Director's Forum

A Primer on Clinical Pathways

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Leaders in health-system pharmacy are challenged to maintain the highest quality pharmacy service at the lowest cost. Clinical pathways are evidence-based road maps that assist in reducing variations in clinical practice. Integration of clinical pathways within the electronic health record further helps to facilitate evidence-based practice. This article reviews the evolution of the clinical pathways, describes their clinical and economic impact, and identifies ways pharmacy directors can successfully implement these pathways into their institutions. Pharmacy directors can utilize their skills in this area or task clinical pharmacists to serve as members of the clinical pathway development team to further enhance patient-centered pharmacy services.

INTRODUCTION

Despite a historic slowing since 2010, health care spending in the United States still ranks among the highest per capita while quality outcomes and access to care are lagging.¹ There have been some improvements, including a \$316 B Medicare spending decrease between 2009 and 2013.²

However, significant changes in payment reform bring a heightened awareness of the need to focus on improving delivery of care. The US Department of Health and Human Services (HHS) has set a goal for 30% of Medicare payments to be based on alternative payment models by the end of 2016, increasing to 50% by the end of 2018. Additionally HHS aims to associate 90% of the remaining fee for service (FFS) payments with quality or value in some fashion by the end of 2018.³

Changes in health care reimbursement demonstrate how financial incentives are being realigned to facilitate medical practice and behavioral modification. This modification is imperative in transforming health care delivery in the United States around the fundamental aspects of economic viability, global health, and social revitalization and accountability for the betterment of public health. Inappropriate variations in care contribute to inefficiency in health care. When variations are based on preference rather than evidence-based decision making, they result in inappropriate expenditures in labor costs, increased supply chain waste or redundancy, and inefficient communication.

Clinical pathways are used to reduce variations in practice and align decisions with evidence-based medicine, operational efficiency, and quality. A clinical pathway provides clinical oversight and standard expectations for a patient's clinical course in disease state management or recovery to achieve 4 common goals – decreased care fragmentation, optimized cost effectiveness, improved patient throughput, and enhanced patient and family education regarding an anticipated treatment course.⁴

Multiple providers interact with patients during their stay, which can result in fragmentation within the system and create poor outcomes for the patients. With their unique skill-set for the management of medication therapy across the continuum of care, pharmacists play a key role in the development of clinical pathways. These pathways allow proactive engagement and positioning of the core clinical services that pharmacists provide including drug use evaluation, drug information, adverse drug reaction management, drug therapy and pharmacokinetic monitoring, drug counseling, emergency response participation, medication histories, and reconciliation.

The American College of Clinical Pharmacy (ACCP) has published several position statements on the pharmacists' role in clinical pathways. They promote the pharmacist as a pharmacology and pharmacotherapy expert who is specifically involved in guideline development and implementation and

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policy development and creation.⁴ Clinical pathways, supported by evidence-based medicine, can serve as a roadmap to guide practitioners in providing patient-centered care; clinical pathways can also serve as a way to control escalating health care costs, particularly in the area of pharmaceuticals.⁵

Pharmacy directors must continue to investigate ways to enable pharmacist engagement in patient-centered care while facilitating enhancements in upstream efficiency, safety, and improved outcomes. The goal of this article is to highlight the importance of the pharmacy department's proactive engagement in clinical pathway development and the integration of optimal pharmacy care within the standardized progression of the pathway. This article will (a) summarize the evolution of clinical pathways, (b) describe the clinical and economic impact of clinical pathways for health systems, and (c) identify ways that pharmacy leaders can successfully integrate and implement clinical pathways to grow and leverage patient-centered pharmacy services.

HISTORY AND EVOLUTION OF CLINICAL PATHWAYS

Clinical pathways emerged in the early 1980s in response to changes in health care reimbursement.⁴ Reimbursement had been tied to the volume of care delivered, with little focus on quality. Restructuring realigned the incentives for care, basing them on population health management principles that were focused on positive health care outcomes. Initially, these pathways concentrated on high-yield opportunities for specific patient populations: high risk, high dollar, or high volume.⁴ These medical or surgical populations have conditions that are consistent and predictable, and their care is standardized based upon medical evidence shown to improve outcomes and efficiency while reducing costs and variability. Identification of the correct patient populations for whom to create a clinical pathway is a crucial step in the development phase. Such populations will have high volume conditions that are addressed with consistent evidence-based management and established landmarks in care progression and length of stay. Opportune areas for clinical pathway development and integration are those that exhibit the above characteristics but that still demonstrate considerable care variation or are beyond benchmark targets for performance. **Table 1** lists a sample clinical pathway for coronary artery bypass postoperative care.

Clinical pathways are different from clinical guidelines. Clinical guidelines are based upon primary evidence, extensive analysis, and discussion amongst

field experts to establish expectations for best practices.⁶ Clinical pathways are operational tools for executing best practices based upon local practice and clinical guidelines that are shaped by interdisciplinary teams. These pathways create a consistent workflow for care delivery. For example, a total hip replacement clinical pathway depicts the workflow expected of health care practitioners, establishing the time frame for an evidence-based practice to occur. This pathway provides a standard framework of expectations in the pre-, intra-, and postoperative phases for integrating the practical deliverables from the clinical practice guidelines for antibiotic prophylaxis, glucose management, thrombosis prophylaxis, and much more.

Paper Pathway Use and Process

Prior to the development of the electronic medical record (EMR), clinical pathways were part of a paper documentation system.^{5,6} Caregivers documented the completion of activities in one location within the paper chart. These pathways required multiple documents, including order sets, educational materials, and variance reporting documents.⁶ The patient chart and clinical pathway were usually located at the patient bedside, allowing limited staff to gain access to relevant documents at the same time. After integration of EMRs, all staff can access patient records and the clinical pathway for their treatment. Furthermore, paper documentation of pathway progression that is not integrated into the natural workflow and management of the patient is redundant. Limited technological capabilities require the use of paper documentation; however, technological advancements within health systems will increase the ability for implementation of clinical pathways into the electronic EMR.

Electronic Integration

Health care information technology (HIT) has evolved over the past decade with the implementation of the EMR and standards, such as the Center for Medicare & Medicaid's (CMS) Electronic Health Record Incentive Program or "meaningful use criteria." These criteria are used to incentivize and guide facilities in upgrading paper documentation to a safe and efficient electronic process. Hospitals need to comply by these standards for reimbursement from CMS.⁷ Clinical pathways may serve as an integration tool, assisting providers to document achievement of specified outcomes or variances in patient-related activities. Wakamiya and colleagues proposed standard

Table 1. Coronary artery bypass surgery postoperative clinical pathway^a

Steps	Predominant outcome goals	Outcome variances documented	Pertinent orders released	RN care plan documented	Patient education
Clinical pathway entered at end of OR before transfer to ICU					
0-24 h	<ul style="list-style-type: none"> • Extubation in <6 h • Hemodynamic stability • Central lines removed if criteria met 	✓	✓	✓	✓
POD 1	<ul style="list-style-type: none"> • ICU-PCU transition (order reconciliation and patient transfer) • Antibiotics completed, beta-blocker started, analgesia optimization, VTE prophylaxis, advance diet, convert medications to PO if able <ul style="list-style-type: none"> ■ Evaluate for core measure qualifications ■ Initiate discharge planning ■ Ambulate ■ Foley removal if criteria met ■ Ambulate at least x1 	✓	✓	✓	✓
POD 2	<ul style="list-style-type: none"> • Rehab and diabetes assessments completed • Ambulate x3 • Pacing wires and chest tubes removed if criteria met 	✓	✓	✓	✓
POD 3	<ul style="list-style-type: none"> • Disposition and DC anticoagulation plan established • Escalate bowel regimen if needed • Ambulate x3 	✓	✓	✓	✓
POD 4	<ul style="list-style-type: none"> • All meds converted to PO (including diuretics) • DC readiness order set placed and initiate DC teaching • Ambulate x3 	✓	✓	✓	✓
POD 5	<ul style="list-style-type: none"> • Assessment of DC preparedness (discharge if able) • Chest tube sutures removed • Ambulate x3 	✓	✓	✓	✓
POD 6	<ul style="list-style-type: none"> • Assessment of DC preparedness (discharge if able) • Ambulate x3 	If still an inpatient			
POD 7	<ul style="list-style-type: none"> • Assessment of DC preparedness (discharge if able) • Ambulate x3 	If still an inpatient			

Note: DC = discharge; ICU = intensive care unit; OR = operating room; PCU = progressive care unit; PO = oral; POD = postoperative day; RN = nurse; VTE = venous thromboembolism.

^aAdapted from the clinical pathway used at The Ohio State University Wexner Medical Center.

functions that are necessary to maintain a user-friendly electronic clinical pathway.⁸ These include displaying, recording, ordering, editing, variance, and statistics. Clinical pathways can be set up in a variety of modes, whether they are within the physical EMR itself or viewed as paper documentation⁸; paper documentation is commonly less successful and may serve as a distractor or introduce variance in electronic documentation. Clinical pathways can have multiple layers of functionality based upon the program used and developer, allowing analysis of patient outcomes in terms of the individual patient and/or target population as a whole. Options include

integration of order sets, educational materials, nursing documentation sections, and medication, lab, and procedure ordering or discontinuation.⁷

Clinical pathway integration into HIT also has limitations; health care providers will need to adapt to a new workflow and come to a unified decision about large variances in their practice. Equipment, including computers and scanners, must be more readily available for nurses and rounding teams. Compliance with the new system can be increased when clinical pathways are embedded into routine work practices and rounding discussions and staff have been fully educated on the application.⁹

Pharmacy directors should work with senior leadership and the informatics department and their clinicians to identify opportunities for clinical pathways to assist with frontline supply chain control, operational workflow, and improved patient outcomes.

CLINICAL AND ECONOMIC IMPACT FOR HEALTH SYSTEMS

Measuring the outcomes of the use of clinical pathways is an important yet challenging process. During the early years, most research was associated with the studying the most efficient ways to implement a clinical pathway process.¹⁰ With the implementation of electronic clinical pathways, clinical outcomes data are more readily accessible. Husini and colleagues surveyed hospitals in 4 states and found that patients who received total knee replacements in institutions with clinical pathways had a 0.5-day shorter length of stay (LOS) than patients in institutions who did not.¹¹ They also determined that there were 32% fewer adverse events for patients on clinical pathways. Norton and colleagues demonstrated a decrease in pediatric asthma patient hospital admissions (13.5% vs 27.5%) when patients were on a clinical pathway.¹² By utilizing a paper clinical pathway, life-saving medications were administered more often to patients who required it and in a shorter amount of time. A recent study completed by Katzan and colleagues compared the inpatient mortality and LOS for patients with ischemic stroke before and after implementation of a clinical pathway.¹⁰ A decrease in hospital mortality rate (7.2% pre vs 6.6% post; $p = .003$) and LOS (6.3 pre vs 6.2 post days; $p = .047$) was observed for ischemic stroke patients on the clinical pathway.¹⁰ Physicians also noted easier documentation and EMR review post implementation.

The reimbursement landscape continues to change to alternative payment models. Demands for higher quality of care place increased financial risk on the provider and the institution. With this change in financial accountability, providers need to provide integrated care models across the continuum of care to enhance safer and more efficient care. Starting in January 2016, a new initiative under CMS titled Comprehensive Care for Joint Replacement Model (CJR) offers an opportunity for electronic clinical pathways to ensure patient success and positive financial return for hospitals.¹³ The model mandated movement of hospitals in 67 selected geographic areas into an bundled payment model spanning from 3 days prior to admission through 90 days after

discharge for Medicare beneficiaries undergoing hip or knee replacement. Leaders should remain vigilant when this standard expands. The CJR stresses the need for quality and efficiency improvement through multimodal efforts: preoperative risk mitigation strategy, assessment of standard complication rates, acute care throughput, supply chain management, causal analysis and mitigation of readmission rates, post-acute care care planning and coordination, as well as patient engagement and satisfaction.¹³ Some of these indicators have established performance requirements, and quality indicators will continue to evolve over time. Electronic clinical pathways with multireporting functionality will allow hospital leaders to more efficiently assess patient outcomes and identify areas for improvement within the pathway.

PHARMACY LEADERS AND CLINICAL PATHWAY DEVELOPMENT PROCESS

The clinical pathway team determines the goals of management for each clinical pathway. The team must be diverse and inclusive. Members should include physicians, pharmacists, nurses, nurse practitioners, physical and occupational therapists, speech therapists, case managers, social workers, laboratory members, and others depending on the type of pathway.⁴ Pharmacy directors place themselves within these teams or identify competent clinical pharmacists to review guidelines and ensure efficacy and safety of therapies and procedures. It is important that individuals from the informatics department be included to ensure the clinical pathway is successful alignment of clinical and operational consideration upon implementation.

For pharmacy leaders, evaluation of outcomes is critically important. They must determine the variance, the intervention, or outcome that did not occur as predicted. Variances may include LOS, complication rates, mortality rates, or financial outcomes. The selection of an outcome depends on what is best for the assessment of the institution's clinical pathway. Analyzing variances can be a time intensive process; thus when a new clinical pathway is created, results should be reviewed in standard intervals to ensure continued control of process variance and to identify new process improvement opportunities. Identification of key variances and successful countermeasures may not only improve the outcomes of the patients, but may also improve staff satisfaction.⁴

Pharmacists play a specific role in the development, implementation, and assessment of the clinical pathway. Table 2 describes the roles and activities pharmacists can contribute.

Table 2. Pharmacy role in clinical pathways

Role	Activities
Medication therapy management	Medication selection; review of high-risk medications
Medication assistance	Identify need; assist in obtaining medication during transitions of care
Patient and family educator	Educate family and patient on medication changes, side effects, expected outcomes
Medical staff educator	Educate staff on medication place in therapy, duplications, optimal timing, drug interactions; assist in creation of educational materials
Revise and establish policies and protocols	Review current policies in place and recommend amendment based upon changes in evidence-based medicine or to reflect clinical pathway management
Research and evaluate outcomes	Complete medication use evaluations; create reports and present to leadership

Resistance to Adopting Clinical Pathways

Understanding the potential of a clinical pathway also comes with recognizing the limitations and resistance to the growth of clinical pathways. The pathway strives for standardization to improve patient outcomes and create institution efficiency. Opponents fear that this standardization is in conflict with the goal of personalized or precision medicine and creates “cookbook” medicine, threatening the autonomy of physicians.⁴ Conversely, clinical pathways allow abandonment or discontinuation of the pathway if patients no longer meet requirements. Institutions can build flexibility into their clinical pathways to ensure that enough patients within a specific population will fit within the pathway framework. Clinical pathways are evidence-based road maps that assist institutions in reducing variation in care and in promoting best practice and providing better outcomes for patients.

CONCLUSION

Pharmacy directors can serve as integral role in promoting a clinical pathway development team. These pathways, along with HIT, have evolved to ensure successful care management within institutions. Hospitals can achieve better clinical and financial outcomes by utilizing an effective clinical pathway that impacts a high risk, high dollar, or high volume medical or surgical condition. Pharmacy directors can utilize their skills in this endeavor and engage clinical pharmacists as members of the clinical pathway development team to ensure medications are utilized appropriately to provide patient-centered care.

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