

# Effect of PDCA on Improving the Compliance of Sepsis Bundles

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## Research Article

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# Abstract

**Background** To explore the application effect of plan, do, check and action circulation management mode in improving the compliance of sepsis bundle treatment.

**Methods** 132 patients with sepsis admitted from January 1 to December 31, 2018 were selected as the control group, and the bundle treatment measures of sepsis were routinely implemented, that is, the nurses received the confirmation notice of sepsis, measured the body temperature, blood pressure, central venous pressure (CVP), central venous oxygen saturation ( $S_{cv}O_2$ ), indwelling catheter, etc., and the doctor ordered the infusion of antibiotics, rehydration, application of pressor drugs, blood culture and blood gas analysis, blood routine test, procalcitonin and other sample medical orders were immediately implemented by nurses, and the improvement of blood pressure, urine volume and skin endings was closely observed, Doctors and nurses reminded each other to complete the above treatment measures within 6 hours; 138 patients with sepsis admitted from January 1 to December 31, 2019 were selected as the observation group. The Department established a sepsis treatment group. All medical staff, under the leadership of the medical and nursing team leaders, took the same measures as the control group, supplemented by PDCA cycle management. Objective to compare the changes of compliance of medical staff to sepsis bundle treatment before and after the implementation of PDCA cycle management.

**Results** Compared with the control group, the observation group achieved the completion rate of sepsis bundle treatment in 1 hour was 76.8% (65.9%), the completion rate in 3 hours was 82.6% (69.7%), and the completion rate in 6 hours was 87.7% (77.3%). The difference was statistically significant ( $P < 0.05$ ).

**Conclusions** The implementation of PDCA cycle management mode can effectively improve the compliance of medical staff to the bundle treatment of sepsis, improve the treatment efficiency of sepsis, and improve the quality of medical care.

## Background

The *Chinese Guidelines for the Emergency Treatment of Sepsis/Septic Shock (2018)* defines sepsis as life-threatening organ dysfunction caused by a dysregulated host response to infection <sup>[1]</sup>. Prompt diagnosis and treatment of sepsis is very important, and according to the World Health Organization, sepsis should be treated as a priority by global health systems <sup>[2]</sup>. More than 80% of patients survive when shock is treated within one hour; if shock is diagnosed and treated after six hours, the survival rate drops to 30% <sup>[3-4]</sup>. The Saving Sepsis Campaign (SSC) is a joint initiative by the European Society of Intensive Care Medicine and the Society of Critical Care Medicine that is dedicated to reducing the morbidity and mortality of sepsis and septic shock worldwide. Sepsis bundles have always been the core strategy of the SSC guidelines. It emphasizes the necessity and importance of timely and effective implementation of cluster therapy within three hours and six hours of diagnosis of sepsis or septic shock. It has been proven by many countries that it can significantly improve the prognosis of patients with sepsis and septic shock and has been considered a cornerstone for improving the quality of treatment of

sepsis and septic shock since 2005 [5-7]. However, health care workers, especially nurses, are not aware of the guidelines. The overall compliance during the course of cluster therapy is low and there is a large variation in the attainment rate among the items of the treatment bundles recommended by the guidelines with a completion rate of 23.5% (16/68) for cluster therapy within three hours after septic shock and 33.3% (20/68) within six hours. There is also a large gap between the effective implementation of cluster therapy and the requirements [8]. Poor adherence to guidelines and poor implementation by medical staff directly affect and increase the 28d mortality of patients with severe sepsis and septic shock [9]. At present, the methods to improve the compliance of sepsis bundles include the establishment of departmental medical and nursing teams for sepsis treatment, the use of checklists, training, assessment and educational supervision, but the highest rate of adherence to the standard is only at 81% [10-11]. The Plan, Do, Check, Act (PDCA) Cycle, also known as the Deming Cycle, can assist medical and nursing staff in clinical work to proactively identify problems, strictly link quality control and management and optimize workflow [12-13]. The PDCA method gradually improves the quality of work through a closed loop system and circular management of improvement projects in four stages: Plan, Do, Check, and Act [14]. This kind of quality management method has the characteristics of "big ring sets small ring, small ring ensures big ring, step-by-step promotion and continuous improvement". The clinical use of PDCA for management can not only ensure more rigorous and effective medical and nursing practices, but also improve medical and nursing quality [15]. PDCA cycle management is effective in improving the compliance of medical staff to sepsis bundles.

## **1. Data And Methods**

### **1.1 General Data**

#### **1.1.1 Study subjects:**

132 septic patients admitted to the Department of Critical Care Medicine of our hospital from January 1 to December 31, 2018 were selected as the control group; 138 septic patients admitted from January 1 to December 31, 2019 were selected as the observation group. This study was conducted in accordance with the Declaration of Helsinki and approved by the ethics committee of Hebei General Hospital.

#### **1.1.2 Inclusion criteria:**

Meeting the diagnostic criteria of the *Chinese Guidelines for the Treatment of Severe Sepsis/Septic Shock (2014)* by the Chinese Society of Intensive Care Medicine Branch [3], and admission to the ICU to confirm the diagnosis of sepsis with a duration of stay longer than six hours.

#### **1.1.3 Exclusion criteria:**

Termination of treatment, discharge or death within six hours after admission.

### **1.1.4 Ethics:**

The study was approved by the hospital's medical ethics committee; approval number (2020), ethical review No. 108. The Informed Consent Form was signed with the patient's family and the subject could voluntarily terminate their participation in the study at any time and would not be prevented from receiving further treatment.

## **1.2 Study methods:**

A prospective cohort study was used.

### **1.2.1 Control group:**

As required by the *Chinese Guidelines for the Treatment of Severe Sepsis/Septic Shock* and the *Professional Quality Control Index for Critical Care Medicine (2015)*, the physician diagnosed sepsis and notified the nurse. The nurse immediately measured temperature, blood pressure, central venous pressure (CVP), and central venous oxygen saturation ( $S_{cv}O_2$ ) and inserted an indwelling urinary catheter. The doctor gave medical orders for antimicrobial infusion, rehydration, application of antihypertensive drugs, collection of blood culture, blood gas analysis, blood routine, calcitonin, and other specimens. The nurse immediately carried out these orders and closely observed the improvement of blood pressure, urine volume, skin endings, etc. The doctors and nurses reminded each other to complete the above treatment measures within six hours.

### **1.2.2 The sepsis treatment team**

for observation group A was established in the department and all medical and nursing staff under the leadership of medical and nursing team leaders applied PDCA cycle management to the problems in the sepsis bundles.

#### **1.2.2.1 Plan (P):**

132 cases of sepsis from January to December 2018 were retrospectively investigated. The problems identified in the process of cluster therapy were that antibiotics could not be given in time, the retention rate of blood culture before the application of antibiotics was low, the measurement of  $S_{cv}O_2$  and CVP was delayed or not measured, the measurement of lactic acid was delayed, and the volume of fluid and dosage did not meet the guideline requirements (see Table 1). The main reasons for poor adherence were analyzed as busy medical and nursing staff, insufficient knowledge of guidelines, poor awareness of

S<sub>cv</sub>O<sub>2</sub> and CVP measurement, lack of antimicrobial stockpiles in the department, and a delay in medical record transfer and order creation resulting in a medication time greater than one hour. The causes of poor adherence were plotted into a fishbone diagram of cause analysis (see Fig. 1). Group members used evaluation methods and other means to identify the main causes and highlighted them with red circles on the fishbone diagram.

### **1.2.2.2 Development (D):**

From January 2019, corresponding improvement strategies were formulated for different causes and medical staff continued to implement the cluster therapy strategies for sepsis on the basis of improvement. Specific improvement measures are shown in Table 2.

### **1.2.2.3 Check (C):**

After the implementation of improvement measures, the completion rates of the sepsis bundles for one hour, three hours, and six hours were calculated, respectively.

### **1.2.2.4 Assessment (A):**

Standardize the process of sepsis cluster treatment (see Table 3) and continuously evaluate future implementation processes to ensure the scientificity and effectiveness of the measures.

## **1.3 An evaluation index**

was used to compare the completion rates for one hour, three hours, and six hours for sepsis bundles in the observation and control groups.

## **1.4 Statistical methods:**

The data used in this study were analyzed using SPSS 18.0. The comparison of the count data was performed by the  $\chi^2$  test and the mean  $\pm$  standard deviation ( $\pm s$ ) was used for statistical description. The t-test and ANOVA (with necessary correction in case of variance) were used for the comparison of differences between groups, F-values were calculated, and a P-value under 0.05 was considered statistically significant.

Table 1  
The compliance of 132 sepsis patients with 1 h, 3 h and 6 h of cluster bundle (n = 132)

<b>Indicators</b>	<b>1 h cases (n) /compliance rate (%)</b>	<b>3 h cases (n) /compliance rate (%)</b>	<b>6 h cases (n) /compliance rate (%)</b>
Measurement of lactate concentration	119/(90.1)	130/(98.5)	131/(99.2)
Blood culture before antibiotic therapy	87/(65.9)	92/(69.7)	103/(78.0)
Administer broad-spectrum antimicrobial drugs	91/(68.9)	95/(72.0)	105/(79.5)
Give 30 ml/kg crystalloid for target resuscitation for hypotension or lactate $\geq$ 4 mmol/L	93/(70.5)	96/(72.7)	102/(77.3)
Administering antihypertensive drugs	132/(100)	132/(100)	132/(100)
Measure CVP	90/(68.2)	102/(77.3)	110/(83.3)
Measure ScvO <sub>2</sub>	87/(65.9)	93/(70.5)	108/(81.8)
Repeat lactate level measurement	92/(69.7)	99/(75.0)	113/(85.6)

Table 2  
Countermeasures for poor compliance of sepsis bundle

Problems	Countermeasures
<p>Poor awareness of doctors in ScvO<sub>2</sub> measurement</p>	<ol style="list-style-type: none"> <li>1. Strengthen the awareness of doctors and nurses on the importance and necessity of sepsis centralized treatment.</li> <li>2. Formulate the process of sepsis centralized treatment and emphasize the joint compliance of doctors and nurses.</li> </ol>
<p>Poor awareness of nurses in active CVP measurement</p>	<ol style="list-style-type: none"> <li>3. Dedicated personnel for supervision and quality control.</li> <li>4. Develop a reward and punishment program.</li> </ol>
<p>Antimicrobials cannot be retrieved within 1 h</p>	<ol style="list-style-type: none"> <li>1. Apply to the pharmacy department to reserve commonly used antimicrobials as base drugs.</li> <li>2. Communicate with the pharmacy department to be able to temporarily borrow medication when the department's reserve is insufficient or cannot meet treatment needs, and then return the borrowed medication after the medical records are transferred and the medical orders are promptly made up.</li> <li>3. When the preparation is insufficient, the nursing team leader is responsible for having the antimicrobial agent ready at the first time after the diagnosis of sepsis is confirmed.</li> <li>4. For antimicrobials requiring skin tests, the deputy team leader on duty is responsible for the configuration of the skin test solution, implementation of the skin test and observation of the results.</li> </ol>
<p>Lack of process system</p>	<ol style="list-style-type: none"> <li>1. Develop a departmental management system for improving compliance with sepsis bundle.</li> <li>2. Formulate a flow chart of sepsis bundle.</li> <li>3. Dedicated person is responsible for supervision and quality control of the implementation of the established system and process.</li> <li>4. Set up a sepsis treatment team including doctors and nurses, and have team members on duty in every shift to ensure the timeliness and effectiveness of sepsis bundle.</li> </ol>

Table 3  
Flow of sepsis bundle

Time	Admission to ICU 1 h	Admission to ICU 3 h	Admission to ICU 6 h
Indicators to be completed	<input type="checkbox"/> Assess the condition and execute emergency medical orders, such as cooperate with doctors for tracheal intubation  <input type="checkbox"/> Establish dual fluid lines with $\leq$ 22G indwelling needle, and establish central venous access with the physician  <input type="checkbox"/> perform invasive blood pressure monitoring by puncturing artery  <input type="checkbox"/> collect various specimens, especially blood gas, and measure blood lactate concentration  <input type="checkbox"/> Perform blood culture before applying antimicrobial drugs  <input type="checkbox"/> give broad-spectrum antibacterial drug treatment  <input type="checkbox"/> Resuscitate with 30 ml/kg crystalloid solution as prescribed for hypotension or lactate $\geq$ 4 mmol/L	<input type="checkbox"/> Continue the items not completed within 1 h, especially  <input checked="" type="checkbox"/> Measure blood lactate concentration  <input checked="" type="checkbox"/> Blood culture before applying antimicrobial drug treatment  <input checked="" type="checkbox"/> Treat with broad-spectrum antibacterial drugs  <input checked="" type="checkbox"/> Give 30 ml/kg crystalloid for target resuscitation for hypotension or lactate $\geq$ 4 mmol/L  <input type="checkbox"/> Perform other monitoring, treatment and care	<input type="checkbox"/> Continue the program within 3 h  <input type="checkbox"/> Give blood pressure raising drugs  <input type="checkbox"/> Measure CVP  <input type="checkbox"/> Measure $S_{cv}O_2$  <input type="checkbox"/> Repeat measurement of blood lactate level

## 2. Results

### 2.1 General information (see Table 4):

There was no statistically significant difference between the two groups in terms of age, gender and APACHE II score;  $P > 0.05$ .

### 2.2 Completion rates of one hour, three hours and six hours of sepsis bundles in both groups (see Table 5):

After the implementation of PDCA cycle management in the observation group, the completion rate of the one-hour sepsis bundles increased from 65.9–76.8%, the three-hour completion rate increased from 69.7–82.6%, and the six-hour completion rate increased from 77.3–87.7%. These produced a  $P$ -value  $< 0.05$ , meaning the differences were statistically significant. The compliance of the sepsis bundles had significantly improved in the observation group compared with the control group.

Table 4  
Comparison of general information of patients in two groups

Groups	Cases (n)	Gender (n)		Age (years)	APACH-II score
		Male	Female		
Control group	132	72	60	77.24 ± 6.91	20.13 ± 5.18
Observation group	138	77	61	78.73 ± 7.22	21.48 ± 6.35
$\chi^2$ /t		0.043		1.733	1.918
P		0.836		0.084	0.056

Table 5  
Comparison of 1 h, 3 h and 6 h completion of sepsis bundle in two groups n (%)

Groups	cases	1 h completion (%)	3 h completion (%)	6 h completion (%)
Control group	132	87(65.9)	92(69.7%)	102(77.3%)
Observation group	138	106(76.8)	114(82.6%)	121(87.7)
$\chi^2$		3.934	6.219	5.084
P		0.047	0.013	0.024

### 3. Discussion

Since 2004, international sepsis guidelines have been updated four times, domestic guidelines have been launched successively, quality control standards for sepsis diagnosis and treatment have been improved and the optimal time period for cluster therapy has been adjusted from three hours and six hours to one hour. This was proposed in 2018, which has put forward higher requirements for standardized diagnosis and treatment of sepsis, comprehensive management of critically ill patients by medical institutions, and coordination among hospital departments [16-17]. The completion rate of sepsis bundles has become one of the criteria for quality control of critical care by hospital management [18]. The New York Centers for Medicare and Medicaid Services in the United States require hospitals to report sepsis cluster therapy performance rates to them as part of the inpatient quality reporting program and as a condition of payment [19]. Therefore, it is necessary to correctly calculate the completion rates of sepsis cluster therapy at one hour, three hours, and six hours, and to take effective measures to continuously improve the completion rates. Despite the various measures taken to improve compliance for sepsis cluster therapy, the attainment rate is still unsatisfactory [10-11]. In this study, the PDCA cycle management model was adopted, in which the medical and nursing team leaders regularly informed and analyzed data on the compliance of sepsis bundles, summarized the problems and difficulties in the implementation process and the sepsis treatment team members then discussed and formulated corresponding countermeasures. According to the inspection, additional points were rewarded or deducted on the basis

of the original performance. This cycle is repeated, which promotes the effective operation of PDCA cycle management, improves the sense of responsibility and urgency of medical and nursing staff and ensures the improvement of sepsis bundle compliance. The compliance rates of one hour, three hours and six hours for sepsis cluster treatment reached 76.8%, 82.6%, and 87.7%, respectively, which is related to the fact that the department has repeatedly trained staff and emphasized the importance of cluster treatment for three years. Additionally, the compliance of treatment has improved to a certain extent through methods such as checklists. However, due to the existence of objective reasons, such as low bed-to-nurse ratios and delayed transfer of medical records, further improvement of medical and nursing staff compliance to sepsis cluster therapy needs to be addressed in terms of rationalization and maximization of ICU human resource allocation, optimization of the referral process and medication pick-up process. One-hour cluster therapy can achieve the goal of reducing 28d morbidity and mortality rate<sup>[20]</sup>, but mandatory rapid use of broad-spectrum antimicrobials, especially in patients without shock, may lead to their overuse<sup>[21]</sup>, a viewpoint that influences some physicians' prescription of broad-spectrum antimicrobials and contributes to the low overall treatment adherence rate.

## 4. Conclusion

The PDCA cycle management model, in which existing and potential problems are identified in clinical work, a problem-based improvement plan is developed, corresponding measures are implemented strictly according to the rectification plan and the results of implementation and execution are checked, standardized, or process-oriented, and the above links are cycled back and forth to better highlight the advantages of continuous improvement in quality management, continuously improve the quality of medical care and ensure medical safety<sup>[22]</sup>. However, objective reasons hindering the implementation of cluster therapy and subjective factors exist, such as cognitive bias and poor practice of cluster therapy by medical personnel, which makes 100% compliance of sepsis cluster therapy difficult to reach. The sample size of this study is relatively small and regional in nature, and as an observational cohort study it also has its inherent limitations and biases. We will continue to conduct in-depth multidisciplinary and multicenter studies on adherence to the processes for sepsis bundles to provide more bases for clinical decisions.

## List Of Abbreviations

PDCA: The Plan, Do, Check, Act

CVP: central venous pressure

S<sub>cv</sub>O<sub>2</sub>: central venous oxygen saturation

SSC: Saving Sepsis Campaign

## Declarations

# Ethics approval and consent to participate

This study was conducted in accordance with the Declaration of Helsinki and approved by the ethics committee of Hebei General Hospital. The consent was obtained via a signed and dated written consent form. The Informed Consent Form was signed with the patient's family and the subject could voluntarily terminate their participation in the study at any time and would not be prevented from receiving further treatment.

## Consent for publication

Not applicable.

## Availability of data and materials

All data generated or analyzed during this study are included in this published article

## Competing interests

All of the authors had no any personal, financial, commercial, or academic conflicts of interest separately.

## Funding

Not applicable.

## Authors' contributions

LCX and LY conceived of the study, and TYQ, ZK, HGZ and SLM participated in its design and coordination and DQS helped to draft the manuscript. All authors read and approved the final manuscript.

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Not applicable

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## Figures

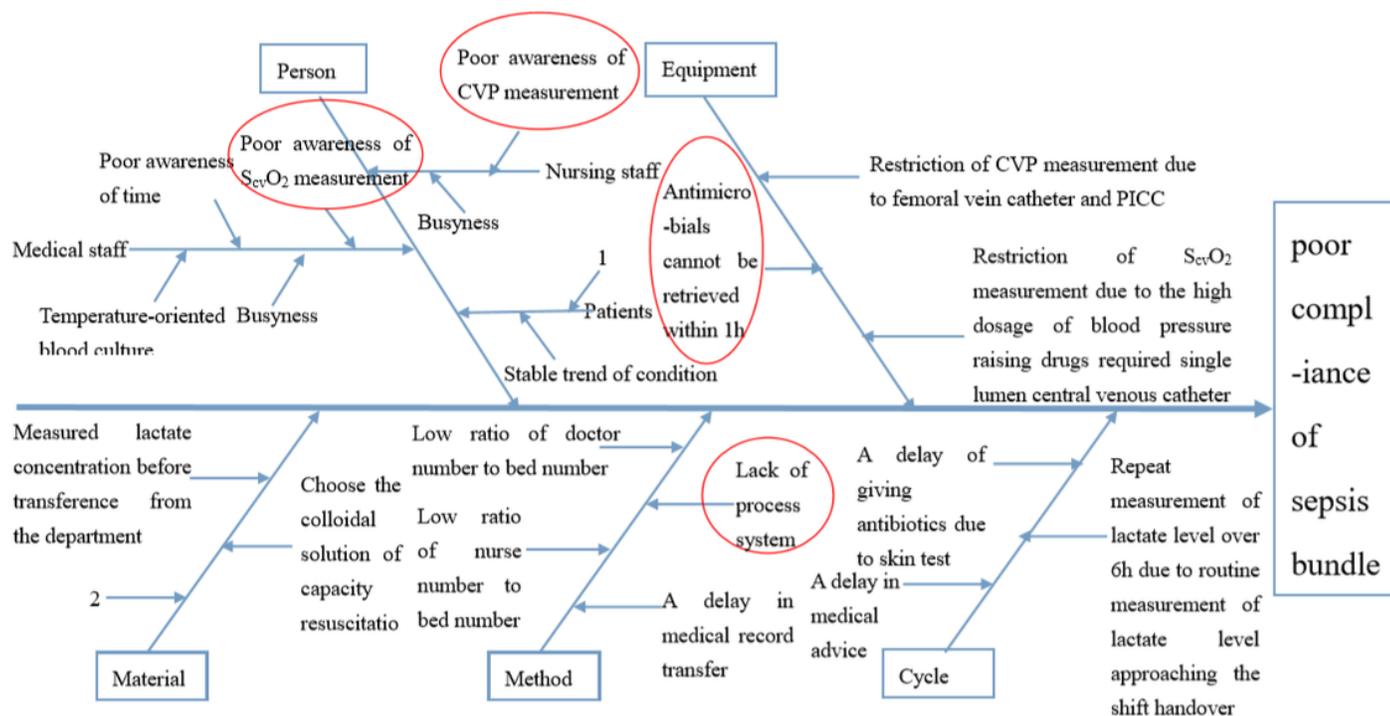


Figure 1

Financial trouble and difficulties to make use of PICCO and so on for target capacity resuscitation;