

Review

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Review

Application of the Kern Six-Step Method in Curriculum Design for Postgraduate Clinical Pharmacy and International Practice Experience

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Abstract

The development of postgraduate course cases for clinical pharmacy plays a pivotal role in facilitating professional knowledge acquisition for postgraduate students majoring in this discipline. The Kern Six-Step Approach serves as an innovative paradigm for curriculum construction, comprising six core components: needs assessment, objective formulation, content design, implementation strategies, evaluation and feedback, and continuous improvement. This paper reviews the existing challenges in the construction of course cases for postgraduate clinical pharmacy programs, the implementation procedures, current application status, as well as the effectiveness evaluation of the Kern Six-Step Teaching Approach.

Keywords: kern six-step teaching method; clinical pharmacy; curriculum development

1. Introduction

Clinical pharmacy education is currently undergoing a paradigm shift from traditional knowledge transmission to competency-based training. This transformation stems from the increasing demand for comprehensive professional capabilities in the healthcare system. Against the background of growing attention to the social determinants of health, educational evaluation criteria have moved beyond traditional learner-centered indicators to focus on the responsiveness of curricula to societal health needs [1]. Such a transition requires medical education to establish a more systematic and scientific curriculum development framework to meet the emerging demands of clinical practice for interdisciplinary integration and public health literacy.

As the gold standard for systematic curriculum development, the original Kern Six-Step Approach consists of six progressive phases: problem identification and general needs assessment, targeted needs assessment, goals and objectives formulation, educational strategies design, implementation planning, and evaluation and feedback mechanism establishment [1]. This framework emphasizes an evidence-based curriculum development pathway, requiring sufficient evidence to support each step. In terms of implementation principles, it particularly stresses the full participation of stakeholders, ensures close alignment between curriculum content and clinical practice through modular design, and establishes a dynamic cyclical improvement mechanism.

Compared with the traditional linear curriculum development model, the innovation of the Kern Six-Step Approach is mainly reflected in three aspects: first, it adopts a dual needs assessment system (general and targeted), ensuring that curriculum design is grounded in systematic needs analysis [1]; second, it matches educational strategies with competency objectives in a matrix format, breaking disciplinary boundaries to achieve cross-domain integration; finally, it establishes a multidimensional evaluation system including formative and summative assessment, forming a closed loop for continuous improvement of curriculum quality. These characteristics make it

particularly suitable for addressing the complex competency development requirements in clinical pharmacy education, as demonstrated in the development of modules such as healthcare quality improvement and health equity curricula [1].

2. Problem Identification and Needs Assessment in Clinical Pharmacy Curriculum Development

2.1. Systematic Analysis of Gaps in Pharmacy Practice Competencies

A core contradiction facing current clinical pharmacy education is the structural mismatch between graduates' practical competencies and the demands of the healthcare service system. Studies have revealed three critical competency gaps during the transformation of pharmaceutical care: first, insufficient clinical judgment in analyzing patient behaviors and identifying unmet needs; second, a lack of systematic thinking for integrating ethical, legal, and social issues (ELSI) into clinical decision-making regarding pharmacotherapy [2]; and third, weak communication and coordination abilities based on structural competencies during interdisciplinary collaboration [3]. These gaps directly limit the performance of clinical pharmacists in core practice scenarios such as prescription verification and pharmacotherapy optimization.

Standardized assessments have shown that approximately 15.2% of clinical pharmacists exhibit significant deficiencies in basic skill modules such as drug laboratory monitoring [4], while the lag in knowledge updating is more prominent in advanced practice areas such as specialized pharmacotherapy management[5]. The formation of these competency gaps is attributed to the delayed response of the education system to the rapid iteration of medical technologies, as well as the neglect of emerging competency training such as system-based practice in traditional curricula [6].

2.2. Stakeholder Demand Investigation Methods (Hospitals/Universities/Regulatory Authorities)

A mixed-methods framework can be adopted to comprehensively capture the needs of multiple stakeholders. At the healthcare institution level, two rounds of expert consultations using the modified Delphi method can effectively identify 25 key pharmacist performance indicators (9 basic-level, 10 intermediate-level, and 6 advanced-level) [7]. University educators should employ a three-stage investigation strategy: first, determine the global disciplinary development trends through bibliometric analysis [5]; second, conduct cross-institutional baseline assessments using a modified 20-item knowledge questionnaire [8]; and finally, organize focus group discussions to clarify the priority sequence of competency training [3].

For collecting needs from regulatory authorities, it is necessary to combine policy document analysis and structured interviews, with a particular focus on the alignment between healthcare quality indicators and educational standards [9]. An innovative improvisational theater simulation method has been found to effectively stimulate in-depth interactions among stakeholders, and is especially suitable for revealing implicit cross-departmental collaboration needs [10]. Notably, feasibility assessment under resource constraints should be regarded as a necessary step in needs validation [11].

2.3. Construction of the Requirement Matrix Based on Post Competence

Drawing on the ACGME Core Competency Classification System, a six - dimensional clinical pharmacy requirement matrix can be established: Patient Care (PC), Medical Knowledge (MK), Practice - Based Learning and Improvement (PBLI), Systems - Based Practice (SBP), Professionalism (PROF), and Interpersonal and Communication Skills (ICS) [12]. The construction of the matrix needs to follow three principles: First, adopt an iterative development process to respond to dynamic needs through continuous optimization of work processes and adjustment of measurement tools [13]. Second, implement the classification of competence levels, and divide the 2,919 identified practice

gaps into three training levels: basic, intermediate, and advanced [4]. Third, introduce a federal regulatory perspective to make the matrix meet both institutional - specific requirements and national certification standards [12,14]. Empirical research shows that the standardized competence scores can effectively predict the clinical practice performance of graduates. Among them, the training effect of the Systems - Based Practice (SBP) dimension is significantly positively correlated with the effectiveness of medical quality improvement [6,12]. The matrix should ultimately be transformed into an operational ‘Department Competence Letter’ to clarify the milestone - like goals to be achieved at each training stage (Table 1) [14].

Table 1. Clinical Pharmacy Needs Matrix.

Domain	Principle
Patient Care (PC)	Iterative development process: Continuously optimize workflows and measurement tools
Medical Knowledge (MK)	
Practice-Based Learning and Improvement (PBLI)	Competency level grading: 2,919 practice gaps corresponding to basic/intermediate/advanced tiers
Systems-Based Practice (SBP)	Federal regulatory perspective: Balancing institutional specificity with national certification standards
Professionalism (PROF)	
Interpersonal and Communication Skills (ICS)	

3. Scientific Design of Teaching Objectives and Curriculum Structure

3.1. Hierarchical Goal Setting for Core Competencies of Clinical Pharmacy

Based on the core competency framework of the European Association of Percutaneous Cardiovascular Interventions (EAPCI) certification system [12], the clinical pharmacy curriculum adopts a progressive - ability goal design, dividing core competencies into three levels: basic skills, professional application, and advanced decision - making. The basic skills level focuses on cultivating basic practical abilities such as laboratory operation skills and infection prevention and control [15]. The professional application level emphasizes clinical core competencies such as drug treatment decision - making and antimicrobial stewardship [15]. The advanced decision - making level cultivates comprehensive judgment abilities in complex clinical situations through case - based teaching (Table 2) [16]. Referring to the Gender Minority Health Competency Standards of the Association of American Medical Colleges (AAMC) [17], the curriculum integrates 30 basic competencies into 12 thematic areas and ensures the measurability of competency achievement through standardized assessment tools [17]. This hierarchical design not only guarantees the standardized training required by the European Specialist Physician Certification System [18] but also adapts to the ability development trajectories of different learners [16].

Table 2. Important Elements of the Ladder-Type Competency Training System for Pharmacy Talents.

Train ing Level	Core Training Content	Competency Type
Basic Skill Level	Laboratory operation skills, basic practical abilities such as infection prevention and control	Basic Practical Competency
Professional Application Level	Clinical core competencies such as drug therapy decision-making and antimicrobial stewardship	Clinical Core Competency
Advanced Decision-Making Level	Comprehensive judgment ability in complex clinical scenarios	Comprehensive Decision-Making Competency

3.2. Modular Curriculum System and Spiral Progression Design

Drawing on the modular framework of the training program of the European Centre for Disease Prevention and Control (ECDC) [19], the curriculum divides the teaching content into independent modules corresponding to 23 competency domains. Each module includes clear learning objectives, practical tasks, and assessment criteria. For example, the drug treatment module is subdivided into sub - modules such as prescription review, adverse reaction monitoring, and drug - drug interaction management [19]. With a spiral progression design, basic modules (such as laboratory skills) are intensively trained in the lower grades [15], while high - order modules (such as interdisciplinary team management) reappear in multiple academic years with an increasing difficulty of cases [15]. The distance teaching module innovatively uses High - Fidelity Simulators (HFS) to train the handling of adverse events following immunization, strengthening skills through clinical scenario simulation (Figure 1) [20]. This design not only maintains the advantage of process standardization of the TinyTalks curriculum at Massachusetts General Hospital for Children [21] but also adapts to the needs of different teaching scenarios through flexible combinations of modules [22].

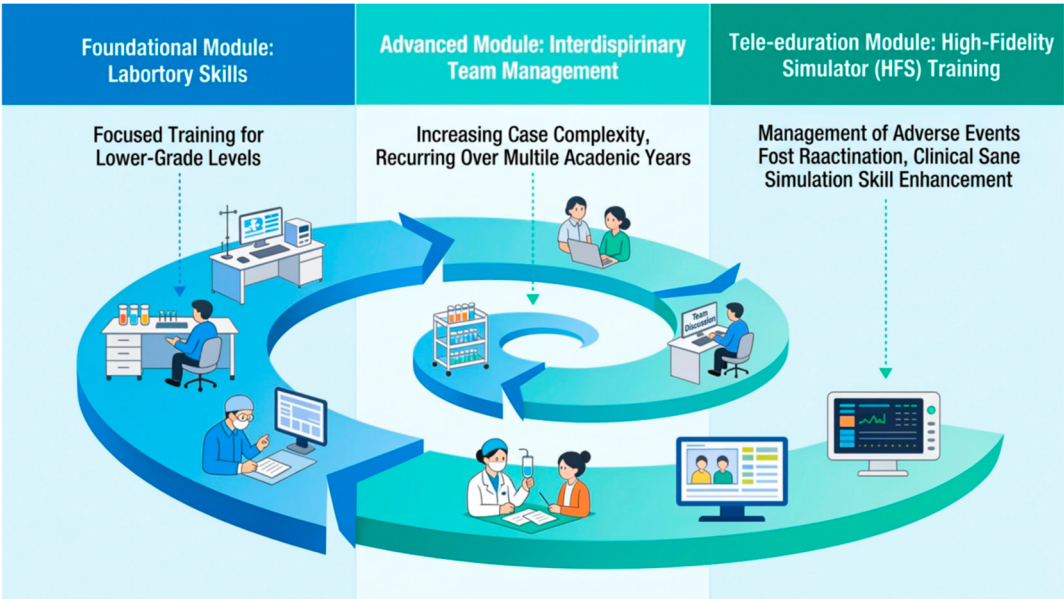


Figure 1. A spiral progressive design was adopted. Basic modules (such as laboratory skills) were intensively trained in lower grades, while advanced modules (such as interdisciplinary team management) appeared repeatedly in multiple academic years through the way of increasing case difficulty. The distance teaching module innovatively adopted high-fidelity simulators (HFS) for training in the handling of adverse events following vaccination, and skill enhancement was achieved through clinical scenario simulation.

3.3. Optimization Strategy for Interdisciplinary Integrated Teaching Content

The curriculum development team uses the modified Delphi method to construct an interdisciplinary competency matrix [22], integrating the eight core areas required for cardio - oncology [18], including basic oncology knowledge, cardiotoxicity monitoring, and specialized service organization. By analyzing the 344 assessment items of the Japanese National Licensing Examination for Pharmacists (JNLEP) [23], knowledge in cross - disciplinary areas such as drug - disease interactions and therapeutic drug monitoring is emphasized and strengthened. The design of teaching content follows the "six - dimensional integration" principle [24]. In terms of temporal arrangement, it achieves alternating penetration between basic sciences and clinical practice. In terms of teaching methods, it integrates multiple strategies such as case discussions and simulation training. Special attention is paid to cultivating core communication skills in the context of telemedicine [25], transforming traditional consultation skills into professional expression norms in video - interaction scenarios. This integration strategy not only refers to the OSCE assessment experience of the pediatric telephone consultation course at Johns Hopkins University [26] but also absorbs the successful experience of the standardization of dermatoscope technology in the German dermatology residency training [27].

4. Implementation and Dynamic Assessment Mechanism

4.1. Selection and Combined Application of Evidence - Based Teaching Methods

In the implementation of clinical pharmacy courses, blended teaching methods demonstrate significant advantages. Research shows that the flipped classroom model combined with case - based teaching can effectively enhance student engagement. After adopting the remote flipped classroom at the School of Pharmacy in Malaysia, students significantly improved their clinical decision - making ability through a combination of pre - class video learning and in - class case discussions [25,28]. Team - Based Learning (TBL), as a core teaching method, after two years of continuous application, has led to the most significant improvement in the computational ability of pharmacy students in the Health Sciences Reasoning Test (HSRT - N), confirming the promoting effect of social

learning on the cultivation of professional capabilities [24,29]. It is worth noting that the evidence - based medicine teaching method based on the GRADE system, through a hybrid model of online modules combined with face - to - face teaching, achieved teaching effects comparable to those of pure face - to - face teaching in a 90 - minute teaching unit. This provides a replicable teaching model for the cultivation of evidence - assessment capabilities in clinical pharmacy courses (Figure 3) [26,30].

4.2. *Standardized Development of Formative Assessment Tools*

A diversified formative assessment system has taken shape in clinical pharmacy education. The 344 standardized assessment items developed for the Japanese National Licensing Examination for Pharmacists (JNLEP) provide an objective tool for clinical competence assessment [31]. In the teaching of drug treatment for urinary tract infections, the method of combining Key Feature Questions (KFQs) with spaced - repetition testing was adopted. By implementing three formative tests over five consecutive days, students' clinical reasoning ability was effectively enhanced. There was no significant difference in assessment scores between the automated feedback generated by ChatGPT and the expert - manual feedback group [32,33]. The combined use of the ACE (Assessment of Competence in Evidence - Based Medicine) tool and Educational Prescriptions (EPs) can not only provide real - time feedback on learning progress but also guide students in translating theoretical knowledge into clinical practice behaviors [21]. The development of standardized assessment tools needs to follow the needs assessment principle in Kern's six - step method. For example, the 16 - item knowledge test questions and 5 - level Likert - scale confidence assessment developed by the University of Colorado showed a significant improvement in teaching effectiveness after pre - test and post - test verification [34].

4.3. *PDCA Cycle Management Model for Curriculum Iteration*

The improvement of curriculum quality requires the establishment of a systematic iterative mechanism. Using the Kirkpatrick four - level evaluation model in combination with the RISE2 Genomics Education Reporting Standards can comprehensively evaluate the teaching impact from the reaction level to the result level [35]. In the family medicine residency training, the curriculum update mechanism based on the PDCA cycle enables the evidence - based practice course to continuously integrate the latest clinical evidence. Its core strategy is to replace time - consuming in - depth evidence evaluation with pre - evaluated summary evidence, improving the efficiency of curriculum updates [36]. The programmed evaluation framework developed by the Canadian CRAFT project integrates formative and summative evaluation data over a 24 - month cycle, demonstrating the adaptability of this model in different teaching environments [37]. During the curriculum iteration process, special attention should be paid to the feedback data from 115 students on the five - level Likert scale, as well as the results of teacher teaching behavior analysis. These multi - dimensional data jointly form the decision - making basis for curriculum optimization [38,39].

5. Data on the Effectiveness Evaluation of Clinical Competency Training

5.1. *Analysis of Objective Structured Clinical Examination (OSCE) Scores*

The Objective Structured Clinical Examination (OSCE), as an important tool for evaluating the clinical competence of clinical pharmacy postgraduates, demonstrates significant evaluation value in the Kern six - step curriculum system. Research data shows that an OSCE assessment with three simulated cases can effectively identify students' knowledge reserve and clinical reasoning deficiencies during clinical rotations, providing a clear direction for subsequent teaching interventions [28]. In the special training for vaccine management, the OSCE scores of students in the intervention group increased significantly after the training, especially in the links of adverse reaction identification and management [40]. Cross - institutional research indicates that in a dual - rater OSCE

system composed of clinical and teaching experts, when the number of cases increases to 12, the scoring reliability coefficient can reach 0.76, meeting the measurement requirements for high - risk decision - making [41]. The implementation experience of the virtual OSCE (vOSCE) in Malaysian pharmacy schools shows that although 51.9% of the participants reported that network connection problems affected their performance, students interested in clinical pharmacy courses had significantly higher satisfaction in dimensions such as teacher support, preparation time, and operation procedures than other students [42,43].

5.2. Indicators of Prescription Review and Drug Treatment Decision - Making Ability

The drug treatment decision - making ability of clinical pharmacy postgraduates is evaluated through multi - dimensional indicators. The analysis framework of the Japanese National Licensing Examination for Pharmacists (JNLEP) shows that among the 344 assessment items, the correct rate of items related to drug treatment decision - making can reflect the clinical thinking level of students [24]. A consensus study among experts has established 25 quality indicators for pharmacists' actions, and 6 advanced indicators (such as the development of individualized drug administration plans for complex cases) are particularly suitable for the ability assessment of postgraduates [44]. In standardized clinical scenario tests, the identification accuracy rate of drug interactions and adverse reactions by pharmacy postgraduates is 32.8% higher than that of undergraduates, demonstrating the effect of curriculum training in enhancing clinical alertness [45]. A multi - center study has confirmed that postgraduates who have received systematic training have a 92.4% correct rate in basic items (such as dose calculation) and a 73.6% correct rate in advanced items (such as the application of pharmacogenomics) in prescription review tasks, reflecting the differences in the cultivation of different - level abilities by the curriculum [44].

5.3. Career Development Data from Longitudinal Tracking Studies

Longitudinal tracking data of graduates reveals the long - term impact of the curriculum system. Data from a Canadian residency training program shows that pharmacists who received six - year training had a significantly higher increase in OSCE scores (28.7% vs 15.3%) after 11 months of training compared to those in a seven - year program, suggesting that curriculum compression may affect the development of clinical competence [46]. A study on pharmacist intervention in general practice clinics in the UK shows that clinical pharmacists who have received systematic training can improve the prescription quality index by 41.2%, and this effect peaks in the second year after employment [47]. In the pharmaceutical service evaluation of the Tokyo Olympics, the knowledge scores (17.72/28) of pharmacy staff who completed the special training were significantly higher than the industry average, with the highest score (63.29%) in the knowledge domain of diagnosis and clinical features, confirming the value of training for special scenarios [48,49]. A comparative study in three African countries found that continuous career development support can maintain an upward trend in pharmacists' clinical practice levels, while the effect of single - session training significantly decays after six months [50].

6. Current Controversies and Optimization Directions in Application

6.1. Exploration of the Boundaries of Cultural Adaptability Adjustment

The Kern six - step method faces significant challenges of cultural adaptability in the process of cross - cultural application. Research indicates that when applying Western educational models to non - Western educational systems, careful cultural adaptation is necessary [50]. For example, during the development of a cross - cultural nursing curriculum in Korean nursing education, researchers found that the original curriculum needed to be compressed in content and localized in language according to local cultural characteristics [51]. Although this cultural adaptation has increased the curriculum's acceptance, it has also sparked academic discussions about the balance between

curriculum fidelity and adaptability [52]. Especially in the field of pharmacy education, there are significant differences in the competence requirements for clinical pharmacists in different countries and regions. This requires curriculum developers to adapt the specific teaching content to local conditions while maintaining the core principles of the Kern method [53]. It is worth noting that excessive cultural adaptation may cause the curriculum to lose its original educational value. Therefore, a scientific assessment mechanism for the boundaries of adaptation is needed [54].

6.2. Feasibility of Artificial Intelligence - Assisted Needs Assessment

Artificial intelligence technology brings new possibilities to the needs assessment stage in the Kern six - step method. Existing research shows that the most prominent application scenarios of AI in medical education are concentrated in the sixth step (evaluation and assessment) of the Kern framework, accounting for 66% [55]. In the development of pharmacy curricula, large - language models such as ChatGPT have demonstrated the potential to process complex educational needs data. For example, in the Japanese National Licensing Examination for Pharmacists, the GPT - 4 model can handle various question types including those with charts [56]. However, these AI tools still lack stability when dealing with the unique cultural contexts and complex language scenarios in pharmacy [57]. More critically, AI - assisted needs assessment needs to address ethical issues such as data privacy and algorithm transparency, which requires educational institutions to establish corresponding regulatory frameworks [58]. Future development may focus on developing AI assessment modules dedicated to pharmacy education, combining natural language processing and knowledge graph technologies to improve the accuracy and efficiency of needs analysis [59].

6.3. Collaborative Development Mechanism of Cross - institutional

Education Alliances Establishing cross - institutional collaboration networks is an important way to enhance the implementation effect of the Kern six - step method. The practical experience in California, USA, shows that by forming an interdisciplinary working group consisting of 24 teachers, a certificate program including 7 new workshops can be developed within 24 months [60]. In the field of pharmacy education, this collaborative mechanism is particularly crucial because the competence standards for clinical pharmacists need to be jointly determined by hospitals, universities, and regulatory authorities [61]. The practice in Manchester, UK, has confirmed that a pharmacy service improvement project involving 41 institutions has successfully established a multi - dimensional cooperation framework including education and training, clinical support, and policy coordination [62]. Effective collaborative development needs to address several key issues: establishing a unified competence standard system [63], designing a reasonable intellectual property sharing mechanism [64], and developing a digital platform to support remote collaboration [65]. It is particularly noteworthy that cross - institutional cooperation should not remain at a superficial level of union but should build a full - process collaborative mechanism from curriculum design to effect evaluation. This requires participating parties to make substantial adjustments in organizational culture and work processes [66].

7. Implications and Prospects for Clinical Pharmacy Education Reform

The Competency - Based Medical Education (CBME) model has become the cornerstone of global medical education reform. Its core lies in clearly defining learning outcomes as measurable clinical practice competencies [67]. In the field of pharmacy education, the implementation path of CBME first requires establishing a professional competence framework closely related to pharmacy practice, dividing competencies into different development stages from novice to expert, and developing corresponding Entrustable Professional Activities (EPAs) assessment tools, which can significantly improve the quality of cultivation. The successful implementation of CBME requires the development of a programmed assessment system, which can achieve continuous evaluation of learners' competencies by integrating formative and summative assessment data. Global pharmacy

education is facing the dual challenges of standardization and localization. Digital technology provides new ideas for balancing this contradiction. The Global Health Classroom (GHCR) model, through transnational collaborative learning, not only maintains the unity of educational standards but also respects regional practice differences [68]. It is recommended to establish cross - institutional education alliances and adopt a modular curriculum design so that global core competence standards can be flexibly adapted to the needs of different healthcare systems. Lifelong learning has become the key to the continuous development of the pharmacy profession.

Conflicts of Interest: The author declare no conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

ELSI	ethical, legal, and social issues
SBP	system-based practice
PC	Patient Care
MK	Medical Knowledge
PBLI	Practice - Based Learning and Improvement
SBP	Systems - Based Practice
PROF	Professionalism
ICS	Interpersonal and Communication Skills
EAPCI	the European Association of Percutaneous Cardiovascular Interventions
AAMC	the Association of American Medical Colleges
HFS	High - Fidelity Simulators
JNLEP	Japanese National Licensing Examination for Pharmacists
HSRT	the Health Sciences Reasoning Test
KFQs	Key Feature Questions
CBME	The Competency - Based Medical Education
OSCE	Objective Structured Clinical Examination
JNLEP	Licensing Examination for Pharmacists
EPs	Educational Prescriptions
GHCR	The Global Health Classroom

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