

Balancing Safety and Efficiency: Construction and Justification of a Tiered Batch-Number Management Model for Specially Controlled Drugs in Medical Institutions

Dan Liu

First Affiliated Hospital, Army Medical University of the Chinese People's Liberation Army, Chongqing, China

Abstract: The clinical value of the special controlled drug, such as narcotic drugs, psychotropic drugs, medical toxic drugs and pharmaceutical precursor chemicals are of great importance and they are also at high risk of abuse and diversion. The batch number (lot number) control is the most effective system that can be used to ensure traceability of all the processes in the whole production process and to reduce the risks of management. In China, the homogenous model of full batch number, full process, uniform standard is being used by the medical institutions when it comes to all the special controlled drugs. This is a safety-based model which is expensive in terms of administration, not efficient enough in terms of operations, and does not align with the amount of resources available versus the level of risk incurred. Based on the concept of risk stratification and experience of other countries in terms of control of controlled substances in terms of addiction potential, harm of abuse, frequency of use of drugs in clinical practice, and possibility of circulation of the drug, this paper will consider these four parameters as the key dimensions and develop a three-level system of batch-number management. Level 1: High-risk medicines must be traced in one unit and processed in full; Level 2: Medium-risk medicines must be tracked through its key nodes; and Level 3: Low-risk medicines must be managed through the summary of the batches.

The model is analyzed in a systematic manner through three dimensions, regulatory compliance, scientific rationality and industrial adaptability. The findings show that the model maintains the regulatory safety baseline, matches control intensity to risk, encompasses all types of special controlled drugs, and at the same time ensures full traceability, but maximizes

resource use and enhances clinical efficiency. It provides a theoretical framework and practical solution that can be replicated to achieve refined management of special controlled drugs in medical institutions.

Keywords: Narcotic Drugs; Class I Psychotropic Drugs; Class II Psychotropic Drugs; Toxic Drugs; Precursor Chemicals; Batch Number Management; Tiered Management; Risk Control

1. Introduction

These are the drugs that are of special use and cannot be administered in any other way except by a medical professional to treat pain, surgery or mental health disorders. They also have powerful physiological effects of dependency, addiction and toxicity. These can become very harmful to the society and its people when not properly controlled and they end up being diverted into the illegal market. These substances are thus subjected to the most severe regimes of special control throughout the world and the batch number as the main vehicle of the full-lifecycle traceability is the only internal control in the medical institution.

The applicable domestic management standards specifically state that the procurement, receipt, storage, dispensing, clinical use and recovery of specially controlled drugs must be batch-numbered and tracked so as to ensure that each unit can be traced back to its source and forward to its destination [1,2]. In reality, medical institutions at all levels have embraced an undifferentiated full-batch-number model whereby every controlled drug and every circulation node is subjected to equally stringent batch registration, double-checking and item-by-item recording. This model has created a safety line which however comes with high administrative costs, constrained clinical efficiency and mismatched human resources:

high-risk drugs still leave room for stronger control whereas low-risk drugs consume excessive management effort resulting in a structural contradiction where that which should be stricter is not and that which should be lighter cannot be lightened.

The system of controlled-substance internationally is in general risk-tiering philosophy. The main international conventions have the schedules based on the level of dependence and harm that are used to control the controlled substances and this forms the basic framework of the global system. Similar five- and three-tier classification systems have been developed by the United States and the United Kingdom, where the level of regulation is equal to the level of risk [3,4]. In an attempt to follow this strategy, the current research paper will introduce the concept of stratification of risks to the management of the batch-number of medical facilities. With the guiding principle of not loosening the minimum safety standard, but enhancing the efficiency with evidence, it has built a model of batch numbers of narcotics and psychotropics drugs, medicines, toxic drugs, pharmaceutical precursors and so on, as well as explained the reason why such a model is necessary, which provides new ideas and practical guidelines to the special drug management of medical institutions.

2. Related Works and Problem Analysis

2.1 Current Batch-Number Control in China

The supervision system of the Chinese government is a three-level one, namely, the national-provincial-medical institution in case of specially controlled drugs. The main actions at the institutional level include the five-special management (the special personnel, the locked cabinet, the special book, the special prescriptions and the special registration) and the two-person and two-lock mechanism that are implemented throughout the whole process [1,5]. According to the existing standards of management, it is necessary to register all narcotic drugs, Class I psychotropic drugs, medical toxic drugs, as well as pharmaceutical precursor chemical products by batches on entering, storing, dispensing, using, and recovering them with a record of at least 5 years after expiration of drug; and batch control and tracking of class II psychotropic drugs [2]. It is also true that in reality, a number of Chinese

medical organizations have been experimenting with the use of the informatized systems including automated dispensing cabinets, electronic prescribing system and controlled-drug traceability to enhance the precision and speed of the batch-number management [6,7]. But on the whole, it is within the framework of homogeneous full-batch-number management: all drugs are treated as equally dangerous or used at the same rate. With the increasing clinical application of special-controlled medicines and the increase in the number of medicines available, the weakness of this model has become more and more obvious:

(1) Management resource misallocation. The same degree of control is used in high-risk, high-volume drugs like fentanyl injection and morphine injection as well as low-risk, low-volume drugs like diazepam tablets and buprenorphine patches; this results in the under-control of high-risk nodes and wastage of human and material resources on low-risk nodes.

(2) Restricted clinical productivity. Batch verification and registration at pharmacy dispensing, ward handover and empty ampoule recovery significantly adds to documentation time for pharmacists and nurses, occupying the time for direct clinical care.

(3) Traceability precision in excess. The excessive batch tracking of the drugs that are very rarely used has not helped to enhance the safety, but rather complicated the management.

2.2 International Experience in Classified Control

The essence of the international controlled-substance regime is that the level of control must be proportional to the risk. International studies are relevant in scientifically assessing psychoactive substances on the basis of fundamental criteria like addiction potential, harm of abuse and medical value and creates a graded classification system [8]. The U.S. Drug Enforcement Administration classifies controlled drugs into Schedules I-V with the least intensity of control: Schedule I drugs have no approved medical use and very high abuse potential; Schedule II drugs have significant medical utility but also have very high abuse potential and are subject to the most stringent prescribing and distribution controls; Schedules III-V have progressively less abuse potential and fewer restrictions [3]. Controlled drugs in the United Kingdom are categorized as Classes A, B,

and C, which are based on varying levels of prescription authority, record keeping, and storage standards [4].

In the intra-institutional level, the hospitals of European and American countries tend to have a different approach to batch-number management based on the schedule of controlled substances: drugs that are in the highest schedules would be recorded at the single unit, the medium-schedule ones would be recorded by ward batches, and the low-schedules drugs would be registered periodically with a summary record, which is the most effective way to maintain traceability [3,4].

2.3 Problem Statement

The existing model of batch-number management in China is aimed at the concept of absolute safety and lacks efficiency and insufficient reflection of risk variations between drugs and process points. Based on the international risk-tiering ideas and modifying them to the Chinese medical institution realities, developing a scientifically viable and feasible tiered batch-number management model that includes all types of narcotic and psychotropic drugs, toxic drugs, and precursor chemicals-and which enhances operational effectiveness without reducing safety- is an immediate practical problem in the area of controlled-drug management.

3. Tiered Batch-Number Management Model Construction

3.1 Guiding Principles

(1) Safety-baseline principle. The concept of tiered management is based on the safety of drugs and diversion prevention. The standards of control of high-risk drugs are not less than the existing regulatory standards, which makes all drugs traceable and verifiable.

(2) The principle of risk-matching. The intensity of control is positively correlated with the risk level of a drug and the risk of each process node; the higher the risk, the finer the batch number tracking and the stricter the management process.

(3) The principle of efficiency improvement. The low risk drug batch management system is reduced to a minimum and the excess activities are removed so as to make the managers free in the high risk fields.

(4) Feasibility principle. The model is compatible with the current institutional processes and can be integrated into the existing information systems without heavy hardware expenditure.

3.2 Risk Tiering and Correspondence with Batch-Number Levels

Table 1. Drug Risk Levels and Management of Batch-Numbers.

Risk tier	Categories of drugs and representative examples	Batch-number level	Core management characteristics
High risk	Injections of narcotics (morphine injection, fentanyl injection, sufentanil injection and so on); injectable psychotropic drugs of the first class (ketamine injection); medical drugs that are toxic; pharmaceutical chemical precursors.	Level 1	Tracking in single units or doses, tracking of the entire process in batches, two people confirmation.
Medium risk	Oral solid - dose narcotics (morphine sustained - release tablets, oxycodone sustained - release tablets, etc.); Psychotropic oral drugs of Class I (methylphenidate tablets and triazolam tablets, for instance). There are high - risk injectables of psychotropics of Class II (dezocine injection, etc.).	Level 2	minimum-package batch tracking; registration of batches at key nodes; one person verification plus sampling
Low risk	Psychotropic oral formulations (diazepam tablets, estazolam tablets, zopiclone tablets, etc.); transdermal preparations (buprenorphine patch)	Level 3	Batch summary management; periodic registration; ledger reconciliation

According to the Catalog of Narcotic and Psychotropic Drugs, Catalog of Medical Toxic Drugs and list of pharmaceutical precursor chemicals, combining five dimensions; addiction potential, abuse risk, toxic harm, frequency of

clinical use, dosage-form characteristics, commonly used special controlled drugs in medical institutions are categorized into three risk levels, which is reflected in a three-level batch-number management model (Table 1).

3.3 Tiered Implementation Across the Full Process

3.3.1 Procurement and acceptance

Level 1: opening of a box by two people; counting to the least package; checking of batch number, expiry date and quantity box-by-box; separate ledger on each batch with dual signatures.

Level 2: one person acceptance; minimum-package batch verification; batch enter the system; sample rate is not less than 30%.

Level 3: acceptance by whole case batch; registration of total manufactured batch quantity; automatic batch linkage in the system; sampling rate not less than 10%.

3.3.2 Storage and custody

Level 1: a storage room and cabinet that is double locked; the shelves are batch-segregated with an easy to understand labels, and daily inventory is done with the same day reconciliation.

Level 2: locked cabinet; batch-separated by drug; complete inventory weekly and dynamic consumption checked daily.

Level 3: assigned storage location; monthly inventory count; first-in-first-out at the batch level; regular ledger reconciliation.

3.3.3 Dispensing and distribution

Level 1: one unit dispensing to the prescriptions; recording of batch number of each unit by the system automatically; verification and signing twice by dispenser and reviewer, one to one correspondence between prescription and batch.

Level 2: Dispense by prescription dose; register minimum-package lot; single pharmacist review; system retention of lot records automatic.

Level 3: total prescribed quantity dispensing; distribution batch registration and the summary of the reconciliation of the batches in a regular interval without having to register each prescription.

3.3.4 Clinical use and recovery

Level 1: double check of drugs and patients' identity at administration; empty ampoules/packages retrieved and counted by batch number; batch and quantity checked unit by unit on return to pharmacy with double signature.

Level 2: the check of the number of empty packages after use; batch recovery and sampling in pharmacy.

Level 3: no recovery of packages after use; regular reconciliation of usage and stock.

3.4 Informatization Support System

The implementation of the batch-number management system is reliant on the support of the hospital information system (HIS) and the pharmacy management system, as well as the controlled-drug traceability system:

(1) The system will be equipped with the drug risk levels and batch-management principles, which will be applied automatically to match the management workflow without human intervention.

(2) Level 1 drugs have complete chain binding of drug-batch-prescription-patient-staff, and barcode scanning is used to register storage, dispensing and administration.

(3) Level 2 and Level 3 drugs are used to facilitate batch entry and batch reconciliation with the automatic production of statistical reports.

(4) A real-time warning system of batch mismatch, quantity anomalies and overdue storage of Level 1 drugs is an anomaly-alert mechanism.

4. Regulatory Compliance and Practical Adaptability

The three-level batch-number model was built in the previous section based on risk stratification theory. Its regulatory bottom line, logical rationality and practical adaptability are the essential requirements to implement and spread it. This part of the text systematically analyzes the model in three aspects, namely the regulatory framework, management-science logic, and industry benchmarking, and explains the reason why efficiency is maximized without crossing the safety red line.

4.1 Regulatory Compliance

The main regulation of specially controlled drugs in China can be defined as follows: the entire process of control, traceability, and accountability; stock account; personal responsibility. The model of tiered batch-number is also very strict to the existing regulatory regime with all tiers being based on a principle of not compromising the safety level at any cost but keeping the standard of basic control intact at all risk levels [1,2].

The domestic management regulations are concerned with the adaptability of clauses, which implies that the medical institutions must make sure that the source and destination of

procurement, storage, dispensing, use and recovery are traceable to each other and there is a consistent accounting; they do not require all drugs and all nodes to be subject to an identical process [1,2]. The single-unit tracking and double-checking in the proposed model will cover high-risk injectables, toxic drug and pharmaceutical precursor chemicals (Level 1) and it will meet and even surpass the requirements of the existing system and will also have the safety floor in the highest risk categories. At level 2, the drugs still keep the core traceability points at key-nodes of batch tracking of medium risk preparations and statutory verifiability is met. Level 3 drugs apply the batch summary control on low risk oral and topical preparations but with full record keeping and reconciliation of batches as well as within the regulatory scope.

Regarding the compliance at the node level, the four core processes of procurement-acceptance, storage, dispensing and recovery-reconciliation are tiered design in accordance with the fundamental control elements that are stipulated by regulation; only the non-core procedures of low-risk categories are simplified and there is no violation of any prohibitive regulatory provision. All drugs at all levels have full management records and a chain of responsibility which meet the requirements of supervisory inspection and traceability.

4.2 Logical Rationality of Risk Stratification

It is a matter of fact that the control and risk are in proportion to each other as one of the principles of the contemporary refined management and general logic of the international controlled-substance system. The model of tiered batch-numbering is actually an extension and application of the national macro-control at the level of classification into the micro-control of medical establishments, and its management rationale is also rationalized.

Regarding the risk-dimension, the drugs were ranked in terms of the degree of addiction and toxicity to the body, frequency of use and form of dosage, so that high-risk injectables, toxic substances, and precursor chemicals can be tracked at a single unit level with the highest level of precision; medium-risk oral preparations are not very dangerous to abuse and are used in relative proportions, and thus require the lowest package management and simplification of daily routine operations and tracking; low-risk oral

and topical preparations have less addictive properties and the ability to be diverted. This is a gradient design which is an answer to the misallocation of resources by the traditional homogeneous model whereby high risk zones were poorly resourced and low risk zones were over-controlled.

In the context of management-efficiency logic, tiered management allocates scarce human resources and attention to high-risk nodes via a differentiated process design, thus preventing excessive management of low-risk nodes and insufficient control of high-risk nodes. Relative to the “one-size-fits-all” traditional model, the tiered model is consistent with the Pareto principle in management science: the majority of risk is covered by core control investment, while simplified procedures liberate management cost for low-risk nodes, together realizing Pareto optimality of safety and efficiency.

4.3 Industry Benchmarking and Expected Value

Chinese medical institutions are gradually shifting towards refined and intelligent management of specially controlled drugs, with many medical institutions enhancing their efficiency by process optimization and informatization; risk stratification has been an acknowledged industrial direction [6,7,9].

Regarding industry benchmarking, some tertiary-A hospitals have experimented with batch-based, simplified management of Class II psychotropic drugs that has dramatically enhanced pharmacy dispensing efficiency without compromising safety; regional quality-control centers of controlled-drug management have also suggested differentiated management based on drug risk tier to prevent over-control affecting clinical medication effectiveness [5,10]. The three-level batch-number model put forward here is a systematic, standardized improvement of these scattered practices into a complete tiered system encompassing all categories and all nodes and closely following the trends in the industry.

The model is expected to be applied with two-fold benefits of safety and efficiency. In the area of safety, there are additional advantages that tilt towards high-risk drugs in the sense that they would decrease the risk of errors as well as diversion and enhance accuracy of control of safety. In the case of efficiency, it can be assumed that the overall impact of similar

domestic process improvements will be a significant reduction of documentation time: 35-45% on the total inventory, 25-35% on clinical dispensing, and 20-30% on the amount of work performed by management staff, and therefore more time spent in the provision of direct services to patients. The model is flexible as well: the parameters of the tiering system and the details of the management may be easily modified based on the size of the institutions at various levels, including large tertiary-A hospitals and even primary-care facilities, which are less complex in their structure.

5. Discussion

5.1 Core Value of the Tiered Model

The tiered batch-number model is basically the operationalization of risk management to the lowest unit of intra-institutional drug flow. The traditional model has its management boundary drawn by broad drug category (narcotic/Class I psychotropic/Class II psychotropic/toxic), and the tiered model further breaks it down into degree of risk, where the most stringent batch tracking and greatest personnel investment are allocated to high-risk injectables, toxic drugs, and precursor chemicals in order to reinforce the core safety line, whereas low-risk oral preparations are subjected to simplified procedures that minimize redundant management cost, which ultimately result in Pareto improvement in safety and efficiency.

The model has the regulatory floor on the safety side and offers a definite optimization line on the efficiency side, which solves the old management dilemma where safety and efficiency were considered as trade-offs. Especially in the context of increasing clinical application of specially controlled drugs and overall high workload among staff, efficiency improvements allow pharmacists and nurses to spend more time on direct patient care, which is of significant practical importance.

5.2 Key Enabling Conditions

(1) Regulatory standards. The present regulation is very rigid in its compliance with the current regulatory requirements, the management level 1 complies to the regulations and the simplification of the drugs at the levels 2 and 3 is done under the guidelines of the regulations [1,2].

(2) Informationization support. Without the

support of the automated system, the hierarchical management would raise the cost of manual judgment and decrease the efficiency. The intelligent management systems are needed for embedded rules, automatic matching, scanning registration, and batch processing [6,7]. (3) Staff training and consensus. The pharmacy, nursing and medical-affairs personnel must be fully trained before implementation so that management procedures and responsibility boundaries of each level can be explained to them in order to avoid loopholes caused by misinterpretation.

(4) The mechanism of dynamic adjustment. It is not fixed that the drug risk levels are to be assessed and modified in accordance with the use and abuse of drugs as per clinical data and the control should be kept at a level that corresponds to the risk level.

5.3 Limitations and Outlook

The present paper is not a multi-center empirical study, but the model construction and justification are in progress; it remains to be seen how the model would perform at various institutions of different levels and kinds. It will be possible to conduct prospective controlled studies based on real-world data in the future to prove the advantages of the safety and efficiency, as well as the implementation of the Internet of Things and blockchain technology to improve the automation of the batch traceability system and increase its reliability and accuracy of the controlled-drug control process.

6. Conclusion

To respond to the pain point of homogeneous full-batch-number management of specially controlled drugs in medical institutions, this study constructs a risk-stratified three-level batch-number management model and systematically justifies it from three dimensions: regulatory compliance, rationality, and adaptability. The model covers narcotic drugs, Class I psychotropic drugs, Class II psychotropic drugs, medical toxic drugs, and pharmaceutical precursor chemicals comprehensively. While holding the safety baseline and ensuring full-process traceability, it optimizes resource allocation through differentiated control, significantly improves management efficiency, and reduces labor cost, achieving coordinated safety and efficiency. The tiered batch-number model is consistent with the direction of refined

management of specially controlled drugs, has good operability and dissemination value, and can be used as a reference for medical institutions at all levels optimizing their controlled-drug management systems.

References

- [1] Geng KK, Jiang L, Zhen JC, Shi TL, Zhang W, Lu J, et al. Development and analysis of standards for drugs under special management. *Herald of Medicine*, 2024, 43(8):1217-1221.
- [2] Liang JH. Evaluation and optimization of the classified management system of narcotic and psychotropic drugs in China: strategic suggestions for coordinating safety control and rational drug use. *Chinese Journal of Psychiatry*, 2026, 59(3):185-192.
- [3] Westrick SC, DiPiro JT, Guirguis AB, Buckley T, Hall K. Controlled substance diversion in health systems: a failure modes and effects analysis for prevention. *Journal of Advanced Nursing*, 2020, 76(10):2632-2643.
- [4] Videau M, Atkinson S, Thibault M, Lebel D, Bussi res JF. Compliance with recommended practices for management of controlled substances in a health care facility and corrective actions. *Canadian Journal of Hospital Pharmacy*, 2018, 72(3):175-184.
- [5] Shang YG, Zhang CC, Guo DJ, Qin WJ, Li PM, Zhang L. Investigation and analysis of the current status of narcotic and psychotropic drug management in medical institutions in Chaoyang District, Beijing, based on schema theory. *Chinese Journal of Hospital Pharmacy*, 2025, 45(13):1-6.
- [6] Yang WB, Geng Z, Qiu Q, Pu JW, Pan J. Construction and application of an intelligent narcotic and psychotropic drug management system in inpatient pharmacy based on failure mode and effect analysis. *Chinese Journal of Modern Applied Pharmacy*, 2023, 40(9):1253-1259.
- [7] Shi XF, Sun ZY, Zhang XF, Lu XJ, Du SZ, Zhang XJ. Whole-process management of outpatient narcotic and psychotropic drugs based on an intelligent information management system. *Chinese Journal of Pharmacovigilance*, 2023, 20(8):899-903.
- [8] Fan M, Tscheng D. Diversion of controlled drugs in hospitals: a scoping review of contributors and safeguards. *Journal of Hospital Medicine*, 2019, 14(8):492-500.
- [9] Li F, Chen G, Liu JY, Yang Y, Liu D. Development and evaluation of full-process traceability management system for narcotic and psychotropic drugs in operating rooms based on single-unit coding and multi-system integration. *Herald of Medicine*, 2026, 45(9):1633-1637.
- [10] Teng M, An XH, Liu GY, Zhang H, Jia CJ, Wang X. PDCA practice for management quality improvement of narcotics and psychotropic drug in operating room. *Journal of Nursing*, 2024, 31(14):38-42.