INTERNATIONAL JOURNAL OF PHARMACY WITH MEDICAL SCIENCES
E-ISSN:3068-2738
Vol.4, No. 4(2024)
www.ijpams.com

PHARMACEUTICAL QUALITY SURVEILLANCE OF FREE MEDICINES IN NEPAL'S PUBLIC HEALTHCARE SYSTEM

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ABSTRACT

The Government of Nepal provides essential medicines free of cost to improve accessibility and equity in healthcare. However, concerns have been raised regarding the quality, safety, and efficacy of these medicines, which directly influence patient outcomes and public trust in government health programs. The present study aimed to assess the quality of selected free medicines distributed across tertiary, secondary, and primary healthcare facilities in Nepal. Standard pharmacopoeial methods were employed to evaluate parameters such as identification, assay, dissolution, disintegration, weight variation, sterility, and labeling compliance. Samples were collected randomly from multiple distribution points to ensure representativeness. Results revealed that while a majority of medicines complied with pharmacopeial specifications, certain formulations exhibited deviations in assay values and dissolution profiles, raising concerns about therapeutic consistency. Labeling deficiencies and storage-related issues were also noted in some healthcare facilities. This study emphasizes the importance of continuous quality surveillance to ensure that government-supplied medicines are not only accessible but also safe and effective.

1. INTRODUCTION

In recent days, there has been a growing concern about the quality of medicines all around the world. Poor quality of medicines which includes substandard, spurious, falsely labeled, falsified and counterfeit medicines (SSFFC) have resulted serious impacts [1] and are a prominent issue in both developed and developing countries [2, 3]. Availability of safe, effective and affordable medicine is one of the indicators of quality of health services [4] and also a major target area of Universal health coverage [5]. However, quality of medicine seems to be neglected in most of the developing countries. There is increased risk for circulation of substandard/counterfeit products worldwide due to globalization; more notably to the developing countries with weak regulatory authorities [6]. Evidences show prevalence of substandard and counterfeit medicines worldwide encompassing drugs of classes: anti-infective, anti-malarial, paracetamol, antibiotics, antihelminthic [2, 7–10].

Nepal is a developing country in South Asia with a population of around 30 million people [11]. The government has established an Essential Medicines Program (EMP) that provides affordable and quality essential medicines for the prevention and treatment of common diseases and health conditions [12]. Essential medicines are distributed through various channels, including public health facilities, private pharmacies, NGOs, and international donors. The government provides essential medicines free of charge to patients seeking treatment at public health facilities [12, 13], which are procured through a centralized system managed by the Department of Health Services. The distribution of essential medicines is facilitated by a network of warehouses and distribution centers throughout the country. However, despite all these initiatives, the country is still facing challenges to improve the quality of essential medicines.

The presence of substandard medicines in the pharmaceutical market of Nepal has been a concern for many years. Several studies and investigations have found evidence of substandard medicines being sold in Nepal [14, 15]. Studies have found substandard

Received: 03-11-2024 | Accepted: 10-12-2024 | Published: 17-12-2024 |

medicines in a range of therapeutic areas, including antibiotics, which can lead to treatment failure, drug resistance, and adverse effects. However, no studies have been found that assess the quality of essential medicines being supplied free of cost at the public health facilities of Nepal. Thus, this study aimed to assess the quality of selected essential medicines available in public health care facilities of Nepal.

2. METHODOLOGY

A cross sectional descriptive design was used and the study was conducted in 21 districts of Nepal representing all seven provinces. Data and medicine sample collection was carried out from June to October, 2018 in 20 districts; while data collection in Mustang was possible only on April, 2019 due to unfavorable geographical conditions and transportation barriers. Altogether 63 health facilities were selected randomly comprising one Zonal / Regional/District Hospital, one PHCC and one HP from each selected district. However, one HP of Mustang district was dropped owing to unfavorable geographical condition during data collection. In total, 3 Zonal Hospitals, 1 Regional Hospital, 17 District Hospitals (DH), 21 PHCCs, 20 HPs and 5 Regional Medial Stores (RMSs) were included in the study. Districts were selected proportionately from all three ecological regions i.e. Terai, Hill and Mountain using lottery method. From each selected district, one Zonal / Regional/District Hospital, one Primary Health Care Center (PHCC) and one Health Post (HP) were identified using random number generator. Numbers of health facilities to include in the study was determined based on WHO guidelines on 'how to investigate drug use in health facilities' [16]. The WHO guidelines provide a step-by-step approach to investigating drug use in health facilities including designing study, collecting data, analyzing and reporting findings.

Face-to-face interview was taken with health facilities in-charge of selected health facilities regarding medicine procurement and storage. Structured questionnaire based on WHO guidelines- 'how to investigate drug use in health facilities' [16] was used to collect the information. To assess the storage condition of medicine store room i.e. protection from sunlight, humidity, heat, maintenance of cleanliness and ventilation, observation checklists were prepared based on Management Division guidelines [17]. The information was recorded based on observation. Digital device was used to record temperature and humidity of the storage room.

Altogether 20 molecules were selected from essential medicines list for this study. The selection criteria of medicines were made based on the therapeutic category and their used frequency. Medicines were selected such that the sample list includes all the major therapeutic category medicines which were considered to be commonly prescribed in various illnesses by the technical working team which includes members from regulatory authorities and different stakeholders. The list of selected molecules includes:

10 molecules from hospitals- Tinidazole 500 mg tablet, Ciprofloxacin 250 mg tablet, Paracetamol syrup 60 ml, Azithromycin 500 mg tablet, Iron supplement tablet, Povidone-iodine liquid 500 ml 5% w/v solution, Aluminium Hydroxide + magnesium hydroxide 250 mg tablet, Hyoscine butylbromide 10 mg tablet, Amlo225dipine 5 mg tablet, Metformin 500 mg tablet;

5 molecules from PHCCs- Cetrizine Hydrocloride 10 mg tablet, Metronidazole 400 mg tablet, Ciprofloxacin eye and ear drops, 5 ml 0.3%w/v, Sulfamethoxazole + trimethoprim tablet 960 mg DT, Fluconazole 150 mg tablet/capsule; 5 molecules from HPs- Amoxycillin capsule 500 mg, Ranitidine 150 mg tablet, Oral rehydration salt, Salbutamol 4 mg tablet, Paracetamol 500 mg tablet.

In addition to this, 6 molecules were collected from Regional Medical Stores (RMS) which included- Paracetamol 500 mg tablet, Tinidazole 500 mg tablet (130 tablets), Ciprofloxacin 250 mg tablet (130 tablets), Oral Rehydration Salts (25 sachets), Iron supplement (130 tablets) and Amlodipine 5 mg

tablet (150 tablets). Medicine samples were collected on a zip lock bag with adequate label on it. In total, 244 batches of medicines were collected.

The drug samples collected from different health facilities were sent for testing to National Medicine Laboratory (NML)—the central laboratory that operates under the Ministry of Health and population of Nepal and is responsible for testing, analyzing, and verifying the quality, safety, and efficacy of various drugs, vaccines, and medical devices used in Nepal. The test results obtained from NML are deemed reliable and accurate as it regularly validates its analytical methods to meet international standards and guidelines.

The drug samples were tested for identification, weight variation, uniformity of content, dissolution, disintegration test, friability test, fill volume test, assay and PH based on the respective pharmacopeial guidelines that the drug sample followed. Drug samples were analyzed based on the pharmacopeial guidelines written on the label of the sample which included either United States Pharmacopeia(USP), Indian Pharmacopeia (IP) or British Pharmacopeia (BP).

The collected data were entered in epidata version 3.00 and Microsoft Excel 2007 before being analyzed with SPSS version 21.00. Ethical approval was obtained from Ethical Review Board of the Nepal Health Research Council (NHRC) prior to the onset of this study. Administrative approval was taken from Ministry of Health and Population (MoHP) to collect medicine samples from selected health facilities. An informed written consent was obtained before collection of data and medicine samples from health facilities in-charge of selected health facilities. A health facility in-charge is a health professional who is responsible for managing and overseeing the operation of the health facility including procurement of medicines, equipment, resource allocation, planning, coordination and reporting to the concerned authorities.



Findings

Out of 244 batches of 20 generic medicines sent for in vitro analysis, 37 batches failed to comply the required pharmacopeal standard i.e. 15.2% of medicines were found substandard. Among the failed medicine samples, 23 (62.2%) batches of medicines were among the federal government supplied and 14 (37.4%) batches of medicine samples were procured by local health facilities. The list of substandard medicine samples included 4 batches of medicines (3 batch of ciprofloxacin eye/ear drop vial and 1 batch of ferrous sulphate with folic acid tablet) collected from RMS. The medicine samples were found substandard with respect to dissolution test, fill volume test, assay, friability test, uniformity of content and leakage test parameters. Table 1 demonstrates the list of substandard medicines along with their source of supply. The Table 2 depicts the storage condition of medicine store room of selected health facilities. The data shows that only 13% of health facilities, out of 62 selected health facilities, followed all the storage guideline of Management Division [17] for medicine storage i.e. protection from sunlight, humidity, heat and maintenance of good ventilation. Fig 1 illustrates the storage condition of medicine storeroom of five RMS. The data shows that all the recommended guidelines for medicine storage were found to be followed by 3 (60%) RMSs only



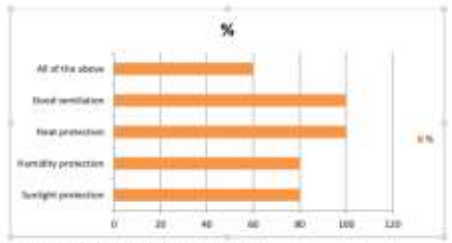


Fig 1. Storage condition of Regional Medical Stores.

The Table 3 demonstrates the range of temperature and humidity recorded at a point of time in the medicine store of health facilities. Out of total health facilities, maximum temperature record was found to be 37˚C which is greater than the recommended temperature i.e 15˚C to 25˚C [18]. Likewise, among total health facilities, maximum humidity recorded was 86% which is also higher than the recommended humidity i.e. 60% or lower [18]. The data shows that temperature and humidity measure exceeded the recommended range for medicine storage in RMS also.

3. DISCUSSION

It has been found that about 15 percent of the 244 batches of essential medicines tested were identified as substandard. Only 13% of the 62 health facilities followed the drug storage guidelines. Moreover, the highest temperature and humidity record of the drug storage room among the selected health facilities were 37˚C and 86 percent, respectively, which is greater than the recommended range. Despite the emphasis of Sustainable Development Goal (SDG) on "access to safe, effective, quality and affordable essential medicines and vaccines for all", these findings are likely to put the SDG's aim of Universal Health Coverage in jeopardy. Section 12 of the Drug Act 1978 AD states that drugs meant for public consumption should be safe, efficacious and of quality standard complying the prescribed quality standard. The Act also prohibits on manufacture, sell, import, export or store of the drugs that do not adhere to the prescribed quality standard [19]. However, out of 244 batches of essential medicines tested for quality about 15% of medicines failed to meet the pharmacopeia requirement mentioned in their respective label hence found substandard. Substandard medicines are those medicines which fail to comply with the prescribed quality standard. Similar studies conducted in Nepal by Gyanwali P. et. al. [14] and Karki KB et al. [15] also identified 32.5% (out of 40 brands) and 4.21% (out of 214 samples) substandard drugs respectively in Nepal. Thus, the availability of substandard medicines in Nepal suggests for the improvement in the national regulatory



system. This has prompted the need to review the prevailing law, regulation and policies and their implementation efficiency. Otherwise, the substandard quality of essential medicines even poses greater threat to public health and in achieving SDG goal including universal health coverage.

Evidences show that issues regarding substandard, spurious, falsely labeled, falsified and counterfeit (SSFFC) medicines have become pandemic in developing countries as well as in developed countries including India [3, 20–23]. The evidences reveal that India and China are the largest countries in manufacturing SSFC medicines [20, 24, 25]. As Nepal relies largely on neighboring countries India and China for import of medicine, the risk of SSFC medicines is inevitable in Nepal. A study carried out in Africa, Asia and South America identified both substandard and counterfeit medicines in Africa, Asia and South America with the highest number of counterfeit medicines in Asia [26]. The substandard medicines constituted 10.4% (out of 3,371 samples), 2.9% (out of 10,737 samples) and 11.5% (out of 955 samples) in Africa, Asia and South America respectively [26]. The therapeutic categories of those substandard medicines were: antimalarial, anti-tuberculosis, antibiotic, antiretroviral, anti-inflammatory and analgesics. A similar study carried out among seven countries of Africa and Asia, 21 substandard or falsified medicines out of 869

medicines sample were identified with anti-malarial drugs being greater in number [27]. Similarly, a systematic review on substandard and counterfeit medicines found that median prevalence of substandard or counterfeit medicines as 28.5% with greater prevalence of antimicrobials followed by anti-malarial and antibiotics [2].

4. CONCLUSION

The quality assessment of free medicines provided by the Government of Nepal indicated that, although most samples met pharmacopeial standards, instances of substandard quality and non-compliance were observed. These findings highlight the urgent need for strengthening pharmaceutical quality assurance systems, including stringent procurement policies, improved storage and distribution practices, and regular post-marketing surveillance. Ensuring the quality of free medicines is critical for safeguarding patient health, enhancing therapeutic outcomes, and maintaining public confidence in government healthcare initiatives. Future strategies should focus on capacity building of regulatory authorities, training of healthcare workers, and the establishment of robust monitoring mechanisms to achieve sustainable improvements in Nepal's public health system.

REFERENCES

1. Newton PN, Green MD, Ferna´ndez FM. Impact of poor-quality medicines in the 'developing'world. Trends in pharmacological sciences. 2010; 31(3):99–101. https://doi.org/10.1016/j.tips.2009.11.005 PMID: 20117849

2. Almuzaini T, Choonara I, Sammons H. Substandard and counterfeit medicines: a systematic review of the literature. BMJ open. 2013; 3(8):e002923. https://doi.org/10.1136/bmjopen-2013-002923 PMID: 23955188

3. Caudron JM, Ford N, Henkens M, Mace C, Kiddle-Monroe R, Pinel J. Substandard medicines in resource-poor settings: a problem that can no longer be ignored. Tropical Medicine & International Health. 2008; 13(8):1062–72. https://doi.org/10.1111/j.1365-3156.2008.02106.x PMID: 18631318

4. World Health Organization. How to investigate drug use in health facilities: selected drug use indicators: World Health Organization1993.

5.Procurement handbook: storage and warehouse practice. In: Management Division, editor.2074. 18. Off PL, Home P. Essential Medicines and Health Products Information Portal A World Health Organization resource. WHO Drug Information. 2003; 17(4).

6. Drug Act, (2035). Government of Nepal. https://www.dda.gov.np/content/drugs-act-2035

7. Khan A, Khar R. Current scenario of spurious and substandard medicines in india: A systematic review. Indian journal of pharmaceutical sciences. 2015; 77(1):2. https://doi.org/10.4103/0250-474x.151550 PMID: 25767312

8. Khan AY, Ghilzai NMK. Counterfeit and substandard quality of drugs: the need for an effective and stringent regulatory control in India and other developing countries. Indian journal of pharmacology. 2007; 39(4):206.

9. Behrens R, Awad A, Taylor R. Substandard and counterfeit drugs in developing countries. SAGE Publications Sage UK: London, England; 2002.

10. Christian L, Collins L, Kiatgrajai M, Merle A, Mukherji N, Quade A, editors. The problem of substandard medicines in developing countries. Madison: Workshop in International Public Affairs, La Follette School of Public Affairs at the University of Wisconsin–Madison; 2012.

11. Morris J, Stevens P. Counterfeit medicines in less developed countries. London: International Policy Network, May 2006; 3(6).

12. Kumar DP, Umasankar K, Alagusundaram M, Jayachandra Reddy P. Current Trends in Regulatory Authority Actions against Misbranded and Adulterated Drugs. International Journal of Advance Research, Ideas and Innovation in Technology. 2017; 3(3):1513–21.

13 Hajjou M, Krech L, Lane-Barlow C, Roth L, Pribluda VS, Phanouvong S, et al. Monitoring the quality of medicines: results from Africa, Asia, and South America. The American journal of tropical medicine and hygiene. 2015; 92(Suppl 6):68. https://doi.org/10.4269/ajtmh.14-0535 PMID: 25897073

14. Petersen A, Held N, Heide L, Group D-EMS. Surveillance for falsified and substandard medicines in Africa and Asia by local organizations using the low-cost GPHF Minilab. PLoS