

Assessment of the Management Practices of Controlled Medicines in a District General Hospital in Sri Lanka

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Publication Date: 2026/04/17

Abstract: Drug conventions and local drug ordinance and its management regulate the management of controlled drugs. Sri Lanka is signatory for above three drug conventions and takes necessary measures to prevent the misuse of controlled substance while ensuring their adequate availability of Medical and scientific purposes. Non - medical use of Pharmaceutical are increasing. There may trend of diversion of controlled substance. Diversion of Contolled drug may cause personal and social problems.

A descriptive cross-sectional study was done at District General Hospital Avissawella Sri Lanka to assess Management Practices of Controlled Medicines in District General Hospital Avissawella. Structured facility observation was done for data collection by using check list.

Principles of controlled drug management are largely followed however ,several gaps exist, indicating the need for further system strengthening and improvements. Assurance of availability of relevant acts and manuals in drug store, strengthening the supervision by respective supervisors, strengthening the infrastructure development, conduct staff training programmes and encouraging research studies are recommended.

Keywords: Drug conventions Drug ordinance Controlled Medicine

How to Cite: Indika Wanninayake; Mayoni Abenayake; Sashi Samarasinghe (2026) Assessment of the Management Practices of Controlled Medicines in a District General Hospital in Sri Lanka. *International Journal of Innovative Science and Research Technology*, 11(4), 817-820. <https://doi.org/10.38124/ijisrt/26apr636>

I. INTRODUCTION

According to international treaties and Sri Lankan law Narcotic drugs, psychotropic substances and precursors are categorised as control substances (1). 1961 convention which expand in 1972 protocol controls Narcotic drugs. They are mainly natural products like opioids and its derivatives, morphine and codeine...etc. Methadone and pethidine are also called synthetic narcotic drugs. Overall, hundred and forty-five narcotics which in yellow list are considered as controlled substances. The green list contains four schedules of control for psychotropic substance under the 1971 convention (2)

The effective management of controlled medicines are a crucial component of national drug control strategies. Prescribing, dispensing, administration, storage and destruction of these controlled medicines rely on a structured process which involves several professionals, policies,

procedures, tools, technologies and several national laws in Sri Lanka(3)(4)(5). Because, it is important to ensure the availability of these substances for legitimate medical use for patient care while preventing their diversion, misuse and trafficking (6)(7)(8).

Sri Lanka as a party to the three United Nations Conventions; Single Convention on narcotics Drugs 1961, Convention on Psychotropic Substances 1971 and Convention against Illicit traffic in Narcotic Drugs and Psychotropic Substances 1988 is internationally obligated to establish comprehensive system for the regulation, monitoring and reporting of controlled substances. (9)(10)(11)(12) The purpose of these international conventions is for ensuring availability for medical and scientific purposes while preventing of abuse. Therefore, the International Narcotics Control Board (INCB) continuously monitor the compliance

with these international obligations, emphasizing accurate estimates and secure supply chain.

Accordingly, align with these three international conventions, Sri Lanka has developed a domestic legal and regulatory framework to ensure the proper control of narcotic drugs and psychotropic substances. Key legislations in Sri Lanka includes, Poisons Opium and Dangerous Drugs Ordinance (amendment) Act, No. 41 of 2022 and Conventions against Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, No.01 of 2008. In Sri Lanka, these acts provide legal framework for the importation, storage, prescribing, dispensing, monitoring and disposal of controlled substances including controlled medicines. These controlled medicines include opioids, benzodiazepines, amphetamine type stimulants and other psychotropic substances. Many of these substances play a crucial role in modern healthcare system in Sri Lanka (13).

Emerging challenge in the diversion of these controlled medicine for non-medical use is affect in different ways and costs the individual, family, neighbours, friends, workforce and the community in significant and measurable ways including loss of productivity, unemployment, impairment in mental and physical health, reduce quality of life, increase of violence and crimes, abuse and negligence of children, treatment costs and finally become a huge burden to the economy of the country(14).

Diversion of these pharmaceutical substances can occur at any point of original manufacturing premises, storage, distribution, import, export, sale, consumption and destruction(14). Moreover, diversion of pharmaceutical substances may lead to insufficient availability for legitimate purposes in medical system. Therefore, Assessing the management practice in selected medical settings will help to identify these gaps and recommend improvements to ensure that the controlled medicines are managed in accordance with both International and National obligations.

Statistics are shown that drug menace is a significant problem to the country. Being its strategical location for maritime travel there is a risk for transport hub, However, arrest for trafficking of controlled medicine has shown increasing trends (15). Controlled medicines are used for patient management though it has risk of diversion. Controlled medicines are vital for management of some patients. Therefore, it is high time to assess management of controlled medicine in hospitals as they are the end users.

➤ *Objective of the Study*

- To Assess Management Practices of Controlled Medicines in a District General Hospital in Sri Lanka

II. METHODOLOGY

Descriptive Cross-sectional study was done at District General Hospital Avissawella. Observations were done in main drug store ,indoor and outdoor pharmacies. Data collection was done through structured facility observation by using check list

Two reviewers were independently reviewed the documents by data extraction form and arrived on agreements by discussions. if any disagreements. Observations were done by both investigators. Through the data extraction tool following thematic areas are assessed (16)

- Policies and governance:
- Forecasting and procurement
- Receipt and documentation:
- Security and storage
- Environment
- Inventory and stock control
- Issuing and distraction
- Losses, wastages and returns
- Disposal
- Audit, monitoring and risk assessment

III. RESULTS AND DISCUSSION

As Director General of Health Services is the main responsible person in Poisons Opium and Dangerous Drugs Ordinance (amendment) Act, No. 41 of 2022 Ministry of Health is Key focal point and Medical Supplies Division and National Medicinal Regulatory authority has key roles. According to board act 1984 and Conventions against Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, No.01 of 2008 National Dangerous Drug Control Board also has major role for Controlled medicine management. Therefore, hospital should available relevant documents for compliance. Table 1 shows the controlled medicines which are commonly used in last three years and its ordered amount

Table 1 Commonly Used Controlled Medicine and Its Consumption

Drug	2023	2024	2025
Tab Morphine 10mg IR	1000	3500	3200
Tab Morphine 10mg CR	200	300	1750
Tab Morphine 30mg IR	100	500	0
Tab Morphine 30mg CR	200	600	3100
Inj Morphine 15mg	2000	7360	4525
Inj Pethidine 50mg	1745	600	650
Inj Pethidine 75mg	377	2270	0
Inj Fentanil 100mcg	3075	4840	3155

General principles in handling-controlled medicines. They include security, access, documentation monitoring, auditing and disposal (16). These medicines must store in safe place and keep under lock. It should be non-portable metal cabinet or dedicated room. Access is given only authorized persons (Doctor, pharmacist and nurse]). Key must be kept in designated person in the shift. Accurate and complete documentation on ordering, receipt, issuing and usage. Regular monitoring and auditing should be required. Specific procedures should be followed for disposal.

District General Hospital Avssawella, follow instructions given by Medical Supplies Division (MSD) Ministry of Health According to the manual of drug management supplies (17) Principles of controlled drug management can be categorized as follows

➤ *Policies and Governance:*

MSD manual is available in the main drug store. No any standard operating procedure available in drug store.

➤ *Forecasting and Procurement*

Annual forecasting of controlled drugs is done through 'Swastha' system with other drugs. Annual forecast is depended on previous year consumption, availability of drugs in the store and prescribe pattern of the physicians.

➤ *Receipt and Documentation:*

Pharmacists who responsible for managing controlled drugs received the total amount. Then dispatch on request. Records are updated and completed. There are gaps seen in completeness of documentation

➤ *Security and Storage*

Controlled drugs are stored in a lockable cabinet in the main store and double locking system is available. Access is restricted but no CCTV monitoring available. Temperature and humidity are maintained and it is supervised by pharmacist. First in first out management is done and regular expire checks is also done

➤ *Environment*

Temperature is maintained and environment is air conditioned

➤ *Inventory and Stock Control*

Separate stock cards are not maintained however controlled drug registry is maintained. Regular stock assessment daily, weekly and monthly done through digital 'Swastha' system. No frequent internal audits done.

➤ *Issuing and Distraction*

Documentations are done during issuing and Transport

➤ *Losses, Wastages and Returns*

There is a mechanism to manage damaged and expired medicines. Further there are procedure to discrepancies. No missing stocks were reported. Documentation of Disposal were available.

➤ *Disposal*

Documentation of disposal were available. Documented destruction procedure and witnessed signature were available

➤ *Audit, Monitoring and Risk Assessment*

No CCTV monitoring and no regular auditing. No risk assessment was done

IV. CONCLUSION

Although the principles of controlled drug management are largely followed, several gaps exist, indicating the need for further system strengthening and improvements

RECOMMENDATION

- Assurance of availability of relevant acts and manuals in the drug store
- Strengthening the supervision of Director and Chief pharmacist
- Strengthening the infrastructure development: eg CCTV instalment, improve store conditions
- Conduct staff training
- Encourage to conduct research studies

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