Research on the Rule of Law for Drug Safety Governance Based on Contradiction Matrix

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Abstract. Objective To construct a contradiction matrix for rule of law in drug safety governance, provide scientific tools for solving drug safety governance problems, and improve the level of rule of law in drug safety governance. Methods Firstly, the problems in the rule of law of drug safety governance were extracted from two perspectives of system management and process management, and constructed into the parameters of rule of law for drug safety governance. Secondly, the parameters and the 40 innovative principles are combined to build the contradictions matrix of rule of law for drug safety governance. Finally, taking the construction of China's pharmacovigilance system as an example, we discuss the practical application of the contradiction matrix and translate the innovative principles into concrete solutions. Results Twenty-three parameters of the rule of law in drug safety governance, including 8 system management parameters and 15 rule of law process parameters, were constructed into a 23*23 contradiction matrix of rule of law in drug safety governance. Conclusion The contradiction matrix can be applied to the field of drug safety governance to provide innovative solutions for drug safety governance challenges.

Keywords: drug safety; rule of law in governance; contradiction matrix; contradictory parameter

1 Introduction

The rule of law is the basic way to govern the country. After the concept of social governance was first introduced at the Third Plenary Session of the 18th CPC Central Committee, it was emphasized that social conflicts should be resolved by applying rule of law thinking and methods [1]. In the field of food and drug safety governance, General Secretary Xi Jinping proposed the guiding ideology of four strictest, which provides theoretical guidance and development direction for the rule of law of drug safety governance in China. The connotation of the rule of law in drug safety governance is to improve the variety, quantity and quality of medicines for the public, to establish and improve a fair, orderly and predictable drug regulatory environment, to strengthen the

A. Rauf et al. (eds.), *Proceedings of the 3rd International Conference on Management Science and Software Engineering (ICMSSE 2023)*, Atlantis Highlights in Engineering 20,
https://doi.org/10.2991/978-94-6463-262-0_109

awareness of the rule of law among law enforcement personnel and the people, and to reduce the occurrence of drug-related incidents.

At present, the new revised Drug Administration Law and Vaccine Administration Law have been formally implemented. The new versions responded to social concerns and further improve the provisions of the whole process of drug regulation. Meanwhile, after the institutional reform, China has formed a comprehensive regulatory model of big market - special drugs, so the drug regulatory mechanism and the capacity has been gradually improved [2]. However, the reform of regulatory agencies and the implementation of the new law have also brought new problems, such as the increased difficulty in judging the qualification of cases, the poor connection between the drug security investigations and the supervision, and the difficulties in the implementation of pharmacovigilance systems. In addition, law enforcement officers, pharmaceutical staff and the public all need some guidance and control in learning and abiding by the law.

The contradiction matrix is an innovation method in the theory of inventive problem solving (TRIZ), which was proposed by the Soviet inventor Archishuler based on the study of a large amount of patent literature. It specifically includes generic parameters for expressing the performance of engineering systems (which can be divided into improved parameters and deteriorated parameters), and a set of guiding principles (the 40 innovation principles) that can resolve the contradictions. The aim is to avoid compromises and trade-offs and to maximize the benefits as much as possible when faced with a pair of conflicting things in a system (e.g., cost and quality). The general steps for solving problems in the field of drug safety governance using the contradiction matrix are (1) transforming the particular problem into a generic problem in the matrix, i.e., describing the problem in the field of drug safety governance using the parameters in the matrix; (2) finding the appropriate innovation principles in the matrix; and (3) combining the principles with the actual situation and relevant knowledge to generate a specific solution for the specific problem. The details are shown in Figure 1

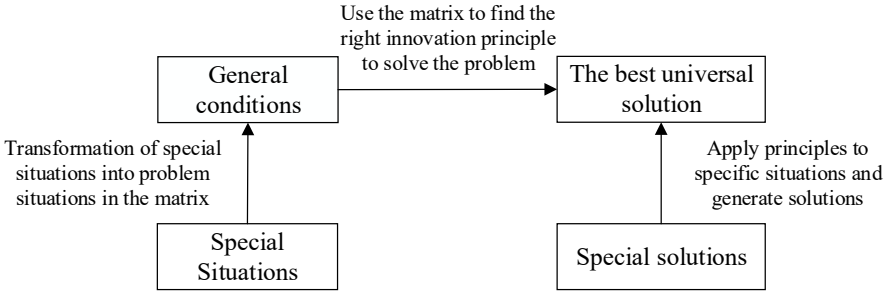

Fig. 1. General steps of problem solving with contradiction matrix

2 Parameters of rule of law for drug safety governance

To transform the problems in the field of drug safety governance into matrix generic problems, the original parameters in the matrix need to be transformed so that they can represent the main problems in the field of drug safety governance. Referring to the

construction method of commercial management parameters [3], the rule of law parameters of drug safety governance are constructed from two perspectives of system management and process management, so that situations that may generate management compromises as well as conflicts can be mapped into the constructed parameters as much as possible.

2.1 System management parameters

System management parameters are the factors that should be considered when designing or improving a system. By taking a problem-oriented approach to sort out the current problems in the rule of law of drug safety governance, and dividing the problems into national level and local government departments by the subject of formulation. In selecting and defining the parameters, eight system management parameters for the rule of law in drug safety governance were formed by referring to the management consulting service parameters [4] and the general management parameters [5] and combining the issues of public demand, specialization, institutionalization, program design, internal conflict, relationship complexity, control complexity and information technology.

The national level refers to the laws and regulations promulgated by the National People's Congress and the State Council, such as the Drug Administration Law, the Criminal Law, and the Regulations for the Implementation of the Drug Administration Law. The main problems include the inadequacy of the legal system and the lack of fluency in the articulation of sectoral laws, corresponding to the 2 main contradictory parameters of program design and relationship complexity. This is shown in Table 1.

Table 1. Rule of law issues and corresponding parameters for drug safety governance at the national level

Problems	Parameters to be improved	management parameters and sources	TRIZ engineering parameters
The definition of fake and inferior medicines in the *Drug Administration Law* is unclear, such as the definition of fake medicines *beyond the scope of the prescribed* refers to what range [6]	Program Design	Program Design, [4]	Manufacturing Precision
Poor legislative convergence between administrative responsibility for drug management and criminal liability, such as inconsistencies in the provisions of the *Drug Administration Law* and the *Administrative Penalties Law* and the *Criminal Law* on law enforcement, penalties, etc., and the subjective elements are more difficult to grasp[7]	Relationship Complexity	Relationship Complexity, [4]	System Complexity
The vaccine marketing authorization holder system is not perfect, the rules of the production access system are incomplete [8]	Program Design	Program Design, [4]	Manufacturing Precision

Poor interface between the *Vaccine Control Law* and the *Criminal Law*, such as failure to respond to previous cases of vaccine crimes adjudicated as illegal business[9]	Relationship Complexity	Relationship Complexity，[4]	System Complexity

Local government departments refer to local governments, departments of the State Council and other institutions, such as the national and provincial Drug Administration, Health and Wellness Committee, etc. The main issues include the content details of regulations and enforcement practices, which correspond to six contradictory parameters: internal conflict, control complexity, institutionalization, informatization, specialization, and public demand. This is shown in Table 2.

Table 2. Rule of law issues and corresponding parameters for drug safety governance in local government departments

Problems	**Parameters to be improved**	**management parameters and sources**	**TRIZ engineering parameters**
Local laws and regulations have not been revised in a timely manner, so there are inconsistencies between these and the newly revised *Drug Administration Law* [10] Laxity and loopholes in relevant laws and regulations in drug administration, such as drug manufacturing license renewal provision are vague definitions, not clearly defined renewal and late renewal procedures[11]	Internal Conflict	Internal Conflict，[4]	Other Harmful Effects Generated by System
Poor connection between administrative and criminal liability procedures for drug management, such as lack of standardized procedure for transferring administrative detention cases, and difficulties in identifying fake and substandard drugs in law enforcement practice[12] Fake and substandard drugs identified poor interface between the testing agency and the judiciary, the division of labor requirements, workflow is not clear [13]	Controlling Complexity	Controlling Complexity，[4]	Controlling complexity
The administrative penalty procedures, discretionary system, evidence proof standards and other issues in drug supervision and enforcement practice need to be clarified and refined, such as the definition of *first violation*, the proof of *subjective fault*, etc.[14] The interpretative rules in drug regulation need to be improved in terms of formulation procedures and contents, such as not listening to the opinions of administrative counterparts, not consulting the opinions of lower-level regulatory departments and staff, and	Institutionalization	Institutionalization，standardization，[5]	Duration of Action of Moving Object

whether they are consistent with the provisions of the higher law[15] The management of preparation use in hospital groups and medical associations is not perfect, such as the concept of *disguised sales* is vague, *unauthorized use of preparations* is not clear; and the subject of responsibility for illegal acts such as the purchase of fake and inferior drugs is not clear, and the penalty department is not clear[16] The rules of *Good Clinical Practice* are not perfect, such as drug types, review subjects, review contents, review points, review procedures, etc.[17] The pharmacovigilance system is fragmented and lacks a systematic regulatory system, including poor implementation rules, monitoring scope, database and reporting format [18]			
Pharmacovigilance segmentation regulation and information sharing is not in place, active monitoring technology is not mature[18] Drug traceability technology is immature and cannot be traced to each pharmacy and medical institution, and cannot meet the traceability requirements of Internet drug purchase[19] China's drug standards information query system has not been established, drug registration standards are scattered and not uniform, so it is difficult to obtain the corresponding standards when the grass-roots drug testing organizations sampling test [20]	Informatization	Informatization level, [4]	Automation
Inadequate rule of law thinking and capability of drug regulatory personnel, the use of laws and regulations in specific administrative law enforcement is not in place[10]	Specialization	Specialization, [5]	Strength
The form, content, scope and frequency of legal popularization are not deep enough to match the legal revision, social environment and public demand, and fail to reduce the occurrence of drug violations at the source[10]	Public Demand	Public Demand, [4]	Stress
Unclear responsibility for the supervision of vaccine production and unclear institutional responsibilities; local governments relax the supervision of vaccine production due to financial taxation[8] The courts' sentencing of vaccine crime cases is characterized by improper penalties and misdemeanors, such as the crime of manufacturing and circulating vaccines without a marketing license, which can only be dealt with under the crime of illegal operation[9]	Controlling complexity	Controlling complexity, [4]	Controlling complexity

2.2 Process management parameters

In the business management parameters, management is divided into four segments: R&D (research and development) - production - supply - support, and each segment is divided into five aspects: capacity, cost, time, risk, and interface, resulting in 20 business process parameters.

The rule of law in drug safety governance can be generally divided into three parts: legislation – implementation - supervision. Among them, legislation can correspond to R&D and production in the business process, because public services such as laws and regulations are one-off services and cannot be clearly distinguished from R&D and production, so they should be considered as a link [3]. Legislation mainly includes the formulation, deliberation, and public announcement of drug-related laws. The word implementation may correspond to supply. In jurisprudence, the implementation of law refers to the application and realization of the requirements of legal norms in social life through various forms of law enforcement, justice, law compliance, and legal supervision [21]. Here, from the rule of law process, only law enforcement, justice and law compliance are included, such as drug safety special rectification action, adverse drug reaction monitoring, and the implementation of the main responsibility of drug quality and safety by drug marketing authorization holders. The term supervision can correspond to support, which refers to the supervision of state organs, social organizations and citizens on the legality of legal activities related to drug safety, such as the supervision of state power organs on legislation and law enforcement in the field of drugs, the supervision of inspection organs, as well as the supervision of social organizations and public opinion.

Similarly, each part of the rule of law process can be divided into five areas: capacity, cost, time, risk, and interface, which constitute the 15 rule of law process parameters.

2.3 Parameter normalization

Combining the 8 system management parameters and 15 process management parameters, a total of 23 drug safety governance rule of law parameters were obtained, as shown in Table 3.

Table 3. Parameters of rule of law for drug safety governance

Legislative Capacity	Implementation Capacity	Supervision Capacity	Public Demand	Relationship Complexity
Legislative Costs	Implementation Costs	Supervision Costs	Specialization	Control Complexity
Legislative Time	Implementation Time	Supervision Time	Institutionalization	Informatization
Legislative Risk	Implementation Risks	Supervision Risks	Program Design	
Legislative Interface	Implementation Interface	Supervision Interface	Internal Conflict	

3 Construction and application of the contradiction matrix of rule of law for drug safety governance

The vertical axis of the contradiction matrix is the parameter that needs to be improved, the horizontal axis is the parameter that causes deterioration in the improvement process, and the square corresponding to the intersection of the two axes is the number of the innovation principle that can resolve the contradiction. Experts believe that the 40 innovation principles can spread thinking and provide effective directions and ideas for solutions, so the way of interpretation should not be overly restricted [22]. Therefore the 40 innovation principles can be given different connotations according to the characteristics of the management profession and the actual situation, and for innovative ideas of management challenges.

3.1 Constructing the contradiction matrix of rule of law for drug safety governance

Combining the 40 innovative principles, the 23 parameters of the rule of law for drug safety governance were constructed into a 23*23 contradiction matrix. Some examples are shown in Table 4.

When faced with a pair of conflicts in the field of drug safety, the table can be searched to quickly find the most common and effective solution ideas. Often there will be more than one principle corresponding to a pair of conflicts, and the most useful principle can be selected for a given situation, or several principles can be used in combination.

Table 4. Example of rule of law contradiction matrix for drug safety governance (partial)

Worsening parameters / Improving parameters		Legislative Capacity L1	Legislative Costs L2	Legislative Time L3	Legislative Risk L4	Legislative Interface L5
Legislative Capacity	L1	——	2,4,15,38,5,27,1	21,38,35,23,5,6,20	3,9,24,23,24,35,10	3,13,24,33,5,6,17, 40
Legislative Costs	L2	2,4,15,38,37,35,10,3	——	26,34,1,10,5,29,35,2	27,9,34,16,5,35,40,23	13,26,35,10,15,23,29, 5
Legislative Time	L3	21,38,35,23, 6,10,2	26,34,1,10,2,6,15	——	1,29,10,40,5,20,15	15,25,35,1,40,23,3
Legislative Risk	L4	3,9,24,23,5,10,2	27,9,34,16,6,7,23,26	1,29,10,40,6,15,7,37	——	6,29,15,14,7,5,3,37
Legislative Interface	L5	3,13,24,33,5,7,37,1	13,26,35,10,15,25	15,25,35,1,23,29	6,29,15,14,7,3,17, 23	——

3.2 Application Case Study

The most important step in using the contradiction matrix to solve problems in the field of drug safety governance is to translate the corresponding innovation principles in the

matrix into specific solutions for specific problems. In this case, we choose the practice of building pharmacovigilance management system in China to explore the contradictions in the practical implementation of legal regulations and how to use the contradiction matrix and the innovation principles to propose specific solutions.

Because the management system itself is complex in nature and contains multiple management issues, only the most significant management issues are analyzed in the case study from the perspective of the rule of law in drug safety governance.

3.2.1 Description of the case background.

Pharmacovigilance refers to the activities of monitoring, identifying, evaluating and controlling adverse drug reactions and other harmful reactions related to drug use. The newly revised *Drug Administration Law of the People's Republic of China* in 2019 proposes the establishment of a pharmacovigilance system, which is of great significance for future new drug development and drug regulation. However, China's pharmacovigilance system is still in its infancy, the pharmacovigilance system is not perfect, monitoring data is not effective enough, and drug risks cannot be effectively identified and controlled, which poses challenges to drug regulation and policymaking [23].

3.2.2 The main innovation issues in the case and the main contradictions involved.

The main problem to be solved in this case is how to establish and improve China's pharmacovigilance management system and improve the government's ability to manage drug safety risks from the legal level. This coincides with the *implementation capacity* in the rule of law parameter of drug safety governance, i.e., the improvement parameter is: implementation capacity (L6). While improving the ability to implement drug safety risk management, risks of system implementation may arise, such as deterioration in cost, time, or ultimate goal achievement. This coincides with the *implementation risk* in the rule of law parameter of drug safety governance, i.e., the deterioration parameter is: implementation risk (L9).

3.2.3 Find the innovation principle against the conflict matrix.

7 Nested doll, 8 Anti-weight, 11 Beforehand cushioning, 10 Preliminary action.

3.2.4 Analyze the principles and propose solutions.

According to the principle of nested doll, the following measures can be proposed in the case: First, China should improve the pharmacovigilance organization system as soon as possible, to achieve full coverage of monitoring from pre-marketing to post-marketing of the whole life cycle of drugs. At the same time, clarify the work responsibilities of drug approval centers, drug evaluation center and monitoring institutions at all levels, and improve the construction of four levels of national, provincial, municipal and county level monitoring institutions for adverse drug reaction [24]. Second, according to the *Pharmacovigilance Quality Management Standard* released in 2021, drug marketing authorization holders can commission third-party organizations to carry out pharmacovigilance-related work to ensure that information on the whole process of

pharmacovigilance activities is true, accurate, complete and traceable.

According to the principle of anti-weight, the following measures can be proposed: First, strengthen the technology and regulations of active monitoring to change the passive monitoring to active, and realize the compensation of information. Patients receiving specific drug therapy are followed up through a risk management program to detect problems or potential risks in a timely manner and give appropriate guidance to medication users. Secondly, we make full use of high-tech signal mining and analysis techniques to develop and use alert signal detection tools to rapidly detect adverse reactions or suspected adverse reaction reports in a cluttered, passive and relatively slow-responding information report, and to mine, verify and confirm the information [23].

According to the principle of beforehand cushioning, the following measures can be proposed in the case: First, the government needs to improve the support system for regulatory, including infrastructure construction, pharmacovigilance personnel team construction, expert committee construction, pharmacovigilance-related work procedures that are guidelines, etc., so that it has the appropriate drug risk tolerance [23]. Secondly, drug marketing authorization holders should carry out drug safety risk assessment regularly and timely, determine the type of risk and take risk control measures. And establish a good emergency response system to avoid the continuous expansion of the harmful effects of adverse reactions.

According to the principle of preliminary action, the following measures can be proposed: First, to increase the publicity and training of pharmacovigilance system, and enhance the awareness of pharmacovigilance in the whole society. Make the public and society have correct knowledge about drug safety and pharmacovigilance. Eliminate the concerns of enterprises and medical institutions about adverse drug reaction reporting and increase public awareness of spontaneous reporting and pharmacovigilance participation [25]. Second, to simplify the public participation in pharmacovigilance pathways and build pharmacovigilance social co-governance mechanism.

4 Conclusion

The rule of law for drug safety in China is developing continuously, while new conflicts continue to emerge. By introducing research methods from the field of engineering into the field of drug safety governance, we provide scientific tools for drug safety governance. We build a contradiction matrix of rule of law for drug safety governance and make full use of 40 innovative principles to provide innovative ideas for solving actual contradictions. This will improve the level of drug safety rule of law and better protects people's drug safety.

Acknowledgment

Prject supported by the academic leader candidate of Ningxia Medical University in 2020; National Social Science Fund of China Program (17XGL016).

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