

ASHP Guidelines on the Pharmacist's Role in the Development, Implementation, and Assessment of Critical Pathways

Purpose

The purpose of these guidelines is (1) to describe the pharmacist's role in the development, implementation, and assessment of critical pathways (CPs) and (2) to help pharmacists prepare for that responsibility. Because pharmacotherapy is a central component of many CPs, pharmacists should take leadership roles in the development, implementation, and assessment of CPs. By assuming leadership roles, pharmacists can help improve patient outcomes, contribute to cost-effective patient care, and promote multidisciplinary approaches to patient care and performance improvement. Although pharmacist involvement in the early stages of CP development is crucial to success, CP development is generally cyclical, and pharmacists should seek opportunities to become involved at any stage in the cycle of CP development, implementation, and assessment.

Background

The development of CPs has been stimulated by the desire to improve patient outcomes by applying evidence-based clinical practice guidelines; increased interest in measuring and improving the quality of health care, including continuous-quality-improvement (CQI) initiatives; and managed care and other market-driven health care reforms. CPs can be defined as patient care management plans that delineate key steps along an optimal treatment timeline to achieve a set of predetermined intermediate and ultimate goals for patients who have clearly defined diagnoses or require certain procedures.¹ CPs have also been called care guides, clinical pathways, clinical care plans, and care maps.² CPs derive from the industrial engineering concept of critical paths³ and were originally associated with inpatient acute care and used primarily by nurses. CPs have evolved to incorporate the spectrum of patient care providers and settings and to include CQI concepts.⁴ CPs and similar tools are developed in many facilities for many purposes.^{5–20} Although dismissed by some critics as “cookbook medicine,” CPs have in some cases been shown to improve patient outcomes^{21–26} and to reduce health care expenses.^{27–36} ASHP believes that carefully developed and skillfully managed CPs can improve the care of patients across the spectrum of health-system settings, as well as improve the allocation of scarce health care resources.

Typical CP Process

Each health system will use a process of CP development, implementation, and assessment that meets its own needs within its own structure, culture, practice settings, and policies and procedures, but these processes do share common elements. Typically, once a disease or procedure is selected for CP development, a multidisciplinary team analyzes its current management (including process variances, costs, and outcomes), evaluates the scientific literature, and develops a plan of care. The planned actions for each discipline on the health care team are mapped on a timeline for the specific

Summary of guidelines. Because pharmacotherapy is a central component of many critical pathways, pharmacists should take leadership roles in their development, implementation, and assessment.

Pharmacists can improve the development of critical pathways by ensuring the evidence-based selection of medications, establishing measures for monitoring patients for drug efficacy and adverse effects, and evaluating the proposed critical pathway for patient safety.

Pharmacists can improve the implementation of critical pathways by documenting processes and outcomes, ensuring proper patient selection and medication use, monitoring patients for drug efficacy and adverse effects, and providing for continuity of care. Pharmacists can improve the assessment of critical pathways by measuring and analyzing processes and outcomes, disseminating the results of those analyses, and reviewing the critical pathways' pharmacotherapy to keep pace with changes in best practices.

disease or procedure.³⁷ Pharmacists perform the following functions in a typical CP: oversee the selection of medications by using an evidence-based approach, develop the criteria for medication selection or dosages, monitor patients for drug efficacy and adverse effects (or establish parameters for monitoring), and ensure continuity of care across the health system. The following describes common steps in the development, implementation, and assessment of CPs.³

1. *Select diagnoses and procedures.* Diagnoses and procedures selected for CP development usually include those with high process variability, high cost, high patient volume, and high risk. CPs can be developed for common or specialized diagnoses (e.g., myocardial infarction, diabetes mellitus) or procedures (e.g., transurethral prostatectomy, coronary artery bypass grafting), for diagnoses that are likely to cause changes in health status (e.g., uncontrolled asthma), and for diseases requiring complicated pharmacotherapeutic regimens (e.g., AIDS). The criteria for selection should be developed with input from administrative and clinical leaders to ensure institutionwide acceptance and should be based on scientific evidence.
2. *Appoint a development team.* The development team should include key health care providers from all organizational components involved in the CP. The importance of a multidisciplinary approach to CP development cannot be overemphasized. If possible, consideration should be given to including a patient representative on the CP development team. Although insurance carriers and managed care providers may not have representatives on the development team, their protocols or guidelines should be evaluated by the team for inclusion in the CP as appropriate.

3. *Conduct a search of the scientific literature.* A literature and database search conducted early in the process will help identify measures for assessing current processes and outcomes and will help ensure an evidence-based approach to the CP.
4. *Document current processes and outcomes.* The current processes, costs, variances, and outcomes need to be documented, usually through flow charting of the current process, retrospective chart review, and benchmarking. Benchmarking may be internal or external to the health system. Depending on the health system's resources, benchmarking may rely on chart review or may use computerized databases that compare physicians' use of resources, health-system costs, and outcomes for specific diagnosis-related groups. This step identifies the health system's practice and compares it with published clinical guidelines that are preferably consensus based (e.g., guidelines from the Agency for Healthcare Research and Quality or the American Heart Association). The team developing the CP should use an evidence-based approach to identify, discuss, and resolve the gaps between clinical guidelines and current local practice. Input from the practitioners who will be involved in the CP is crucial to the success of this process evaluation and CP development in general.
5. *Develop the CP.* Multidisciplinary, standardized development of the CP ensures integration of care and elimination of duplication and oversights. The CP should state its goals, define actions essential to achieving those goals, provide for patient education, outline assessment of patient safety, identify measures of conformance and outcomes, and describe required documentation. The actions and resources required for implementation should be discussed and agreed upon by all disciplines involved.
 - a. *Goals and outcomes*
 - Define the specific goals or measurable outcomes of the CP (e.g., decreased length of stay, decreased ventilator time, reduced overall patient cost, decreased pain scores, early ambulation).
 - Select the areas of focus or categories of actions essential to achieving the goals and outcomes. To ensure consistency and continuity, these areas of focus should be standardized for all CPs developed within a health system; examples of focus areas are treatments, medications, and patient education and counseling.
 - Determine the appropriate time frame. This will vary according to the disease or procedure being addressed and the practice setting (e.g., emergency room, ambulatory care clinic, acute care hospital). The time frame may be specified in minutes, hours, days, or phases. A workload assessment may be required to develop appropriate time frames.
 - Define the activity for the focus area under the appropriate time frame (e.g., "pharmacist provides medication-use education and counseling on discharge day").
 - b. *Patient education*
 - Modify the CP, using lay terms in the patient's primary language, to educate the patient about activities to be performed, time frames, and expected outcomes. In some practice settings, the patient may be an active partner in CP decision-making and implementation.
 - c. *Patient safety*
 - Identify potential risks to the patient that may arise from use of the CP. For example, the CP could be subjected to the institution's failure-mode and effects analysis, or the medication safety self-assessment tool of the Institute for Safe Medication Practices could be used to assess the safety of the practices outlined in the CP.³⁸
 - d. *Monitoring*
 - Identify measures of conformance and variance so that the CP and the resulting outcomes can be continuously improved. Variances are deviations from the CP that may be positive or negative, avoidable or unavoidable, consequential or inconsequential. Sources of variances include patient responses to medications, physician decisions, and system breakdowns.
 - e. *Documentation*
 - Develop a single, multidisciplinary work sheet or other tool that describes the CP's actions and time frames and provides spaces for documenting that actions were performed.¹² Describe how this tool will be used and how data will be collected.
6. *Obtain approval for the CP and educate participants.* To ensure global acceptance among all health care provider groups, the CP should be approved by appropriate committees, especially those of the medical staff. The impact of CP implementation on practitioner workloads will require careful consideration, and departmental policies or procedures may need to be modified. The pharmacy and therapeutics (P&T) committee should review pharmacotherapeutic issues associated with the CP early enough during development that therapeutic concerns can be addressed as they arise rather than after the CP is implemented. After the CP is approved, all health care team members involved in the care of the patients affected by the CP should be educated about the anticipated outcomes, specific actions and time frames, and professional responsibilities associated with the CP.
7. *Implement the CP.* After the necessary education and training of providers, the CP is available for use. Starting the CP as a pilot project for a small number of patients may provide valuable initial assessments that will facilitate wider implementation. Staff members should be designated to identify patients suitable for the CP and to guide their enrollment and the CP's use. Patients enrolled in a CP are assigned to a health care team whose members have specific responsibilities for actions and time frames.
8. *Assess the CP.* Because not all consequences of a CP are foreseeable, CPs require periodic assessment. Assessments after a few days or weeks of use may gauge only the feasibility of the CP and not its success in achieving desired goals, but they should identify unexpected problems that may require modifications to the CP. Surveys of health care practitioners may be useful in such initial assessments. Assessments after a few months of use may provide an initial perspective

on the CP's success but may not be sufficient to fully evaluate outcomes. Assessments after longer periods should produce evidence supporting the CP's original goals. Regular analysis of the results and variances, as well as new information (e.g., new indications for medications) and technologies (e.g., new pharmacotherapy), provides data for a root-cause analysis and continuous improvement of the CP.

9. *Disseminate the results of the assessment.* The results of the assessment should be shared not just with health-system managers or members of the CP development or oversight committees but with all staff involved in the CP. Widespread dissemination allows for more suggestions for improvement from all members of the health care team and encourages acceptance of any alterations in the CP required by the assessment. Publishing the results in a journal, sharing the experience with a practice network, or presenting the results at a meeting expands the general pool of knowledge concerning CPs.

Pharmacist Involvement

These guidelines suggest actions to help prepare pharmacists and pharmacy departments for involvement in the development, implementation, and assessment of CPs at various levels of care and in different practice settings. The applicability of these guidelines depends on a pharmacist's or pharmacy department's current level of involvement in patient care and CPs. Pharmacists should focus on incorporating contemporary pharmaceutical care principles (e.g., assessing medication orders, developing pharmacotherapeutic regimens and monitoring plans, educating and counseling patients, calculating doses according to pharmacokinetic principles, conducting medication-use evaluations [MUEs], and managing anticoagulation therapy) in the development, implementation, and assessment of CPs.^{39–42}

Preparing for Involvement in CP Development. Pharmacists should learn about their health system's approach to CP development and assess their readiness for involvement. They should

1. Review the health system's current strategic plan with respect to CPs. Because CPs are inherently collaborative, pharmacists should try to understand this strategic plan from the perspective of other health care providers, seeking advice from them when necessary. When reviewing the strategic plan, pharmacists should also consider the needs of specific patient populations served by their institutions.
2. Educate the pharmacy staff on the purposes and processes of CP development and the contents of CPs. The patient care decisions required in CPs demand clinical knowledge, and the pharmacotherapy involved should be based on evidence in the scientific literature. This clinical knowledge is fundamental to the CP. An effective contributor to the CP process needs to first acquire the clinical knowledge on which the CP is based and then use CQI, teamwork, negotiation, and administrative skills to develop, implement, and assess the CP.
3. Discuss CP experiences with pharmacy colleagues within and outside the health system. Pharmacists should create a forum within the health system for ongoing dialogue about CPs; for example, CPs could be made a regular agenda

item for the P&T committee meeting and for other multidisciplinary clinical and departmental meetings.

4. Monitor pharmacy, nursing, quality management, health-system, health care, and management literature for ideas on CP development, implementation, and assessment. CPs from other institutions may be used as examples of and frameworks for mapping care, but they should not be adopted directly, because acceptance and use are greater when CPs are developed or adapted by their users.
5. Identify opportunities for contributing, through the provision of pharmaceutical care, to the health system's patient care delivery and improvement efforts.

Initiating Involvement. Pharmacists should begin their involvement in the CP process in ways most appropriate to their health system's structure, culture, practice settings, and policies and procedures. Involvement may vary substantially from one health system to another, but in general pharmacists should

1. Develop relationships with nursing, medical, dietary, laboratory, quality management, risk management, respiratory care, and other personnel through routine meetings, nursing and medical forums, and other multidisciplinary opportunities. These relationships should be used to promote pharmacists' contributions to collaborative patient care. The pharmacy department should support the use of CPs as an effective way to integrate and align services, processes, and costs.
2. Support or initiate the implementation of a multidisciplinary team for CP development and oversight and ensure that the pharmacy department and the P&T committee are represented on the oversight committee.
3. Seek leadership roles on the health system's CP oversight committee and development teams but be willing to accept subordinate roles. For example, pharmacists should be willing to lead or assist with literature evaluation for the health system's CP development teams.
4. Identify qualities required for the pharmacist's role and develop a consistent process for selecting the most appropriate pharmacists to participate on the various CP development teams.
5. Ensure the ongoing involvement of the P&T committee in the CP process. The P&T committee can facilitate the process by
 - Reviewing and endorsing the pharmacotherapy proposed for inclusion in each CP.
 - Establishing a standing P&T subcommittee or liaison position to assist CP development teams. The subcommittee or liaison would have the opportunity to educate the CP team about the formulary process, the process for MUE, the appropriate use of restricted medications, and other critical medication-use issues.
 - Publishing CPs and information about the health system's experiences with CPs in the P&T committee newsletter.
 - Developing the drug therapy portion of the CP assessment into an MUE.
6. Emphasize to pharmacists, other health care providers, and health-system administrators pharmacists' responsibility for implementing CP steps that involve pharmacotherapeutic regimens and monitoring, medication distribution, and patient education and counseling.

7. Initiate, after appropriate approvals, the development of the pharmacotherapeutic components of CPs.
8. Offer to evaluate and adapt the pharmacotherapeutic components of existing protocols and guidelines for CPs under development. Maintain a pharmacotherapy database to facilitate CP updates when new medications and pharmacotherapeutic alternatives become available.
9. Develop patient education and counseling materials for the pharmacotherapeutic components of CPs and develop plans for pharmacists or other members of the health care team to provide education and counseling to patients.
10. Advocate the development and use of preprinted medication orders (hard copy or electronic) and consistent use of terminology (e.g., generic drug names, decimals and units of measurement, and standardized terms and abbreviations) within the CP.
11. Be proactive in anticipating alternative processes or drug regimens that may be required in unusual circumstances, such as drug shortages.

Maintaining Involvement. Pharmacists' continued involvement in CPs will depend on their ability to demonstrate their contributions to patient care delivery and improvement to the CP oversight committee and development teams and to the health system's administration. To accomplish this, pharmacists can

1. Monitor the literature of pharmacy, nursing, quality management, health systems, health care, and management for ideas on CP development, implementation, and assessment.
2. Identify new areas for CP development on the basis of medication-use data (e.g., medication error data and MUE findings).
3. Incorporate CPs into the pharmacy department's culture by building responsibilities and performance expectations for CP development, implementation, and assessment into pharmacists' job descriptions.
4. Identify and train pharmacy staff on their roles and responsibilities for implementing the pharmaceutical care components of CPs.
5. Provide objective clinical input that is based on scientific evidence.
6. Ensure consistent use of terminology (e.g., generic drug names, decimals and units of measurement, and standardized terms and abbreviations), rational medication use, and appropriate monitoring. This could be done by the P&T committee or by a pharmacist who coordinates and reviews the pharmacotherapeutic efforts of all CPs.
7. Maintain good working relationships with CP development teams. The pharmacist member should be confident, assertive, cooperative, and effective in communicating with other health care providers.
8. Develop and maintain clinical and management skills through ongoing self-education.

Contributing to the CQI Aspects of CPs. The pharmacist should ensure that the pharmaceutical care actions of the CP contribute to patient satisfaction, desired clinical outcomes, and financial goals by

1. Monitoring the literature for best-practice results relating to specific disease states (as defined by federal

- diagnosis-related-group classification) and comparing these results with the health system's experience.
2. Ensuring that an internal system of CP tracking and therapeutic review is in place for the rapid insertion of new, more effective therapies into the CP and that CPs are integrated into the institution's CQI processes.
3. Assisting the development of patient satisfaction surveys.
4. Monitoring the results of the CPs and using them to perform MUEs.⁴² Since patients enrolled in CPs are receiving predetermined pharmacotherapeutic regimens and monitoring, this is an excellent opportunity to perform disease- and outcome-oriented MUEs. The pharmacist should review the variances and outcomes associated with the CP, determine the effects of pharmacotherapy, and use this analysis to modify the CP. The pharmacotherapeutic component must be specific enough (e.g., specifying the medication and dosage) that its influence on the outcomes can be determined with confidence.
5. Ensuring that CPs are updated when there are changes in institutional practices (e.g., formulary changes) or when external practices change (e.g., guidelines are revised, dosage or monitoring recommendations are revised).

Ensuring the Continuity of a CP. Many CPs require continuity of care across various levels of care and practice settings. Such CPs should specify referral patterns among the levels of care and practice settings. To help accomplish this, pharmacists can

1. Ensure that members of all organizational components are included in the development and assessment of the CP as appropriate for the particular disease or procedure. Included might be personnel in the emergency department, the operating room, the intensive care unit, the step-down unit, the general nursing unit, the rehabilitation unit, the long-term-care facility, the ambulatory care clinic, the laboratory, and the home care service.
2. Develop relationships with ambulatory care, home care, and long-term-care pharmacists and other health care providers to foster the seamless provision of pharmaceutical care by inviting pharmacist members of managed care organizations to participate in CP development, exchanging CPs with the managed care organizations, and creating work teams to ensure the continuity of care.
3. Organize interdisciplinary sharing of information (e.g., recent laboratory test results) and documentation that are useful to all health care providers.
4. Develop a plan to communicate and monitor both internal and external CPs so that pharmacists have a full understanding of the CP process and can evaluate and adjust the CP as necessary when new therapeutic modalities emerge. Optimize this by using electronic and Internet technology to rapidly insert new pharmacotherapies into CPs when appropriate and evaluate which pharmacotherapies are included in which CPs to ensure consistency in medication management.
5. Initiate dialogue among pharmacists to ensure the continuity of the individual patient's CP. For example, when a patient is admitted, the hospital pharmacist should, if necessary and with the patient's permission, contact the patient's community pharmacist or managed care company to obtain information as allowed

under local, state, and federal laws (e.g., the Health Insurance Portability and Accessibility Act). The pharmacist should document an accurate medication history (prescription and nonprescription products, dietary supplements, and home remedies), the patient's history of adverse drug reactions and allergies, the patient's medication-taking behaviors (adherence, health beliefs, and social and cultural issues), and any self-monitoring. This does not obviate the requirement for the pharmacist to establish a professional relationship with the patient and to obtain information directly. When the patient is discharged, the hospital pharmacist could (in accordance with the institution's policies and procedures and with the patient's permission) prepare an original discharge summary or append to the physician's discharge summary any necessary notes regarding medications. An appropriate member of the discharge team should forward the discharge summary to relevant health care providers (e.g., physicians, home care nurses, and community or home care pharmacists). The summary should include the patient's chief complaint, the patient's height and weight, a history of the present illness (including the hospital course), pregnancy and lactation status, prescription and nonprescription medications on admission and at discharge, patient education and counseling, the monitoring plan (including patient self-monitoring and a plan for long-term monitoring of the patient's pharmacotherapeutic regimen), and a person to contact if the patient has questions. The pharmacist should check any discharge prescriptions against the indications listed in the discharge summary.

The Pharmacist's Responsibility

Carefully developed and skillfully managed CPs can improve the quality of care and the allocation of health care resources. Because pharmacotherapy is a central component of many CPs, pharmacists can help improve patient outcomes, contribute to cost-effective patient care, and promote team approaches to patient care and performance improvement by incorporating contemporary pharmaceutical care principles, activities, and services into the development, implementation, and assessment of CPs. Health systems will develop CPs in ways that are most appropriate to their patient populations, organizational structure, culture, and environment, so it is the responsibility of health-system pharmacists to identify opportunities to become involved in and improve the CPs in their institutions.

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These guidelines were reviewed in 2009 by the Council on Pharmacy Practice and by the Board of Directors and were found to still be appropriate.

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