten that majority of the doctors are lagging in their knowledge to distinguish between counterfeit drugs from the original. Most of the participants have opined that severe punishment should be given to stop counterfeiting.

Keywords: Counterfeit drug, Doctors, Questionnaire, Age, Experience

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INTRODUCTION

Counterfeit medicines create a major threat to health and economic aspects of a community. The correct knowledge about counterfeit medicine is most important to control it. This problem is worldwide; almost all the developed and developing countries are suffering with major impact on health and economics respectively. The poor quality of medicine represents a positively dangerous and detrimental effect on public health, in terms of human suffering and produce harmful impact on the health care system.

Though counterfeiting means copying or imitating, they represent an enormous public health challenge, why because, any consumer in the world can encounter medicines packed in the right way, which do not contain the correct ingredients but on top it may contain a highly toxic substances.¹

Counterfeiting, including the entire range of activities from manufacturing to providing them to patients, is a *vile and serious criminal offence* that puts human lives at risk and undermines the credibility of health care system. Counterfeit pharmaceuticals are produced with *substandard quality, less safety and efficacy*, when compared with the standards by Drug Regulatory Authorities which holds true for both branded and generic medicines.²

The United States of America Drug and Cosmetic Act, defines counterfeit drugs as, "A drug which, or the containers or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor".³

WHO states that, "A Counterfeit Medicine is one which is deliberately and fraudulently mislabeled with respect to identity and or source" That means they intentionally carry a wrong label of identity and or origin which indicates, the product with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging.⁴

Counterfeit Categories as per WHO: Based on type and prevalence 6 categories has been identified;1.No active ingredients (32.1%),2.Incorrect ingredients 21.4%),3.Incorrect amounts of active ingredients (20.2%),4.Correct

quantities of active ingredients but fake packaging (15.6%),5.High levels of impurities and contaminants (8.5%),6.An original product that has been copied (1%).⁵

Indian perspective of counterfeit drugs: Our Indian drug laws do not define or make note of the term "Counterfeit drugs" throughout the statute, but the urgent need arises to incorporate this term under its purview. India being a bulk manufacturer and exporter of drugs and pharmaceuticals, the quality of manufacturing as per the regulatory norms is of paramount importance, which should be streamlined universally.⁶

Consequences of counterfeit drugs on Indian Economy: After effect of sale of counterfeit drugs will definitely prevent investing companies on research and development, also it will deter foreign companies, leading to significant revenue loss to the Government. So also the Government will face additional economic expenses, incurring with severe financial loss to protect the supply chain and creation of systems to detect counterfeit drugs. Another major outcome of counterfeit drugs can lead to the regression of Indian companies and foreign exchange along with an additional expenditure for payment of fine leading to financial crisis for developing countries like India.⁷

Need for the study: Reports from various studies have stated, India's poor history of protecting *Intellectual Property Rights (IPR)*. This statement should be viewed with utmost importance because there had been incidences where counterfeit drugs were clearly responsible for several fatalities, which was supported by death of 13 women who attended squalid sterilization camp at Chhattisgarh, the cause of death due to use of one particular batch of oral contraceptive pills manufactured by a small drug factory in Raipur in 2012. Hence this study was undertaken to analyze the knowledge and attitude regarding counterfeit drugs among the doctors in a tertiary care hospital.

OBJECTIVE

To analyze the knowledge and attitude regarding counterfeit drugs among the doctors in a tertiary care hospital.

MATERIALS AND METHODS

This was a cross sectional questionnaire based study, conducted among doctors in Sri Venkateshwaraa Medical College Hospital & Research Centre, Puducherry, for a period of 3 Months (November 2018 – January 2019) after getting Institutional Ethics Committee approval. Written informed consent was obtained. Sample size was calculated as 203 using the formula $n = 4pq/d$ based on previous study.¹ The nature and

purpose of the study with respect to identification, hazards associated, regulatory authorities and modern technologies to combat and prevent the counterfeit drugs was explained in detail to all the study participants. 146 Doctors of both the gender were recruited by simple random sampling with an exclusion of 57 due to incomplete questionnaire forms. 13 predesigned and validated questions focused on knowledge (5) and attitude (8) was enlisted. The response was evaluated for a total score of 18, pertaining to knowledge 10 points and 8 points allocated for attitude. (Questionnaire enclosed in Annexure 1)

Data Analysis: The scores obtained by participants to the questions in each series were categorized as ≤ 5 and > 5 for knowledge and for attitude ≤ 4 and > 4 . The results were analyzed with descriptive statistics.

RESULTS

Demographic profile of the 146 entrants showed more number of male 84 over 62 female participants. The mean age group was 33.27 ± 9.59 , with an average experience of 7.32 ± 9.173 . The overall score was 11.25 ± 3.187 , shared by Knowledge and attitude 5.07 ± 1.995 , 6.18 ± 1.943 respectively (Table 1). The age distribution showed that 86 respondents were 25 to 30 years (fig 1) and among them 98 subjects were, with an experience of 0 to 5 years (fig 2). There was an inappropriate knowledge among 129 physicians regarding percentage of counterfeit drugs in India and 116 felt that it is very dangerous to take counterfeit drugs. 132 participants accepted the fact that severe action should be taken to stop the counterfeit drugs while 41 were hesitant to report the counterfeit drugs for various reasons (Fig 3).

DISCUSSION

The Knowledge score obtained by the study subjects, greater than 5 was relatively low in the age group of 25 to 30, when compared with doctors of increasing age and experience. This could be due to lack of awareness and appropriate guidelines by regulatory authorities to be developed for the doctors to execute anti-counterfeit measurement as stated by Yadav V et al.¹

There was a positive attitude in the age group of 36 and above, regarding actions taken against counterfeit drugs and methods to combat counterfeiting which was well supported by increasing years of experience (≥ 11 years) than the new entrants which can be overcome by appropriate decision making capability as expressed by Shahverdi Sh et al suggestions.² 12% of our study subjects had knowledge about

prevalence of counterfeit drugs in India whereas, WHO report quotes that, 35% of counterfeit drugs come from India, but the actual scenario according to the studies conducted by Central Drugs Standard Control Organization (CDSCO) is only 0.05% to 0.3% which is supported by a study, conducted by Delhi Pharmaceutical Trust (SEAR Pharm Forum) in 2007, funded by WHO. In that study out of 10743 samples analyzed, collected from 234 pharmacies throughout India it was found, that only 0.3% of the samples was counterfeit.⁴

Out of 146 participants, majority (105) of the candidates were willing to report a counterfeit drug which could decrease the risk of developing unexpected adverse drug reactions (ADRs) in consumers. The adverse effects in turn will have a specific impact on the health such as

1. **Increased duration of illness** - as counterfeit drug might contain no active ingredient and or no harmful ingredients ,
2. **Development of antibiotic resistance** - as a result of the ineffective ingredient / or less efficacy of the counterfeit drug,
3. **Death or Morbidity** - due to wrong active ingredients akin to the patient taking another drug, instead of the prescribed drug without knowing it, or highly toxic ingredient,
4. **Loss of confidence in Health Care providing system** -due to high prevalence of counterfeit drugs with substandard quality.⁵

Majority of the participants had awareness about **IMPACT** (International Medicinal Products Anti counterfeiting Drugs) and the key members of Task force which includes National Regulatory Authorities, International Organizations Pharmaceutical manufactory and wholesale industry Association as per WHO (Fig 3). Marketing counterfeit drugs will harm sale of genuine drugs thus, affecting companies that have invested in quality, research and development of drugs and the consequences of loss of economic potential.⁶

CONCLUSION

Observation of this present study has en-lighted that, majority of the doctors are lagging in their knowledge to distinguish between counterfeit drugs from the original. Most of the participants had accepted the fact that, severe action should be taken to stop the counterfeit drugs. Hence, implementation of educational interventions pertaining to identify, combat counterfeiting, and modern technological approaches in prevention of counterfeit medicines. At the same time, the results

of this study pointed out *the need for stringent laws*, for thwart the society from counterfeit medication behavior.

ROLE OF PHARMACOVIGILANCE IN COUNTERFEIT DRUGS

1. Pharmacovigilance programs must consider the possibility of counterfeit drugs in their assessments and the personnel in particular must keep counterfeit drugs in view, when coming across strange or unexpected adverse reactions.

Table 1: Overall Results

| | Mean ± S.D |
|--------------------------------|--------------|
| Age | 33.27 ±9.591 |
| Experience in years | 7.32±9.173 |
| Knowledge (total score - 10) | 5.07±1.995 |
| Attitude (total score - 8) | 6.18±1.943 |
| Total score (total score - 18) | 11.25±3.187 |

2. The Key factor in Pharmacovigilance programs rely on spontaneous reporting of ADRs and subsequent casualty analysis. They work with an assumption that, the suspected drug formulation includes all correct ingredients in the doses as given on the label. The high prevalence of counterfeit drugs would alter casualty analysis and interference including, incorrect attributions of ADR to specific active ingredient.

3. Care must be taken, not to be “*over vigilant*” so that patients are not deprived of much needed medications.

Table 2: Knowledge and Attitude age-wise (parenthesis indicates percentage)

| Age in years | Knowledge (Total score – 10) | | Attitude (Total score – 8) | |
|--------------|------------------------------|----------|----------------------------|-----------|
| | <5 | ≥5 | <4 | ≥4 |
| 25 to 30 | 40 (46.5) | 46(53.5) | 14 (16.3) | 72 (83.7) |
| 31 to 35 | 15 (45.5) | 18(54.5) | 2 (6.1) | 31 (93.9) |
| 36 to 40 | 2 (22.2) | 7 (77.8) | 0 | 9 (100) |
| 41 to 45 | 2 (33.3) | 4 (66.7) | 0 | 6 (100) |
| 46 to 50 | 0 | 2 (100) | 0 | 2 (100) |
| >50 | 5 (50) | 5 (50) | 3 (30) | 7 (70) |

Age wise Statistical analysis showed appreciable knowledge about counterfeit drugs as 53.5% among 25 to 30 years, 54.5% in 31 to 35, followed by 77.8% with 36 to 40 and 66.7% in 41 to 45, satisfactory knowledge about counterfeit drugs were noticed among 46 to 50 years and above 50 years respectively. 83.7% of 25 to 30 years old study subjects showed a positive attitude towards identifying, combating counterfeit drugs with available technologies and reporting of counterfeit drugs with full acceptance and also from other age groups.

Table 3: Knowledge and Attitude experience-wise (parenthesis indicates percentage)

| Experience in years | Knowledge (Total score – 10) | | Attitude (Total score – 8) | |
|---------------------|------------------------------|---------|----------------------------|-----------|
| | <5 | ≥5 | <4 | ≥4 |
| 0 to 5 | 48 (49) | 50 (51) | 9 (9.2) | 89 (90.8) |
| 6 to 10 | 9 (31) | 20 (69) | 7 (24.1) | 22 (75.9) |
| 11 to 15 | 0 | 3 (100) | 0 | 3 (100) |
| 16 to 20 | 2 (50) | 2 (50) | 0 | 4 (100) |
| 21 to 25 | 0 | 2 (100) | 0 | 2 (100) |
| ≥ 26 | 5 (50) | 5 (50) | 3 (30) | 7 (70) |

Doctors with 6 to 10 years of experience had higher understanding (69%) of counterfeit drugs followed by 51% with 0 to 5 years of experience. Equal knowledge was noticed with 20 years of experience and above.

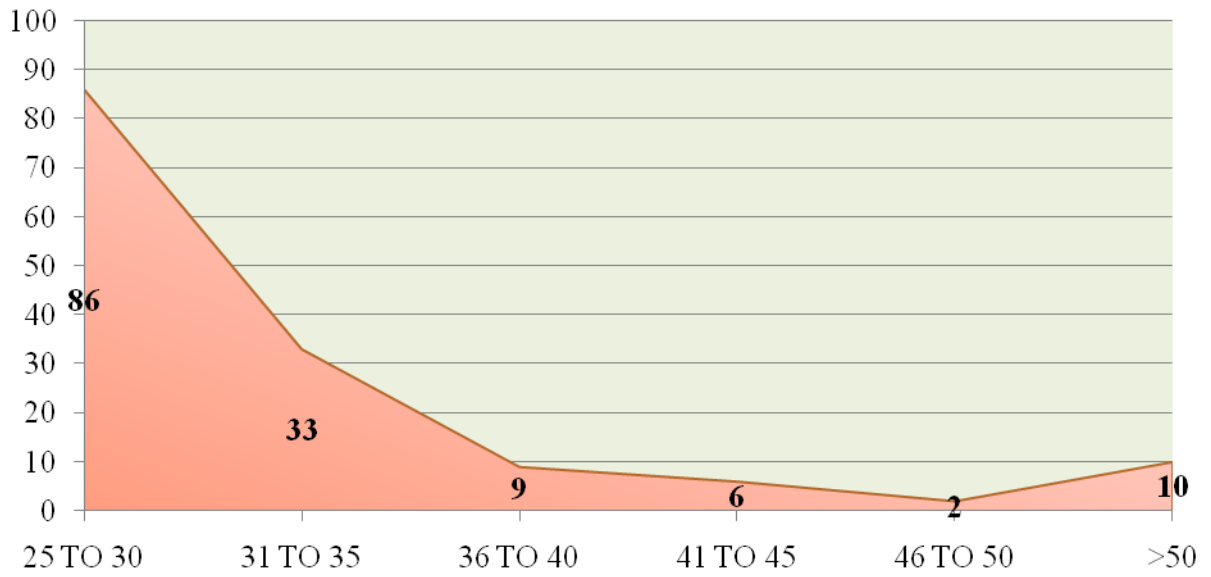


Fig 1: Distribution of age in years

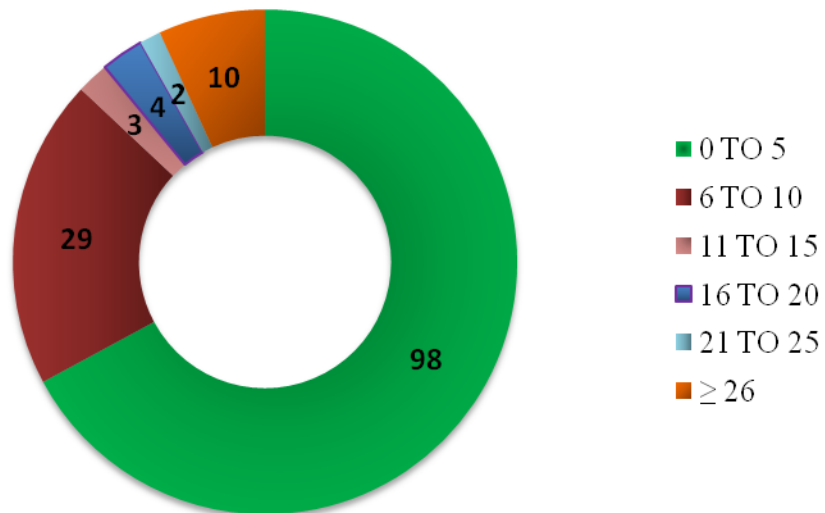
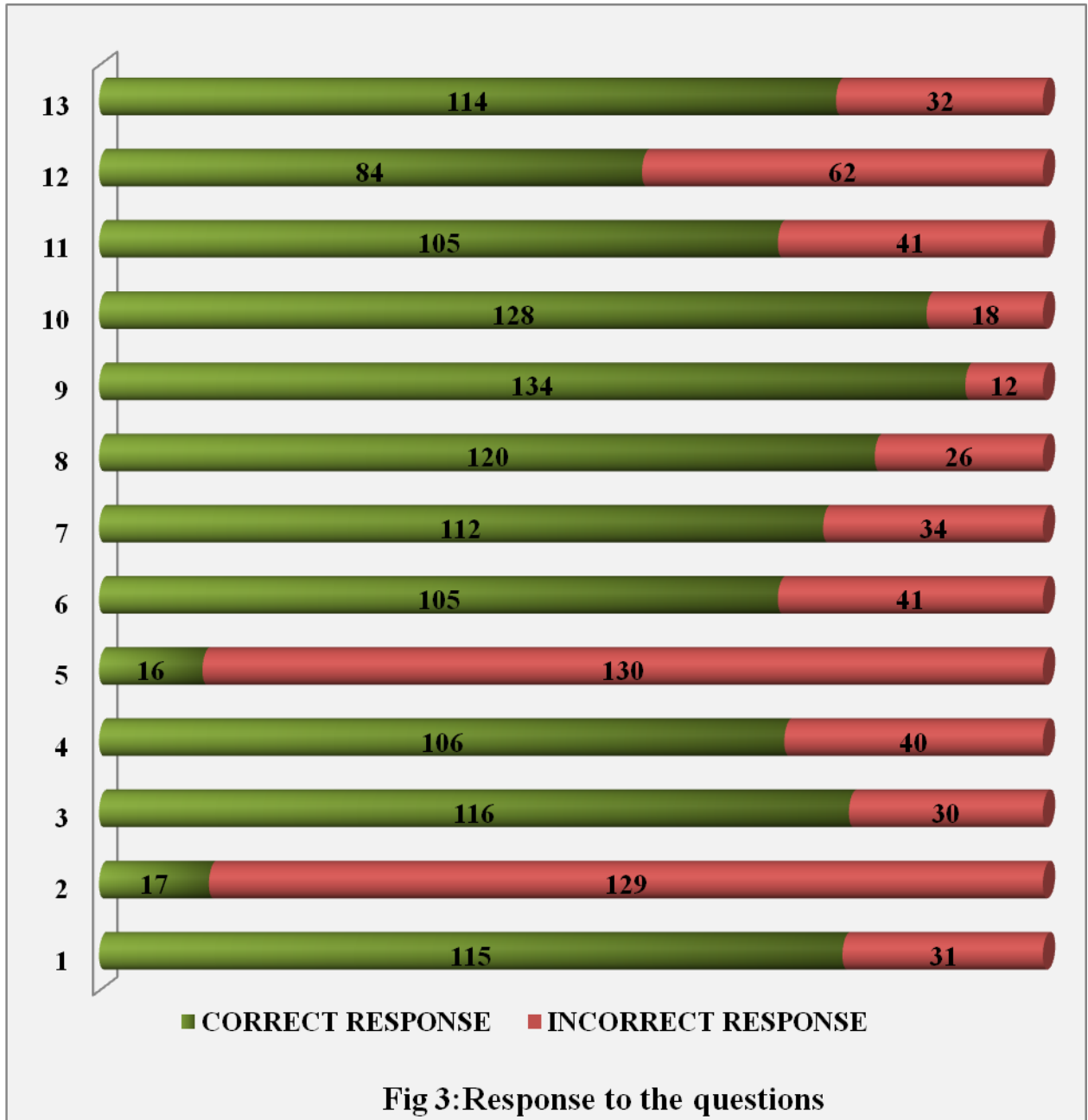


Fig 2: Distribution of experience in years



ANNEXURE 1

1. What do you mean by counterfeit drugs?

- A. Placebo drugs
- B. Orphan drugs
- C. Fake drugs
- D. Substandard drugs
- E. Don't Know

2. In your opinion, how much percentage of drugs are counterfeit in India

- A. 0%-2.5%
- B. 2.6%-5%
- C. 5.1-10%
- D. >10%

3. Is it dangerous to take counterfeit drugs?

- A. Yes
- B. No
- C. Don't Know

4. Hazards associated with counterfeit drug

- A. Treatment failure
- B. More side effects
- C. Increase in cost of treatment
- D. All of the above
- E. None of the above

5. Do you think you are able to distinguish a counterfeit drug from the original?

- A. Yes B. No C. Don't Know

6. Methods to identify the counterfeit drugs

- A. By physical observation B. By unexpected side effects
C. By lack of effectiveness D. All of the above
E. None of the above

7. Technologies that have the capability of preventing counterfeiting drugs?

- A. Barcodes B. Radio frequency identification (RFID)
C. Both A and B D. None of the above

8. Do you think the actions taken against counterfeit drugs are severe enough to stop you from buying these drugs?

- A. Yes B. No C. Don't Know

9. Would more severe action should be taken to stop the counterfeit drugs?

- A. Yes B. No C. Don't Know

10. Methods to combat counterfeit drugs?

- A. Technological tools B. Enforcing regulatory bodies
C. Public awareness D. All of the above

11. If you encounter with a counterfeit drug then would you like to report it?

- A. Yes B. No C. Don't Know

12. IMPACT means

- A. International medical parameters action control trafficking
B. Indian Medico-Pharmaceutical Adverse Committee Taskforce
C. International Medicinal Products Anti counterfeiting Drugs Taskforce
D. International Management Pharmaco Advanced Communication Taskforce

13. Key members of Task force

- A. National Regulatory Authorities
B. International Organizations
C. Pharmaceutical manufactory and wholesale industry Association
D. All of the above
E. None of the above

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