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A FOCUS PDCA Quality Improvement Model for Reducing the Withdrawal of Traditional Chinese Medicine Injection in Wards

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Abstract: *Objective:* To explore the application of FOCUS-PDCA quality improvement model to reduce the withdrawal of traditional Chinese medicine injections in the ward. *Methods:* A total of 780,794 medical orders were selected from November 2023 to January 2024 in our hospital, of which 13,612 medical order were for traditional Chinese medicine (TCM) injections, with a total number of 56,457 vials. With the orientation of TCM injection withdrawal in the ward, we used Balaido's law to screen the catalog of medicines whose withdrawal/usage rate exceeded 80% of the total Chinese medicine injection withdrawal, set up a CQI team, and then analyzed the reasons for their withdrawal by using Plato, Fishbone diagram, and "80/20 rule". Set goals, formulated countermeasures, implemented countermeasures and solved problems. At the same time, we compared the rate of withdrawal/use of TCM injections in the ward before and after the activity, evaluated the effectiveness of FOCUS PDCA in reducing the rate of withdrawal/use of TCM injections in the ward, and standardized the interventions. *Results:* The number of withdrawals of Shuxuening injection and Guanxinning injection accounted for 94.93% of the total number of TCM injections withdrawn, of which medical order revision, patient discharge, medical order discontinuation accounted for 82.10% of the total reasons for withdrawals of this medicine. With the reduction of the number of withdrawals of Shuxuening injection and Guanxinning injection as the improvement goal, and with the medical order revision, patient discharge, medical order discontinuation as the improvement target, after the implementation of the FOCUS-PDCA quality improvement model, the number of withdrawals/administrations of Shuxuening injection and Guanxinning injection from April 2024 to June 2024 was reduced from 54.30‰ (1/1,000) before the improvement to 36.00‰ (1/1,000), a decrease of 33.70% ; the number of withdrawals/administrations of our total TCM injections decreased from 52.97‰ (1/1,000) to 34.30‰ (1/1,000) ($P<0.05$), a decrease of 35.25%; and the number of withdrawals/administrations of our total TCM injections decreased from 4.10% to 3.60% ($P<0.05$), a decreased of 12.20%. At the same time, the error rate of medication withdrawal was significantly reduced compared with that before the improvement ($P < 0.05$). *Conclusion:* The application of the FOCUS-PDCA quality improvement model could effectively reduce the problem of the withdrawal of TCM injections in the hospital district, reduce the transfer of TCM injections from the pharmacy to the hospital districts, and avoid the quality problems that may arise in the process due to improper storage , so as to improve the safety of patients' use of medicines.

Keywords: FOCUS-PDCA quality improvement model; TCM injection; withdrawal rate; withdrawal error

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1. Introduction

Traditional Chinese Medicine (TCM) Injections, as an innovative dosage form integrating modern pharmacy technology and TCM theory, breaks through bioavailability limitations through intravenous administration, and has unique therapeutic value in sepsis and cardiovascular etc[1-3]. However, the stability challenges derived from its complex components have significantly increased the difficulty of quality control, and improper storage may induce drug degradation and elevate the risk of adverse reactions[4-6]. In order to cope with these problems, there is an urgent need to build a standardized whole-process management system to reduce the frequency of ineffective transfer between "ward-pharmacy" and reduce the error rate of drug return, and ultimately to ensure the safety of patients' medication.

The FOCUS-PDCA quality improvement model is a continuous quality improvement model expanded on the PDCA framework [7], consisting of 9 steps:FOCUS phase (problem-oriented): Find(F), Organize(O), Clarify(C), Understand(U), Selec(S)t; PDCA phase (improvement) implementation): Plan(P), Do(D), Check(C), Act(A) [8]. The model achieves systematic optimization through the synergy of prospective risk identification (FOCUS) and closed-loop quality improvement (PDCA) [9].

Studies on the FOCUS PDCA model was applied to the management of the withdrawal of Chinese medicine injections in the ward, aiming at optimizing the withdrawal management path, reducing the ineffective transfer rate; circumventing the risk of deterioration of medicines due to improper storage; and establishing a sustainable medication safety guarantee mechanism to ultimately ensure the safety of patients' medication.

2. Relevant information

Before applying the FOCUS PDCA quality improvement model, there were 780794 medical order from November 2023 to January 2024, of which there were 13612 medical order for TCM injections with a total number of 56457 vials. Of these, a total of 536 medical order with a total number of 2,840 vials of TCM injections were withdrawn, which were categorized as the control group. After the implementation of FOCUS PDCA quality improvement model, a total of 471 medical order for withdrawal of TCM injections with a total number of 2217 vials were withdrawn from April 2024 to June 2024, which were categorized as the observation group.

3. Method

3.1. Application of the FOCUS PDCA quality improvement model

3.1.1. Finding (F)

We counted the withdrawal of TCM injections from November 2023 to January 2024, in order to reduce the transfer of TCM injections in the pharmacy - the wards, to avoid the quality problems that may arise in the process due to improper storage, and to reduce the workload of the pharmacists and nurses, and to standardize the process of withdrawing medicines. Therefore, "Reducing the withdrawal rate of traditional Chinese medicine injections in hospital districts" was taken as the theme of the continuous quality improvement project.

3.1.2. Organization (O)

A Continuous Quality Improvement (CQI) team was established by the director of the pharmacy department, led by the director of the pharmacy department, together with the medical department and the nursing department. The director of the pharmacy department is the leader, the head of the inpatient pharmacy is the deputy leader, and there are 10 members of the team, with an average working experience of more than 10 years, to jointly promote the implementation of the project.

3.1.3. Clarify (C)

The CQI team members counted the number of drug withdrawals in the ward. TCM injections include:Shuxuening injection , Guanxinning injection, Xingnaojing injection, Shenkan injection, Kanglaite injection, Xiaozhiling injection, Astragalus injection, Salvianolic Acid for injection, Salvia Miltiorrhiza injection and Chaihu injection. According to the "80/20 rule"[10], the number of withdrawals of Shuxuening injection and Guanxinning injection accounted for 94.93% of the total number of withdrawals of TCM injections(as shown in **Figure 1**). The reasons for withdrawals included:Medical Order Revision, Patient Discharge, Medical Order Discontinuation, Interdepartmental Patient Transfer, Medication Order Error, Patient Demise, Adverse Drug Reaction, Nursing Practice Deviation and Substandard Medicinal Product.According to the "80/20 rule", Medical Order Revision, Patient Discharge and Medical Order Discontinuation accounted for 82.10% of the total reasons for withdrawal of the drug(as shown in **Figure 2**).

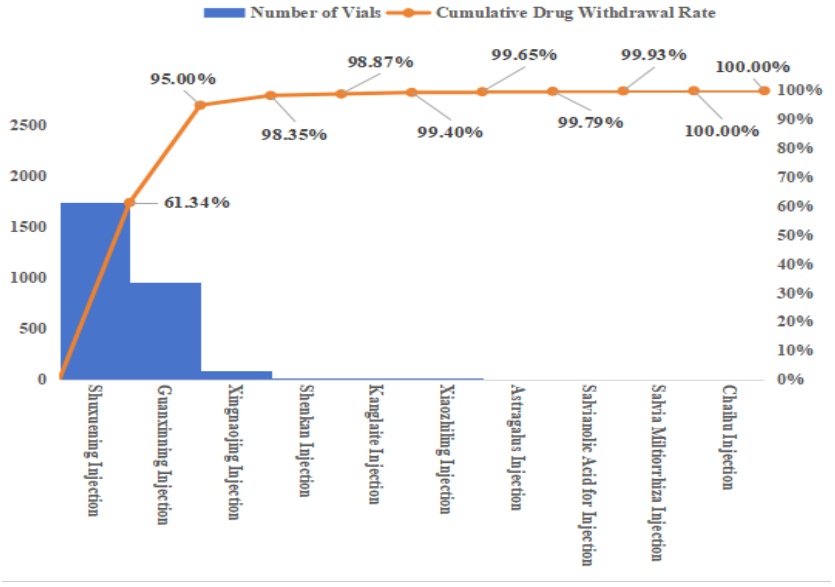

Figure 1. Para graph of the number of withdrawn drugs for each TCM injection before the implementation of FOCUS PDCA management model

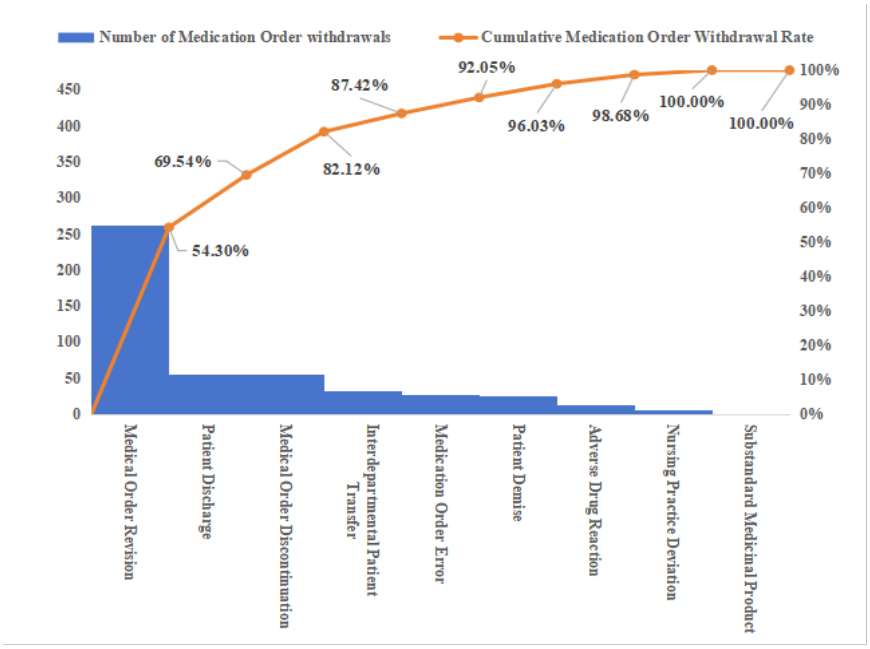

Figure 2. Para chart of reasons for withdrawal of each TCM injection before the implementation of the FOCUS PDCA management mod

3.1.4. Understanding (U)

Based on the findings of the CQI team, the team analyzed the reasons for the withdrawal of Chinese medicine injections from four aspects: doctors, nurses, pharmacists, and institutional processes. The reasons for the withdrawal of Chinese medicine injections are as follows:

(1) Untimely adjustment of medical orders by doctors, resulting in medications that have been delivered to the ward and then returned. Lack of communication with patients and insufficient consideration of patients' opinions, resulting in patients' refusal to take the medicine. Lack of familiarity with drug information, resulting in the adjustment of medical advice and the return of drugs.

(2) Nurses are not strong in responsibility and do not pay enough attention to the attitude. The returned medicines are directly sent to the inpatient pharmacy by the field staff without checking, or there is no effective handover with the field staff, without sufficient risk awareness.

(3) Pharmacists' professionalism is not enough to audit the errors of medical orders in a timely manner. Poor accountability of the dispensing and auditing staff led to errors in the delivery of medicines to the ward. Drugs were not delivered to the ward in time, and patients were transferred to other departments and discharged from the hospital, which led to the withdrawal of drugs.

(4) The process of drug withdrawal is not standardized enough, and the implementation of the drug withdrawal program is not in place. The pharmacist's operation of checking the returned medicines varies from person to person and is not standardized. The management of confusable drugs in the Pharmacy Department is chaotic.

3.1.5. Select (S)

Through the fishbone diagram analysis (as shown in **Figure** 3)[11], the CQI team made improvements at the system level, personnel level, and institutional level, respectively, to improve and implement the withdrawal system as well as to improve the professionalism and work attitude of the team of doctors, pharmacists, and nurse practitioners in order to reduce the rate of withdrawal of TCM injections.

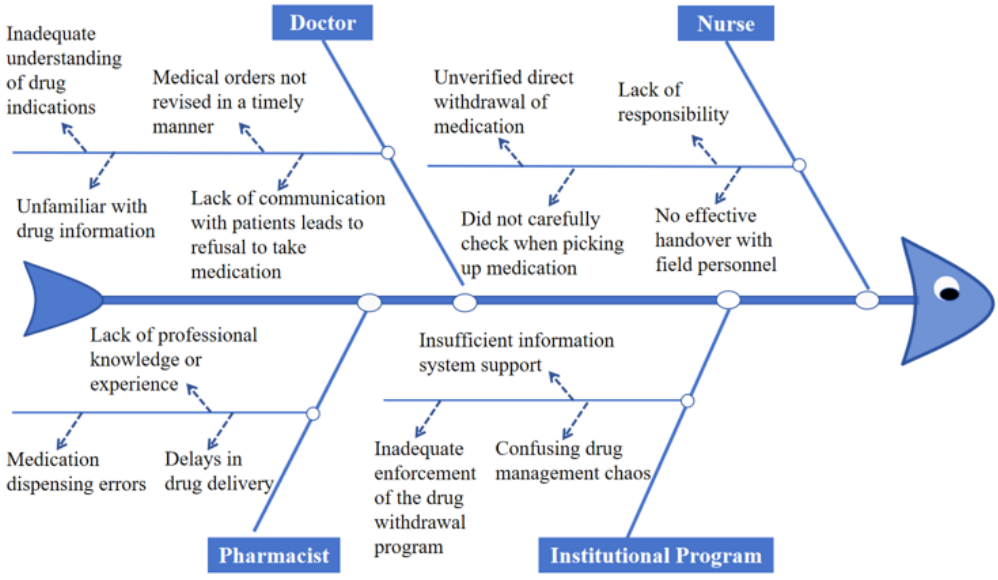

Figure 3. Fishbone diagram for analyzing the reasons for withdrawal of Chinese medicine injections

3.1.6. Plan (P)

Advance interventions in phases:

System upgrade phase (weeks 1-2): Modify HIS system: integrate 1,238 TCM injectable medication rule base and add real-time alerts for drugs with high risk of drug withdrawal.

Personnel empowerment and system development phase (weeks 3-5):

doctors: Increase drug policy training for doctors and standardize the timeliness of medical prescriptions.

Nurses: Improve the work responsibility of nurse practitioners and enhance the checking process of drug refunds.

Pharmacists: Enhance the reviewing medical orders ability of pharmacists and standardize the management of confusing drugs.

Institution: Issue a standardization of the management of the refunds of traditional Chinese medicine injections, and focus on the policy of no refunds of this type of drugs for non-quality issues.

Pilot operation phase (week 6): Cardiovascular Medicine and Neurology Departments implement the new refund process

Operation phase (week 7-8): Hospital-wide implementation of the new refund process.

3.1.7. Do (D)

(1) Convene a pharmacy department-medical department-nursing department special communication meeting on Chinese medicine injections.

Under the leadership of the director of the pharmacy department, hold a special meeting on the issue of withdrawal of TCM injections. Reinforce nurses' awareness of the safety risks of Chinese medicine injection withdrawal, focusing on warning of allergic reactions and other hazards that can be triggered by inappropriate storage of Chinese medicine injections; establish a real-time notification system for withdrawal errors, and instantly push typical cases of errors through the hospital's OA platform and nursing work groups; implement a monthly withdrawal quality analysis report system to quantify the types of withdrawal errors for Chinese medicine injections in each ward, with the results being communicated to the head nurses of each department and to the The results are notified to the head nurse and responsible pharmacist of each department.

Establishing a risk catalog for the use of Chinese medicine injections and strengthening the training of doctors and nurses

The pharmacy quality control team takes the lead in compiling a catalog of contraindications to the compounding of Chinese medicine injections, a catalog of special storage requirements, and a comparative chart of the appearance of easily confused ampoules. The pharmacist, combined with doctors and nurses, compiled the "Handbook of Clinical Use of Chinese Medicine Injections", focusing on the requirements for selecting solvents, limitations on the speed of titration, and the precursors of adverse reactions. The handbook is distributed to the dispensary of each ward, and the pharmacists conduct patients bedside training with the commonly used varieties in the department and verify the nurses' mastery through quarterly assessment. Establishment of new drug access response and change warning mechanism: the Department of Pharmacy's We Chat public number pushes out dispensing warnings and identifying features of newly introduced varieties in the form of graphic and textual comparisons.

Standardize the verification process for the withdrawal of Chinese medicine injections

We formulate the "Two-person Verification System for the Withdrawal of Chinese Medicine Injections", and set up a triple barrier for the withdrawal of medicines: ① check the lot number of the ampoule, the expiration date, and the number of varieties; ② check the clarity of the medicine and the integrity of the package; ③ confirm the continuity of varieties that need to be sheltered light or cool place. Categorize the withdrawal box according to the characteristics (avoid light withdrawal area, cool withdrawal area, regular withdrawal area), and clarify the path of withdrawal on the shelves. We incorporate the implementation of the process into the pharmacist's performance appraisal, and ensure the standardization of operation through blind testing and spot-checking.

Optimize the informatization management of Chinese medicine injection refund

① For the special characteristics of TCM injection medical prescription, add the function of Chinese medicine identification information in the HIS system, and automatically pop-up window warning for over-specification of solvent compounding. ② We developed an exclusive channel for the withdrawal of TCM injections, realizing the rapid withdrawal of medicines from the ward-pharmacy to avoid the quality and safety risks caused by the withdrawal process.

(5)Design of Chinese medicine injections withdrawal handover signs

We use three-color dynamic signage to manage the withdrawal box:

Green signage: routine withdrawal, checking is complete;

Yellow signage: light-sheltered drugs, stored in the shade box;

Red signage: cool drugs, stored in a special box;

Logistics personnel according to the color of the signage to carry out a hierarchical handover, no signage or signage discrepancies in the withdrawal of the box refused to receive. We synchronize the configuration of light-avoidance transfer box and cool preservation box to ensure the quality stability of special drugs in the transfer process.

3.1.8. Check (C)

After the implementation of the above measures, the withdrawal of TCM injections in the improved ward was collected. The results showed that the withdrawal rate of Chinese medicine injections in the ward was reduced after the improvement.

3.1.9. Act (A)

To maintain the effectiveness of the improvement, we have standardized and formatted the documentation of the measures that have been implemented with effective results into regulations and operational standards, and revised the “Description of the Process for withdrawal Drug Refunds from Inpatient Pharmacies” and the “Operational Procedures Related to the withdrawal Drugs from Nursing Vials”, so that they can be implemented in the long term.

3.2. Statistical methods

All data analyses were performed using the SPSS 24.0 software, in which the statistical significance of difference between experimental groups was analyzed with t-test or Kruskal-Wallis rank sum test. Significant differences were defined as $p<0.05$.

4. Results

4.1. Comparison of the basic situation of TCM injection withdrawal before and after the management of FOCUS PDCA quality improvement mode

After the implementation of the FOCUS PDCA quality improvement model, the number of withdrawals/administrations of Shuxuening injection and Guanxinning injection decreased from 54.30‰(1/1000) before improvement to 36.00‰(1/1000) in April 2024-June 2024, a decrease of 33.70%, and the number of withdrawals/administrations of our hospital’s total TCM injections decreased from 52.97‰(1/1000) to 34.30‰(1/1000) ($P<0.05$), a decrease of 35.25%. Our hospital’s total TCM injection drug withdrawal medical orders/medication orders decreased from 4.10% to 3.60% ($P<0.05$), a decrease of 12.20% (as shown in **Table 1**).

Table 1. Comparison of the basic situation of Chinese medicine injection withdrawal before and after improvement

	Time	Medical orders for the withdrawal of TCM injections (item)	Number of TCM injections withdrawn (ampule)	Medical administrations for TCM injections (item)	Number of TCM injections administrations (ampule)	Proportion of medical orders for withdrawal / administrations (%)	Proportion of the number of TCM injections withdrawal / administrations(%)
Before Improvement	2023.11	204	917	4467	14042		
	2023.12	168	992	3961	12152	4.10	5.30
	2024.1	164	931	4648	27423		
After Improvement	2024.4	159	726	4366	19926		
	2024.5	162	794	4531	22086	3.60	3.43
	2024.6	150	697	4174	20413		
P/t						P < 0.05	P < 0.05

Table 2. Comparison of the error rate of TCM injection withdrawal before and after improvement

Time	Whether there is an error in the withdrawal of TCM (ampule)		Error rate in drug withdrawals (%)
	Yes	No	
Before Improvement	63	2777	2.22
Before Improvement	17	2200	0.77
P	< 0.05		< 0.05

4.2. Comparison of the error rate of TCM injection withdrawal in the ward before and after the implementation of FOCUS PDCA quality improvement model

Compared with the before implementation period, the number of errors of TCM injection withdrawal in the ward was significantly lower after implementation (P<0.05), and the error rate of TCM injection withdrawal was significantly lower (P<0.05).

5. Conclusion

A FOCUS PDCA quality improvement model significantly reduces the withdrawal rate of TCM injections. In this study, the FOCUS PDCA quality improvement model was applied to the field of TCM injection withdrawal management. After the intervention, the number of TCM injection refunds/administrations decreased from 52.97‰(1/1000) to 34.30‰(1/1000) (P<0.05), a decrease of 35.25%; the total TCM injection refunds/administrations in our hospital decreased from 4.10% to 3.60% (P<0.05), a decrease of 12.20%. This result confirms the generalizability of the FOCUS PDCA model in medical process optimization, and is consistent with the findings of Yongdeng Huang et al[12], who found that after implementing the FOCUS PDCA quality improvement model, the defective rate of aseptic packaging distribution decreased from 1.74% to 0.37% (P < 0.05). The key improvement in this study came from the precise location of the core contradiction: Shuxuening injection and Guanxinning injection accounted for 95.00% of the total number of withdrawals, and 82.12% of the reasons for withdrawals were medical order revision, patient discharge, medical order discontinuation. By focusing on the key issues anchored by the “80/20 rule”, the applicability of the FOCUS PDCA quality improvement

model in the field of drug management was confirmed.

Synergy of multidimensional intervention mechanisms. Establishing a tripartite verification mechanism for drug refunds (pharmacists-nurses-field personnel) to clarify operating standards and resolve process implementation discrepancies. We have carried out training on the characteristics of drugs for doctors, strengthened the pre-review of pharmacists' prescriptions, and implemented the handover system of nurses' drug return lists. We standardize the process of drug withdrawal, and implement color-coded management for confusing drugs to reduce the error rate of drug withdrawal. The pharmacy department has combined with the medical department and the nursing department to form a CQI team, breaking down departmental barriers. This integration strategy highlights the need for in-depth teamwork for medical quality improvement.

Despite the significant results of this study, it is still limited by the function of the hospital information system, the current management of medication return still relies on manual intervention, and the risk of medication safety caused by the error rate rate still exists. In the future, we will establish an automatic offsetting system for the cache of returned medication in the ward to completely realize the closed-loop management of information technology, avoid the risk of medication and ensure the health of patients.

In summary, this study reduces the problem of drug withdrawal of TCM injections based on the FOCUS PDCA quality improvement model, reduces the risk of drug stability due to round-trip transportation of withdrawal drugs, and ensures the safety of TCM injections. At the same time, by reducing the round-trip transportation of medicines, the workload of nurses and pharmacists is reduced, and could be shifted to higher-value clinical services. Further, the establishment of a "pharmacist-doctor-nurse collaborative decision-making" mechanism provides a reference template for similar medical institutions. Subsequent studies could be extended to the management of chemotherapeutic drugs and biologicals to validate the applicability of the model for migration.

Disclosure Statement

The authors have declared no conflict of interest.

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