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Clinical Pathway Management Under the Reform of the DSP-CTB Payment System in Chengdu, China: A Case-Based Study

WEN Yong

Doctor of Management

Supervisor:
PhD Elizabeth Reis, Full Professor,
ISCTE University Institute of Lisbon

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Abstract

The reform of the medical insurance payment system affects the efficiency of medical insurance fund utilization and the sustainability of the healthcare security system. It plays a crucial role in optimizing the allocation of medical resources, improving the level of medical services, and avoiding unreasonable growth in medical expenses. Countries and regions worldwide actively experiment payment system reforms based on Diagnosis Related Groups (DRG) according to their specific circumstances.

This research, from an empirical analysis perspective, focuses on a grade-A tertiary hospital (K Hospital) in Chengdu, Sichuan, China. The research investigates the combined effects of a new payment system based on DRG and clinical pathways, specifically referred to as Disease-based Score Payment under the Control of Total Budget (DSP-CTB), which is being piloted in the hospital. The results indicate that, compared to the period before adopting the DSP-CTB payment system, the hospital showed varying degrees of improvement in the hospitalization outcomes and costs of patients following the reform. However, suboptimal combined effects were observed. To address this issue, a multiple linear regression model was further established to analyze key factors influencing hospitalization costs of the DSP-CTB group. Based on this, a Define-Measure-Analyse-Improve-Control DMAIC clinical pathway management model tailored to the DSP-CTB payment system is proposed, aligning with the principles of comprehensive quality management. This model aims to provide management methods for healthcare institutions to better adapt to the DSP-CTB payment system. Additionally, four criteria for the integration of payment systems and clinical pathways are provided, offering guidance for clinical pathway management under the DSP-CTB payment system. In summary, this research provides essential theoretical guidance and a reference for clinical pathway management to healthcare institutions that adopt the DSP-CTB payment system, aiming to enhance medical quality and reduce healthcare costs.

Keywords: Hospital management, medical insurance payment system, clinical pathway management, total payment control

JEL: M10, M38

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Resumo

A reforma do sistema de pagamento de seguros de doença afeta a eficiência da utilização dos fundos de seguros de doença e a sustentabilidade do sistema de pagamento de cuidados em saúde. Esta reforma desempenha um papel crucial na otimização da afetação dos recursos em saúde, na melhoria da qualidade dos serviços e na prevenção do crescimento excessivo das despesas. Países e regiões em todo o mundo experimentam ativamente reformas dos sistemas de pagamento com base em Grupos de Diagnósticos Homogêneos (GDH), adaptados às suas características específicas.

A investigação apresentada nesta tese adota uma perspetiva de análise empírica centrada num hospital terciário de nível A (Hospital K) em Chengdu, Sichuan, na China. O estudo investiga os efeitos combinados de um novo sistema de pagamento baseado em GDH e percursos clínicos, especificamente designado por Pagamento Baseado na Pontuação da Doença sob Controlo Orçamental Total (DSP-CTB), que está a ser testado no hospital K. Os resultados indicam que, em comparação com o período anterior à adoção do sistema de pagamento DSP-CTB, o hospital apresentou diferentes graus de melhoria nos resultados dos internamentos e nos custos dos doentes após a reforma. No entanto, foram observados efeitos combinados não óptimos. Para resolver esta questão, foi estabelecido um modelo de regressão linear múltipla para analisar os principais factores que influenciam os custos de internamento nos grupos DSP-CTB. É, assim, proposto um modelo de gestão dos percursos clínicos DMAIC, adaptado ao sistema de pagamento DSP-CTB, de acordo com os princípios da gestão pela qualidade total. Este modelo tem como objetivo fornecer métodos de gestão para as instituições de saúde se adaptarem melhor ao sistema de pagamento DSP-CTB. Além disso, são identificados quatro critérios para a integração dos sistemas de pagamento e dos percursos clínicos, oferecendo orientações para a gestão dos percursos clínicos no âmbito do sistema de pagamento DSP-CTB. Em suma, esta investigação fornece às instituições de saúde que adoptam o sistema de pagamento DSP-CTB orientações teóricas essenciais para a gestão dos percursos clínicos, com o objetivo de melhorar a qualidade do serviço e reduzir os custos dos cuidados de saúde.

Palavras-chave: gestão hospitalar, sistema de pagamento de seguros de saúde, gestão dos

percurso clínicos, control de pagamentos

JEL: M10, M38

摘 要

医保支付制度改革直接关系到医保基金的使用效率和医疗保障制度的可持续性。它在推动医疗资源的优化配置，提高医疗服务水平、避免不合理的医疗费用增长方面发挥着至关重要的作用。世界各国和地区都根据自身实际情况，积极探索并实施基于诊断相关分组（Diagnosis related groups, DRG）的支付制度改革。

本研究从实证分析角度，以四川成都地区一家三级甲等综合性公立医院（K医院）为调研对象，调查了该医院试点的一种基于DRG的新支付制度与临床路径结合效果。该支付制度被称为医疗保险总额控制按病组分值付费制（Disease-based score payment under the control of total budget, DSP-CTB）。研究结果表明，与实施DSP-CTB支付制度前相比，该医院在实施了DSP-CTB支付制度改革后执行临床路径的患者住院效果和住院费用均呈现不同程度的改善，但也发现存在结合效果不佳的情形。针对这种情形，进一步建立多元线性回归模型，分析了DSP-CTB病组下影响住院费用的关键因素。在此基础上，结合全面质量管理理论提出一种面向DSP-CTB支付制度的DMAIC临床路径管理模式，以便为医疗机构更好的适应DSP-CTB支付制度提供管理方法支持。另外，给出了支付制度与临床路径结合的四个判定准则，为开展面向DSP-CTB支付制度的临床路径管理指明了方向。总的来说，本研究能够为实施DSP-CTB支付制度的医疗机构提高医疗质量，降低医疗费用提供重要的理论指导和临床路径管理方法参考。

关键词：医院管理，医保支付制度，临床路径管理，总额控制

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List of Acronyms

Acronym	Full title
DSP-CTB	Disease-based Score Payment under the Control of Total Budget
DRG	Diagnosis Related Groups
DMAIC	Define-Measure-Analyze-Improve-Control
PCA	Principal Components Analysis
PCCL	Patient Clinical Complexity Level
PCI	Process Capability Indices
PCR	Principal Component Regression
PD	Pancreatoduodenectomy
PDCA	Plan Do Check Action
PERT	Program Evaluation and Review Technique
PIDOV	Plan-Identify-Design-Optimize-Verify
POCT	Point-Of-Care Test
PPS	Prospective Payment System
PPTP	Payment Per Therapeutic Procedure
PSQA	Patient-Specific Quality Assurance
RW	Risk Weight
SDP	Single Disease Payment
SERVQUAL	Service Quality
SIPOC	Supplier-Input-Process-Output-Customer
SOP	Standard Operating Procedure
SPC	Statistical Process Control
TEI	Time Efficiency Index
TQC	Total Quality Control
TQI	Total Quality Improvement
TQM	Total Quality Management
Tw-DRGs	Taiwan-DRGs
UCL	Upper Control Limit
VMAT	Volumetric Modulated Arc Therapy
VSM	Value Stream Mapping

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Chapter 1: Introduction

1.1 Research background

Health insurance is an important part of the modern social security system. The establishment of the health insurance system can be traced back to the German medical insurance system in the late 19th century, which required employers to provide workers with medical insurance, and to compensate workers for their health care expenditures through the financing of sickness funds at that time. This early social medical insurance system is also known as the Bismarck model (Busse et al., 2017). In the first half of the 20th century, social medical insurance systems established by European countries were mainly based on the Bismarck model and the British Beveridge model proposed in 1948 (Sheingold & Hahn, 2014). And the purpose of social medical insurance system is to achieve universal healthcare coverage.

The reform of social medical insurance in China began at the end of the 20th century. In 1997, China issued the Decisions of the Central Committee of the Communist Party of China and the State Council on Health Reform and Development, proposing to establish a medical insurance system that combines general social planning and personal accounts, and gradually expand coverage to provide basic medical insurance for all urban workers. In 1998, China issued the Decision on Establishing the Urban Employees' Basic Medical Insurance System and began to establish a basic medical insurance system for urban employees across the country. To further expand the coverage of medical insurance, China established the new-type rural cooperative medical care system and the basic medical insurance system for urban residents in 2003 and 2007 respectively. From 2003 to 2011, the social medical insurance system, with the basic medical insurance for working urban residents, the new-type rural cooperative medical care system and the basic medical insurance for non-working urban residents as the mainstay, increased China's medical insurance coverage from 29.7% to 95.7% (R. Wu et al., 2020). It is during this period that public medical institutions (or public hospitals), as the main institution providing health care services in China, have grown rapidly. The financing methods of public hospitals in China are mainly financial allocation and medical service charges from the society.

Public hospitals have been well developed, while medical resources have not been well utilized. From 2002 to 2008, public hospitals realized a threefold increase in revenue, but

consumed half of China's total medical expenditure; the utilization rate of medical resources in public hospitals was low and the income brought by medicines exceeded 40% of public hospitals' total income (Xu et al., 2019). Therefore, in 2009, China issued the Opinions of the CPC Central Committee and the State Council on Deepening the Reform of the Medical and Health Care System, requiring the reform of public hospitals as one of the key areas of the medical and health care system reform, and the reform of the payment system as the important part of the medical and health care system reform.

China issued the Opinions on Further Promoting the Reform of Medical Insurance Payment Methods and the Opinions on Carrying out the Control of Basic Medical Insurance Payment's Total Budget in 2011 and 2012 respectively. These two policies further clarified that the reform of the medical insurance's payment method was the main direction of the payment system reform. The latter requires the "gradual establishment of a health care evaluation and supervision system centered on quality assurance, cost control, and standardized diagnosis and treatment, to control the excessive growth of medical expenses, improve the performance of basic medical insurance, and better protect the people's rights and interests concerning basic health care service". Governments and medical insurance departments at all levels in China have carried out exploration on payment methods, and some cities and towns have introduced the diagnosis related groups-prospective payment system (DRGs-PPS). DRGs-PPS was proposed by the United States in 1983 and applied to the "medical care" insurance payment for the elderly over 65 and the disabled. This method was then applied to many other countries (Annear et al., 2018).

The above-mentioned concepts of medical insurance payment can be divided into two categories, one refers to the expenditure of medical insurance institutions to the insured and the other refers to medical insurance institutions' compensation for resources consumed by health care provided by medical institutions, namely the payment of medical insurance institutions to the hospitals. The concept of medical insurance expenditure or payment involved in this study specifically refers to the latter.

Medical insurance payment includes two types: "post-payment" and "pre-payment". "Post-payment" means that the medical insurance institution pays the hospital according to the health care items that have occurred after the hospital provides the health care items to the patient. "Pre-payment" means that the medical insurance institution presets a payment standard before the hospital provides health care services, and then pays the hospital according to the standard afterwards. The "post-payment" method tends to generate moral hazards that induce demand, while the "pre-payment" method provides incentives for saving resources. The DRG is a

strategy of case-mix that divides patients into different groups for treatment and management according to factors such as disease diagnosis, treatment method, complication, age, disease severity, and medical resource consumption. And DRGs-PPS is a medical insurance payment standard, payment system and settlement method that implements the pre-payment method in accordance with DRG. Compared with the fee-for-service policy, the prospective payment system (PPS) is more likely to reduce the waste of medical resources by changing the way the cost is reimbursed, because the PPS reduces costs by setting a fixed fee for a certain group of diseases and making the service provider financially responsible. In other words, DRG is one such PPS, which fixes the price for the DRG group. This DRG payment system changes the behavior of doctors and hospitals, forcing them to participate in the allocation of financial and medical resources in order to control the increase in medical expenditure (Chiang et al., 2023).

In 2017, China issued the Guiding Opinions on Further Deepening the Reform of Basic Medical Insurance Payment Methods, requiring the reform of the medical insurance payment system to cover all medical institutions, and all regions must integrate the budget management of the medical insurance fund to improve the control method of the total budget. Under the requirements of this policy, various regions started to explore the localization of the DRGs payment system, and successively proposed BJ-DRG (Beijing-DRG)、CHS-DRG (China Healthcare Security Diagnosis), and other DRGs-like systems (Yu & Lang, 2020).

In July 2020, Chengdu started a pilot project called the disease-based score payment under the control of total budget (DSP-CTB) (Xiao et al., 2020). The DSP-CTB combines the control of medical insurance's total budget and the settlement method by disease group/kind. In order to give full play to the role of DRG in medical payment, it is necessary to widely promote DRG-based clinical pathway management in the implementation area and ensure that the coordination mechanism between medical insurance management departments and medical institutions is sound. However, these prerequisites are not yet perfect in Chengdu. Therefore, to accumulate experience in the formal introduction of the DRG payment system in the future, it is necessary to carry out a transitional exploration of the reform of the DRG-based payment system. In this context, the DSP-CTB reform project came into being, aiming to lay the foundation for the full implementation of the DRG system in Chengdu through practical exploration.

The payment logic of DSP-CTB can be summarized as:

- (1) Pre-set the list of disease groups;
- (2) Calculate the score based on the disease group according to specific rules, the disease-based scores reflect the relative consumption of medical resources;
- (3) Medical institutions accumulate scores by providing health care services to patients

(annual score);

(4) Sets a total limit according to the medical insurance fund's budget of the region where the medical institution is located;

(5) Determine the unit price of the score based on the region's total limit;

(6) Multiply the unit price by the accumulated scores of each medical institution to determine the settlement (payment) amount of each medical institution.

(7) Expenses exceeding the payment standard shall be paid by the medical institution.

The purpose of implementing the DSP-CTB payment system is to reasonably control medical expenses and ensure that the medical insurance fund is not overspent. It encourages medical institutions to carry out refined management and standardized diagnosis and treatment activities, thereby reducing the waste of medical resources. At the same time, it alleviates the economic burden of patients seeking medical care, allowing them to enjoy high-quality medical services. All in all, the original intention of the reform of the medical insurance payment system is to achieve expense control while ensuring the quality of medical care, that is, the so-called "expense control and quality assurance".

The DSP-CTB system, as deduced from its settlement logic, serves as a macro economic management tool solely designed to prevent the overspending of medical insurance fund. While it is effective in controlling costs, quality assurance still requires the support of micro-level quality management methods. In other words, DSP-CTB lacks a clear management methodology for guiding the refinement of medical institution management and the standardization of clinical diagnosis and treatment. DSP-CTB's cap on total expenditures can decelerate the growth of medical insurance fund spending. However, it cannot avoid the increase of individual cash payment due to the transfer of some expenses to the patient's out-of-pocket program by medical institutions (Xu et al., 2019). One way to achieve the quality assurance is to improve the quality of medical services and control expenses through the standardization (or normalization) of clinical services (Xu et al., 2019), and an important means to realize the standardization of clinical services is to carry out clinical pathway management (Napolitano, 2005; Wu & Zheng, 2007).

The concept of clinical pathway (CP) emerged in the mid-to-late 1980s (Wakamiya & Yamauchi, 2009). The management of clinical pathways is considered to be effective in improving medical quality and medical service efficiency (Lanska, 1998; Yang et al., 2012). In China, the implementation of clinical pathway management began in 2009, but the combination of clinical pathway management and payment methods in China remains suboptimal (Mo et al., 2021). Medical institutions should explore disease management models tailored to their own

circumstances and in line with the medical insurance payment system, so as to achieve an organic balance between clinical pathway management and medical insurance payment system (Mo et al., 2021). Obviously, under the DSP-CTB system, hospitals need to explore medical clinical management methods that adapt to the DSP-CTB system in order to achieve reasonable expense control, standardize the clinical diagnosis and treatment process, and improve the quality of medical services.

Given that the author's institution is among the first institutions in southwest China to carry out the pilot reform of the DSP-CTB payment system, this presents a significant advantage for this study. Consequently, this study will focus on the DSP-CTB payment system implemented by our institution and the clinical pathway implemented, so as to provide method support for the achievement of the original intention of expense control and quality assurance of medical institutions.

Clinical pathway in China is not specifically proposed for the medical insurance payment system; rather, it evolved as a tool for improving treatment quality for specific diseases during medical practice. Therefore, it is an important clinical management method that has been tested by long-term medical practice and is recognized by most medical professionals. This indicates that merely integrating clinical pathway management with the DSP-CTB system is not sufficient. Therefore, the dilemma of this study lies in how to make medical institutions better adapt to the DSP-CTB payment system through clinical pathway management, so as to promote the achievement of the original intention of medical insurance reform with expense control and quality assurance. This study is helpful to help medical institution managers in China better understand the relationship between medical expense control and medical quality assurance.

1.2 Research problem

Although the clinical pathway, as a tool to improve the quality and efficiency of treatment, has been widely used in medical practice in China, its integration with the medical insurance payment system still faces major challenges. The clinical pathway was not originally designed for Medicare payment mechanisms, but as a disease-based quality improvement tool. Therefore, the direct application of China's current clinical pathway to the DSP-CTB system cannot fully achieve the goal of medical insurance reform, that is, to ensure the quality of medical care while controlling medical costs.

The main problem of this study is how to make medical institutions better adapt to the requirements of the DSP-CTB payment system through clinical pathway management. This not

only involves the improvement of medical technology, such as the formulation of more refined clinical pathway guidelines for a certain disease, but also involves the transformation of medical management methods, such as the innovation of clinical diagnosis and treatment process management models, and the collaborative management between various departments of medical institutions. Solving this dilemma is of great significance for promoting the sustainable development of the medical insurance system, promoting the achievement of the original intention of medical insurance reform of cost control and quality assurance, and improving the quality and efficiency of medical services.

1.3 Research questions

As mentioned earlier, the DSP-CTB system is only a macro cost containment method and incentive mechanism, which can realize the optimal allocation of medical resources at macro level, but lacks the safeguard means of micro medical quality. From the perspective of individual rationality, hospitals may choose to accept patients based on the severity of their diseases (refusing to accept patients), reduce necessary healthcare services, affect patient experience and aggravate the contradiction between doctors and patients. The clinical pathway can be regarded as a standardized standard process of diagnosis and treatment, which can play a role in the quality assurance of micro medicine. The formulation of clinical pathway depends more on doctors' professional medical knowledge and technology for diagnosis and treatment. However, physicians rarely or hardly consider the problems of medical costs and limited medical resources from an overall perspective. Therefore, there is a lack of reasonable economic standard regarding the formulation of clinical pathway, and it is highly possible to fall into excessive pursuit of high-quality medical technology and effects while ignoring the limitation of medical resources and cost containment.

If the DSP-CTB system can provide a cost target constraint (reference standard) for the management of clinical pathways to achieve cost control, and the standardization of clinical pathways can ensure that the quality of medical care under DSP-CTB will not be reduced, which will undoubtedly provide a feasible way to achieve the original intention of cost control and quality assurance. Obviously, this has important management practice significance and academic research value. Therefore, the author further puts forward the following questions:

Q1: What is the effect of combining the DSP-CTB system with the clinical pathway?

Q2: What are the factors that affect the cost of hospitalization under the DSP-CTB system?

Q3: How can medical institutions better integrate the clinical pathway with the DSP-CTB

system?

1.4 Research objectives

Based on the above questions, the objectives of this study are:

Objective 1: To evaluate the combination effect of DSP-CTB payment system and clinical pathway, including hospitalization effect and hospitalization expenses, to grasp the actual situation of the combination.

Objective 2: To identify the influencing factors of hospitalization cost in the DSP-CTB disease group, so as to clarify the improvement direction of clinical pathway management.

Objective 3: According to the improvement direction, a new clinical path management model for DSP-CTB payment system is proposed, to better integrate the clinical pathway with the DSP-CTB system, so that medical institutions can better adapt to DSP-CTB payment system, promote the achievement of the original intention of medical insurance reform with cost control and quality assurance.

1.5 Research content and technical route

This thesis capitalizes on the implementation of the DSP-CTB payment system reform at the author's institution, referred to as K Hospital. It involves collecting the data on the Front Sheet data of inpatient for the analysis of combination effect of the DSP-CTB payment system and the clinical pathway, and the analysis of the influencing factors of hospitalization expenses and construct a clinical road management model for the DSP-CTB payment system. The relevant chapters and research contents of this thesis are arranged as follows:

Chapter 2 presents a literature review, which first defines the important concepts related to this thesis, sorts out the relevant theoretical knowledge of total quality management, and lays a theoretical foundation for the subsequent clinical pathway management model, and then reviews the status of DRG-based payment reform, clinical pathway management, and the application of quality management methods in medical quality improvement. Chapter 3 defines the important concepts relevant to this thesis, sorts out the relevant theoretical knowledge of comprehensive quality management, and lays a theoretical foundation for the subsequent clinical pathway management model. Chapter 4 outlines the survey participants, data collection, and the methods employed in the study. Chapter 5 presents the research findings. It includes a retrospective analysis of the effects of integrating the DSP-CTB payment system with the

clinical pathway to answer Question 1. A stepwise regression model was constructed to analyze the influencing factors of hospitalization cost in the DSP-CTB group to answer Question 2. Chapter 6 proposes a clinical path management strategy for DSP-CTB payment system - DMAIC clinical path management model is proposed by combining related theories and methods of quality management to answer Question 3. Chapter 7 discusses these findings and provides a comprehensive conclusion.

The technical route of this thesis is shown in Figure 1.1. The technical route is mainly developed according to the classical research ideas of raising questions, analyzing questions and answering to questions. In the problem-identification stage, the background and challenges of the medical insurance payment system reform are first explored through a literature review, leading to the identification of the research dilemma. Subsequently, research questions and research objectives are refined based on this dilemma, integrating relevant concepts and theoretical foundations to finalize the scope of the research. In the problem-analysis stage, data from the initial medical records of the surveyed hospital are collected to assess the effectiveness of integrating the DSP-CTB payment system with the clinical pathway. This is followed by a focus on the factors affecting the hospitalization expenses of DSP-CTB patient group. The problem-solving stage involves proposing management strategies tailored to the DSP-CTB payment system based on the findings of the analysis. Finally, these findings are discussed in order to derive insightful research conclusions.

Clinical Pathway Management Under the Reform of the DSP-CTB Payment System in Chengdu, China: A Case-Based Study

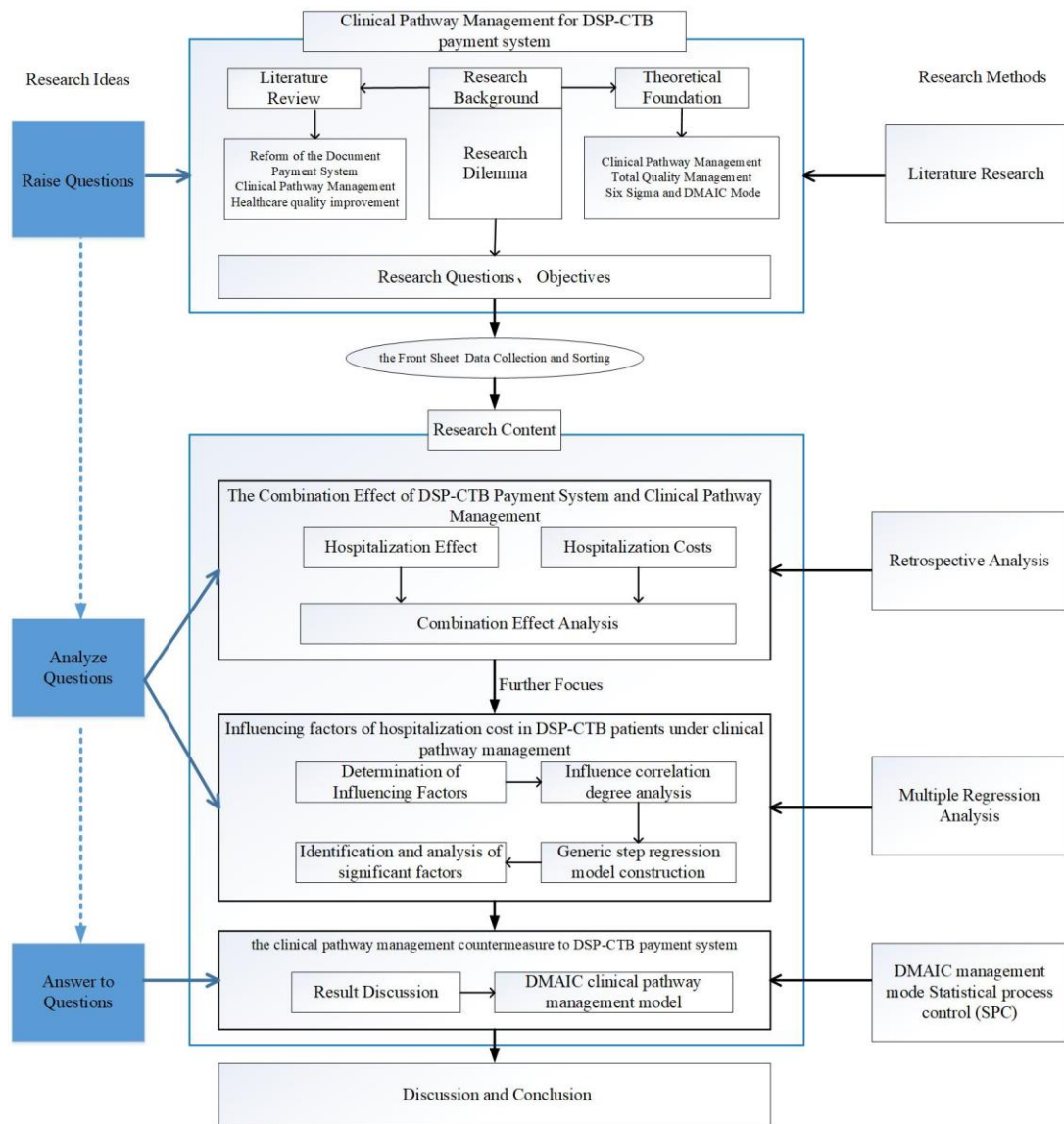


Figure 1.1 Research technical route

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Chapter 2: Literature Review

2.1 Related concepts and theoretical basis

2.1.1 Clinical pathway

The clinical pathway is a standardized treatment and care plan, which provides a sequential standardized diagnosis and treatment process for a specific disease or surgery, including examination, treatment, surgery, care and other links. Healthcare professionals need to follow this process to ensure that patients receive consistent and efficient treatment and care throughout their treatment. It is a procedural and standardized diagnosis and treatment implementation plan based on evidence-based medicine, aiming at expected treatment effect and expense control, with strict work sequence and accurate time requirements. The clinical pathway is considered to be a tool to support clinical decision-making, providing patients with standardized treatment procedures in specific clinical settings (Cho et al., 2020).

Guided by evidence-based medicine, the clinical pathway is developed and followed by physicians, nurses, and other healthcare professionals. This ensures that the diagnostic and treatment measures within the pathway are effective and safe, and can improve patient outcomes and satisfaction. In other words, the clinical pathway is used by healthcare providers to define the best procedures, processes, and timing in their organizations, and it is a clinical management tool for the treatment of patients with specific diseases based on evidence-based medicine, which can positively impact the quality of care (Panella et al., 2003). Buchert and Butler (2016) mentioned that the quality of medical services is highly variable in the process of medical practice (e.g., different healthcare providers and care settings), and that the clinical pathway can improve process quality, improve efficiency, and eliminate waste just as standardized processes do in industrial production. For this reason, the clinical pathway is also referred to as the critical pathway, the care pathway, or the integrated clinical pathway (Graeber et al., 2007; Hensen et al., 2005).

The standardization of clinical pathways can easily be misinterpreted as a concept of “recipe medicine” approach, raising concerns about interference with physician autonomy (Hipp et al., 2016; Lanska, 1998). However, it is crucial to understand that clinical pathways are not intended to be rigid, recipe-like operational procedures. Healthcare professionals

involved in clinical practice still need to flexibly adjust their diagnosis and treatment activities according to the patient's treatment effect. When a patient no longer meets the requirements of the clinical pathway, the physician has the right to ask the patient to abandon or withdraw from the pathway (Hipp et al., 2016). Kurtin and Stucky (2009) pointed out that the clinical pathway is not “recipe” medicine, which does not interfere with the autonomy of physicians to guide patients in treatment, but rather improves treatment by reducing or eliminating many barriers to provide safe, effective, and highly-effective treatment.

The advantages of the clinical pathway can be summarized as:

Clinical pathways can be instrumental in mitigating unnecessary differences in care. Differences in care refer to similar treatments for similar patients based on the best evidence or expert consensus, while patients with significant differences in disease conditions should be treated differently. The clinical pathway standardizes the process of care and has the potential to reduce unnecessary disparities in care, improve medical outcomes and reduce the expense of care.

Clinical pathways expedite the application of medical literature knowledge to routine clinical care practices. Pathways are regularly reviewed and updated through effective clinical pathway management to help physicians provide access to the latest treatment options. Each clinical pathway designates content experts who assess the importance and relevance of new information, such as a new drug or treatment, and then incorporate appropriate drugs or treatments into the pathway for use. Doing so can reduce the gap between knowledge and practice from years to months or even weeks.

Clinical pathways facilitate the coordination of complex tasks, especially in inpatient treatment, which encompasses multidisciplinary approaches, extensive doctor-patient interactions, and various treatment measures. In most inpatient care, the clinical pathway developed involves all providers involved in the patient's care, including nurses, social workers, dietitians, pharmacists, and respiratory therapists. Care coordination can be explicitly addressed through the clinical pathway.

Clinical pathways enhance the safety of clinical interventions for patients. The variability in care processes due to differences among doctors or patients significantly increases the risk of errors and potential harm. By standardizing clinical interventions, as well as the selection and implementation of processes through the clinical pathway, the safety of these interventions is greatly improved.

The clinical pathway addresses the slow adoption of some practices by healthcare providers to improve outcomes and ensure patient safety.

Another concept often mistaken for clinical pathways is that of clinical guidelines. Clinical guidelines represent best practices established on preliminary evidence, extensive analysis, and discussion among clinical experts. The clinical pathway can be understood as an operational tool for implementing clinical guidelines based on local practice and best practices developed by interdisciplinary teams (Hipp et al., 2016). Clinical pathways can be seen as a complement to, not a replacement, of the clinical guidelines. Clinical pathways may be easier to use in practice as a means of assisting in the implementation of guidelines, or as a concise learning tool for learning guidelines (Toy et al., 2018). Hooda and Fields (2021) argues that clinical practice guidelines provide an evidence-based roadmap for most care, but often lack guidance on specific patient factors and treating disease conditions. The clinical pathway serves as a real-time clinical decision support system that transforms clinical guidelines into clinical practice. The pathway allows for the creation of a standardized and multidimensional roadmap for the continuum of care that can support clinical decision-making, maintain optimal medical outcomes, and limit unwanted variation in treatment.

In general, the clinical pathway can be understood as a standard operating procedure (SOP) similar to that used in industrial production. It routinizes and standardizes the stages of diagnosis, treatment, rehabilitation, nursing and discharge planning, and formulates strict operation sequences, time plans and allocation of medical resources, so as to provide patients with orderly and efficient medical services.

2.1.2 Clinical pathway management

Clinical pathway management refers to the systematic management of the formulation, implementation, monitoring and continuous improvement of clinical pathways. Clinical pathway management involves many aspects such as organizational structure, personnel training, system guarantee, and quality evaluation. Its core mission is to ensure the smooth implementation of clinical pathways, improve the quality of care, and ensure patient safety.

Clinical pathways are designed to enhance the quality and efficiency of care for patients admitted (Lanska, 1998; Pearson et al., 1995), but they cannot address all aspects of patient management. Several factors can increase the risk of clinical pathway failure, including inadequate management capacity, lack of multidisciplinary involvement, resistance from clinicians, unclear quality and cost objectives, resource shortages, poor timing and scheduling, and incomplete coverage of the entire treatment process (Lanska, 1998). Therefore, it is necessary to combine the clinical pathway with other management methods or strategies (e.g., administrative rules and regulations, bonuses and penalties, education and training, and

supervision) to reduce the risk of clinical pathway failure. For instance, combining clinical pathways with quality assurance programs can help assess the quality of care and identify significant deviations from standard medical care quality. Similarly, integrating clinical pathways with continuous quality improvement programs can enhance various aspects of the nursing process (Lanska, 1998). Effective clinical pathway management is an important guarantee for the successful implementation of clinical pathways in hospitals. It can provide methodological support for the quality improvement of clinical pathways and systematic methodological support for scientific evaluation and effective monitoring of clinical pathway quality.

The general management pathways to ensure that the clinical pathway works can be summarized as:

- (1) Powerful administrative and medical leadership;
- (2) All clinical disciplines along the pathway are actively involved in patient care;
- (3) Providing clinicians with regular feedback on quality and cost goals, compliance, disparities, and care outcomes;
- (4) Adequate resources (including manpower, time and money);
- (5) Documentation improvements, including simple and effective charting and variant reporting processes;
- (6) Integrating the entire care process into the pathway, not just the components of the hospital;
- (7) The development and implementation process of clinical pathways should be combined with continuous quality management;
- (8) Evaluating and modifying clinical pathways regularly if necessary.

2.1.3 Total quality management

Total quality management (TQM) is a customer-centric quality management theory and method that maximizes organizational performance through full participation, process focus and continuous improvement (Dotchin & Oakland, 1992; Maiden, 1993). Its core philosophy is to improve product quality, reduce costs, meet customer needs, and improve the competitiveness of the organization. The theoretical model of TQM covers quality culture, communication, commitment, standards system, quality improvement team and continuous improvement approach (Dotchin & Oakland, 1992).

The TQM was first developed from the concept of total quality control (TQC) proposed by Feigenbaum (Hamid et al., 2019). In particular, the continuous improvement of TQM theory by

gurus such as Deming, Juran and Crosby has elevated TQM to a management philosophy (Kumar et al., 2023; Pietro, 2020).

The continuous improvement approaches of TQM involve statistical process control, Six Sigma management, and lean improvement (Boaden et al., 2008). In addition, the standard system represented by ISO9000 can be regarded as a practical guide to the theoretical thinking of TQM, which provides a set of specific requirements and standards to better help organizations implement TQM. The quality management principles in the ISO9000 quality management system standards can be regarded as the principles of total quality management, or they are essentially the same. The quality management principles in the ISO9000 new version (2015 version) are revised to seven principles, as follows.

Principle 1: Customer focus

Principle 2: Leadership

Principle 3: Engagement of people

Principle 4: Process approach

Principle 5: Improvement

Principle 6: Evidence-based decision making

Principle 7: Relationship management

Although TQM originated in the manufacturing industry, its core philosophy of improving product quality, reducing costs, satisfying customer needs, and improving the competitiveness of the organization is also used in other industries (Anifowose et al., 2022). In particular, in the medical field, TQM has long been concerned by many researchers as a management theory to reduce medical costs and improve medical quality (Bigelow & Arndt, 1995; Boaden et al., 2008).

In summary, the basic ideas of TQM can be summarized as follows:

(1) Customer-centric, and user-first. TQM emphasizes that the customer is the ultimate judge of the organization, and all work should be centered around meeting and exceeding customer needs. This view requires all functions within the organization to work closely together to ensure that the quality of a product or service meets customer expectations at every step of the process, from design and development to delivery.

(2) Quality first. All work is incorporated into the quality-centered track to improve quality and efficiency. In TQM, quality is seen as the most important asset of an organization. It requires organizations to put quality first, ensuring that the quality of a product or service is always at the highest level through strict quality standards and process controls.

(3) Prevention first, and continuous improvement. Transform post-event checks into pre-

event prevention, in-process control, and continuity. TQM emphasizes that prevention is better than cure, and that problems can be prevented through prior planning and control. At the same time, it also emphasizes the importance of continuous improvement and encourages organizations to continuously optimize processes and products to achieve continuous quality improvement.

(4) Making decisions based on data. In the process of quality management, respect objective facts, make decisions based on factual data, and reflect the quality status with data. Correct the “possible” and “probable” work methods based on experience and feeling, emphasize quantitative analysis, and make quality management based on scientific management. TQM believes that data is the basis for decision-making. It requires organizations to pay attention to the collection, analysis and application of data in the process of quality management, so as to reflect the quality status and guide the formulation of improvement measures. This perspective helps organizations overcome the limitations of decision-making based on experience and feeling and makes quality management more scientific and systematic.

(5) Standardization. Formulate quality standards for all management of quality-related technical operations, job responsibilities, and the goods and equipment, and take the standards as laws and regulations, so that everyone can abide by them to achieve standardization of work. TQM believes that standardization is an important means of achieving quality control. It requires the organization to formulate quality-related standards for technical operations, job responsibilities and equipment management, and ensure that all work can be carried out in accordance with the standards through strict implementation and supervision, so as to improve the quality level.

(6) Comprehensive. All staff, the whole process and the comprehensive work should achieve quality control according to the standards. TQM requires that the quality management of the organization should be comprehensive, including all employees, the whole process and comprehensive work. This means that the implementation of quality management requires the participation of all employees, throughout the entire life cycle of a product or service, and covers all aspects of work within the organization. This point of view helps to form the quality awareness of all employees and realize the all-round improvement of quality management.

2.1.4 Six Sigma management and DMAIC model

Six Sigma management is a methodology and set of tools designed to improve business processes (procedures) by eliminating defects and minimizing variability. Its objective is to achieve near-flawless process execution through continuous improvement, thereby increasing

customer satisfaction, reducing costs and boosting the overall performance of the enterprise. It emphasizes defining clearly defined processes, measuring process performance, analyzing the causes of process variation, improving processes, and controlling improved processes to prevent defects from occurring again.

Six Sigma management applies statistical methods to substantially lower the rate of defects as defined by customers (Linderman et al., 2003). In statistics, the standard deviation is usually represented by the symbol σ (Sigma), which is used to measure the degree of dispersion of data. In the field of quality, “Sigma” is a statistical unit of standard deviation, assessing the level of perfection in a process. A process operating at a 6σ level experiences about 3.4 defects per million opportunities (DPMO), equating to an almost defect-free rate of 99.9996%. Calculating DPMO allows for the determination of the Sigma value, thus establishing the expected degree of improvement. Essentially, 6σ represents an extremely high-quality standard, where the pass rate is only 3.4 defective items per million products, closely aligning with the “zero defects” goal. A smaller σ indicates that the distribution of process quality characteristics is more concentrated in the target value, and also means that the probability of the process output quality characteristics falling outside the upper and lower control boundaries is smaller, that is, the less likely it is to have defects. The method is named Six Sigma management to reflect the highest quality, fastest speed, and lowest price to provide products and services to customers or markets.

Six Sigma management was first proposed by Motorola in the 1980s, and has since been popularized in the manufacturing and service industries (Schroeder et al., 2008). While the Six Sigma approach has some things in common with TQM, such as an emphasis on process improvement, there are many differences. The main goal of Six Sigma is to control and eventually eliminate the number of defects that arise in the process. Although TQM encourages data collection and analysis, it is not typically implemented to understand detailed process variation (Revere & Black, 2003). Six Sigma can draw attention to the cause of errors and is reflected in the Six Sigma scale of process variation (Woodard, 2005). Implementing improvements early in process variation with minimal cost can prevent these errors from causing huge losses later on (Samuels & Adomitis, 2003). Overall, however, most researchers agree that it is a quality improvement approach based on TQM (Boaden et al., 2008).

The principles of Six Sigma management include:

(1) Genuine focus on customers: Six Sigma management emphasizes customer centricity, which is the starting point and end point of all its activities. Enterprises need to deeply understand the needs and expectations of customers through market research, customer feedback, data analysis, etc., and translate these needs and expectations into specific business

goals and improvement measures. This customer-focused approach requires companies to always put the interests of their customers first in product design, service delivery, and internal processes.

(2) Making decisions based on data and facts: Six Sigma management emphasizes that decisions should be based on data and facts, rather than subjective judgment or personal experience. This means that companies need to rely on accurate data analysis to ensure that decisions are scientific and effective when making strategic planning, process improvement, and problem solving. A data-driven decision-making process helps organizations evaluate performance more objectively, identify problems, and develop actionable improvements to improve.

(3) Focus on process: Six Sigma emphasizes the importance of the process, whether it is product development or service improvement, and sees the process as a vehicle to success, by identifying key links and potential sources of defects in the process, and then optimizing these links to improve efficiency and quality. Six Sigma Management believes that by standardizing and optimizing processes, variation can be reduced, and product and service consistency can be improved to meet customer expectations.

(4) Active management: Enterprises should manage actively rather than passively, and continuously improve and enhance the quality of management by setting ambitious goals, clarifying priorities, and preventing defects.

(5) Building cross-process and cross-department teams: To effectively solve problems and drive improvements, Six Sigma management emphasizes the importance of cross-functional teamwork. These teams are made up of professionals from different departments who work together to solve the challenges faced by the business by drawing on their expertise and experience. This cross-process, cross-departmental teamwork helps break down organizational silos and foster knowledge sharing and collaborative innovation.

(6) Pursuit of perfection and tolerance of failure: Six Sigma management pursues perfection with “zero defects”, but in the process of pursuing perfection, it also encourages tolerance of failure and learning from failure to promote continuous improvement.

Typically, Six Sigma management adopts a structured approach to facilitate quality improvements, employing different methodologies for specific objectives. The DMAIC (Define-Measure-Analyze-Improve-Control) model is used for process improvement, while the DMADV (Define-Measure-Analyse-Design-Verify) model is tailored for product design enhancement (Boaden et al., 2008; Patyal & Maddulety, 2015), in addition to the IDDOV (Identify-Define-Design-Optimize-Verify) model, and the PIDOV (Plan-Identify-Design-

Optimize-Verify) model. Combined with the focus of this thesis on clinical pathway process management, the DMAIC model will be focused here.

The DMAIC model is an important tool in Six Sigma management, which represents a combination of five phases: Define, Measure, Analyze, Improve, and Control. This model aims to improve business processes and design through a series of systematic steps to achieve the goals of increased customer satisfaction and reduced defect rates. These five stages can be summarized as:

(1) Define phase: This phase focuses on defining the project goals and teams, as well as defining the problems and processes. The team needs to clarify the project goals, identify the key process steps, draw a flowchart, define the key terms in the process, and identify the relevant stakeholders. In addition, the team identifies the assumptions and prerequisites of the project, as well as the possible risks.

(2) Measure phase: In the measure phase, the team collects baseline data of the current process to quantify process performance and defect rate. This includes identifying metrics, collecting data, and creating data collection tables and control charts. The purpose of the measurement phase is to establish a reliable data base for subsequent analysis and improvement.

(3) Analyze stage: The task of the analysis stage is to deeply understand the problems in the process and identify the root causes of defects. Teams use a variety of tools and techniques, such as fishbone diagrams, cause and effect plots, scatter plots, and more, to analyze the data, look for patterns and trends, and identify the root cause of the problem.

(4) Improve stage: In the improvement stage, the team proposes and implements solutions based on the results of the analysis stage. This phase may involve process redesign, process adjustments, personnel training, etc. The purpose of the improvement phase is to eliminate the root cause, optimize the process, and improve process performance.

(5) Control phase: The purpose of the control phase is to ensure that the improvement results are continuously implemented and maintained. The team establishes a control plan and a monitoring mechanism to ensure that the process remains in the improved state. This may include measures such as regular audits, employee training, process documentation, etc.

The DMAIC model is a Six Sigma management model (or framework) that aims to improve business processes and design through a systematic approach. It consists of five sequential phases, each of which addresses a different aspect of problem solving. This model was proposed by General Electric (GE) Company in the 1990s based on the experience of many companies implementing 6sigma, and is now widely recognized and used to achieve the 6sigma quality level to achieve the goal of complete customer satisfaction. Figure 2.1 shows the

implementation process and related descriptions of this model.

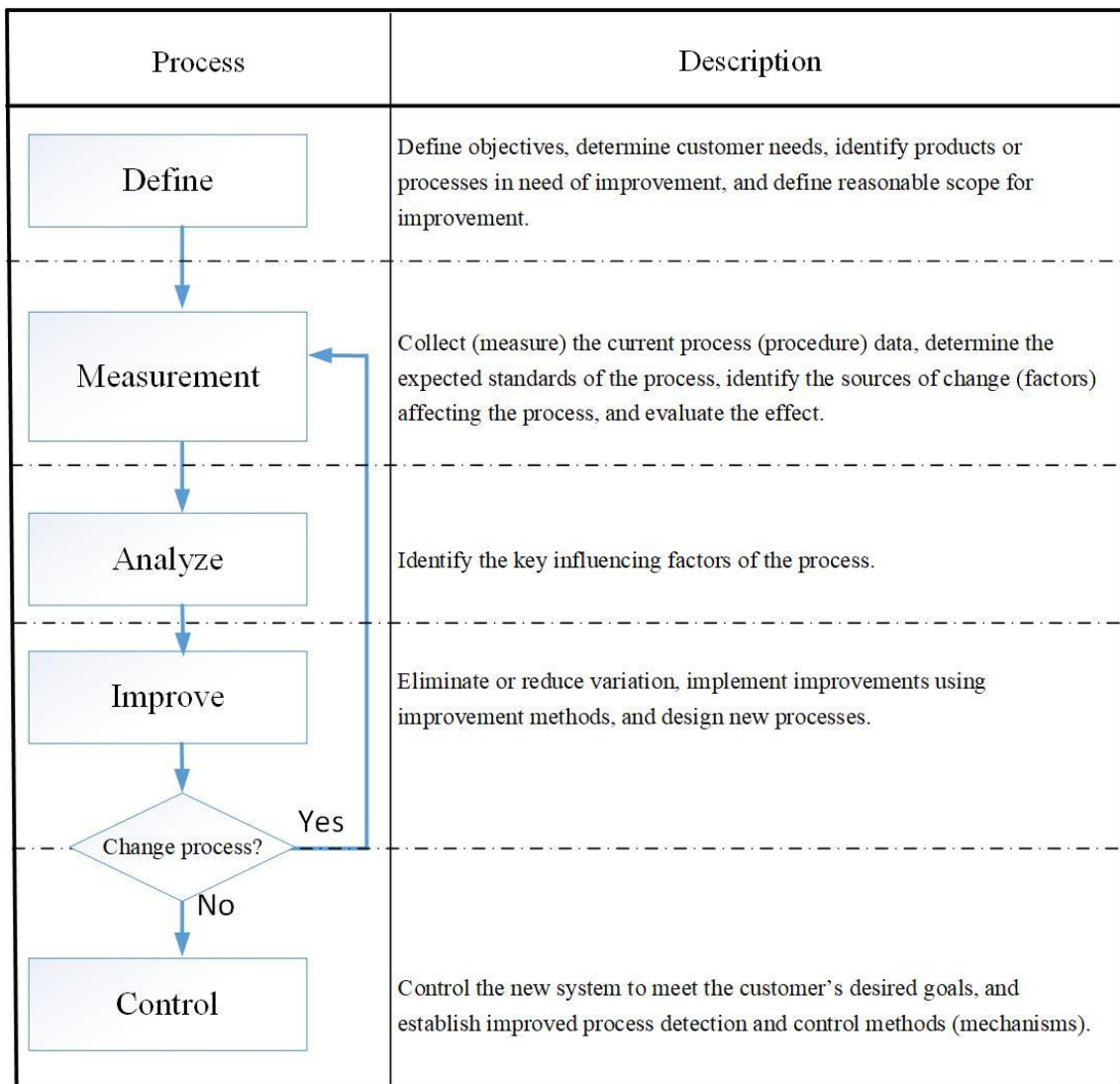


Figure 2.1 DMAIC model process

There are a number of tools and techniques integrated in the DMAIC model, and one or more can be selected according to the specific requirements of the specific improvement researchers. Specifically, the tools and techniques commonly used in the D phase (Define) include: fish bones, brainstorming, affinity diagrams, flowcharts, etc., and the commonly used tools and techniques in the M phase (Measure) include: Permutation diagrams, fishbone diagrams, process capability indexes, etc., commonly used tools and techniques in phase A (Analyze) include: regression analysis, analysis of variance, hypothesis testing, etc., and in phase I (Improve). Commonly used tools and techniques include industrial engineering improvement methods, process analysis and improvement, measurement system analysis, etc., and in phase C (Control) Commonly used tools and techniques include: statistical process control charts, standard operating procedures, process capability index, etc.

2.2 DRG payment mode

2.2.1 DRG-based healthcare cost containment measures and their localization

2.2.1.1 Cost containment measures

Global healthcare expenditure has been increasing, and hospitalization is one of the most expensive types of healthcare treatment, accounting for about 31% of the total expenditure (Muka et al., 2015). Many countries or regions take DRG payment as an important means to contain the rapid surge of medical expenses, and actively explore the research and reform of DRG-based payment system based on their own situations. DRG is a method of classifying cases according to principal and secondary diagnoses, patient age and sex, the presence of co-morbidities and complications and the procedures performed (Mathauer & Wittenbecher, 2013). Patients with the same use of DRG payment require the same medical resources, which means that their clinical process is homogeneous and similar in resource consumption (Aktas, 2022), so the payment standard can be set for each disease group (Wu et al., 2020). Therefore, the use of DRGs can realize greater financing equity (Islam et al., 2021) and standardize the expected reimbursement amounts of hospitals (Aktas, 2022). In other words, DRG is both a case classification system and a mechanism for allocating funds based on the number of healthcare services provided by hospitals (Annear et al., 2018). Medical insurance institutions can restrict the behavior of medical institutions through the payment standard of disease groups, so DRG is essentially a measure to contain medical costs.

Establishing cost containment measures is a means of management for medical institutions to maintain normal operation. An important part of these measures is the reimbursement scheme of medical expenditure. There are three types of reimbursement schemes: global budgets, fee-for-service (FFS) and DRGs (Aktas, 2022). Among these reimbursement schemes, the DRG model has been widely implemented in different healthcare systems, with an emphasis on its effectiveness in increasing efficiency in healthcare provision and to control hospital budgets. DRGs is considered as a supplementary mechanism for reimbursement of hospital services according to global budgets (Annear et al., 2018). The primary reason for countries to introduce DRG-based payment is to improve the efficiency of health service system and contain costs (Mathauer & Wittenbecher, 2013). Mathauer and Wittenbecher (2013) suggested that most of the financing of medical institutions should come from the public sector rather than the private sector; secondly, the reform of medical payment system should be piloted first and sets expenditure ceilings; thirdly, countries should develop payment systems suitable for their own

context based on DRG; and cooperation between healthcare service providers should be promoted.

2.2.1.2 Localization of foreign DRG payment methods

In 2004, the German's healthcare system began to implement the DRG-based reform of reimbursement systems, and set DRG-based payment as the statutory regime based on the German Hospital Reimbursement Act and Case Fees Act (Hermanns et al., 2021). The hospitals have to submit DRG coding to the insurance company of the patients to obtain reimbursement of hospitalization. Furthermore, all hospitals submit their hospitalization data annually to the Hospital Remuneration System for a continual adjustment of the DRG system. Hermanns et al. (2021) studied the data of DRG-based treatment of head and neck cancer (HNC) in Germany. They used the DRG data to analyze nationwide treatment rates of HNC from 2005 to 2018 and used Poisson regression to analyze the changes of annual treatment rates. The study considers that the calculated treatment rates can only be seen as a proxy for the incidence rates, and the DRG statistics can provide a unique epidemiological data source for the quantification of treatment rates for HNC. Kalanj et al. (2021) reported on the financing reforms of hospitals in Croatia in 2002. This reform replaces the previous budget hospital financing model with an output-based system. At that time, the hospital activity payment criteria were introduced in the form of classifications, namely payment per therapeutic procedure (PPTP). The PPTP system comprised 116 broad payment groups. Although well intended, the system proved ineffective due to flaws in both its pricing and the structure of the payment mechanism. In 2007, Croatia procured a license for the Australian Refined Diagnosis Related Groups (AR-DRG) to implement the DRG with the assistance of the Ministry of Health (MOH), the Croatian Health Insurance Fund (CHIF), county governments and the city of Zagreb. Kalanj et al. (2021) investigated the impact of Croatia's reform in funding hospitalization on the efficiency of acute hospitals. They analyzed resources, performance, and financing data for 33 hospitals specializing in emergency treatments between 2009 and 2018. These data were drawn from CHIF and the Croatian Institute of Public Health (CIPH), and included information such as DRG, average length of stay (ALOS), hospital staffing, CHIF revenue streams, and the hospital incomes and expenditures. Although the study indicated that the Croatian health system can access necessary funds to meet the current costs of hospital production, significant shortcomings exist in hospital funding flows and the payment model. The study holds that consideration may be given to amalgamating the available funds from MOH, CHIF, and the State Budget into a single funding pool that reimburses hospitals with the implementation of

payment system reform which provides incentives for improvements of medical care efficiency as well as quality.

Aktas (2022) introduced a payment model proposed in Turkey's healthcare reforms, which is a mixed reimbursement scheme based on the DRG model and global budget. The first step of the scheme is to establish public Social Security Institution (SSI), the only purchaser of healthcare services from public and most private providers. SSI introduced flat-rate co-payments for public hospital visits, and floating co-payments for private hospital visits and medications, since the reform also aimed to control healthcare expenditures as one of the main policy targets. With the goal of controlling hospital expenditure, a mixed reimbursement scheme, based on the DRG and a global budget approach, was introduced. Under this scheme, the SSI allocates a global budget to the Ministry of Health (MoH) at the beginning of each year for the purchase of healthcare services for the beneficiaries of public health insurance. The global budget amount is calculated according to the previous year's budget, plus expected increases in the number of services provided, planned investments, and inflation. The MoH distributes the total budget to public hospitals according to the number of services they are expected to provide. Public hospitals are obliged to limit the fund of healthcare service provided within the scope of the total budgets allocated to prevent over-expenditure. Aktas (2022) studied the impact of the DRG model on medical practice in Turkey. This study used qualitative methods to explore physician perceptions working at public and private hospitals on the DRG model and its impact on medical practice. Semi-structured interviews were used to collect data to comprehensively explore physicians' perspectives on the implications of the DRG for their practice to facilitate the conversation between the researcher and the respondents. Semi-structured face-to-face interviews were conducted with 14 physicians between March and May 2019. The interviews were conducted in Turkish and lasted for an average of an hour. The interviews took place at the physicians' clinics, were recorded with participants' written consent and transcribed verbatim. The findings reveal that the DRG regulations force some physicians working at public hospitals to make cost-benefit calculations to meet patients' medical needs while remaining within the hospital's budget. Hence, medical practice now involves an optimization process, that is, the balance and optimization of hospital incomes and expenditures and patients' medical needs. What's more, since the inadequate reimbursements provided by the MoH cause budget deficits for public hospitals, such hospitals are forced to cover additional expenditures. This leads to lower remuneration for physicians under the performance-based payment system. The study also discussed the prioritization of the financial sustainability of medical institutions and the medical needs of patients. To maintain the provision of healthcare

services for future patients, this prioritization needs to be considered in the DRG model. Therefore, this means that the DRG model practiced in Turkey may still need reform.

Gartner and Kolisch (2014) mentioned a variant of DRG-based payment system used in Australia, Switzerland, France and Germany in their research. In this payment system, the reimbursement depends not only on DRG, but also on the length of stay (LOS) to some extent. More precisely, if LOS is below a low range, the daily fixed reimbursement will be reduced by a certain amount; if LOS required for medical treatment exceeds a high range, the fixed reimbursement amount is increased by a certain amount every day.

Kim et al. (2020) investigates the localization of DRG in South Korea and calls for evaluation of KDRG. Korean Diagnosis-Related Group (KDRG) in South Korea is built upon the Australian DRG (AR-DRG) and is categorized based on International Classification of Diseases, Tenth Revision (ICD-10), and the South Korean Health Insurance Fee Standards. KDRG is used in South Korea for the prepayment system for hospitalized patients, serving as a tool for the comparison, designation, and evaluation of the hospital performance. The latest version as of 2016 is KDRG 4.0. Kim highlights that the evaluation was prompted by a report from 2014 by the Australian Independent Hospital Pricing Authority and the University of Sydney's National Centre for Classification in Health. The report reflected a lack of academic and economic evidence for the complexity adjustment scheme of Complication and Comorbidity Level (CCL) and Patient Clinical Complexity Level (PCCL) algorithms in AR-DRG. AR-DRG includes a list of complexity adjustments for complications or comorbidities, assigning a CCL value to each complication or comorbidity. Any diagnosis not included in the list is assigned a CCL value of 0. The PCCL is then calculated using a specific formula designed to prevent the repeated calculation of similar diseases and reflects the cumulative effects of patient complications or comorbidities. The effectiveness of the PCCL method is influenced by the CCL. The report found that AR-DRG 7.0's complexity adjustment scheme using the CCL/PCCL algorithm lacks detailed theoretical literature or evidence. Additionally, the correlation between CCL and costs is very low, making it unsuitable for describing cost variations between diagnosis-related groups. As AR-DRG serves as the basis for KDRG, there is a necessity to evaluate the complexity adjustment system of KDRG.

2.2.1.3 Localization of DRG payment methods in China

Wu et al. (2021) investigated the efficiency and cost of treating the most common acute cholecystitis (AC) patients under the DRG system in Taiwan (Tw-DRGs). They selected 246 AC cases who underwent laparoscopic cholecystectomy (LC) (between October 2015 and

December 2016) and respectively considered the demographic characteristics, medical outcomes and financial performance of the DRG group with complications and the DRG group without complications. The results show that hospitals started to enhance their management to maintain profits from the DRG payment system, and DRGs can be well adopted for acute care surgery, and hospitals can still provide satisfactory services without losing profit.

In October 2011, China's health policy department selected six Beijing hospitals to pioneer the first DRG payment system (Jian et al., 2015). The payment system is localized version based on DRG, named BJ-DRGs (i.e., Beijing DRGs) (Zeng, 2019). In order to investigate the implementation effects of BJ-DRGs-based payment in pilot hospitals, Jian et al. (2015) used the difference-in-difference (DID) method to compare the discharge data of the six pilot hospitals and eight other hospitals which continued to use FFS payments and evaluated the impacts of the pilot payment system on cost containment from 2010 to 2012. The study found that after the implementation of the DRG payment system, the medical service expenditure and out of pocket expenses of patients per admission were reduced by 6.2% and 10.5% respectively, and there was no evidence of a shift in readmission rates or costs from cases eligible for DRG payments to cases ineligible for DRG payments. However, the study also mentioned that hospitals used FFS payment for elderly patients with more complications, which reduced the effectiveness of the DRG payment reform. Moreover, it is necessary to link continuous and evidence-based monitoring and evaluation with appropriate management systems, which can enable China and other low- and middle-income countries to widely implement DRGs payment and refine payment systems. Zeng (2019) surveyed the profit and loss situation of 47148 cases of hospital discharged patients in 107 groups of pilot BJ-DRGs-based payment from December 2011 to July 2018 in certain top tertiary hospital in Beijing. Logistic regression showed that whether the pilot hospital of BJ-DRGs-based payment was in profit or loss was correlated negatively with inpatient expenditure, length of inpatient stay, drug expenditure, expenditure of medical consumables, and pilot years, and positively with DRGs standard unit price, self-pay expenditure, and age and gender. The study mentioned that BJ-DRGs-based payment is the first implemented DRG-based prospective payment system in China. The current DRGs pilot model reveals that pilot hospital gain profits and the length of inpatient stay declines.

Yuan et al. (2019) introduced the implementation of DRG payment reform in Zhongshan, China. In 1999, China's Zhongshan City established a social health insurance scheme. At the beginning, FFS was adopted to pay for all health care fees, which resulted in a rapid increase in the expenditures of the medical system in Zhongshan in the following three years. In 2002, the local health insurance administration department explored a special capitation-like

retrospective payment method to replace FFS system and this has been formally carried out in 2004. Under this system, the middle cases of the 95% hospitalized patients were reimbursed through the retroactive payment method. Other cases were reimbursed through the original FFS approach. However, a rapid growth in health volumes and inpatient expenses was observed during 2004 to 2009. The inpatient visits had increased by 52% during this period, nearly tripled the average provincial level of 19% for the same period. And the fiscal deficit ratio of the insurance fund reached 35.6% in 2009. Additionally, due to the great variation of care costs among different cases, this kind of payment system caused frequent conflicts between the insurance management department and the hospital directors. To address the above problems, Zhongshan proactively launched its hospital payment reform combining DRGs with global budget in 2010.

Under the new system, all inpatient cases were classified into different payment groups based on two factors: 1) patients' primary diagnoses, which were identified by the ICD-10 code (International Classification of Diseases, the 10th revision); and 2) four medical treatment process categories: internal medical treatment, traditional operations, minimally invasive surgery and interventional therapy. Through this approach, each payment group is defined with a diagnostic group together with a specific procedure category. A total of 4630 DRGs was included in the latest version of the DRG system in Zhongshan, with a cost weight assigned to each DRG. The cost weight reflects the average claimed expense of patient care compared with other DRGs. The payment rate for a specific DRG was calculated as its cost weight multiplied by the base payment rate. The base payment rate equals the overall budget available for the DRG payment system (approximately 73% of the social insurance expenditures) divided by the total weights of all DRGs in the same period. It's the same for all DRGs during a certain period (usually a fiscal year). The base payment rate was determined at the end of the fiscal year and the final reimbursement amount was calculated for each hospital.

An important feature of Zhongshan DRG payment reform is that the DRG payment rates in Zhongshan were determined flexibly with global budget. Actually, the global budget and DRG-based payment are the two main pilot methods in China. In this circumstance, it's hard to give full play to their strengths in payment by implementing them separately (Yuan et al., 2019). Zhongshan innovatively merged the two payment methods into one composite payment system which united the patient's cost containment with hospital cost containment. To investigate the effects of this composite payment system, Yuan et al. (2019) selected a total of 2895 patients diagnosed with acute myocardial infarction (AMI) from the two largest tertiary hospitals in the area, among which 727 were discharged before the reform and 2168 afterwards. The study used

DID regression models to examine the impacts of payment policy on patients' use of percutaneous coronary intervention (PCI) and hospital expenses, in-hospital mortality, and re-admission rates within 30 days after discharge. The research results supposed that the DRG-based payment reform in Zhongshan demonstrated a positive effect on AMI patient's cost containment but negative effect on promoting resource use, and no effect on patient's quality of care. In addition, the study emphasizes that more evidence of the impacts of the DRG-based payment on China's health sector is needed before it is generalized nationwide.

Ma et al. (2023) delved into the localization issues of the DRG payment system in China. The research notes that the Chinese government has developed three local DRG systems, namely Single Disease Payment (SDP, also known as Simplified DRG), DRG, and Big Data Diagnosis-Intervention Packet (DIP). Using gallbladder inflammation as an example, Ma and the team validated the effectiveness of the localized DRG system in China, combining primary and secondary data. The primary data were derived from the medical records of Qilu Hospital from 2019 to 2021, comprising a population of 2,738 gallbladder-related disease patients. The research divided them into two groups based on the DRG indicators before ($N = 1,172$) and after ($N = 1,566$) October 1, 2019. All costs were analyzed based on the hospital's billing reports. Secondary data were collected from literature published between 2004 and 2016. The research suggests that SDP is effective in saving hospitalization costs, although few medical institutions have adopted it. DRGs have a broader application, but their effectiveness still needs validation. DIP, as a new concept in China combining big data and traditional DRG features, was a creative notion proposed by the National Healthcare Security Administration in 2020. However, DIP requires more data for a thorough evaluation of its efficiency. Notably, the researchers highlighted three shortcomings in the existing literature regarding DRG. Firstly, there were reports of a higher post-DRG group mortality rate compared to the pre-DRG group, possibly due to a higher number of critically ill patients leading to inadequate compensation in some healthcare institutions, resulting in a higher mortality rate in the DRG group. Secondly, two studies using data envelopment analysis found that DRG was not sufficiently effective in improving medical efficiency, especially in clinical departments. Thirdly, DRG relies on high-quality medical records but lacks universal standards, making it challenging to be promoted in hospitals with limited medical resources. In contrast to DRG, DIP uses big data to categorize different diseases and surgeries into distinct groups, eliminating the reliance on high-quality medical records and enabling implementation in remote hospitals with limited medical resources.

Ding et al. (2022) conducted a comparative analysis of the revenue structure and efficiency

metrics in the Endocrinology Department of a grade-A tertiary hospital in Wuhan, China, during the first half of 2019 and 2021. The research observed changes in Cost Efficiency Indexes (CEIs), Time Efficiency Indexes (TEIs), Case-Mix Index (CMI), the number of Diagnosis-Related Groups (DRGs), Risk Weight (RW) ratios, and the quantity of surgical procedures in the inpatient department. Additionally, it analyzed the distribution of diabetic inpatients throughout the hospital and improvements in treatment efficiency indexes in subspecialty departments. The findings of the research indicated that in the first half of 2021, compared to the same period in 2019, the total revenue in the Endocrinology Department decreased by 20.05%, and the average hospitalization cost decreased by 11.72%. CEI decreased from 1.31 to 1.06, and TEI from 0.74 to 0.64. Furthermore, the number of DRGs increased from 162 to 176, and the average CMI value increased from 0.80 to 0.84, with an increase in the proportion of RW for 1-5 cases. Surgical case numbers increased by 60.50%, minimally invasive surgeries increased by 53.54%, and fourth-level surgeries increased by 66.67%. The proportion of cases entering clinical pathways increased from 77.76% to 86.64%. In the period from May to August 2021, there was a significant increase in the admission rate in the Endocrinology subspecialty, a rising trend in DRGs, and a significant decrease in CEI and TEI. In the first half of 2021, diabetic inpatients in the Rehabilitation Department, Neurology Department, Nephrology Department, Ophthalmology Department, and Administrative Management Department accounted for 21.99-38.54%. The research's conclusion suggests that DRGs tools can be adopted to enhance the clinical diagnostic and treatment capabilities of the Endocrinology Department while optimizing CEI, TEI, CMI, and RW values. Under the new DRGs payment policy, this approach serves as an effective means to promote the development of the Endocrinology Department, implement hospital-wide blood glucose management, establish Endocrinology subspecialties, and improve surgical and operational capabilities. Additionally, to enhance the clinical capabilities of different departments using DRGs tools, the research recommends assessing the department's DRGs payment data and clinical capabilities, making it easier to find ways to enhance CMI, such as establishing subspecialties and employing new technologies for patient treatment. CMI is a metric measuring the complexity of patients' conditions within a healthcare institution. It assesses the diagnoses, treatments, and rehabilitation of patients, calculating a comprehensive index used for comparing the complexity of patients' conditions across different healthcare institutions.

Qiao et al. (2020) analyzed the pertinent influence factors of DRGs-based stroke patients on the in-hospital costs in Jiaozuo city of Henan province, China, to provide the theoretical guidance for medical payment and medical resource allocation in Jiaozuo city. They collected

the medical data records of 3590 stroke patients from the First Affiliated Hospital of Henan Polytechnic University between 1st January 2019 and 31st December 2019, which is a Class A tertiary comprehensive hospital in Jiaozuo city. By using the classical statistical and multivariate linear regression analysis, this study is conducted to investigate the influence factors of the stroke patients on in-hospital costs, such as age, gender, LOS, and outcomes. The essential findings of this research are shown as follows: (1) age, LOS, and outcomes have significant effects on the in-hospital costs of stroke patients; (2) gender is not a statistically significant influence factor on the in-hospital costs of the stroke patients; (3) DRGs classification of the stroke patients manifests a reduced mean LOS.

Zhao et al. (2018) held that China's social and economic conditions differ across regions, so the establishment of a national payment standard will take time and involve difficulties. Measures to monitor and minimize the negative ethical implications and unintended effects of a DRG-based case-mix payment system are essential for ensuring the lasting social benefits of payment reform in Chinese public hospitals. On the basis of literature review, they summarized the advantages and disadvantages of an FFS system and a case-mix funding system, and pointed out that the current FFS system in China created inefficiencies, high costs and wastes of medical resources, and resulted in unaffordable and poor-quality health care. The DRG-based case-mix payment system, in which the financial risk is shifted from payers of medical insurance to providers of health care, is more likely to contain costs, lower the financial barriers to care, and improve efficiency. This method of payment is a promising alternative to the FFS payment system in China.

Considering the aforementioned measures to control medical costs through the DRG system and the corresponding reports on their localization, it is evident that the global adoption of DRG payment systems is extensive. Many countries and regions consider DRG as a crucial tool for mitigating the rapid rise in healthcare expenses. Developed nations such as Australia, Switzerland, France, and Germany widely implement DRG payment systems. Essentially, the DRG payment system serves as a mechanism for controlling healthcare costs (Annear et al., 2018; Mathauer & Wittenbecher, 2013). By establishing payment standards for each disease group, it helps restrict the behavior of healthcare institutions, thereby realizing cost control. This system has the capacity to enhance the efficiency of medical services while managing hospital budgets. DRG instills homogeneity in the clinical processes of diverse cases, fostering similarity in resource consumption. This standardization allows for the formulation of unified payment standards.

The advantages of the DRG payment system lie in promoting fair funding and standardizing

expected reimbursement amounts for hospitals (Islam et al., 2021). Cases within the same DRG group require comparable medical resources, ensuring equitable payment for healthcare institutions. Additionally, the DRG payment system fosters collaboration among healthcare service providers (Aktas, 2022). Health insurance organizations can utilize DRG payment standards to restrain the behavior of healthcare institutions, encouraging them to improve service efficiency.

However, despite the global popularity of DRG payment systems, there is a need for localization and customization according to the specific conditions of each country. It is crucial to tailor DRG payment standards to suit the local context. Particularly, cases of DRG localization from various countries and regions highlight the complexity of the implementation process and the local factors that must be considered. There are some common focal points in the localization process across different countries, such as the ongoing need for supervision and improvement of DRG systems (Aktas, 2022; Gartner and Kolisch, 2014; Jian et al., 2015; Zhao et al., 2018). Each country's unique circumstances must be individually considered (Mathauer & Wittenbecher, 2013). In China, where there is economic disparity among different regions (Zhao et al., 2018), the implementation of DRG payment system reform faces certain challenges. Therefore, a tailored and phased approach is necessary. Based on the viewpoints presented in the above literature, the challenges and issues faced by China in the localization process of implementing DRG payment systems can be summarized as follows:

(1) Insufficient data for disease spectrum and medical resource allocation: China's data on disease spectrum and medical resource allocation are relatively insufficient compared to developed countries. This poses a challenge in formulating DRG grouping schemes that align with the Chinese context.

(2) Controversies in the formulation of DRG grouping schemes: The DRG grouping schemes currently introduced in China face controversies regarding disease selection and grouping logic. Further improvements are necessary.

(3) Limited capacity of medical insurance payments: China's capacity for medical insurance payments is limited, and the implementation of DRG payments may exacerbate the burden on medical insurance. There is a need to enhance the coordination of medical insurance and improve the payment capacity.

(4) Increased operational pressure on healthcare institutions: DRG payment systems shift some financial risks to healthcare institutions, intensifying their operational pressure. Establishing a scientific incentive and constraint mechanism is essential to control healthcare institution costs effectively.

(5) Need for improvement in supporting systems: DRG payment systems require complementary systems, including a comprehensive medical record quality management system and a well-developed medical insurance information system. These systems still need further refinement in China.

2.2.2 Deficiencies in DRG-based payment reform

In addition to focusing on the advantages brought by the DRG payment system, some scholars have also noticed the problems in implementing it. Kotherová et al. (2021) reported the problem in the Czech medical reimbursement system, where different healthcare providers are reimbursed differently for the same medical services they provide, regardless of the quality of the services. The Czech DRG system does not appear to incentivize healthcare providers to become more efficient. To improve the situation, the Czech Republic is currently implementing a DRG restart program with the aim of improving reimbursement mechanisms for hospital admissions. In a bid to gain an in-depth understanding of the causes of problems in the Czech DRG system and to develop countermeasures, Kotherová et al. (2021) adopted a qualitative research method to evaluate three selected medical institutions that implemented the DRG system between 2012 and 2018. The study results reveal that the current Czech DRG system is implemented in a very similar way to the traditional flat rates, and thus cannot play a positive role. Thereby, it is necessary to carry out a profound systemic reform of the reimbursement mechanism in the Czech Republic. The current study proposes some measures to foster the Czech DRG system, including the correct diagnostic triage setting and cost predictability, the availability of standardized and high-quality cost information, and an attainable hospital benchmark. The study considers these measures to be an indispensable prerequisite for promoting systemic changes in the reimbursement mechanism in the Czech Republic. Additionally, the study mentions that one of the constraints to the role of the DRG is the lack of transparency, which often leads to abuse of DRG groupings and compromises between quality of care and financial assessment. Therefore, the successful implementation of the DRG payment system should meet the following requirements. First, the DRG payment system should increase the hospital's transparency in its provision of effective services (through patient classification, hospital output measurement and the like). Second, the DRG payment system should be based on the number and type of patients in paying the hospital, thereby incentivizing the efficient use of resources within the hospital. Third, the integration of increased transparency and efficient use of resources is necessary, which is conducive to improving (or at least guarantee) the quality of medical services.

Wu et al. (2020) focused on the rationality of DRG grouping. They collected data on the hospitalization expenses of 1053 patients with Colorectal cancer (CRC) from a Level-A tertiary hospital in Beijing from 2014 to 2018. Their research believed that a more practical method needs to be devised to clarify the classification in order to calculate the payment standard of the DRG group more accurately, and strengthen the control of medical expenses. Therefore, they used a Decision Tree Model to divide CRC cases into specific DRGs payment groups and adopted the Kruskal-Wallis method to test the differences between groups and the Coefficient of Variation to test the rationality and effectiveness of grouping, after taking the indicators reflecting the intensity of resource consumption as the grouping nodes of the decision tree.

Chiang et al. (2023) emphasized the crucial importance of accurately assigning patients to their corresponding DRGs as a key factor in determining hospital costs within the DRG payment system. However, the actual DRG grouping is only known upon the patient's discharge. Incorrect grouping could significantly complicate DRG cost control. Therefore, the research proposed a predictive method for patient DRG grouping, aiming to enable hospital administrators to more accurately allocate medical resources, effectively control healthcare costs, and enhance the quality of patient care. The research aimed to obtain patient DRG codes using classification methods and utilized the C4.5 decision tree classification algorithm and backpropagation neural network to address the DRG grouping issue. These methods were applied specifically to predict DRG grouping for patients with a history of appendectomy to validate their effectiveness. To enhance the accuracy of DRG grouping, the research employed Bagging, a machine learning method based on bootstrap aggregating, to reduce the risk of model overfitting and improve the predictive performance on unknown data. The research highlighted deficiencies in DRG grouping within the DRG payment system. It recommended the construction of targeted DRG classification models based on the types and characteristics of hospital records for practical significance. Additionally, Liu et al. (2021) addressed shortcomings in the expert-oriented DRG grouping, describing it as a "black box" where the design and updates of disease groups heavily relied on expert decisions. The study mentions that medical experts are grouped based on the similarity of clinical symptoms and managed by DRG, and when the grouping is found to be inappropriate or the DRG group is modified, the expert needs to update the grouping. The study mentions that medical experts are grouped based on the similarity of clinical symptoms and managed by DRG, and when the grouping is found to be inappropriate or the DRG group is modified, the expert needs to update the grouping. Due to the extensive involvement of professional medical associations, experts, and consultants through scientific and standardized procedures (such as committees, expert hearings, and

consultations), providing localized grouping for different hospitals was deemed impossible. Thus, the research suggested using machine learning to enhance the accuracy of DRG grouping, proving that machine learning can effectively support hospital management and resource allocation. The proposed method involved generating simulated cases based on real case feature distributions for model training. The groups trained on simulated data exhibited excellent performance on real data test sets. In the application of machine learning to DRG grouping, simulated data can assist researchers in validating assumptions about algorithm usage and optimization during the exploration phase. The research also compared five typical machine learning classification algorithms, recommending the use of the CART algorithm as the core for multi-class classification when computational resources are limited and opting for the XGBoost algorithm when resources are more abundant.

Duan et al. (2021) explored the issue of medical service pricing in DRGs. They mentioned that in the DRG operation in many countries including India, China and other developing countries, the unreasonable pricing of medical services and government reimbursement for medical services usually lead to two major problems: either the pricing is too low, leading to medical institutions evading responsibility for critically ill patients, or there is overpricing that leads to sharp increases or even loss of control in medical costs. To balance the interests among governments, patients and medical institutions, this study proposes an improved bargaining game model based on the Stackelberg game model, thus achieving this balance and improving the social total utility. The study found that a patient's absolute risk aversion coefficient affects the relationship between the co-payment rate and total social welfare. Besides, with the increased investment in public health education, the government can control the moral hazard of overtreatment of patients under the DRG payment system by affecting the absolute risk aversion coefficient of patients and limiting it to a certain range.

Islam et al. (2021) argued that reasonable compensation through DRGs depends on the accuracy of clinical coding, but choosing the right code is always challenging and requires specialized knowledge. Incorrect disease diagnosis-related grouping rates are always high due to heavy workload, poor documentation and lack of computer assistance. Therefore, this study developed a deep learning model to realize automatic DRGs coding, which helps cut down incorrect coding, thereby increasing hospital revenue, ensuring fair distribution of medical resources, and boosting hospital performance.

In general, no payment method is perfect, as each payment method has its own pros and cons and can bring about unforeseen consequences. For example, DRG-based case-mix payment system enjoys strong incentives in the aspect of reducing costs. However, this may

lead to lower medical service quality, insufficient medical service supply, and buck passing on patients (Zhao et al., 2018) . Consequently, the comprehensive promotion of payment reform needs to be more cautious and rigorous, and more evaluations should be carried out to verify the advantages and applicability of DRG-based case mix payment systems (Yuan et al., 2019; Zeng, 2019; Zhao et al., 2018).

In summary, according to the literature that highlights the shortcomings of the DRG payment reform, the DRG payment system emerges as a potent tool capable of incentivizing healthcare institutions to enhance their service efficiency and quality. However, its implementation faces various challenges, including issues of unfair compensation, inadequate accuracy and transparency in grouping, and the complexity of localized implementation. Unfair compensation and a lack of transparency pose threats that may undermine the potential of the DRG system to improve efficiency and quality of healthcare services. Incorrect grouping can complicate medical cost control, leading some scholars to introduce machine learning into DRG grouping to enhance accuracy. This demonstrates the potential of artificial intelligence technologies in improving DRG grouping accuracy and healthcare service pricing. The application of these technologies can provide healthcare institutions with more effective tools for resource management and cost control. However, the successful implementation of DRG requires more than technological support; it necessitates collaboration among policymakers, healthcare institutions, and experts, along with continuous evaluation and improvement of the DRG system.

2.3 Clinical pathway management

2.3.1 Clinical pathway management in the context of DRGs

Cornwell (1995) pointed out that as the cost-based reimbursement model of medical institutions was replaced by DRG-PPS, medical institutions are often faced with the situation where medical costs exceed compensation, and therefore are being forced to compete for the dwindling resources and find new ways to maintain economic compensation (Cornwell, 1995). The most direct way to maintain compensation is to reduce the investment in the quality of medical services and select patients who will not cause losses for treatment (Chu, 2001; Jiao, 2018; Zhang & Sun, 2021). It is obvious that the introduction of the prospective payment system into the medical insurance settlement system is to reduce the cost of over treatment and improve the efficiency of the medical system, not at the expense of reducing the quality of medical

services.

It is not easy to cap the rise of medical expenditure without reducing the quality of medical service in carrying out medical practice. In order to achieve a balance, Cornwell (1995) believed that we should learn from the method used in the manufacturing industry that can produce high-quality automobile products with low costs, that is, paying attention to in-process quality control and standardization. He proposed to set standards for the utilization of medical service resources for each DRG to determine when to use these resources (like nursing and laboratory). Although medical services are not and should not be standardized products, reducing variations through standardization when providing medical services is the best way to control cost (Cornwell, 1995; Hensen et al., 2005). To make a hospital accountable for delivering high quality medical services, three measures are required: evidence of continuous quality improvement, outcome management and standards and guidelines governing clinical practice. Pathway management can be viewed as a tool for quality management that effectively combines these three measures (Hensen et al., 2005). Maliapen and Dangerfield (2010) pointed out that each DRG or disease group has its own pathway which documents the details of recommended procedures, expected treatment outcomes, pharmaceuticals, clinical investigations, prognosis monitoring and instrumentation for surgeries. They established a system dynamics-based model to analyze the medical expenses grouped by DRG. The study held that simplifying clinical practice through appropriate clinical pathways in DRG groups with many cases can significantly reduce medical costs.

2.3.1.1 Clinical pathway management effect

Many countries that adopt DRG payment system have carried out clinical pathways management (Hensen et al., 2005; Hoffmann et al., 2014). Early research on the combination of DRG and clinical pathways can be traced back to Massachusetts in 1985 (Vanhaecht et al., 2010). Some local medical institutions that adopted DRGs payment system found that the model of clinical pathway management can shorten the time of hospitalization and in-hospital costs for patients without affecting the expected treatment effect. With the expansion of diseases scope and coverage of clinical pathways, by 2013, more than 60% of the medical institutions in the United States had adopted the clinical pathways model for over 80% of the diseases (Mo et al., 2021). Hensen et al. (2005) mentioned that clinical pathways are utilized by a multidisciplinary medical team with a primary focus on the quality and coordination of care and held that the term clinical pathways can be referred to as care paths, clinical pathways, care maps, integrated maps and anticipated recovery pathways.

Hoffmann et al. (2014) thought that diagnostic pathways are an important subset of clinical pathways and a logical consequence of DRG-based reimbursement. Their study analyzed the advantages and disadvantages of diagnostic pathways from medical, organizational and economic perspectives. They concluded that diagnostic pathways can integrate laboratory, medical and administrative processes, which can meet the requirement of improving the efficiency of medical services by DRG. Additionally, their study suggested that well-defined pathways can make sure that state-of-the-art tests are arranged for patients so that outdated and unnecessary tests are avoided and that identical strategies are targeted for identical diagnostic issues throughout the hospital. Gartner and Kolisch (2014) discussed the issue of decision optimization for clinical pathways under the DRG system from a perspective of operational research. Their research proposed two models to plan the patient flow in hospitals subject to scarce medical resources with the objective to maximize the contribution margin. In the proposed models, elective patients can be classified according to DRG. The clinical pathway defines the procedures (such as different diagnostic activities and surgeries) as well as the sequence according to which the procedures have to be applied to the patient. Then the goal of decision-making is to determine the best procedure of each patient's clinical pathway, taking into account the sequence of procedures as well as scarce clinical resources, so that the contribution margin can be maximized.

Collier (1997) studied whether the implementation of clinical pathways for patients who underwent major vascular surgeries in a community hospital would shorten the time of hospitalization and reduce in-hospital costs. These patients were grouped by vascular DRG categories. The study found that clinical pathways can improve the quality of care and at the same time shorten time of hospitalization, and reduce the costs for patients. Yan et al. (2011) analyzed treatment outcomes and cost indicators before and after the revision of the clinical pathway for cardiac catheterization with the Tw-DRGs approach. A total of 439 patients hospitalized during January and June 2009 (with non-revised clinical pathway) and during January and June 2010 (with revised clinical pathway) were selected for a comparative survey to measure the average medical costs, number of patients, quality of care, duration of hospital stays, and financial risk indicators before and after the clinical pathway was revised. The results of the statistical analysis showed that the revised clinical pathway can improve not only the financial indicators of the hospital but also the quality of care. They concluded that clinical pathway revisions in organization, operation process, and performance management have significant impacts on patients, and that clinical pathway revisions in operation process greatly shortened the average time of hospital stay and reduced financial risks.

Hertler et al. (2020) demonstrated a cost-saving solution for a private community oncology care clinic in the United States. Saving costs was out of the reason that the clinic had to spend less than the price cap set by the Center for Medicare and Medicaid Innovation for each treatment phase to obtain performance-based payments (reimbursement). The clinic hired a hospital service provider to help it with clinical care and finances to cut down drug expenses and improve treatment outcomes. The provider developed a value-based clinical pathway, which began with an analysis of medical literature through a clinical pathway algorithm developed on its own to identify the therapeutic fields corresponding to each clinical setting and evaluate treatment alternatives in these fields. These treatment alternatives were evaluated, with the greatest weight given to efficacy and clinical effectiveness, followed by toxicity. Treatment cost was only considered in the final step. Finally, all the alternatives were reviewed and approved by an independent board of scientific review composed of oncologists. By adopting this value-based clinical pathway, the clinic reduced drug expenses and improved patients' adherence to the clinical pathway.

Feyrer et al. (2005) studied the clinical pathway-based Cost Unit Accounting methodology. This study mentioned that establishing a reliable cost unit accounting system in a hospital is a fundamental demand for survival, given the current conditions in the healthcare system. Determining an appropriate cost unit is the key. Since clinical pathways limit the options for major diagnostic and treatment process, the variance within the pathway will be much lower than that within DRG. In this case, clinical pathways are more advantageous as cost units than DRGs. This study presented a clinical pathway for elective coronary artery bypass grafting and calculated the cost by regarding the pathway as the cost unit. In the study, the proposed method can be used as a practical tool for implementing the DRG reimbursement system.

Based on the comprehensive review of literature regarding the effectiveness of clinical pathway management, it is evident that clinical pathway management has been widely applied in countries implementing the DRG payment system. The combination of DRG-based payment methods with clinical pathways demonstrates feasibility and holds potential in ensuring healthcare service quality and controlling service costs. The DRG-based payment method provides an economic standard for the formulation of clinical pathways. In other words, while traditional clinical pathway development focuses on technical issues guided by clinical guidelines, the development of clinical pathways under DRG payment requires consideration of both technical and economic aspects. Clinical pathways offer a practical approach to address the constraints imposed by DRG payments, enabling a feasible balance between maintaining quality and reducing costs. Thus, from this perspective, clinical pathways offer robust support

for the widespread adoption of the DRG payment system (Feyrer et al., 2005; Gartner and Kolisch, 2014; Yan et al., 2011). Notably, in the United States, clinical pathways have become a crucial tool for healthcare institutions to enhance efficiency and reduce costs (Hertler et al., 2020). Clinical pathways extend beyond disease-specific management, encompassing multiple stages from diagnosis to treatment. They are believed to shorten hospital stays, reduce healthcare costs, and simultaneously uphold medical quality. The diverse and flexible application of clinical pathway management is highlighted in various studies. However, the implementation of clinical pathway management faces challenges such as balancing collaboration among multidisciplinary teams and addressing differences between clinical pathways and DRGs. Furthermore, clinical pathway management not only impacts internal healthcare institution management but also has profound effects on the entire healthcare system. By optimizing the diagnostic and treatment processes, clinical pathway management contributes to enhancing the efficiency and quality of the entire healthcare system. In summary, clinical pathway management, as a crucial tool for improving healthcare service efficiency and quality, has been widely applied in multiple countries and regions. Despite its diversity and flexibility in different healthcare settings and demands, addressing challenges in the implementation process and optimizing strategies through operations research methods are essential to fully leverage the effectiveness of clinical pathway management.

2.3.1.2 Current status of clinical pathway management in China

China has also actively explored the combination of clinical pathway and DRG. In 2012, the Ministry of Health of the People's Republic of China issued the Guidance on Promoting Clinical Pathway Management during the “Twelfth Five-year Plan Period” with the key tasks as follow: (1) expand the coverage of clinical pathway management; (2) continuously improve the case enrollment rate and completion rate of clinical pathway management; (3) refine and improve the clinical pathway and the sub-pathway of each kind of disease; (4) establish and improve the comprehensive performance appraisal mechanism; (5) strengthen clinical pathway management by using information technology; (6) control unreasonable medical expenses and link up with the reform of payment systems. The guidance requires that based on the implementation of clinical pathway management, scientific calculation of the diagnosis and treatment expenses of single disease should be conducted, hospitals and medical staff should be guided to rationally utilize medical resources, and unreasonable medical expenses should be controlled by standardizing diagnosis and treatment procedures and improving medical service efficiency, so as to lay a foundation for the reform of payment systems for single disease and

according to DRGs. In 2017, Ministry of Health of China issued the Guiding Principles for Clinical Pathway Management of Medical Institutions, asking medical institutions to coordinate price management with health insurance management to calculate costs based on clinical pathways and promote the reform of payment methods such as the DRGs payment system. In 2020, Nation Health Committee of the People's Republic of China issued the Notice on Issuing the Guiding Opinions on Further Standardizing Medical Behavior and Promoting Reasonable Medical Examination, which proposed to strengthen clinical pathway management, gradually improve the rates of entry and completion in clinical pathway management and reduce the rates of variation and withdrawal. By the end of 2022, 50% of patients discharged from tertiary hospitals and 70% of patients discharged from secondary hospitals should be managed according to clinical pathways. In addition, the guidance proposes to further promote the reform of medical insurance payment system, carry out pilot programs for DRG payment, timely summarize experience and steadily expand the scope of reform.

The three important policies mentioned above reflect a trend of China's medical insurance reform, which is to strengthen the connection between clinical pathway and DRGs. Clinical pathway management is regarded as an important foundation for DRGs payment (Mo et al., 2021). Despite the vigorous promotion of policies and the continuous implementation of relevant pilot programs, there are still some problems in practice, such as the untimely revision of the standardization process, the lack of systematic theoretical guidance for clinical pathway management, over emphasis on the enrollment rate in the evaluation of clinical pathway management and few focus on the quality of clinical pathway management (Mo et al., 2021).

It remains to be discussed how to effectively combine the clinical pathway with the reform of medical insurance payment mode so that clinical pathway can help in standardizing medical behavior, improving medical efficiency and ensuring reasonable medical expenses. Yao et al. (2018), using the DRGs benchmarking data of Beijing tertiary hospitals released by the Beijing Performance Center, compared the ALOS, total cost, drug proportion, drug cost ratio and consumable cost ratio of the patients in the pathway, the patients out of the pathway and the patients not managed by clinical pathway in a hospital of Beijing in 2015. It was found that clinical pathway management played a significant role in controlling total cost, LOS, drug proportion, drug cost and consumable cost, and the effect of clinical pathway management was measured with the use of the time consumption index and the charge consumption index of DRGs evaluation system. In this study, patients were divided into four categories according to the time consumption index and charge consumption index: the first category involves patients whose LOS and medical expense are longer and higher than the average level of the patients in

the same type of cases in the tertiary hospitals in Beijing; the second category includes patients with lower medical expenses but longer LOS for the same type of cases in the tertiary hospitals in Beijing; the third category are patients with lower cost, shorter LOS and higher efficiency for the treatment of the same type of cases; the fourth category are those patients whose LOS is shorter but cost is higher compared to the cases in the same type. Researchers compared the data of these four types of patients from departments that conducted clinical pathway management in 2014 and 2015. The result showed that the time-efficiency ratio of the average LOS and the cost-efficiency ratio of the average expense of the patients in this hospital are all less than 1, indicating that the hospital's efficiency is higher as there are lower cost and shorter LOS for the cases in the same type and at the same level of difficulty. The research concluded that the clinical pathway management combined with DRGs is more effective; clinical pathway management can give patients access to homogeneous medical services by standardizing the process of diagnosis and treatment; and the diagnosis and treatment services can be more accurate with the use of DRGs.

Wang et al. (2019) analyzed the in-hospital costs in the clinical pathway based on DRGs, with data collected from the first page of the hospitalization records of 18 general hospitals above the second level in Tai'an City in the past three years (2015-2017). At first, with the use of retrospective method, researchers analyzed the in-hospital costs and discrete trends of 10 DRGs with ischemic diseases with major complication and comorbidity, respiratory infection/inflammation (less than 18 years old), intestinal obstruction or abdominal pain (without complication and comorbidity) and cesarean section (without complication and comorbidity), all of which were managed under clinical pathway. Secondly, a comparative analysis was made on the in-hospital costs and dispersion of clinical pathway group and non-clinical pathway group in a tertiary hospital in Tai'an City. In this study, the quantitative data in non-normal distribution were represented by median and interquartile range. Chi-square test was used for qualitative analysis and inter-group comparison was carried out by the Mann-Whitney test, with $P < 0.05$ considered as statistically significant. The result revealed that the average in-hospital cost (median) and dispersion (interquartile range Q) of each DRG in these hospitals showed a downward trend from 2015 to 2017. The average in-hospital cost of each group decreased by 4.72% annually, and the dispersion declined by 6.37% annually. Since the implementation of the clinical pathway, the in-hospital cost had shown a decreasing trend and the dispersion had been more concentrated. The in-hospital costs of 10 DRGs in 2015, including the ischemic disease with major complication and comorbidity, were compared, and analyzed between the clinical pathway group and the non-clinical pathway group. It was found that the

average in-hospital cost (median) and dispersion (interquartile range Q) decreased after the implementation of clinical pathway, which shows that DRGs-based clinical pathway management can promote the improvement of medical outcomes.

Wei et al. (2016) conducted an analysis of 10 departments of a hospital in Beijing, which ranked top 10 according to the DRGs settlement. It was found that the Neurology Department suffered a loss. Besides, in this department, the number of cases of BR21 (cerebral ischemic disease with major complication and comorbidity), BR23 (cerebral ischemic disease with general complication and comorbidity) and BR25 (cerebral ischemic diseases without complication and comorbidity) accounted for about 83.28% of the medical insurance patients settled by DRGs. In 2013, the Neurology Department ranked in the bottom 3 of the 29 clinical departments of the hospital in terms of the coverage rate, participation rate, non-participation rate and variation rate, indicating that the department did not use clinical pathway reasonably, effectively and scientifically. Therefore, it was hoped that the optimization of the corresponding clinical pathway can improve the situation of losses in the department, providing reference for the fine management of hospital DRGs. This study attributed the poor implementation of clinical pathway to the outdated and unfounded pathway, the great influence of doctors' subjective factors such as diagnosis and treatment habits, not formulating the branch pathway or modifying and refining the clinical pathway in time. After analyzing the data of BR21, BR23 and BR25, the researchers reconstructed the standard clinical pathway of cerebral ischemic disease with complication and comorbidity and established the branch clinical pathway by analyzing the types of complication and comorbidity. This study analyzed the total cost, the proportion of drugs, the proportion of examination fees, the proportion of treatment, the average LOS of the same disease group from 2014 to 2015. Variance analysis was used for the data that conformed to normal distribution, and rank sum test was used for those did not. It was shown that the average cost of the cases treated according to the clinical pathway was RMB 11420.94, while that of the control group was RMB 13887.04. The cost of experimental group was significantly lower than that of the control group, with a surplus in the experimental group settled by DRGs and a deficit in the control group. There were significant differences between the two groups, so it could be considered that the total cost of the experimental group was more effectively controlled than that of the control group. The proportion of drug cost in the experimental group was significantly lower than that in the control group, while the proportion of examination fee in the experimental group was higher than that in the control group, which showed that the diagnosis and treatment of patients cost more than drugs and the cost structure had been effectively adjusted. The average lengths of stay of the experimental group and the

control group were 11.7 days and 12.4 days respectively, in which the difference was not statistically significant. It was found that the reason why there was no significant difference in the average LOS was the lack of consideration of reducing the number of consultation procedures and shortening the waiting time of examination appointments when they formulated the clinical pathway incorporating diseases in other systems.

Li et al. (2021) carried out DRGs simulation calculation on the discharge data of a tertiary specialized hospital in Tianjin from 2016 to 2019, in order to analyze the impact of the upcoming DRG payment on hospital operation and management and to explore the problems of clinical pathway management under the DRGs reform. The measured data met the following criteria: (1) diagnosed as primary hematological diseases and the clinical pathway in line with the Current Practice of Blood Diseases; (2) patients with medical insurance in Tianjin; (3) have complete first page data and the correct diagnosis. Comparison was made between the total costs shown on the first page of patients' medical records and the costs calculated by the simulation test. If the calculated cost was higher than the real in-hospital cost, it was considered that the case income would increase after the DRG payment reform; if the calculated cost was lower than the real in-hospital cost, it was considered that the case income would decrease after the DRG payment reform, and the profit would be negative. The result showed that the DRG payments of the hospital's top 10 patient groups ranked by the number of discharged cases reduced and the DRG payments of the hospital's ten main diagnosis and treatment departments also decreased. In the process of calculating the DRG payment, the problems related to clinical pathway management were exposed: (1) the first page of medical record was not well filled out. As the core of DRGs is to classify the cases with the same characteristics into one category according to the main diagnosis, as well as the age, surgery, operation, and complication of patients, the correct diagnosis and accurate coding of diseases is the basis of the reform of DRGs payment model, and it also determines the payment group and amount of patients' in-hospital cost. Because the above information is all extracted from the first page of medical record, the department controlling medical quality should start with standardizing the clinical diagnosis and treatment pathway, regulating doctors' writing of the first page of medical record and enhancing the audit of data. (2) The blood diseases examination was massive, with long course of treatment and multiple diagnosis and treatment. Therefore, it is necessary for hospitals to control medical costs under the DRGs payment system, gradually shorten the LOS with the help of clinical diagnosis and treatment pathway, strictly control the use of high-priced drug consumables, reasonably control the frequency of using large-scale equipment such as MRI and expensive examinations, strengthen the assessment of LOS and charge consumption index, and

improve the efficiency of using medical resources.

Li et al. (2022) introduced the DRG-based clinical pathway management system of a tertiary general hospital in Beijing, whose purpose is to improve medical quality and promote the reform of DRG payment. The first step of building a clinical pathway management system based on DRG is to determine the corresponding clinical pathway of each group according to CHS-DRG. The established clinical pathway includes the benchmarking days needed in each stage of diagnosis and treatment (admission, pre-operation, intraoperative, postoperative, and discharge), the mandatory and optional items set for the main tasks of each stage (diagnosis and treatment work, key medical orders, main nursing work), and display of the cost of corresponding project and total cost. The standard cost and LOS of clinical pathway are referenced by DRG benchmarking cost and benchmarking LOS. Secondly, during the whole process of diagnosis and treatment of patients, the clinical pathway is determined by the cooperation of clinicians, coders for disease classification and information systems. Specifically, before patients' admission, physicians determine the clinical pathway to be taken based on the admission diagnosis and the operation to be carried out. On the second day after admission, the disease classification coders log the first course and diagnosis of the patients, based on which the information system alerts the standard LOS, standard diagnosis and treatment and costs of the patients. During hospitalization, the system automatically updates the DRG grouping results by defining diagnosis and performing specific operations, and prompts the differences in doctors' implementation of clinical pathway to ensure the consistency of diagnosis and treatment among doctors, thus ensuring medical quality; for cases with great differences, the system actively reminds disease classification coders to intervene in the analysis and communicate with clinicians in time. After patients' discharge, the disease classification coders check the information on the first page of medical records to improve the accuracy of filling in the first page of medical records and the accuracy of grouping. The clinical pathway management based on DRG adopts PDCA (Plan-Do-Check-Action) in quality management for continuous supervision and improvement. Li et al. (2022) suggested that in order to ensure the function of the clinical pathway management system based on DRG, the corresponding performance appraisal and reward and punishment system should also be designed.

The synthesis of the status of clinical pathway management in China reveals significant progress since 2012. Efforts have been concentrated on expanding the coverage of clinical pathway management, increasing the admission and completion rates, refining clinical pathways and sub-pathways, establishing comprehensive performance assessment mechanisms, utilizing information technology for enhanced management, and controlling unreasonable

medical expenses. The enactment of relevant regulations has provided institutional safeguards and policy support for clinical pathway management, contributing to the implementation of DRGs payment reform in China. Studies indicate that clinical pathway management has achieved notable success in controlling medical expenses, improving the efficiency and quality of healthcare services. Additionally, it has assisted hospitals in optimizing cost structures, reducing unnecessary drug and examination expenses, and enhancing the efficiency of medical resource utilization. However, challenges persist in the practical application of clinical pathway management, including delays in standard process revisions, lack of systematic theoretical guidance, and an assessment focus on admission rates at the expense of management quality. Addressing these issues requires further standardization and meticulous management. Specifically, continuous updates and optimization of clinical pathways are essential to ensure their alignment with medical practices. Enhancing the standardization of clinical pathway management involves establishing a robust theoretical framework and practical guidance. Monitoring and evaluating the execution of clinical pathways are crucial to ensuring their quality and effectiveness. In summary, while China has made significant strides in clinical pathway management, further reform and resolution of practical challenges are necessary to achieve more efficient and higher-quality healthcare services. This requires the close integration of policies, practices, and research, as well as collaborative efforts from healthcare institutions, medical professionals, and patients.

2.3.2 Evaluation and improvement of clinical pathways

2.3.2.1 Evaluation of clinical pathways

Luo et al. (2021) asserted that understanding the practical scope of clinical pathways is vital for assessing and improving clinical pathway management, bridging the gap between clinical evidence and practice. The research discusses the design and evaluation model of clinical pathways to help designers know the actual functional scope of clinical pathways and identify effective key management steps for specific diseases. According to the research, an intervention can be considered a clinical pathway if it meets the following four criteria:

Criterion 1: It is a structured, multidisciplinary care plan.

Criterion 2: It is used to guide the translation of guidelines or evidence into local structures.

Criterion 3: The steps in the treatment or care process are detailed in plans, pathways, algorithms, guidelines, protocols, or other “action lists,” with a time frame or standards-based progression for the intervention.

Criterion 4: It aims to standardize diagnostic and therapeutic behaviors for specific clinical issues, procedures, or episodes of care within a specific population.

However, as an implementation strategy, the clinical pathway differs significantly in practice from treatment outcomes in relatively controlled trial environments. Luo et al. (2021) proposed a process for pathway design and evaluation. However, the research also pointed out that in some cases, even with well-designed clinical pathways, their functionality might be weakened or impractical. The research reported a case in China, demonstrating that before the national health system reform in 2009, 30% of departments in pilot hospitals refused to implement clinical pathways because it would reduce the hospital's revenue. After the national health system reform in 2009, there were structural barriers to implementing clinical pathways, and their effectiveness was undermined by a poorly controlled institutional environment, especially an unsound payment mechanism. Luo et al. (2021) emphasized the necessity of considering the actual functional scope of clinical pathways in the management of specific diseases before designing them, which can be reflected at least on two dimensions of their goals. The first dimension is the degree of diagnostic and therapeutic benefits produced by the operation of clinical pathways (benefit dimension), reflecting the net benefits of medical cost control and treatment outcomes. The second dimension is the standardization level of the entire disease diagnosis and treatment process by clinical pathways (process dimension), reflecting the degree of standardization of medical procedures or the extent to which clinical pathways are used in disease treatment.

Sun et al. (2021) identified several shortcomings in traditional clinical pathway management in practice. To overcome these limitations, they proposed the establishment of an adaptive clinical pathway management approach. The identified shortcomings include:

(1) Path dependency: Clinical pathways excessively rely on established processes and lack the ability to dynamically generate personalized paths based on individual patient conditions.

(2) Lack of global perspective: Clinical pathways only focus on the direct process from the current state to the target state, without considering the comprehensive impact of all paths, potentially overlooking conflicts in future states.

(3) Subjectivity in path selection: Path selection primarily depends on the experience of doctors rather than a system that can automatically infer and recommend based on all available information.

(4) Current state focus: Clinical pathways formulate plans based solely on the patient's current state, without considering possible disease progression, making it unable to predict and adapt to future conditions.

(5) Lack of support for comorbidities: Clinical pathways are typically designed for a single disease, and in cases of multiple coexisting diseases, conflicts or contradictions may exist between different paths.

(6) Lack of continuous validation: Clinical pathways cannot continuously verify whether they can achieve the expected goals during execution, unable to detect potential execution conflicts or issues in advance.

(7) Lack of comprehensive evaluation metrics: Existing tools lack overall evaluation metrics for different pathways, such as cost, time, comfort, etc., and cannot support pathway selection.

(8) Barriers in implementation: Various obstacles may exist in the implementation process of clinical pathways, such as clinical habits, limited resources, insufficient information technology, etc., affecting their execution effectiveness.

(9) Inability to adapt to changes in patient conditions: Clinical pathways cannot be dynamically adjusted based on changes in the patient's condition after their formulation.

The research proposes an adaptive clinical pathway management system based on weighted state transition logic. This system can generate clinical pathways by predicting changes in the patient's state. The logic allows for changing weights in state transition rules to represent the quality of actions or the overall quality of the clinical pathway. It not only generates clinical pathways but also detects potential conflicts in the paths and validates them before execution. The system is adopted combining semantic web technology, allowing easy integration of semantic data and rules as background knowledge. The researchers believe that this system can be utilized for adaptive clinical pathway management based on predictive future states.

Yeh et al. (2015) investigated medical staff's evaluation on the effect before and after the clinical pathway implementation through using a Fuzzy Rating Scale-Based Questionnaire. This study investigated the relationship between clinical pathway implementation and patient satisfaction. They used canonical correlation analysis to find the correlation between clinical pathway implementation and quality of care, and the correlation between clinical pathway implementation and patient satisfaction. The results showed that medical staff generally responded positively to the implementation of the clinical pathway. In addition, regarding the correlation between clinical pathways and patient satisfaction, the research results displayed that medical quality is positively correlated with the response of medical consumers, and that integrating clinical pathways into medical practice can improve medical quality and patient satisfaction.

Toy et al. (2018) assessed interest and availability of clinical pathways among primary care professionals. Their research took the form of an online survey in which participants completed basic questions followed by two pathway-related question sets about chronic disease management. Of the 115 participants, 17.4% used the clinical pathway. Over 75% respondents were interested in using the clinical pathway daily or weekly. The study demonstrated that primary care clinicians have low utilization of clinical pathways but high interest.

Téoule et al. (2020) assessed the impact of clinical pathways on the quality of care in pancreatoduodenectomy (PD), by analyzing data from patients undergoing continuous PD preoperative (n=147) or postoperative (n=148). The study evaluated the introduction of clinical pathways in terms of catheter drainage management, postoperative mobilization, pancreatic enzyme replacement, recovery diet, and length of hospital stay. Outcome quality was assessed by blood glucose management, morbidity, mortality, reoperation rates, and readmission rates. They found that catheters and peritoneal drainage could be removed significantly earlier in patients who had implemented the clinical pathway ($p < 0.0001$). Patients in the clinical pathway group were able to initiate first intake of liquids, nutritional supplements, and solids earlier ($p < 0.0001$). After implementing the clinical pathway, exocrine insufficiency was significantly reduced ($p < 0.0001$) and the number of patients receiving intraoperative blood transfusions was significantly lower ($p = 0.0005$), while the non-clinical pathway group had a higher rate of blood transfusion ($p = 0.05$). The median number of days with a maximum pain level >3 was significantly higher in the clinical pathway group ($p < 0.0001$). There were no significant differences in mortality, morbidity, reoperation and readmission rates between the clinical pathway group and the nonclinical pathway group. The study revealed that after implementing a clinical pathway for pancreaticoduodenectomy, some measures related to the course of care and efficacy were improved, while others such as mortality and reoperation rates remained unchanged. Clinical pathways are a promising tool for improving the quality of pancreatic surgery care. Karunakaran et al. (2021) also investigated the impact of deviation/non-compliance with clinical pathways in PD postoperative outcomes. They conducted a systematic review of major reference databases from January 2000 to November 2020 on adherence to clinical pathways and their impact on treatment outcomes in PD patients. They performed a meta-analysis using a fixed-effects or random-effects model, which concluded that adherence to the clinical pathway after PD remained low. Enhanced postoperative recovery seemed very important in patients undergoing pancreatic surgery, such as PD. Nevertheless, the study also pointed out that while clinical pathways aimed at enhancing recovery can have the desired effect in shortening the length of hospital stay, there is still a lack

of understanding of the adherence and relevance of these pathways. Van der Kolk et al. (2019) collected data on 7553 patients undergoing cardiac surgery between 2007 and 2015. These patients were divided into three categories: those treated by the clinical pathway, those who were excluded from the clinical pathway 48 hours before surgery, and those who were not included in the clinical pathway at all. The study concluded that the introduction of clinical pathways in the patient group resulted in improved medical outcomes related to Length of Stay, readmissions, and mortality, which was consistent with low- and moderate-risk procedures. The study mentioned that in fields such as cardiology, it is well-known that the use of clinical pathways in standardized care can reduce disparities in care and medical outcomes. This study concluded that implementing a clinical pathway to treat acute coronary syndromes could improve compliance with treatment regimens. In addition, Lagergren et al. (2020) presented a case study of a standardized clinical pathway for performing Fontan surgery in children with cardiac disease. In this case, 37 patients (2014-2015) who did not implement the clinical pathway after surgery were selected for analysis in comparison with the data of 30 patients (2017-2018) who implemented the clinical pathway after surgery. The results of the study showed that the length of hospital stay for patients who implemented the postoperative clinical pathway decreased from 12 days to 9 days, with no increase in readmissions. According to this study, standardized care in the clinical pathway can improve clinical outcomes and financial performance in the Fontan patient population without compromising quality of care.

Nagarsekar et al. (2021) introduced an innovative clinical pathway for the treatment of children and adolescents with mental health problems in the emergency department, the KALM (Kids Assessment Liaison for Mental Health) clinical pathway. Compared with the conventional clinical pathway, the KALM clinical pathway reduced the average hospital stay in the emergency department and improved their nursing satisfaction.

Mine et al. (2020) investigated the relationship between regional clinical pathways and postoperative length of stay (LOS) in patients with hip fractures. The regional clinical pathway is a new type, which realizes the standardization and optimization of medical services through the cooperation of multiple medical institutions in the region. This study established a multi-factor and multi-level regression model to analyze the influence of hospital-level factors and patient-level factors on postoperative hospital stay. The results showed that hospital-level factors are related to shortening the postoperative hospital stay, and that regional clinical pathways can improve the nursing effect of inpatients.

Marbus et al. (2021) described the implementation of a new clinical pathway for the treatment of patients with suspected influenza virus infection at Jeroen Bosch Hospital (JBH)

in the Netherlands during the 2017-2018 influenza season. The pathway includes three interventions: clinical practice for influenza diagnosis in emergency department patients, influenza testing (influenza point-of-care test, POCT) and temporary influenza quarantine. The study compared the newly implemented clinical pathways for the 2017-2018 flu season with data from the originally implemented clinical pathways for the 2016-2017 flu season. This study demonstrates that a new clinical pathway involving POCT has favorable economic outcomes and is more effective in the care of suspected patients with influenza in the emergency department.

Butow et al. (2021) developed a clinical pathway for the screening, assessment, and management of anxiety and depression in adult cancer patients (ADAPT). The clinical pathway had been implemented in twelve Australian oncology medical service institutes for 12 months. This study compared the acceptability and suitability of staff-perceived clinical pathways for ADAPT. In each health service, a multidisciplinary leadership team would specialize in setting, planning, supporting, and implementing clinical pathways. Individuals selected to participate in healthcare services were asked to complete a survey and accept an interview before, during, and at the end of the clinical pathway. Their interviews were then recorded, transcribed and thematically analyzed. As a result, this study concluded that the ADAPT clinical pathway enjoys high employee-perceived acceptability and suitability.

2.3.2.2 Improvement of clinical pathways

Shoji et al. (2011) studied the performance of clinical pathways of pneumectomy from 2005 to 2009 and retrospectively analyzed the data of 383 patients. Their study suggested that there is room for improvement in clinical pathways, and in particular electronic clinical pathways outperform thesis clinical pathways. They thought that electronic clinical pathways can help doctors, nurses and health professionals share the information of patients and use the accumulated data to easily conduct various analysis. Li et al. (2014) also noticed that thesis clinical pathways impeded information sharing and affected the accuracy of information in the treatment process. In this case, they put forward a Co-design integrating clinical pathways management and a hierarchical information system for clinical pathways management and illustrated the effectiveness of their methods through case evaluation. Besides, Chu (2001) was also a critic of thesis clinical pathways, who believed that since all the patient management strategies are pre-designed according to the clinical management agreement adopted by hospitals or related departments, and are published as thesis documents in advance in the form of a task list, thesis clinical pathway is not flexible enough to adapt to the dynamic changes of

patients' conditions.

Du and Sun (2019) mentioned that as the incidence rate of type 2 diabetes is relatively high in China in the past two years, they chose type 2 diabetes as their research object. Their research aims to discuss the effectiveness of the tools for chronic disease management in aspects such as diagnosis and treatment standardization, the improvements of work efficiency of doctors as well as patient satisfaction and the adaptation to the current demands of communities in chronic disease management. They used empirical research to evaluate the effect of the electronic clinical pathway for type 2 diabetes. To be specific, they set a community-based clinical pathway for type 2 diabetes with the methods of literature review and experts conference, and developed it into an electronic clinical pathway platform. They divided patients into two groups: the clinical pathway group (on which electronic clinical pathway management was conducted) and the control group (that received routine control and the treatment of blood glucose) and their study lasted for one year. Through comparing and analyzing metabolism markers, standardized management rate and the rate of blood glucose control, the research evaluated the results of electronic clinical pathway management for type 2 diabetes. With the data of 264 patients, statistical analysis found that the differences in blood glucose and blood lipid levels between the clinical pathway group ($n=132$) and the control group ($n=132$) were statistically significant ($P<0.0001$). In addition, the fasting plasma glucose level, glycolated hemoglobin level and blood lipid level of the clinical pathway group was significantly lower than that of the control group. The study showed that the electronic clinical pathway for type 2 diabetes can effectively improve diabetes management and promote the standardization as well as diagnosis and treatment quality of family doctors in the process of community-based chronic disease management. The application of electronic clinical pathways in community health centers can be further improved and expanded.

Vanhaecht et al. (2006) studied the capacity of different tools for clinical pathway evaluation to grade different clinical pathways and concluded that many researchers made efforts to develop new tools for clinical pathway evaluation, but till now, these tools haven't made any substantial contributions to clarifying what characteristics of clinical pathways can affect the outcomes of medical diagnosis and treatment. In essence, clinical pathways are still running in a black box and how the characteristics of each clinical pathway affect the pathway-related outcomes is still unknown.

Jabbour et al. (2018) explored a set of comprehensive factors that have impacts on the implementation of clinical pathways in complex dynamic settings like community emergency department. The comprehensive factors can be perceived by the workers and managers in the

emergency department. The researchers conducted a descriptive qualitative study of emergency health professionals and managers in 15 community hospitals in Ontario, Canada. The data were collected from three sources: (1) group discussions on-site with the project leaders during the project initiating meeting; (2) semi-structured on-site interviews with each emergency department; (3) interviews with executive directors of each hospital. By using the qualitative method, the study identified a series of factors that may negatively or positively affect the implementation of clinical pathway in community emergency department, which can be categorized into seven aspects: CP and Standardization, Pediatric/Patient-Specific Issue, Professional Issues, Team Dynamics, Strategies for Success and Sustainability, Hospital Resources and Processes and Quality and Process Improvement.

Buchert and Butler (2016) believed that clinical pathways can positively impact the nursing quality of a single patient, health of patients with specific diseases and the working process of front-line medical staff and medical organizations. The study held the opinions that the most successful clinical pathway is the one that has evidence-based interdisciplinary and multidisciplinary medical cooperation and conforms to local medical environments and the strategies of local medical organizations. According to the study, the successful development and maintenance of clinical pathway is summarized into the ability to obtain buy-in at all levels in the organization and among front-line employees and continuously monitor all factors that can affect the pathway, and the establishment of feedback measures to be implemented in real time or as close to real time as possible so as to ensure that all stakeholders participate in the continuous evaluation of the pathway and its impact. Besides, the study mentioned that designating appropriate resources for a specific evidence-based treatment process or diagnosis can help organizations calculate the approximate cost of caring for the patient. Based on this calculation, organizations can properly estimate their budget and the resources required to provide the best care, and better determine how to allocate resources.

Kaiser et al. (2020) made a qualitative analysis of the clinical pathway of asthma treatment applied to hospitalized children and considered that shortening hospitalization time through clinical pathways can reduce both caregivers' absenteeism and the costs for the health-care system. The study concluded that successful implementation of clinical pathways requires (1) quality improvement and data-driven approaches; (2) integration of clinical pathways with electronic medical records; (3) participation of hospital leaders in the implementation of clinical pathway; (4) commitment of a whole organization to common goals and overcoming inconsistencies during the implementation process; (5) multidisciplinary support.

Hooda and Fields (2021) reported their work on developing and implementing clinical

pathways in electronic health records. These efforts involve visualizing care pathways, formalizing pathway approval processes, and transforming clinical pathways into clinical decision supporting tools that integrate electronic medical records. Cho et al. (2020) developed a data-driven clinical pathway on the basis of health record data. Their study proposed a matching rate-based clinical path mining algorithm that uses the matching rate to generate the optimal set of clinical orders in different clinical stages. To validate the method, they used two datasets of inpatient records directly related to total laparoscopic hysterectomy (TLH) and rotator cuff tears (RCTs) from a hospital in South Korea. The two datasets were compared by medical professionals with knowledge-based models and data-driven clinical paths. Two different clinical pathways, TLHs and RCTs, were generated by using the matching rate-based clinical pathway mining algorithm. The study found that the data mining model and the knowledge-based model had significant differences in clinical doctor orders, and the proposed data-driven clinical pathway algorithm was superior to the clinical expert model, with an average matching rate of 82.02% and 79.66%, respectively.

Graeber et al. (2007) focused on the importance of business process management (BPM) for clinical pathway development and implementation. Their study concluded that BPM did enhance the development and implementation of clinical pathways, and that the introduction of BPM reduced hospital stay, number of laboratory tests, number of consultations, and imaging procedures, and improved patient satisfaction. BPM is responsible for the purposeful planning, direction and control of business processes. There are three different levels of BPM, strategic, tactical and operational. Tasks at the strategic level include defining goals, planning processes, and providing resources. Tasks at the tactical level include process design and implementation. The main goals of BPM are to achieve customer (patient) satisfaction, enhance quality, reduce time and cost, and promote scheduling. This study reports the use of BPM for clinical pathway development in General Surgery, Abdominal and Vascular Surgery, and Paediatric Surgery at Saarland University Hospital. Specifically, first, the Steering Committee, which is made up of Department Director, Senior Surgeon, Head Nurse, Computer Administrator of the Department, functions at the strategic level of BPM, including defining goals, time limits, milestones, priorities, granularities (actions, detail level of time and path conditions included) and consensus process, as well as providing resources. Second, the path team at the tactical level consists of a senior surgeon, four surgeons, four nurses and computer administrators. This team is responsible for the design, development, and introduction of paths, as well as appropriate project management. At the operational level, computer administrators and other staff provide mechanisms for routine process monitoring and periodic execution to control clinical pathway

variability. To assess the effectiveness of this clinical pathway, a prospective observational study was conducted. They collected treatment data for 67 patients with six different diagnoses without clinical pathways from January 1st and March 9th, 2005, and data for 62 patients with the same diagnosis and treated with the clinical pathway during the period from October 1st, 2005, to February 28th, 2006. The findings suggested that reengineering of clinical pathways can reduce effort and cost and improve patient satisfaction.

Wendel et al. (2023) reported that during the COVID-19 pandemic in 2019, clinical guidance rapidly changed, which was very unfavorable for evidence-based clinical pathways. A large hospital in Colorado has established a clinical pathway based on electronic health records (EHR) to guide clinical practice. The EHR platform system embedded with clinical pathways can provide the latest clinical guidance information for medical staff. The hospital has developed nine unique clinical pathways for emergency, outpatient, inpatient, and surgical care. Due to the different needs and available resources of different departments (such as drug therapy and nursing level), these initially developed 9 pathways were re-customized, and 69 pathways for different departments to guide clinical decision-making and practice were ultimately developed. These pathways include but are not limited to: (1) outpatient symptom detection standards; (2) nursing and treatment in the emergency department; (3) hospitalization treatment and discharge standards; (4) drug management guidelines, such as anticoagulation recommendations and supplemental oxygen supply, mechanical respiration settings, nursing transition, and end-of-life treatment. Due to the rapid mutation of the COVID-19 virus, this EHR platform system embedded with clinical pathways is rapidly updated, sometimes daily, with the constantly emergence of new evidence. To ensure that medical staff know when the pathway has been updated and optimized, the path subheading in the EHR platform system is marked with “last update date”. The used evidence is made as a hyperlink for medical staff to refer to. Through this platform system, all medical staff can immediately send pathway feedback and optimization suggestions to the Clinical Pathway Management Committee. Based on the feedback, treatment recommendations, and resource availability, each COVID-19 clinical pathway has iterated at least once. From the perspective of workflow, each department is able to manage clinical pathways according to its own needs. In addition, Wendel et al. (2023) pointed out that the emergency department used the platform the most often, which is probably because the emergency department is the first place for patients with COVID-19 symptoms to seek treatment. And emergency nursing department was accustomed to using clinical pathways to address various issues before the pandemic, and medical staff in the department had become familiar with and adapted to this form of clinical guidance. Therefore, in the early stages of the

COVID-19 pandemic, the emergency department can quickly adjust its pathways based on evidence, especially in terms of detection, management, and discharge standards.

Viney et al. (2022) studied personalising clinical pathways through interviews and analysis of data from a breast cancer service center in London, UK. This study suggests that the prerequisites for personalising clinical pathway are adaptability, flexibility, and revision and it argues that the clinical pathway is a tool for guiding treatment decisions and needs to be continuously adjusted to reflect new research evidence and treatment methods. Researchers have found that adjustments to clinical pathways affect the workload and tasks of medical staff, expectations and demands of patients, demand for new testing procedures, and the interaction and tension between research and clinical care. Clinical paths are not predetermined but rather become clear in practice. They are not a set of “care processes” specifically defined for a group of patients in a certain period of time. Instead, personalising clinical pathways are formed by categorizing patients and monitoring their compliance with these categories during treatment. They are based on disease monitoring and treatment response.

Based on the literature on the evaluation and improvement of clinical pathways mentioned above, it can be concluded that clinical pathways are important tools for guiding medical practice, standardizing diagnosis and treatment processes, and improving medical quality and efficiency. By following clinical pathways, indicators such as length of stay in hospital, readmission rate, and medical outcomes can be improved, and thereby medical quality and patient satisfaction can be improved. Clinical pathways can standardize diagnosis and treatment behavior and optimize resource allocation based on clinical evidence and standardized processes. The design and evaluation of clinical pathways need to consider the actual functional scope, including efficacy dimensions (cost control and treatment effectiveness) and process dimensions (standardization of medical procedures). There are certain obstacles to the implementation of clinical pathways, such as path dependence, subjectivity, and consideration of only current status. An adaptive clinical pathway management system needs to be established to dynamically adjust itself according to changes in patient status. Clinical pathway management requires recognition and participation from all levels within the organization, and establishing a monitoring and feedback mechanism is crucial to achieve continuous improvement in medical quality. Of course, the clinical pathway is not static and needs to be adjusted and updated based on new clinical evidence and treatment methods. During the implementation process, attention should be paid to the execution and impact of the pathway, and the system should be optimized in a timely manner when problems occur. Clinical pathway management will tend to adopt personalising clinical pathways. In short, clinical pathways are

effective tools for improving healthcare quality and efficiency, but their design and implementation still need to be continuously improved to make the pathways adaptive, flexible, and targeted. It is crucial to establish a monitoring and feedback mechanism in clinical pathway management.

2.4 Application of quality management methods in the improvement of medical service process

The commonly used quality management methods in medical service process improvement include checklists, standardized clinical diagnosis and treatment pathways, lean methods, Six Sigma strategies, and total quality management (Pinney et al., 2016). The checklist typically includes a series of precautions or tasks that need to be completed to help the medical team ensure standardized processes and communication are followed at every stage. Both quality and process improvement tools follow the basic principles of quality improvement. These principles include focusing on results, optimizing communication among healthcare team members, improving process standardization, and reducing process variability. Barros et al. (2021) mentioned that the most commonly used lean tools in the healthcare field are DMAIC, VSM (Value Stream Mapping), SIPOC (Super Input Process Output Customer), Ishikawa Diagram (Fishbone Diagram), and 5S (Seiri, Seiton, Seiso, Seiketsu, and Shitsuke). This study indicates that Six Sigma is very useful. The application of this tool has shown positive effects, such as increasing time directly used for patient care, reducing unnecessary processes, and reducing rate of nosocomial infection. However, the study also pointed out that more extensive research is still needed on the application of Six Sigma tool in various fields of medical services. Pinney et al. (2016) summarized 14 quality and process improvement methods used in the medical field, as shown in Table 2.1

Table 2.1 Quality and process improvement tools in the medical field

Quality and process improvement tools	Description	For events/whole process	Static/ Iterative	Standard-ized/ Redesigned
Checklist (point checklist)	Pre-designed checklists to improve team communication standards in specific events.	For specific events (such as operation time warning)	Static	Standardized
Clinical practice guideline	Develop formal diagnostic or management guidelines for specific clinical situations, typically based on evidence-	For specific events	Static	Standardized

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	based methods.			
Applicability criterion	Develop appropriateness guidelines for diagnostic tests and treatment choices based on expert collective judgment for specific clinical situations.	For specific events	Static	Standardized
Clinical pathway	It describes the specific conditions that need to be met throughout the entire treatment service process.	For whole process	Static	Standardized
PACA Circle (Deming Circle)	A four-step continuous improvement cycle which envisions what the process should look like (plan), implementing the plan (do), recording the results (check), and adjusting the process (action) based on the results.	For specific events/whole process	Iterative	Standardized/Redesigned
Statistical process control	Continuously improve the process and provide early detection of issues through the output data collected during the process.	For specific events/whole process	Iterative	Standardized
Lean process improvement	A process improvement strategy based on multidisciplinary teams aimed at enhancing the value and efficiency of services and delivery.	For specific events/whole process	Iterative	Standardized/Redesigned
Six Sigma	A method to reduce defect occurrence rate and production process variation.	For whole process	Iterative	Standardized/Redesigned
Lean Six Sigma	A management method that combines lean thinking and Six Sigma.	For specific events/whole process	Iterative	Standardized/Redesigned
Total quality management (TQM)	A comprehensive and continuous quality improvement approach involving all members of the healthcare team, including patients.	For whole process	Iterative	Standardized/Redesigned
Patient-and family-centered therapy	A six-step continuous improvement process specifically developed for healthcare based on the principles of total quality management.	For whole process	Iterative	Standardized/Redesigned
Root cause analysis (RCA)	Assess the cause and effect of adverse events in a formal way.	For specific events	Static	Standardized/Redesigned
Failure mode and effect analysis	A proactive method to prevent adverse events by identifying potential failure modes in existing systems.	For specific events	Static	Standardized/Redesigned

2.4.1 Six Sigma management

Improving methods used in the process has drawn increasing attention in the field of medical services (DelliFraine et al., 2010). Varkey et al. (2007) introduced some methods for improving quality in the medical services process, such as plan-do-study-act, Six Sigma and lean strategy, and discussed the differences between quality improvement and nursing quality research. This study reported on a project by the Charleston Area Medical Center, in which Six Sigma was used to assess the incidence of infections at colonic and vascular surgical sites. At the beginning of the project, the surgical infection rate was zero Sigma. Since the implementation of the project, the infection rate of surgical sites at the Charleston Area Medical Center had dropped by 91% (2.86 Sigma), saving more than \$1 million a year. Six Sigma technology, founded by Motorola in the mid-1980s, is a rigorous statistical measurement designed to reduce costs, reduce process variations, and eliminate defects (Chassin, 1998).

The Six Sigma method was first mentioned in the medical field in 1998 (Niñerola et al., 2020). At present, the Six Sigma method is used in cardiology, nursing, emergency, traumatology, management, ICU, laboratories, radiology, surgery, oncology, pediatrics, and ophthalmology (Niñerola et al., 2020). Niñerola et al. (2020) systematically summarized the application of Six Sigma as a quality improvement tool in the field of medical services. They mentioned that Six Sigma is widely used as a management tool in the medical service industry to improve the quality and safety of patient treatment.

Henrique and Godinho Filho (2020) carried out a statistical analysis of the departments using Six Sigma. It was found that the Emergency Departments carried out the biggest number of Six Sigma studies, most of which sought to reduce the waiting time of patients, improve bed turnover, and eliminate waste in the process of diagnosis and treatment. There are few reports on the use of Six Sigma in the Intensive Care Units (ICU) and Purchasing and Central of Material and Sterilization. In addition, there is no Six Sigma study involving the health insurance organization.

Woodard (2005) mentioned that nursing quality has become a focus of medical service. The uneven quality of nursing provided by the health care system would lead to the dissatisfaction of customer and inefficient processes and outputs. Therefore, hospital managers are faced with the challenge of improving the quality of nursing in medical service organizations. The author believes that the Six Sigma project can provide managers with feasible solutions for quality improvement. Johnson et al. (2005) introduced a Cardiac Six Sigma program of New York-Presbyterian (NYP) Hospital. The goal of this program was to standardize nursing process and

reduce clinically related variations. The indexes used to measure the results of improvement included the turnover time of cardiac catheterization room, and the actual LOS. The improvement measures included changing the working hours of medical staff, modifying the process of patient visit, determining the rest time of the laboratory and operating room, adjusting the operation time of doctors, and establishing the clinical pathway. These improvements had enabled the hospital to perform more catheterization without adding cardiac catheterization laboratories. The study attributed the hospital's success in improving and streamlining process to the Six Sigma approach. This method helps to increase the consistency and reliability of clinical and management processes, and gives sufficient quality control for continuous improvement. Shaikh and Moiz (2016) mentioned that about two thirds of the major clinical decisions about patient management were based on the test results of laboratories, and laboratories were required to take quality control measures to ensure the accuracy of analysis results. The study evaluated the performance of hematological parameters based on Sigma index to identify gaps in patient care and directions for improvement. Ha et al. (2016) introduced the Six Sigma method to improve the mass vaccination process of the United States Naval Academy. Capability indices were used to calculate the corresponding value of Six Sigma, which was used to assess the quality of process improvement. Through a series of improvements, the vaccination process capacity was close to 4 times the Sigma level. The authors believe that this improvement is clinically acceptable in the medical industry.

Define-Measure-Analyse-Improve-Control (DMAIC) model is a Six Sigma management model. However, DMAIC is not exclusive to Six Sigma. It can also be applied with another methodology for improvement (Gijo & Antony, 2014). In order to shorten LOS and improve nursing efficiency, Niemeijer et al. (2013) used the Six Sigma DMAIC model to improve the admission process, preoperative consultation process and discharge process in the treatment of osteoporotic hip fracture. Statistical analysis showed that the LOS and operation time had significantly decreased since the improvement of clinical pathway. Chyon et al. (2020) conducted a survey on the Dialysis Department of a medical institution in Bangladesh, and the Six Sigma DMAIC model was applied for its improvement. In addition, total quality management, statistical quality control and lean manufacturing tools, such as the SIPOC Diagram, P-chart, Ishikawa Diagram and Pareto Analysis, were all used at different stages of the DMAIC model. Moffatt et al. (2022) used the Six Sigma approach to evaluate and improve the nursing and surgical pathway of patients with anterior cruciate ligament reconstruction in a private hospital in Ireland, so as to reduce the LOS of these patients, reduce any non-value-added activities in the diagnosis and treatment pathway, and improve patient flow, bed capacity

and benefits of the hospital while maintaining patient satisfaction. The results of this study revealed that patients' LOS reduced by 57%, and non-value-added activities reduced by 88%. Besides, a new day-case procedure was provided for patients with anterior cruciate ligament reconstruction. The study noted that six months after the start of the improvement activity, the goal of reducing the LOS for patients with anterior cruciate ligament reconstruction was successfully achieved.

Improta et al. (2019) introduced the application of the Six Sigma DMAIC model to solve the problem of prolonged preoperative length of hospital stay of patients with femoral fractures at a hospital in Naples, Italy. The average length of stay before a surgery in this hospital reaches 9 days, which is much longer than the national average of 4 days. Only 4% of patients can receive surgery within the recommended 48 hours. Therefore, the hospital has decided to adopt Diagnostic Therapy Assistance Path (DTAP). When developing DTAP, the Six Sigma DMAIC model was adopted for process improvement. DMAIC played a great role in the development of DTAP. It can be summarized as follows:

(1) DMAIC makes the development process of DTAP more systematic: DMAIC provides methodological guidance for the development and implementation of DTAP, ensuring that DTAP can be improved in a systematic and standardized manner.

(2) DMAIC helps DTAP solve problems in a more comprehensive way: Based on the DMAIC mode, the entire process of DTAP has been defined, measured, analyzed, improved, and controlled, which enables DTAP to solve problems more comprehensively.

(3) DMAIC makes the improvement measures of DTAP sustainable: DMAIC provides a standardized framework within which DTAP's improvement measures are taken, making the measures more replicable and sustainable.

(4) DMAIC helps optimize the process of DTAP in a data-driven approach: DMAIC emphasizes speaking with data and facts, so DTAP can adopt a data-driven approach for optimization under the guidance of DMAIC framework.

(5) DMAIC provides a clearer direction for the implementation of DTAP: DMAIC is a project management framework which provides direction and steps for the implementation of DTAP, making the implementation of DTAP more orderly and predictable.

In short, DMAIC provides a systematic methodological framework for the development, implementation, and continuous improvement of DTAP, ensuring that DTAP can be continuously optimized in a standardized and repeatable manner. This study analyzed the data of two groups of sample patients (534 and 562 patients respectively) before and after the implementation of DTAP. It was found that, without considering factors such as patient history,

the average preoperative length of stay of patients before implementing DTAP was 6.90 days (n=534), and after implementing DTAP, the average preoperative length of stay of patients was 3.15 days (n=562). The length of stay has shortened by an average of 54%. This study fully demonstrates the positive role of the Six Sigma DMAIC model in optimizing clinical pathways, improving patient surgical efficiency and satisfaction, and reducing medical costs.

After reviewing the literature on Six Sigma management mentioned above, it can be concluded that the Six Sigma method has been widely applied in multiple medical fields, including cardiology, nursing, emergency, and surgery, and has shown its potential in improving medical quality, reducing medical errors, improving patient safety, reducing variability, and eliminating defects. The Six Sigma method is a multifunctional tool that can be used to improve the quality of medical processes. Through the Six Sigma method, hospitals have achieved significant results in reducing surgical site infection rates, shortening length of hospital stay, and improving bed turnover. These improvements not only increase patient satisfaction, but also reduce medical costs. The DMAIC model, as a systematic Six Sigma implementation tool, can define, measure, analyze, improve, and control issues in the medical service process. It provides a structured methodological framework for healthcare quality management personnel, helps to address quality issues more comprehensively and ensure the sustainability of improvement measures, and especially can be used to design and optimize clinical pathways. Six Sigma can be seen as a data-driven quality improvement tool that emphasizes the importance of data and facts, which is in line with the growing demand for data analysis in the current healthcare industry. The use of data-driven methods to optimize medical processes and improve service quality is an important trend in future medical management.

However, it should also be noted that although Six Sigma is a powerful tool and method, its successful implementation still relies on hospital culture, employee engagement, continuous training, and supervision. The Six Sigma method may not always be applicable to all types of medical problems. It is more suitable to solve process problems that can be quantified and improved through statistical methods. Therefore, when applying the Six Sigma method, medical institutions need to make appropriate adjustments according to different medical environments and needs in order to more effectively provide high-quality medical services and control medical service costs.

2.4.2 Medical quality process control

Rah et al. (2014) used Process Capability Indices (PCIs) to analyze the process quality of treating diseases in the head and neck (41 cases), spinal cord (29 cases), lung (28 cases), liver

(30 cases), pancreas (26 cases), and prostate (24 cases) in a hospital from November 2011 to December 2012. The results of this study demonstrated process capability in the treatment of all the body parts were acceptable except that of spinal cord. The process for the spinal cord cases was capable but biased, which meant the process mean deviates from its target value. Process capability is an indicator that describes the relationship among the three parameters of allowable specification, central tendency, and error in the production process. The stronger the process capability is, the more the products produced will meet the standard specification (Dong et al., 2021). If a process capability index is greater than 1, it indicates that a process is “capable”. Conversely, if a process capability index is smaller than 1, it indicates that most of the output of the process exceeds the specification limits (Rah et al., 2014).

Koetsier et al. (2012) focused on the application of statistical process control technology in the field of healthcare, systematically reviewed the application of Shewhart control charts in the improvement of healthcare quality, and examined whether the control charts used in the published study on the healthcare quality improvement followed the methodological standards for control charts. This Shewhart control chart is a statistical process control tool for monitoring process variation. It consists of the Upper Control Limit (UCL), Lower Control Limit (LCL), and Central Line (CL). The CL is the center of the control chart and usually represents the average or expected value of the process. The UCL is the highest control limit on the control chart and is usually set to 3 times the standard deviation above the central line, and the LCL is the lowest control limit on the control chart and is usually set to 3 times the standard deviation below the central line. In a Shewhart control chart, if the data points fall within the control limits and are not trending, this usually means that the process is stable. If the data points fall outside the control limits, this indicates that there is systematic variation in the process that needs to be investigated and improvement measures taken. Koetsier et al. (2012) argue that there is room for improvement in the Shewhart control charts used in the published study, and following stricter methodological standards would reduce erroneous judgments about the monitored process.

Neuburger et al. (2017) mentioned that clinical effects are often measured by binary counting indicators, for example, whether care meet specific criteria or mortality. The study compared four control charts based on binary data: Shewhart’s p-chart, Exponentially Weighted Moving Average (EWMA) chart, Cumulative Sum (CUSUM) chart and the g-chart. They concluded that Shewhart’s p-chart was the most convenient control chart to implement and interpret process quality control, and it performed well in detecting large changes, which might be useful for monitoring the nursing process. Shewhart’s p-chart uses a 3-sigma control limit

where sigma is the standard deviation of the data. When the rule (a point is outside the 3σ limit; 2 out of consecutive 3 points is outside the 2-sigma limit; when 8 consecutive points are always above or below the baseline) appears, it is usually thought that there is a systematic bias, i.e. the process needs improving. Schmidtke et al. (2017) believed that it's a wrong opinion that the Shewhart's p chart data cannot be used if it is not normally distributed. The use of control charts is largely unaffected by the distribution of data. When a process over a period of time is measured, it is often not known whether the process is stable enough, and control charts can help determine whether it is stable or not (Schmidtke et al., 2017).

Van Schie et al. (2020) collected data from 86,468 cases of total hip arthroplasty (THA) and 73,077 cases of total knee arthroplasty (TKA) between 2014 and 2016, and used Shewhart's p-chart (with 2-sigma and 3-sigma control limits) and cumulative sum (CUSUM) chart (with 3.5-sigma control limits and 5-sigma control limits) to detect variation in repair rates. An abnormal signal is generated when the variation reaches the control chart control limits. Shewhart's p-chart and CUSUM chart are both statistical process control (Statistical process control, SPC) charts, both of which can be used to draw the process quality characteristic value over time. In the study, it is concluded that using a CUSUM chart with a 5-control limit) to monitor variation in repair rates could detect their deterioration earlier, allowing doctors and nurses to improve nursing earlier. The study suggested that SPC chart should be incorporated into variant detection as additional hospital feedback so as to provide early warning when repair rates deteriorate and provide hospitals with an opportunity to introduce quality improvement measures earlier to improve patient care.

Xiao et al. (2020) noted that the American Association of Physics in Medicine recommended applying statistical process control (SPC) to patient-specific quality assurance (patient -specific quality assurance, (PSQA) program in IMRT (intensity-modulated radiotherapy)/VMAT (volumetric modulated arc therapy). However, there is currently a lack of research on non-normally distributed PSQA process. The existing research focus on SPC and process capability analysis (PCA) methods for non-normally distributed IMRT/VMAT PSQA process. This study used the Anderson--Darling statistic to test for normality. Control charts for each PSQA process were obtained by using three non-normal distribution-based methods and these methods were compared with the traditional Shewhart method. The capability of each PSQA process within specification limits was measured by using the Process Capability Indices. This study shows that for the non-normally distributed VMAT PSQA process, traditional SPC and PCA methods increase the false alarm rate and overestimate the process capability. On the contrary, non-normal distribution based SPC and PCA are more reliable and accurate in non-

normally distributed PSQA process. They argued that PCA can be used to measure the potential and performance of a process when it is under statistical control.

Altuntas et al. (2020) proposed a patient satisfaction monitoring method based on statistical process control charts and SERVQUAL (Service Quality) scales. The purpose of the study is to continuously improve patient satisfaction and reduce patient dissatisfaction by monitoring and controlling the quality of medical services. Specifically, this study used the SERVQUAL scale to measure and evaluate the quality of medical services. Firstly, data on patient satisfaction with medical services was collected through a questionnaire survey, and the questions in the questionnaire were designed based on the dimensions and sub items of the SERVQUAL scale. The SERVQUAL scale is a 5-point Likert-type scale. It includes the following 5 dimensions:

Dimension 1: Tangibles (tangible facilities): including whether there are updated equipment, and whether the environment is clean.

Dimension 2: Reliability: including whether the service is provided as promised and whether the patient's problems can be solved.

Dimension 3: Responsiveness: including whether to inform the service time and actively respond to patient requests.

Dimension 4: Assurance: including whether employees are trustworthy and polite.

Dimension 5: Empathy: including whether personal attention is given and whether the patient's needs are understood.

The above dimensions contain different sub items to measure patient satisfaction with medical services, and patients need to rate each of the sub items. The score of each SERVQUAL dimension is calculated after the questionnaire is collected. Then the scores are converted into binary data of conforming/non-conforming (attribute data), with 0 indicating conformity and 1 indicating non-conformity. Standardized u control chart is used to control and monitor the process of attribute data. Furthermore, the mean and standard deviation of the data in each SERVQUAL dimension is calculated to plot the control limits of the u control chart. If the points in the control chart exceed the control limit, there is a problem with the quality of medical services, and patients have a high level of satisfaction in this dimension. Therefore, the results of the SERVQUAL scale make it easier to find out how to improve the medical services. Finally, through quality tools such as Pareto diagram and fishbone diagram, the main causes of quality issues in medical services can be further analyzed to take proper improvement measures. It should be noted that the statistical process control chart used in this study is a standardized u chart. This is because standardized u chart has stable control limits. In the study of Altuntas et al. (2020), the survey questionnaire was not distributed on the same day, and the sample size

varied, which may make it difficult to obtain enough subgroups to accurately estimate the control limit. Therefore, standardized u chart is needed. Standardized u chart is suitable for quantitative measurement, but satisfaction is difficult to quantify. However, it is possible to use standardized u chart to measure satisfaction when satisfaction is converted into a numerical scale of 1-5 levels. This study demonstrated the effectiveness of chart through empirical research on two cases. The results indicate that this chart can be easily and effectively used in practice. Overall, this study provides a practical method for monitoring and reducing patient dissatisfaction in hospital services, which helps to improve the overall service quality of hospitals.

Chang et al. (2016) used multilevel control chart and Fuzzy Set Theory to monitor falls in hospitalized patients. The multilevel control chart is a process control chart that adds severity information to the u control chart and is used to monitor events of different severity levels. The monitoring methods can be summarized as follows:

Firstly, establish a multilevel control chart. Collect process data and calculate the quantity distribution of events of different severity levels. Calculate the upper and lower control limits of the multilevel control chart based on the quantity distribution. Draw a multilevel control chart to monitor processes of different severity levels.

Secondly, use Fuzzy Set Theory to analyze the severity level. Divide the severity into fuzzy levels, such as mild, moderate, and severe. Use Fuzzy Set Theory to describe the fuzzy relationships between events of different severity levels. Determine the severity status of the process based on fuzzy relationships.

Finally, integrate the multilevel control chart and fuzzy analysis results. Combine the monitoring results of the multilevel control chart with the severity judgment of fuzzy analysis. Analyze the status of the process to make more comprehensive process control decisions.

This study applied this monitoring method to analyze fall events related abnormal events in the Taiwan Patient Safety Reporting System from 2011 to 2014, and validated the effectiveness of the proposed method. The application of the multilevel control chart and Fuzzy Set Theory has improved the monitoring of the incidence and severity of fall events, which helps to identify problems in a timely manner and take measures to make improvements. Traditional u control charts only focus on the quantity of process outputs, without considering the severity of the outputs. The multilevel control chart has included a severity dimension, which can distinguish events of different severity levels.

From the literature on medical quality process control mentioned above, it can be concluded that SPC technology can not only be used in manufacturing, but also be applied in the healthcare

field, especially in monitoring the quality of treatment processes and patient satisfaction. SPC technology can help healthcare providers evaluate the quality of treatment processes and determine whether the processes meet the specified specifications limitations. This is crucial for ensuring patient safety and quality of life. SPC emphasizes that it is important to select appropriate control charts and implement them correctly, including setting control limits, making detection rules for special cause variations, and determining the number of data points. There may be problems when using the traditional SPC method to deal with non-normal distribution data, so the SPC and PCA methods based on non-normal distribution have been proposed, which provides a new perspective for medical quality control. Overall, the literature mentioned above provide rich theoretical and practical experience in the application of statistical process control, evaluation of process capabilities, and monitoring of service quality. And these studies provide practical methods and techniques for improving medical quality, which helps to enhance the overall service quality of hospitals. Meanwhile, the studies also point out potential issues and challenges in the application of SPC and other quality improvement tools, such as heterogeneity of data distribution and implementation of control charts, which provides direction for future research and practice.

2.4.3 Other quality management methods

Except for the Six Sigma method, other quality methods have also been used for medical process improvement. Luttman et al. (1995) mentioned that implementing clinical pathway was the best choice for providers of medical service to strengthen the planning and management of patient care. This study used the Program Evaluation and Review Technique/Critical Path Method (PERT/CPM) as a potentially valuable complement to clinical pathway and showed how medical teams can use PERT/CPM to improve the timeliness of heart surgery. PERT/CPM is one of the seven quality planning and management tools. In the 1950s, PERT and CPM were widely used in the industries with complex process to achieve reasonable process planning and management. Since PERT and CPM are very similar, they are together referred to as the PERT/CPM tool. The study suggests that the PERT/CPM tool is likely to improve the development process of clinical pathway in the field of medical services in two ways. First, PERT/CPM can enhance people's understanding of the relationship among activities in the nursing process, and deepen people's understanding of the impact of these relationships on hospital costs and LOS. Luttman et al. (1995) illustrated the steps for using PERT/CPM to develop the best clinical pathway. First, constructing network flow diagram, in which a node represents an activity or outcome, and the sequence of activities is indicated by arrows between

nodes. Then, determining activity time. Calculating the activity time on the entire pathway and determining the clinical pathways. Finally, monitoring and conducting variance analysis on the clinical pathways of the clinical pathway. Activities here include the identification of caregiver activities and the identification of patient activities. Caregiver activities cover not only doctors, nurses, therapists, but also laboratories, radiology departments, operating rooms, or any other department that provides testing and treatment services. Patient activities are often difficult to predict or control. The inclusion of patient activities in PERT/CPM analysis is not to optimize these activities, but to provide sufficient information to optimize other processes around these activities. In short, there is a high chance that PERT/CPM can improve the process of medical care, especially in optimizing the efficiency of hospitalization for common diseases (Lanska, 1998).

Tilley et al. (1997) used TQI (Total Quality Improvement) to examine hospital procedures and reduce emergency admission time. The theoretical assumption of this approach is that a highly variable process will result in additional steps and extra time and may even lead to waste or rework. With patients suspected of acute stroke as a case study object, the Critical To Quality (CTQ) was set as the time from patients' admission to the Emergency Department because of suspected acute stroke to the start of intravenous medication. The study suggested that the application of TQI is helpful in identifying and solving many process problems related to the treatment implementation of Emergency Department, but the process improved by the TQI method needs to be constantly reviewed in the future.

Jiang et al.(2021) believed that after implementing the quality improvement tool PDCA (Plan-Do-Check-Action) for nursing work, practical plans and measures can be formulated to achieve standardized management combined with the 5S management method. The application of PDCA to clinical nursing work can not only conduct quantitative evaluation of all aspects of the work, but also analyze the existing deficiencies and propose reasonable solutions, which is conducive to standardizing nursing operations and improving the work efficiency of nursing staff. PDCA is a well-known improvement tool in the field of quality management, also known as Deming circle or PDCA cycle. PDCA first processes and confirms the results of the Check part, promotes and applies the effective results, analyzes the reasons for the failed results and puts them into the next PDCA cycle for improvement. Through cycles and controls, PDCA becomes reliable and can achieve the purpose of continuous quality improvement (Chen, 2017).

In general, the application of quality management methods in improving the quality of medical service process has received great attention. Techniques such as Six Sigma theory and method, process capability indices, statistical process control have been applied in different

fields of medical service. Due to the differences in economic status, policy support, medical service business, and medical resources among medical service institutions, different medical institutions have different concerns and achievements in improving the quality of medical services. Therefore, to play its role, the quality improvement method needs to be analyzed according to the specific conditions of medical institutions. The existing literature has extensively and deeply studied the DRG payment methods, the role of clinical pathways, and the improvement of medical service quality, which has effectively promoted the development of related academic fields. However, there are few research on the new DRG-based payment system (i.e. DSP-CTB) and the clinical pathway management under this payment system, domestic or foreign. Considering that the system is starting to be implemented in the southwest China, policy-making departments, medical insurance institutions, pilot hospitals and other stakeholders are paying attention to its implementation effect and various impacts. Therefore, the research questions of this study have important academic value and policy guiding significance.

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Chapter 3: Research Methods

3.1 Research objects

Chengdu Medical Security Bureau required designated medical institutions in the city to begin implementing the reform of the DSP-CTB payment system on July 1, 2020 (Chengdu Medical Insurance Office (2020), covering the hospitalization expenses incurred by Chengdu's basic medical insurance insured personnel in the city's designated medical institutions, as well as the payment of the basic medical insurance pooling fund. This reform excludes the expenses incurred by designated medical institutions such as chronic disease and geriatric specialized hospitals, psychiatric specialized hospitals, and nursing homes that involve payments by days in the bed. It adopts flat-rate payment according to the disease type and excludes expenses paid on a per-person basis, and per-bed-day basis, as well as the medical institutions causing changes to the total fund pool by new additions, termination and rescission of agreements, and adjustments to the level of fees within the year. The municipal medical insurance management agency releases the current year's disease group in the first quarter of each year and dynamically adjusts the disease group in the following year based on the changes in the disease spectrum and the development of medical technology in the previous year.

K Hospital, listed as a designated medical institution for medical insurance in Chengdu, is a comprehensive public tertiary grade A hospital that integrates medical treatment, prevention, healthcare, scientific research, and teaching, with respiratory medicine, cardiovascular medicine, gynecology and obstetrics as key specialties at the municipal level, and its ophthalmology department as the Chengdu Ophthalmology Center. Before the reform of the DSP-CTB payment system, K Hospital adopted a medical insurance policy that charges fees for treatment items, opened new departments, expanded the number of beds, and upgraded medical equipment so as to improve competitiveness in the medical service market. The revenue from diagnosis and treatment items was taken as an important hospital management indicator to optimize costs and improve performance. However, the implementation of the reform has changed the payment target of medical insurance from diagnosis and treatment items to disease groups and fixed the total amount of the medical insurance fund pool. Such transformations make it difficult for K Hospital cope with the new payment system. This is

because if the medical institutions in the same pool increase the value of medical services in the group by expanding the size of admissions, and the total amount of the pool remains unchanged, the payment amount represented by the unit value of the group will depreciate, i.e., a decrease in capital efficiency.

According to the financial data from 2018 to 2021 provided by the financial department of K Hospital (Figure 3.1), the hospital's revenue savings from 2018 to 2019 respectively reached 325,000 yuan and 418,000 yuan. In 2020, the hospital had a revenue loss of 683,000 yuan, with the DSP-CTB medical insurance payment and settlement loss accounting for 33.1%, and a year-end special financial subsidy of 117,000 yuan provided by the medical insurance management agency. In 2021, the hospital suffered a loss of 652,000 yuan in revenue, with the DSP-CTB medical insurance payment and settlement loss accounting for 28.8% and a year-end special financial subsidy of 340,000 yuan. It is noted that without the year-end financial special subsidy from the medical insurance management agency, K Hospital would have faced a negative settlement in terms of the DSP-CTB payment.

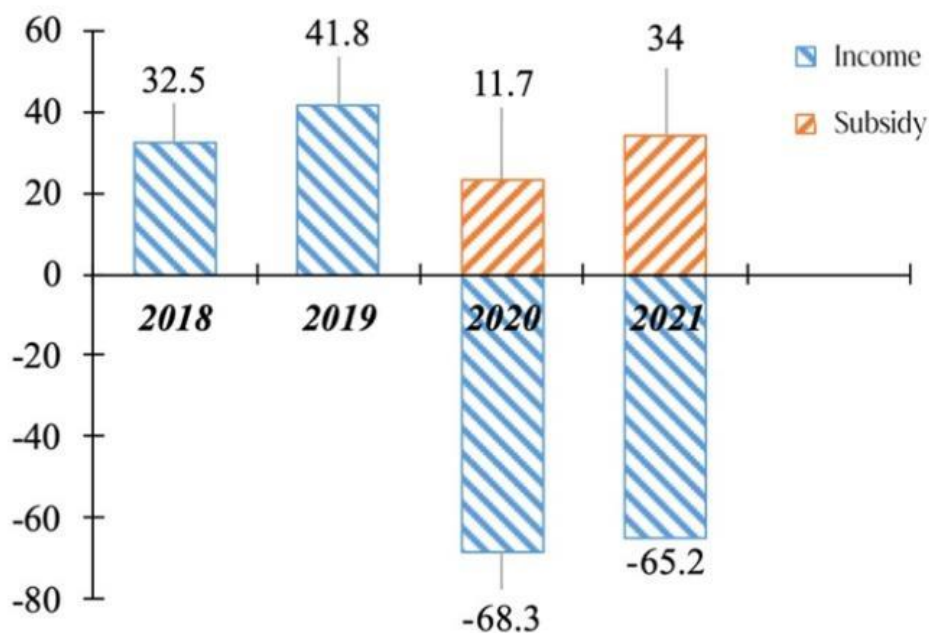


Figure 3.1 Revenue and Subsidy Status of K Hospital, 2018-2021 (in million yuan)

Given the payment rules of the DSP-CTB system, the hospital bears self-responsibility for profits and losses when facing a negative payment state. Therefore, K Hospital needs to explore a hospital management method suitable for the DSP-CTB payment system so as to achieve the original intention of reforming the medical insurance payment system with cost control and quality assurance.

Considering the negative payment state under the implementation of the DSP-CTB payment system in K Hospital, the author selected the data of patients with cataracts, adult pneumonia, acute cardiovascular infarction, and cesarean section diseases in provincial and municipal key departments mentioned above (i.e., ophthalmology, respiratory medicine, cardiovascular medicine, and obstetrics and gynecology) in K Hospital. The requirements of this study are fulfilled thanks to the massive and representative patients with such diseases annually seeking treatment, the most complete records on the Front Sheet data of the relevant cases, and the implementation of clinical pathway management as of 2018.

3.2 Data collection

The data to be analyzed is the Front Sheet data of inpatient cases in K Hospital with cataracts, adult pneumonia, acute myocardial infarction, and cesarean section included in the clinical pathway management from January 2018 to December 2021. Case data that exited the pathway due to clinical variations, as well as missing values or logical errors in the Front Sheet data, have been excluded. Finally, 9,056 sample data have been retained.

Considering that K Hospital became a DSP-CTB payment system reform pilot in July 2020, this study divided 9,053 cases of data into two categories based on the time of the reform: data during the period when the DSP-CTB payment system reform was not implemented (2018.01-2020.6) and data during the period when the DSP-CTB payment system reform was implemented (2020.07-2021.12). The chi-square test indicated that there was no significant difference between the two types of data before and after the implementation of the DSP-CTB system reform ($P\text{-value}>0.05$), and hence the data are comparable, as shown in Table 3.1.

Table 3.1 Classification of sample data ($n=9056$)

Diseases	Without Implementing the DSP-CTB system (2018.01-2020.06) n=4608	Implementing the DSP-CTB system (2020.07-2021.12) n=4448	χ^2	P- value
Adult Pneumonia	3257	3086	7.275	0.064
Acute Myocardial Infarction	422	455		
Cesarean Section	457	404		
Cataracts	472	503		

In Table 3.1, the author noted that the sample size for adult pneumonia is very large, and the sample size for the rest of diseases is also more than 400 cases. Due to these large sample sizes, the degrees of freedom are also considerable, making even minor deviations from normality statistically significant and potentially influencing the interpretation of results.

Therefore, to reduce the effect of this, a normality test is performed first. If the data deviates significantly from the normal distribution, a nonparametric test will be chosen. Nonparametric tests do not rely too much on the distribution assumptions of the data, so they are less sensitive to changes in sample size and can mitigate the impact of large sample sizes to a certain extent. In addition, when interpreting statistical results, considering the statistical problems that may result from large sample sizes, the results will be comprehensively interpreted in combination with clinical expertise and actual conditions, so as to avoid directly equating statistical significance with practical significance. The subsequent section provides a more comprehensive description of the statistical methods employed in the study.

3.3 Statistical analysis methods

Firstly, in this study, the sample data during the period of non-implementation of the DSP-CTB system is used as the control group, and the sample data during the implementation of the DSP-CTB system is used as the experimental group. A retrospective method is adopted to analyze the length of hospital stay, recovery rate, improvement rate of patients and hospitalization expenses under the clinical pathway before and after the reform of the DSP-CTB payment system, to understand the effects of the DSP-CTB payment system combined with the clinical pathway. Secondly, the influencing factors of hospitalization costs were further analyzed for the poor combination effect. Univariate correlation analysis was used to find the factors that had a significant impact on hospitalization costs ($P\text{-value} < 0.05$). These factors were used as independent variables to construct a multiple linear regression model divided by DSP-CTB disease group, so as to observe whether there were differences in the influencing factors of different disease groups, so as to point out the direction for the subsequent formulation of clinical pathway management countermeasures for DSP-CTB disease group.

Statistical analysis was conducted by using SPSS 22.0 software, and the research methods required are further described as follows:

(1) T-test is a parametric that allows the comparison of 2 population means, assuming that the 2 populations follow a normal distribution, or the sample dimensions are big (bigger than 30 for each group).

(2) ANOVA is a parametric that allows the comparison of more than 2 population means, assuming that all populations follow a normal distribution or the sample dimensions are big (bigger than 30 for each group) and that population variances are equal.

(3) To compare populations not normally distributed when sample sizes smaller than 30,

non-parametric tests should be applied: Mann-Whitney test to compare 2 population distributions, Kruskal-Wallis test to compare more than 2 population distributions.

(4) To decide if a population follows a normal (Gauss) distribution non-parametric Kolmogorov-Smirnov (or Shapiro-Wilk if samples are smaller than 50) test are used.

(5) Pearson correlation coefficient will be calculated to identify the level of linear association between two variables (quantitative or metric); before computing the Pearson's correlation coefficient, four assumptions must be validated:

A. Both variables are metric or numeric measured at the interval level or ratio level;

B. The relationship between two variables should be linear (use the scatterplot to find out if there is a linear relation);

C. Severe outliers should not be present;

D. The variables should follow a normal distribution (or approximately normal distribution), or sample dimension are big ($n > 30$). When sample dimensions are high, even if the populations are not normal, parametric tests such as t-test or ANOVA can still be applied, because these tests are robust and have higher power than alternative non-parametric tests (Mann-Whitney and Kruskal-Wallis, respectively).

(6) When variables are ordinal, to measure linear association Spearman correlation coefficient should be applied. While Pearson's coefficient measures the strength of the linear association between two metric normal variables, Spearman's coefficient, measures the degree of monotonicity between two ordinal or numeric variables. If an increasing or decreasing but nonlinear relationship is suspected, Spearman's is an alternative to the Pearson's coefficient when its assumptions aren't validated, Spearman's correlation is more appropriate to be used and it is robust to outliers. It is a nonparametric method that converts the data to ranks maintaining the paired ranks.

(7) To identify the association between 2 qualitative (nominal) variables apply the Chi-square statistic or Cramer's V coefficient which measures the association between two nominal variables and its values range between 0 and +1 (inclusive). The Chi-square test for independence of the 2 variables is based on the chi-square statistic and tests the deviation between the observed cells and the expected cells if the variables were independent.

(8) A multiple linear regression analysis is carried out to predict the values of a dependent variable Y, given a set of p explanatory variables $X_1, X_2, \dots, X_p$. The existence of a dependent variable in a regression model implies a causal relationship between different variables, which can be properly described by the following mathematical equation:

$$Y = \beta_0 + \beta_1 X_1 + \beta_2 X_2 + \dots + \beta_i X_i + \dots + \beta_p X_p + \varepsilon$$

Coefficients $\beta_1, \beta_2, \dots, \beta_p$ are known as the regression coefficients and ε represents the model errors or residuals. β_0 is the intercept and corresponds to the value of Y when $X_i = 0$. The unstandardized regression coefficients estimates show the contribution of each independent variable to explain the dependent variable when the effects of the other variables in the model are controlled.

A residual is a deviation of an observed Y score from its estimated value from the equation line. Residuals are conceived as measures of the error component. When a regression model is estimated, reality is simplified, so the random error includes all the information not included in the model by absent independent variables. But when human relationships are modelled there are changes in attitudes, values, beliefs, and behaviors which are impossible to predict. Then, the random error will include the changes of individual's unpredicted changes. Finally, random error can also be the result of measuring error. Residuals can then be used as a basis for several statistics useful in deciding whether the fit of the regression equation is "good" or "bad", whether the proportion of linear variation of the dependent variable by the linear variation of the independent variables is acceptable.

The model goodness of fit can be measured by the determination coefficient R^2 , which measures the proportion of variation of the dependent variable explained by the variation of the independent variables, or the adjusted determination coefficient. The overall model validity can be tested with ANOVA, which tests that the model has no capacity to explain the dependent variable, or the population $R^2=0$.

The assumptions of the multiple linear regression model are:

- (1) The relationship between the dependent and the independent variables are linear
- (2) The random error follows a normal distribution
- (3) The mean of the random error is zero
- (4) The variance of the random error is constant
- (5) Independence between the random error and the independent variables
- (6) Independence of random errors related to different time periods (if the data is longitudinal, over time)
- (7) No collinearity between independent variables.

When hypothesis (7) is not satisfied, Principal Component Regression (PCR) is used to solve the collinearity effect, to improve the influence of multiple linear regression model on collinearity. PCR is a method that combines Principal Components Analysis (PCA) and

multiple linear regression.

PCR first normalizes the raw independent variable data, and then extracts the principal components using PCA. Principal components are linear combinations of original variables that are unrelated to each other and are ordered by their ability to account for variability in the data. The first few principal components are selected based on the proportion of variability explained (e.g., cumulative variance contribution rate). These principal components can retain most of the information of the original data, but the number is less than the number of original independent variables, thus achieving dimensionality reduction. A new multiple linear regression model was constructed using the selected principal component as the independent variable and the dependent variable remained constant. This model uses principal components to predict dependent variables instead of raw independent variables. Therefore, caution is required when interpreting the model, and information from the original independent variables may need to be combined.

The advantage of PCR is that it can reduce multicollinearity problems and improve the stability and predictive power of the model. However, it is difficult to identify the specific effects of a single independent variable in the model, so a stepwise regression model is used to assist in the explanation.

To evaluate if the data is adequate for the application of principal components analysis, both the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy and the Bartlett's test of sphericity (which tests the overall significance of all correlations in a matrix) can be applied. The recommended cut-off for the KMO statistic is 0.70. The p-value of the Bartlett's test should be below 0.001. In terms of sample size required for reliable principal components, a minimum ratio of 5 observations per item is accepted.

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Chapter 4: Research Results

4.1 Combined effect of the DSP-CTB payment system and clinical pathway

4.1.1 Analysis of hospitalization effects

Firstly, the K-S normality test is conducted on the length of hospital stay for the four diseases. The results are shown in Table 4.1.

Table 4.1 Normal distribution test for the length of hospital stay

Category	Diseases included in clinical pathway management	The length of hospital stay	
		K-S Test	<i>P-value</i>
Control Group (without implementing the DSP-CTB system)	Adult Pneumonia	0.133	0.000
	Acute Myocardial Infarction	0.141	0.000
	Cesarean Section	0.242	0.000
	Cataracts	0.265	0.000
Experimental group (implementing the DSP-CTB system)	Adult Pneumonia	0.140	0.000
	Acute Myocardial Infarction	0.142	0.000
	Cesarean Section	0.241	0.000
	Cataracts	0.366	0.000

From Table 4.1, it can be noted that these case data do not conform to a normal distribution. Therefore, the Mann–Whitney test is used for inter-group comparison, and the analysis is shown in Table 4.2.

Table 4.2 Comparative analysis of the length of hospital stay (in days)

	Control group		Experimental group		Mann-Whitney test	
	Median	(Q25-Q75)	Median	(Q25-Q75)	Z	p-value
Adult pneumonia	13	(10-17)	12	(9-17)	-6.100	0.000
Acute Myocardial Infarction	8	(5-11)	8	(6-12)	1.503	0.220
Cesarean Section	7	(6-8)	6	(6-8)	4.427	0.035
Cataract	5	(3-8)	6	(4-11)	-11.909	0.000

The test results show that there is a significant difference in the length of hospital stay for adult pneumonia, cesarean section, and cataract diseases included in the clinical pathway before and after the implementation of the DSP-CTB payment system reform ($p\text{-value} < 0.05$). The median length of hospital stay for adult pneumonia patients decreases by 7.7%, for cesarean section patients decreases by 14.3%, but for cataract patients increases by 20. The difference in the median length of hospital stays for acute myocardial infarction patients before and after the implementation of the DSP-CTB payment system reform included in the clinical pathway is

not statistically significant ($p\text{-value} > 0.05$). Next, the differences in treatment effects will be compared from the perspectives of recovery rate and improvement rate (Chi-square detection), as shown in Table 4.3.

Table 4.3 Comparative analysis of improvement rate and recovery rate

		Number of cases	Number of cases with improved conditions	Improvement Rate	P- value	Number of recoveries	Recovery rate	P- value
Adult pneumonia	Control group	3257	2377	72.98%	0.364	495	15.20%	0.000
	Experimental group	3086	2440	79.07%		644	20.87%	
Acute Myocardial Infarction	Control Group	422	296	70.14%	0.278	73	17.30%	0.419
	Experimental group	455	323	70.90%		81	25.08%	
Cesarean Section	Control group	457	35	7.66%	0.622	412	90.15%	0.175
	Experimental group	404	31	7.67%		374	92.57%	
Cataract	Control group	472	14	2.97%	0.384	438	92.80%	0.221
	Experimental group	503	19	3.78%		475	94.43%	

Note: Improvement rate = number of cases with improved condition/number of cases $\times 100\%$; Recovery rate = number of recoveries/number of cases $\times 100\%$.

The results in Table 4.3 shows that the recovery rate of adult pneumonia has significantly decreased compared to the rate before the implementation of the DSP-CTB payment system ($p\text{-value} < 0.05$), and the improvement rate has slightly increased. However, the chi-square test shows no significant differences ($p\text{-value} > 0.05$). The improvement and recovery rates of acute myocardial infarction, cesarean section, and cataracts all have improved compared to the rate before the implementation of the DSP-CTB payment system. Still, the chi-square test shows none of the differences are significant ($p\text{-value} > 0.05$).

4.1.2 Analysis of hospitalization expenses

As an important indicator of hospital management and social concern, the hospitalization expenses in this study refer to all expenses incurred during the hospitalization period, including medical service fees, diagnostic fees, surgical treatment fees, rehabilitation fees, medical fees, surgical material fees, and other expenses incurred during the clinical pathway implementation process, which constitutes the total amount of hospitalization expenses. K-S normality test is

conducted on the hospitalization expenses of the four diseases, and the test results are shown in Table 4.4.

Table 4.4 Normal distribution test for hospitalization expenses

Categories	Diseases	Hospitalization expenses	
		K-S Test	P-Value
Control group	Adult Pneumonia	0.215	0.000
	Acute Myocardial Infarction	0.066	0.000
	Cesarean Section	0.085	0.000
	Cataracts	0.324	0.000
Experimental group	Adult Pneumonia	0.204	0.000
	Acute Myocardial Infarction	0.094	0.000
	Cesarean Section	0.161	0.000
	Cataracts	0.323	0.000

The K-S normality test in Table 4.4 shows that hospitalization expenses do not follow the normal distribution, so the Mann-Whitney test is adopted for inter-group comparison. The analysis is shown in Table 4.5.

Table 4.5 Comparative analysis of hospitalization expenses (in yuan)

Diseases	Control group		Experimental group		Mann-Whitney test	
	Median	(Q25-Q75)	Median	(Q25-Q75)	Z	P-value
Adult Pneumonia	12540.41	(9228.49-17869.37)	12104.49	(8228.89-18345.72)	-2.789	0.005
Acute Myocardial Infarction	54492.94	(38121.73-76018.12)	34359.60	(21105.63-50645.26)	-8.804	0.000
Cesarean Section	13872.60	(13825.93-13939.48)	13757.43	(12483.14-15029.62)	-1.599	0.110
Cataracts	7229.92	(7146.58.79-7319.21)	7783.18	(6951.55,8838.13)	10.778	0.000

The data in Table 4.5 indicate that the hospitalization expenses of adult pneumonia and acute myocardial infarction patients are significantly lower than those before the implementation of the DSP-CTB payment system ($p\text{-value} < 0.05$), but the hospitalization expenses of cesarean section patients are not significantly reduced ($p\text{-value} > 0.05$). Compared to the data before the implementation of the DSP-CTB payment system, the hospitalization expenses of cataract patients significantly increased ($p\text{-value} < 0.05$).

Combined with the analysis in Tables 4.2, 4.3 and 4.5, we can answer research question Q1: How well does the DSP-CTB system work with the clinical pathway?: not all disease clinical pathways can be well integrated with the DSP-CTB system. In the previous analysis, acute myocardial infarction only significantly shortened the hospitalization cost, cesarean section only significantly shortened the number of hospital days, especially cataract not only did not significantly improve the recovery rate, but significantly increased the number of

hospital days and hospital costs.

4.2 Influencing factors of hospitalization expenses in DSP-CTB patients under clinical pathway management

It was found in the analysis in section 4.1 that the combination of K Hospital's DSP-CTB payment system and cataract clinical pathway has an unacceptable effect, resulting in a significant increase in hospitalization expenses. Therefore, it is necessary to further conduct analysis of the influencing factors of hospitalization expenses.

4.2.1 Correlation analysis of influencing factors of hospitalization expenses

Under the DSP-CTB payment system, there were 503 cataract patients at K Hospital from July 2020 to December 2021, all of whom required clinical surgery. According to ICD-10 diagnosis, they were divided into three types: cataract, complicated cataract, and senile cataract. According to the DSP-CTB disease group code, these three diseases are classified into CB38 disease group, CB29 disease group, and CB39 disease group, as shown in Table 4.6.

Table 4.6 DSP-CTB grouping of cataract cases

Disease group code	ICD-10 diagnosis	Number of cases
CB38	Senile cataract	311
CB29	Complicated cataract	83
CB39	Cataract	109

For easier description, the senile cataracts, complicated cataracts, and cataracts classified into the DSP-CTB disease groups are named as C1, C2, and C3 categories respectively, and the hospitalization expenses of these three categories of cataracts patients are tested for normality. The results indicate that the hospitalization expenses of these three categories of cataract patients (cases) do not follow a normal distribution, as shown in Table 4.7. Therefore, the comparison of hospitalization expenses was conducted by using Kruskal-Wallis test.

Table 4.7 Normal distribution test of hospitalization expenses

Classification by disease group	Hospitalization expenses		
	Category	K-S test	P-value
CB38-senile cataract	C1	0.092	0.035
CB29-complicated cataract	C2	0.104	0.028
CB39-cataract	C3	0.298	0.000

The Kruskal Wallis test results are shown in Table 4.8, indicating that there is a significant difference (p -value < 0.05) among the hospitalization expenses of the three categories of cataract groups, with the median hospitalization expenses of CB29 (complicated cataract) being much higher than those of the other two groups.

Table 4.8 Comparison of hospitalization expenses among different groups

Types	Hospitalization cost/yuan		Kruskal-Wallis test	
	Median	(Q25-Q75)	H-value	<i>P-value</i>
C1	7777.19	(7080.41-12809.35)	145.270	0.000
C2	21231.60	(14909.17-30442.73)		
C3	8011.03	(7083.50-9137.95)		

A correlation analysis on the influencing factors of hospitalization expenses (Y) was also conducted. We consider the diagnosis fees (X1), treatment fees (X2), medical service fees (X3), nursing fees (X4), proportion of consumables (X5), proportion of drug fees (X6), as well as hospitalization days (X7), age (X8), and medical payment method (X9) involved in the clinical pathway before, during, and after surgery as influencing factors of hospitalization expenses. Medical payment methods were correlated using ETA coefficient for categorical variables and Pearson's correlation coefficient for other variables.

Correlation analysis showed that diagnostic costs, surgical costs, medical service costs, treatment costs, nursing costs, the proportion of pharmaceutical expenses, and a number of days in the hospital were highly correlated with hospitalization costs (see Table 4.9).

Table 4.9 Correlation analysis between hospitalization expenses of cataract patients and independent variables

Influencing factors	$\bar{x} \pm s$	Pearson/Eta coefficient	<i>p-value</i>
Diagnosis fees ^a	3080.60±2387.44	0.883	0.000
Treatment fees ^b	2087.00±901.76	0.510	0.000
Medical service fees	186.82±245.35	0.743	0.000
Nursing fees	111.17±144.46	0.726	0.000
Proportion of consumables ^c	0.376±0.105	-0.221	0.000
Proportion of drug fees ^d	0.041±0.050	0.232	0.000
Hospitalization days	5.55±6.42	0.856	0.000
Age	72.88±8.038	-0.051	0.287
Medical payment method	Number of cases (%)		
Provincial social security	78 (15.5%)	0.097	0.115
Urban workers	301 (59.8%)		
Urban and rural residents	39 (7.8%)		
Self-funded medical care	26 (5.2%)		
Out-of-province offsite	59 (11.7%)		

Note: a. diagnosis fees include: pathological diagnosis fees, laboratory diagnosis fees, imaging diagnosis fees, clinical diagnosis project fees; b. Treatment fees include: surgical fees, anesthesia fees, non-surgical treatment project fees, general treatment operation fees; c. Proportion of consumables=(cost of disposable medical materials for examination + cost of disposable medical materials for treatment + cost of disposable medical materials for surgery) /total expenses×100%; d. Proportion of drug fees=(western medicine fees + traditional Chinese patent medicines and simple preparations fees + Chinese herbal medicine fees) /total expenses×100%.

Table 4.9 shows that the proportion of diagnosis cost, operation fee, medical service fee, treatment fee, nursing fee, drug cost and length of hospital stay are highly correlated with hospitalization cost (*p-value* <0.01), while age is not significantly correlated with hospitalization cost (*p-value* >0.05). The Eta correlation coefficient between medical payment

and hospitalization cost is close to 0, indicating that the correlation is also very weak.

Correlation between independent variables was tested and the results were shown in Table 4.10.

Table 4.10 Matrix of Spearman correlation coefficient among independent variables

	Nursing fees	Medical service fees	Treatment fees	Diagnosis fees	Hospitalization days	Proportion of drug fees	Proportion of consumables
Nursing fees	1						
Medical service fees	.942**	1					
Treatment fees	.411**	.411**	1				
Diagnosis fees	.663**	.668**	.418**	1			
Hospitalization days	.982**	.960**	.424**	.667**	1		
Proportion of drug fees	.340**	.370**	.206**	.189**	.344**	1	
Proportion of consumables	-.199*	-.204**	0.024	-.534**	-.187**	-.214**	1

** shows significant correlation at 0.01 level (bilateral).

From Table 4.10, it is possible to conclude that there is a significant correlation between independent variables, indicating that using all independent variables to establish a regression model leads to multicollinearity. Therefore, to reduce the interference of multicollinearity, this study chooses the Principal Component Regression method (PCR, Principal Component Regression) to reduce the effect of multicollinearity and combines it with a stepwise regression model to aid in the interpretation of the independent variables where the dependent variable has a significant effect. By introducing explanatory variables into the regression model one by one and observing the change in goodness of fit (R^2) of the regression model at the same time, whether the introduced variables are independent can be determined. If a significant change in R^2 is caused by the introduction of a new independent variable, it indicates that there is no multicollinearity between the explanatory variable and other variables in the model. If R^2 changes little, it indicates that there is multicollinearity between the independent variables. Besides, by calculating the variance inflation factor (VIF) of independent variables in the regression model, whether there is multicollinearity can be verified. When $VIF > 10$, it shows the existence of multicollinearity among independent variables in the regression model. In the event that multicollinearity arises, the independent variables will be removed, or alternative methods will be applied to get rid of it. It should be noted that in the case of strong covariance, but at the same time it may also increase the bias (Greenland et al., 2016).

4.2.2 Regression analysis of hospitalization costs for C1 patients

4.2.2.1 Principal component regression analysis

Firstly, principal component analysis of the independent variables affecting the hospitalization costs of C1 patients (senile cataract-CB38 disease group) was carried out using SPSS22.0. The Kaiser-Meyer-Olkin metric was 0.867 (p-value <0.01), which indicated that the data of the disease group was suitable for principal component analysis. The two principal components with the largest eigenvalues (eigenvalues >1) were selected, in which the eigenvalues of the first principal components were 5.579 and the eigenvalues of the second principal components were 1.237. The cumulative contribution rate of the two principal components reached 85.198%, which indicates that principal components 1 and 2 contain more than 85% of the information of the original data, as shown in Table 4.11.

Table 4.11 Score Coefficient Matrix

	Principal component 1	Principal component 2
Number of days in hospital	0.196	0.118
Service fees	0.197	0.085
Nursing fees	0.197	0.072
Treatment fees	0.112	0.588
Portion of pharmaceutical expenses	0.169	-0.238
Portion of consumables	-0.101	0.616
Diagnostic fees	0.196	0.118

Secondly, the two factor columns generated in SPSS 22.0 (named F1_C1, F2_C1) were used as independent variables, and the hospitalization cost of patient C1 was used as the dependent variable (Y) to construct a binary linear regression model, and the coefficients of this regression model are shown in Table 4.12.

Table 4.12 Principal Component Regression Model Coefficients

	Unstandardized coefficient		Standardized coefficient	Covariance statistic		
	B	Standard error	Beta	T	Significance	VIF
(Constant)	10599.195	197.005		53.802	0.000	
F1_C1	6886.158	197.323	0.853	34.898	0.000	1.000
F2_C1	2406.801	197.323	0.298	12.197	0.000	1.000

Table 4.12 shows that the estimated principal component regression model does not have multicollinearity. In addition, the model's R² (adjusted) reaches 81.7%, indicating that the model has sufficient explanatory power. Next, the independent variables in the principal component regression model were reduced (X1 to X8), as presented in Table 4.13.

Table 4.13 Principal Component Regression Model Dependent Variable Reduction

Original Independent Variable	(1) F1_C1a × Score Coefficient of 1st Principal Component	(2) F2_C1a × Score Coefficient of 2st Principal Component	(3)= (1)+ (2)	(4) Coeff icient = (3)/St andar d Devi ation	(5)=(4))×mea n values	(6) Inter cept = Con stant a - Σ(5)
Number of days in hospital	1351.352	285.073	163 6.42 5	227.8 60	1442. 625	- 273 0.94 0
Service fees	1357.317	204.859	156 2.17 6	5.759	1235. 821	
Nursing fees	1356.157	173.356	152 9.51 2	9.482	1207. 038	
Treatment fees	770.351	1416.267	218 6.61 8	2.211	4827. 345	
Proportion of pharmaceutical expenses	1166.593	-571.843	594. 750	1104 4.776	480.3 37	
Proportion of consumables	-693.611	1481.709	788. 098	7534. 899	2848. 945	
Diagnostic fees	1278.821	-230.348	104 8.47 2	0.399	1288. 022	

a: The coefficient of the F1_C1 in Table 4.12 = 6886.158, the coefficient of the F2_C1 pair = 2406.801, and the constant = 10599.195

b: the standard deviation of the original independent variable;

c: the mean of the original independent variable.

Finally, based on the coefficients in Table 4.13, the reduced regression equation can be presented in equation (4.1).

$$Y_{C1} = -2730.940 + 0.399X_1 + 2.211X_2 + 5.759X_3 + 9.482X_4 + 7534.899X_5 + 11044.776X_6 + 227.860X_7 \quad (4.1)$$

Where Y_{C1} indicates the hospitalization cost of senile cataract patients in the CB38 disease group, X_1 indicates the diagnostic fee, X_2 indicates the treatment fees X_3 indicates the service fees, X_4 indicates the nursing fees, X_5 indicates the proportion of

consumables, X_6 indicates the proportion of pharmaceutical expenses, and X_7 indicates the number of hospital days.

From equation (4.1), it can be seen that for every unit increase in diagnostic costs, the average increase in hospitalization costs for C1 patients is 0.399 units; for every unit increase in treatment costs, the average increase in hospitalization costs for C1 patients is 2.211 units; for every unit increase in service charge, the average increase in hospitalization costs for C1 patients is 5.759 units; for every unit increase in nursing fee, the average increase in hospitalization costs for C1 patients is 9.482 units; for every 1 unit increase in the proportion of consumables, the average increase in hospitalization costs for C1 patients was 7,534.899 units; for every 1-unit increase in the proportion of pharmaceutical expenses, the average increase in hospitalization costs for C1 patients was 11,044.776 units; for every 1 unit increase in the number of hospital days, the average increase in hospitalization costs for C1 patients was 227.860 units; and vice versa.

4.2.2.2 Stepwise regression analysis

The construction process of the stepwise regression model for hospitalization expenses of C1 (senile cataract-CB38 disease group) patients is shown in Table 4.14. It can be seen that as the independent variables are introduced into the model, the coefficients of the independent variables in Model 4 pass the significance test (p -value < 0.01) and R^2 (adjusted) reaches 86.7%, which indicates that the model has sufficient explanatory power; its autocorrelation $DW=1.98$ meets the autocorrelation test requirements (DW value close to 2 without first-order autocorrelation). In addition, compared with other models, Model 4 had the best effect without multicollinearity, with a variance inflation factor of 4.51 for diagnosis costs, 4.56 variance for days of hospitalization, 1.91 for treatment costs, and 1.76 for consumables.

Table 4.14 Stepwise regression results of the model for C1 group

	Model 1		Model 2		Model 3		Model 4	
	Coefficient	<i>P</i> -value	Coefficient	<i>P</i> -value	Coefficient	<i>P</i> -value	Coefficient	<i>P</i> -value
Constant	4546		3005		-9111		-9302	
Hospitalization days	956.1	0.000	580.6	0.000	449.6	0.000	307.5	0.000
Diagnosis fees			1.213	0.000	2.087	0.000	2.051	0.000
Proportion of consumables					26769	0.000	21207	0.000
Treatment fees							1.516	0.000
Nursing fees								
Medical service fees								
R^2		72.31 %		76.76 %		84.93 %		86.74 %

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	Model 1		Model 2		Model 3		Model 4	
R ² (adjusted)	72.22 %		76.61 %		84.78 %		86.56 %	
	Model 5		Model 6		Model 7			
	Coefficient	P-value	Coefficient	P-value	Coefficient	P-value		
Constant	-9222		-9155		-9156			
Hospitalization days	-252	0.149	-390	0.047	-328	0.105		
Diagnosis fees	1.96	0.000	1.924	0.000	1.903	0.000		
Proportion of consumables	20968	0.000	21145	0.000	21237	0.000		
Surgical fees	1.799	0.000	1.793	0.000	1.815	0.000		
Nursing fees	25.35	0.001	22.12	0.005	19.93	0.014		
Medical service fees			5.98	0.122	4.9	0.218		
R ²	87.21 %		87.31 %		87.37 %			
R ² (adjusted)	87.00 %		87.06 %		87.08 %			

Therefore, the final constructed C1 hospitalization expenses regression model is shown in equation (4.2).

$$Y_{C1} = -9302 + 307.5X_7 + 1.516X_2 + 21207X_5 + 2.051X_1 \quad (4.2)$$

Among them, Y_{C1} represents the hospitalization cost of senile cataract patients in the CB38 disease group, X_7 the hospitalization days, X_1 the diagnosis fees, X_5 the proportion of consumables, X_2 the treatment fees.

According to equation (4.2), the significant factors affecting the hospitalization expenses of C1 patients include hospitalization days, diagnosis fees, proportion of consumables, and treatment fees. With each additional unit of hospitalization days, the average hospitalization cost for C1 patients increases by 307.5 units; with every 1 unit increase in diagnosis fees, the average hospitalization expenses for C1 patients increases by 1.516 units; with every 1 unit increase in the proportion of consumables, the average hospitalization expenses of C1 patients increases by 21207 units; with every 1 unit increase in treatment fees, the average hospitalization expenses for C1 patients increases by 2.051 units; the reverse is also true.

In addition, the above two regression analyses show that the trend of the influence of the independent variable on the dependent variable reflected by the principal component regression model and the stepwise regression model is consistent, and they are not necessarily incompatible. Therefore, the significant influence factors retained in the constructed stepwise regression model can reflect a certain reality, which is explicable.

4.2.3 Regression analysis of hospitalization costs for C2 patients

4.2.3.1 Principal component regression analysis

As mentioned above, principal component analysis was first performed on the independent variables that affect the cost of hospitalization for patients with C2 (Complicated cataract-CB29 disease group). The Kaiser-Meyer-Olkin metric was 0.623 (p -value < 0.01), which did not reach 0.7. This indicates that the data for this disease group was suitable for using principal component analysis. The two principal components with the largest eigenvalues (eigenvalues > 1) were selected, in which the eigenvalues of the first principal component were 5.022 and the eigenvalues of the second principal components were 1.069. The cumulative contribution rate of the two principal components reached 87.014%, which indicates that principal components 1 and 2 contain more than 87% of the information of the original data, as shown in Table 4.15.

Table 4.15 Score Coefficient Matrix

	Principal component 1	Principal component 2
Number of days in hospital	0.195	0.040
Service fees	0.178	0.342
Nursing fees	0.195	-0.050
Treatment fees	0.117	0.376
Portion of pharmaceutical expenses	0.180	-0.121
Portion of consumables	-0.086	0.810
Diagnostic fees	0.195	-0.056

Secondly, the two factor columns generated in SPSS22.0 (named F1_C2, F2_C2) were used as independent variables, and the hospitalization costs of C2 patients were used as the dependent variable (Y) to construct a binary linear regression model, and the coefficients of this regression model are shown in Table 4.16.

Table 4.16 Principal Component Regression Model Coefficients

	Unstandardised Coefficient		Standardized Coefficient	Covariance Statistic		
	B	Standard Error	Beta	T	Significance	VIF
(Constant)	16202.178	759.916		21.321	0.000	
F1_C2	12064.024	764.592	0.871	15.778	0.000	1.000
F2_C2	337.321	764.592	0.024	0.441	0.660	1.000

From Table 4.16, it can be seen that the constructed principal component regression model does not have multicollinearity, but the independent variable F2_C2 is not significant, so the constructed principal component regression model only includes the independent variable F1_C2. In addition, the model's R^2 (adjusted) reaches 75.3%, which indicates that the model has a better explanatory power. Next, the independent variables in the principal component regression model are reduced (X_1 to X_8); see Table 4.17.

Table 4.17 Table of Independent Variable Reductions in Principal Component Regression Models

Original Independent Variable	(1) $F1_C2^a \times \text{Score}$ Coefficient of 1st Principal Component	(2) Coefficient = (1)/Standard Deviation	(3)=(2) $\times$ Mean Value ^c	(6) Intercept = Constant ^a - Σ (3)
Number of days in hospital	2357.260	191.580	1962.524	5538.017
Service fees	2143.385	3.675	1547.411	
Nursing fees	2355.636	7.954	1755.492	
Treatment fees	1406.272	0.960	2492.517	
Proportion of pharmaceutical expenses	2168.574	21363.733	2112.925	
Proportion of consumables	-1042.612	-4884.855	-1720.422	
Diagnostic fees	2348.258	0.518	2513.714	

a: The coefficient of $F1_C2$ in Table 4.16 = 12064.024, the coefficient of $F2_C2$ = 337.321, and the constant = 16202.178;

b: the standard deviation of the original independent variable;

c: the mean of the original independent variable.

Finally, based on the coefficients in Table 4.17, the reduced regression equation can be presented in equation (4.3).

$$Y_{C2} = 5538.017 + 0.518X_1 + 0.960X_2 + 3.675X_3 + 7.954X_4 - 4884.855X_5 + 21363.733X_6 + 191.580X_7 \quad (4.3)$$

Where Y_{C2} denotes hospitalization costs for patients with concurrent cataracts in the CB29 disease group, X_1 indicates diagnostic fees, X_2 indicates treatment fees, X_3 indicates service fees, X_4 indicates nursing fees, X_5 indicates the proportion of consumables, X_6 indicates the proportion of pharmaceutical expenses, and X_7 indicates the number of days in the hospital.

From equation (4.3), it can be seen that for every unit increase in diagnostic costs, the average increase in hospitalization costs for C2 patients is 0.518 units; for every unit increase in treatment fees, the average increase in hospitalization costs for C2 patients is 0.960 units; for every unit increase in the service fees, the average increase in hospitalization costs for C2 patients is 3.675 units; for every unit increase in nursing costs, the average increase in hospitalization costs for C2 patients is 7.954 units; for 1 unit increase in the proportion of consumables, the average decrease in hospitalization costs for C2 patients is 4884.855 units, a situation that contradicts common sense, and it is possible that there are factors not taken into account in this principal component regression model that has a relationship with the proportion of consumables and hospitalization costs, which affects the interpretation of the model. For every 1 unit increase in the proportion of pharmaceutical expenses, the average increase in hospitalization costs for C2 patients was 21,363.733 units; for every 1 unit increase in the number of hospital days, the average increase in hospitalization costs for C2 patients was

191.580 units; and vice versa.

4.2.3.2 Stepwise regression analysis

The process of constructing a stepwise regression model for the hospitalization expenses of C2 (with complicated cataract CB29 disease group) is shown in Table 4.18. The R^2 (adjusted) of Model 3 reached 76.7%, indicating sufficient explanatory power of the model. Its autocorrelation DW=2.08 meets the autocorrelation test requirements. Compared with other models, Model 3 had the best effect without multicollinearity, with a variance inflation factor of 1.21 for diagnosis costs, 3.43 for days of hospitalization, 1.40 for surgical expenses, and 3.21 for the proportion of drug costs.

Table 4.18 Stepwise regression results of the model for C2 group

	Model1		Model2		Model3	
	Coefficient	P-value	Coefficient	P-value	Coefficient	P-value
Constant	6505		5048		1694	
Hospitalization days	946.6	0.000	599	0.000	510	0.000
Proportion of pharmaceutical expenses			50982	0.000	47563	0.006
Treatment fees					1.770	
R^2		70.72%		75.09%		77.59%
R^2 (adjusted)		70.35%		74.46%		76.63%

Therefore, the constructed C2 hospitalization expenses regression model is shown in equation (4.4).

$$Y_{C2} = 1694 + 510X_7 + 47563X_6 + 1.770X_2 \quad (4.4)$$

Among them, Y_{C2} represents the hospitalization expenses of patients with complicated cataract in the CB29 disease group, X_7 represents the hospitalization days, X_6 represents the proportion of pharmaceutical expenses, X_2 represents the treatment fees.

From equation (4.4), we can know that the significant factors affecting the hospitalization expenses of C2 patients are the hospitalization days, proportion of pharmaceutical expenses and treatment fees. With every 1 unit increase in hospitalization days, the average hospitalization expenses for C2 patients increase by 510 units; with every 1 unit increase in proportion of pharmaceutical expenses, the average hospitalization expenses increase by 47563 units; with every 1 unit increase in treatment fees, the average hospitalization expenses increase by 1.770 units; the reverse is also true.

In addition, the above two regression analyses show that the trend of the influence of the independent variable on the dependent variable reflected by the principal component regression model and the stepwise regression model is consistent, and they are not necessarily incompatible. Therefore, the significant influence factors retained in the constructed stepwise

regression model can reflect a certain reality, which is explicable.

4.2.4 Regression analysis of hospitalization costs for C3 patients

4.2.4.1 Principal component regression analysis

Similarly, principal component analysis of the independent variables affecting the cost of hospitalization for C3 patients (cataract-CB39 disease group) was carried out using SPSS 22.0. The Kaiser-Meyer-Olkin metric was 0.635 (p-value <0.01), indicating that the data for this disease group was suitable for using principal component analysis. The two principal components with the largest eigenvalues (eigenvalues >1) were selected, in which the eigenvalues of the first principal components were 3.507 and the eigenvalues of the second principal components were 1.276. The cumulative contribution rate of the two principal components reached 68.327%, which indicates that principal components 1 and 2 contain more than 68% of the information of the original data, as shown in Table 4.19.

Table 4.19 Score Coefficient Matrix

	Principal component 1	Principal component 2
Number of days in hospital	0.223	0.027
Service fees	0.265	-0.149
Nursing fees	0.271	-0.100
Treatment fees	0.203	0.412
Portion of pharmaceutical expenses	0.150	-0.178
Portion of consumables	0.015	0.739
Diagnostic fees	0.166	-0.046

Secondly, the two factor columns generated in SPSS 22.0 (named F1_C3, F2_C3) were used as independent variables, and the hospitalization costs of C3 patients were used as the dependent variable (Y) to construct a binary linear regression model, and the coefficients of this regression model are shown in Table 4.20.

Table 4.20 Principal Component Regression Model Coefficients

	Unstandardized Coefficient		Standardized Coefficient				Covariance Statistic
	B	Standard Error	Beta	T	Significance		VIF
(Constant)	7777.456	161.504		48.157	0.000		
F1_C3	1728.919	162.250	0.651	10.656	0.000		1.000
F2_C3	1124.310	162.250	0.424	6.930	0.000		1.000

From Table 4.20, the constructed principal component regression model does not have multicollinearity. In addition, the model's R² (adjusted) reaches 59.6%, indicating that the model has some explanatory power. Next, the independent variables in the principal component regression model are reduced (X1 to X8), see Table 4.21.

Table 4.21 Principal Component Regression Model Dependent Variable Reduction

Original Independent Variable	(1) F1_C3 ^a × Score Coefficient of 1st Principal Component	(2) F2_C3 ^a × Score Coefficient of 2nd Principal Component	(3)=(1)+(2)	(4) Coefficient = (3)/Standard Deviation	(5)=(4)× Mean Value ^c	(6) Intercept = Constant ^a - Σ (5)
Number of days in hospital	385.140	30.414	415.554	223.089	765.461	-645.408
Service fees	458.553	-167.908	290.645	3.782	436.346	
Nursing fees	469.156	-112.331	356.825	7.802	563.803	
Treatment fees	350.781	463.664	814.445	1.387	2558.061	
Proportion of pharmaceutical expenses	259.800	-199.806	59.994	3552.822	105.933	
Proportion of consumables	26.451	831.372	857.823	8808.953	3264.161	
Diagnostic fees	287.175	-51.340	235.835	0.310	729.099	

Finally, based on the coefficients in Table 4.21, the reduced regression equation can be presented in Equation (4.5).

$$Y_{C3} = -645.408 + 0.310X_1 + 1.387X_2 + 3.782X_3 + 7.802X_4 + 8808.953X_5 + 3552.822X_6 + 223.089X_7 \quad (4.5)$$

Where Y_{C3} denotes the hospitalization cost of cataract patients in the CB39 disease group, X_1 indicates the diagnostic cost, X_2 indicates the treatment cost, X_3 indicates the service cost, X_4 indicates the nursing cost, X_5 indicates the proportion of consumables, X_6 indicates the proportion of pharmaceutical expenses, and X_7 indicates the number of days in the hospital.

From equation (4.5), it can be seen that for every unit increase in diagnostic costs, the average increase in hospitalization costs for C3 patients is 0.310 units; for every unit increase in treatment costs, the average increase in hospitalization costs for C3 patients is 1.387 units; for every unit increase in the service fee, the average increase in hospitalization costs for C3 patients is 3.782 units; for every unit increase in nursing costs, the average increase in hospitalization costs for C3 patients is 7.802 units; for every 1 unit increase in the proportion of consumables, the average increase in hospitalization costs for C3 patients was 8808.953 units; for every 1 unit increase in the proportion of drug costs, the average increase in hospitalization costs for C3 patients was 3552.822 units; for every 1 unit increase in the number of hospital days, the average increase in hospitalization costs for C3 patients was 223.089 units; and vice versa.

4.2.4.2 Stepwise regression analysis

The construction process of the stepwise regression model for hospitalization expenses of C3 patients (cataract-CB39 disease group) is shown in Table 4.22. It can be seen that as the independent variable is introduced into the model, the R^2 (adjusted) of Model 4 reaches 73.39%, indicating that the model has sufficient explanatory power; its autocorrelation DW=1.90 meets the requirements of autocorrelation testing. In addition, compared with other models, Model 4 had the best effect without multicollinearity, with a variance inflation factor of 1.21 for diagnosis cost, 1.45 for days of hospitalization, 1.74 for treatment cost, and 1.28 for consumables.

Table 4.22 Stepwise regression results of the model for C3 group

	Model1		Model2		Model3		Model4	
	Coefficient	P-value	Coefficient	P-value	Coefficient	P-value	Coefficient	P-value
Constant	2375		-341		-2653		-2832	
Treatment fees	2.93	0.000	2.229	0.000	1.602	0.000	1.082	0.000
Diagnosis fees			1.703	0.000	1.885	0.000	1.726	0.000
Proportion of consumables					8212	0.000	9229	0.000
Hospitalization days							330	0.000
R^2		42.00%		63.46%		70.66%		74.37%
R^2 (adjusted)		41.46%		62.77%		69.83%		73.39%

Therefore, the final constructed C3 hospitalization expenses regression model is shown in equation (4.6).

$$Y_{C3} = -2832 + 330X_7 + 1.726X_1 + 9229X_5 + 1.082X_2 \quad (4.6)$$

Among them, Y_{C3} represents the hospitalization expenses of cataract patients in the CB39 disease group, X_7 hospitalization days, X_1 diagnosis fees, X_5 the proportion of consumables, X_2 the treatment fees.

According to equation (4.6), the significant factors affecting the hospitalization expenses of C3 patients include hospitalization days, diagnosis fees, proportion of consumables and treatment fees. With every 1 unit increase in hospitalization days, the average hospitalization expenses for C3 patients increase by 330 units; with every 1 unit increase in diagnosis fees, the average hospitalization expenses for C3 patients increase by 1.726 units; with every 1 unit increase in the proportion of consumables, the average hospitalization expenses for C3 patients increase by 9229 units; with every 1 unit increase in treatment fees, the average hospitalization expenses for C3 patients increase by 1.082 units; the reverse is also true.

In addition, the above two regression analyses show that the trend of the influence of the independent variable on the dependent variable reflected by the principal component regression model and the stepwise regression model is consistent, and they are not necessarily incompatible. Therefore, the significant influence factors retained in the constructed stepwise regression model can reflect a certain reality, which is explicable.

By combining the stepwise regression analysis in sections 4.2.2.2, 4.2.2.3 and 4.2.2.4, we can answer research question Q2: What are the factors that affect the cost of hospitalization in the clinical pathway under the DSP-CTB regime?: there are both common and different factors affecting hospitalization costs in each disease group under the DSP-CTB system. In the previous analysis, hospitalization expenses of cataract patients in C1 and C3 groups are significantly influenced by the same factors, including hospitalization days, diagnosis fees, proportion of consumables and treatment fees; the significant influencing factors for hospitalization expenses of cataract patients in C2 group are hospitalization days, treatment fees and proportion of pharmaceutical expenses. The length of hospital stay and treatment cost are the common factors affecting the hospitalization cost of the clinical pathway in the three cataract groups, while the proportion of consumables, the proportion of drug cost, and the diagnosis cost vary from one disease group to another, and are not significant factors in all cataract groups.

It is worth emphasizing that the diagnosis and treatment links corresponding to these significant influencing factors are the key nodes of clinical pathway management. From the perspective of total quality management, critical nodes refer to those specific steps or links that have a significant impact on process outputs (e.g., product quality, production costs, etc.). These critical points are often the parts of the process that are most prone to problems and have the greatest impact on the outcome. Therefore, to improve the management effect of clinical pathways, it is necessary to focus on the corresponding key nodes identified by the above-mentioned stepwise regression analysis.

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Chapter 5: DMAIC Clinical Pathway Management Model

5.1 Introduction

The influencing factors of expenses (hospitalization expenses) among patient groups are different from the results of the analysis in the previous chapter. Which means that the clinical pathway improvement measures formulated uniformly according to disease types are likely to have different effects under different disease groups. Combined with the current situation of clinical medical management in China, this study believes that it is necessary to establish a clinical pathway management model suitable for the DSP-CTB payment system.

The necessity of a clinical pathway management model for the DSP-CTB payment system is summarized as:

(1) There is a disconnection between the disease-oriented clinical pathway management mode and the cost control requirements of the disease group. In the existing clinical pathway management, pathways are often formulated and implemented according to the type of disease, which lacks a close connection with the cost control of the disease group. Because it is difficult for the heads of departments of each disease to grasp the cost status of the patient group during the implementation of the clinical pathway, it is difficult to detect and prevent the cost excess in time, which may lead to an increase in the risk of systemic loss of control.

(2) The economic consideration of diagnosis and treatment activities in the clinical pathway is insufficient. At present, the economics of diagnosis and treatment activities mainly rely on the experience and intuition of medical experts, and there is no clear set of guidelines oriented to the cost control of disease groups. Healthcare professionals pay more attention to treatment outcomes and less attention to economic rationality when implementing clinical pathways.

(3) When the cost of the patient group is excessive, the improvement activities of the clinical pathway are not systematic. The implementation of improvement measures is often haphazard, and there are no clear criteria to guide the extent and effectiveness of improvements. As a result, improvements are uneven, and it is impossible to define whether they are system-level or case-by-case.

(4) Under the DSP-CTB payment system, the amount of the fund pool will change dynamically every year, and the standard of disease group fee control is not fixed. This requires

clinical pathway management to have a dynamic response mechanism to adapt to this change. However, existing clinical pathway management models often lack this dynamic adjustment ability.

(5) Under the DSP-CTB payment system, the year-end medical insurance payment settlement of the medical insurance management institution can clarify whether the medical institution is losing money. As a result, interventions developed by clinical pathway managers are often post-facto interventions, lacking timeliness and effectiveness. At the same time, this type of intervention may also lead to excessive intervention and increased intervention costs.

This management model needs to have the following characteristics:

(1) It can realize the effective connection between clinical diagnosis and treatment activities and the disease group, and ensure that the implementation of the clinical pathway is consistent with the cost control requirements of the disease group;

(2) The economy of diagnosis and treatment activities should be fully considered, and clear guidelines should be provided to guide the clinical practice of medical staff;

(3) It is necessary to have the ability to dynamically adjust and be able to adjust according to the changes in the fund pool and the changes in the cost control standards of the sick group.

From a management point of view, an effective plan must be accompanied by rigorous implementation process controls to ensure that the goals are achieved. The implementation of a plan is often disturbed by numerous internal and external factors that can cause the plan to deviate from its intended trajectory. As a standardized process of medical services, the clinical pathway provides clear guidance for diagnosis and treatment activities, ensuring the stability of medical quality and the rational use of medical resources. In China, the construction of clinical pathways is based on different diseases, aiming to improve treatment effects and reduce medical costs through standardized treatment plans. However, under the DSP-CTB (Disease Grouping) payment system, diseases are further subdivided into multiple disease groups, each with its own independent cost control indicators. This cost control mechanism poses new challenges to the implementation of clinical pathways. Because the cost of diagnosis and treatment activities is directly limited by the cost control of the disease group, any diagnosis and treatment behavior that exceeds the budget may lead to the cost overrun of the entire disease group. Therefore, on the premise of ensuring the quality of medical services and patient safety, effectively controlling the cost of diagnosis and treatment has become a problem that must be considered when implementing the clinical pathway.

In short, the development of various diagnostic and treatment activities in the clinical pathway needs to consider the impact of the cost control in the DSP-CTB disease groups.

5.2 Construction ideas of the DMAIC clinical pathway management model

Considering that the clinical pathway is essentially a standardized operating process, there is great potential for applying the Six Sigma DMAIC model to reduce the variability of the operating process for clinical pathway management. In this study, statistical process control technology in the field of quality control and the DMAIC (Define-Measure-Analyze-Improve-Control) Process in Six Sigma Management are used to construct a clinical pathway management model with DSP-CTB disease group cost control as the goal orientation, which owns pre-warning and in-event control capabilities, referred to as DMAIC clinical pathway management model. The object of the model is the key node (diagnosis and treatment activity) corresponding to the salient factors identified by the stepwise regression analysis in Chapter 4.

Therefore, the construction of the DMAIC clinical pathway management model is as follows:

Firstly, the clinical pathways being performed under the disease groups are managed in stages according to the DMAIC Process.

(1) In the D (Define) stage, the management goal oriented by DSP-CTB disease group cost control is established;

(2) In the M (Measure) stage, the cost of each diagnosis and treatment activity involved in the clinical pathway is measured, and whether the management goal was reached has to be judged (i.e. identifying key nodes);

(3) In the A (Analyze) stage, the reasons for key nodes that did not meet the management goals are analyzed;

(4) In the I (Improve) stage, countermeasures are developed and improved according to causes;

(5) In the C (Control) stage, the cost and standards of care arising from key nodes (diagnosis and treatment activities) in the clinical pathway are monitored.

Secondly, considering that the cost control goal of the disease groups is not fixed, to reflect the close relationship between the clinical pathway management effect and the cost control, the statistical process control technology is used to monitor the cost incurred during the implementation of the clinical pathway in the disease groups (that is, the corresponding diagnosis and treatment activity cost) (shown in Figure 5.1).

In Figure 5.1, the statistical process control chart can show the deviation between the clinical pathway cost and the new target in real time when the patient group cost control target is adjusted, so as to provide clinical pathway managers with intuitive monitoring of the

implementation status of the plan. Specifically, when a new cost control goal emerges, the statistical process control chart shows the clinical pathway manager how far the clinical pathway cost deviates from the new goal, which reflects the supervision and management of program implementation. The improvement of the diagnostic and treatment activities involved in the clinical pathway can also be presented through statistical process control charts (shown in Figure 5.1), so that the improvement effect can be quantitatively displayed, and the degree of improvement can be answered, and whether to continue to improve or maintain the status quo can be determined.

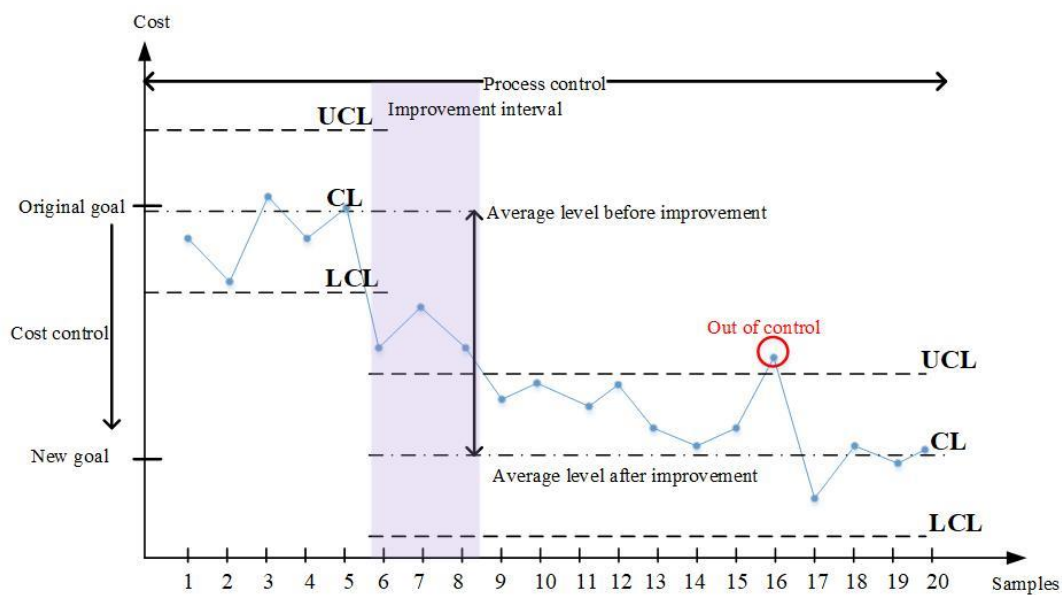


Figure 5.1 Clinical pathway management and control idea with disease group cost control as goal orientation

In addition, the SPC chart can also reflect the optimization effect of clinical pathway diagnosis and treatment activities and show the results of cost control and quality improvement in a quantitative form. By comparing the control limits on the SPC chart with the actual data points, the clinical pathway manager can clearly determine the current status of cost control and quality of care and determine whether further optimization or maintenance is needed. The SPC diagram defines the acceptable mass range by the control limits (UCL upper control limit, CL centerline, LCL lower control limit). When the actual cost data points of the clinical pathway fall within the control limit, it indicates that the process is under control, and the cost control and quality of diagnosis and treatment are in line with expectations, while if the data points are outside the control limit, it means that the process is out of control or there is a systematic deviation, and the cause needs to be further analyzed and corrective actions need to be taken.

It is worth emphasizing, statistical process control technology can monitor the process for a long time in the C (Control) stage, and once it is found that the cost of a case (sample)

implementing the clinical pathway is beyond the control range, it triggers the out-of-control alarm. This means that the risk of systemic out-of-control increases, and the clinical pathway manager needs to immediately carry out cause analysis and improve intervention to avoid the subsequent larger systemic cost exceeding the standard, thus achieving the ability requirements of pre-warning and in-event control.

5.3 Framework for the DMAIC clinical pathway management model

5.3.1 Framework structure

According to the above construction ideas and combined with the characteristics of the DSP-CTB payment system, this section proposes a clinical pathway management model framework for the DSP-CTB payment system, as shown in Figure 5.2.

The framework consists of four parts: the clinical pathway management unit, the DSP-CTB payment and settlement unit, the control process and the control objectives.

(1) Clinical pathway management unit:

Diseases are grouped according to the DSP-CTB payment system.

Monitoring of diagnostic and therapeutic activities during the execution of clinical pathways.

(2) DSP-CTB payment and settlement unit:

According to the DSP-CTB payment system, we will settle insurance premiums with medical institutions.

Set the standard of disease group cost control.

Monitor the expenses of medical institutions.

(3) Control process:

Definition stage: Establish the management objectives oriented to the cost control of DSP-CTB disease group.

Measurement phase: The cost of each diagnosis and treatment activity involved in the clinical pathway is measured.

Analysis phase: Analysis of the clinical pathway causes that did not meet the management objectives.

Improvement stage: We will formulate countermeasures based on the causes and make improvements.

Control phase: monitoring of the costs and treatment norms incurred by diagnostic and

therapeutic activities in the clinical pathway.

(4) Control objectives:

Set goals for cost control and quality assurance.

Respond to Medicare payment constraints.

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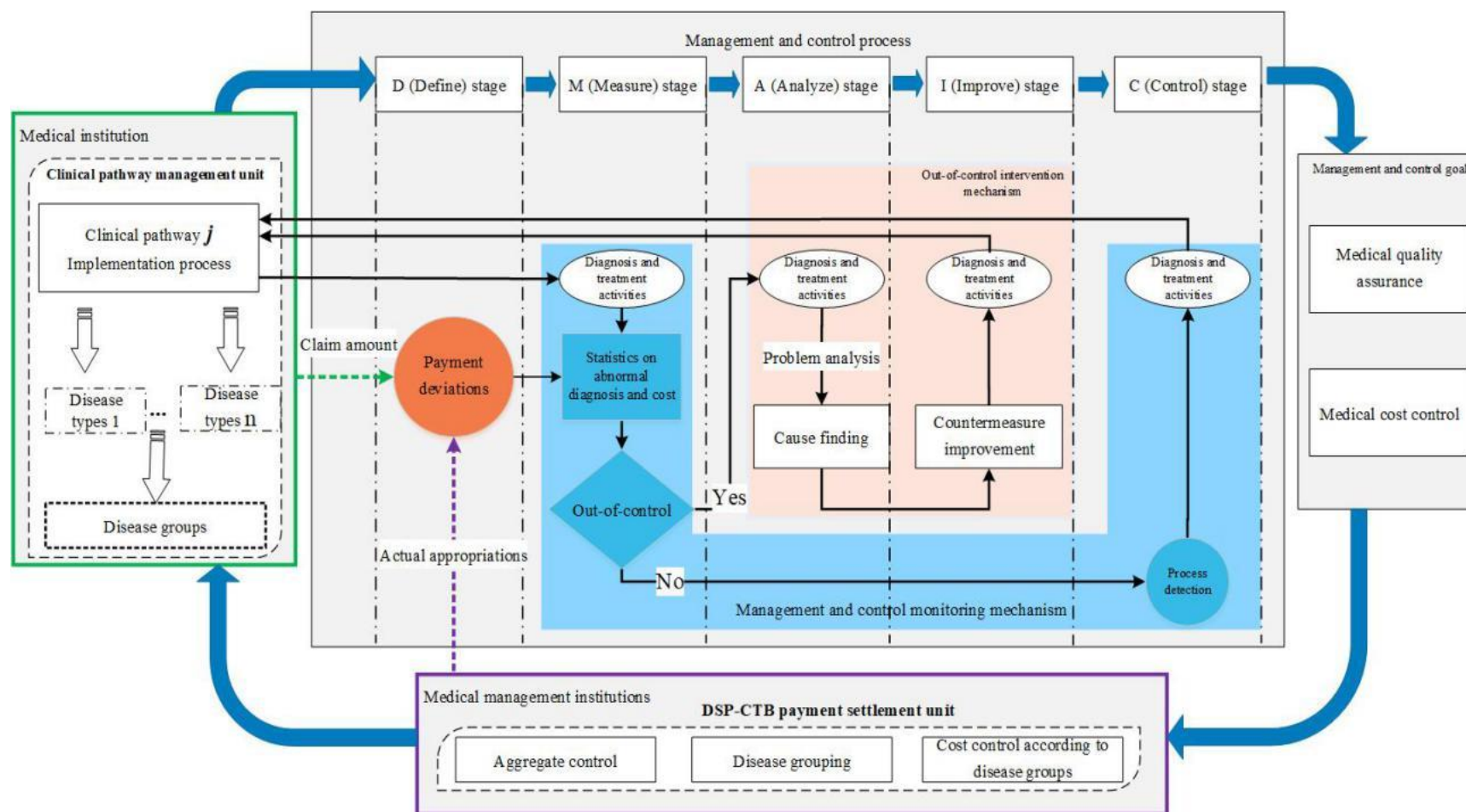


Figure 5.2 DMAIC clinical pathway management model framework for DSP-CTB payment system

The DSP-CTB payment settlement unit is managed by the medical insurance management institutions, which settles insurance premiums with medical institutions according to the DSP-CTB payment system. The clinical pathway management unit is managed by medical institutions, which is responsible for the implementation of the clinical pathway for each disease and the grouping of diseases according to the DSP-CTB payment system. The management and control process adopts the DMAIC Process to monitor the clinical diagnosis and treatment activities of patients in the clinical pathway management unit, and its management and control goal is to ensure that the cost does not exceed the standard and ensure the due medical quality. These four parts of the framework are organically combined to form a feedback control system, which can closely combine the diagnosis and treatment activities of medical institutions and the cost control of medical insurance management institutions with the quality management and control goals. The management and control goal is the original intention of the medical insurance management institution to carry out the DSP-CTB payment system, and the clinical pathway management of medical institutions is an important part of achieving the management and control goal, while the management and control process is an important guarantee to ensure that the clinical pathway management process does not deviate from the cost control and quality management and control goal.

5.3.2 Management and control process of the DMAIC clinical pathway management model

The management and control process of the DMAIC clinical pathway management model consists of five stages (D-define, M-manage, A-analyze, I-improve, C-control) and two mechanisms (management and control monitoring mechanism and out-of-control intervention mechanism). The implementation of the management and control process begins with defining a suitable problem and the goals to be achieved in the D (Define) stage. In this study, cost control in medical institutions under the DSP-CTB payment system can be used as a problem to be defined, and the goal is obviously to control cost while taking into account the quality of care.

However, if the medical cost control is directly defined as the problem to be solved by the DMAIC clinical pathway management model, there will be difficulties in the M (Measure) stage, because it is difficult to convert the medical cost control into a measurable form in the M (Measure) stage. This is because the DSP-CTB payment system does not simply set an upper limit for each medical institution to control the cost of a disease group, and the accounting of the cost of the disease groups requires the same disease group data of all medical institutions of

the same level in the fund pool to be calculated, but the relevant data can often be accurately grasped by the medical insurance management institution. In other words, the disease group cost accounting value of medical institutions cannot be directly used as the critical to quality (CTQ) of medical cost control. Therefore, a more appropriate problem needs to be redefined in order to make the problem measurable.

Considering that the DSP-CTB payment system is a monthly fund prepayment system, that is, monthly pre-allocation, pre-settlement in the following month, and prepayment returned. Every month medical institutions report the inpatient medical cost of the basic medical insurance pooling fund to medical insurance management institutions, and medical insurance management institutions make pre-allocation according to the inpatient medical cost declared by medical institutions. Here a payment deviation will be formed, that is: monthly payment deviation = monthly actual settlement allocation amount - monthly declaration fee of medical institutions.

According to the DSP-CTB settlement rules for disease groups, the score calculation of disease groups should consider the average medical cost of disease groups in the fund pool in the current year, and then determine the adjustment coefficient and the basic score coefficient according to the level of the medical institution itself. The adjustment coefficient and the base score coefficient for each medical institution is specified to fluctuate between 0.95 and 1.05. In the case of ignoring these two coefficients, the medical insurance allocation standard of the same disease group is generally relatively fixed in the same fund pool. Therefore, the monthly amount allocated by medical insurance management institutions to medical institutions is an important basis for controlling costs. If the monthly payment deviation < 0 , it means that the cost of the medical institution exceeds the average medical insurance cost of the same disease group in the fund pool, and if the monthly payment deviation is negative for a long time, it will inevitably lead to the eventual loss of medical institutions. Therefore, it is more appropriate to use the monthly payment deviation as the problem defined in the D (Define) stage, and the payment deviation value as the critical to quality (CTQ) value reduces the difficulty of data acquisition, which can be used to construct a management and control monitoring mechanism based on statistical process control method.

The specific implementation steps of the management and control process are as follows:

Step 0 (involving the D stage and M stage): Define the monthly payment deviation in the D (Define) stage. Every month, medical institutions submit the declaration amount to medical insurance institutions according to the cost incurred by the DSP-CTB disease groups, and the DSP-CTB payment settlement unit allocates medical insurance fees to medical institutions in

accordance with the payment policy formulated by medical insurance management institutions. Then the difference between the declared amount and the actual appropriation amount is calculated, that is, the payment deviation value. In the M (Measure) stage, the payment deviation value is used as the measurement basis.

Step 1 (involving M stage): The cost of diagnosis and treatment activities (the cost of care) during the clinical pathway is measured and compared to the measurement benchmark to determine whether it is abnormal. When the cost of care is abnormal, it will be judged to be unacceptable (out of control), and then it will turn to step 3, otherwise move to step 2.

Step 2 (involving C stage): The clinical pathway diagnosis and treatment activities are monitored, and the diagnosis and treatment activities are carried out according to the clinical pathway standards. Then move to step 1.

Step 3 (involving A stage): The out-of-control problems of clinical pathway diagnosis and treatment activities are analyzed, and the cause is found.

Step 4 (involving I stage): Based on the identified causes, countermeasures to improve clinical pathway diagnosis and treatment activities are developed. Then proceed to step 1.

Among the above steps, steps 1 and 2 constitute the management and control monitoring mechanism of the DMAIC clinical pathway management model for the DSP-CTB payment system (blue area in the management and control process in Figure 5.2), and steps 3 and 4 constitute the out-of-control intervention mechanism of the DMAIC clinical pathway management model for the DSP-CTB payment system (pink area in the management and control process in Figure 5.2). The management and control monitoring mechanism can be operated and implemented by the medical office or medical quality management department of the medical institution, and the out-of-control intervention mechanism can be formed by the relevant departments of the clinical pathway to form a medical service expert improvement team to propose intervention plans for specific problems.

5.3.3 Clinical pathway management and control monitoring mechanism

In order to effectively monitor the clinical pathway process and transform post-event improvement into in-event control, this thesis uses statistical process control theory to establish a clinical pathway management and control monitoring mechanism.

If the actual settlement appropriation amount of the medical insurance management institution in the month of $t-1$ is A_{t-1} and the fees declared by the medical institution are y_{t-1} , then the percentage deviation of the relative monthly payment E can be defined as:

$$E = \frac{A_{t-1} - y_{t-1}}{A_{t-1}} \times 100 \quad (5.1)$$

$E < 0$ indicates a negative payment in the month of $t-1$, and a positive payment on the contrary. The tightness level of the disease group in the t month is determined by the payment status in the month of $t-1$. In other words, the standard of disease group cost control in the t month is set based on the negative payment ratio allowed by the medical institution in the current month. The ratio of the cost overruns of the medical institution to the total overruns ($A_{t-1} - y_{t-1}$) of the medical institution in the month of $t-1$ can be used to estimate the negative payment ratio α allowed by the medical institution in the month of $t-1$. The reason for thinking this way is based on a reasonable assumption that the cost overruns of the disease groups in the next month should not be higher than that of the previous month, otherwise it means that the negative payment situation will be further aggravated, so the disease group cost control standard in the current month needs to be determined based on the cost overruns of the disease groups in the previous month. However, considering the different financial situations and social service capacity of medical institutions at all levels, medical institutions can tighten or relax the ratio every month according to their own circumstances, and the revised ratio can be used as the monthly negative payment ratio allowed by the medical institution.

In addition, a more direct way of thinking is to set a lower bound experience value (such as 5% or 10%) for the payment deviation percentage E , which can be understood as negative payments that do not exceed the lower bound. It means that a negative payment that does not exceed the lower bound is allowed by the medical institution, so the lower bound can be used as α . If the assumption $E < 0$ occurs, the lower bound constraint on the percentage of negative payment deviation can be written as formula (5.2).

$$\alpha \leq E \quad (5.2)$$

Formula (5.3) can be obtained from formula (5.1) and formula (5.2).

$$y_{t-1} \leq A_{t-1}(1-\alpha) \quad (5.3)$$

When the equation in formula (5.3) is established, $A_{t-1}(1-\alpha)$ will be used as the limit standard for monthly cost control of medical institutions. Here it is represented by y'_t , namely:

$$y'_t = A_{t-1}(1-\alpha) \quad (5.4)$$

As mentioned above, formula (5.4) reflects that the disease group cost control standard of the t month is set based on A_{t-1} and the negative payment ratio α allowed by medical institutions in the same month.

If the set of DSP-CTB disease groups (hereinafter referred to as disease groups) in medical institutions is $J = \{1, 2, \dots, m\}$, where m can be used as the total amount of disease groups, then $\frac{y'_t}{m}$ is regarded as the monthly cost control benchmark for each disease group. The daily cost control benchmark is $\frac{y'_t}{mn}$, and $\hat{y} = \frac{y'_t}{mn}$, where n is the number of days per month. In addition, if C_j^r is used to represent the set of patients diagnosed as disease $r \in R$ and classified into the disease group $j \in J$, where R is the set of diseases, then the hospitalization expenses of the patient $k \in C_{ji}^r$ who is subject to clinical pathway management on the day of i can be expressed as y_{ji}^k , where $i \in \{1, 2, \dots, n\}$. When y_{ji}^k exceeds the benchmark $\hat{y}$, the count is performed. Here, ℓ_{ji}^k is used to represent the 0-1 count variable. The expression for ℓ_{ji}^k can be written as formula (5.5).

$$\ell_{ji}^k = \begin{cases} 1 & y_{ji}^k > \hat{y} \\ 0 & y_{ji}^k \leq \hat{y} \end{cases} \quad (5.5)$$

If $\sum_{i \in I} \sum_{k \in C_{ji}^r} \ell_{ji}^k$ is greater, it means that the number of cost excesses in the implementation of the clinical pathway of patients classified under r disease in the j group increases, and the more likely it is that the disease group j exceeds the average level of the fund pool of the same level set up by the medical insurance management institution. In other words, there is a greater risk of loss. If the disease case in the set C_{ji}^r is taken as a sample, and a certain number (or all) of the case samples are selected every day to compare their cost with the cost control standard in disease groups, the daily change of cost deviation can be observed. It is important to note that the number of cases in C_{ji}^r per unit time such as on the day of i may vary, which means that the sample size for comparison is not fixed daily. Therefore, in this thesis, the p control chart, which obeys the binomial distribution statistical assumption, is used to monitor the clinical pathway process, to achieve the dynamic monitoring and in-process control of the hospitalization expenses of patients with clinical pathway management in disease group j .

Daily statistics are made on whether the hospitalization expenses incurred by patients in C_{ji}^r exceed the standard, and the daily excess rate (non-conformity rate) and monthly average over-standard rate of hospitalization expenses of patients in C_{ji}^r are calculated according to

formula (5.6) and formula (5.7).

$$p = \frac{\sum_{k \in C_{ji}^r} \ell_{ji}^k}{|C_{ji}^r|} \quad (5.6)$$

$$\bar{p} = \frac{\sum_{i \in I} \sum_{k \in C_{ji}^r} \ell_{ji}^k}{\sum_{i \in I} |C_{ji}^r|} \quad (5.7)$$

By consulting the SPC control chart, the monthly P-chart control limit can be established, as shown in formula (5.8).

$$\begin{cases} UCL = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{|C_{ji}^r|}} \\ CL = \bar{p} \\ LCL = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{|C_{ji}^r|}} \end{cases} \quad (5.8)$$

In formula (5.8), UCL indicates the upper control limit of the cost incurred by patients with disease r in group j to be included in clinical pathway management; CL represents the center line, and LCL represents the lower control limit of fees incurred by patients with disease r in group j to be included in clinical pathway management. It is worth noting that the excessive cost is the concern of the medical institution managers, so the lower control limit in the P-control chart is very low or even zero, which is obviously a good situation.

There are two states for a P-control chart: under control and out of control. The clinical pathway process can be continuously monitored under control, and the “normal-tight-relaxed” management strategy can be dynamically adjusted. The adjustment rules are shown in Figure 5.3.

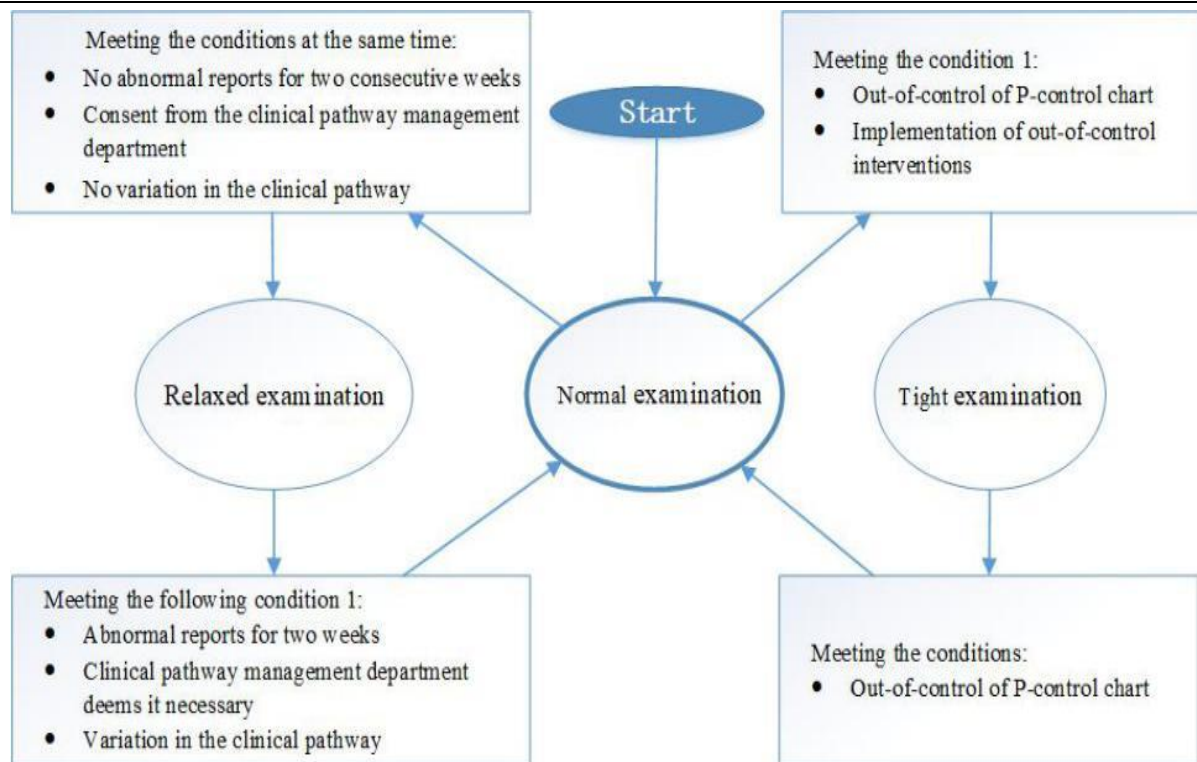


Figure 5.3 “Normal-tight-relaxed” management strategy

In Figure 5.3, the dynamic management strategy, which consists of three states: normal inspection, intensified inspection, and relaxed inspection, can be regarded as a reward and punishment incentive mechanism. Under normal examination, the clinical pathway process meets the preset criteria, indicating that the clinical pathway is well executed. Therefore, it is possible to move to relaxed inspections.

The relaxation of the examination can be regarded as a positive incentive, because it shows that the clinical pathway process does not require additional supervision, the clinical pathway is implemented efficiently, and the cost control of the clinical pathway is good. Relaxation of management status can reduce management costs by reducing the frequency of supervision.

When there is an abnormality in the clinical pathway process, such as the cost is beyond the control range, it will enter the normal examination or even tighten the inspection state. The change from relaxed inspection to normal inspection, and from normal inspection to stricter inspection status are all regarded as punishments, i.e., negative incentives. Because it requires the clinical pathway management department to increase the frequency of monitoring or sample size to monitor the clinical pathway process, find and solve problems more closely. Through stricter management, the clinical pathway implementation department can be prompted to take measures to improve the standardization of clinical pathway implementation and ensure that the cost is controlled within the standard range.

The specific execution logic of the "normal-stricter-relaxed" management policy is

described as follows:

(1) The clinical pathway process management starts with the normal examination, when the P control chart is out of control or the out-of-control intervention is performed, the clinical pathway process management is tightened - the enhanced inspection is performed.

(2) When the P control chart returns to the controlled state, the clinical pathway process management becomes normal examination again. When the conditions of no abnormal report for 2 consecutive weeks are met at the same time, and the clinical pathway management department agrees to relax the examination and the clinical pathway has no variation, the clinical pathway process management is relaxed - the relaxation examination is performed.

(3) During the relaxation period, when there are 2 cases of abnormal situation reported, the clinical pathway management department deems it necessary to switch to normal examination, or the clinical pathway changes during the relaxation examination, the clinical pathway process management will be changed back to normal examination.

The relaxation of inspection here refers to the relaxation of the sample size and frequency of monitoring required for normal inspection, for example, from daily monitoring to monitoring sampling every three days or once a week. Tighter inspection refers to increasing the frequency of monitoring during normal inspections or increasing the sample size of sampling. Of course, the specific setting needs to be flexibly determined in combination with the medical institution's own conditions and relevant management systems. It must be pointed out that the specific setting of the conversion conditions in Figure 5.3 needs to be set according to the medical technical requirements, medical quality level, and strictness of the specifications of the medical institution. For example, one of the conditions for switching from normal inspection to relaxed inspection is that there are no abnormal reports for 2 consecutive weeks. Therefore, it may be more appropriate for a 3A hospital and intensive care ward to set it to 3 consecutive weeks without abnormal reports, and for county-level medical institutions, it may be set to 1-2 weeks due to the limitation of clinical level and medical resources, which is more in line with the actual management.

5.3.4 Intervention mechanism of out-of-control clinical pathway

When the P-control chart triggers a runaway alarm, it means that the patient's cost of diagnosis and treatment activities during the execution of the clinical pathway exceeds the standard (out of control), and the out-of-control problem needs to be intervened. In a schematic diagram of the runaway intervention mechanism, in which when the runaway intervention mechanism is implemented, the influencing factors of the clinical pathway cost should be analyzed for the

diagnosis and treatment activities involved in the sample that triggered the runaway alarm to find out the causes, and some methods that can be used for the analysis of influencing factors include regression analysis, analysis of variance, permutation analysis, fishbone diagram, hypothesis testing, etc. Based on the reasons analyzed, we will formulate measures to improve the diagnosis and treatment activities. Some of the improvement methods that can be adopted include resource scheduling optimization, process reengineering, action improvement, SOP (Standard Operation Procedure) optimization, and rule improvement. Obviously, this needs to be carried out in collaboration with multiple departments such as medical technology, clinical pathway development committee, and hospital quality management department, and it is recommended to form an out-of-control intervention team in order to carry out targeted interventions according to different causes of out-of-control.

Chapter 6: Discussion and Conclusion

6.1 Discussion

This study found that the combination of the DSP-CTB payment system and the clinical pathway has positive significance in improving hospitalization outcomes and reducing hospitalization expenses, but individual diseases have poor performance in these two goals (e.g., cataracts), as shown in Table A.1.

This study reveals significant disparities in the combined effects across different diseases. In this study, the answer to research question 1 (What is the effect of the combination of the DSP-CTB system and the clinical pathway?) is that merely combining disease-based clinical pathway management with payment systems is insufficient. There is a need to revise clinical pathways or establish branch paths around the new payment system. This finding is quite similar to the research conclusion of Li et al. (2021). After analyzing the data on the home page of the medical records of 10,462 inpatients with medical insurance for hematological diseases from January 2016 to December 2019 in a tertiary specialized hospital in Tianjin, these authors found that the expenses of the hospital's 10 departments carrying out clinical pathways have been reduced after the implementation of DRG, but they also exposed the problems that the clinical diagnosis and treatment pathway is not refined and the management model has not kept up with the change of DRG payment methods. However, the study by Li et al. (2021) only mentioned the performance of the combination of DRG payment system and clinical pathway management on hospitalization expenses, and did not consider the treatment effect. Mo et al. (2021) also pointed out that the combination of clinical pathway management and payment methods in China is still poor, and there are problems such as untimely revision of clinical pathways. The same problems will occur when the DSP-CTB payment system is combined with clinical pathway management. Therefore, the discussion on the combination of the DSP-CTB payment system and clinical pathway management and the management model proposed in this study (see Chapter 5) can provide better coping strategies for medical institutions implementing the DSP-CTB payment system to transition to the DRG pilot.

In this study, the answer to research question 2 (What are the factors that affect the cost of hospitalization in the clinical pathway?) is that some of the factors affecting hospitalization

expenses under different DSP-CTB groups were significant in multiple disease groups, such as length of hospitalization and treatment expenses (see Section 4.2). However, some factors have a significant impact on the hospitalization expense of individual disease groups, such as diagnosis expenses and the proportion of consumables (see Section 4.2). This result was also observed in the study of Ye (2020) on influencing factors of hospitalization expenses in groups related to the diagnosis of cerebral infarction disease. Ye analyzed the hospitalization expenses of 2434 patients with cerebral infarction grouped by DRG and found that the length of hospitalization was a common important factor affecting the three groups. Obviously, this means that the clinical pathway under the DSP-CTB payment system is actually the disease pathway, and the factors affecting the expenses and process quality of the disease group pathway need to be controlled. Maliapen and Dangerfield (2010) mentioned that each DRG-based disease group should have its own clinical pathway. Their study showed that the use of an appropriate clinical pathway in the large patient group could significantly reduce medical costs, while the combination of the clinical pathway in the small patient group had no significant effect on expense control. It is necessary to develop corresponding clinical pathway management measures according to the status of the DRG disease group. The compensation system such as DRG is difficult to take into account the major factors that affect the length of hospitalization, so it is necessary to establish a clinical pathway for the DRG disease group to more effectively shorten the length of hospitalization and hospitalization expenses (Collier, 1997). Clinical pathways can both reduce costs and standardize diagnosis and treatment, that is, reduce expenses and ensure quality (Wei et al., 2016).

The length of hospitalization in this study can reflect the efficiency of clinical pathway management. From the perspective of the whole process of the clinical pathway, the fact that the preoperative examination is not carried out in time or the waiting time for the examination report is too long, the resource scheduling of the operating room or the surgeon is unreasonable, the sudden variation occurs during the operation, and the postoperative nursing work is not in place will lead to the increase of hospitalization days. The longer the hospitalization days are, the more likely it is to increase the risk of hospitalization infection. When the hospitalization days increase to a certain extent, the increase in hospitalization expenses will reach the maximum (Ye, 2020). Therefore, the effective management of the whole process of the clinical pathway can reduce the risk of delayed discharge of patients and reduce hospitalization expenses.

The diagnosis expenses are indicative of the performance of the diagnostic activities in the clinical pathway, and the reduction of unnecessary or repetitive diagnostic items in the

diagnostic activities and the development of some lower-cost diagnostic procedures can help reduce the diagnosis expenses.

In terms of treatment costs, clinical pathways generally adopt surgical and anesthesia methods that offer good therapeutic outcomes at a relatively reasonable cost as their execution standards. Therefore, non-surgical treatment items and general treatment operations can be used to reduce treatment expenses, and more economical and effective treatment means can be selected or developed. Of course, the clinical pathway itself can also develop a more cost-effective surgical program according to the individual differences of cataracts patients in different disease groups.

The proportion of consumables reflects the usage of medical materials throughout the implementation of a clinical pathway. Especially in ophthalmology, orthopedics, cardiovascular and cerebrovascular departments, which are highly dependent on medical materials, the expenses of medical materials are often higher than the treatment expenses, which occupy a large proportion in the composition of hospitalization expenses. Therefore, in order to reduce the proportion of consumables, in addition to the provincial collection of medical materials, cross-regional joint procurement and other means, attention should also be paid to the internal management of hospitals to reduce the waste of medical materials, and it is recommended to carry out ABC classification management of consumables and strengthen the management of class A high-value consumables.

Clearly, the effectiveness of clinical pathway management is determined by the efficient identification and control of these influencing factors. In particular, the traditional disease-based clinical pathway management lacks the ability to control the behavior of clinical pathways according to the constraint requirements of the payment system. Given the variance in factors influencing hospitalization costs across different DSP-CTB disease groups, coupled with varying cost control standards of DSP-CTB payment systems for different disease groups, establishing a new clinical pathway management model that aligns with medical insurance payment constraints is essential. Therefore, this study is very helpful for answering question 3 (How can medical institutions better integrate the clinical pathway with the DSP-CTB system?). Compared with the implementation of the original clinical pathway under the DSP-CTB system, the establishment of a clinical pathway management model based on Six Sigma DMAIC for the DSP-CTB system can better integrate the DSP-CTB system with the clinical pathway, to form a comprehensive quality management system for the diagnosis and treatment process of medical institutions for the purpose of cost control and quality assurance.

6.2 Conclusion

In recent years, China has vigorously promoted the reform of the medical insurance payment system, and many cities are exploring the localization strategy of DRG. The DSP-CTB payment system was put forward in this context, and it was piloted in medical institutions in Chengdu, Sichuan Province as an alternative scheme without DRG implementation conditions. The medical management department expects to accumulate practical experience through the DSP-CTB payment system pilot work for the follow-up better docking DRG localization reform. The medical insurance payment system is an economic driving mechanism focusing on expense control, and clinical pathway management can make up for the shortcomings of the DSP-CTB payment system in refined management. If there is no clinical pathway to regulate medical activities, it is easy to over-pursue expense control and lead to undesirable medical behaviors, such as reducing the use of expensive new technologies, case splitting, patient selection, and accepting more non-medical insurance patients (Zhang & Sun, 2021). The clinical pathway management in other countries is an inevitable need for the implementation process of DRG, while China's medical insurance system did not have a system like DRG in the early days. The clinical pathway in China was originally designed to improve the quality of treatment of diseases. Therefore, the role of clinical pathway management in controlling the expenses of DSP-CTB disease groups is limited. Exploring the clinical pathway management for the DSP-CTB payment system will help to better achieve the original intention of the reform of the medical insurance payment system.

This thesis investigates K Hospital in Chengdu, Sichuan, which implemented the pilot DSP-CTB payment system, by selecting four types of inpatient case, the Front Sheet data of cataract, adult pneumonia, acute cardiac infarction, and cesarean section from the representative departments of the hospital that were included in the clinical pathway management.

It is found that the combination of DSP-CTB payment system and clinical pathway management has certain effects, but there are also cases of poor medical cost control and treatment effect. This is the answer to research question 1 of this thesis. Secondly, the influencing factors of hospitalization cost of clinical pathway were different among different disease groups, and some factors were common factors affecting hospitalization costs in multiple groups, and some factors only had an impact on hospitalization costs in individual groups. This answers research question 2. In addition, this study believes that the links corresponding to these influencing factors are an important part of the clinical pathway process, so to control the influencing factors (key nodes) in these different disease groups, it is necessary

to establish a systematic clinical pathway management model. This model can standardize the various diagnosis and treatment activities involved in the patient group pathway, monitor the cost, and intervene in a timely manner, to ensure that the clinical pathway of each DSP-CTB disease group is effectively managed. In this way, the clinical pathway can be better integrated with the DSP-CTB system. This answers question research 3. Focusing on question 3, this thesis proposes a DMAIC clinical pathway management model for the DSP-CTB payment system so as to ensure that hospitals carrying out the pilot of the DSP-CTB payment system can better achieve the original intention of reasonable cost control and simultaneously ensure the quality of patients care.

Furthermore, based on the enlightenment obtained from the previous research results, the following four judgment criteria are summarized for the combination effect of payment system and clinical pathway management, to provide some meaningful decision-making references for those who study the combination effect of payment system and clinical pathway management and hospital quality management.

Criterion 1: When the hospitalization effect is improved and the hospitalization expense is reduced, it can be considered that the original intention of expense control and improvement of medical care quality is satisfied, so the combination of the medical payment system and clinical pathway management is effective.

Criterion 2: When the hospitalization effect remains unchanged and the hospitalization expense decreases, the combination of the medical payment system and clinical pathway management is considered acceptable.

Criterion 3: When the hospitalization effect is improved but the hospitalization expense remains unchanged, the combination of the medical payment system and clinical pathway management is acceptable.

Criterion 4: When the hospitalization effect decreases or the hospitalization expense increases, the combination effect is considered unacceptable.

These four judgment criteria are proposed from the original intention of reasonable expense control and quality assurance, and here the original intention is regarded as the basic principle for judging the quality of the effect. Clearly, Criterion 1 is fully consistent with the basic principle of the combination effect of the medical payment system with the clinical pathway management. Criterion 2 and Criterion 3 also do not contradict that basic principle. Criterion 4 indicates the circumstances in which this basic principle is violated. It should be further clarified that Criterion 4 can be considered as a strong criterion, and it is still considered unacceptable for the improvement of the hospitalization effect and the increase in hospitalization expenses.

However, this situation may be considered acceptable in medical management practice. In addition, Criterion 2 and Criterion 4 can be considered weak criteria, and both cases may be considered unacceptable in healthcare management practice. In summary, based on these four criteria, it is easy to divide the combination effect of clinical pathway management and the DSP-CTB payment system.

In general, this study deeply discusses the effect of the combination of DSP-CTB payment system and clinical pathway management, and proposes a new clinical pathway management model, the DMAIC clinical pathway management model, which provides effective management tools for medical institutions to cope with the challenges brought about by the reform of the DSP-CTB payment system. Through empirical analysis, the study reveals the positive effect of the combination of DSP-CTB payment system and clinical pathway management on improving hospitalization outcomes and reducing hospitalization costs, but also points out that there are significant differences in the combination effect between different diseases. In addition, the study also found that there were differences in the influencing factors of hospitalization costs under different DSP-CTB groups, which provided an important basis for further formulating clinical pathway management strategies. On this basis, this study proposes a DMAIC clinical pathway management model, which uses statistical process control technology to monitor and control the clinical pathway execution process in real time to ensure the cost control and quality assurance of the clinical pathway. Through the establishment of the management strategy of "normal-stricter-relaxed", the pre-warning, in-process control and post-analysis of the clinical pathway process were realized. The conclusions of this study highlight the importance of establishing a clinical pathway for DSP-CTB disease groups in medical institutions under the reform of the DSP-CTB payment system. This study is helpful to better understand the relationship between the DSP-CTB payment system and clinical pathway management and the existing problems, and to provide a decision-making reference for pilot medical institutions to better manage the DSP-CTB payment system, so as to promote the realization of the medical insurance reform goal of reasonable cost control and ensuring medical quality.

6.3 Important Implications for Clinical Pathway Management for Medical Institutions

6.3.1 Regularly evaluate and adjust the criteria for binding effect

Regularly evaluate the combined effect of the DSP-CTB payment system with clinical pathway management, including hospitalization effectiveness and hospitalization costs, to guide continuous improvement. Timely update the guidelines for the effectiveness of the DSP-CTB payment system and clinical pathway management. It is recommended that medical institutions set up a special evaluation team for the effectiveness of the combination of DSP-CTB payment system and clinical pathway management, which is responsible for regularly collecting and analyzing relevant data, such as hospitalization effect and hospitalization costs. The evaluation team should consist of medical personnel with extensive experience and expertise to ensure the accuracy and reliability of the assessment results.

In the evaluation process, hospitals should pay attention to the following aspects: first, evaluate whether the combination of DSP-CTB payment system and clinical pathway management improves the quality and efficiency of medical services, such as shortening the length of hospital stay and reducing the incidence of complications. Second, it is necessary to assess whether medical costs have been effectively controlled, such as reducing the cost of medicines and unnecessary examinations. In addition, attention should be paid to changes in patient satisfaction and the workload of healthcare providers.

According to the evaluation results, the hospital should update the guidelines for the combination of DSP-CTB payment system and clinical pathway management in a timely manner to ensure the realization of the quality of medical services and the goal of cost control. The updated guidelines should include specific improvement measures, assignment of responsibilities, implementation timelines, etc., to ensure that the improvement work is carried out smoothly.

6.3.2 Establish a refined management system for clinical pathways for DSP-CTB disease groups

The DSP-CTB payment system further subdivides the disease into different disease groups, which requires that the clinical pathway must be matched to achieve refined management. Each disease group needs to develop a specific diagnosis and treatment plan based on its own characteristics and resource consumption. The core of this system is to formulate a specific

clinical pathway diagnosis and treatment plan for each disease group to achieve accurate management of the disease group.

When formulating a diagnosis and treatment plan, hospitals should fully consider the characteristics and resource consumption of each disease group. This includes in-depth research and analysis of the disease characteristics, severity of the disease, treatment difficulty, and medical resource needs of the disease group. Based on this information, the hospital can develop a personalized diagnosis and treatment plan for each disease group to ensure that the treatment process is targeted and efficient. It is worth noting that in the process of formulating the diagnosis and treatment plan, the hospital should strengthen communication and collaboration with doctors to ensure that they fully understand and agree with the rationality and necessity of the plan. At the same time, hospitals should regularly evaluate and adjust their diagnosis and treatment plans to adapt to the changing healthcare environment and patient needs. In addition, hospitals should also strengthen the implementation and supervision of diagnosis and treatment plans to ensure that doctors follow the prescribed path for diagnosis and treatment. By establishing an effective supervision and feedback mechanism, hospitals can identify and solve problems in the diagnosis and treatment process in a timely manner and improve medical quality and patient satisfaction.

By establishing a refined management system for the clinical pathway of DSP-CTB disease groups, hospitals can better adapt to the requirements of the DSP-CTB payment system, realize the rational allocation and utilization of medical resources, improve the quality and efficiency of medical services, and ultimately improve the medical experience and satisfaction of patients.

6.3.3 Establish a process control mechanism

In order to ensure that the diagnosis and treatment activities in the clinical pathway are carried out in a standardized manner, the hospital should establish a process control mechanism. The core of this process control mechanism is to formulate standardized and streamlined diagnosis and treatment activities, so that doctors have clear guidance and requirements in the treatment process. When formulating standardized and process-based diagnosis and treatment activities, hospitals should refer to relevant medical norms and guidelines to ensure the scientificity and rationality of diagnosis and treatment activities. At the same time, hospitals should also consider the practical operation ability of doctors and the availability of medical resources, so that diagnosis and treatment activities can be both challenging and practically executed.

In the process of clinical pathway implementation, hospitals should use statistical process control and other methods to dynamically monitor the cost of diagnosis and treatment activities.

This can help hospitals detect expense anomalies in a timely manner so that they can take appropriate measures to adjust. In the case of abnormal expenses, the hospital should conduct an in-depth analysis to find out the cause and develop a corresponding solution. From the perspective of management practice, hospitals should also establish an effective feedback and communication mechanism to encourage doctors and patients to provide opinions and suggestions in the implementation of clinical pathways. By collecting and analyzing these opinions and recommendations, hospitals can continuously improve the clinical pathway, increasing its feasibility and effectiveness.

By establishing a process control mechanism, hospitals can ensure the standardized implementation of clinical pathways and improve the quality and efficiency of medical services. At the same time, this process control mechanism can also help hospitals better manage and control medical costs and improve the operational efficiency and economic benefits of hospitals.

6.3.4 Establish a multi-departmental collaborative management mechanism for out-of-control intervention

To ensure the effectiveness and efficiency of clinical pathway management, hospitals must establish a multi-departmental collaborative management mechanism for out-of-control interventions. This mechanism is designed to ensure that any loss of control or deviation during the implementation of the clinical pathway can be identified in a timely manner and effectively addressed. The core of this treatment is that in the event of an out-of-control incident, the relevant responsible departments should immediately activate the emergency plan and communicate and coordinate with other departments efficiently to resume normal operations as soon as possible.

Another key component of the multisectoral coordination mechanism for runaway interventions is the in-depth analysis and summary of runaway events. This means that the relevant authorities need to conduct a thorough review of the specific links involved in the runaway incident and take corresponding remedial measures. After the out-of-control incident has been properly handled, the relevant departments should jointly analyze the cause of the incident, summarize lessons learned, and formulate practical improvement measures. These measures will help the hospital continuously optimize the clinical pathway management process and improve the quality of medical services and patient satisfaction.

It is of great significance to establish a multi-departmental collaborative management mechanism based on the runaway intervention mechanism for clinical pathway management. This mechanism not only ensures that hospitals can respond quickly and resolve issues in the

face of out-of-control incidents, but also enables hospitals to learn and improve from them, thereby improving the overall quality of medical services. In addition, this mechanism also helps to enhance the collaboration between various departments of the hospital, improve team cohesion and work efficiency, and lay a solid foundation for the continuous improvement and development of the hospital.

By implementing this mechanism, hospitals can provide safer and higher-quality medical services to patients, while also improving their competitiveness and market position. Therefore, hospitals should pay attention to the establishment and implementation of a multi-departmental collaborative management mechanism for runaway intervention to ensure that clinical pathway management can truly play its due role.

6.3.5 Personnel training and supervision and feedback of diagnosis and treatment behaviors

To ensure that healthcare facilities can implement clinical pathways accurately and follow the latest payment system requirements, hospitals must enhance the training and guidance of personnel. This process involves not only clinicians but also other medical professionals such as nurses, pharmacists, therapists, etc. The training content should comprehensively cover the basic principles, operating procedures, quality standards, and relevant payment policies of the clinical pathway.

To improve the training effect, hospitals can explore the correlation between abnormal diagnosis and treatment costs and diagnosis and treatment activities according to the early warning function of runaway diagnosis and treatment costs in the DMAIC clinical pathway management model, to lock down the executors or responsible persons and strengthen their skills in a targeted manner.

In addition, hospitals should adopt a variety of training forms, such as seminars, workshops, online courses, and simulation training, to meet the learning needs of different personnel. At the same time, hospitals should encourage healthcare providers to actively participate in professional learning and continuing education to keep their professional knowledge updated and skills upgraded.

In addition to training, hospitals need to establish sound monitoring and feedback mechanisms to ensure that improvement measures are implemented effectively and achieve the desired results. This mechanism can include regular quality checks, peer reviews, patient satisfaction surveys, and data analysis. These monitoring activities help hospitals identify potential problems in a timely manner and take corrective actions accordingly.

Feedback mechanisms allow providers or leaders to understand their performance and areas for improvement. Hospitals can collect feedback through regular feedback sessions, performance reviews, and anonymous suggestion boxes. Encouraging suggestions and feedback from participants in the medical care process, including patients, helps to continuously optimize the clinical pathway practice.

By strengthening staff training and establishing a monitoring and feedback mechanism, hospitals provide high-quality medical services that meet the requirements of the latest clinical pathways and payment systems. This not only helps to improve patient outcomes and satisfaction, but also promotes the professional growth of the medical team and the overall quality of service of the hospital.

6.3.6 Information system construction based on DMAIC clinical pathway management model

The DMAIC clinical pathway management model proposed in this study involves the cost monitoring and process early warning of each diagnosis and treatment activity, so it is necessary to build an information system in combination with modern information technology to improve the diagnosis and treatment decision-making and management level of the clinical pathway. Through the establishment of this information system, data collection, analysis of the main factors affecting costs and early warning information can be automatically released. Such an information system can help medical staff make timely decisions and ensure that the implementation of clinical pathways is more efficient and accurate. In addition, the information system should be mobile-accessible, so that healthcare workers can access critical information from anywhere, further improving productivity.

6.4 Research contributions

The main research contributions of this study are as follows:

(1) Through empirical analysis, the combination effect of DSP-CTB payment system and clinical pathway was explored, and a clinical pathway management model for DSP-CTB payment system, namely the DMAIC clinical pathway management model, was proposed, providing a theoretical framework for clinical pathway management based on the payment system. This framework provides important practical guidance for medical institutions that use the DSP-CTB payment system to carry out clinical pathway management. The specific operational steps and implementation details of this model provide important management

method references for medical institutions to carry out clinical pathway management based on the DSP-CTB payment system.

(2) The four criteria for determining the combination effect of payment systems with clinical pathway management summarized in this study provide valuable decision-making references for hospital quality managers. These criteria are instructive and can help hospitals develop quality improvement plans, providing important basis for evaluating the combination effect of payment systems with clinical pathway management.

(3) In this study, the theory of Total Quality Management Theory was applied to the formulation of clinical pathway management model, expanding the application scope of Quality Management Theory in the medical field, providing new ideas and methods for quality management in medical institutions, and pointing out the direction for improving the cost control of DSP-CTB disease and optimizing diagnosis and treatment processes in medical institutions. This study poses positive significance on the deepening and expansion of quality management theory. In addition, to a certain extent, it enriches the theoretical research on the combination of payment system and quality management, providing a new perspective for theoretical exploration in this field.

6.5 Research limitations

This study only analyzed the clinical pathway diagnosis and treatment results before and after the implementation of DSP-CTB payment system reform in K Hospital in Chengdu, so the conclusions are not universally applicable. More medical institution sample data is needed to analyze the combination effect of DSP-CTB payment system with clinical pathways to increase external validity and make research results more applicable. In addition, the proposed DMAIC clinical pathway management model in this study has not been applied in sample hospitals, so this model still needs to be tested to assure internal validity and reliability.

6.6 Further research directions

Further studies can be as follows:

(1) Conduct a broader horizontal survey. Collect more data from medical institutions which implement the DSP-CTB payment system to make research findings valid outside K Hospital.

(2) Evaluate the effect of DMAIC clinical pathway management model. Conduct practice and evaluation of the DMAIC clinical pathway management model in medical institutions

which implement the DSP-CTB payment system to provide a basis for further improving the DMAIC clinical pathway management model.

(3) Based on the DMAIC clinical pathway management model, designing a branch clinical pathway based on DSP-CTB disease group will also be meaningful.

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Annex A: Table

Table A.1 Combination effect

Diseases	Hospitalization outcomes			Hospitalization expenses
	Length of hospitalization	Improvement rate	Recovery rate	
Adult pneumonia	Decreased**	Increased	Increased**	Decreased**
Acute myocardial infarction	No difference	Increased	Increased	Decreased**
Caesarean section	Decreased**	Increased	Increased	Decreased
Cataracts	Increased**	Increased	Increased	Increased**

Note: This table is a collation of the research results in Section 4.1; **: $P\text{-value} < 0.05$