ACCP White Paper

Clinical Pharmacy Should Adopt a Consistent Process of Direct Patient Care

American College of Clinical Pharmacy
Ila M. Harris,* Beth Phillips, Eric Boyce, Sara Griesbach, Charlene Hope, Cynthia Sanoski, Denise Sokos, and Kurt Wargo
American College of Clinical Pharmacy, Lenexa, Kansas

Although the application of a consistent process of care serves as a foundational principle for most health care professions, this is not true for the discipline of clinical pharmacy. Without an explicit, reproducible process of care, it is not possible to demonstrate to patients, caregivers, or health professionals the ways in which the clinical pharmacist can reliably contribute to improved medication-related outcomes. A consistent patient care process should describe the key steps that all clinical pharmacists will follow when they encounter a patient, regardless of the type of practice, the clinical setting, or the medical conditions or medications involved. Four essential elements serve as the cornerstones of the clinical pharmacist's patient care process: *assess* the patient and his or her medication therapy, *develop* a plan of care, i*mplement* the plan, and *evaluate* the outcomes of the plan. Despite the fact that several processes of care have been advocated for clinical pharmacists, none has been adopted by the clinical pharmacy discipline. In addition, numerous publications evaluate outcomes related to clinical pharmacy services, but it is difficult to determine what process of patient care was used in most of these studies. In our view, a consistent process of direct patient care that includes the four essential elements should be adopted by the clinical pharmacy discipline. This process should be clear, straightforward and intuitive, readily documentable, and applicable to all practice settings. Once adopted, the process should be implemented across practice settings, taught in professional degree programs, integrated into students' clinical rotations, refined during residency training, and used as a foundation for future large-scale studies to rigorously study the effects of the clinical pharmacist on patients' medication-related outcomes.

Key Words clinical pharmacy, clinical pharmacist, direct patient care, process of care.
(Pharmacotherapy 2014;34(8):e133–e148) doi: 10.1002/phar.1459

Clinical pharmacists focus on identifying, resolving, and preventing medication-related problems (MRPs); improving medication use; and optimizing patients' pharmacotherapeutic outcomes. However, their approach to patient care can vary greatly. Even within similar practice environments, the process of direct patient care used by clinical pharmacists is often not uniform or consistent. As the U.S. health care system increases emphasis on providing high-quality

This document was prepared by the 2011–2012 ACCP Professional and Public Relations Committee: Ila M. Harris, Pharm.D., FCCP, BCPS (Chair); Beth Phillips, Pharm.D., FCCP, BCPS (Vice Chair); Eric Boyce, Pharm.D.; Sara Griesbach, Pharm.D., BCPS; Charlene Hope, Pharm.D., BCPS; Cynthia Sanoski, Pharm.D., FCCP, BCPS; Denise Sokos, Pharm.D., BCPS; and Kurt Wargo, Pharm.D., BCPS. Approved by the American College of Clinical Pharmacy Board of Regents on October, 13, 2013.

*Address for correspondence: Ila M. Harris, American College of Clinical Pharmacy, 13000 W. 87th Street Parkway, Suite 100, Lenexa, KS 66215; e-mail: accp@accp.com.

patient-centered and team-based care, defining how and what the clinical pharmacist contributes to that care is of paramount importance. However, without an explicit, reproducible process of care, it is not possible to demonstrate to patients, caregivers, or health professionals the ways in which the clinical pharmacist can reliably contribute to improved medication-related outcomes. Therefore, it is imperative that a well-defined process of direct patient care be adopted by the clinical pharmacy discipline and that this process be used consistently in patient-centered, team-based care environments.

In a 2008 paper, the American College of Clinical Pharmacy (ACCP) defines clinical pharmacy as "that area of pharmacy concerned with the science and practice of rational medication use."[1] In that paper, ACCP notes that "clinical pharmacists are involved in direct interaction with, and observation of, the patient." It is this "direct patient care" approach that forms the foundation of the practice of clinical pharmacy. However, using a consistent process to render direct patient care is essential. In a recent commentary, the ACCP Board of Regents emphasizes this point, stating, "This consistent process, as applied by clinical pharmacists when collaborating with the patient's other health professionals, is the critical factor in 'operationalizing' direct patient care."[2]

Patient Care Processes in Other Health Care Professions

The application of a consistent process of care serves as a foundational principle for most health care professions. For example, when a patient interacts with a physician, nurse, physical therapist, or dentist, the patient knows the approach to care that will be used.

The nursing profession has used a systematic approach to the care of patients ("the nursing process") for more than 25 years.[3] Although this process is dynamic and its steps are continually reevaluated, the basic approach to the patient remains the same. The American Nurses Association describes the following five steps in its process of care: assessment, nursing diagnosis, outcomes/planning, implementation, and evaluation. This process, used by nurses in all practice settings, ensures consistency in nursing care. The approach also provides quality control in the provision of individualized nursing care, promotes professional growth, establishes a foundation for nursing's scope of practice, and reinforces professional autonomy.[4] Nurse practitioners use a systematic approach to patient care similar to that used in the nursing process, but their standards of practice include some additional dimensions.[5]

The American Physical Therapy Association provides standards of practice for physical therapy. These standards address patient care management criteria including patient/client collaboration; initial examination, evaluation, diagnosis, and prognosis; plan of care; intervention; reexamination; discontinuation of intervention; and communication/coordination/documentation.[6]

Although a discipline may define its own standards of practice, all patient care practices have three common components: a philosophy of practice, a process for patient care, and a system to manage the practice.[7] This white paper focuses on the second component, the process for direct patient care used by clinical pharmacists. The process of care may be applied differently by each health care discipline and in varied practice settings, but it should always involve key components focused on assessment, planning, and follow-up.[7]

A seminal examination of quality in health care and medical outcomes research in 1966 noted three aspects of caregiving that could be evaluated: structure, process, and outcomes.[8] Applying these aspects to the subject of this white paper, it can be stated that one potential strength of clinical pharmacy as a discipline lies in its fundamental "structure"—the education, training, and clinical experience of the clinical pharmacists who provide direct patient care in team-based settings.[1] However, the lack of a well-defined direct patient care process has made the study of the clinical pharmacist's impact on patient outcomes difficult. Although studies assessing the effects of clinical pharmacists on health care outcomes have shown positive results in varied practice settings, these studies used different or unspecified processes of care.[9–11] Thus, as one might expect, applications of these research results can be highly variable, and their impact on patient outcomes may not be reproducible. Therefore, establishing a well-defined, consistently delivered process of care is needed to fully evaluate the impact and transferability of the clinical pharmacist's direct patient care activities.[1]

The Rationale for Adopting a Consistent Process of Care

The clinical pharmacy discipline should adopt a single, consistent direct patient care process

for several reasons including the wide variation in patient care processes used across different practice settings or even within similar practice settings, the use of terminology by pharmacists that differs from what is used outside the profession, the use of inconsistent terminology *within* the profession, and the uncertainty that other health professionals, patients, and caregivers may have regarding the patient care services that can be consistently expected from clinical pharmacists.

In addressing the four reasons just listed, the variability in the patient care process both within and across practice settings is reflected by the differing priorities given to various clinical pharmacist activities. Some inpatient clinical pharmacists are responsible for performing medication histories on all new patients, when appropriate (i.e., if the patient/caregiver is able to provide a history), whereas other clinical pharmacists are not involved in this activity consistently or at all. Some outpatient clinical pharmacists are engaged in assessing all of the patient's medication-related needs, whereas others may address only a specific pharmacotherapeutic issue (e.g., antithrombotic or lipid-lowering therapy). Moreover, outpatient and inpatient clinical pharmacists differ in the degree to which they directly interact with both patients and other health professionals, even when opportunities for such direct interactions are readily available.

In addition, the terminology used by clinical pharmacists is not always consistent with that used outside the profession. For example, many pharmacists use the term *counseling* to define the provision of education to patients regarding their medications. To clinical psychologists and most other health care professionals, counseling involves active listening and feedback when needed, with or without behavioral intervention.

Moreover, the terminology used within the profession of pharmacy is sometimes inconsistent. For example, many clinical pharmacists use the term *medication therapy management* or *medication management* to define their practice, even if the process is completely different from the pharmacy profession's consensus medication therapy management (MTM) process as described in the literature. The term *medication-related problem* (MRP) is used interchangeably with the terms *drug therapy problem* and *drug-related problem*, depending on the process being described. For consistency, we use the term *MRP* throughout this paper. However, to confuse matters further, definitions of current terminology such as "practice," "patient care process," "clinical service," and "practice model" are often interchanged loosely or inappropriately. This imprecise use of terms is confusing and adds to the profession's concern that a single patient care process used in different clinical settings may not be possible. Establishing consistent terminology within the clinical pharmacy discipline can help establish specific quality measures by linking the clinical pharmacist's patient care process to outcomes, fostering the use of these measures in conducting more rigorous and reproducible research, and stimulating the use of appropriate third-party billing codes for the payment of services.

Given the inconsistent terminology and the ill-defined process of care described earlier, it is not surprising that a general lack of understanding exists among other health care professionals and patients regarding what a clinical pharmacist does. Other health professionals often may not know how to determine when a clinical pharmacist is needed, frequently may not understand what to expect from him or her, and invariably are not certain what to ask for from the clinical pharmacist. In addition, employers and health care payers are not likely to know how to compensate a clinical pharmacist if they do not understand the clinical pharmacist's actual practice process and, consequently, cannot readily determine how he or she contributes to improved patient outcomes as a member of the health care team.

However, with the adoption of the Patient Protection and Affordable Care Act (ACA) in 2010,[12] opportunities finally exist for clinical pharmacists to positively affect patients' medication-related outcomes within ACA-driven initiatives including the patient-centered medical home (PCMH) and the Independence at Home program. To establish clinical pharmacists as integral members of the health care team central to the success of these recently introduced programs, the clinical pharmacy discipline must communicate the unique set of knowledge, clinical skills, and experience that qualified clinical pharmacists bring to the health care team, and the consistent process of direct patient care that clinical pharmacists use to help improve patient outcomes. Specifically, it is essential that well-trained, experienced clinical pharmacists leverage a predictable and reproducible care process that can be counted on to optimize patients' medication-related outcomes.

The Essential Elements of a Consistent Patient Care Process

A consistent patient care process should describe the key steps that all clinical pharmacists will follow when they encounter a patient, regardless of the type of practice, the clinical setting, or the medical conditions or medications involved. This process should reflect the knowledge, skills, and experience needed to help optimize patients' medication-related outcomes. In this respect, published clinical pharmacist competencies serve as a basis for this process.[13] The process should be easily understood, measurable, researchable, and readily documented and coded by the practice or other organization in which the clinical pharmacist works. This process should also comprehensively address patients' MRPs as well as apply to patients in all types of clinical settings.

Four essential elements serve as the cornerstones of the patient care process component in a clinical pharmacist's practice: *assess* the patient and his or her medication therapy, *develop* a plan of care, *implement* the plan, and *evaluate* the outcomes of the plan. Each essential element should involve specific steps that provide more detail (Table 1). These elements and steps are purposely broad so that they can be applied to all types of patient care settings. The essential element of *assess* includes the key steps of collecting information, assessing the patient's medication experience and medication-related needs, and identifying MRPs. The medication experience can be defined as "the patient's beliefs, concerns, understanding, and expectations about his or her medications."[14] The patient's medication experience may be shaped by experience, culture, traditions, and/or religious beliefs, and this experience influences his or her decisions regarding medications including medication adherence. *Develop a plan of care* includes the key steps of establishing goals of therapy, developing a plan to resolve MRPs, and formulating a strategy for follow-up. *Implement the plan* includes the key steps of communication and documentation. As the last step, *evaluate the outcomes of the plan* includes providing monitoring and follow-up of the patient and his or her medication-related outcomes.

Table 1. Essential Elements and Steps of a Consistent Process for Direct Patient Care Provided by Clinical Pharmacists

I. Assess the patient and his or her medication therapy
a. Collect information from the patient, caregiver(s), and/or medical record
b. Assess the patient's medication experience and medication-related needs
c. Identify medication-related problems
II. Develop a plan of care
a. Establish goals of therapy and outcome parameters
b. Develop a plan to resolve medication-related problems
c. Develop a follow-up plan
III. Implement the plan
a. Communicate the plan with the provider and patient, as appropriate
b. Document the plan
IV. Evaluate the outcomes of the plan
a. Monitor the plan
b. Provide follow-up care

Current Clinical Pharmacy Patient Care Processes

Several clinical pharmacy patient care processes have been described in the literature. Examples are pharmaceutical care,[7] the Patient-Centered Primary Care Collaborative's (PCPCC's) comprehensive medication management (CMM) in the PCMH,[14] MTM,[15] *individualized* Medication Assessment and Planning (*i*MAP),[16, 17] and the Society of Hospital Pharmacists of Australia (SHPA) Standards of Practice for Clinical Pharmacy Services.[18] Pharmaceutical care is a professional *practice* with elements that include a defined patient care *process* as well as ethical and practice management dimensions. Likewise, the SHPA standards are actually standards of practice, describing what the practice is, the extent and operation of what a clinical pharmacy service should be, procedures for individual patients, training requirements, competencies and accreditation frameworks, research, staffing, quality assurance, and documentation. However, the SHPA procedures in a clinical pharmacy service for individual patients outline the fundamental components of a process of care, which is the component we focus on in this paper. A summary of how each of these current patient care processes matches the proposed essential elements and key steps is provided in the sections that follow. A detailed composite analysis is presented in Table 2.

Essential Element I: Assess the Patient and His or Her Medication Therapy

Pharmaceutical Care

Medication management within pharmaceutical care includes assessment as an essential element as well as the key steps of collecting information, understanding the patient's medication experience,

Table 2. How Published Patient Care Processes Match the Proposed Essential Elements in Table 1

	Pharmaceutical care	Comprehensive medication management in the PCMH	Medication therapy management	Individualized medication assessment and planning	SHPA standards of practice for clinical pharmacy services
Assess patient's medication therapy	**The practitioner** 1. Collects patient-specific information 2. Analyzes the assessment data to determine whether the patient's drug-related needs are being met; ensure that all medications are indicated, effective, and safe; and determine whether the patient is able and willing to take the medication as intended 3. Identifies MRPs **Assessment of the patient's drug-related needs** Includes a pharmacotherapy workup and a full review of systems. *MRPs are identified and categorized.* Four categories/ seven types of MRPs: a. Indication Unnecessary drug therapy Needs additional drug therapy b. Effectiveness Ineffective drug Dosage too low c. Safety Adverse drug reaction Dosage too high d. Adherence Patient unable or unwilling to take medication	**Assessment of the patient's medication-related needs** a. Review, assessment, and documentation of all medications b. Uncovering and documenting the patient's medication experience c. Obtaining the patient's medication history d. Review and documentation of how patient takes medications e. Assessment of each medication to indication and goals of therapy (should be electronically linked) f. Assessment of the patient's clinical status for each drug/condition being treated/prevented g. Assessment and documentation of clinical goals for each medication **Medication-related problems:** four categories a. Appropriateness Medication appropriate for the medical condition being treated? Untreated condition or preventive medication needed? b. Effectiveness Most effective medication being used? Dose appropriate to achieve the goals? c. Safety Adverse event(s) present? Dose too high (toxicity)? d. Adherence Patient able and willing to take the medication as intended?	**MTR components** **After collecting all patient-specific information:** a. Assess medications to identify MRPs by reviewing indication, effectiveness, safety, and adherence b. Develop a prioritized list of MRPs **MRP categories** (four categories; seven types of MRPs): a. Indication Unnecessary drug therapy Needs additional drug therapy b. Effectiveness Needs different drug product Dosage too low c. Safety Adverse drug reaction Dosage too high d. Compliance Noncompliance *Two main types of MTR:* Comprehensive: all patients medications are reviewed to identify MRPs; done annually and after transitions of care Targeted: addresses specific or potential MRPs **The MTR includes:** Determining the patient's thoughts and feelings about their medication use, values, preferences, quality of life and goals of therapy (consistent with the medication experience)	**Ten-step model** **Steps related to *assess* are as follows:** 1. Review and synthesize information from the medical record 2. Conduct comprehensive medication review with patient 3. Identify potential MRPs **Seven MRP categories and 33 subcategories:** 1. Drug therapy needed a. Additional therapy b. Untreated medical condition 2. Suboptimal dosing a. Dose too low b. Dose too high 3. Medication monitoring needed a. To assess effectiveness/response b. To assess for/prevent potential ADEs c. For both of the above 4. Suboptimal drug a. Safer alternative available b. Not effective c. No indication d. Potential drug interaction e. Therapeutic duplication f. Contraindication g. Generic alternative available h. Preferred formulary alternative i. Less-expensive OTC alternative available 5. ADE present a. Moderate b. Severe 6. Suboptimal duration, administration, or frequency a. Duration too short b. Duration too long c. Administration not ideal or correct d. Frequency not correct 7. Nonadherence a. Misunderstood directions b. Transportation c. Could not afford d. Felt better e. Regimen complex f. Felt worse g. Fear of ADRs h. Not aware of medication changes i. Disbelief in drug effectiveness j. Patient overusing medications k. Memory/cannot remember to take medications	**MMP** The MMP focuses on overall patient outcomes and specific clinical activities. Components of *assess* in the MMP are: 1. Assess current medication management 2. Develop medication management goals 3. Clinical review a. Evaluate the response to therapy b. Identify, prioritize and manage actual and potential MRPs c. Individualize therapy **Categories of MRPs:** 1. Drug selection/ indication 2. Over or Underdose 3. Compliance 4. Undertreated condition 5. Monitoring needed 6. Education or information 7. Non-classifiable 8. Toxicity, allergy or ADR *Clinical activities contributing to the above:* Medication reconciliation, especially at transitions of care Medication order review; assessing for clarity, validity and appropriateness Clinical review Therapeutic drug monitoring ADR management The term *medication experience* is not included, but a process is described in which: activities are focused on assessing patients' understanding of, attitude toward and perceived problems with, their therapy, in addition to perceived effectiveness of therapy

(continued)

Table 2 (continued)

	Pharmaceutical care	Comprehensive medication management in the PCMH	Medication therapy management	Individualized medication assessment and planning	SHPA standards of practice for clinical pharmacy services
Develop plan of care	**Care plan development** 1. Establish goals of therapy 2. Develop a care plan that includes interventions to: a. Resolve MRPs b. Achieve goals of therapy c. Prevent new MRPs *Types of interventions* Initiate new drug Change dosage regimen Change the drug Discontinue the drug Institute a monitoring plan Patient-specific instructions Removal of barriers to obtaining medication Drug administration device provided Refer patient 3. Develop follow-up schedule	**Development of a care plan** (Done directly with the patient and in collaboration with the PCMH team or the patient's other health care providers) a. Intervene to solve the patient's MRPs (e.g., initiating medications, changing drug products or doses, discontinuing medications, and educating the patient) b. Establish individualized goals for each medical condition c. Design personalized education and interventions to optimize medication experience d. Establish measurable outcome parameters to determine the impact of the therapies and the service e. Determine follow-up times to ensure efficacy of interventions and presence of new safety issues	**MTR development** a. Develop a prioritized list of MRPs b. Create a plan to resolve MRPs **Medication-related action plan** a. Intended for patient use; contains a list of actions for self-management b. The pharmacist-created MAP includes items that can be acted on by the patient	**10-step model** **Steps related to *develop plan* are as follows:** Formulate assessment/propose plan to optimize medication use **20 categories of recommendations/ resolutions** 1. Add drug 2. Change administration/ time/route/dosage form 3. Change duration 4. Change frequency 5. Discontinue drug 6. Decrease dose 7. Educate 8. Enroll in Rx benefit 9. Increase dose 10. Provide adherence aid 11. Recommend laboratory test 12. Recommend other test 13. Refer to other health care professional 14. Refer to physician 15. Switch to preferred formulary agent 16. Switch to generic alternative 17. Switch to more effective agent 18. Switch to safer alternative 19. Switch to OTC alternative 20. Other	**MMP** The MMP focuses on overall patient outcomes and specific clinical activities Components of the MMP related to *develop plan* are as follows: 1. Establishment of goals of therapy 2. Formulation of a management plan 3. Evaluation of the response to therapy **Categories for pharmacist recommendations to resolve MRPs:** 1. Change of therapy/dose 2. Referral required 3. Provision of information 4. Monitoring 5. No recommendation necessary

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Table 2 (continued)

	Pharmaceutical care	Comprehensive medication management in the PCMH	Medication therapy management	Individualized medication assessment and planning	SHPA standards of practice for clinical pharmacy services
Implement plan	**Communication** 1. Implementation directly by the pharmacist (75%–80%) or with involvement of prescriber (20%–25%), either by direct contact or collaborative practice agreement 2. Details not provided how implementation by contact with prescriber should occur **Documentation requirements:** 1. Care plan 2. Goals of therapy 3. Instructions for patient 4. Schedule for follow-up 5. Personalized care plan, which the patient also receives 6. Medication management summary (or physician report), which includes: a. patient identification, b. allergy/alerts, c. all drug therapies organized by medical condition, d. identification of MRPs, and e. the pharmacist's recommendations 7. Reports documenting workload, activity, quality indicators, etc. Documentation should also occur in an ETR (electronic therapeutic record), a system separate from the EMR used in physician offices and different from the dispensing system. The system should interface with all other records (EMR, pharmacy records, laboratory records)	**Communication** 1. Implementation occurs by taking action on items highlighted in the care plan 2. The care plan allows a provider to intervene to solve the patient's MRPs; interventions include: a. Initiating drug therapy b. Changing drug products or doses c. Discontinuing medications d. Educating patient **Documentation should include** 1. Patient's medication experience 2. Medication allergies and adverse reactions 3. Medication history 4. Current medication record (indication, product, dose, duration, how medication is actually being taken) 5. Active MRPs including the cause (MRPs related to indication, effectiveness, safety, and adherence are determined and documented for each medical condition or preventive therapy, based on the accepted pharmaceutical care taxonomy of drug therapy problems) 6. Therapeutic treatment plans for the patient and practitioner 7. Clinical status vs. goals of therapy Documentation should occur in an ETR (electronic therapeutic record) which has detailed requirements that may not be included in existing EMRs used in physician offices and hospitals. Documentation should also include postmarketing surveillance on appropriateness, effectiveness, safety, and adherence variables; recording MRPs specific to drug products, medical conditions, and patient parameters; offering clinical decision support and analysis; supporting patient participation and decision making in drug therapy; and providing patients with medication information that is individualized and that complements the therapeutic care plan	**Personal medication record** Documentation for patient Record of all medications to use in medication self-management; includes drug allergies and MRPs **Medication therapy review** Final step: Communicating recommendations to other health care professional to resolve MRPs and recommend follow-up care **Implementation/ documentation** 1. Patients may receive the PMR, MAP, and educational materials 2. Physicians may receive a cover letter, the patient's PMR, the SOAP note, and the care plan MTM services should be documented consistently and can be either in an electronic format (optimal) or on paper and should be provided to patients, physicians, and payers (if applicable)[a] The plan recommended to the physician should include suggestions on selecting the appropriate medications, addressing each of the MRPs, monitoring the patient's drug therapy regimen, and providing follow-up. The plan may also include referral of the patient to a physician or another health care professional	**10-step model** **Steps related to *implement plan* are as follows:** 1. Communicate proposed plan to primary care provider 2. Implement plan once consensus reached 3. Educate patient 4. Document plan in medical record and provide written summary to patient **Implementing the plan may include:** 1. Writing a prescription to give to the patient, 2. Calling/faxing/ electronically submitting a prescription to the pharmacy, 3. Creating or updating the patient's medication list, 4. Ordering laboratory tests, and/or 5. Providing a medication aid such as a medication box The step of educating the patient regarding the plan may include educating the patient's caregiver or family member instead of, or in addition to, the patient. Education may be provided verbally and/or in a written format Documentation should include two forms: in the medical record and to the patient	**Clinical activities contributing to implementation** 1. Participation in interdisciplinary care planning (includes ward rounds, clinics, meetings) 2. Provision of medicines information to health professionals and patients 3. Collaboration with prescriber to resolve medication issues **Categories of response to action taken to resolve MRPs:** 1. Prescriber accepted 2. Prescriber not accepted 3. Pharmacist provided service 4. Patient accepted 5. Patient not accepted 6. Unknown at time **Documentation** Included in documentation: 1. Medication reconciliation 2. Plan for management of clinical problems and therapeutic goals 3. Allergies/ADRs 4. Actual or potential MRPs and management 5. Therapeutic drug monitoring recommendations 6. ADR assessment and management recommendations 7. Medicine education performed 8. Assessment of adherence and adherence plan 9. Clinical pharmacy activities and interventions, and risk category of intervention a. includes MRPs identified, risk, b. recommendation, category of action taken 10. Document outcomes and when goals are achieved

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Table 2 (continued)

	Pharmaceutical care	Comprehensive medication management in the PCMH	Medication therapy management	Individualized medication assessment and planning	SHPA standards of practice for clinical pharmacy services
Evaluate outcomes	**Follow-up evaluation** a. Evaluate effectiveness of drug therapies b. Evaluate for adverse events and adherence issues c. Assess if any new MRPs **Follow-up evaluation** Each condition is categorized into eight outcomes: Resolved Stable Improved Partly improved Unimproved Worsened Failure Expired (patient died)	**Follow-up evaluation** If goals are not met, a reassessment is done to determine if any MRPs are interfering or new MRPs have developed Outcome parameters are evaluated against the intended outcomes Follow-up evaluations occur in a clinically appropriate timeframe	**Medication therapy review** The care plan should include recommendations for monitoring the patient's drug therapy for effectiveness and safety **Intervention and/or referral** Recommended actions to address MRPs and follow-up care **Documentation and follow-up** a. Follow-up MTM visits based on the patient's medication-related needs (e.g., after undergoing a transition) b. Documentation for patients: PMR, MAP, and educational materials c. Documentation to physicians: cover letter, patient's PMR, SOAP note, care plan	**10-step model** Steps related to *evaluate* are as follows: 1. Reconcile medications at all encounters, when possible, including transitions of care 2. Provide ongoing face-to-face and telephone follow-up Follow-up should include objective (e.g., laboratory values) and subjective (direct communication with patient) components	**MMP** The MMP focuses on overall patient outcomes and specific clinical activities. Components of the MMP related to *evaluate* are as follows: Monitoring of patient outcomes Document outcomes and when goals are achieved Modify goals when outcomes are not achieved Recognize that timeframe depends on clinical situation and complexity of therapy Clinical activities contributing to the above: Therapeutic drug monitoring Participation in interdisciplinary care planning Clinical review Information for ongoing care ADR management

ADR = adverse drug reaction; EMR = electronic medical record; MAP = medication action plan; MMP = medication management plan; MRP = medication-related problem; MTM = medication therapy management; MTR = medication therapy review; OTC = over the counter; PCMH = patient-centered medical home; PMR = personal medication record; SHPA = Society of Hospital Pharmacists of Australia; SOAP = subjective, objective, assessment, and plan in the problem-oriented medical record.

[a]However, a letter to a physician with recommendations does *not* mean the plan was implemented! Implementation is only partly addressed.

and identifying MRPs.[7] Medication-related problems can be classified as one of seven types, and they fall into one of four categories: indication, effectiveness, safety, or adherence.

Comprehensive Medication Management

The PCPCC's resource guide for CMM draws directly from and mirrors much of the pharmaceutical care process. It includes assessment as an essential element, together with the key steps that fall under assessment. Assessment also includes identifying and categorizing all of the patient's MRPs for appropriateness, effectiveness, safety, and adherence for each medical condition or preventive therapy. Within these four categories, there are seven specific types of MRPs.[14]

Medication Therapy Management

The MTM process of care includes assessment as a key element primarily through the medication therapy review (MTR).[15] In the MTM process are four major categories (and seven specific types) of MRPs (indication, effectiveness, safety, and compliance), which is similar to the taxonomy used in the pharmaceutical care process of care. MTM does not explicitly use the term *medication experience*, but the components included are similar to those used in the pharmaceutical care process.

Individualized Medication Assessment and Planning

In the *i*MAP assessment process, MRPs are classified into seven broad categories and then further delineated into one of 33 different subcategories, in addition to an "Other" category. This process differs from other processes in which MRPs are not as clearly defined. Although the *i*MAP process does not specifically address the patient's medication experience (a key step), the patient's medication-related needs are evaluated after collecting the relevant information.[16, 17]

SHPA Standards of Practice for Clinical Pharmacy Services

The SHPA standards include the essential element of assessment and all the key steps involved therein.[18] In providing a clinical pharmacy service, clinical pharmacists are to develop a medication management plan (MMP) for each patient. The standards consider the medication action plan (MAP) or pharmaceutical care plan to be synonyms for MMP. The MMP focuses on overall patient outcomes and the many clinical activities to be carried out by the clinical pharmacist in implementing the plan. Patient assessment is a key component within the SHPA practice standards and includes identifying, prioritizing, and managing actual and potential "medicines-related problems." Seven categories of problems are provided that are similar to those used in other processes, in addition to a category designated "nonclassifiable." Although the terminology used by SHPA is slightly different, we refer to "medicines-related problems" as MRP in this paper. The SHPA standards provide explicit procedures for carrying out each activity. Although the MMP does not use the term *medication experience*, it describes a process that generally encompasses the many elements of assessing the patient's medication experience.

Essential Element II: Develop a Plan of Care

Pharmaceutical Care

Medication management under pharmaceutical care includes the essential element of developing a plan of care as well as the key steps of establishing goals of therapy, developing a plan to resolve MRPs, and developing a follow-up plan.[7] Nine types of interventions or resolutions can occur through these steps.

Comprehensive Medication Management

The CMM process includes developing an individualized care plan, in collaboration with the patient and other members of the patient's health care team, as a key element as well as establishing goals of therapy, developing a care plan to resolve MRPs, and conducting follow-up evaluations to determine actual patient outcomes.[14] Developing a care plan to meet patient needs includes identifying the therapeutic changes necessary to achieve optimal outcomes and conducting follow-up evaluations to determine the effects of the changes on patient outcomes.

Medication Therapy Management

The MTM process includes the essential element of developing a plan, as well as the three key steps (Table 1), but it adds another dimension to the process.[15] In addition to the practitioner's care plan, the patient receives a plan to follow (the MAP). Development of the practi-

tioner's plan occurs as part of the MTR. In contrast, the MAP, which is intended for patient use, contains an individualized list of actions for self-management that have been agreed on by the patient's physician. Because the MAP is different from the therapeutic plan developed as part of the MTR, it should be written in language the patient can understand and should contain action steps to be completed by the patient. The MAP should also contain space for the patient to include his or her accomplishments and the timeframe in which each action was completed. Information regarding the patient's next follow-up appointment with the pharmacist can also be included as part of the MAP.

Individualized Medication Assessment and Planning

One step (step 4) in the *i*MAP process pertains to the essential element of developing a plan ("formulate assessment/propose plan to optimize medication use").[16, 17] When developing the plan for implementation or discussion with the provider, the drug therapy recommendations to resolve the MRPs may be classified into 20 different categories. The categories appropriately classify most of the recommendations clinical pharmacists provide or implement, whereas other processes do not have as many category choices. The last category is essentially a miscellaneous category for recommendations not otherwise classified. Establishing goals of therapy and developing a follow-up plan are not explicitly mentioned in the *i*MAP process.

SHPA Standards of Practice for Clinical Pharmacy Services

The SHPA standards include the essential element of developing a plan and include the key steps of establishing goals and developing a plan.[18] Although developing a follow-up plan is not explicitly stated, it is included in the clinical review step of evaluating response to therapy. Four categories of pharmacist resolution of MRPs are provided, as well as a category of "no recommendation necessary."

Essential Element III: Implement the Plan

Pharmaceutical Care

Medication management within the practice of pharmaceutical care involves implementation as a key element, and the key steps of communication and documentation are within this element.[7] Plan implementation can be carried out directly by the pharmacist or with involvement of the prescriber (with or without a collaborative practice agreement). Depending on the setting, the pharmacist may or may not have face-to-face contact with the patient's physician, and the physician may be difficult to reach by telephone during every encounter. Nevertheless, this element includes a description of the pharmacist's documentation and communication, both to the patient and to the physician. Moreover, this element contains detailed recommendations on the type of documentation system necessary in the medication management process.

Comprehensive Medication Management

Plan implementation is incorporated into the CMM model by addressing and acting on specific items in the collaborative care plan.[14] Medication management cannot be done effectively unless all the patient's providers are informed and care is coordinated with the team. Specific guidelines outline the essential components of documentation that support the process of CMM in the PCMH.

Medication Therapy Management

The MTM process addresses the essential element of plan implementation including communication and documentation in the MAP, development of a personal medication record (PMR), pharmacist intervention and/or referral, and follow-up.[15] The patient implements the plan detailed in the MAP, as it is his or her personal document. However, the provision of evidence by the pharmacist for implementation of the plan is a key step that is missing. To be compensated for MTM services, pharmacists must submit documentation to payers. Several different pharmacist-specific electronic systems are available to facilitate the documentation process, especially with payers.

Individualized Medication Assessment and Planning

Steps 5, 6, 7, and 8 of the *i*MAP process address plan implementation. These steps delineate the basic processes for implementing a drug therapy plan that include communicating the plan to the primary care provider, reaching consensus

with the provider, and implementing the plan. Alternatively, some steps may be modified if the pharmacist is working under a collaborative drug therapy management agreement or other scope of practice privileging arrangement. Under these circumstances, the plan may be communicated to the provider through the medical record including notification of any medication changes that were made. Educating the patient and documenting the plan (both to the patient and in the medical record) are included.[16, 17]

SHPA Standards of Practice for Clinical Pharmacy Services

The SHPA standards include the element of implementing the plan and the key steps of communicating and documenting the plan.[18] Pharmacists should participate in interdisciplinary care planning and collaborate with the prescriber to resolve medication issues (i.e., implement the plan). The pharmacist communicates recommendations to the prescriber through this collaboration. However, communicating recommendations do not ensure that those recommendations will be implemented. The SHPA standards also include detailed requirements for documenting patient-specific clinical pharmacist activities including medication reconciliation, plan for management of clinical problems and attainment of therapeutic goals, actual or potential MRPs, and recommendations for management of MRPs. In addition, documentation of pharmacist interventions is also recommended including MRPs identified, level of risk, recommendations to resolve problems, and the category of action taken. There are five categories of possible actions and one category of "unknown at the time."

Essential Element IV: Evaluate the Outcomes of the Plan

Pharmaceutical Care

Pharmaceutical care includes the essential element of evaluating plan outcomes including the critical key steps of monitoring and follow-up.[7] Evaluation is achieved by subjective and objective monitoring, by asking the patient and/or reviewing/checking laboratory results and other data. During follow-up evaluations, each health condition is classified into one of eight outcome categories.

Comprehensive Medication Management

Comprehensive medication management relies on follow-up evaluations to determine actual patient outcomes. The patient is evaluated on an ongoing basis to determine whether appropriate outcomes are being achieved and/or maintained.[14] Care is coordinated with the team, which is particularly important during care transitions (e.g., during hospital admission and discharge).

Medication Therapy Management

The MTM process addresses plan evaluation, monitoring, and follow-up during the MTR and documentation/follow-up steps.[15] A follow-up MTM visit is recommended depending on a patient's medication-related needs and when the patient undergoes a transition of care. In the latter scenario, the pharmacist responsible for conducting the initial MTM visit with the patient may need to work with another pharmacist who is located in the patient's current care setting to ensure the continuity of MTM services.

Individualized Medication Assessment and Planning

The final two steps in the *i*MAP model focus on plan evaluation and include monitoring and follow-up.[16, 17] These steps involve the monitoring of laboratory results or other objective data as well as the provision of a direct follow-up with the patient. Together with the subjective information provided by the patient, the pharmacist determines what, if any, adjustments need to be made to the plan.

SHPA Standards of Practice for Clinical Pharmacy Services

The SHPA standards include plan evaluation as a part of the MMP step that involves monitoring patient outcomes to determine if goals are achieved.[18] In addition, there is a step included to modify goals when outcomes are not achieved, but other follow-up steps are not explicitly stated. Nevertheless, monitoring is intended to be patient focused and related to the clinical problems identified. As articulated by the standards, the medication use process/plan is ongoing; thus care is intended to be continuous.

Summary of Published Patient Care Processes

After reviewing the published clinical pharmacy patient care processes, it is evident that

most of them contain most, if not all, of the proposed essential elements: assess the patient and his or her medication therapy, develop a plan of care, implement the plan, and evaluate the outcomes of the plan. Three of the four processes do not use the term *medication experience* (MTM, *i*MAP, SHPA), but they do describe a similar consideration within their respective steps of care. Implementing the plan a critical element of the care process is not explicitly described as a component of MTM when physician involvement is necessary. Although the process includes sending a formal communication to the provider, this step does not ensure the plan is implemented. Yet without this implementation step, the outcome of any care process is uncertain.

Applicability of Current Processes Across Clinical Practice Settings

Ideally, clinical pharmacists should be able to use a single comprehensive process of patient care that includes the four essential elements and is flexible enough to be applied in any clinical practice setting or type of practice. Toward that end, we review the potential application of published patient care processes across different clinical practice settings.

Pharmaceutical Care

The concept of pharmaceutical care was introduced more than 20 years ago and is widely recognized within the pharmacy profession. The medication management described as part of the pharmaceutical care process is comprehensive and systematic. It includes the necessary key elements, and the pharmacist takes responsibility for the outcomes pertaining to a patient's medication-related needs. Detailed descriptions of the process and its outcomes are available in textbooks,[7] but they have not been published in the biomedical literature. Therefore, the specifics of the pharmaceutical care process are not readily accessible to all practitioners and providers.

Pharmaceutical care practice is usually used in primary care practices, although it is proposed to be applicable to all patient care settings including hospitals and long-term care facilities. It is described as a generalist practice but can be applied in specialist practice as well. As currently used, this process of care is most often observed in independent practice and is less common in collaborative practices with physicians and other health professionals.

Comprehensive Medication Management

The CMM process can also be applied to various practice settings. However, it was designed for use in the PCMH and other collaborative outpatient primary care settings.[14] The process can be implemented outside the office or clinic setting, such as in a community pharmacy, within a health plan, or in the institutional environment. In addition, because face-to-face contact is not required in this model, telephonic or "virtual" interactions with patients and health care professionals are acceptable. This flexibility regarding how communication can take place allows the involvement of clinical pharmacists who may be at distant locations and obviates the need to place a clinical pharmacist physically within every practice locale.

When a prescriber identifies a patient in need of CMM, a referral is made to the qualified medication management practitioner. In many practices, the CMM practitioner is engaged by the PCMH as either a full-time or a part-time employee. Other medication management practices may be established outside the PCMH (associated with a community pharmacy, health plan, or health system), where the referral is made to a non-PCMH employee practitioner. The patient is followed by the CMM practitioner until medication therapy goals are met or until the physician determines CMM is no longer necessary. Comprehensive medication management frequently involves the use of collaborative practice agreements between the physician and the practitioner providing medication management. In the inpatient or specialty setting, CMM may be more difficult to implement in its entirety because of its comprehensive nature. Nonetheless, it can be modified as needed yet still retain the four essential elements.

Medication Therapy Management

The MTM process was developed for application in any health care setting where patients or their caregivers can be actively involved in managing individual medication therapies. Medication therapy management services can be provided in the community pharmacy, in a primary care clinic, within a long-term care facility, or in the institutional setting during admission or discharge. Technically, the provision of MTM

services does not depend on the care setting. However, it does require that an opportunity be provided for the pharmacist to conduct a medication evaluation with the patient.

Although it is preferable for MTM to occur during face-to-face encounters, this service is also frequently provided by telephone. Although the MTM process was developed for use in any clinical setting, two of its core elements, the PMR and the MAP, may have to be omitted in acute care settings when patients are unable to actively participate in their care (e.g., while hospitalized with a very acute or critical illness). In addition, the MTM process does not address the pharmacist's role in providing MTM services when the patient cannot actively participate in his or her own care. Therefore, the MTM process tends to be implemented more often in the community pharmacy or primary care settings.

Individualized Medication Assessment and Planning

To date, *i*MAP has only been studied in a geriatric ambulatory patient population.[17] However, the components of *i*MAP involve the basic processes a clinical pharmacist can use when providing patient care to any patient population. Moreover, this patient care process can be implemented in all types of clinical practice including primary care and acute care settings. The only step that might require modification in an acute care setting involves situations in which a discussion with the patient might not be possible. In these cases, retrieving data solely from other sources such as the medical record, prescription refill history, and/or caregivers or family members would be appropriate.

SHPA Standards of Practice for Clinical Pharmacy Services

This process and set of practice standards is straightforward, flexible, and systematic. The SHPA standards state that the clinical pharmacy activities described can be delivered in many settings and are not restricted to hospital practice alone; however, the designation of a clinical pharmacy service usually relates to a hospital practice.[18] The standards provide more details on institutional practice but are definitely applicable to other practice settings. The components of the MMP and the clinical activities associated with it are familiar to clinical pharmacists. In addition, the SHPA definition of clinical pharmacy practice is closely aligned with ACCP's definition. However, the standards may not be widely recognized by health care professionals or payers in the United States.

Evidence Supporting Processes of Care

Although many publications evaluate outcomes related to clinical pharmacy services, it is difficult to determine what process of patient care was used in most of these studies. Inconsistent terminology and definitions of "medication therapy management," "pharmaceutical care," "comprehensive medication management," and "clinical pharmacy practice" are used. Many studies state that an MTM service was evaluated. However, a close review of the study reveals that some other process of care or clinical service was evaluated or that the precise care process was not adequately described. Older studies usually call the process of care "pharmaceutical care," whereas newer studies often label the process "medication therapy management," reflecting the terms in vogue when the research was conducted. However, although the actual processes studied involved components of clinical pharmacy practice, they frequently did not fully meet the criteria for any defined process of care. Furthermore, no clinical studies exist that compare different processes of care. Therefore, it cannot be determined whether a particular process is responsible for improved patient outcomes, nor can it be determined whether one process is associated with better outcomes than another.

Pharmaceutical Care

One report described the outcomes of an "MTM" service.[19] However, the service provided in this study was actually a pharmaceutical care practice because all providers first received training in pharmaceutical care, and the practice was described as the collaborative practice of pharmaceutical care. Although the background of the study described what a patient care process should include (assess the patient, identify MRPs, develop a care plan, and perform a follow-up evaluation), the study did not describe the specific process of care the pharmacists followed, other than "MTM." Nonetheless, pharmacists in the study did identify, categorize, and resolve MRPs, identify goals of therapy, determine whether goals were being met, and document the information. Moreover, the study compared preintervention data with those

obtained postintervention. At study conclusion, 637 MRPs in 285 patients had been resolved (2.2 per patient). In addition, this study showed that the percentage of patients meeting their goals of therapy increased from 76% preintervention to 90% postintervention; moreover, the Healthcare Effectiveness Data and Information Set (HEDIS) measures improved for hypertension (71% vs 59%; p=0.03) and hypercholesterolemia (52% vs 30%; p=0.001). Furthermore, the total expenditure per person significantly decreased by 31.5% postintervention compared with preintervention, and after factoring in the estimated cost of providing these services, the reduction in total yearly health expenditures still exceeded this cost by a factor of 12 to 1.

In another study, the researchers summarized data from 2985 adult patients who received pharmaceutical care.[20] They reported the number of MRPs identified and resolved as well as the estimated improvement in status by virtue of the practitioner's interventions, with 83% of patients reaching a stable or improved status. The estimated health care savings was $1,124,162, which represented a benefit-cost ratio of 2:1. However, this article was descriptive, provided limited specific data, and did not use a comparative group.

Another study described the outcomes from a "pharmaceutical care–based MTM practice" in a population of 9068 adults.[21] The patient care process used in this study included assessment of the patient; performance of a comprehensive medication review; identification, resolution, and prevention of MRPs; formulation of a medication treatment plan; provision of follow-up assessment (including monitoring and evaluating patient's response to therapy); and documentation of the care delivered. *Implementation* in this study was described as collaborating with all members of a patient's care team and communicating with the patient and prescriber. Over 10 years, 38,631 MRPs were identified and addressed. In patients who were not at goal at baseline, clinical status was improved in 55%, was unchanged in 23%, and had worsened in 22%.[21]

Comprehensive Medication Management

We identified one study addressing the impact of team-based care and incorporation of CMM on per capita expenditures, quality performance measures, and resolution of MRPs in the PCMH setting.[22] The essential elements (assessment, plan development, plan implementation, and follow-up evaluation) were included in the care process. Comprehensive medication management in this team-based care environment helped achieve quality performance and control spending growth.

Medication Therapy Management

Although numerous published studies have evaluated the outcomes associated with the provision of MTM services, the investigators' methods must be closely analyzed to determine whether the MTM process was the process of patient care actually studied. Indeed, in many of the studies, the term *medication therapy management* is often used interchangeably with other patient care processes including pharmaceutical care and disease state management. After carefully analyzing the interventions used, we found only a few studies that evaluated the outcomes associated with the MTM process using the previously defined core elements.[15] In one study, which had enrolled employees who were taking at least seven prescription medications, the outcomes of an employer-based MTM program were evaluated.[23] Individuals enrolled in the study were randomized to either the MTM group or the control group (i.e., patients for whom no MTM services were provided). Participants randomized to the MTM group received two face-to-face meetings with a clinical pharmacist. Pharmacist recommendations were either implemented by the patient or communicated to the patient's prescriber through the university's electronic medical record. All employees received a written copy of the MAP. A total of 128 employees completed both of the designated MTM visits and were compared with a similar number of participants in the control group. Overall, pharmacists identified 385 MRPs, which translated into about 3.3 problems per patient. The majority of these MRPs (55%) were classified in the safety category. Most of the recommendations (80%) made to resolve the MRPs suggested a change in medication therapy. During this 1-year study, out-of-pocket costs for patients in the MTM group were significantly reduced compared with baseline. No significant difference in these costs occurred in the control group.

In another study, the clinical and economic outcomes associated with a pharmacist-delivered comprehensive MTM model were evaluated in 13 community pharmacies in rural Mississippi.[24] In this study, the services provided, which were

based on the MTM process of care, were either specialized (focusing on asthma and/or diabetes; delivered by school of pharmacy faculty, community pharmacy residents, or student pharmacists) or general in scope (any patient with at least two chronic medical conditions; delivered by community pharmacists).[15] For the 468 patients enrolled, 1471 MRPs were identified. Most of the MRPs (48–55%) in both the specialized and the generalized MTM cohorts were related to indication (needing additional therapy). After a 2-year period, the patients' therapeutic goals for diabetes (hemoglobin A1C), hypertension (systolic and diastolic blood pressure), dyslipidemia (total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, and triglycerides), and asthma (peak expiratory flow rate) were significantly improved. Use of health care resources was also reduced in both MTM groups, with avoidance of clinic visits and laboratory visits the most common.

Individualized Medication Assessment and Planning

To date, only one study has been published to validate the use of the *i*MAP tool in older patients, and no studies have evaluated its use in actual patient care practice.

SHPA Standards of Practice for Clinical Pharmacy Services

To our knowledge, no published studies have formally evaluated the SHPA standards of practice.

Conclusion and Recommendations

Although several processes of care used by clinical pharmacists have been developed and published, none has been practiced consistently or adopted as the standard by which clinical pharmacists provide direct patient care. Because the outcomes of clinical pharmacist practice are inconsistent and often not reproducible, it is difficult to ascertain the application to real-world practice of the data generated from the studies cited earlier.

In our view, a consistent process of direct patient care that includes the four essential elements identified in Table 1 should be adopted by the clinical pharmacy discipline. This process should be clear, straightforward and intuitive, readily documentable, and applicable to all practice settings. Once adopted, the process should be implemented across practice settings, taught in professional degree programs, integrated into students' clinical rotations, and refined during residency training. In addition, we believe that embracing a consistent, reproducible, and transferrable process of care is needed to establish a foundation for future large-scale studies that rigorously study the effects of the clinical pharmacist on patients' medication-related outcomes. These data will be critical to validating the need for clinical pharmacists as members of health care teams in the future.

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