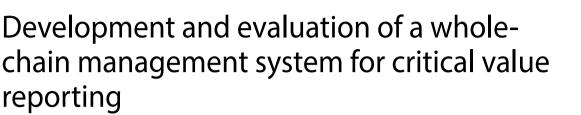
RESEARCH

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Abstract

Background Critical value (CV) management is vital for patient safety and shows the quality of critical care. This study aimed to develop a whole-chain management system (WCMS) for CV reporting and evaluate its impact on clinical practice.

Methods A WCMS for CV reporting, considering sample, process and patient population, was developed. A quasiexperimental study was conducted at Zhoushan Hospital. 591 CVs were divided into two groups: the postapplication group (n = 298) and the preapplication group (n = 293). CV quality-related indicators were compared between the two groups, including the timely reporting rate, timely receiving rate, timely treatment rate, completeness of treatment records and closed-loop rate.

Results Before system implementation, the timely treatment rate (93.17%), completeness of treatment records (78.16%), and closed-loop rate (88.05%) were lower than the timely reporting rate (94.54%). After implementation, there were significant differences between the two groups in timely reporting rate (94.54% vs. 97.99%, P < 0.05), timely treatment rate (93.17% vs. 97.65%, P < 0.01), completeness of treatment records (78.16% vs. 94.97%, P < 0.01), and closed-loop rate (88.05% vs. 97.32%, P < 0.01).

Conclusion Implementing the WCMS from sample, process and patient population has improved patient safety. The system's successful integration also shows its potential for use in health information systems of various healthcare facilities.

Keywords Chain management, Information system, Critical values, Chain flow, Whole process, Whole sample, Whole patient population

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Introduction

Critical value (CV), characterised by pathophysiologic derangements posing immediate life-threatening risks without prompt intervention, necessitates swift and accurate communication for timely clinical response [1]. Delayed or ambiguous transmission of CVs can have severe repercussions, potentially jeopardising patient safety [2]. Conversely, reporting nonurgent or inappropriate CVs may burden healthcare providers and impede efficient patient care [3]. Both the Joint Commission and the College of American Pathologist (CAP) emphasise the importance of the timeliness of CV reporting and a clear record of the date and time of communication, responsible laboratory personnel, recipient details, and test results [4, 5]. Similarly, the Key Points of the Core System for Medical Quality and Safety, released by the National Health Commission of China in 2018, stress the importance of accurate and timely transmission of CV information, seamless information connectivity, and traceability of crucial reporting elements [6]. From 2010 to 2021, medical damage liability dispute cases related to hospital CV reports in China consistently highlighted the delay or absence of CV treatment as the primary reason for courts attributing responsibility to medical providers [7]. However, publications offering detailed procedures for subsequent treatment and retesting to guarantee the integrity and continuity of CV management are scarce.

Chain management, operating by the inherent laws of interconnectedness and development, links diverse internal elements, ensuring continuity and effectiveness [8]. Increasingly, this approach has found widespread application across various enterprises and industries [9, 10]. In China, notable strides have been made in applying chain management to areas such as pain care [11], operation room equipment management [12], and pressure injury prevention [13]. The delivery of CVs entails a series of interdepartmental procedures, spanning from initial reporting and clinical receipt to subsequent measures taken and tracing retest results. This process demands seamless coordination and interaction among departments and health systems. Additionally, patient transfers between departments further underscore the interconnected nature of CV management, necessitating collaborative efforts across various units. Despite these complexities, few reports address quality improvement across the entirety of the CV delivery process [14]. Existing research on CV information management predominantly focuses on CV notification rather than tracing changes in patients' laboratory or imaging indicators [2, 15], making it challenging to evaluate relevant patient treatment outcomes. Determining an appropriate endpoint for CV management still needs to be addressed owing to challenges such as variability in retest time standards, the contextual importance of certain CVs, and the potential for healthcare interventions before result availability. In summary, exploring the implementation of information systems based on chain management principles holds promise for enhancing the quality control of CVs.

In this study, a Whole Chain Management System (WCMS) for CV reporting was developed, which focuses on three perspectives: sample, process and patient population, and was applied in clinical practice. The new system involved the entirety of the workflow, from initial reporting to determining exact endpoints. And various CVs including laboratory values, pathology findings, endoscopic results, and ECG results, were set to trigger reminders from the information system. Bedside glucose results are also integrated into the system. Regarding patient population management, a dynamic chain workflow was designed to ensure a smooth handover of CVs during patient transport. The new system was seamlessly integrated into our hospital's existing information systems, including the Hospital Information System (HIS), Laboratory Information System (LIS), and Picture Archiving and Communication System (PACS). Prior to implementation, CV delivery and inspection in our hospital relied entirely on manual processes. Individuals in the medical technology department would initiate a phone call to the attending nurse when a CV was identified. Subsequently, both the reporter and the notified nurse logged the test result, communication date, time, and relevant staff member numbers in a logbook before the nurse contacted the ordering provider. However, this method is considered time-consuming, complex, and inefficient. Regarding the sampling, only laboratory values were delivered in an informative manner. As for patient population, CVs may be overlooked, posing a hidden danger to patient safety. Additionally, to meet the requirements of the National Health and Family Planning Commission in China [16], the quality control office collected CV quality-related indicators monthly as part of routine inspections in our hospital. It includes timely reporting, receiving and treatment rates, completeness of treatment records, and closed-loop rates. However, CV inspection data collection and delivery were manual, resulting in a significant workload and delayed feedback from the quality control office to clinical practice.

Therefore, this study aimed to develop and evaluate a WCMS for CV reporting to optimise CV delivery, achieve whole-process traceability, ensure full-sample coverage, realise dynamic control of the entire patient population, and enable information-based quality control to enhance patient safety ultimately.

Methods

Research design and participants

This study obtained approval from the Ethics Committee of Wenzhou Medical University Affiliated Zhoushan Hospital (Approval No. 2021048). A quasi-experimental design with pre- and post- test assessments was used. The WCMS for CV reporting was based on the HIS, LIS, and PACS. Due to the complex and time-consuming nature of constructing and implementing a new system, conducting a randomised controlled trial was deemed impractical. Participants were required to have a CV reported. The inclusion criteria for participants was to have at least one CV and potential participants who refused to participate were excluded.

Sample and allocation

By convenience sampling, patients with CVs before and after the application of the WCMS were recruited from a triple-A hospital from January to June 2020 and March to August 2021, respectively. Ultimately, 591 patients were eligible to participate, with 293 in the preapplication group and 298 in the postapplication group.

Intervention

Form a multidisciplinary team

A multidisciplinary team was assembled consisting of a deputy director of the quality control office, the director of the nursing department, two engineers, an information nurse from the information office, two medical technologists from the laboratory and electrocardiographic (ECG) room, a physician from the intensive care unit, and the director of the outpatient department. All team members are trained in Quality Control Circles and have a clear division of responsibilities.

Proactively identifying existing issues related to CV management and diligently seeking suitable solutions to address them

The identified core issues effectively outline key challenges in CV management. Here, they are refined for clarity:

- 1. From the entire sample perspective: How can delayed or missed reporting of CVs be prevented or reduced?
- 2. From the entire process perspective: What constitutes an appropriate endpoint for the CV management chain?
- 3. From the entire patient population perspective: How can CVs be seamlessly transferred when patients are transferred between departments or outpatients come back during non-normal working hours?

4. From the information-based quality control **perspective**: Is remote and real-time inspection of the entire CV management process feasible?

A total of 19 measures were proposed through brainstorming. After five team members had voted based on three criteria, namely, superior policies, quality circle advantage, and ability to handle, 15 measures scoring above 25 were selected, seen in Fig. 1.

Solution to issue 1 A CV dictionary database in Fig. 2 was established to reduce the false negative rate in CV delivery, focusing on the entire sample perspective. Specifically, a database of CVs was constructed and integrated into the Laboratory Information System (LIS) and Picture Archiving and Communication System (PACS). This integration enables the system to automatically identify CVs and remind personnel in medical technology departments to report promptly, thereby reducing underreporting and delayed reporting. When laboratory and serum concentration monitoring values meet threshold criteria, the system recognises and generates custom CV notifications. Additionally, abnormal results in the radiology, ultrasound, pathology, endoscopy, and ECG rooms can be detected to trigger reminders for medical technologists to check. Notably, bedside blood glucose CVs were also defined for real-time input, identification, and reporting by the integrated system, as it is essential to have a defined process for communicating and documenting bedside blood glucose CVs at the point of care [17].

Solution to issue 2 The appropriate endpoints for the CV management chain in various scenarios, highlighted in red in Fig. 3, were explored and applied from the perspective of the entire process based on clinical practice and policy requirements related to CV management in China [6, 18]. In our integrated system, the CV chain for inpatients and emergency patients was confirmed to be closed by the clinician's retest prescription and recording of the retest results, while the endpoint for outpatient is treatment taken. Early closure was permitted in various clinical scenarios.

Solution to issue 3 A dynamic chain workflow for the CV management has been seamlessly integrated into the system with a holistic patient perspective, as presented in Fig. 3, ensuring smooth CV handover during patient transport. For outpatients, the trigger point is designated as "visiting", prompting a box to appear on the clinician's interface upon receiving a CV patient. For inpatients or emergency patients, the trigger point is set as "bed assignment", triggering a box to appear on both the clinician's and nurse's interfaces when a CV patient is assigned a bed.

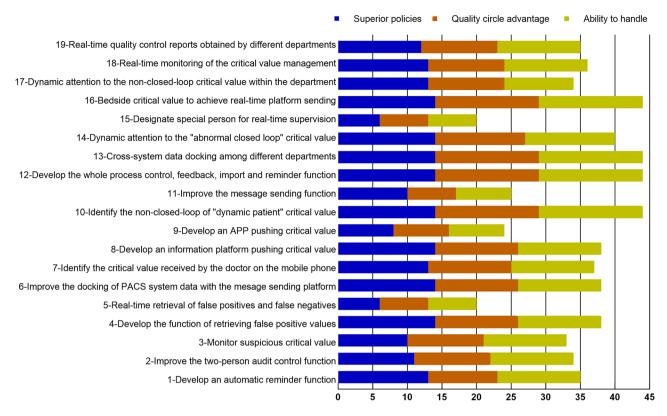


Fig. 1 Measures scoring

Solution to issue 3 Two main solutions were determined to achieve remote and real-time inspection of CV management. First, an information chain list was planned for each CV, accompanied by a quality inspection platform displaying all CV chains. Regardless of the patient's location, their CV chain is tracked, clearly revealing the processing of CVs. All CV chains are collected in the quality inspection platform, and instances of delayed reporting, receiving, or treatment are highlighted in red font. Similarly, CVs that have not completed the closed-loop process are highlighted with a red background. Second, an internal quality control interface for CV management was designed within the PACS. Medical technologists can manually enter keywords in the CV search box and then click the query button to display a list of all relevant reports, which facilitates internal quality control from the reporting side's perspective.

System optimisation and medical personnel training

Throughout the commissioning period, which lasted from October 2020 to December 2020, any issues or problems encountered during the system use were collected and reported by the information nurse to the multidisciplinary team responsible for system development and implementation. This feedback loop allowed for continuous improvement and refinement of the system based on real-world usage and user experiences. In addition to addressing technical issues, the quality control office provided system application training for medical staff to ensure proficiency and effective utilisation of the WCMS. Training sessions were conducted to familiarise medical personnel with the system's functionalities, workflows, and best practices. After addressing any identified issues and completing the necessary training, the WCMS was officially launched in March 2021, marking the culmination of the development and implementation process. This milestone signified the beginning of full-scale system utilisation to enhance CV management and improve patient safety within the healthcare organisation.

Effect evaluation

The CV quality-related indicators, including the timely reporting rate, timely receiving rate, timely treatment rate, completeness rate of treatment records, and closedloop rate were formulated according to the hospital's system. These indicators were collected and compared to evaluate the effectiveness of the WCMS implementation.

1. Timely Reporting Rate: This indicator measures the proportion of CVs reported within 5 min of identification. It is calculated by dividing the number of CVs reported within 5 min by the total number inspected per unit time.

				Dictionar	ry Database	e of Critical Values			
Critical Values in Laboratory						Critical Values for Reg	ular ECG Examination		
Parameter	Critical Range		Parameter	Parameter Critical Range		1. Long R-R interval ≥3.0s;			
Serum potassium, mmol/L	<3, >6		Serum sodium, mmol/L < 125,		> 158	2. Bradycardia: mean ventricular rate < 35 beats/min;			
Serum calcium, mmol/L	um, mmol/L <1.5		Serum glucose, mmol/L	< 2.8, > 28		3. First-degree third-degree atrioventricular block, or r degree atrioventricular block;	mean ventricular rate < 40 beats/minute in third-		
Serum magnesium, mmol/L	< 0.5		PH	<7.2, >7.58		4. Markedly prolonged Q-T interval with premature Ro	onT ventricular contractions;		
Plasma D-Dimer, ng/ml	Plasma D-Dimer, ng/ml > 1000		Plasma international normalia	al normalized ratio		5. Ventricular tachycardia: ventricular rate ≥ 150 beat	s/minute for ≥ 30 seconds;		
Activated partial thromboplastin time,s > 80		> 80	Activated partial thromboplastin time,s >		> 45	6. Torsades de pointes, polymorphic ventricular tachycardia;			
Arterial partial pressure of cart	Arterial partial pressure of carbon > 65		Arterial partial pressure of oxygen,mmHg		< 50	7. Ventricular flutter, ventricular fibrillation;			
dioxide,mmHg						8. Supraventricular tachycardia: ventricular rate ≥ 230) beats/min;		
Leukocyte count, L	.eukocyte count, L <1×10 ⁹ (<0.5×10 ⁹ for hematologic patient), >100×10 ⁹					9. Atrial fibrillation, atrial flutter, mean ventricular rate	≥ 180 beats/min;		
Hemoglobin, g/L	< 60(< 40 f	or hematolog	gic patient)			10. Atrial fibrillation with ventricular preexcitation with	a minimum R-R interval < 250ms;		
Platelet count, L				109		11. ECG changes consistent with acute myocardial infarction (limb leads, V4-V6ST elevation \geq 0.1 mv, V1- V3 elevation \geq 0.3 mv) and ECG changes consistent with re-infarction after old myocardial infarction (ST retraction re-elevation with acute chest pain to exclude ventricular aneurysm).			
q	ritical Values	in Radiolo	gical Diagnosis Center			Critical Values for Dyna	Critical Values for Dynamic ECG Examination		
	С	entral Nervo	us System			1. R-R interval ≥5.0s in atrial fibrillation;			
1. Acute subdural/epidural hem	atoma(hemato	oma ≥ 3cm) (or midline structure displacement	nt ≥1.0cm;		 Long R-R interval of 3 or more ≥3.0s; 			
 Supratentorial cerebral hemo 30ml); 	 Supratentorial cerebral hemorrhage(hematoma ≥ 50ml) or infratentorial cerebral hemorrhage(hematoma ≥ 30ml); 					3. Markedly prolonged Q-T interval with ventricular tachycardia;			
3. Newly discovered brainstem	hemorrhage;					 Ventricular tachycardia: ventricular rate ≥ 200 beats/minute for ≥ 30 seconds; 			
4. Fracture and dislocation of th	ne neck 4 verte	ebrae and ab	pove;			5. Torsades de pointes, polymorphic ventricular tachycardia;			
5. Cerebellar hemisphere infarc	tion (≥ 50%).					6. Ventricular flutter, ventricular fibrillation;			
Respiratory System			Digestive System			 Supraventricular tachycardia/atrial fibrillation/atrial flutter ventricular rate ≥ 250 beats/min; 			
1. Tracheal and bronchial foreign bodies;		1.	1. Perforation of the digestive tract;			8. Atrial fibrillation with ventricular preexcitation with a minimum R-R interval <250ms;			
 Pneumothorax, compression of one lung ≥70%; 			Rupture and bleeding of abdominal organs such as liver, spleen, pancreas, and kidney.			9. ECG changes consistent with acute myocardial infarction (limb leads, V4-V6 ST elevation 20.1 mv, V1 -V3 elevation > 0.3 mv) and ECG changes consistent with re-infarction after old myocardial infarction (posterior re-elevation with acute chest pain in old myocardial infarction);			
 Pulmonary artery above grade II branch embolization. 		3.	3. Traumatic large pericardial effusion.			 ECG changes consistent with variant angina pectoris (ST segment transiently arched dorsal upward type, giant R type and other elevation). 			
Circulatory System			Reproductive System			Critical Values in Endoscopy Center			
1. Aortic dissection;		1.	1. Ectopic pregnancy.			1. Those with active bleeding at the examination site;			
2. Superior mesenteric artery embolization;						2. Those who have a perforation at the examination site.			
Critical Values in Ultrasound Diagnosis Center					Critical Values in Pathological Diagnosis Center				
 Critically ill patients with peritoneal effusion in emergency trauma and suspected rupture and bleeding of internal organs such as liver, spleen or kidney; 				 The results of the pathology report submitted by the outpatient clinician for examination are malignant turnors; 					
2. Ectopic pregnancy;					2. When the intraoperative rapid freezing pathology report is inconsistent with the routine pathology report;				
3. Umbilical cord prolapse, placental abruption;					3. Positive resection margins for malignant tumors (intraoperative rapid freezing of pathological sections);				
 Amniotic fluid index < 30mm or the dark area of amniotic fluid in the second trimester of pregnancy less than10mm; 					The clinical diagnosis of inpatients is inconsistent with the pathological diagnosis of benign and malignant.				
5. Fetal heart rate < 100 beats/min or > 180 beats/min;						Critical Values for Serum Concentration Monitoring			
Absence or inversion of end-diastolic blood flow, S/D>5.0;					Drug Name	Critical Range			
7. Extensive myocardial necrosis;						.45			
7. Extensive myocardial necros	is;					Carbamazepine, ug/ml	>15		
 7. Extensive myocardial necros 8. Large pericardial effusion wit 		oonade;				Carbamazepine, ug/mi Valproic acid, mg/L	>15 >250		

Fig. 2 Dictionary database of CVs

- 2. Timely Receiving Rate: This indicator assesses the proportion of CVs received within 15 min of identification. It is calculated by dividing the number of CVs received within 15 min by the total number inspected per unit time.
- 3. Timely Treatment Rate: This indicator evaluates the proportion of CVs clinicians handle within 30 min of identification. It is calculated by dividing the number of CVs handled by clinicians within 30 min by the total number inspected per unit time.
- 4. Completeness Rate of treatment records: This indicator measures the completeness of the treatment records associated with CVs. It is calculated by dividing the number of CVs with complete treatment records by the total number inspected per unit time.
- Closed-Loop Rate: The closed-loop rate is a crucial indicator that measures the effectiveness of the response to CVs within the healthcare system. It designates that appropriate actions have been

taken to address the identified CV, ensuring patient safety and continuity of care. The closed-loop rate is calculated by dividing the number of CVs undergoing the closed-loop process by the total number inspected per unit time. For inpatients and emergency patients, the closed-loop process entails the clinician prescribing a retest and recording the retest results. On the other hand, for outpatients, the closed-loop process involves notifying the patient of the CV and implementing appropriate measures based on its nature. It is important to note that under certain circumstances, early closure of the closed-loop process may be permitted, such as when the patient refuses to return after notification or when dealing with chronic conditions where intervention may not be necessary. These instances allow for flexibility in the closed-loop process while maintaining patient safety and quality of care.

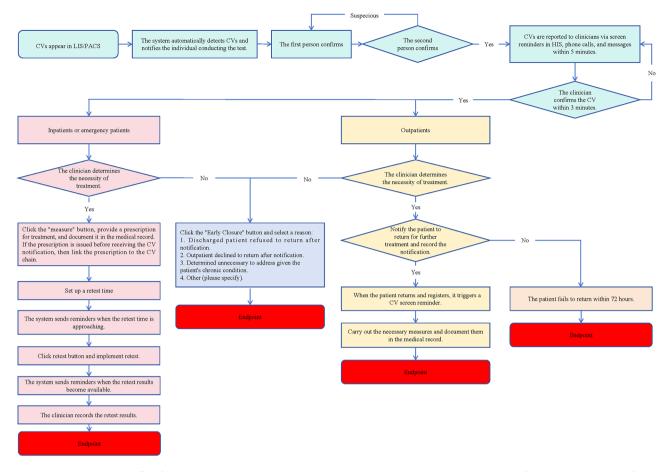


Fig. 3 A dynamic chain workflow for the CV management with appropriate endpoints in various clinical scenarios. CV refers to critical value. LIS refers to laboratory information system. PACS refers to picture archiving and communication system

All the data for these indicators were obtained from the quality inspection platform after implementing the WCMS. The data collected before the implementation were sourced from the CV log and electronic medical records. Comparing these datasets allows us to assess the impact of the WCMS on CV management effectiveness and patient safety within the hospital setting.

Statistical analysis

The statistical analysis of the data was performed using SPSS 23.0 statistical software. Count data are presented as percentages (%). The chi-square test was employed to conduct overall multiple rates and pairwise comparisons. Bonferroni correction was applied as a statistical adjustment that helps control the overall rate of false positives when making multiple comparisons on the same dataset. The chi-square test was also used to compare CV types and rates before and after the implementation of the WCMS. A *p*-value of less than 0.05 indicated a statistically significant difference between the compared rates or groups.

Results

Comparison of CV types between the two groups

In the preapplication group, there were 293 CVs in total, with 259 (88.4%) laboratory values, 11 (3.8%) ECG results, 9 (3.1%) pathology findings and 14 (4.8%) imaging results. In the postapplication group, there were 298 CVs in total, with 268 (89.9%) laboratory values, 10 (3.4%) ECG results, 7 (2.3%) pathology findings and 13 (4.4%) imaging results, shown in Fig. 4. The analysis revealed no significant difference between the two groups concerning CV types (P>0.05). These findings indicate that the distributions of CV types were similar before and after the implementation of the WCMS, making the two groups comparable for further analysis.

Comparison of the differences among the five quality-related indicators regarding CVs before the implementation of the WCMS

Before the implementation of the WCMS, the accordance rate for timely reporting, timely receiving, timely treatment, the completeness of treatment record and closed-loop were 94.54%, 99.66%, 93.17%, 78.16% and 88.05%, respectively, as presented in Fig. 5. The differences in

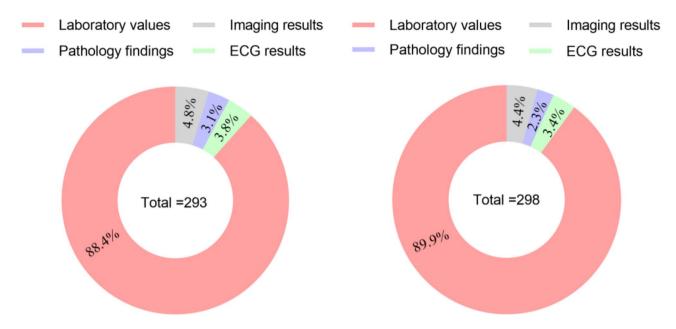


Fig. 4 CV types in (a) the preapplication group; (b) the postapplication group. CV refers to critical value. ECG refers to electrocardiographic

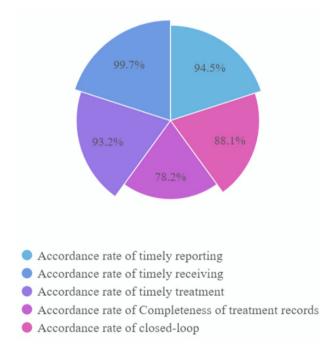


Fig. 5 The Nightingale Rose for comparison of CV quality-related indicators before the implementation of the WCMS

accordance rates among the five quality-related indicators regarding CVs were compared using the chi-square test. The overall chi-square value was 92.352 (P<0.01), indicating a statistically significant difference among the indicators. As depicted in Table 1, subsequent pairwise comparisons between different indicators were performed and Bonferroni correction was applied to reduce type-1 statistic error when performing pairwise comparisons of multiple rate comparison. According to Fig. 6, the **Table 1** Pairwise comparisons of multiple rate comparisons for quality-related indicators before the implementation of the WCMS for CV. *P. adj* refers to Bonferroni corrected *p* value. WCMS refers to the whole Chain Management System. CV refers to critical value

Pairwise comparison of multi (Percentage, %)	<i>x</i> ²	P.adj	
Timely reporting rate (95.44%)	Timely receiving rate (99.66%)	13.631	< 0.01
Timely reporting rate (95.44%)	Timely treatment rate (93.17%)	0.474	6.060
Timely reporting rate (95.44%)	Completeness rate of treatment records (78.16%)	33.353	< 0.01
Timely reporting rate (95.44%)	Closed-loop rate (88.05%)	7.753	0.080
Timely receiving rate (99.66%)	Timely treatment rate (93.17%)	17.829	< 0.01
Timely receiving rate (99.66%)	Completeness rate of treatment records (78.16%)	68.680	< 0.01
Timely receiving rate (99.66%)	Closed-loop rate (88.05%)	34.213	< 0.01
Timely treatment rate (93.17%)	Completeness rate of treatment records (78.16%)	26.904	< 0.01
Timely treatment rate (93.17%)	Closed-loop rate (88.05%)	4.515	0.340
Completeness rate of treat- ment records (78.16%)	Closed-loop rate (88.05%)	10.222	0.010

accordance rates for timely treatment, completeness of treatment records, and closed loops were significantly lower than those of timely reception. These results suggest variations in performance across different aspects of CV management, highlighting potential need to improve

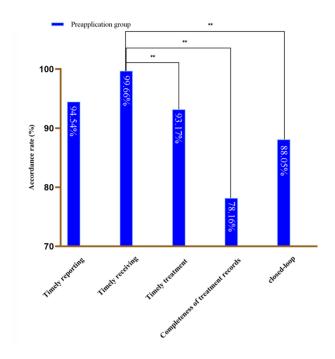


Fig. 6 The histogram for comparison between CV quality-related indicators before the implementation of the WCMS. ** represents P < 0.01

timely treatment, completeness of treatment records and CV closed-loop.

Comparison of CV quality-related indicators before and after the implementation of the WCMS

A comparison of the two groups revealed significant differences in several critical aspects of CV management, as shown in Fig. 7. Specifically, there were significant increases between the groups in terms of timely reporting rate(94.54% vs. 97.99%, P<0.05), timely treatment rate (93.17% vs. 97.65%, P<0.01), completeness of treatment records (78.16% vs. 94.97%, P<0.01), and closedloop rates (88.05% vs. 97.32%, P<0.01). However, there was a slight decrease of 0.33% between the two groups regarding timely receiving and no significant difference was observed (99.66% vs. 99.33%, *P*>0.05). This analysis highlights areas where implementing the chain management system may have notably impacted CV management practices. The increase in timely reporting rate underscores the effectiveness of the measures taken to prevent or reduce delayed or missing reporting from the entire sample perspective. While the improvement in timely treatment rate reveals the effectiveness of measures taken to constitute appropriate endpoints from the perspective of the entire process and the rise in the completeness of treatment records illustrates seamless CV handover during patient transfer across departments from the perspective of whole patient population. In

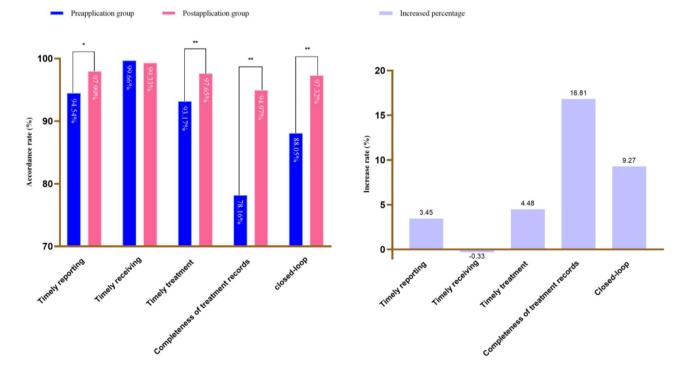


Fig. 7 (a) The histogram for comparison of CV quality-related indicators before and after the implementation of the WCMS. (b) the histogram for increase rates of CV quality-related indicators after the implementation of the WCMS. * refers to P < 0.05. ** refers to P < 0.01.

addition, the increase in the CV closed-loop rate displays the effectiveness of the overall measures.

Discussion

It is widely recognised that timely reporting of CVs and prompt action are crucial determinants of patient outcomes [1, 19]. For instance, a study assessing 28-day mortality after cardiac surgery identified CVs reported in the early postoperative period as independent risk factors [20]. However, there is a lack of consensus on the criteria for CV reporting [21]. A survey assessing staff perception of CV practice in government hospitals in Kuwait showed that the notification of CVs differs between participated laboratories in delivery protocol and time duration [22]. Our study addresses this gap by focusing on developing and applying WCMS for CV reporting, aiming to streamline CV management processes. Our approach involves several key steps. First, a multidisciplinary team was formed and four core existing issues were identified in CV management based on clinical practice and a literature review. Through brainstorming and voting, 15 measures were determined to address these issues and integrated into four corresponding solutions. (1) A CV dictionary database was established to reduce the false negative rate in CV delivery from the perspective of the entire sample. (2) Exploring and applying appropriate endpoints for the CV management chain in various clinical scenarios from the perspective of the entire process. (3) A dynamic chain workflow was integrated into the system from the perspective of the entire patient. (4) Implement an information chain for each CV and create an internal quality control interface for CV management to enable remote and real-time inspection. Finally, the WCMS was developed based on our existing health system, considering compatibility, proficiency, and economic cost. This development was accompanied by comprehensive medical personnel training to ensure effective implementation.

Establishing a CV dictionary database integrated into the health information system advances CV reporting. From literature review, we could recognize that some previous studies focus on the cut-offs for a specific value [23-25] or analysis of practical CV occurrence [26, 27], rare paper emphasize the establishment of the whole CV dictionary database and automatic identification of CVs. In our study, the database established serves two essential functions. First, it identifies the scope and specific cut-offs for CVs in different departments, providing clarity and consistency across the healthcare system. Second, it enables intelligent decision support to enhance the timeliness of CV reporting and the transition toward paperless reporting. While most CVs are laboratory values, abnormal results often exhibited in character rather than numerical data are extracted from imaging departments, pathology, and ECG rooms. Previously, these abnormal results were identified solely by medical technologists, leading to potential instances of false negative reporting. However, integrating the CV dictionary database allows the system to automatically identify CVs across various departments, reducing the risk of missed reporting. The implementation of the WCMS resulted in a significant improvement in CV reporting efficiency (P<0.05). It is particularly noteworthy given the previous wide variation in CV reporting practices in China, where the median reporting time ranged from 8 to 9 min [28], exceeding the requirement of reporting within 5 min in our study. Thus, establishing a chain management approach from the perspective of whole samples represents a significant step toward enhancing the accuracy and efficiency of CV reporting.

The transmission method for CVs is crucial to ensuring timely and accurate communication within the healthcare system. Telephone communication has traditionally been the dominant method for transmitting CVs in healthcare settings despite the heavy workload it entails [29–31] and the possibility of information miscommunication [32]. CAP acknowledges that electronic means of transmission can also be acceptable, provided that confirmation of receipt is closely monitored to ensure effective notification [33]. In this study, multiple modes of transmission were integrated to transmit CVs, with particular attention given to receiving acknowledgement from the intended recipient within 3 min. Although there was a suggestion to eliminate telephone communication by laboratory technicians, this proposal was not implemented following a multidisciplinary team discussion. Future research may explore the most suitable transmission mode among the available options. This could involve evaluating different communication methods' effectiveness, efficiency, and user satisfaction to optimise the CV transmission process in healthcare settings.

Our study stands out from previous research, which has focused primarily on the CV notification procedure [2, 15, 29] by delving into the endpoints of the CV chain across various clinical scenarios, thereby achieving whole-chain management. Indeed, the significance of CV management lies not only in the notification process but also in the subsequent actions taken to address CVs promptly and effectively, ultimately aiming to improve patient outcomes. As highlighted by Lynn and Olson [2], operationalising an endpoint for measurement poses a challenge due to the inherent flexibility in clinical practice. This underscores the importance of developing unambiguous endpoints tailored to specific clinical situations, as demonstrated in this study. Allowing clinicians to determine the retest schedule and granting permission for early closure enhances the clarity and rationality of the transmission process. This embodies effective humancomputer interaction and intelligent decision-making. A comparison of accordance rates before and after the implementation of the WCMS revealed notable improvements in several key aspects of CV management and indicates that

the WCMS effectively addressed deficiencies and achieved comprehensive improvement in CV management from a holistic process perspective.

Addressing noncommunication among various departments is critical in electronic CV management. This issue often leads to gaps in communication and coordination, affecting patient care and safety [30, 34]. Designing and integrating a dynamic chain workflow effectively addresses the challenge of connecting intended providers or patients involved, especially considering the high mobility of outpatients and the transfer of inpatients and emergency patients. This dynamic workflow ensures the effectiveness and timeliness of intercommunication by facilitating seamless coordination and information sharing across departments, ultimately enhancing patient care and safety. Similarly, Harris et al's article switched the "first call" clinician from the admitting clinician to the most recent document writer [35]. This change ensures that the most up-to-date and relevant information is accessed promptly, optimising communication and potentially reducing delays in CV reporting and management. These measures collectively contribute to achieving a comprehensive chain management approach from the perspective of the whole patient.

The study has several limitations. First, it was developed and applied in a single hospital, the clinical practicality and effectiveness in other medical institutions remain unknown. Second, non-random sampling is adopted, which indicates that there may be a selection bias. Third, the result part only involves in CV qualityrelated indicators, which are process indicators, while clinical outcomes of patients and user evaluations are out of consideration. In the future, multicenter, non-randomized, multiple-type index trials should be conducted to determine the utility and effectiveness of WCMS for CV reporting.

Conclusions

Our study designs and applies a chain management system for CV management based on the existing information system. By integrating a CV dictionary database, determining endpoints of CV delivery on various occasions, designing a dynamic workflow for transport patients, and formulating a quality control information section for CV management, a WCMS was created from the perspective of the whole sample, the whole process and the whole patient population, respectively, to ensure patient safety and could be applied in the health information systems of other medical institutions. Our study presents the design and implementation of the WCMS for CV management, built upon the foundation of existing information systems. By integrating a CV dictionary database, determining endpoints of CV delivery in various scenarios, designing a dynamic workflow for transported patients, and establishing a quality control information section for CV management, a comprehensive WCMS was developed. This system operates from the perspective of the entire sample, process, and patient population, thereby enhancing patient safety. Furthermore, the system's adaptability suggests its potential applicability in the health information systems of other medical institutions.

Abbreviations

CV	Critical value
WCMS	Whole Chain Management System
CPA	College of American Pathologists
HIS	Hospital information system
LIS	Laboratory information system
PACS	Picture archiving and communication system
ECG	Electrocardiographic

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Not applicable.

Author contributions

Dongdong Wu drafted the initial manuscript, conducted the initial analysis, and interpreted the data. Feng Zhu and Yifan Sheng provided valuable feedback and revised the manuscript. Hanbo Le and Guoqiang Zhang contributed significantly to the conception and design of the work. Lei Wang and Weiwei Zhang were responsible for developing the integrated information system. Boer Yan collected the data and critically reviewed the manuscript for important intellectual content. All the authors approved the final manuscript for submission and agreed to be accountable for all aspects of the work.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

All participants signed informed consent forms for this research. This research was approved by the Ethics Committee of Wenzhou Medical University Affiliated Zhoushan Hospital under approval ID NO. 2021048.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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