Voting Review of Draft Report
National Voluntary Consensus Standards for
Therapeutic Drug Management Quality

On March 13, 2008 NQF Member primary contacts were sent voting instructions for the draft report National Voluntary Consensus Standards for Therapeutic Drug Management Quality Practices.

Voting closes Friday, April 11, 2008 at 6 p.m. EDT – no exceptions.

All voting is by electronic submission only.

Revised voting documents

The voting draft document, including a cover memo, the redlined report, practice specifications, and references, is available for review here.

The voting draft has been revised based on the comments received during the review period and consultation with the Steering Committees.

Access the comment letters received here.

A table of the comments received and the actions taken may be accessed here.

Access the timeline for consideration here.

Access a sample ballot (for Member internal use only) here. **No hard copy ballots will be accepted or counted.**

This project is being conducted under NQF's Consensus Development Process v 1.8.

Notice to Members: Electronic Balloting

Only designated member representatives have been authorized to access the electronic balloting system; if you have questions about the electronic balloting system, please contact your organization's designated member representative.

Member Representatives: Click Here to Access Online Balloting (requires unique ID and password provided by NQF)

In addition, please forward any comments you want to submit with your ballot to votingcomments@qualityforum.org, *Attn: "Drug Management Quality"* using the comment submission form, by Friday, **April 11, 2008 at 6:00 p.m. EDT.**

THE NATIONAL QUALITY FORUM

A NATIONAL FRAMEWORK AND PREFERRED PRACTICES FOR THERAPEUTIC DRUG MANAGEMENT QUALITY MEASUREMENT AND REPORTING

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A NATIONAL FRAMEWORK AND PREFERRED PRACTICES FOR THERAPEUTIC DRUG MANAGEMENT QUALITY MEASUREMENT AND REPORTING

CHAPTER 1

FRAMEWORK FOR THERAPEUTIC DRUG MANAGEMENT QUALITY

INTRODUCTION

Despite substantial advances in pharmaceutical science and subsequent improvements in outcomes for patients with many conditions, problems of effective and efficient medication selection and monitoring, patient adherence, medication safety, and system coordination present significant barriers to optimal outcomes intended for medication therapy.

More than 40 percent of Americans take at least one prescription drug, and 16 percent take at least three. Nearly 90 percent of Medicare beneficiaries report taking prescription medicines, and nearly half of those individuals use five or more different medications.[1] With such a high prevalence of the population using medications, there are many opportunities for misuse, overuse and underuse of medications, which may either render the medications ineffective or expose patients to increased risk of adverse events. Twenty-two percent of hospitalizations have been attributed to patient non-adherence.[2] Studies indicate that between 14 and 23 percent of elderly patients receive inappropriate medications and up to 40 percent of patients do not take their medications as prescribed[3,4,5,6]. Adverse drug events contribute to 2.5% of emergency department visits for unintentional injuries and 0.6% for all visits.[7] Medications that are ineffective, clinically inappropriate, or cause an adverse event lead to wasted and additional

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[1] Bedell SE, Jabbour S., Golbert R, et al. Discrepancies in the use of medications. *Arch Int Med:* 2000; 160(14):2129 – 2134.

[2] Stagnitti MN. Trends in outpatient prescription drug utilization and expenditures: *1997 – 2000* – Statistical Brief #1. Rockville, MD: Agency for Healthcare Research and Quality; July 2003.

[3] Aparasu R, Mort J. Inappropriate prescribing for the elderly: Beers criteria-based review. *Ann Pharmacother* 2000; 34:338-46.

[4] Stuck A, Beers M, Steiner A et al. Inappropriate medication use in the community-residing older persons. *Arch Intern Med* 1994;154:2195-2200.

[5] Chrischilles E, Segar E, Wallace R. Self-reported adverse drug reactions and related resource use: A study of community-dwelling person 65 years of age and older. *Ann Intern Med* 1992;117:634-40.

[6] Bond W, Hussar D. Detection methods and strategies for improving medication compliance. *Am J Hosp Pharm* 1991;48:1978-88.

[7] Butdnitz DS, Pollock DA, et al. National surveillance of emergency department visits for outpatient adverse drug events. JAMA 2006;296:1858-1866.

treatment costs, increased emergency department visits and hospital admissions, and may result in patient morbidity and mortality.

The profession of pharmacy is integral to the delivery of appropriate drug therapy and drug therapy management. An increased awareness of the lack of coordination of care among providers, including pharmacists, an increase in adverse drug reactions, and the passage of the Medicare Modernization Act of 2003 and the Medicare Prescription Medication Benefit (Part D) have prompted calls for an enhanced role for pharmacists in ensuring effective drug use and patient safety. This enhanced role for pharmacists may require some changes in the views of the pharmacists' role, responsibilities and contributions to the medication management process. The specific role of the pharmacist in therapeutic drug management and coordination with other providers and the patient is the focus of this report.

Pharmacists are in ~~the best~~ an important position to lead a wide range of therapeutic drug management activities, such as generic drug programs, education to increase medication adherence, identification of potentially inappropriate medications, and medication review with patients. Clearly, there is the need to measure the quality of therapeutic drug management to establish baseline performance and monitor improvement over time as efforts to improve the quality of therapeutic drug management gain momentum. Furthermore, there is the need to recognize pharmacists as health care providers for the purpose of practice liability and billing.

In 2005 NQF hosted an invitational workshop to address the need for a coordinated, national action plan to improve consumer use of prescription medications. The Workshop Proceedings, "Improving Use of Prescription Medications: A National Action Plan" offered three major recommendations[8]:

- Data and measurement. Identify and implement a standardized set of measures that uses existing data to measure provider performance, drawing on the wealth of information available from pharmacies, PBM organizations, state Medicaid agencies, and other available sources. Promote the sharing of those data with pharmacists, physicians, and other prescribers in order to facilitate the evaluation and improvement of patient adherence.

[8] National Quality Forum. *Improving Use of Prescription Medications: A National Action Plan*. Washington, D.C.: National Quality Forum, 2005.

- Practices for Healthcare Providers. Evaluate and identify a set of practices for improving medication use adherence that healthcare providers at the individual and organization levels can use and that addresses medication use over the continuum of care. The set should include practices that apply to all patients and those that address the additional needs of populations that face challenges in understanding healthcare information, such as those with LEP, limited literacy, and/or cognitive impairments, as well as other vulnerable or high-risk populations. Goals for improvement in a set of provider-focused practices should include facilitating care coordination; improving written information and verbal communication; routinely assessing patient adherence; providing tools patients can use to take charge of their own care; and addressing poor adherence resulting from cost/access issues.
- Stakeholder engagement. Engage a broad array of stakeholders, including consumers, pharmacies, provider organizations, purchasers, policymakers, pharmaceutical manufacturers, and IT vendors, in developing and implementing strategies to improve adherence. Establish a case for each respective stakeholder that emphasizes how improving medication adherence meets its established needs and interests. Implement system-level changes through a combination of policy and purchasing strategies that will support and facilitate action by all involved stakeholders to improve medication adherence.

The national action plan promotes evidence-based metrics and practices for medication use. As the field of performance and quality measurement has advanced, measures have emerged addressing medication use for specific clinical areas, conditions, or circumstances, largely related to prescribing and monitoring. Despite a recent surge in the interest in the quality of therapeutic drug management, an urgent need exists for a comprehensive approach for measurement of the activities and services related to effective therapeutic drug management that can drive improvements in the near future.

Given the sense of urgency for standardization across the continuum of therapeutic drug management, the National Quality Forum (NQF) began a project, *'National Voluntary Consensus Standards for the Reporting of Therapeutic Drug Management Quality'* in June 2006 to identify a national framework, preferred practices, and a set of measures to evaluate and report therapeutic drug management. The framework for therapeutic drug management quality

measurement and reporting, based on the medication use process, sets priorities in this area and establishes principles to guide the development and use of measures for therapeutic drug management quality by pharmacists, physicians and other health professionals.

FRAMEWORK FOR THERAPEUTIC DRUG MANAGEMENT QUALITY MEASUREMENT AND REPORTING

Identifying the Framework

A Steering Committee (appendix C) guided the development of the framework relying heavily on two preliminary activities – a commissioned paper, "*A Comprehensive Framework for Measuring the Quality of Therapeutic Drug Managemen*t" (appendix A) and a workshop on "Building a Framework for Measuring Therapeutic Drug Quality" in December 2006 (appendix B).

Purpose of the Framework

The framework establishes a conceptual model to identify and organize NQF-endorsed™ preferred practices and performance measures based on a set of therapeutic drug management domains and subdomains within the context of national priorities and goals. The framework also serves as the basis to assess what is currently available and to identify areas where gaps in practices and measures exist. Guided by the framework, a set of preferred practices and measures should provide comprehensive evaluation and reporting tools to ensure that therapeutic drug management meets the Institute of Medicine's six aims—care that is safe, effective, timely, patient-centered, efficient, and equitable.

Guiding Principles

Nine guiding principles for Therapeutic Drug Management (TDM) quality measurement and reporting establish the framework as a basis for identifying measures and preferred practices. The principles include standards for measurement that have been established by the National Quality Forum to apply to all endorsed consensus standards, as well as guiding principles specific to Therapeutic Drug Management quality measurement and reporting.

Principle 1: Domains

This conceptual framework for TDM specifies five essential areas, based on the micro level of the drug use process, where quality can be measured. A comprehensive set of TDM practices and measures should address each of these domains. Given the overlapping components and activities, the five domains are not mutually exclusive.

Domain 1: Therapeutic decision-making. This domain encompasses services and evidence-based medication therapy decisions related to patient assessment and diagnosis, medication selection, prescribing and patient monitoring; includes appropriateness and optimization of medication selection, regimen, dosage and dosing.

Domain 2: Safe medication use. This domain encompasses safe medication use and the prevention and avoidance of medication errors, adverse drug events, adverse drug reactions, and drug interactions through safe medication prescribing, dispensing and administration.

Domain 3: Medication adherence and education. This domain involves the availability, adequacy, use, understanding, and documentation of patient education with respect to knowledge about their medications and their medication use behaviors; also includes behavior healthcare professionals engage in to promote adherence, including education and counseling.

Domain 4: Efficiency. Using the definition from the NQF Priorities and Goals report, Efficiency is defined as a measurement construct of cost of care or resource utilization associated with a specified level of quality of care, where cost of care is defined as a construct characterizing the resources used to deliver a service or set of services, and quality of care is defined as a construct of pure benefit that is multidimensional and is characterized by care that is safe, timely, effective, efficient, equitable and patient centered (taken from the AQA Principles of Efficiency Measures. See http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)

~~Efficiency of care is defined as a measurement construct of cost of care or resource utilization associated with a specified level of quality of care. Cost of care is a construct characterizing the resources used to deliver a service or set of services; Quality of care is a construct of pure benefit that is multidimensional and is characterized by care that is safe, timely, effective, efficient, equitable and patient centered (taken from the AQA Principles of Efficiency Measures).~~
~~See http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril 2006.doc~~
~~A process that operates effectively while consuming a minimum amount of resources and maintaining quality of care;~~
Additionally, this domain ~~is more~~ can be population-based and may also apply to the subpopulation or individual patient levels. It specifically includes ~~cost–~~clinical effectiveness and value analysis, i.e., the comparison of medication benefits and costs, as well as formulary management, benefit designs, and related institutional and organizational policies.

Domain 5: System coordination and communication. This broad domain includes the documentation, reporting, coordination and communication of therapeutic drug management quality activities as related to the other domains. This domain specifically includes the role of technology, including health information technology, as a critical resource to drive system coordination.

Principle 2: <u>Subdomains</u>

Within the domains listed above, subdomains or subcategories of TDM activities and services have been identified to provide further guidance for the identification of preferred practices and performance measures for TDM. For some domains, there are certain primary subdomains that are highly associated with that domain; however, a domain may also have secondary, applicable subdomains. Table 1-1 shows a "crosswalk" between the domains and the subdomains.

Subdomain 1: Medication selection. This subdomain includes the use of guidelines and scientific evidence base in selecting appropriate medications, based on patient assessment, comprehensive patient review, and diagnosis, while avoiding contraindications, duplicative therapy, and drug interactions.

Subdomain 2: Medication use monitoring. This subdomain includes the ongoing collection and analysis of information (observations; test results) and comparison to baseline data to ascertain patient's response, detect any complications or adverse consequences, support decisions to modify therapy.

Subdomain 3: Provider documentation. This subdomain includes the placement or recording of data and information in a retrievable form, including electronically accessible and written formats.

Subdomain 4: Medication reconciliation. This subdomain includes the process of comparing the medications a person provided and/or taking across settings and/or providers (IOM 2006, modified).

Subdomain 5: Patient engagement and communication. This subdomain includes counseling, advising, instructions, and discussions with the patient or caregiver about the prescribed medication regimen.

Subdomain 6: Medication adherence promotion. This subdomain includes the support and promotion of the appropriate and timely filling of prescription orders and use/consumption of prescribed medications.

Subdomain 7: Preventing adverse drug events (ADE), includes medication errors and adverse drug reactions, drug interactions, drug duplications, and the avoidance of high alert medications. This subdomain includes the avoidance of an event in which there is the potential for injury or unintended harm to the patient due to medication errors (commission or omission); also includes the prevention of adverse drug events and special attention directed to the management of situations involving the use of high alert medications.

Subdomain 8: Processing medication orders. This subdomain includes the range of activities that include receipt of medication orders, and the handling, providing, storage, labeling and disposal of the medication product.

Subdomain 9: Maximizing efficiency. This subdomain includes the promotion of rational drug therapy that maximizes benefit and quality of care while considering the utilization of only necessary resources. ~~utilizing the least amount of resources necessary~~.

Subdomain 10: Formulary system management. This subdomain includes the management of an ongoing process through which a healthcare organization establishes policies and procedures on the use of medications, therapies, related products and information.

Subdomain 11: Drug utilization reviews (population based). This subdomain includes systematic, population-based review of medication utilization patterns and trends.

Subdomain 12: Communication and coordination among providers. This subdomain includes the exchanging and sharing of information among providers; collaboration, facilitating transfer across care settings.

Subdomain 13: Use of technology. This subdomain includes information, dispensing and care coordination technologies.

Table 1-1. Therapeutic Drug Management Domains and Subdomains

	DOMAIN				
Subdomain	**Decision-Making**	**Safe Medication Use**	**Education and Adherence**	**Efficiency**	**System Coordination and Communication**
Medication Selection	√	√		√	
Medication Use Monitoring	√	√	√		
Provider Documentation	√	√			√
Medication Reconciliation	√	√			√
Patient Engagement and Communication		√	√	√	
Medication Adherence Promotion		√	√		
Preventing Adverse Drug Events		√			
Processing Medication Orders		√		√	
Maximizing Efficiency				√	
Formulary System Management				√	
Drug Utilization Reviews				√	
Communication and Coordination		√			√
Use of Technology	√	√	√	√	√

Principle 3: Priorities for Infrastructure, Cross-Cutting Areas, and Conditions:

The set of measures and preferred practices for therapeutic drug management should address NQF-endorsed priority areas, which include the 20 Institute of Medicine Priority Areas and two additional infrastructure areas identified by NQF (Table 1-2). These priorities highlight the importance of a healthcare infrastructure that supports patient safety and advances the incorporation of information technology. Priorities for cross-cutting areas, including care coordination and self-management/health literacy emphasize the importance that measures and practices are patient-centered. While preference should be given to measures and practices that apply to all or a variety of conditions, the priority healthcare conditions provide a starting point for identification of condition-specific measures. These conditions are chosen because they are high risk, high volume, and/or high cost problem areas.

Table 1-2. NQF-Endorsed™ Priority Areas

NQF INFRA-STRUCTURE ISSUES	IOM CROSS-CUTTING AREAS	IOM HEALTHCARE CONDITIONS
• Information technology • Patient safety	• Care Coordination and communication • Care at the end of life • Immunizations • Pain Management • Self-management/ health literacy	• Asthma • Cancer • Pneumonia • Depression • Diabetes • Children with Special Healthcare needs • Frailty associated with old age • Hypertension • Ischemic heart disease • Kidney Disease • Mental Illness • Obesity • Pregnancy, childbirth, newborn care • Stroke • Tobacco Dependence

Principle 4: Content of the Sets of Measures and Practices:

The sets of TDM measures and practices should include measures and practices that:

- address each of the IOM six aims for quality improvement: safe, effective, efficient, timely, equitable, and patient-centered;

- address therapeutics, including FDA approved medications (prescription and non-prescription), biologics, supplements and herbal remedies;
- apply to all populations, with consideration for disparities reduction; and
- apply across the full continuum of care.

Principle 5: Standardization

Standardization of the measures used for TDM quality measurement and reporting is critical. NQF should promote standardization of the measures used for TDM performance measurement and reporting by identifying a parsimonious set of measures in this area and encourage measure developers with similar measures to harmonize specifications.

Principle 6: Evaluation Criteria for Inclusion in the Set of Measures and Practices

Measures within the scope of TDM should be evaluated for inclusion using the NQF-endorsed™ standardized criteria (see Chapter 3). ***Preferred practices*** should be evaluated for inclusion using the NQF criteria for preferred practices (see Chapter 2).

Principle 7: Accountability

Measures and practices for TDM should be appropriate for public reporting. NQF has made a commitment to endorse measures and practices that fulfill standards for accountability. While measures must be appropriate for public reporting, they can also be used for quality improvement purposes.

Principle 8: Emphasis on Outcomes

Measures and practices should reflect an emphasis on maximizing healthcare outcomes for the patient. Evidence should indicate that process measures are strongly related to improved outcomes. Outcomes should include the targeted clinical indicator, as well as patient satisfaction, and patient quality of life.

Principle 9: Focus on measures and practices that apply to all settings and providers

Many patients have multiple chronic conditions, and see several providers in a range of settings for their care. In order to improve outcomes for these patients, it is necessary to employ a

patient-centered approach that focuses on improving care for the patient regardless of where they receive that care and from whom.

Definitions

Therapeutic Drug Management : A service or group of services that optimize therapeutic outcomes for individual patients to help ensure that the goals of drug therapy are achieved (IOM, 2006 [1]); a complex set of practices that includes medication-related assessment; guideline/treatment plan decisionmaking and adherence; cost-effective, value-based product selection; dispensing and administration; supporting patient adherence; patient education and training; monitoring and evaluating outcomes; identifying, resolving and preventing drug-related problems; documentation, coordination and communication of treatment.[2,3,4]

Medication : includes any prescription medications; sample medications; herbal remedies; vitamins; nutriceuticals; over-the-counter drugs; vaccines; diagnostic and contrast agents used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions; radioactive medications; respiratory therapy treatments; parenteral nutrition; blood derivatives; intravenous solutions (plain, with electrolytes and/or drugs); and any product designated by the Food and Drug Administration (FDA) as a drug. This definition of medication does not include enteral nutrition solutions, which are considered food products, oxygen, and other medical gases (Joint Commission, 2006 [5]).

[1] Institute of Medicine, Preventing Medication Errors. Washington, DC: National Academies Press, 2006.
[2] Academy of Managed Care Pharmacy, the American Association of Colleges of Pharmacy, the American College of Apothecaries, the American College of Clinical Pharmacy, the American Society of Consultant Pharmacists, the American Pharmacists Association, the American Society of Health-System Pharmacists, the National Association of Boards of Pharmacy, the National Association of Chain Drug Stores, the National Community Pharmacists Association, and the National Council of State Pharmacy Association Executives. Available at www.aacp.org/Docs/MainNavigation/Resources/6308_MTMServicesDefinitionandProgramCriteria27-Jul-04.pdf
[3] Bluml, BM. Definiton of medication therapy management: development of professionwide consensus. J Am Pharm Assoc. 2005; 45:566-72.
[4] See description of Pharmaceutical Care, available at http://www.managingmedicines.com/resources.php/page=glossary
[5] Joint Commission 2007 Patient Safety Goals. Available at www.jointcommission.org.

CHAPTER 2

PREFERRED PRACTICES FOR THERAPEUTIC DRUG MANAGEMENT

INTRODUCTION

Therapeutic drug management occurred across the entire spectrum of healthcare delivery and involves multiple providers and settings of care. The purpose of measures and preferred practices for therapeutic drug management quality is to:

- improve the quality of therapeutic drug or medication use, and therefore achieve positive patient outcomes (clinical, humanistic and economic) through safe and effective medication use;
- ensure that medications are provided to individuals who need them in a safe, effective, patient-centered, timely , efficient, and equitable manner, as defined by the IOM's six quality aims;
- provide guidance for therapeutic drug management quality by identifying the core elements and components that can be used by providers, purchasers, and consumers in making decisions about medication use; and
- serve as the basis for quality measures, or the development of quality measures, that can be used for public accountability.

Additionally, measures and practices in the set should apply to:

- FDA approved medications (prescription, non-prescription, both over-the-counter, and behind-the-counter ~~and over the counter medications~~), biologics, supplements and herbal remedies;
- all populations, including children;
- individual and group providers, healthcare organizations and systems; and
- a comprehensive range of activities and settings across the full continuum of care.

Existing performance measures tend to be narrowly focused on medication use for specific clinical conditions or issues. Since measures do not exist to address comprehensive therapeutic drug management, a set of evidence-based preferred practices can serve as the building blocks

for promoting high quality therapeutic drug management across many practice settings and can serve as the basis for developing performance measures.

The project Steering Committee and Technical Advisory Panels (appendix C) have recommended a set of 20 preferred practices that are suitable for implementation for therapeutic drug management quality. The preferred practices address the framework domains of therapeutic decision-making, safe medication use, adherence and education, efficiency, and system coordination and communication. Many of these practices are based on published studies, or widely-accepted experiential or consensus information. These practices were evaluated based on the NQF criteria specified in NQF's 2003 report *Safe Practices for Better Healthcare*: evidence of effectiveness, generalizability, benefit, and readiness (Box A).

Box A – Criteria for Evaluation of Practices

Evidence of Effectiveness
There must be clear evidence that the practice (if appropriately implemented) would be effective in improving outcomes (e.g., reduced substance use). Evidence may take various forms, including:

- research studies (syntheses) showing a direct connection between the practice and improved clinical outcomes;
- experiential data (including broad expert agreement, widespread opinion, or professional consensus) showing the practice is "obviously beneficial" or self-evident (i.e., the practice absolutely forces an improvement to occur) or organization or program data linking the practice to improved outcomes; or
- research findings or experiential data from other healthcare or non-healthcare settings that should be substantially transferable.

Generalizability
The practice must be able to be utilized in multiple applicable clinical care settings (e.g., a variety of

inpatient and/or outpatient settings) and/or for multiple types of patients.

Benefit
If the practice (determined to be effective) were more widely utilized, it would improve or increase the likelihood of improving patient outcomes (e.g., improved patient function). If an effective practice already is in near universal use, its endorsement would lead to little new benefit to patients.

Readiness
The necessary technology and appropriately skilled staff must be available to most healthcare organizations. For this project, opportunity for measurement also was a consideration.

Specificity
The practice must be a clearly and precisely defined process or manner of providing healthcare service. For this project, specificity was not a threshold criterion; rather, specifications were identified as a result of the evaluation process. The target outcome for the practice was identified and, to the extent possible, additional specifications of what the practice entailed, for whom it was indicated, by whom it should be performed, and where (setting) it should be implemented were identified.

Preferred Practices For Therapeutic Drug Management

Domain 1. Therapeutic Decision-making (DM)

This domain primarily encompasses services and evidence-based medication therapy decisions related to patient assessment and diagnosis, medication selection, prescribing and patient monitoring. This includes appropriateness and optimization of medication selection, regimen, dosage and dosing. Identified practices in this area are not condition specific, but instead point to services that should be included in therapeutic decision-making regardless of the condition or setting.

Primary Sub-domain: Medication selection

Preferred Practice 1. Information and Documentation: Patient assessment and drug selection should include consideration and documentation of patient history, demographics, co-morbidities, assessment of risk benefit balance, allergies, laboratory values, vital signs, measurements and current prescription and non-prescription medications, as well as the patient's education level, health literacy, cultural beliefs and economic access. This should be documented in a format that is electronically available and easily transferable between providers, including pharmacists, and to patients/caregivers.

Rationale: Documentation of patient medication information is essential in providing for communication among health care practitioners. Numerous documentation styles can be used by pharmacists to record pharmacy interventions. From a clinical standpoint, accurate

documentation is essential in preventing future adverse drug events as it serves to warn against drug administration at a particular dosing level and establishes the dosing ranges that are considered unsafe for a particular patient. Medication documentation that is accurate, appropriate, and concise is a key component of ensuring that each patient's course of care is personalized, accounts for patient safety, and also provides documentation for cases where levels of reimbursement and quality of care is being questioned. This documentation should be electronically available and transferable, whenever possible, and should protect patient confidentiality and privacy.

Preferred Practice 2. Patient factors: Therapeutic decision making should include ~~consideration~~ the objective assessment and documentation in the medical recordof patient education level, cultural beliefs, health literacy, native language, and physical and mental capacity, patient preferences, ~~and~~ availability of assistance/support network, ability to make follow-up appointments and pharmaceutical access (affordability, benefit design, and geographic barriers).

Rationale: To the extent possible, providers should consider patient characteristics and preferences when determining treatment plans. Treatment should be appropriately tailored to patient characteristics that might affect adherence, including education level, cultural beliefs, health literacy, primary language, and physical and mental capacity. Considering these characteristics can allow providers to provide patients with appropriate tools to maximize adherence, and subsequently maximize targeted clinical outcomes.

Preferred Practice 3. Indications and diagnoses: Patient assessment and drug selection should include documentation in the medical record of the diagnoses, ~~indications, rationale,~~ intended use and goals for treatment. ~~Indications/d~~ Diagnoses and~~, when appropriate, rationale~~ intended use should be electronically available and easily transferable between providers, including pharmacists, and patients/caregivers. ~~Indications/d D~~iagnoses should be linked within the electronic documentation system to medication regimen.

Rationale: Documentation of ~~indications, rationale,~~ diagnoses, reasons for use and goals for treatment can help other health care professionals involved in the care of a particular patient easily understand the purpose of prescribed treatment. This documentation should be electronically available and transferable, whenever possible, and should protect patient confidentiality and privacy.

Preferred Practice 4. Scientific evidence: Medication selection should be informed by best scientific evidence and clinical guidelines for a given therapeutic area, and individualized for the patient. Prescribers ~~and other providers~~ should document ~~rationale~~ the specific clinical reasons and/or patient preferences resulting in a patient not receiving a recommended medication based on current ~~when therapeutic decision-making goes against~~ guidelines. This information should be electronically available and easily transferable between providers, including pharmacists, and to patients/caregivers.

Rationale: Medication selection that includes consultation of clinical practice guidelines and scientific evidence helps to ensure that patients are prescribed medications that are most likely to benefit them, and that don't expose them to unnecessary risk.

Primary Sub-domain: Medication Use Monitoring

Preferred Practice 5. Patient Monitoring: After medication therapy is prescribed, providers, including the pharmacist, should monitor the patient regularly, based on patient needs and best evidence, for effectiveness, adherence, persistence, ~~prescription filling,~~ and avoidance of adverse events. Information about monitoring should be communicated among providers and to patients and caregivers. The plan for monitoring should be documented in the patient chart, electronically available and easily transferable between providers, including pharmacists, and to patients/caregivers. Electronic systems should generate notices to prescribers and patients/caregivers when any of the monitoring documentation is not present in the record/chart. ~~above criteria are not met~~. (what criteria???)

Rationale: Monitoring medication therapy across all aspects of care for effectiveness and adherence assists in prevention of disease exacerbation, increased health care costs and death.[9] Particularly among patients with chronic conditions, adequate adherence to medication is essential for improvement in disease-specific quality of life and patient satisfaction.[10] Ranges of 30-70% of medication-related hospital admissions are due to poor adherence to medication.[11] In addition to reducing medication benefits, nonadherence can bias the effectiveness of treatment therapies and adversely affect the prognosis of a

[9] Osterberg L, Blaschke T. Drug Therapy: Adherence to Medication. *The New England Journal of Medicine* 2005; 353:487-497.

[10] Murray MD, Young J, Hoke S, et al. Pharmacist Intervention to Improve Adherence in Heart Failure. *Annals of Internal Medicine* 2007; 146:714-725.

[11] Osterberg L, Blaschke T. Drug Therapy: Adherence to Medication. *The New England Journal of Medicine* 2005; 353:487-497.

condition.[12] It is estimated that approximately 50% of patients with chronic illnesses do not take their medication as prescribed; reasons are complex and multifactorial, and include lack of knowledge and support for management of complicated regimes and cost of medications.[13]

Due to the critical nature of medication adherence, it has often been referred to "the key mediator between medical practice and patient outcomes."[14]

Domain 2. Safe Medication Use (SF)

This domain encompasses safe medication use and the prevention and avoidance of medication errors, adverse drug events, adverse drug reactions, and drug interactions through safe medication prescribing, dispensing and administration. This domain also focuses on avoiding inappropriate, high alert or high risk medications, as their use is likely to be preventable. Several NQF-endorsed *Safe Practices* related to medication use also are applicable to this TDM domain.

Primary Sub-domain: Patient engagement and communication

Preferred Practice 6. Side Effects/Adverse Effects: Patients and their caregivers should be instructed how to identify and manage routine side effects, and to know when and whom to contact if they believe they are experiencing any serious adverse effects of drug therapy.

Rationale: An important component of therapeutic drug management is reducing unfavorable outcomes through continuous assessment that includes the prevention, identification, and treatment of adverse drug events. Patients and caregivers play an important role in these assessments. Monitoring for and acting on symptoms of adverse

[12] McDonald HP, Garg AX, Haynes RB. Interventions to Enhance Patient Adherence to Medication Prescriptions. *Journal of the American Medical Association* 2002; 288:2868-2879.

[13] Murray MD, Young J, Hoke S, et al. Pharmacist Intervention to Improve Adherence in Heart Failure. *Annals of Internal Medicine* 2007; 146:714-725.

[14] Kripalani S, Yao X, Haynes RB. Interventions to Enhance Medication Adherence in Chronic Medical Conditions. *Archives of Internal Medicine* 2007; 167:540-550.

and side effects is also important. Improving communications between patients and providers may help prevent adverse drug-related events.

Primary Sub-domain: Processing medication orders

Preferred Practice 7. Proper use and handling: Patients and their caregivers should be routinely informed of the proper use (e.g., with or without food, dose, frequency, special instructions, medication action, and side effects to monitor and when to report them) and administration of medications, as well as the storage and disposal of medications (e.g., refrigeration, protection from heat and light, the use of safety closures, and the proper use of any devices to administer medications).

Rationale: Effective handling of the medication product involves more than drug distribution and dispensing. Verification that patients and caregivers have sufficient understanding about medication products and regimens is likely to produce the best therapy outcomes. Education and counseling sessions should include information on medication storage, preparation and administration, as well as proper medication use, and take into account patient factors that may affect comprehension and adherence.

Primary Sub-domain: Preventing adverse drug events

Preferred Practice 8. Safety CQI: Health care practitioners including pharmacists and healthcare organizations should assure patient safety through a organizational culture of safety and continuous quality improvement process. This includes dedicated responsibility, continuous assessment of and learning from injurious and non-injurious medication errors from internal as well as external sources, and product quality problems.

Rationale: Medication safety is an important component of patient safety. Medication errors and adverse drug events need to be continuously assessed and whenever possible, avoided. This can be done by health care practitioners through continuous quality improvement processes in all health care settings.

Domain 3. Medication Adherence and Education (AE)

This domain involves the availability, adequacy, use, understanding, and documentation of patient education with respect to knowledge about their medications and their medication use

behaviors, such as seeking information, and care. In a patient-centered environment, patient decisions and behaviors impact numerous aspects of the medication use process. This domain recognizes the important role patient medication taking behavior plays in achieving desired outcomes, including clinical and patient satisfaction outcomes, as well as cost savings. The World Health Organization (WHO) estimates only 50% of patients take medications as prescribed, and has identified medication adherence as an urgent health problem world-wide. This domain includes behavior healthcare professionals engage in to promote adherence, including education and counseling. Adherence is an important component of therapeutic drug management, and factors associated with adherence such as health literacy and cultural competence were summarized in a previous NQF paper.[15, 16, 17]

Primary Subdomain: Medication Adherence Promotion

Preferred Practice 9. Dosing: Patients, especially those with multiple chronic conditions, should be prescribed the simplest feasible dosing schedule available, while maintaining the desired total dose and the desired clinical outcome.

Rationale: Simplified dosing schedules have obvious implications for patient adherence to prescribed medication regimes, and subsequently for clinical outcomes targeted by medication regimes. Particularly for patients with chronic conditions, simplified dosing schedules can also improve patient satisfaction and quality of life—by reducing time spent taking, planning for, and being conscious of medication use. Several studies have demonstrated the impact reducing the number of medication doses per day has on adherence[18,19,20,21]

[15] National Quality Forum. Wu HW, Nishimi RY, Kizer KW, eds. Improving use of prescription medications: a national action plan: workshop proceedings. Washington: National Quality Forum, 2005

[16] Vik SA, Maxwell CJ, Hogan DB. Measurement, correlates, and health outcomes of medication adherence among seniors. Ann Pharmacother 2004; 38:303-12

[17] Osterberg L. and Blaschke T. Adherence to medication N Engl J Med 2005; 353:487-497

[18] Kruk ME, Schwalbe N. The relation between intermittent dosing and adherence: Preliminary insights. *Clinical Therapeutics* 2006:28;1989-1995.

[19] Claxton AJ, Cramer J, Pierce C. A systematic review of the associations between dose regimens and medication compliance. *Clinical Therapeutics* 2001:23;1296-1310.

[20] Schedlbauer A, Schroeder K, Peters TJ, et al. Interventions to improve adherence to lipid lowering medication (review). *The Cochrane Library* 2007: Issue 1.

[21] Schroeder K, Fahey T, Ebrahim S. Interventions for improving adherence to treatment in patients with high blood pressure in ambulatory settings (review). *The Cochrane Library* 2007: Issue 1.

Preferred Practice 10. Patient Ability: Assess and document ability of the patient to understand and follow the prescribed medication regimen. This should include assessment of comprehension of reasons for use, details of medication regimen, as well as barriers to adherence, including cost (especially out-of-pocket costs), cognitive, physical and environmental, cultural issues and benefit design barriers. Consider the teach-back method as an assessment mechanism.

Rationale: By assessing potential barriers to medication adherence at treatment initiation, providers can alter the prescribed therapy or provide adherence tools for the patient, and thus maximize clinical and patient satisfaction outcomes. Cost of medications to patients is a critical factor in adherence to prescribed medication therapy. Discussion of cost-related barriers to adherence at treatment initiation can allow providers to suggest alternative therapy or adjust the prescription. This can result in better outcomes for the patient, including improved health outcomes and patient satisfaction. Asking patients to recount, or "teach back," the proposed treatment or procedure is one method providers can use to determine how well patients understand as it requires patients to translate the information into words and concepts they understand thus demonstrating their comprehension and the degree to which their consent is truly informed.

Preferred Practice 11. Adherence Aids: Adherence promoting aids, including blister packs, pill boxes, or memory cues, should be offered to patients.

Rationale: Adherence aids, including reminder packaging, for patients with chronic conditions can improve adherence to medication regimen by reducing time required to take medications and by reducing the chance that a patient will think he or she has already taken a dose or will take a dose twice. Better adherence to medication regimen leads to improvement of targeted clinical outcomes and minimization of adverse events related to overdose.

Domain 4. Efficiency (EF)

The other four TDM domains largely focus on individual patients; this domain is more population-based and includes the issues of cost-effectiveness and value analysis, i.e., the comparison of medication benefits and costs. This domain includes administrative and clinical programs that ultimately affect drug therapy access at the group or population level (e.g.,

formulary models, benefit designs, and related institutional and organizational policies). For these purposes, efficiency is a process that operates effectively while consuming a minimum amount of resources and maintaining quality of care.

Primary Sub-domain: Formulary system management

Preferred Practice 12. Formulary system: Healthcare organizations should have a formulary system that includes interdependent principles related to formulary decisions, policies, procedures, management and education.

The principles are:

1. Formulary system decisions should be based on scientific considerations of safety and efficacy. Economic considerations that achieve appropriate, safe and cost effective drug therapy are also important and may be considered after safety and efficacy are evaluated.
2. The formulary system encompasses drug selection based on scientific review, drug utilization review, and other tools to foster best practices in prescribing, dispensing, administration, consumption, and monitoring of outcomes.
3. The Pharmacy and Therapeutics (P&T) Committee, or equivalent body, comprised of actively practicing physicians, pharmacists, other health care professionals, and a consumer/patient representative is the mechanism for administering and providing oversight of the formulary system, which includes developing and maintaining the formulary and establishing and implementing policies on the use of the drug products.
4. The formulary system must have its own policies, or adhere to other organizational policies, that address conflicts of interest and disclosure by P&T committee members.
5. The formulary system should include educational programs and a communication system for payers, practitioners, and patients concerning their roles and responsibilities.
6. The formulary system should include~~, where possible,~~ a well-defined and easy-to-use process for the physician or other prescriber to use a non-formulary drug when medically indicated.

Rationale: The presence of consensus-based formulary system principles can assist decision-makers who must ~~balance~~ consider the health care quality and cost equation. With the widespread use of medication formularies in a variety of inpatient and outpatient settings, along with the prescription drug benefit for Medicare beneficiaries, there has been increased attention to the appropriate role and management of medication formulary systems.

Primary Sub-domain: Maximizing efficiency

Preferred Practice 13: Lower cost drugs: Lower cost drugs should be considered whenever clinically appropriate and possible, based on the following principles:

1. Communicate with and educate patients and providers on the relative clinical (e.g., safety and efficacy) and economic value of all treatment options, including generics.
2. Communicate with and educate patients on the difference between generic substitution versus therapeutic interchange.
3. Promote selected generic equivalent drugs that have an FDA-designated AB-equivalency rating. ~~except when using narrow-therapeutic index medications and the switching between medications could yield a negative health outcome.~~
4. When ~~possible, implement~~ therapeutic interchange programs are implemented, they should be clearly defined and linked to cost and quality considerations and outcomes. They should be transparent to the patient.
5. In healthcare organizations, the use and evaluation of substitution and interchange programs are linked to considerations of quality, outcomes, and cost.
6. In healthcare organizations, substitution and interchange programs are overseen by the Pharmacy and Therapeutics (P&T) Committee, or equivalent body, and include physician/prescriber approval in the process.
7. When clinically necessary, there is a clearly defined, broadly communicated, and easy to use process for physicians to prescribe and patients to obtain medicines outside of a substitution or interchange program.

Rationale: The use of lower cost drugs, including generic products, available through substitution and interchange programs has been demonstrated to reduce medication costs. Furthermore, substitution and interchange programs in which health care practitioners collaborate and then communicate with patients help provide the best patient care at the most affordable cost.

Preferred Practice 14: Medication options: Patients and providers should be informed of ~~all~~ available therapeutic drug options and their relative costs, effectiveness and safety.

Rationale: Traditionally, patients have been viewed as passive receivers of care who require expert direction from healthcare professionals. However, the active involvement of patients

and caregivers in all aspects of care decision-making is desirable and indicative of patient-centered care. Likewise, providers also have the need to be informed about medication product selection options in order to be an effective resource of such information in the care decision-making process.

Primary Sub-domain: Drug utilization review

Preferred Practice 15: Drug Utilization Review: Comprehensive analyses of patient treatment patterns should be used to evaluate and improve the quality of drug therapy.

Rationale: Increases in prescription drug utilization and expenditures continue to present challenges on how to best manage this aspect of healthcare. Effective strategies include comprehensive analyses of population-based treatment patterns and outcomes which provide useful information for evaluating the value of drug therapy options and improving drug therapy management and the quality of care. With these analyses, health care organizations can utilize strategies and programs to impact the utilization and costs of prescriptions. Using both sound clinical evidence as well as financial data are important aspects of comprehensive drug utilization analyses.

Domain 5. System Coordination and Communication (CC)

This domain involves the documentation, reporting, technology, coordination and communication of therapeutic drug management quality activities related to the other domains, but also involves the issues related to the implementation of the quality measures and practices of the other domains. The use of new technology (e.g., bar-coding, unit-dose medications, and electronic prescribing) can drive improvements in the quality of care. System coordination and communication are especially critical at transition points within the healthcare system when a patient moves between different units in a facility.

Primary Sub-domain: Provider Documentation

Preferred Practice 16: Provider Documentation: There should be a process for accurate and timely documentation of recommendations and actions taken to ensure safe and effective medication management.

Rationale: Documentation in the medical record facilitates diagnosis and treatment, communicates pertinent information to other providers as well as patients and caregivers. Documentation is an essential component to patient care, and the quality of documentation may also reflect the quality of care delivered.

Primary Sub-domain: Communication and coordination among providers

Preferred Practice 17: Patient Medication List: A complete list of the patient's medications, specifying the details of dose, frequency, route, and reason for use, should be maintained up-to-date and communicated electronically for easy access and transferability between all providers involved in the patient's care. This list should be electronically available and follow electronic interoperability standards wherever possible and should be transferable among providers, including pharmacists, and to the patient/caregiver, while maintaining patient privacy and confidentiality.

Rationale: Proper management of a patient's medication therapy is predicated on the availability of complete and accurate information on that therapy. Having a complete list of patient's medications (prescription, non-prescription, herbal and other dietary supplements) that is readily available electronically and easy access and transferability and shared among all providers is an important aspect of patient care.

Preferred Practice 18: Access to Patient Information: Health care practitioners, ~~and~~ including pharmacists have convenient access to, share openly, and use all necessary clinical and patient data [e.g., assessment findings, health screening, results, drug therapy notes, medication-related problems, complications, medication refill rates, and other patient-specific findings]. This information should be electronically available and transferable among providers, including pharmacists, and to patients.

Rationale: Having access to and exchanging patient information is important to the coordination of care among providers. This information sharing should be convenient, accessible, and ideally electronically available and transferable, and such patient information should be kept confidential and private. Every health care interaction depends on effective communication which is then linked to patient satisfaction, adherence to medication recommendation and treatment plans, and health outcomes.

Primary Sub-domain: Medication Reconciliation

Preferred Practice 19: Medication Reconciliation: There is a process for comparing the patient's current medications with those ordered for the patient. And when the patient is unable to actively or fully participate in the medication reconciliation process and has requested assistance from another person, involve the authorized person in the medication reconciliation process. (JCAHO Patient Safety Goals 2007)

Rationale: Experience from hundred of healthcare organizations has shown that poor communication of medical information at transition points of care is a major contributing factor to the occurrence of medication errors and adverse drug events. Each time a patient moves from one setting to another, even within the same organization, clinicians should compare previous medication orders with new orders and new plans for care, and reconcile and differences.

Primary sub-domain: Use of Technology

Preferred Practice 20: Electronic Patient Health Information: There should be a process for electronically sharing relevant patient health information, including medication-related information, among all health systems, health care providers, and patients.

Rationale: There seems to be agreement among health policymakers and industry experts that there are improvements needed in the area of health information technology. There is a developing presence of electronic systems such as electronic health records that support and facilitate a process for sharing and exchanging patient health information. Medication management will be better supported when clinicians have more information available and when effective electronic exchange supports the process.

Because consensus standards must be consistently specified to meet the goal of standardization, detailed specifications are provided in Table 2-2. Additionally, the Preferred Practices for Therapeutic Drug Use have been evaluated against the six IOM aims in Table 2-3. For each recommended preferred practice, the practice specifications in Table 2-2 provide additional details and include the following components:

- Preferred practice statement - a description of the care that should be provided.

- Target outcomes - the primary objectives or desired results from performing the practice.
- Additional specifications and implementation recommendations - those elements considered to enhance the likelihood of achieving the target outcomes for the practice; they are not intended to imply a direct cause of the desired outcome. The specifications are not intended as clinical practice guidelines, but may include recommendations for the implementation of the practice. The additional specifications include:
    - a description of **what** the practice entails,
    - **for whom** it is indicated,
    - **by whom** it should be performed, and
    - in what **settings** it should be implemented.

It is important to note that therapeutic drug management practices and measures may present real challenges in some settings, especially resource-poor community settings where relationships among practitioners and medication sources are less structured, or there are more transient, mobile, uninsured and/or cash-paying patient populations.

SAFE PRACTICES FOR THERAPEUTIC DRUG MANAGEMENT

Additionally, NQF has endorsed eight *Safe Practices* relevant to therapeutic drug management quality, in particular the 'Safe Medication Use' domain, and are aimed at reducing the risk of harm resulting from processes, systems or environments of care. These endorsed *Safe Practices (2006)* (Table 2-1) are also preferred practices for therapeutic drug management.

721 **Table 2-1 Safe Practices for Therapeutic Drug Management**

Domain	Practice	Type	Source
SAFETY	Healthcare organizations should dispense medications, including parenterals, in unit-dose or, when appropriate, in unit-of-use form, whenever possible. (#18)	Process	NQF Safe Practices (updated 2006)
SAFETY	Standardize a list of "do not use" abbreviations, acronyms, symbols, and dose designations that cannot be used throughout the organization (#13)	Process	NQF Safe Practices (updated 2006)
SAFETY	Standardize methods for the labeling and packaging of medications. (#16)	Structure	NQF Safe Practices (updated 2006)
SAFETY	Identify all "high alert" drugs, and establish policies and processes to minimize the risks associated with the use of these drugs. At a minimum, such drugs should include intravenous adrenergic agonists and antagonists, chemotherapy agents, anticoagulants and anti-thrombotics, concentrated parenteral electrolytes, general anesthetics, neuromuscular blockers, insulin and oral hypoglycemics, and opiates). (#17)	Structure	NQF Safe Practices (updated 2006)
SAFETY and SYSTEM COORDINATION AND COMMUNICATION	Pharmacists should actively participate in medication management systems by, at a minimum, working with other health professionals to select and maintain a formulary of medications chosen for safety and effectiveness, being available for consultation with prescribers on medication ordering, interpretation and review of medication orders, preparation of medications, assurance of the safe storage and availability of medications, dispensing of medications, and administration and monitoring of medications. (#15)	Process	NQF Safe Practices (updated 2006)
SYSTEM COORDINATION AND COMMUNICATION	For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person who is receiving the information record and read back the complete order or test result. (#9)	Process	NQF Safe Practices (updated 2006)
SYSTEM COORDINATION AND COMMUNICATION	Implement a computerized prescriber order entry (CPOE) system built upon the requisite foundation of re-engineered evidence-based care, an assurance of healthcare organization staff and independent practitioner readiness, and an integrated information technology infrastructure. (#12)	Structure	NQF Safe Practices (updated 2006)
SAFETY and SYSTEM COORDINATION AND COMMUNICATION	The healthcare facility must develop, reconcile, and communicate an accurate medication list throughout the continuum of care. (#14)	Structure	NQF Safe Practices (2006)

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723 SERIOUS REPORTABLE EVENTS RELATED TO THERAPEUTIC DRUG MANAGEMENT

724 NQF's *Serious Reportable Events in Healthcare: 2006 Update* identifies as a serious adverse event
725 that should be reported by all licensed healthcare facilities 'patient death or serious disability
726 associated with a medication error.' This Serious Reportable Event captures one of the most
727 harmful outcomes related to therapeutic drug management.

728

TABLE 2-2: SPECIFICATIONS FOR PREFERRED PRACTICES		
Practice Domain/ Subdomain	Practice Statement/Target Outcome	Additional Specifications[22]
Therapeutic Decisionmaking		
Medication Selection/Documentation	1. Information and Documentation. Patient assessment and drug selection should include consideration and documentation of patient history, demographics, co-morbidities, assessment of risk benefit balance, allergies, laboratory values, vital signs, measurements and current prescription and non-prescription medications, as well as the patient's education level, health literacy, cultural beliefs and economic access. This should be documented in a format that is electronically available and easily transferable between providers, including pharmacists, and to patients/caregivers. **Target Outcome:** Improved clinical outcomes, decrease in ADEs, more patient-centered approach to therapeutic decisionmaking. Improved communication among providers and between providers and patients/caregivers.	**What:** Consider and document patient history, comorbidities, risk benefit analysis, allergies and current medications. Information should be documented in an electronic record that can be transferred to other providers involved in care, including pharmacists. **For Whom:** All patients. **By Whom:** Prescribers. **Where:** All settings where medications are prescribed.
Medication Selection	2. Patient factors: Therapeutic decision making should include ~~consideration~~ objective assessment and confidential documentation in the medical record of patient education level, cultural beliefs, health literacy, native language, and physical and mental capacity, patient preferences, ability to make follow-up appointments, pharmaceutical access (affordability, benefit design and geographic barriers) and availability of assistance/support network.	**Additional Specifications:** Modify dosing, education, counseling, written materials, and/or adherence aids as appropriate based on identified factors. **What:** Identify and address factors that might impact a patient's understanding of instructions, ability to follow prescribed medication regimen, or satisfaction with care. **For Whom:** All patients as appropriate. **By Whom:** Prescribers and pharmacists.

[22] The additional specifications are not intended to imply a direct cause of the desired outcome, but are those elements considered to enhance the likelihood of achieving the target outcome for the practice.

TABLE 2-2: SPECIFICATIONS FOR PREFERRED PRACTICES		
Practice Domain/ Subdomain	Practice Statement/Target Outcome	Additional Specifications[22]
	Target Outcome: More patient-centered approach to therapeutic decisionmaking, provision of appropriate adherence promoting aids, counseling, education, or written materials. Improved adherence and clinical outcomes/patient satisfaction.	**Where:** All settings where medications are prescribed or dispensed.
Medication Selection	3. Intended use and diagnoses: Patient assessment and drug selection should include documentation in the medical record of the diagnoses ~~indications,~~ intended use, ~~rationale~~, and goals for treatment. ~~Indications/~~ Diagnoses, intended use and, when appropriate, rationale should be electronically available and easily transferable between providers, including pharmacists, and patients/caregivers. ~~Indications/d~~Diagnoses should be linked within the electronic documentation system to medication regimen. **Target Outcome:** Improved communication among providers and between providers and patients/caregivers, decrease in ADEs.	**What:** ~~Indications/d~~ Diagnoses should be documented in an electronic format that is transferred to the pharmacist, when appropriate. Rationale should also be included and transferred to the pharmacist. Goals should also be documented in patient record. Electronic resources should allow links to be made between diagnoses and the medication regimen prescribed. **For Whom:** All patients. **By Whom:** Prescribers. **Where:** All settings where medications are prescribed.
Medication Selection	4. Scientific evidence: Medication selection should be informed by best scientific evidence and clinical guidelines for a given therapeutic area, and individualized for the patient. Prescribers ~~and other providers~~ should document the specific clinical reasons and/or patient preferences resulting in a patient not receiving a recommended medication based on ~~readily available~~ current guidelines. ~~rationale when therapeutic decision-making goes against guidelines.~~ This information should be electronically	**Implementation Recommendation:** Availability and transfer of patient information should be done in a manner to protect patient confidentiality and privacy. **What:** Adherence to scientific evidence and clinical guidelines in therapeutic decisionmaking, documentation thereof, and documentation of reason when this does not occur. ~~of care that does not adhere to guidelines/best evidence.~~ **For Whom:** All patients.

TABLE 2-2: SPECIFICATIONS FOR PREFERRED PRACTICES		
Practice Domain/ Subdomain	Practice Statement/Target Outcome	Additional Specifications[22]
	available and easily transferable between providers, including pharmacists, and to patients/caregivers**.** **Target Outcome:** Improved clinical outcomes and patient satisfaction, reduction in ADEs. Improved documentation and communication among providers and between providers and patients/caregivers.	**By Whom:** Prescribers. **Where:** All settings where medications are prescribed.
Medication Use Monitoring	5. Patient Monitoring: After medication therapy is prescribed, providers, including the pharmacist, should monitor the patient regularly, based on patient needs and best evidence, for effectiveness, adherence, persistence, ~~prescription filling~~, and avoidance and management of adverse events. Information about monitoring should be communicated among providers and to patients and caregivers. The plan for monitoring should be documented in the patient chart, electronically available and easily transferable between providers, including pharmacists, and to patients and caregivers. Electronic system should generate notice to prescriber and patients when the monitoring documentation is not present in the record/chart. ~~any of the above criteria are not met.~~ **Target Outcome:** Improved clinical outcomes and patient satisfaction, reduction in ADEs and resource waste.	**Implementation Recommendations:** 1.Monitoring information should be documented, and communicated to the patient/caregiver. 2.Electronic prompts should also be made to alert providers, especially for high alert medications. 3. Patient comprehension should be checked whenever there is patient engagement, communication, and instruction. **What:** Monitoring for medication use, including adherence, ADEs, prescription filling (including refilling) and effectiveness. **For Whom:** All patients on chronic medications and/or patient caregiver **By Whom:** All providers, including pharmacist. **Where:** All settings, including pharmacy.
Safety		
Patient Engagement and Communicatio	6. Side Effects/Adverse Effects: Patients and their caregivers should be instructed how to identify and manage routine side effects, and to know when and whom to contact if they believe they are	**Implementation Recommendations:** 1. Patient comprehension should be checked whenever there is patient engagement, communication, and instruction. 2.It is important to evaluate for the existence of factors that may be

TABLE 2-2: SPECIFICATIONS FOR PREFERRED PRACTICES		
Practice Domain/ Subdomain	Practice Statement/Target Outcome	Additional Specifications[22]
n	experiencing any serious adverse effects of drug therapy. **Target Outcome:** Improved clinical outcomes, decrease in adverse drug events, improved communication between patient and provider.	likely to cause less than optimal patient engagement, such as emotional stress, physical limitations, and other distractions. 3. Instructions should also include specific adverse reactions that should be communicated to providers immediately. **What:** Provide patient-centered instruction on potential adverse drug events, and how to manage them, while ensuring, as best as possible, optimal engagement and comprehension. **For Whom:** Patients and/or caregivers **By Whom:** Pharmacists, prescribers, other health practitioners **Where:** All settings where medications are prescribed, dispensed, or administered.
Processing medication orders; patient engagement and communication	7. Proper use and handling: Patients and their caregivers should be routinely informed of the proper use (e.g., with or without food, dose, frequency, special instructions, medication action, and side effects to monitor and when to report them) and administration of medications, as well as the storage and disposal of medications (e.g., refrigeration, protection from heat and light, the use of safety closures, and the proper use of any devices to administer medications). **Target Outcome:** Improved clinical outcomes, decrease in adverse drug events	**Implementation Recommendations:** 1. Patient comprehension and effective use of the medication should be checked and documented whenever there is patient engagement, communication, and instruction. 2. Consideration of patient factors (education level, health literacy, beliefs, language, preferences, etc.) should be made whenever there is patient engagement, communication and instruction. **What:** Patient-centered instruction on the use and handling of medications is provided. **For Whom:** Patients and/ or caregivers **By Whom:** Pharmacist, prescribers, other health practitioners **Where:** All settings where medications are prescribed, dispensed or

TABLE 2-2: SPECIFICATIONS FOR PREFERRED PRACTICES		
Practice Domain/ Subdomain	Practice Statement/Target Outcome	Additional Specifications[22]
		administered.
Preventing adverse drug events	8. Safety CQI: Health care practitioners, including pharmacists, and healthcare organizations should assure patient safety through a culture of safety and a continuous quality improvement process. This includes dedicated responsibility, continuous assessment of and learning from injurious and non-injurious medication errors from internal as well as external sources, and product quality problems. **Target Outcome:** Decrease in adverse drug events	**What:** A comprehensive quality improvement process is implemented to minimize medication errors. **For Whom:** Patients and/or caregivers **By Whom:** All health care practitioners and healthcare organizations. **Where:** All settings where medications are prescribed, dispensed or administered.
Education and Adherence		
Adherence Promotion	9. Dosing: Patients, especially those with multiple chronic conditions, should be prescribed the simplest feasible dosing schedule available, while maintaining the desired total dose and the desired clinical outcome **Target Outcome:** Improved adherence, improved clinical outcomes/patient satisfaction	**Implementation Recommendation:** The concept of cost-effectiveness should be considered when recommendation the simplest dosing schedule. **What:** Reduce dosing frequency when possible, when the increased economic burden is not so great to negate any improvement in adherence. **For Whom:** Patients, especially those on chronic medications. **By Whom:** Prescriber, pharmacist. **Where:** All settings where medications are prescribed or dispensed.
Adherence Promotion	10. Patient Ability: Assess and document ability of the patient to understand and follow the prescribed medication regimen. This should include assessment of comprehension of reasons for use, details of	**What:** Assess barriers to adherence including cognitive barriers, cost barriers, physical barriers (i.e. inability to swallow pills) at treatment initiation and at each clinical encounter, if necessary.

TABLE 2-2: SPECIFICATIONS FOR PREFERRED PRACTICES		
Practice Domain/ Subdomain	Practice Statement/Target Outcome	Additional Specifications[22]
	medication regimen barriers to adherence, including cost (especially out-of-pocket costs), cognitive, physical and environmental, cultural issues and benefit design barriers. Consider the teach-back method as an assessment mechanism. **Target Outcome:** Improved adherence, improved clinical outcomes/patient satisfaction	**For Whom:** All patients prescribed medications. **By Whom:** Prescriber, pharmacist. **Where:** All settings where medications are prescribed or dispensed.
Adherence Promotion	11. Adherence aids. Adherence promoting aids, including blister packs, pill boxes, or memory cues, should be offered to patients. **Target Outcome:** Improved adherence, improved clinical outcomes/patient satisfaction	**What:** Use adherence promoting aids that fit the needs of the patient. Adherence promoting aids include blister packs, pill boxes, calendars, etc. **For Whom:** All patients prescribed medications. **By Whom:** Prescriber, pharmacist. **Where:** All settings where medications are prescribed or dispensed.
Efficiency		
Formulary System Management	12. Formulary system. Healthcare organizations should have a formulary system that includes interdependent principles related to formulary decisions, policies, procedures, management and education. The principles are: 1. Formulary system decisions should be based on scientific considerations of safety and efficacy. Economic considerations that achieve appropriate, safe and cost effective drug therapy are also important and may be considered after safety and efficacy are evaluated.	**Implementation Recommendation**: Consumer input on individual reactions to medications can be collected by staff or through committees specifically developed for member input and participation (as an alternative to having a consumer/patient representative as a member of the P&T Committee)

TABLE 2-2: SPECIFICATIONS FOR PREFERRED PRACTICES		
Practice Domain/ Subdomain	Practice Statement/Target Outcome	Additional Specifications[22]
	2. The formulary system encompasses drug selection based on scientific review, drug utilization review, and other tools to foster best practices in prescribing, dispensing, administration, consumption, and monitoring of outcomes. 3. The Pharmacy and Therapeutics (P&T) Committee, or equivalent body, comprised of actively practicing physicians, pharmacists, other health care professionals, and a consumer/patient representative is the mechanism for administering and providing oversight of the formulary system, which includes developing and maintaining the formulary and establishing and implementing policies on the use of the drug products. 4. The formulary system must have its own policies, or adhere to other organizational policies, that address conflicts of interest and disclosure by P&T committee members. 5. The formulary system should include educational programs and a communication system for payers, practitioners, and patients concerning their roles and responsibilities. 6. The formulary system should include~~, where possible,~~ a well-defined and easy-to-use process for the physician or other prescriber to use a non-formulary drug when medically indicated. **Target Outcome:** Effective process for managing formulary system	

TABLE 2-2: SPECIFICATIONS FOR PREFERRED PRACTICES		
Practice Domain/ Subdomain	Practice Statement/Target Outcome	Additional Specifications[22]
Maximizing efficiency	13. Lower cost drugs. Lower cost drugs should be considered whenever clinically appropriate and possible, based on the following principles: The principles are: 1. Communicate and educate patients and providers on the relative clinical (e.g., safety and efficacy) and economic value of all treatment options, including generics. 2. Communicate and educate patients on the difference between generic substitution versus therapeutic interchange. 3. Promote selected generic equivalent drugs that have an FDA-designated AB-equivalency rating, ~~except when using narrow-therapeutic index medications and the switching between medications could yield a negative health outcome.~~ 4.When ~~possible, implement~~ therapeutic interchange programs are implemented they should be clearly defined and linked to cost and quality considerations and outcomes. They should be transparent to the patient. 5.In healthcare organizations, the use and evaluation of substitution and interchange programs are linked to considerations of quality, outcomes, and cost. 6.In healthcare organizations, substitution and interchange programs are overseen by the Pharmacy and Therapeutics (P&T) Committee, or equivalent body, and include physician/prescriber approval in the process.	**Definitions:** Generic Substitution - substitution with a generic alternative with the same active ingredient Therapeutic interchange-the dispensing of a alternate medication, brand or generic, that is therapeutically equivalent to but chemically different from the drug originally prescribed. **Implementation Recommendations:** Therapeutic interchange is only appropriate in settings that have an organized formulary system and Pharmacy and Therapeutics Committee that provides oversight of the therapeutic interchange program. **What:** Implement strategies to maximize efficiency with respect to quality of care and costs associated with the total healthcare system, and to ensure patients understand such strategies. **For Whom:** Patients, providers. **By Whom:** Pharmacist, prescriber, health plan, purchaser **Where:** All settings where medications are prescribed or dispensed

TABLE 2-2: SPECIFICATIONS FOR PREFERRED PRACTICES		
Practice Domain/ Subdomain	Practice Statement/Target Outcome	Additional Specifications[22]
	7.When clinically necessary, there is a clearly defined, broadly communicated, and easy to use process for physicians to prescribe and patients to obtain medicines outside of a substitution or interchange program. **Target Outcome:** Use of only necessary resources; ~~Increased use of lower cost medications;~~ patient understanding of strategies to maximize efficiency; improved patient satisfaction	
Maximizing efficiency; patient engagement and communication	14.Medication options. Patients and providers should be informed of ~~all~~ available therapeutic drug options and their relative costs, effectiveness and safety. **Target Outcome:** improved patient understanding and satisfaction; maximized efficiency	**What:** Information provided to patients on medication options and the relative costs. **For Whom:** Patients and providers. **By Whom:** Pharmacists, health plans, purchasers **Where:** All settings where medications are prescribed or dispensed
Drug utilization review.	15. Drug Utilization Review. Comprehensive analyses of patient treatment patterns should be used to evaluate and improve the quality of drug therapy. **Target Outcome:** Improved clinical outcomes	**What:** Analysis of drug therapy utilization patterns and outcomes are used to evaluate and improve the use of alternate drug therapy options for the entire patient population. **For Whom:** Patient population and providers. **By Whom:** Healthcare organizations, health plans, purchasers **Where:** Organized healthcare systems

TABLE 2-2: SPECIFICATIONS FOR PREFERRED PRACTICES		
Practice Domain/ Subdomain	Practice Statement/Target Outcome	Additional Specifications[22]
System Coordination and Communication/Implementation		
Provider Documentation	16. Provider documentation. There should be a process for accurate and timely documentation of recommendations and actions taken to ensure safe and effective medication management. **Target Outcome:** Improved clinical outcomes, improved documentation and communications among providers	**Implementation Recommendation:** The pharmacist or health care practitioner with knowledge of and training in medication management will facilitate the accurate and timely documentation and actions taken to ensure safe and effective medication management in the patient's medical record, in all care environments. **What:** Documentation in patient's record of medication details, including indication/diagnosis. **For Whom:** Patients; health system **By Whom:** Prescribers, pharmacists, other health practitioners **Where:** All settings where medications are prescribed, dispensed or administered
Communication and coordination among providers	17. Patient Medication List: A complete list of the patient's medications,specifying the details of dose, frequency, rout and reason for use, should be maintained up-to-date and communicated between all providers involved in the patient's care. This list should be electronically available and follow electronic interoperability standards wherever possible and should be transferable among providers, including pharmacists, and to the patient/caregiver, while maintaining patient privacy and confidentiality. **Target Outcome:** Improved clinical outcomes, improved communications among providers	**Implementation Recommendation:** The pharmacist or health care practitioner with knowledge of and training in medication management is responsible for communicating the patient's medication therapy plan, medications and known allergies whenever the patient transitions from among different care settings.A complete list of medications is also provided to the patient on discharge from the facility. **What:** Complete medication information for a patient is shared among providers as patient goes from one care setting to another **For Whom:** Patients; health system **By Whom:** Prescribers, pharmacists, other health practitioners

TABLE 2-2: SPECIFICATIONS FOR PREFERRED PRACTICES		
Practice Domain/ Subdomain	Practice Statement/Target Outcome	Additional Specifications[22]
		Where: All settings where medications are prescribed, dispensed or administered.
Communication and coordination among providers	18. Access to Patient Information: Health care practitioners, including ~~and~~ pharmacists, have convenient access to, share openly, and use all necessary clinical and patient data [assessment findings, health screening, results, drug therapy notes, medication-related problems, complications, medication refill rates, and other patient-specific findings]. This information should be electronically available and transferable among providers, including pharmacists, and to patients. **Target Outcome:** Improved clinical outcomes, improved communications and coordination among providers	**Implementation Recommendation :** Healthcare practitioners and pharmacists should implement the technology requirements and modify or develop a process to comply with the components of this practice guideline that are pertinent to their practice setting. **What:** Access to complete patient information and data is available to all practitioners involved in the management of a patient's medication therapy. **For Whom:** Patients; health system **By Whom:** Prescribers, pharmacists, other health practitioners **Where:** All settings where medications are prescribed, dispensed or administered.
Medication Reconciliation	19. Medication Reconciliation:There is a process for comparing the patient's current medications with those ordered for the patient. And when the patient is unable to actively or fully participate in the medication reconciliation process and has requested assistance from another person, involve the authorized person in the medication reconciliation process. (JCAHO Patient Safety Goals 2007) **Target Outcome:** Improved clinical outcomes, improved documentation and communications among providers, decrease in adverse drug events	**Implementation Recommendation:** 1.With access to necessary information and technical support, the pharmacist or health care practitioner with knowledge of and training in medication management reconciles the patient's medications, given input from the patient and/or family, as part of each care transition between care settings, services, level of care and providers. 2. Access to important information for reconciling medications should be easily transferable (preferably electronically) from one healthcare provider to another. **What:** A complete list or record of patient's medication is transferred from one setting to another, and current medications are compared with those previously ordered, and discrepancies are identified and

TABLE 2-2: SPECIFICATIONS FOR PREFERRED PRACTICES		
Practice Domain/ Subdomain	Practice Statement/Target Outcome	Additional Specifications[22]
		reconciled. **For Whom:** Patients; health system **By Whom:** Prescribers, pharmacists, other health practitioners **Where:** All settings where medications are prescribed, dispensed or administered.
Use of Technology; Communication and coordination among providers	20. Electronic Patient Health Information: There should be a process for electronically sharing relevant patient health information, including medication-related information, among all health systems, health care providers, and patient. **Target Outcome:** Improved clinical outcomes, improved documentation and communications among providers	**Implementation Recommendation:** A universal Electronic Health Record will be developed that will allow information to follow patients through the healthcare system. **What:** Technology, in particular an electronic health record, is used to communicate patient health information among providers. **For Whom:** Patients; health system **By Whom:** Prescribers, pharmacists, other health practitioners **Where:** All settings where medications are prescribed, dispensed or administered.

Table 2-3. Practices for Therapeutic Drug Management Quality and NQF Quality Aims

Practices		IOM Quality Aims					
		SAFE	Patient - Centered	Effective/ Beneficial	Efficient	Timely	Equitable
Domain 1: Therapeutic Decision-making							
1	Patient assessment and drug selection should include consideration and documentation of patient history, demographics, comorbidities, assessment of risk benefit balance, allergies, and current medications that is electronically available and easily transferable between providers, including pharmacists, and to patients/caregivers.	X	X	X			
2	Therapeutic decision making should include consideration of patient education level, cultural beliefs, health literacy, native language, and physical and mental capacity, patient preference, and availability of assistance/support network.	X	X	X			X
3	Patient assessment and drug selection should include documentation of the indications, rationale, and goals for treatment. Indications/diagnoses and, when appropriate, rationale should be electronically available and easily transferable between providers, including pharmacists, and patients/caregivers. Indications/diagnoses should be linked within the electronic	X	X	X			

Practices		IOM Quality Aims					
		SAFE	Patient - Centered	Effective/ Beneficial	Efficient	Timely	Equitable
	documentation system to medication regimen.						
4	Medication selection should be informed by best scientific evidence and clinical guidelines for a given therapeutic area, and individualized for the patient. Prescriber and other providers should document rationale when therapeutic decision-making goes against guidelines. This information should be electronically available and easily transferable between providers, including pharmacists, and to patients/caregivers.	X		X			
5	After medication therapy is prescribed, providers, including the pharmacist, should monitor the patient regularly, based on patient needs and best evidence, for effectiveness, adherence, prescription filling, and avoidance of adverse events. Information about monitoring should be communicated among providers and to patients. The plan for monitoring should be documented in the patient chart, electronically available and easily transferable between providers, including pharmacists, and to patients. Electronic system should generate notice to prescriber and patients when any of the above criteria are not met.	X	X	X			
Domain 2: Safe Medication Use							
6	Patients and their caregivers should be instructed how to identify and manage routine side effects, and to know when and whom to contact if they believe they are experiencing any serious adverse effects of drug therapy.	X	X	X		X	
7	Patients and their caregivers should be routinely informed of the proper use (e.g., with or without food, dose, frequency, special instructions, medication action, and side effects to monitor and when	X	X	X			

Practices		IOM Quality Aims					
		SAFE	Patient - Centered	Effective/ Beneficial	Efficient	Timely	Equitable
	to report them) and administration of medications, as well as the storage and disposal of medications (e.g., refrigeration, protection from heat and light, the use of safety closures, and the proper use of any devices to administer medications).						
8	Health care practitioners and healthcare organizations should assure patient safety through a continuous quality improvement process. This includes dedicated responsibility, continuous assessment of and learning from injurious and non-injurious medication errors from internal as well as external sources, and product quality problems.	X	X				
Domain 3: Education and Adherence							
9	Patients, especially those with multiple chronic conditions, should be prescribed the simplest feasible dosing schedule available, while maintaining the desired total dose and the desired clinical outcome.		X	X			
10	Assess ability of the patient to follow the prescribed medication regimen. This should include assessment of barriers to adherence, including cost (especially out-of-pocket costs), cognitive, physical and environmental, and benefic design barriers. Consider the teach-back method as an assessment mechanism.		X	X			
11	Adherence promoting aids, including blister packs, pill boxes, or memory cues, should be offered to patients.		X	X			
Domain 4: Efficiency							
12	Healthcare organizations should have a formulary system that includes interdependent principles related to formulary decisions,			X	X	X	

Practices		IOM Quality Aims					
		SAFE	Patient - Centered	Effective/ Beneficial	Efficient	Timely	Equitable
	policies, procedures, management and education. The principles are: 1. Formulary system decisions should be based on scientific considerations of safety and efficacy. Economic considerations that achieve appropriate, safe and cost effective drug therapy are also important and may be considered after safety and efficacy are evaluated. 2. The formulary system encompasses drug selection based on scientific review, drug utilization review, and other tools to foster best practices in prescribing, dispensing, administration, consumption, and monitoring of outcomes. 3. The Pharmacy and Therapeutics (P&T) Committee, or equivalent body, comprised of actively practicing physicians, pharmacists, other health care professionals, and a consumer/patient representative is the mechanism for administering and providing oversight of the formulary system, which includes developing and maintaining the formulary and establishing and implementing policies on the use of the drug products. 4. The formulary system must have its own policies, or adhere to other organizational policies, that address conflicts of interest and disclosure by P&T committee members. 5. The formulary system should include educational programs and a communication system for payers, practitioners, and patients concerning their roles and responsibilities. 6. The formulary system should include, where possible, a well-defined and easy-to-use process for the physician or other prescriber to use a non-formulary drug when medically indicated.						
13	Lower cost drugs should be considered whenever clinically appropriate and possible, based on the following principles:	X	X	X	X		X

Practices		IOM Quality Aims					
		SAFE	Patient - Centered	Effective/ Beneficial	Efficient	Timely	Equitable
	The principles are: 1. Communicate and educate patients and providers on the relative clinical (e.g., safety and efficacy) and economic value of all treatment options, including generics. 2. Communicate and educate patients on the difference between generic substitution versus therapeutic interchange. 3. Promote selected generic equivalent drugs that have an FDA-designated AB-equivalency rating, except when using narrow-therapeutic index medications and the switching between medications could yield a negative health outcome. 4. When possible, implement therapeutic interchange programs clearly defined and linked to cost and quality considerations and outcomes. They should be transparent to the patient. 5. In healthcare organizations, the use and evaluation of substitution and interchange programs are linked to considerations of quality, outcomes, and cost. 6. In healthcare organizations, substitution and interchange programs are overseen by the Pharmacy and Therapeutics (P&T) Committee, or equivalent body, and include physician/prescriber approval in the process. 7. When clinically necessary, there is a clearly defined, easy to use process for physicians to prescribe and patients to obtain medicines outside of a substitution or interchange program.						
14	Patients and providers should be informed of all therapeutic drug options and their relative costs, effectiveness and safety.		X		X		
15	Comprehensive analyses of patient treatment patterns should be used to evaluate and improve the quality of drug therapy.		X	X			X

Practices		IOM Quality Aims					
		SAFE	Patient - Centered	Effective/ Beneficial	Efficient	Timely	Equitable
Domain 5: System Coordination and Communication							
16	There should be a process for accurate and timely documentation of recommendations and actions taken to ensure safe and effective medication management.	X	X	X		X	
17	A complete list of the patient's medications should be maintained up-to-date and communicated between all providers involved in the patient's care.		X	X		X	
18	Health care practitioners and pharmacists have convenient access to, share openly, and use all necessary clinical and patient data [assessment findings, health screening, results, drug therapy notes, medication-related problems, complications, and other patient-specific findings]. This information should be electronically available and transferable among providers, including pharmacists, and to patients.		X	X		X	
19	There is a process for comparing the patient's current medications with those ordered for the patient while under the care of the organization. And when the patient is unable to actively or fully participate in the medication reconciliation process and has requested assistance from another person, involve the authorized person in the medication reconciliation process. (JCAHO Patient Safety Goals 2007)	X	X	X		X	
20	There should be a process for electronically sharing relevant patient health information, including medication-related information, among all health systems, health care providers, and patient.		X	X		X	

CHAPTER 3

PERFORMANCE MEASURES FOR THERAPEUTIC DRUG MANAGEMENT

INTRODUCTION

Few measures have been developed for Therapeutic Drug Management (TDM) beyond those addressing performance related to therapeutic decision-making of specific conditions. No measures currently exist that apply to the domains of Safe Medication Use, Medication Adherence and Education, Efficiency, and System Coordination and Communication. Measure development work has been undertaken by several organizations (e.g., the Pharmacy Quality Alliance, Centers for Medicare and Medicaid Services, URAC, the Academy of Managed Care Pharmacy) in the development of TDM-related standards, measures, frameworks and practices. The TDM framework will provide a structure to bring together the various development activities and identify gaps in measurement.

PREVIOUS NQF WORK RELATED TO THERAPEUTIC DRUG MANAGEMENT

While this project is the first comprehensive effort by the NQF focusing on medication management to date, several completed NQF projects have endorsed performance measures pertaining to therapeutic drug management. NQF evaluation criteria for endorsement of measures are presented in Box B. Twenty-three measures related to therapeutic drug management were endorsed in the project, *National Voluntary Consensus Standards for Hospital Care: An Initial Performance Measure Set.* [23] An additional five hospital-level measures were endorsed for cardiac surgery in 2004.[24] Four measures were endorsed in 2007 to measure hospital care at the clinician level.[25] Forty-one measures related to therapeutic drug management have been endorsed for ambulatory care, in the areas of asthma/respiratory illness; bone and joint conditions; diabetes; heart disease; hypertension; medication

[23] NQF. *National Voluntary Consensus Standards for Hospital Care: An Initial Performance Measure Set: A Consensus Report.* Washington, DC: NQF;2003.
[24] NQF. *National Voluntary Consensus Standards for Cardiac Surgery: A Consensus Report.* Washington, DC: NQF;2004.
[25] NQF. *National Voluntary Consensus Standards forHospital Care: Specialty Clinician Performance.* Washington DC: NQF; 2007. In press.

754 management; mental health and substance abuse; obesity; prenatal care; and prevention/
755 immunization/ screening. [26]
756 The framework can be used to judge the usefulness of these measures for assessing the
757 quality of therapeutic drug management (Table 3-1). The endorsed measures are organized
758 within the framework according to 1) Domain and 2) Priority area. Measures addressing a
759 similar process of care are clustered. Not all of the endorsed measures pertaining to medication
760 use fit into the framework. Measures of medication use for conditions such as COPD, arthritis,
761 and urinary incontinence do not fit into any priority area. The twelve NQF-endorsed measures
762 for influenza and pneumococcal vaccination are not included since NQF is currently working
763 on a project to harmonize and align measures of flu and pneumonia immunization with an eye
764 toward a global measure that crosses all healthcare settings in the future.
765 The sixty-five measures in Table 3-1 may be used to assess the therapeutic decision-making
766 domain of TDM, but also point to both opportunities and challenges in assessing the quality of
767 medication use. As an example, the numerous beta-blocker measures assess medication use at
768 several very important points, i.e., on admission and discharge for AMI and CABG and in the
769 post-hospitalization secondary prevention. Ideally, a set of aligned measures for beta-blocker
770 use could portray a robust picture of the quality of beta-blocker medication use. However, lack
771 of alignment of the specifications regarding inclusion and exclusion criteria, coding and
772 definitions, currently prevents reporting a cohesive picture of performance.
773 Primarily due to different data sources, some of the endorsed measures assess medications
774 *ordered* while other measures evaluate medications *dispensed*. Stakeholders, particularly
775 consumers and purchasers, find the pairing of measures *ordered* and *dispensed* to be desirable as
776 an assessment of clinician and system efforts to encourage medication adherence.
777 Eight medication measures are identified as "disparities-sensitive" in NQF's *National*
778 *Voluntary Consensus Standards for Ambulatory Care: Measuring Healthcare Disparities.* As TDM
779 measures are developed and considered for endorsement, consideration for disparities should
780 be included.
781

[26] National Quality Forum. *National Voluntary Consensus Standards for Ambulatory Care: Part 1.*Washington, DC: National Quality Forum; 2006.

Box B. Criteria for Evaluation and Selection

1. **Importance.** This set addresses the extent to which a measure reflects a variation in quality, low levels of overall performance, and the extent to which it captures key aspects of the flow of care.
   a. The measure addresses one or more key leverage points for improving quality.
   b. Considerable variation in the quality of care exists.
   c. Performance in the area (e.g., setting, procedure, condition) is suboptimal, suggesting that barriers to improvement or best practice may exist.

2. **Scientific acceptability.** A measure is scientifically sound if it produces consistent and credible results when implemented.
   a. The measure is well defined and precisely specified. Measures must be specified sufficiently to be distinguishable from other measures, and they must be implemented consistently across institutions. Measure specifications should provide detail about cohort definition, as well as the denominator and numerator for rate-based measures and categories for range-based measures.

   b. The measure is reliable, producing the same results a high proportion of the time when assessed in the same population.
   c. The measure is valid, accurately representing the concept being evaluated.
   d. The measure is precise, adequately discriminating between real differences in provider performance.
   e. The measure is adaptable to patient preferences and a variety of contexts of settings. Adaptability depends on the extent to which the measure and its specifications account for the variety of patient choices, including refusal of treatment and clinical exceptions.
   f. An adequate and specified risk-adjustment strategy exists, where applicable.
   g. Are patient outcomes or consistent evidence is available linking the structure and process measures to patient outcomes.

3. **Usability.** Usability reflects the extent to which intended audiences (e.g., consumers, purchasers) can understand the results of the measure and are likely to find them useful for decision making.
   a. The measure can be used by the stakeholder to make decisions.
   b. The differences in performance levels are statistically meaningful.
   c. The differences in performance are practically and clinically meaningful.
   d. Risk stratification, risk adjustment, and other forms of recommended analyses can be applied appropriately.
   e. Effective presentation and dissemination strategies exist (e.g., transparency, ability to draw conclusions, information available when needed to make decisions).
   f. Information produced by the measure can/will be used by at least one healthcare stakeholder audience (e.g., public/consumers, purchasers, clinicians and providers, policymakers, accreditors/regulators) to make a decision or take an action.
   g. Information about specific conditions for which the measure is appropriate has been given.
   h. Methods for aggregating the measure with other, related measures (e.g., to create a composite measure) are defined, if those related measures are determined to be more understandable and more useful in decision making. Risks of such aggregation, including misrepresentation, have been evaluated.

4. **Feasibility.** Feasibility is generally based on the way in which data can be obtained within the normal flow of clinical care and the extent to which an implementation plan can be achieved.
   a. The point of data collection is tied to care delivery, when feasible.
   b. The timing and frequency of measure collection are specified.
   c. The benefit of measurement is evaluated against the financial and administrative burden of implementation and maintenance of the measure set.
   d. An auditing strategy is designed and can be implemented.
   e. Confidentiality concerns are addressed.

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RECOMMENDATIONS

Several recommendations to evolve the NQF-endorsed™ measures pertaining to TDM are consistent with the principles in the TDM framework.

Recommendation 1: Harmonization of measures

Measure developers should actively seek to harmonize similar measures that exist as well as for those in development. The multiplicity of similar measures should be aligned along several lines:

- age inclusions as broad as possible, including children, unless the evidence support their exclusion;
- numerator inclusion criteria; and
- evidence-based exclusions only if they have a significant impact on the metric result.

Recommendation 2: Pair measure of medication ordered and medication dispensed

Medication use measures should be developed in pairs to assess medications *ordered* and medications *dispensed* to assess clinician and system efforts to encourage medication adherence.

Recommendation 3: Disparities-sensitive measures

Development and evaluation of measures for therapeutic drug management should consider evidence of disparities and the ability of the measure to provide information about disparities as a priority.

RECOMMENDATIONS FOR MEASURE DEVELOPMENT AND RESEARCH

The Framework for Therapeutic Drug Management identifies many areas for measure development and research. The TDM project Steering Committee and Technical Advisory Panels identified areas where there is the need for more research and measure development. The following research recommendations offer research areas of particular importance.

RESEARCH RECOMMENDATION 1: Therapeutic Decision-making

Research and measure development should address the following:

- therapy duplications;
- pharmacologic antagonists;
- pain management;
- mental health;
- appropriate medication use;
- monitoring for unnecessary antibiotic use;
- migraine headaches;
- anticoagulants and narcotics;
- vaccination measures particularly in children and the elderly; and
- patients with co-morbidities, especially when taking a large number of medications.

RESEARCH RECOMMENDATION 2: Education/Adherence

Research and measure development should address the following:

- literacy, counseling, and consumer/patient education;
- personal medication lists;
- compliance and persistence of stable medication use;
- patient ability to take medications, i.e. vision/cognitive impairment;
- patient partnering in care; and
- tools to assess patient understanding of counseling;
- evaluation of different pharmacy methods and practices related to patient consultation;
- standardized methods and techniques to measure patient adherence.

RESEARCH RECOMMENDATION 3: Safe Medication Use

Research and measure development should address the following:

- dosing for the elderly and children;
- drug interactions; and
- high alert, high risk medications (anticoagulants, narcotics and insulin).

RESEARCH RECOMMENDATION 4: Efficiency

Research and measure development should address the following:

- use of generic drugs;
- efficiency and effectiveness of drugs in the same therapeutic class; and
- transparency of cost.

RESEARCH RECOMMENDATION 5: System Coordination and Communication

Research and measure development should address the following:

- transitions in care and care coordination;
- medication reconciliation;
- bar code administration;
- use of technology;
- standards related to Medication Therapy Management (MTM) services ~~for~~ provided by pharmacists, and other health care professionals;
- use of collaborative models to address resource and time constraints in implementation of quality improvement programs in small practice settings (e.g., pharmacies and other care practice settings);
- establishment of a therapeutic drug management quality research collaborative to promote large, multi-site improvement processes and innovations; and
- assess the current state of pharmacy practice regulation and reimbursement to include pharmacists in "prescriber level" decisions, when appropriate, related to activities such as medication selection and management, and how practice changes will affect pharmacist liability as well as responsibility, and the liability of other members of the TDM teams and overall provider coordination.

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875 TABLE 3-1: NQF-ENDORSED™ MEASURES in the TDM FRAMEWORK

PRIORITY AREA	DESCRIPTION	LEVEL OF ANALYSIS	TYPE	IP OWNER / SOURCE
THERAPEUTIC DECISION-MAKING				
ASPIRIN OR ANTI-PLATLET USE IN ISCHEMIC HEART DISEASE				
Condition: Ischemic Heart Disease	Aspirin at Arrival for Acute Myocardial Infarction (AMI)	Hospital	Process	CMS/Joint Commission
Condition: Ischemic Heart Disease	Aspirin at Arrival for AMI	Clinician	Process	ACEP/ AMA PCPI/ NCQA
Condition: Ischemic Heart Disease	Aspirin Prescribed at Discharge for AMI	Hospital	Process	CMS/Joint Commission
Condition: Ischemic Heart Disease	Coronary Artery Bypass Graft (CABG): Anti-Platelet Medication at Discharge	Hospital	Process	STS
Condition: Ischemic Heart Disease	Coronary Artery Bypass Graft (CABG): Anti-Platelet Medication at Discharge	Clinician	Process	STS
Condition: Ischemic Heart Disease	Coronary Artery Disease (CAD): Anti-Platelet Therapy	Clinician	Process	AMA PCPI/ ACC/AHA
Condition: Ischemic Heart Disease	Ischemic Vascular Disease: Use of Aspirin or Other Antithrombotic	Clinician	Process	NCQA
BETA-BLOCKER USE IN ISCHEMIC HEART DISEASE				
Condition: Ischemic Heart Disease	Beta Blocker at Arrival for AMI	Hospital	Process	CMS/Joint Commission
Condition: Ischemic Heart Disease	Beta Blocker Prescribed at Discharge for AMI	Hospital	Process	CMS/Joint Commission
Condition: Ischemic Heart Disease	Pre-Operative Beta-Blockade in Patients with Isolated Coronary Artery Bypass Graft (CABG)	Hospital	Process	STS
Condition: Ischemic Heart Disease	Pre-Operative Beta-Blockade in Patients with Isolated Coronary Artery Bypass Graft (CABG)	Clinician	Process	STS

PRIORITY AREA	DESCRIPTION	LEVEL OF ANALYSIS	TYPE	IP OWNER / SOURCE
Condition: Ischemic Heart Disease	Pre-Operative Beta-Blockade in Patients with Isolated Coronary Artery Bypass Graft (CABG)	Clinician	Process	CMS
Condition: Ischemic Heart Disease	CABG: Beta-Blocker at Discharge	Hospital	Process	STS
Condition: Ischemic Heart Disease	CABG: Beta-Blocker at Discharge	Clinician	Process	STS
Condition: Ischemic Heart Disease	AMI: Persistence of Beta-Blocker Treatment after a Heart Attack	Clinician	Process	NCQA
Condition: Ischemic Heart Disease	CAD: Beta-Blocker Therapy, Prior MI	Clinician	Process	AMA PCPI/ ACC/AHA
Condition: Ischemic Heart Disease	CAD: Beta-Blocker Treatment after Heart Attack	Clinician	Process	NCQA
Condition: Ischemic Heart Disease	Heart Failure (HF): Beta-Blocker Therapy	Clinician	Process	AMA PCPI/ ACC/AHA
ACEI or ARB for ISCHEMIC HEART DISEASE				
Condition: Ischemic Heart Disease	Angiotensin Converting Enzyme Inhibitor (ACEI)or ACE-Receptor Blocker (ARB) for Left Ventricular Systolic Dysfunction (LVSD) in Patients with AMI	Hospital	Process	CMS/Joint Commission
Condition: Ischemic Heart Disease	ACEI/ARB for LVSD in Patient with Heart Fialure	Hospital	Process	CMS/Joint Commission
Condition: Ischemic Heart Disease	Coronary Artery Disease (CAD): ACE-I or ARB Therapy	Clinician	Process	AMA PCPI/ ACC/AHA
Condition: Ischemic Heart Disease	Heart Failure (HF): ACE-I or ARB Therapy	Clinician	Process	AMA PCPI/ ACC/AHA
Condition: Ischemic Heart Disease	Therapeutic Monitoring – annual monitoring for patients on persistent medications: a. Annual monitoring for patients on ACEI/ARBs	Clinician	Process	NCQA
ANTI-LIPID THERAPY FOR ISCHEMIC HEART DISEASE				
Condition: Ischemic Heart Disease	CABG: Anti-Lipid Medication at Discharge	Hospital	Process	STS
Condition: Ischemic Heart Disease	CAD: Drug Therapy for Lowering LDL-Cholesterol	Clinician	Process	AMA PCPI/ ACC/AHA
THROMBOLYTIC THERAPY				

PRIORITY AREA	DESCRIPTION	LEVEL OF ANALYSIS	TYPE	IP OWNER / SOURCE
Condition: Ischemic Heart Disease	Thrombolytic agent within 30 minutes of arrival for AMI	Hospital	Process	CMS/JC
Condition: Stroke	Tissue Plasminogen Activator (t-PA) Considered	Clincian	Process	AMA PCPI/
WARFARIN THERAPY FOR HEART DISEASE				
Condition: Stroke	Anticoagulant Therapy Prescribed for Atrial Fibrillation at Discharge	Hospital	Process	
Condition: Stroke	Heart Failure: Warfarin Therapy for Patients with A-Fib	Clinician	Process	AMA PCPI/ ACC/AHA
ANTIBIOTICS FOR PNEUMONIA				
Condition: Pneumonia	Initial Antibiotic within 6 Hours of Hospital Arrival	Hospital	Process	CMS/Joint Commission
Condition: Pneumonia	Blood Culture Collected Prior to First Antibiotic Administration	Hospital	Process	CMS/Joint Commission
Condition: Pneumonia	Initial antibiotic consistent with current recommendations	Hospital	Process	CMS/Joint Commission
Condition: Pneumonia	Pneumonia Screen or Pneumonia Vaccination	Hospital	Process	CMS/Joint Commission
Condition: Pneumonia	Empiric Antibiotic for Community-Acquired Pneumonia (CAP)	Hospital Clinician-Level	Process	AMA PCPI/ NCQA/ACEP
MEDICATION USE IN ASTHMA AND UPPER RESPIRATROY CONDITIONS				
Condition: Asthma	Use of systemic corticosteroids for inpatient asthma in children	Hospital	Process	CHCA
Condition: Asthma	Use of Relievers for Inpatient Asthma in Children	Hospital	Process	CHCA
Condition: Asthma	Use of Appropriate Medications for People with Asthma	Clinician	Process	NCQA
Condition: Asthma	Asthma: Pharmacologic Therapy	Clinician	Process	AMA PCPI
Patient Safety	Inappropriate Antibiotic Treatment for Adults with Acute Bronchitis	Clinician	Process	NCQA
Patient Safety	Appropriate Treatment for Children with Upper Respiratory Infection	Clinician	Process	NCQA
PROPHYLACTIC ANTIBIOTICS FOR SURGERY				
Patient Safety	Timing of antibiotic administration (surgical patients)	Hospital	Process	CMS-QIOs

PRIORITY AREA	DESCRIPTION	LEVEL OF ANALYSIS	TYPE	IP OWNER / SOURCE
Patient Safety	Timing of Prophylactic Antibiotics, Ordering Physician	Clinician	Process	ACS/NCQA/ AMA PCPI
Patient Safety	Timing of Prophylactic Antibiotics, Administering Physician	Clinician	Process	ACS/NCQA/ AMA PCPI
Patient Safety	Selection of antibiotic administration (surgical patients)	Hospital	Process	CMS
Patient Safety	Selection of Prophylactic Antibiotics, 1st or 2nd Generation Cephalosporin	I Clinician	Process	ACS/NCQA/ AMA PCPI
Patient Safety	Duration of prophylaxis (non-cardiac patients)	Hospital	Process	CMS
Patient Safety	Duration of prophylaxis (cardiac procedures)	Hospital	Process	CMS
Patient Safety	Discontinuation of Prophylactic Antibiotics, Non-Cardiac Procedures	Clinician	Process	ACS/NCQA/AMA PCPI
PREVENTION OF VENOUS THROMBOEMBOLISM				
Patient Safety	Surgery Patients with Recommended VTE Prophylaxis Ordered	Hospital	Process	
Patient Safety	Surgery Patients who Receive Appropriate VTE Prophylaxis within 24 Hours Prior to Surgery or 24 Hours after Surgery	Hospital	Process	
Patient Safety	Venous Thromboembolism Prophylaxis (VTE) Prophylaxis	Clinician	Process	ASC/ AMA PCPI/NCQA
Condition: Stroke	DVT Prophylaxis for Ischemic Stroke or Intracranial Hemorrhage	Clinician	Process	AAN/ACR/ AMA PCPI/NCQA
ANTI-DEPRESSANT THERAPY				
Condition: Depression	New Episode of Depression: a. Optimal Provider Contacts for Medication Management b. Effective Continuation Phase Treatment c. Effective Continuation Phase Treatment	Clinician	Process	NCQA
OSTEOPOROSIS THERAPY				
Condition: Frailty Associated with Old Age	Osteoporosis: Pharmacologic Therapy	Clinician	Process	AAFP/AAOS/AACE/ACRheum/AMA PCPI/ NCQA
CANCER THERAPY				
Condition: Cancer	Adjuvant Chemotherapy	Hospital	Process	
Condition: Cancer	Adjuvant Hormonal Therapy	Hospital	Process	
PREVENTION/ SMOKING CESSATION				
Smoking Cessation	(1) Percentage of patients who received advice to quit smoking; (2) Percentage of patients whose practitioner recommended or discussed smoking cessation medications; and (3) Percentage of patients whose practitioner recommended or discussed smoking cessation methods or strategies	Clinician	Process	NCQA

PRIORITY AREA	DESCRIPTION	LEVEL OF ANALYSIS	TYPE	IP OWNER / SOURCE
MEDICATION MANAGEMENT				
Patient Safety	Medication Reconciliation	Clinician	Process	AGS/AMA PCPI/ NCQA
Patient Safety	Documentation of Medication List in Outpatient Record	Clinician	Process	NCQA
Patient Safety	Documentation of Allergies and Adverse Reactions in Outpatient Record	Clinician	Process	NCQA
Patient Safety	Annual Monitoring of Patients on Persistent Anticonvulsants	Clinician	Process	NCQA
Patient Safety	Annual Monitoring of Patients on Persistent Digoxin	Clinician	Process	NCQA
Patient Safety	Annual Monitoring of Patients on Persistent Diuretics	Clinician	Process	NCQA
Patient Safety	Combined Annual Monitoring of Patients on Persistent ACE-I or ARB, Anticonvulsants, Digoxin, Diuretics, and/or Statins	Clinician	Process	NCQA
Patient Safety	Elderly Patients who Receive at Least One Drug that should be Avoided	Clinician	Process	NCQA
Patient Safety	Elderly Patients who Receive at Least Two Different Drugs that should be Avoided	Clinician	Process	NCQA
BEHAVIORAL HEALTH				
Behavioral Health/ADHD	(1)Percentage of patients diagnosed with attention deficit hyperactivity disorder (ADHD) and on first-line medication whose medical record contains documentation of a follow-up visit twice a year. (2) Number of medical records of attention deficit hyperactivity disorder (ADHD) patients on first-line medication with documentation of a follow-up visit twice a year. (3) Total number of attention deficit hyperactivity disorder (ADHD) patients on first-line medication whose medical records are reviewed ADHD is defined as International Classification of Diseases, Ninth Revision (ICD-9) codes of 314.00 or 314.01. Diagnosed is defined as documented ADHD in the past 6 to 12 months. First-line medications include: methylphenidate (Ritalin), dextroamphetamine (Dexedrine), and atomoxetine (Strattera).	Clinician	Process	ICSI

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A Comprehensive Framework for Measuring the Quality of Therapeutic Drug Management

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Executive Summary

A therapeutic drug is a medication, which is a chemical entity that treats or prevents or alleviates the symptoms of disease. Therapeutic drugs can be the most cost-effective of healthcare treatments, yet medication–related problems result in patient morbidity and mortality and the need for additional healthcare services. Thus, the goal of therapeutic drug management is to provide medications to individuals who need them in a safe, effective, efficient, timely, equitable and patient-centered manner so that positive patient outcomes can be realized and improvements in quality of life are realized.

In our current system, there is no single person or provider to whom accountability can be assigned. The medication use landscape is broad and the management of medications is affected by multiple and diverse points of care. The healthcare system is increasingly complex and many efforts focus on providing consistent and high quality care that is appropriate, timely and safe. In fact, much attention has been paid to the measurement of quality in healthcare with subsequent reporting of this information to the public. Many of these measures do address medication use for specific clinical issues in prescribing and monitoring, but there are few quality indicators about other aspects of the medication use process. The quality of medication use is much more than prescribing the right drug for the right condition, therefore gaps exist in the comprehensive measurement of therapeutic drug management quality.

The purpose of this paper is to provide a comprehensive framework including the domains upon which to base measures, practices, guidelines, and standards for determining the quality of therapeutic drug management. The framework for measuring the quality of therapeutic drug management specifies five broad categories (domains) where quality should be measured to improve patient outcomes. The comprehensive framework is inclusive of all activities in the medication use process that may influence the quality of therapeutic drug management. The five domains include:

Patient Decisions & Behaviors
Therapeutic Decision-Making
Safe Medication Use
Cost-Effectiveness
System Coordination and Communication

Key components of each quality domain are described and examples of measures or practice guidelines applicable to the domains are included. Formalized measures that pertain to the quality of therapeutic drug management are listed in Table 2 and are categorized by domain. Practice standards or guidelines also categorized by domain are detailed in Table 3. The tables reflect how quality is currently being measured or how practice standards are used to improve the safe, effective and efficient use of medications. The gap analysis suggests that measures related to all domains are needed. For example, patient participation and adherence as well as pharmacists' role in therapeutic decision making should be further developed. This comprehensive framework can be used to develop and promote measures that improve all activities influencing therapeutic drug management throughout the medication use process.

Introduction

Medications can be the most cost-effective healthcare treatment by preventing illness, controlling progression of diseases and enhancing quality of life. However, if medications are ineffective, redundant, abused, clinically inappropriate or cause an adverse event, the money spent on this therapy is wasted and additional treatment costs can be incurred. More importantly, inappropriate and ineffective medication use may result in patient morbidity and mortality and the need for additional healthcare services. The cost of drug therapy problems to the healthcare system in 1995 was estimated at $76.6 billion[1], and in 2001, these costs had nearly doubled.[2] Other statistics on poor medication use illustrate the importance of developing domains of quality assessment in therapeutic drug management. Between 14 and 23 percent of the elderly receive a medication they should not have been prescribed.[3, 4, 5] Up to 40 percent of patients do not take their medications as prescribed and a 76 percent discrepancy was found between instructions for medication use and how the medication was actually taken.[6, 7] Medication problems or errors among older adults lead to a high rate of emergency department visits and hospital admissions.[8, 9, 10] Clearly, there is a need to improve therapeutic drug management, therefore there is a need to measure the quality of therapeutic drug management.

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[1] Johnson JA, Bootman JL. Drug-related morbidity and mortality: a cost of illness model. Arch Intern Me*d* 1995;155:1949-56.
[2] Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: Updating the cost-of illness model J Am Pharm Assoc 2001;41(2):192-199.
[3] Aparasu R, Mort J. Inappropriate prescribing for the elderly: Beers criteria-based review. Ann Pharmacother 34:338-46 2000.
[4] Stuck A, Beers M, Steiner A et al. Inappropriate medication use in the community-residing older persons. Arch Intern Med 154:2195-2200 1994.
[5] Chrischilles E, Segar E, Wallace R. Self-reported adverse drug reactions and related resource use: A study of community-dwelling person 65 years of age and older. Ann Intern Med 117:634-40 1992.
[6] Bond W, Hussar D. Detection methods and strategies for improving medication compliance. Am J Hosp Pharm 48:1978-88 1991.
[7] Bedell, SE, Jabbour S, Goldberg R, et al. Discrepancies in the use of medications. Arch Intern Med 160:2129-2134 2000.
[8] Sullivan S, Kreling D, Hazlet T. Noncompliance with medication regimens and subsequent hospitalizations: A literature analysis and cost of hospitalization estimate. J Research Pharmaceutical Econ 219-33 1990.

Much attention has been paid to the measurement of quality in healthcare with subsequent reporting of this information to the public. For example, the Hospital Quality Alliance and Nursing Home Compare make available measure performance data for consumers to use in comparing facilities. In 2006, the majority of healthcare plans reported on 68 Health Plan Employer Data and Information Set (HEDIS) quality of care measures. Many of these measures address medication use for specific clinical issues in prescribing and monitoring, but there are few quality indicators about other aspects of the medication use process. The quality of medication use is much more than prescribing the right drug for the right condition. Gaps exist in the comprehensive measurement of therapeutic drug management quality.

The purpose of this paper is to provide a comprehensive framework including the domains upon which to base measures, practices, guidelines, and standards for determining the quality of therapeutic drug management. The framework is inclusive of all activities in the medication use process that may affect the quality of therapeutic drug management, and encompasses the actions of many providers across multiple settings where therapeutic drug management occurs or is influenced. The framework specifies broad categories (domains) of therapeutic drug management where quality should be measured to improve patient outcomes. The framework ultimately will be used to inform consumers, purchasers, providers, healthcare professionals, quality improvement organizations and researchers of therapeutic drug management quality. Measures can be used for evaluation, improvement and reporting the impact of therapeutic drug management by specific care settings or across multiple settings, or by individual providers, health systems or healthcare plans.

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[9] Roughhead E, Gilbert A, Primrose J, et al. Drug-related hospital admission: A review of the Australian studies published 1988-96. Med J Australia 168:405-8 1998.

[10] Budnitz DS, Pollock DA, Weidenbach, KN et al. National surveillance of emergency department visits for outpatient adverse drug events. JAMA 296:1858-1866 2006.

Section I. Therapeutic Drug Management and the Medication Use Process

In 2005, 2.6 billion prescriptions were purchased, an increase of 71% from 1994 compared to US population growth of 9%; spending for prescription drugs was 188.5 billion in 2004, up from 20.3 billion in 1990. [11] In a hospital setting, 80 – 200 steps are needed to administer one dose of medication. These figures show the scale of the medication use process, yet the complexity is not clearly conveyed by the numbers as they do not take into account other important factors influencing medication management such as marketing, formularies, staff shortages, patient preference and budgets. This section defines therapeutic drug management in the context of a broad medication use process.

Defining Therapeutic Drug Management

"Therapeutic drug" in the context of therapeutic drug management means a chemical entity approved for human use by the Federal Drug Administration under a New Drug Application (NDA), Abbreviated New Drug Application (ANDA) or Over-the-Counter (OTC) monograph. Brand drugs are approved via NDAs and generic drugs are approved via ANDAs. All therapeutic drugs have an indication or reason for use, daily dose range and documented evidence that their benefits outweigh the risks of use. Throughout this document, the term medication is also used , and a "medication" can be defined as a chemical entity that treats or prevents or alleviates the symptoms of disease. A therapeutic drug is a medication.[12]

In the United States, many therapeutic drugs are obtained via prescriptions from pharmacies and electronic records of these transactions are generally maintained. Therapeutic drugs may also be obtained as OTC products, although the use of OTCs by specific individuals

[11] Prescription Drug Trends - June 2006. Kaiser Family Foundation, http://www.kff.org/rxdrugs/upload/3057-05.pdf, Accessed 27 November 2006
[12] Chicago Style: medication. Dictonary.com WordNet® 2.0, Princeton University. http://dictionary.reference.com/browse/medication (accessed: October 31, 2006)

is generally not recorded by healthcare professionals. Exceptions do exist such as third party payment of selected OTCs including aspirin or nicotine replacement therapy whereby electronic records of the transactions are generated. In addition, insurers often have documentation of OTC use in health savings accounts. Thus, any assessment of the quality of therapeutic drug management will require a variety of data sources so that brand and generic therapeutic drugs as well as OTC drugs can be included.

The word 'management' in therapeutic drug management implies a person or entity is responsible for organizing and controlling processes that efficiently use resources to accomplish a goal. Thus, the goal of therapeutic drug management is to provide medications to individuals who need them in a safe, effective, efficient, timely, equitable and patient-centered manner so that positive patient outcomes can be realized and improvements in quality of life are realized. Yet, in our current system, there is no single "therapeutic drug manager" to whom accountability can be assigned. The medication use landscape is broad and the management of medication use is affected by multiple and diverse points of care. The quality of therapeutic drug management in terms of the processes to deliver it and the resulting patient outcomes depend upon the actions of and communication between several independent persons, systems, and/or entities.

In 1990, a landmark article written by Hepler and Strand, "Opportunities and Responsibilities in Pharmaceutical Care", challenged pharmacists in all settings to adopt a patient-centered practice so that their primary activities were focused on identifying drug-related problems, ensuring optimal therapeutic outcomes and working cooperatively as part of the healthcare team. They wrote that adoption of pharmaceutical care would be a paradigm shift for the pharmacy profession, as pharmacists would need to build practices revolving

around the care of patients rather than the provision of drugs.[13] Strand and Cipolle later defined the patient care process in pharmaceutical care as establishing a therapeutic relationship with the patient, assessment of drug therapy including identification of drug therapy problems, development of a care plan, evaluation and continuous follow-up.[14] Although pharmaceutical care was developed relative to pharmacists' care of patients, other healthcare professionals can and do provide pharmaceutical care, although that specific term may not be used. Pharmaceutical care is a philosophy and practice that underpins all activities in therapeutic drug management because it posits that the right therapeutic drug is used by the right individual and that the right outcomes are being achieved.

A recent development in therapeutic drug management at the policy level is the introduction of Medication Therapy Management (MTM) in the Medicare Modernization Act (MMA) of 2003 and offered by prescription drug plans (PDPs) and Medicare Advantage drug plans (MA-PDs). Broadly, MTM refers to patient-specific services that promote the safe and effective use of medications, similar to activities involved in pharmaceutical care. The Medicare Modernization Act designates pharmacists as providers of MTM, but allows any qualified healthcare provider to offer it. The American Pharmacists Association and National Association of Chain Drug Stores developed a model for community pharmacy MTM, based upon principles of pharmaceutical care, that includes five core elements: (1) medication therapy review; (2) personal medication record; (3) a medication action plan; (4) intervention and referral; and (5) documentation and follow-up. [15] Each of these core components could be used

[13] Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. Am J Hosp Pharm 1990;47:533-43.
[14] CipolleRJ, Strand LM, Morley PC. Pharmaceutical care practice. New York: McGraw-Hill;1998.
[15] Medication Therapy Management in Community Pharmacy Practice: Core elements of an MTM service http://www.aphanet.org/AM/Template.cfm?Section=Search&section=Pharmacy_Practice_Resources1&template=/CM/ContentDisplay.cfm&ContentFileID=848 accessed 19 October, 2006

as a basis for quality measures. The Centers for Medicare & Medicaid Services (CMS) provided general guidance to plans to determine patient eligibility (drug spend, multiple chronic diseases and medications) and service characteristics, e.g., episodic or longitudinal, in-person versus telephonic. As a result, Medicare MTM programs may vary considerably in their ability to improve therapeutic drug management, and determining the specific elements that impact quality is necessary so that findings can be translated to all populations using medications. Thus, the Medicare Modernization Act (MMA) of 2003 and MTM provide a policy context in which therapeutic drug management now exists for a select population, i.e., Medicare, but its tenets of safe and effective use of medications are applicable to all individuals who use medications.

Medication Use Process

To understand and consider all the persons, systems and entities involved in therapeutic drug management, it is helpful to use a comprehensive view of what is termed the "medication use process". The Institute of Medicine indicated that this process involves five steps including: (1) selecting and procuring by pharmacies; (2) prescribing and ordering medications by prescribers; (3) preparing and dispensing by pharmacies; (4) administering by patients/caregivers; and (5) monitoring effects.[16] However, this paper expands the process to more clearly illustrate the complexity of the medication use process in terms of persons, actions and systems using a model adapted from Haaijer-Ruskamp & Hemminki (Figure 1).[17]
The activities/steps in the medication use process that are germane to therapeutic drug management occur within two dimensions including macro and micro. Macro activities are

[16] Committee on Identifying and Prevention Medication Errors. Aspden P, Wolcott J, Bootman JL, Cronenwett LR, eds. Preventing Medication Errors. Washington: National Academy Press, 2006
[17] Haaijer-Ruskamp FM, Hemminki E. The social aspects of drug use. WHO Reg Publ Eur Ser 1993;45:97-124

conducted by organizations or systems and focus on population/groups, and the micro activities are done by health professionals and patients and focus on individuals. The

See other file for Figure 1.

medication use process involves various stakeholders such as FDA, pharmaceutical manufacturers, wholesalers, pharmacies, pharmacists, health plans/pharmaceutical benefit managers, prescribers and patients. As well, therapeutic drugs are considered at different instances in the process as developed/manufactured, available via formulary, prescribed, dispensed, consumed and non-prescribed/self-medication. Outcomes from the medication use process exist at the micro/patient or macro/population levels as well and include health and economic outcomes. Quality of the medication use process can be assessed using several types of measures including structure, process, outcome, patient experience, access or composites of these general measures. An important characteristic of this model is that changes in the medication use process can be accommodated. For example, more intricate medication use processes, such as FDA approval of medications for particular populations or even distribution via specified procedures such as by pharmacists or with documented evidence of lab values, may be mandated by FDA in the future to increase safety monitoring.[18]

Therapeutic drug management encompasses the services provided by professionals and the decisions made by patients that influence the likelihood of a positive effect of drug therapy on the length and/or quality of a patient's life. Thus, therapeutic drug management involves the micro level components of the medication use process, yet the micro level components of the medication use process are clearly impacted by macro level components. The question in measuring the quality of therapeutic drug management becomes: "Does medication use conform with scientific knowledge and positively affect patients' health at a cost that is acceptable given limited resources?

[18] Committee on Assessment of the US Drug Safety System. Baciu A, Stratton K, Burke SP, eds. . Institute of Medicine. The future of drug safety: promoting and protecting the health of the public. Washington DC: National Academy Press, 2006, http://www.nap.edu/catalog/11750.html

Factors Affecting Quality of Therapeutic Drug Management

Safe medication use has been the topic of recent publications.[19, 20] Yet, the quality of therapeutic drug management is more than improving the safe use of medications, and the entire medication use process at the macro and micro level must be involved. The medication use process is complex, involving thousands of different drugs and doses and multiple routes of administration. Caregivers, settings and providers are variable and often have different levels of responsibility and goals. The section outlines how quality of therapeutic drug management can be affected by numerous factors including stakeholders and decision makers, setting, therapeutic drug management activities such as prescribing, dispensing, and monitoring, types of therapeutic drug problems, and individual patient versus population.

Stakeholders

For the purposes of this paper, we defined stakeholders as those who affect or are affected by therapeutic drug management (TDM). It is important to recognize that conflicts of interest may occur between different stakeholders. For example, the demand for prescription medications by our aging population continues to rise while public and private payers are interested in containing costs or shifting some of the financial burden back to consumers. Examples of stakeholders impacting the quality of therapeutic drug management are detailed below.

Patients clearly are the most important part of the medication use process at the micro level, as they determine when to seek care, in most instances. Patients also affect the quality of

[19] Committee on Identifying Priority Areas for Quality Improvement. Adams K, Corrigan JM, eds. Priority areas for national action: transforming health care quality. Washington DC: National Academy Press, 2003
[20] Committee on quality of Health Care in America, Kohn LT, Corrigan JM, Donaldson MS, eds. To error is human: building a safer health system. Washington DC: National Academy Press, 2000

TDM by their adherence to prescribed medications, and the success of TDM is often determined by the patient's ability and motivation to take their medications as prescribed. On a macro level, patients can also be involved in drug policy by lobbying the FDA to approve medication more expeditiously or by requesting changes to drug plans offered by employers.

Prescribers of medications are part of the nucleus of therapeutic drug management, and numerous professionals including physicians, dentists, nurse practitioners, physician assistants, optometrists, podiatrists and pharmacists can prescribe. Appropriate drug selection, monitoring, and education are also important activities of all prescribers.

Pharmacists dispense most prescription medication products. Pharmacists also provide counseling and education to patients and/or caregivers, detect drug therapy problems, and monitor outcomes of medications. Several studies have documented the value of pharmacists' services on the overall quality of healthcare.[21, 22]

Nurses contribute to therapeutic drug management and specifically to monitoring the effects of medications on patients.[23, 24] Nurses have the ability to familiarize themselves with the medication regimen of a patient through frequent and regular visits[25, 26], identify medication adherence problems, monitor medications and provide patient education.[23] Some prescription drug organizations will include face-to-face case management by nurses in their medication

[21] Garret D, Bluml B. Patient self-management program for diabetes. First-year clinical, humanistic and economic outcomes. J Am Pharm Assoc, 2005 45:130-137.
[22] Cranor CW, Bunting BA, Christensen DB. The Asheville project: Long-term clinical and economic outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc, 2003 43(2):173-190.
[23] Griffiths R, Johnson M, Piper M, Langdon R. A nursing intervention for the quality use of medicines by elderly community clients. Int J Nurs Pract. 2004 Aug;10(4):166-76
[24] Baker H Napthine R. Nurses and Medication: a Literature Review. Melbourne: Australia Nursing Federation Publications, 1994
[25] Mbothu K. Polypharmacy and community health. Lamp 1997; 54:23.
[26] Ibrahim IA, Kang E, Dansky KH. Polypharmacy and possible drug-drug interactions among diabetic patients receiving home health care services. Home Health Care Serv Q. 2005;24(1-2):97-99

therapy management programs.[27] The elderly population has been receptive to the new functions of nurse practitioners providing primary care in the homecare setting as access to adequate primary health care has become more difficult in recent years.[28]

Pharmaceutical manufacturing companies determine how and to what extent a medication will be marketed. Direct-to-consumer advertising can induce consumer demand for medications and focused marketing to prescribers also influences prescribing decisions.[29, 30, 31, 32, 33] Varying amounts of information about the benefits and risks of medications are provided through consumer and professional marketing. Prescribing decisions, influenced by marketing information or patient demand to some degree, ultimately affect the quality of TDM.

The US population obtains many of their prescriptions medications via prescription drug insurance that is provided by public and private sources. In 2004, 18% or 45.5 million of the non-elderly US population had no health insurance and thus no prescription drug health insurance. In 2006, HHS estimated that 90% of older Americans had prescription drug coverage via public and private providers. The proportion of Americans non-elderly and elderly with employer-based insurance was 62% in 2003 and nearly all plans had prescription drug

[27] Smith SR, Clacy CM. Medication therapy management programs: forming a new cornerstone for quality and safety in Medicare. AM J. Med Qual. 2006 Jul-Aug; 21(4):276-9
[28] Martin B. Al place to care: the homebound elderly. Home Care Provid. 1999 Apr;4(2):76-9
[29] Murray E, Lo B, Pollack L, Donelan K, Lee K. Direct-to-consumer advertising: public perceptions of its effects on health behaviors, health care and the doctor-patient relationship. J Am Board Fam Pract 2004;17:3-18;
[30] Kravitz RL, Epstein RM, Feldman MK, et al. Influence of patients' requests for direct-to-consumer advertised antidepressants: a randomized trial. JAMA 2005;293:1995-2002
[31] Impact of Direct-to-Consumer Advertising on Prescription Drug Spending, Kaiser Family Foundation. http://www.kff.org/rxdrugs/upload/Impact-of-Direct-to-Consumer-Advertising-on-Prescription-Drug-Spending-Summary-of-Findings.pdf, Accessed 27 November 2006
[32] Schumock GT, Walkton SM, Park HY, et al. Factors that influence prescribing decision. Ann Pharmacother 2004;38:556-62;
[33] Caudill TS, Johnson MS, Rich EC, McKinney WP. Physician, pharmaceutical sales representatives and the cost of prescribing. Arch Fam Med 1996;5:201-6

coverage. About 55 million low-income individuals (elderly and non-elderly) receive Medicaid health insurance including prescription drug insurance.[34, 35]

The design of prescription drug plans affect the access to and use of medications through cost sharing, coverage limits and/or deductibles. Similarly, plan design can determine if medications can be obtained at a network of retail pharmacies, mail-order pharmacy or a combination. Prescription drug plans also set reimbursement rates for pharmacies. Pharmacists must determine which plans will be accepted or rejected based on economic factors. The decision to not accept a prescription drug plan often disrupts an established relationship between provider and patient.

Healthcare companies providing a drug benefit often contract with pharmacy benefit managers (PBM) to administer and manage the drug benefit. PBMs use tools such as formularies, prior authorization, step therapy, quantity limits and disease management protocols to control cost and manage the utilization of medications. Each has the ability to influence the quality of therapeutic drug management by directing the selection of the medication, limiting access and/or improving adherence to disease guidelines.

Healthcare Settings

Care of patients occurs in multiple settings including hospital/acute care facilities, medical clinics and physician offices, nursing homes, pharmacies and even the patient's home via formal home healthcare, family members or other caregivers. The primary responsibility for the quality of therapeutic drug management changes as patient care moves from setting to setting. Quality measures may be specific to a particular setting or integrated across multiple

[34] The Medicare Prescription Drug Benefit Fact Sheet – November 2006, Kaiser Family Foundation, http://www.kff.org/medicare/upload/7044-05.pdf, Accessed 27 Nov 2006
[35] Trends and Indicators in the Changing Health Care Marketplace, Kaiser Family Foundation, http://www.kff.org/insurance/7031/print-sec7.cfm, Accessed 27 Nov 2006

settings centering on the care provided to individual patients. For example, the assessment for prescribing a beta-blocker to patients with post acute myocardial infarction occurs in multiples settings. Administration of influenza vaccine is a common quality measure documented in multiple settings. The quality of care provided to a patient (beta-blocker prescribed, vaccination received) could be measured once within a coordinated care system of multiple settings.

Therapeutic Drug Management Activities

Activities that affect therapeutic drug management and its quality include the many actions of all stakeholders: seeking medical care, selecting and prescribing the drug, obtaining the drug, dispensing the drug, medication counseling, patient education, taking or administering the drug, advertising, drug sampling, professional education, monitoring and acting on monitoring data. This complex set of activities is illustrated in Figure 1.

Therapeutic drug problems

Three broad categories of quality problems, underuse, overuse and misuse, affect therapeutic drug management.[36] Hepler and Strand proposed several categories of drug therapy problems that should be identified in pharmaceutical care,[13] and these drug therapy problems have been mapped onto the general categories of quality problems. In this categorization, drug therapy problems that are preventable are considered errors.

- Too little care: underuse of needed, effective, and appropriate care
  - Untreated indication
  - Subtherapeutic dosage
  - Failure to receive or use drugs
- Too much care: overuse, unnecessary or inappropriate care

[36] Institute of Medicine, Committee on Quality of Health Care in America. Measuring the Quality of Health Care – A Statement by the Roundtable on Health Care Quality. Washington, DC:National Academy Press,1999.

- Overdosage
- Drug use without indication
- Improper drug selection

- Misuse: shortcomings in technical and interpersonal aspects of care
  - Adverse drug reactions
  - Drug-drug and drug-disease interactions

Individual Patient vs. Population Economics

The quality of therapeutic drug management may be quite different when viewed from the perspective of a single patient versus that of the population or group in a health plan. A necessary component of therapeutic drug management is providing medication in the most cost-effective manner possible as resources are limited. Systems that promote cost-effective drug therapy such as prior authorization, formularies or step therapy aim to use limited resources in ways that maximize the quality of care received by the population or group. While cost-effective methods of delivering prescription drug plans may have a positive impact on quality at a population level, it may be a barrier and negatively impact quality of care when viewed from the perspective of an individual patient.

In summary, the medication use process is comprised of micro and macro level components and involves numerous stakeholders providing a variety of activities across and in different settings. At patient and population perspectives, overuse, underuse and inappropriate use of therapeutic drugs occurs. Therapeutic drug management is the set of micro level components and processes focused upon patients' use of medications and health outcomes, recognizing that macro level components also impact therapeutic drug management.

Section II. The Domains of Therapeutic Drug Management Quality

A conceptual quality framework for therapeutic drug management ties together the medication use process and the factors that impact it, as discussed in the previous section. The framework specifies five essential areas or domains of therapeutic drug management where quality can be measured. Ideally, domains would be so clearly defined that every attribute of quality fits into only one domain. Given the overlapping components and activities and their complex inter-relationships, a more realistic goal is to define the domains so that all aspects of quality fit into at least one domain, but may not be exclusive to that domain. In other words, the five domains are exhaustive to determine the quality of therapeutic drug management, but they not mutually exclusive. This section defines the domains and uses research to illustrate the domain and factors that impact it. This section also includes examples of best practices related to each domain. Available measures and potential gaps are the focus of the next two sections of this paper and are categorized according to the outlined domains.

Identifying Domains of Quality for Therapeutic Drug Management

We propose five domains for assessing the quality of therapeutic drug management. These domains are based upon the primary components of the micro level medication use process, but also reflect the impact of macro level components of the medication use process. The five domains to assess the quality of therapeutic drug management include:

Patient Decisions & Behaviors

Therapeutic Decision-Making

Safe Medication Use

Cost-Effectiveness

System Coordination and Communication

Domain 1: Patient Decisions & Behaviors

This domain encompasses patient decisions and behaviors of the micro-level medication use process. Traditionally, patients have been viewed as passive receivers of care who require expert direction from healthcare professionals. This approach may be particularly relevant to in-patient care where diagnoses and symptoms may be severe. In the outpatient setting, however, active involvement of patients in all aspects of care is desirable and indicative of patient-centered care. For example, patients do not want communication directed around or above them; rather, patients and their families/caregivers want to be included in decisions that affect their lives.

In a patient-centered environment, patient decisions and behaviors impact numerous aspects of the medication use process including seeking care, prescribing, dispensing, obtaining medications and monitoring. Specifically, patients will determine where and when to seek care, gather and understand disease and treatment information, determine and obtain self-care treatments, demand medications, obtain prescribed treatments including medications, follow therapeutic regimens, and monitor and report experiences and outcomes with therapeutic regimens. These activities are performed by patients, their family, and/or paid caregivers, depending upon levels of cognitive and functional ability and setting.

It is generally a decision of patients to determine whether and when to seek care from prescribers. The interpretations of symptoms, previous self-care experiences and healthcare

access are just a few of the issues that impact decisions to seek care.[37, 38] Quality measures that could be considered for this behavior could be based upon data from screening activities and then linking subsequent use of healthcare services and/or prescription medications.

When care is sought and prescription medications are prescribed, much of the success or failure of the care lies in the hands of patients, as they manage their diseases and treatments including drugs, diet, exercise, etc. Most individuals immediately consider adherence as the single most important contribution of patients and their caregivers to achieve positive outcomes from medications. Adherence is an important component of therapeutic drug management, and factors associated with adherence such as health literacy and cultural competence were summarized in a previous NQF paper.[39, 40, 41] Best practices from this paper are included in Table 3.

We assert that other activities by patients and/or their caregivers such as maintaining a current medication list, monitoring one's disease and medications[42] and reporting medication experiences and symptoms[43, 44, 45] also have significant impacts that cannot be overlooked. For example, symptom reporting is necessary to identify adverse drug events. Increased symptom reporting, in fact, led to increased recognition of adverse drug effects (ADEs).[43] The extent to

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[37] Leventhal H, Brissette I, Leventhal EA. The common-sense model of self-regulation of health and illness. In The self-regulation of health and illness behavior. Camberon LD, Leventhal H, eds. New York: Routledge, 2003:42-65
[38] Trends and Indicators in the Changing Health Care Marketplace (Exhibit 7.6: Barriers to Health Care by Insurance Status, 2003). Kaiser Family Foundation, http://www.kff.org/insurance/7031/print-sec7.cfm, Accessed 27 Nov 2006
[39] National Quality Forum. Wu HW, Nishimi RY, Kizer KW, eds. Improving use of prescription medications: a national action plan: workshop proceedings. Washington: National Quality Forum, 2005
[40] Vik SA, Maxwell CJ, Hogan DB. Measurement, correlates, and health outcomes of medication adherence among seniors. Ann Pharmacother 2004; 38:303-12
[41] Osterberg L. and Blaschke T. Adherence to medication N Engl J Med 2005; 353:487-497
[42] Clark N, Gong M. Management of chronic disease by practitioners and patients: are we teaching the wrong things? BMJ 2999;320:572-5
[43] Gandhi TK, Weingart SN, Borum J, et al., Adverse drug events in ambulatory care. N Engl J Med 2003;348:1556-64
[44] Dewitt JE, Sorofman BA. A Model for understanding patient attribution of adverse drug reaction symptoms. Drug Information Journal 1999; 33(3) 907-920
[45] Rief W, Avorn J, Barsky AJ. Medication- attributed adverse effects in placebo groups. Arch Intern Med .2006; 166:155-160

which symptoms are conveyed to prescribers by patients or caregivers (or by pharmacists, nurses or other professionals) and then used to make changes in medications and/or monitoring is critical to ensure that outcomes from medications are achieved.

Finally, self-care is an important component of healthcare in the United States: about 65% of individuals seek care for a symptom yet only around 25% of those individuals seek professional help. Thus, individuals use self-care in up to 75% of instances when they respond to their symptoms.[46] Individuals obtain medications from a variety of outlets including pharmacies, grocery stores, mass merchandise stores and gas/convenience stores. Many self-care decisions are determined and executed without consultation with healthcare professionals. Consultation with pharmacists may occur when nonprescription medications are obtained at pharmacies. In addition, prescribers may recommend nonprescription medications for specific conditions such as self-limiting pain or colds. However, documentation of self-care practices including nonprescription and complementary/alternative medication use is generally limited in our healthcare system and therefore difficult to quantify and measure.

Numerous factors will impact the decisions by patients/caregivers in therapeutic drug monitoring. The health decisions and health behaviors by patients that typically impact therapeutic drug management are mentioned above. Factors that predispose individuals to particular health behaviors may include age, sex, education, occupation, ethnicity, health knowledge, health literacy, health beliefs, genetic factors, cognitive impairment and internal locus of control. Factors that may enable or impede health behaviors include income, insurance, social support, social networks, health facilities, regular source of care, concentrations of provider types and travel/waiting time. Satisfaction with the provider and the care received

[46] Montagne M, Basara LR. Consumer behavior regarding the choice of prescription and nonprescription medications. In Smith MC, Wertheimer Al, eds. Social and behavioral aspects of pharmaceutical care. New York: Pharmaceutical Products Press, 1996:253-294.

will also impact subsequent health behavior. Individuals who are satisfied with their physicians and have a high degree of confidence in their medicines are more likely to be adherent to their regimens. Finally, environmental factors such as direct-to-consumer advertising (DTCA) and Internet access may impact health behaviors by, in part, changing health knowledge and/or beliefs.[47, 48, 49]

Existing patient-centered quality measures typically use survey tools to reflect patients' opinions of the care received. The following practice guidelines may provide a basis for quality measures for this domain:

- Maintain a list of all drugs used, the reasons for taking them and any known drug allergies. Every provider involved in the medication use process should have access to this list.[16]
- Provide patient adherence aids
- Revise written information about prescription medication to improve patient understanding - specifically address limited literacy and English language barriers

Domain 2: Therapeutic Decision Making

This broad domain encompasses the prescribing, patient education and monitoring components of the micro-level medication use process. Thus, the primary focus of this section is decision-making related to the original choice to prescribe drugs, patient counseling and the subsequent monitoring to determine the effects of the prescribed drugs on health outcomes. Assessing the need for a non-prescription or complimentary/alternative medicine is clearly

[47] Andersen RM. Revisiting the behavioral model and access to medical care: does it matter? J Health Soc Behav 1995;36:1-10
[48] Baker L, Wagner TH, Singer S, Bundorgf MK. Use of the Internet and e-mail for health care information: Results from a national survey. JAMA 2003;289:2400-6
[49] Green LW, Kreuter MW. Health promotion planning: an educational and ecological approach. 3rd ed. Mountain View, CA: Mayfield Publishing, 1999

within the purview of prescribers, but use of these medications is often determined exclusively by patients.

Once prescribers determine that medications are indicated for patients, they are likely to consider a "set" of medications, followed by a choice of a medication from the set. A novice professional is likely to weigh the benefits and risks of several medications within or across therapeutic class/es and determine which product to prescribe. Among highly experienced professionals, standard treatment and habits based upon prior weighting of benefits and risks or experience are more likely to drive decision-making. In fact, many family physicians or general practitioners have a limited set of 100-200 different drug treatments.[50] Specialists will generally prescribe those medications within their area of specialty. While most prescribers have a "personal formulary" from which they choose medications, drug product selection is impacted by a wide variety of factors including medical, economic, sociologic and psychologic (Table 1).[32, 51, 52,] Measures could be developed to assess how these factors influence the quality of drug selection.

Table 1. Factors impacting therapeutic drug management and selection of medications

Micro Level Factors	**Selected Examples**
Drug	Indication, effectiveness, safety, dose, cost
Patient	Age, sex, allergies, kidney function, patient demand, personal experience
Physician	Age, specialty, personal experience
Payment	Insurance status, co-pays or deductibles
Healthcare system- physician	Ownership of practice, source of payment

[50] Taylor RJ, Bond CM. Change in the established prescribing habits of general practitioners: an analysis of initial prescriptions in general practice. Br J Gen Pract 1991;41:244-8
[51] Chambliss ML. Choosing the best medications. Am Fam Physician 1996;53:2565-2570
[52] Denig P, Haaijer-Ruskamp FM. Therapeutic decision making of physicians. Pharm Weekbl [Sci]. 1992;14:9-15

relationship	
Patient-physician relationship	Satisfy patient
Pharmacist	Information regarding medication product, prescribing error, e.g., duplication, drug-drug interaction, wrong dose, wrong drug
Table 1. Factors impacting therapeutic drug management and selection of medications	
Response to therapy	Information regarding patient symptoms or lab values from patients, pharmacists or others
Macro Level Factors	**Examples**
Promotional activities	Sample drugs, face-to-face detailing, pharmaceutical company continuing education, direct-to-consumer advertising
Educational activities	Feedback on prescribing
Administrative programs	Formularies including prescribing restrictions
Prescribing guidelines/standards	Practice guidelines such as JNC VII

Over the past two decades, important advances in the assessment of quality have taken place in the areas of drug product selection, defining therapeutic goals and monitoring for achievement of goals. We look to specialty groups to continue to publish clinical guidelines against which prescribing data can be compared, as practice guidelines and evidence-based medicine offer numerous measures to determine the quality of prescribed medications. An example of a disease-based measure is "individuals discharged from hospital with myocardial infarction diagnoses should be prescribed beta-blocker medications." There are also several measures that can be used to assess the quality of drug product selection at the macro or drug plan level. HEDIS has numerous measures that examine the quality of prescribing in drug plans such as beta-blocker therapy following myocardial infarction or length of therapy for anti-depressants.

Assessing quality in this domain requires access to various data sources. To assess if medications are associated with indications or if there are untreated medical needs requires

more than prescription data because the indication is not included on the prescription. Medical encounter data or medical records in conjunction with prescription data are needed to assess the prevalence of this type of problem. Much of the evidence about the quality of prescribing is based upon comparisons of computerized prescribing records to clinical guidelines or explicit criteria established by expert panels.

Dosing problems – too high or too low – can be assessed in general terms from prescription data using doses from published literature as standards and dispensing records including strength, number distributed and days supply. Measuring the frequency of drug-drug interaction, and therapeutic duplications can be done with prescription data and computerized decision support systems. In fact, drug utilization review programs have documented the extent of computer messaging sent to pharmacies or other dispensing systems identifying possible drug-drug interactions and therapeutic duplications. Yet, we know that many of these messages are not acted upon because the computerized criteria are not sufficiently sensitive and are unable to incorporate patient factors such as "patient has been stable on this combination for several months" or "patient is being monitored". [53,54] Quality measures involving computer-generated alerts should include only those alerts of high clinical significance.

Important advances were made in terms of patient education for dispensed medications in 1990, when the Omnibus Budget Reconciliation Act (OBRA) 1990 included activities for pharmacists to improve drug utilization in the Medicaid population. This Act required State Medicaid agencies to form Drug Utilization Review Boards to provide oversight of

[53] Chui MA, Rupp MT. Evaluation of online prospective DUR programs in community pharmacy practice. J Managed Care Pharm (2000):6:27-32.
[54] Institute for Safe Medication Practices. Optimizing the use of computer system clinical alerts. ISMP Medication Safety Alert (2000);Volume 5, Issue 2.

retrospective and prospective drug review programs. Under OBRA'90 requirements, pharmacists are responsible for:

1. Evaluating a Medicaid recipient's drug profile prior to dispensing a new prescription to detect drug therapy problem including therapeutic duplications, contraindications and drug-drug interactions
2. Offering to counsel a patient about a new prescription medication on directions for administration, precautions, storage
3. Maintaining patient specific information regarding drug therapy including list of medications, allergies and patient demographic information.

Some evidence suggests that counseling rates by pharmacists have increased.[55, 56, 57] Prospective DUR programs have varying results in terms of impacting prescribing. Measures related to OBRA '90 regulations could be explored.

In terms of monitoring the effects and health outcomes of therapeutic drugs, clinical guidelines are often helpful. For example, the American Diabetes Association set targets for timing and values related to HbA1c, which assesses blood glucose control over time. As well, JNC established target outcomes for blood pressure control. Again, specialty groups will continue to publish such guidelines that can be used to determine the clinical outcomes of individual patients.

Domain 2 is the most developed in terms of quality measures because of the abundance of clinical guidelines that can be used as explicit criteria. Quality measures for therapeutic

[55] Schatz R, Belloto Jr RJ, White DB, Bachmann K. Provision of drug information to patients by pharmacists: the impact of the Omnibus Budget Reconciliation Act of 1990 a decade later. Am J Therapeut 2003;10:93-103
[56] Morris LA, Tabak ER, Gondek K. Counseling patients about prescribed medication 12-year trends. Med Care 1997;35:996-1007
[57] Svarstad BL, Bultman DC, Mount JK. Patient counseling provided in community pharmacies: effects of state regulation, pharmacist age, and busyness. J Am Pharm Assoc 2004;44:22-9

decision making would likely benefit from using composite measures so that prescribing, patient education and monitoring related to diabetes care, for example, could be simultaneously considered. Composite measures may also promote the coordination of providers in their monitoring activities and/or collaborative care models. Quality measures in this area focused on pharmacists' practice would also be beneficial. Some best practices surrounding the prescribing and subsequent follow-up and monitoring of patients could improve the quality of this domain and include:

- Minimize use of free samples
- Documented indication for all medications
- Ask about and document allergies when prescribing new
- Annual review of medication
- Ask regularly about side effects or adverse drug effects
- Actively monitor response to medication therapy using validated instruments where possible
- Ask regularly whether individuals are taking their medications
- Regularly make targeted follow-up call to patients with new prescriptions

Domain 3: Safe Medication Use

This domain encompasses all aspects of the micro level medication use process related to medication safety and also includes some system-level components related to health information systems and communication between providers. Safe medication use exists when medication errors are prevented and avoided. A medication error is defined, according to the National Coordinating Council for Medication Error Reporting and Prevention, as "any preventable event that may cause or lead to inappropriate medication use or patient harm while

the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."[58] Clearly assessing safe medication use is a key component to improving the quality of therapeutic drug management.

When defined broadly to encompass preventable events in prescribing, dispensing or patient use, this domain could encompass most measures for therapeutic drug management of individual patients. Measures in this domain should reflect the portion of the definition focusing on "preventable event" and "while the medication is in control of …" and include all aspects of the medication use process as related to medication errors. For example, preventable errors in prescribing, dispensing, administration, and monitoring of medications, including errors of commission and omission and encompassing overuse, underuse, and misuse of therapeutic drugs are included here. Gurwitz reported that preventable adverse drug events, especially the more serious events such as bleeding, ulcer or hypoglycemia were more likely to be preventable (42%).[59] Adverse drug events contribute to 2.5% of emergency department visits for unintentional injuries and 0.6% for all visits.[60] Quality measures for this domain also focus on avoiding inappropriate or dangerous medications, as they are likely to be preventable.

Measures that center on drug selection, disease monitoring and therapeutic outcomes such as an unexpected adverse drug event best fit in Domain 2. For example, "the number of patients suffering allergic reactions from antibiotics that previously had no known drug

[58] http://www.nccmerp.org/aboutMedErrors.html accessed 10-16-06
[59] Gurwitz JH, Field TS, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. *JAMA* 2003;289:1107-16.
[60] Butdnitz DS, Pollock DA, et al. National surveillance of emergency department visits for outpatient adverse drug events. JAMA 2006;296:1858-1866

allergies" is a measure of an adverse drug event, not a prescribing error. Yet, many of these measures may also be represented in other domains. For example, prescribing a contraindicated drug for congestive heart failure patients may be included in this domain as an error in prescribing, or in domain 2 as an inappropriate choice of medication. Miscommunication is also a common source of medications errors and best practices involving repeating back information may be included in this Domain or in Domain 1.

The IOM report, To Error is Human: Building a Safer Health System, dramatically increased the visibility and public interest in medication errors. [20] A series of IOM reports have followed, including Preventing Medication Errors in 2006, which recommends several actions to decrease the number of preventable medication errors.[16] The recommendations in this report provide a basis for developing measures to assess and promote safe medication use. Four key points in the IOM report are:

- Patients (or their caregivers) need to take more responsibility in their medical care
- Increase utilization of information technology for prescribing and dispensing medications
- Communicate drug information to patients and providers clearly and effectively
- The federal government, regulatory agencies and accreditation agencies need greater involvement in reducing preventable medication errors.

New technology has been developed that is intended to improve safe medication use. Measures related to implementation and use of this technology will drive improvement. Bar coding can improve the medication administration process in an institutional setting by using hardware and software components. Patient wristbands and unit-dose medications are scanned to verify the right patient, drug, dose, route and time prior to administering a

medication. Electronic prescribing will decrease the number of illegible handwritten prescriptions and transcription errors through two-way electronic transmission of information for a new prescription, refill request or refill authorization. Linking e-prescribing technology to other decision support systems or electronic health data may decrease ADEs associated with drug allergies or drug-drug interactions.

The majority of research on safe medication use has been focused in hospitals or ambulatory settings rather than in the home. However, medication errors also occur in the home. A report from the USP's Center for the Advancement of Patient Safety found that 11% of medication errors that occurred in a patient's home resulted in harm.[61] The majority of medication errors revolved around dosing (improper dose/quantity or omission/extra dose). Measures related to patients' understanding of their medications or their role in medication monitoring to decrease preventable adverse drug events may be considered for this domain, though the causes of some errors such as lack of patient understanding or poorly communicated instructions may also be considered in Domain 1 or Domain 2, respectively.

Several committees have produced best practices for pharmacists to prevent dispensing errors.[16, 62] Generally, focusing on transcription and handwriting errors, high-risk medications, safe work environments, double-checking prescriptions and implementing quality assurance programs for dispensing are important in reducing dispensing errors. [16] Measures related to reporting and the evaluation of medication errors are considered in this domain.

Expansion of this domain would include best practices such as:

- Verifying verbal or telephone orders using "read back"
- Standardizing the workflow of processing a prescription

[61] Santell JP, Cousins D. Preventing medication errors that occur in the home, U.S. Pharmacist 2004;9:64-68
[62] Institute for Safe Medication Practices, http://www.ismp.org/about/Default.asp, Accessed 27 Nov 2006

- Report errors and near misses to internal and external medication error reporting systems

Domain 4: Cost Effectiveness

The fourth domain to assess quality of therapeutic drug management is cost-effectiveness. This domain is population-based, in contrast to the previous four that are largely focused on individual patients. Cost effectiveness – the comparison of benefits and costs – typically applies to a population such as a health plan's enrollees. When a group pools its resources to purchase health services, the use of high-cost, low-benefit services by one or a few individuals may harm the overall health of the group. Thus, cost-effectiveness analyses are needed to guide administrative programs that ultimately affect drug therapy access at the group or population level by implementing programs that impact prescribing or purchasing decisions at the individual level. In theory, cost-effectiveness analyses guide formulary and related decisions, e.g., reimbursement rates, cost sharing, coverage gaps and utilization review, which impact drug product selection and utilization within a prescription drug plan.

Cost and quality are related, but they are not necessarily proportional. Less expensive medications are not necessarily better than more expensive medications or vice versa. If a particular medication were acknowledged to be superior to all others in its class via evidence and/or expert opinion, then high quality care would mean using that medication irrespective of its costs. However, resources are limited requiring that quality and cost be considered simultaneously, and cost-effectiveness analyses provide that mechanism.

At the population-level, administrative programs are implemented to impact the use of prescription drugs. Health plans may administer and manage the day-to-day operations of their own prescription drug plans or use pharmaceutical benefit managers to perform these

activities. In almost all prescription drug plans as well as hospitals, formularies are used. (Formularies are lists of medications that can be prescribed and/or reimbursed in certain conditions.) In hospitals, perhaps only two medications in a therapeutic class such as ACE inhibitors are on the formulary. When admitted, patients who already have a similar medication that is not on the formulary will be switched to one of the two ACE inhibitor medications that the hospital has on formulary. In prescription drug plans for ambulatory patients, formularies may not allow certain drugs to be purchased without explicit approval by the plan, i.e. prior approval. Formularies may require individuals to use one medication prior to using another, i.e., step therapy. Typically, the first medication is less expensive than the second medication, and individuals are required to determine if the less expensive medication can achieve the desired therapeutic effect prior to paying for the more expensive medication. Ultimately, formularies are used to help control costs, by managing inventory and purchasing agreements. In some Medicaid programs, the actual number of prescriptions that will be covered or paid by the plan on a monthly basis has been limited.

Plan design is an important factor in administering prescription drug plans. Here, considerations as to the premiums, co-pays and deductibles for each plan and even which pharmacies may be used are determined. For example, co-pays are often tiered, with generic prescription medications having lower co-pays than brand-name prescription drugs. Among name-brand medications, some may be "preferred" with lower co-pays than others because of marketing agreements between the health plans or pharmaceutical benefit managers and pharmaceutical manufacturers. The latter agreements are often termed rebates.

In Medicare Part D, a "donut hole" was used to keep program costs under a specified amount. This donut hole means that medications are covered or paid by the plans for

individuals up to a specified maximum amount of money. When that amount has been reached by the individual, then all medications are out-of-pocket expenses until a second threshold has been reached, when almost all medication costs, i.e., catastrophic coverage, will then be paid by the plan. In reality, the cost to obtain a specific prescription drug will differ by medication and by prescription drug plan, depending upon rates established by the health plans or pharmaceutical benefit manager. In our healthcare system, one is generally not able to compare benefits and costs of medications using a consumer-report approach because prices are often unknown because pharmaceutical manufacturers and insurers do not provide this information to patients.

In another example, health plans may have lower co-pays if medications are purchased within a specified set of pharmacies because the health plan has negotiated lower reimbursement rates with these preferred pharmacies. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) used established access standards (TRICARE) to ensure that healthcare plans had contracted enough pharmacies in their provider networks to serve rural and urban customers.

In reality, cost-effectiveness analyses and rebates are used to gain access to formularies thereby providing access to specific medications in health plans. Clearly, any individual can purchase any medication for which they have a legitimate prescription on a cash basis and an individual's willingness to pay drives that decision.

We have assumed a population-based approach when considering cost-effectiveness as a quality domain of therapeutic drug management. However, patients ultimately perform a personal cost-effectiveness analysis based upon their perceptions of costs and benefits each time they use medications, whether prescription or OTC. This personal cost-effectiveness analysis

boils down to individual preferences, based on a full description of costs, benefits and their probabilities. The costs to patients are impacted by health plan and prescription drug plan administrative programs. The benefits and side effects of prescription drugs are often explained by physicians or pharmacists. Rarely are actual probabilities attached to outcomes that may be used in patients' decision-making; rather, it becomes a question of willingness-to-pay. For example, "am I willing to pay $60 per month for a prescription medicine that my doctor says will reduce my risk of dying of a heart attack within the next 20 years?" may be considered. If patients paid the full cost of medications or other healthcare services, decisions would likely be different than if they paid only a proportion of the costs such as co-insurance or co-pay. When individuals pay less for services, then they may demand services in excess of what they would use if they had to pay the full cost of the services. [63]

Quality measures related to cost-effectiveness cannot focus solely on cost. For example, merely calculating a generic dispensing rate only provides information about cost. It is not clear that higher use of generic medications in a particular drug plan represents higher quality care, rather it represents less expensive care. Any generic dispensing rate must be linked with effectiveness evidence as well. At the same time, we know that individuals may over-use medications including high-cost name-brand prescription medications because they do not have to pay the full price, thereby increasing costs for the plan.[63] We also know that some individuals prefer to use prescription medications to improve their health while others do not.[64] Some administrative programs may contribute to reduced access to necessary medications and

[63] Pauly MV. Medicare drug coverage and moral hazard. Health Affairs 2004;23:113-122
[64] Ganther JM. Third party reimbursement for pharmacist services: why has it been so difficult to obtain and is it really the answer for pharmacy? J Am Pharm Assoc 2002: 42:875-9

poor outcomes. For example, higher co-pays reduced medication use[65] including those that were viewed "necessary" and those that are considered "optional". Higher co-pays can also have unintended effects by resulting in increased use of other healthcare services.[65, 66, 67] As well, limiting the number of monthly prescriptions led to increased nursing home admissions.[68]

Clearly, health plans impact therapeutic drug management in terms of plan design and administrative programs. However, there are few available measures of cost-effectiveness. A number of practice guidelines are included in Table 3 that could be developed into quality measures, and examples include:

- Ensuring sufficient pharmacy access, and
- Addressing how cost/access issues impact poor adherence.

Domain 5: System Coordination and Communication

The final domain encompasses macro and micro aspects of the medication use process, but its primary focus remains at the patient level. The system coordination and communication domain includes all activities related to coordinating therapeutic drug management between providers and institutions, including information transfer and communication. It applies to all stakeholders, including those not in formal, organized healthcare settings.

In the Institute of Medicine Report, *Crossing the Quality Chasm*, there are ten rules for the redesign of the healthcare delivery system. One rule, "knowledge is shared and information flows freely", states that patients should have access to their own medical information and to

[65] Keeler EB. Effects of cost sharing on use of medical services and health. Journal of Medical Practice Management, Vol. 8, Summer 1992, pp: 317-321 http://www.rand.org/pubs/reprints/2005/RP1114.pdf
[66] Hsu J, Price M, Huang J, et al. Unintended consequences of caps on Medicare drug benefits. N Engl J Med 2006;354:2349-2359
[67] Motheral B, Fairman KA. Effect of a three-tier prescription copay on pharmaceutical and other medical utilization. Med Care. 2001;39:1293-304
[68] Soumerai SB, Ross-Degnan D, Avorn J, McLaughlin T, Choodnovskiy I, Effects of Medicaid drug-payment limits on admission to hospitals and nursing homes. N Engl J Med. 1991l325:1072-7

clinical information. This rule directs healthcare providers to communicate effectively and to share information.[69] Measures in this domain may relate to how systems or providers share information related to drug management even if they are not organizationally integrated.

Poor communication about patient medications during points of care transition is a major cause of medication errors.[70, 71, 72, 73] Transition points occur within a healthcare system when a patient moves between different units in a facility. Transition points also occur between settings as patients move from acute care hospitals to long-term care facilities back to homes. The Institute for Healthcare Improvement lists three steps in the medication reconciliation process that should occur whenever patients transfer to other care settings.

1. Verification – collect an accurate and complete list of medications, including the name, dosage, frequency and route. Compare this to medications ordered in each new setting. This assures accuracy and completeness.
2. Clarification – discrepancies are identified and changes to the orders are made, if appropriate.
3. Reconciliation – any changes are documented.

Examples within this domain include measures on sharing diagnoses or drug monitoring information between clinicians, measures for medication reconciliation between care settings or measures regarding patient/provider request of a drug plan for prior authorization of a medication. Collaboration and coordination of care can be facilitated by nurses and models

[69] Crossing the Quality Chasm: A New Health System for the 21st century. Institute of Medicine. Ch. 3. National Academy Press, 2001.
[70] Kuehl AK, Chrischilles EA, Sorofman BA. System for exchanging information among pharmacists in different practice environments. Am J Health Syst Pharm. May 15 1998;55(10):1017-1024
[71] Cromarty E, Downie G, Wilkinson S, Cromarty JA. Communication regarding the discharge medications of elderly patients: a controlled trial. Pharm J 1998;260:62-4
[72] Dudas V, Bookwalter T, Kerr KM, Pantilat SZ. The impact of follow-up telephone calls to patients after hospitalization. American Journal of Medicine. 2001;111(9B):26S-30S
[73] Schnipper JL, Kirwin JL, Cotugno MC, et al. Role of pharmacist counseling in preventing adverse drug events after hospitalization. Arch Intern Med. Mar 13 2006;166(5):565-571

have been developed for nurse-managed healthcare providers to reach out to vulnerable, elderly patients with chronic illness residing in rural areas, for example.[74]

This domain also includes quality measures for collaborative practice. The American Society of Consultant Pharmacists defines collaborative practice agreements as "intended to optimize patient care outcomes and may include protocols, practice guidelines, care plans and formulary systems". The National Association of Boards of Pharmacy (NABP) defines collaborative practice as "practice of pharmacy whereby a pharmacist has jointly agreed, on a voluntary basis, to work in conjunction with one or more practitioners under protocol whereby the pharmacist may perform certain patient care functions authorized by the practitioners(s) under certain specified conditions and/or limitations."[75] Over 40 states have laws that address collaborative practices between physicians and pharmacists and multiple studies have documented the benefits of collaboration. There are still many barriers to widespread collaboration between these healthcare providers, including lack of economic incentives and, in some cases, opposition on the part of physicians.

This domain also includes how a health system's structure or policies may affect the quality of therapeutic drug management. Healthcare providers and healthcare organizations providing prescription drug benefits must be able to communicate effectively to enable timely delivery of care. For example, health plans with prior authorization programs determine who has the authority to submit a prior authorization request. Pharmacists and physicians may find it difficult to comply with different requirements based on the beneficiary's insurance coverage. Additionally, providers need more than one method to submit a prior authorization request

[74] Rosswurm MA. Nursing perspectives on the health care of rural elders. Geriatr Nurs. 2001 Sep=Oct;22(5):231-3
[75] Collaborative Practice: Cutting through the confusion and obstacles The Consultant Pharmacist March 2005 Vol. 20, No. 3

(email, internet, fax, phone, written). Healthcare plans should designate a primary mechanism for prior authorization requests that is supported by back-up mechanisms.

There are no measures in Domain 5. Practice guidelines/standards that could be developed into measures include:

- Standards for medication reconciliation
- Two way electronic transfer of information

In summary, we propose five domains for assessing the quality of therapeutic drug management. As stated, measuring the quality of therapeutic drug management would be easiest to implement and understand if each domain was mutually exclusive. However, given the complex nature of the medication use process, this is not possible. Thus, we have sought to identify domains that can accommodate an exhaustive set of measures of quality. The next section identifies available measures related to each domain.

Section III. Survey of Existing Quality Measurements for Therapeutic Drug Management

Performance measures for therapeutic drug management should be valid and reliable and include the following criteria:

1) clinically important - and able to reflect a variation in quality
2) scientifically sound - evidence based, producing consistent results
3) usable by the intended audience - results can be interpreted and will be useful for decision-making, and
4) feasible - data for the measure can be obtained without extensive cost or effort.

Formalized measures are listed in Table 2 and categorized by quality domain. The vast majority of validated and endorsed quality measures relate to prescribing/monitoring

medication(s) for specific diseases (Domain 2). Since these measures are developed by numerous clinical groups, only a few examples will be included here from Domain 2.

There are many practice standards and statements of best practices that describe important activities related to improving quality in therapeutic drug management. These standards and practices are often practical solutions based on clinical or economic evidence and may provide an excellent basis for development of quality measures. Statements of best practices and practice standards are listed in Table 3 to help identify priority areas for further development. The statements are categorized by quality domain and key elements are noted.

These tables are not intended to be exhaustive, rather they describe how quality is currently being measured or practice standards are used to improve the safe, effective and efficient use of medications. In some instances, measures may not specifically relate to therapeutic drug management, but they reference the care received within the healthcare system that might include therapeutic drug management.

Table 2A. Quality Measures

Domain	Name of Measure	Numerator	Denominator	Source/Sponsor of Measure (date)	Description
1: Patient Factors*	Antidepressant medication management (effective acute treatment phase)	Number of members from the denominator with an 84-day treatment of antidepressant medication	Members diagnosed with a new episode of depression and treated with antidepressant medication	National Committee for Quality Assurance HEDIS 2004 **NQF-Endorsed™ Amb. Care Phase , 2005*	Members diagnosed with a new episode of depression, treated with antidepressant medication, remained on an antidepressant drug during the entire 84-day acute treatment phase
1: Patient Factors*	Home health care: percentage of patients who get better at taking their medicines correctly (by mouth)	Patients from the denominator who improved in the management of their oral medications compared to a prior assessment	Patients with a completed episode of care who were eligible to improve in the management of their oral medications	Centers for Medicare & Medicaid Services (CMS) 2005 **NQF-Endorsed™ Home Healthcare, 2005*	Percentage of home health care patients who improve in their ability to manage their oral medications compared to a prior assessment
1: Patient Factors	Home health care: percentage of patients with stabilization in management of oral medications	Patients from the denominator who stabilized in the management of their oral medications compared to a prior assessment	Patients with a completed episode of care who were eligible to stabilize in oral medications management	Centers for Medicare & Medicaid Services (CMS) 2002	Home health care patients who stabilize in their ability to prepare and take all prescribed oral medications reliably and safely
1: Patient Factors	HIV ambulatory care satisfaction: Percentage of HIV positive adult patients in a methadone maintenance program who reported how often the dispensing line was too slow	Number of patients who indicated "All the time", "Most times", "Sometimes", "Rarely", "Never", or "Does not apply" to the item, "The dispensing line was too slow"	HIV positive adult patients engaged in a methadone maintenance program who completed the survey	New York State Department of Health AIDS Institute 2002	Percentage of HIV positive adult patients in a methadone maintenance program who reported who often the dispensing line was too slow
2: Therapeutic Decision Making	Pain management in the long-term care setting: percentage of patients with appropriate treatment for pain	Number of patients with appropriate treatment for pain	All patients with reported pain	American Medical Directors Association 2004	Assess the percentage of patients with appropriate treatment for pain

* *NQF-Endorsed™ Measure*

Domain	Name of Measure	Numerator	Denominator	Source/Sponsor of Measure (date)	Description
2: Therapeutic Decision Making	Pain management in the long-term care setting: percentage of patients with documented medication regimen with evident of titration	Number with documented medication regimen with evidence of titration/ adjustment in accordance with World Health Organization (WHO) step ladder	All patients receiving pain medication	American Medical Directors Association	This measure is used to assess the percentage of patients with documented medication regimen with evidence of titration/adjustment in accordance with World Health Organization (WHO) step ladder
2: Therapeutic Decision Making*	Asthma: persistent asthma	Members in the denominator, who had one dispensed prescription for inhaled corticosteroids, nedocromil, cromolyn sodium, leukotriene modifiers, or methylxanthines	Members with persistent asthma	National Committee for Quality Assurance HEDIS 2006 **NQF-Endorsed™ Amb. Care Phase 2, 2005*	Members having persistent asthma with appropriately prescribed medication
2: Therapeutic Decision Making	Influenza immunization: percentage of Medicare members age 65 years and older who receive an influenza vaccination	Number of members in the denominator who responded "Yes" to the question "Did you get a flu shot last year?"	Number of members who responded, "Yes" or "No" to the question "Did you get a flu shot last year?"	National Committee for Quality Assurance HEDIS 2004	Members age 65 and older who received an influenza vaccination from September through December
2: Therapeutic Decision Making	Pneumonia vaccination status: percentage of members age 65 years and older who experienced a pneumococcal vaccination	Members in the denominator who responded "yes"	Members who responded "yes" or "no" to the question "Have you ever had a pneumonia shot?"	National Committee for Quality Assurance HEDIS 2004	Percentage of Medicare members who ever received a pneumococcal vaccination
2: Therapeutic Decision Making	Lipid management in adults: percentage of patients on a lipid lowering medication who have a fasting lipid panel every three to twelve months	Patients on lipid lowering medication who have a fasting lipid panel	Patients who are on lipid lowering medication	Institute for Clinical Systems Improvement 2006	Percentage of patients on a lipid lowering medication who have a fasting lipid panel every three to twelve months

* *NQF-Endorsed™ Measure*

Domain	Name of Measure	Numerator	Denominator	Source/Sponsor of Measure (date)	Description
2: Therapeutic Decision Making*	Osteoarthritis: percentage of patient visits during which an anti-inflammatory agent or analgesic was considered	Patient visits during which an anti-inflammatory agent or analgesic was considered	All patient visits for patients with osteoarthritis (OA)	American Medical Association 2005 * *NQF-Endorsed™ Amb. Care Phase 2, 2005*	Percentage of patient visits during which an anti-inflammatory agent or analgesic was considered
2: Therapeutic Decision Making*	Appropriate treatment for children with upper respirator infection	Children from the denominator who were dispensed prescription for antibiotic medication on or three days after the Episode Date	Children outpatient visit with only a diagnosis of nonspecific upper respiratory infection	National Committee for Quality Assurance HEDIS 2006 * *NQF-Endorsed™ Amb. Care Phase 2, 2005*	Percentage of children with diagnosis of upper respiratory infection and were not dispensed an antibiotic prescription on or three days after the Episode Date
2: Therapeutic Decision Making	Inappropriate antibiotic treatment for adults with acute bronchitis	Patients from the denominator who were dispensed outpatient prescription for antibiotic medication on or within three days after the Episode Date	Members 18 years to 64 years with an outpatient visit with any diagnosis of acute bronchitis	National Committee for Quality Assurance HEDIS 2006	Percentage of healthy adults with a diagnosis of acute bronchitis who were dispensed an antibiotic prescription or within three days after the Episode Date
2: Therapeutic Decision Making	Osteoporosis management in women who had a fracture	Members from the denominator who were appropriately treated or tested for osteoporosis after the fracture	Women 67 years of age and older with a Negative Medication History, who suffered a fracture	National Committee for Quality Assurance HEDIS 2006	Percentage of women 67 years of age and older who suffered a fracture, and had a bone mineral density test or prescription for a drug to treat or prevent osteoporosis in the six months after date of the fracture
2: Therapeutic Decision Making	Annual monitoring for patients on persistent medications	Members who received at least a 180-day supply of ambulatory medication therapy for the selected therapeutic agent and received at least one therapeutic monitoring event	Members who received at least a 180-day supply of a selected therapeutic agent	National Committee for Quality Assurance HEDIS 2006	Members who received at least a 180-day supply of ambulatory medication therapy for the selected therapeutic agent and received at least one therapeutic monitoring event for the therapeutic agent in the measurement year

* *NQF-Endorsed™ Measure*

Domain	Name of Measure	Numerator	Denominator	Source/Sponsor of Measure (date)	Description
2: Therapeutic Decision Making	Pain management in the long-term care setting: percentage of patients with adverse drug reactions to pain medications	Number of patients with adverse drug reactions related to pain medications	All patients receiving pain medication	American Medical Directors Association 2004	Percentage of patients who had adverse drug reactions (ADRs) to pain medications
2: Therapeutic Decision Making	Pain management in the long-term care setting: percentage of patients with controlled adverse drug reactions to pain medications	Number with controlled adverse drug reactions (ADRs) to pain medication	All patients with reported pain receiving pain medication who had an adverse drug reaction (ADR)	American Medical Directors Association 2004	Patients whose adverse drug reactions (ADRs) to pain medication were controlled
2: Therapeutic Decision Making	Pain management in the long-term care setting: percentage of patients prescribed narcotics for pain with appropriate bowel management program in place	Number with prescribed narcotics for pain with appropriate bowel management program in place	Patients with prescribed narcotics to treat pain	American Medical Directors Association 2004	Percentage of patients who were prescribed narcotics for pain and had appropriate bowel management program in place

Domain	Name of Measure	Numerator	Denominator	Source/Sponsor of Measure (date)	Description
2: Therapeutic Decision Making	Percentage of HIV positive adult patients who reported whether they needed more information about the purpose of their psychiatric medications and their side effects	The number of patients who indicated a response to the item, "I needed more information about the purpose of my psychiatric medications and their side effects"	HIV positive adult patients who received one or more mental health services in the last 12 months and completed the survey	New York State Department of Health AIDS Institute 2002	Percentage of HIV positive adult patients who reported whether they needed more information about the purpose of their psychiatric medications and their side effects
2. Therapeutic Decision Making*	Timing, Selection, and Duration of prophylaxis for surgery (three measures).	Percentage of surgery patients receiving antibiotics within 1 hour prior to surgery, who receive antibiotics consistent with guidelines, and whose antibiotics are discontinued within 24 hours after surgery (48 hours for Cardiac surgery)	All surgical patients.	Centers for Medicare and Medicaid Services (CMS) **NQF-Endorsed™ Hospital Care, 2003*	
3: Safe Medication Use	Pain management in the long-term care setting: percentage of patients with orders for not recommended drugs	Number of patients with orders for not recommended drugs	All patients receiving medications to treat pain	American Medical Directors Association 2004	This measure is used to assess the percentage of patients receiving pain medication with orders for not recommended drugs
3: Safe Medication Use	Drugs to be avoided in the elderly (DAE)	Medicare members 65 years of age and older who received at least one drug to be avoided in the elderly	Medicare members 65 years of age and older who received any medication	National Committee for Quality Assurance HEDIS 2006	Medicare members 65 years of age and older who received at least one drug to be avoided in the elderly

* *NQF-Endorsed™ Measure*

Domain	Name of Measure	Numerator	Denominator	Source/Sponsor of Measure (date)	Description
3: Safe Medication Use	Potentially harmful drug disease interactions in the elderly (DDI)	History of falls or diagnosis of hip fracture and prescription for tricyclic antidepressants, benzodiazepines and/or typical antipsychotics; dementia and prescription for anti-cholinergic agents; peptic ulcer disease and prescription for analgesics containing aspirin or non-Cox-2 selective NSAIDs; chronic renal failure and prescription for NSAIDS	Patients with history of falls or diagnosis hip fracture; patients with diagnosis of dementia; patients with diagnosis of peptic ulcer; patients with diagnosis of chronic renal failure	National Committee for Quality Assurance HEDIS 2006	This measure reports four rates. Each drug-disease interaction is reported separately and in aggregate.
3: Safe Medication Use*	Home health care: percentage of patients who had to be admitted to the hospital	Patients from the denominator receiving emergent care for improper medication administration or side effects.	Patients with a completed home health episode of care. **NQF-Endorsed™ Home Healthcare, 2005*	Centers for Medicare & Medicaid Services (CMS) 2005 * *NQF-Endorsed™ Home Healthcare, 2005*	Assesses the percentage of home health care patients who were admitted to a hospital for 24 hours or more while a home health patient
4: Cost Effectiveness	Generic dispensing rate: the ratio of paid claims for generic medications divided by the total number of paid claims	Number of paid claims for generic medications	Total number of paid claims	CMS Reporting Requirements of Part D Plans	The ratio of paid claims for generic medications divided by the total number of paid claims
5: System Coordination and Communication	Documentation of a medication list in the outpatient record	Patients with a medication list in their medical record	Patients with CAD, HF or Afib, age 18 yrs or older, who were continuously enrolled during the measurement year	Centers for Medicare & Medicaid Services (CMS) 2005; SCRIPT (2002) * *NQF-Endorsed™ Ambulatory Care, 2005*	Percentage of patients having a medication list in the medical record

* *NQF-Endorsed™ Measure*

Domain	Name of Measure	Numerator	Denominator	Source/Sponsor of Measure (date)	Description
5. System Coordination and Communication	Documentation of adverse reactions and allergies to medications in the outpatient record	Patients with allergy and adverse reaction status present in medical record	Patients with CAD, HF or Afib, age 18 yrs or older, who were continuously enrolled during the measurement year	Centers for Medicare & Medicaid Services (CMS) 2005 * *NQF-Endorsed™ Ambulatory Care, 2005*	Percentage of patients having documentation of allergies and adverse reactions in the medical record

Table 2B. Measures from the Institute for Health Care Improvement

Domain	Name of Measure	Numerator	Denominator	Source/Sponsor of Measure	Description
2: Therapeutic Decision Making	High-risk adverse drug events per 1,000 doses	Total number of ADEs related to a specific high-risk drug or class identified in a sample of patient records	Total number of doses of the high-risk drug or class administered to those patients (multiply the result by 1,000)	Institute for Health Care Improvement	Tracks number of high-risk drug ADEs over time
2: Therapeutic Decision Making	Percent of patients receiving a specific high-risk medication with a related adverse drug event	Total number of patients identified as having experienced any ADE related to the specific high-risk drug or class from a sample of patient records	Total number of records in the sample (multiply the result by 100)	Institute for Health Care Improvement	Tracks the percent of patients identified as having ADE related to a specific high-risk drug
3: Safe Medication Use	Number of self-reported medication errors	Number of medication errors reported using the organization's self-reporting medication error system	None	Institute for Health Care Improvement	Record the absolute number of self-reported medication errors per month
3: Safe Medication Use	Pharmacy interventions per 100 admissions	The total number of pharmacy interventions documented during the data collection period	Total number of patients whose orders were reviewed by pharmacists during the same data collection period	Institute for Health Care Improvement	Pharmacist interventions prevent ADEs. As opportunities for error and adverse drug events decrease, the number of interventions should decrease
3: Safe Medication Use	Errors from unreconciled medications per 100 admissions	Total number of errors related to unreconciled medications found in a sample of patient records	Total number of patient records reviewed (multiply the result by 100)	Institute for Health Care Improvement	Tracks errors related to unreconciled medications

Domain	Name of Measure	Numerator	Denominator	Source/Sponsor of Measure	Description
5: System Coordination and Communication	Percent of unreconciled medications	Number of unreconciled medications (not doses)	Total number of medications ordered for patients in the sample	Institute for Health Care Improvement	Goal is to reduce the percent of unreconciled medications at admission, transfer, or discharge

Table 2C. Draft measures from the Pharmacy Quality Alliance

Domain	Name of Measure	Numerator	Denominator	Source/Sponsor of Measure	Description
2: Therapeutic Decision Making	Dosing of ACEI and ARBs in Heart Failure	Number of patients with dispensed Rx for ACEI/ARB at target dose	All patients with concurrent dispensing of ACE or ARB and loop diuretic and one of three beta blockers (bisoprolol, metoprolol, and carvedilol	Pharmacy Quality Alliance Draft Measures	Assess the percentage of patients with heart failure who have dispensed medications with Class 1 Level A evidence at target or 50% target dose.
2: Therapeutic Decision Making	Contra-indicated Medications in Heart Failure (D-2 Therapeutic Decision Making)	Number of patients with any dispensed, concurrent Rx for verapamil, diltiazem or nifedipine OR for any dispensed, concurrent Rx for any NSAID	All patients with concurrent dispensing of ACE or ARB and loop diuretic and one of three beta blockers (bisoprolol, metoprolol, and carvedilol)	Pharmacy Quality Alliance Draft Measures	Percent of Heart Failure patients dispensed a contra-indicated calcium-channel blocker OR NSAID
2: Therapeutic Decision Making	Adherence to ACEI/ARB	Number of adults in the denominator who have at least one significant gap in ACE/ARB therapy	Number of adults with at least one claim for an ACE or ARB during a six-month period	Pharmacy Quality Alliance Draft Measures	Percentage of prevalent users who were prescribed an ACEI or ARB and experienced a significant gap in medication therapy
2: Therapeutic Decision Making	Adherence to beta-blocker	Number of adults in the denominator who have at least one significant gap in beta-blocker therapy	Number of adults with at least one claim for a beta-blocker during a six-month period	Pharmacy Quality Alliance Draft Measures	Percentage of patients who were prescribed a beta-blocker and had a significant gap in medication therapy

2: Therapeutic Decision Making	Therapeutic Duplication	Number of adults in the denominator who had simultaneous use of at least two drugs within the same class	Number of adults continuously enrolled in a drug plan during the observation period who had at least one claim for a drug from one of the following classes: beta blockers, calcium-channel blockers, ACEI, ARB	Pharmacy Quality Alliance Draft Measures	Measures assesses the proportion of patients experiencing therapeutic duplication

Domain	Name of Measure	Numerator	Denominator	Source/Sponsor of Measure	Description
2: Therapeutic Decision Making	Medication overuse: Dosing	Number of patients in the denominator who are on higher than recommended doses	Number of adults with at least one claim for an oral hypoglycemic agent who were continuously enrolled in a drug plan during the observation period	Pharmacy Quality Alliance Draft Measures	Proportion of patients receiving oral hypoglycemic agents at doses exceeding FDA-approved labeling
2: Therapeutic Decision Making	Inappropriate use of inhaled corticosteroids	Patients with prescription for oral antifungal therapy (note exclusions) within 30 days following a claim for Rx of corticosteroid inhaler	Patients with one or more Rx for inhaled corticosteroids. Patients with drug inferred immunocompromised diseases are excluded from D	Pharmacy Quality Alliance Draft Measures	Measure assesses the percentage of patients receiving oral antifungal therapy (as a proxy for oral thrush) while concurrently receiving inhaled corticosteroid therapy
2: Therapeutic Decision Making	Overall frequency of pharmacy eligible MTM visits provided in pharmacy	Number of patients that receive an MTM visit from a pharmacist	Total number of patients eligible for pharmacist/pharmacy MTM services	Pharmacy Quality Alliance Draft Measures	Measure will quantify the overall frequency of pharmacist provided MTM services for patients eligible to receive MTM
2: Therapeutic Decision Making	Frequency of pharmacy eligible MTM who receive a comprehensive medication review	Number of patients eligible for pharmacists/pharmacy delivered MTM who receive a CMR	Number of patients eligible for pharmacists/pharmacy MTM	Pharmacy Quality Alliance Draft Measures	Quantifies overall frequency of patients eligible for pharmacist provided MTM who receive a comprehensive medication review in a pharmacy
2: Therapeutic Decision Making	Pharmacist Override; Medication dispensed	Number of pharmacy claims for patients with a new prescription for the target medication with identified DUE codes and the dispensed medication equals originally prescribed medication	Number of pharmacy claims for the target medication	Pharmacy Quality Alliance Draft Measures	Percentage of severity level 1 drug interaction DUE alerts overridden by pharmacist resulting in the originally prescribed medication dispensed

3: Safe Medication Use	Patient Safety in Heart Failure	Number of patients with any dispensed, concurrent prescriptions for an NSAID and warfarin	All patients with concurrent dispensing of ACE or ARB and loop diuretic and one of three beta blockers (bisoprolol, metoprolol, and carvedilol)	Pharmacy Quality Alliance Draft Measures	Measure assesses the percentage of patients with heart failure who receive warfarin who have a contraindicated prescription for an NSAID
Domain	Name of Measure	Numerator	Denominator	Source/Sponsor of Measure	Description
3: Safe Medication Use	Drug Interaction Alert; Different Medication Dispensed	Number of pharmacy claims for patients with a new prescription for the target medication with identified DUE codes and the dispensed medication is different from the prescribed medication	Number of pharmacy claims for the target medication	Pharmacy Quality Alliance Draft Measures	Percentage of severity level 1 drug interaction DUE alerts resulting in a different dispensed medication than originally prescribed
4: Cost Effectiveness	Generic Dispensing	Number of prescriptions filled with generics	Total number of prescriptions filled with prescription drugs that are available as generics	Pharmacy Quality Alliance Draft Measures	Assess the percent of prescriptions filled with a generic product when generic alternatives are available.
4: Cost Effectiveness	Generic Intervention Opportunity	Successful pharmacist interventions	Opportunities for change to generic (excludes prescriptions marked DAW)	Pharmacy Quality Alliance Draft Measures	Reports opportunities to change prescriptions for brand drugs to generic alternatives and the actual interventions employed

Table 3. Practice Statements or Practice Guidelines

Domain	Statement	Source/Sponsor of Measure (date if available)	Key Elements
1: Patient Factors	Identify and report instances in which patients fail to receive medication	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	Access underuse
1: Patient Factors	Identify and improve persistence and adherence and reduce identified barriers to claim fulfillment	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	Adherence
1: Patient Factors	Prescriber is required to notify patients that they may request the prescription label list the purpose or symptoms for which the prescription is written. In the case of anabolic steroids, it is mandatory	Colorado State Law	Knowledge
1: Patient Factors	Improve written prescription medication information (Revising various forms of written information and instruction about prescription medication leading to better informed patients, particularly those with limited literacy and English language barriers)	NQF Improving Use of Prescription Medications: A National Action Plan - 2005	Revising written information and instruction
1: Patient Factors	Provide tool patients can use to take charge of their own care (Improve the use of medications with patient adherence aids)	NQF Improving Use of Prescription Medications: A National Action Plan - 2005	Provide tools
2: Therapeutic Decision Making	Pharmacists should actively participate in the medication management systems, including, at a minimum, working with other health professionals to select and maintain a formulary of medications chosen for safety and effectiveness, being available for consultation with prescribers on medication ordering, interpretation and review of medication orders, preparation of medications, assuring safe storage and availability of medications, dispensing of medications, and administration and monitoring of medications	National Quality Forum – Safe Practice 2003 (Updated 2006)	Pharmacist involvement
2: Therapeutic Decision Making	Identify and report optimal drug therapy selection for diseases that can be inferred from pharmacy claims, such as diabetes, asthma and HIV	AMCP/NCQA May 2006: Developing a Robust Quality Measurement Approach for Medicare Part D	Drug selection
2: Therapeutic Decision Making	Identify untreated indications and promote appropriate treatment according to nationally recognized practice standards	AMCP/NCQA May 2006: Developing a Robust Quality Measurement Approach for Medicare Part D	Underuse
2: Therapeutic Decision Making	Identify and report the prevalence of subtherapeutic dosage based on DUR edits	AMCP/NCQA May 2006: Developing a Robust Quality Measurement Approach for Medicare Part D	Dosing

Domain	Statement	Source/Sponsor of Measure (date if available)	Key Elements
2: Therapeutic Decision Making	Identify and prevent medical claims related to medication toxicity and ensuring appropriate laboratory monitoring of high-risk medications	AMCP/NCQA May 2006: Developing a Robust Quality Measurement Approach for Medicare Part D	Monitoring
2: Therapeutic Decision Making	Identify potentially unnecessary medication utilization through integration of pharmacy and medical claims	AMCP/NCQA May 2006: Developing a Robust Quality Measurement Approach for Medicare Part D	Overuse
2: Therapeutic Decision Making	Proportion of patients receiving beta-blocker monotherapy	AMCP/NCQA May 2006: Developing a Robust Quality Measurement Approach for Medicare Part D	Drug selection
2: Therapeutic Decision Making	Measure, assess, and if appropriate, take action to improve the timeliness of reporting, and the timeliness of receipt by the responsible licensed caregiver, of critical test results and values	Joint Commission National Patient Safety Goals 2007	Monitoring
2: Therapeutic Decision Making	Identify and report optimal drug therapy duration for diseases that can be inferred from pharmacy claims, such as depression	AMCP/NCQA May 2006: Developing a Robust Quality Measurement Approach for Medicare Part D	Adherence
2: Therapeutic Decision Making	Sub optimum utilization of diabetic testing supplies	AMCP/NCQA May 2006: Developing a Robust Quality Measurement Approach for Medicare Part D	Monitoring
2: Therapeutic Decision Making	Proportion of patients with glycosylated hemoglobin value at or below the nationally recognized treatment goal	AMCP/NCQA May 2006: Developing a Robust Quality Measurement Approach for Medicare Part D	Therapy outcome
2: Therapeutic Decision Making	Proportion of patients with LDL-cholesterol value at or below the nationally recognized treatment goal	AMCP/NCQA May 2006: Developing a Robust Quality Measurement Approach for Medicare Part D	Therapy outcome
2: Therapeutic Decision Making	MTM programs should be delivered by an interdisciplinary MTM team led by a qualified pharmacist or other health care professional: team members should have expertise in the specifics of the medications in question	AMCP Sound Medication Therapy Management Programs	Professional knowledge
2: Therapeutic Decision Making	Every new drug prescribed to a vulnerable elder on an ongoing basis for a chronic medical condition should have documentation of the response to therapy within 6 months	ACOVE (Addressing Care of Vulnerable Elders) (Knight EL, Avorn) 2001	Therapy outcome
2: Therapeutic Decision Making	All vulnerable elders should have a drug regimen review at least annually	ACOVE (Addressing Care of Vulnerable Elders) (Knight EL, Avorn) 2001	Monitoring

Domain	Statement	Source/Sponsor of Measure (date if available)	Key Elements
2: Therapeutic Decision Making	If a vulnerable elder is prescribed warfarin, then an INR should be determined within 4 days after initiation of therapy and at least every 6 weeks	ACOVE (Addressing Care of Vulnerable Elders) (Knight EL, Avorn) 2001	Monitoring
2: Therapeutic Decision Making	If a vulnerable elder is prescribed a thiazide or loop diuretic, then electrolytes should be checked within one week after initiation and at least yearly	ACOVE (Addressing Care of Vulnerable Elders) (Knight EL, Avorn) 2001	Monitoring
2: Therapeutic Decision Making	If a vulnerable elder is prescribed an oral hypoglycemic drug, then chlorpropamide should not be used	ACOVE (Addressing Care of Vulnerable Elders) (Knight EL, Avorn) 2001	Drug selection
2: Therapeutic Decision Making	If a vulnerable elder begins an angiotensin-converting enzyme (ACE) inhibitor, then serum potassium and creatinine levels should be checked within one week of initiating therapy	ACOVE (Addressing Care of Vulnerable Elders) (Knight EL, Avorn) 2001	Monitoring
2: Therapeutic Decision Making	If a new drug is prescribed for a vulnerable elder, then the prescribed drug should have a clearly defined indication documented	ACOVE (Addressing Care of Vulnerable Elders) (Knight EL, Avorn) 2001	Documented indication
2: Therapeutic Decision Making	If a new drug is prescribed for a vulnerable elder, the patient (or caregiver) should receive education about the purpose of the drug, how to take it and the expected side effects or important adverse reactions	ACOVE (Addressing Care of Vulnerable Elders) (Knight EL, Avorn) 2002	Patient education
2: Therapeutic Decision Making	Frequency of use of a calcium channel blocker without other antihypertensive agent	AMCP/NCQA May 2006: Developing a Robust Quality Measurement Approach for Medicare Part D	
2: Therapeutic Decision Making	Improve verbal communication about prescription medication use. (Pharmacists see patients more than any other health care provider and are a key leverage point for improvement. Proper communication by all providers is critical to improve consumer use of prescription medications. Special communication strategies should be used for populations with limited health literacy.	NQF Improving Use of Prescription Medications: A National Action Plan - 2005	Improve verbal communication
2: Therapeutic Decision Making	Routinely assess patient adherence as a standard "vital sign". (Providers must routinely ask for more detailed information about medications used- not just what they are taking.)	NQF Improving Use of Prescription Medications: A National Action Plan - 2005	Assess patient adherence
2: Therapeutic Decision Making	Medication Therapy Management should strive to obtain appropriate therapeutic outcomes for targeted consumers through improved medication use and reduce the incidence of adverse events	URAC Drug Therapy Management Accreditation Standards Version 1.0	MTM – Appropriate therapeutic outcomes

Domain	Statement	Source/Sponsor of Measure (date if available)	Key Elements
2: Therapeutic Decision Making	Medication Therapy Management Programs should be developed in cooperation with practicing pharmacists and physicians	URAC Drug Therapy Management Accreditation Standards Version 1.0	MTM – Developed in cooperation with practicing pharmacists and physicians
2: Therapeutic Decision Making	Medication Therapy Management Programs should incorporate evidence based medicine; population specifications; and defined service offerings	URAC Drug Therapy Management Accreditation Standards Version 1.0	MTM – Incorporate evidence based medicine
2: Therapeutic Decision Making	Medication Therapy Management Programs should implement programs to identify and enroll at risk individuals for a lack of adherence to medication therapy, inappropriate medication use and adverse events	URAC Drug Therapy Management Accreditation Standards Version 1.0	MT – Identify and enroll at risk individuals
3: Safe Medication Use	Plan identifies and reports the frequency of use of potentially-inappropriate medications among the elderly and other Medicare populations	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	Inappropriate medication
3: Safe Medication Use	Measure the effectiveness and impact of DUR alerts, including drug-drug interactions and drug incompatibilities	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	DUR edits on drug-drug interactions
3: Safe Medication Use	Identify and prevent inappropriate medication-use-induced health care utilization and claims for treatment of known adverse effects	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	Inappropriate medication
3: Safe Medication Use	Frequency of short-acting calcium-channel blocker use	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	Inappropriate combination
3: Safe Medication Use	Frequency of use of an ACE-inhibitor and a potassium-sparing diuretic	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	Inappropriate combination
3: Safe Medication Use	HMG-CoA reductace inhibitor use with verapamil or amiodarone	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	Inappropriate combination
3: Safe Medication Use	HMG-CoA reductace inhibitor use with protease inhibitors (pravastatin patients excluded)	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	Inappropriate combination
3: Safe Medication Use	Frequency of concomitant use of lipid-lowering medications and medications that may worsen the lipid profile, such as rosiglitazone and olanzapine	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	Inappropriate combination
3: Safe Medication Use	Use of at least two patient identifiers when providing care, treatment or services	Joint Commission National Patient Safety Goals 2007	Two patient identifiers
3: Safe Medication Use	For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person receiving the information record and "read-back" the complete order or test result	Joint Commission National Patient Safety Goals 2007	Verification of verbal orders

Domain	Statement	Source/Sponsor of Measure (date if available)	Key Elements
3: Safe Medication Use	Standardize a list of abbreviations, acronyms, symbols, and dose designations that are not to be used throughout the organization	Joint Commission National Patient Safety Goals 2007	Standardize abbreviations
3: Safe Medication Use	Standardize and limit the number of drug concentrations used by the organization	Joint Commission National Patient Safety Goals 2007	Standardize drug concentrations
3: Safe Medication Use	Identify and, at a minimum, annually review a list of look-alike/sound-alike drugs used by the organization, and take action to prevent errors involving the interchange of these drugs	Joint Commission National Patient Safety Goals 2007	List look alike/sound alike drugs
3: Safe Medication Use	Label all medications, medication containers (for example, syringes, medicine cups, basins), or other solutions on and off the sterile field	Joint Commission National Patient Safety Goals 2007	Use of labels
3: Safe Medication Use	Standardize the methods for labeling and packaging medications	National Quality Forum - Safe Practices 2003 (Updated 2006)	Standardize labels, packaging, storing
3: Safe Medication Use	Identify all "high alert" drugs and establish policies and processes to minimize the risks associated with the use of these drugs. At a minimum, such drugs should include intravenous adrenergic agonists and antagonists, chemotherapy agents, anticoagulants and anti-thrombotics concentrated parenteral electrolytes, general anesthetics, neuromuscular blockers, insulin and oral hypoglycemics, narcotics and opiates	National Quality Forum - Safe Practices 2003 (Updated 2006)	Identify high alert drugs
3: Safe Medication Use	Healthcare organizations should dispense medications, including parenterals, in unit-dose, or when appropriate unit-of-use form, whenever possible	National Quality Forum - Safe Practices 2003 (Updated 2006)	Unit dose
3: Safe Medication Use	Standardize the workflow of processing a prescription	The National Alliance of State Pharmacy Associations, Pharmacy Quality Commitment	Workflow
3: Safe Medication Use	Use color-coded baskets to separate prescriptions and facilitate communication during the processing workflow	The National Alliance of State Pharmacy Associations, Pharmacy Quality Commitment	Workflow
3: Safe Medication Use	At each new step, the technician or pharmacists review and checks what has been done during the previous step in the workflow process. If there is only one person in the process, this is a self-check	The National Alliance of State Pharmacy Associations, Pharmacy Quality Commitment	Workflow

Domain	Statement	Source/Sponsor of Measure (date if available)	Key Elements
3: Safe Medication Use	Echo, Verify and Document - when prescriptions are received verbally, the pharmacist repeats (echoes) each element of the prescription, verifies that the information is correct and documents the verification on the prescription with their initials and date	The National Alliance of State Pharmacy Associations, Pharmacy Quality Commitment	Verification of verbal orders
3: Safe Medication Use	The 2-second rule - a container with medications is not allowed to remain unlabeled for longer than two seconds	The National Alliance of State Pharmacy Associations, Pharmacy Quality Commitment	Labeling
3: Safe Medication Use	Verify patient name and medication label on the prescription bottle against the patient name and medication on the package receipt	The National Alliance of State Pharmacy Associations, Pharmacy Quality Commitment	Verification patient and medication label
3: Safe Medication Use	Require prescriptions to be written legibly (various wording)	State Law Delaware, Florida, Idaho, Maryland, Montana, Tennessee, Washington	Legible prescriptions
3: Safe Medication Use	All vulnerable elders should not be prescribed a medication with strong anticholinergic effects if alternatives are available	ACOVE (Addressing Care of Vulnerable Elders) (Knight EL, Avorn) 2001	Wrong drug
3: Safe Medication Use	Unless needed for seizure control, barbiturates should not be prescribed to a vulnerable elder	ACOVE (Addressing Care of Vulnerable Elders) (Knight EL, Avorn) 2002	Wrong drug
3: Safe Medication Use	Meperidine should not be used for a vulnerable elder requiring analgesia	ACOVE (Addressing Care of Vulnerable Elders) (Knight EL, Avorn) 2003	Wrong drug
3. Safe Medication Use	Pharmacists should actively participate in the medication-use process, including, at a minimum, being available for consultation with prescribers on medication ordering, interpretation and review of medication orders, preparation of medications, dispensing of medications, and administration and monitoring of medications	NQF Safe Practices, 2003	Pharmacist participation
3. Safe Medication Use	Verbal orders should be recorded whenever possible and immediately read back to the prescriber—i.e., a healthcare provider receiving a verbal order should read or repeat back the information that the prescriber conveys in order to verify the accuracy of what was heard	NQF Safe Practices, 2003	Information transfer, communication
3. Safe Medication Use	Use only standardized abbreviations and dose designations	NQF Safe Practices, 2003	Information transfer/ communication
3. Safe Medication Use	Implement a computerized prescriber order entry system	NQF Safe Practices, 2003	Information transfer/communication
3. Safe Medication Use	Keep workspaces where medications are prepared clean, orderly, well lit, and free of clutter, distraction, and noise	NQF Safe Practices, 2003	Medication management

Domain	Statement	Source/Sponsor of Measure (date if available)	Key Elements
3. Safe Medication Use	Dispense medications in unit-dose or, when appropriate, unit-of-use form, whenever possible	NQF Safe Practices, 2003	Medication management
4: Cost-effectiveness	Ensure appropriate and timely administration of prior authorization and medical exception process	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	Provide authorization
4: Cost-effectiveness	Ensuring sufficient pharmacy access to members	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	Access
4: Cost-effectiveness	Ensuring appropriate and timely access to a grievance process	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	Grievance process
4: Cost-effectiveness	Ensuring formulary access and compliance with requirements	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	Formulary
4: Cost-effectiveness	Provide oversight of Pharmacy and Therapeutics (P&T) Committee decisions to ensure compliance with requirements	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	P & T oversight
4: Cost-effectiveness	Timely and appropriate resolution of member complaints	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	Complaint resolution
4: Cost-effectiveness	Plans should actively monitor for lapses in adherence during the coverage gap and continue the process put in place to encourage adherence and persistence during this period	AMCP/NCQA May 2006: Health Plan responsibilities for Part D	Adherence
4: Cost-effectiveness	Address poor adherence resulting from cost/access issues. (Providers must be cognizant of how cost and access affect patient adherence, especially those with no or inadequate prescription drug coverage.)	NQF Improving Use of Prescription Medications: A National Action Plan - 2005	Cost/access issues, patient adherence
4: Cost-effectiveness	Drug use management must define optimal drug use and evaluate the effectiveness of the drug use management program.	URAC Pharmacy Benefit Management Accreditation Standards Version 1.0	Drug use management
4: Cost-effectiveness	Coverage decisions must assess peer reviewed literature, practice guidelines, and evaluate the potential benefits, risks, and outcomes for patients.	URAC Pharmacy Benefit Management Accreditation Standards Version 1.0	Coverage decisions
5: System Coordination and Communication	A complete list of the patient's medication is communicated to the next provider of service when a patient is referred or transferred to another setting, service, practitioner or level of care within or outside the organization. The complete list of medications is also provided to the patient on discharge from the facility	Joint Commission National Patient Safety Goals 2007	Communication of medication list

Domain	Statement	Source/Sponsor of Measure (date if available)	Key Elements
5: System Coordination and Communication	Implement a computerized prescriber order entry system built upon foundation of re-engineered evidence-based care, practitioner readiness and integrated information technology infrastructure.	National Quality Forum - Safe Practice 2003 (Updated 2006)	Physician order entry
5: System Coordination and Communication	The healthcare facility must develop, reconcile, and communicate an accurate medication list throughout the continuum of care	National Quality Forum - Safe Practice 2003 (Updated 2006)	
5: System Coordination and Communication	All electronic data fields should be used only for their intended purposes as defined in the current transmission standard	AMCP Guiding Principles for Effective Electronic Messaging	Electronic communication
5: System Coordination and Communication	The most specific applicable standard reject code should be used for claim rejections	AMCP Guiding Principles for Effective Electronic Messaging	Rejection codes
5: System Coordination and Communication	Additional textual information may have to accompany the standard message code to make it actionable	AMCP Guiding Principles for Effective Electronic Messaging	Electronic messaging
5: System Coordination and Communication	Systems should provide the pharmacist with all significant information during the processing of prescription drug claims	AMCP Guiding Principles for Effective Electronic Messaging	Complete information from all sources
5: System Coordination and Communication	Pharmacy systems should transmit with a claims any relevant information about their actions on a claim	AMCP Guiding Principles for Effective Electronic Messaging	Communicates back to prescriber
5: System Coordination and Communication	Processors should not transmit information that is reasonably determined to be redundant	AMCP Guiding Principles for Effective Electronic Messaging	Redundant information
5: System Coordination and Communication	The use of abbreviations in free-text messages is strongly discouraged	AMCP Guiding Principles for Effective Electronic Messaging	Abbreviations
5: System Coordination and Communication	There is a process for comparing the patient's current medications with those ordered for the patient while under the care of the organization	Joint Commission National Patient Safety Goals 2007	Medication reconciliation
5: System Coordination and Communication	For all vulnerable elders, the outpatient medical record of every physician and the hospital medical record should contain an up-to-date medication list	ACOVE (Addressing Care of Vulnerable Elders) (Knight EL, Avorn) 2002	Medication list
5: System Coordination and Communication	MTM program should have effective communication and sharing of pertinent care information between those parties involved in the prescribing, dispensing, monitoring, and educational components that are vital to the successful use of medications	AMCP Sound Medication Therapy Management Programs	MTM communication

Domain	Statement	Source/Sponsor of Measure (date if available)	Key Elements
5: System Coordination and Communication	Facilitate care coordination by improving the exchange of information. (Coordinating the care process, particularly with respect to how information about patient medication use is shared among providers and patients.)	NQF Improving Use of Prescription Medications: A National Action Plan - 2005	Care coordination

Section IV. Gap analysis

Understanding the factors that affect therapeutic drug management and listing current quality measures allow identification of gaps in performance assessment. Current quality measures for therapeutic drug management are fragmented, and providers from different practice settings use different measure specifications to calculate a single clinical quality component. Quality measures related to therapeutic drug management across all care settings should be standardized to drive consistent action and improve patient care. A goal for developing quality measures for therapeutic drug management should be that measures assess care provided to the patient across all care settings. We recommend the following areas for development of a limited number of new measures, which have the potential to impact therapeutic drug management and patient care in multiple settings.

Patient Decisions and Behaviors

The concept of pharmaceutical care, as outlined in the introduction, embodies the principles of patient-centered care and is a necessary foundation for improving the quality of therapeutic drug management. Existing patient-centered quality measures typically use survey tools to reflect patients' opinions of the care received. Since active patient involvement in medication use improves adherence and ultimately the outcomes of therapy, quality measures should be developed that reflect patient participation in their care as it relates to medication use and monitoring. Additional research could develop process measures for determining patient adherence in clinical situations rather than using claims and the medication possession ratio. Such tools do exist, but do not have widespread use.[40] Practical tools to immediately assess patients' understanding of medication counseling would be useful, as health literacy is related

to individuals' correct responses to questions related to timing of medication and understanding directions about taking medications on an empty stomach. Measures that reflect the utilization of a personal medication list by prescribers, patients and pharmacists would be valuable to ensure consistent use of this helpful, yet simple tool.

Therapeutic Decision Making

Prescribers are the primary focus of therapeutic decision making. The value pharmacists provide in the management of drug therapy has been documented in the literature, but quality measures have not been developed to consistently assess pharmacist performance. Current quality measures unique to the practice of pharmacy are focused on the dispensing process, which *is* an important activity. Yet, pharmacists in all settings contribute to the quality of therapeutic drug regimens, medication use, and outcomes in other ways. Quality measures beyond those related to the dispensing process are needed to assess and improve the value provided by pharmacy practice. Standards should be developed and quality measures established that focus on the frequency of comprehensive annual medication reviews, instruction on the use of medications/devices, detection of ADEs and medication reconciliation. Modification or additions to the electronic NCPDP format could be used to capture this information for measure calculation.

Second, determining the impact of new MTM programs on the quality of therapeutic drug management is included as a component in Domain 2 because improvements may be obtained at the patient level. (Improvements at the population level may also be considered in Domain 4.) The design and delivery of MTM programs is likely to vary considerably because CMS provided the PDPs and MA-PDs with general guidelines regarding these programs. Thus, it is

important to determine the specific programs and/or aspects of programs that impact the quality of therapeutic drug management so that findings can be translated to all populations who use medications.

Safe Medication Use

Many measures and best practices specify different lists of inappropriate medications, drug-drug combinations and drug-disease combinations. Standardization of these multiple lists is needed to create a set of measures so that consistent reporting of unsafe prescribing and dispensing practices can be done. Technology exists to measure the rate of inappropriately prescribed and dispensed medications. However, we fail to document when inappropriately prescribed medications are identified and stopped by pharmacists, nurses or other healthcare personnel prior to reaching patients. For example, if physicians in hospitals prescribe beta-blockers to post-MI patients at discharge, it is recognized and rewarded. If a family practice physician then prescribes a different beta-blocker for one of these patients, the standard of care is met and can be documented and measured. The pharmacist in this scenario detects the duplication of therapy, provides appropriate intervention with the healthcare team, and thereby prevents a drug-related problem. Since the prescription for the second beta-blocker was not dispensed, the pharmacist's intervention is not recorded or recognized and there is a negative financial impact with the loss of a dispensing fee. Quality measures should be developed that reflect the pharmacists' role in safe medication use.

Cost Effectiveness

Cost effectiveness measures and best practices for therapeutic drug management center on mechanisms the health care plans use to provide an economically viable prescription drug

benefits. While these practices can be used to develop pertinent measures of cost-effectiveness, research must be done that shows the effect of the practices on patient outcomes. Generic efficiencies, coverage gaps, and formulary design are currently reported, but further work is needed to clearly establish how each element affects the quality of patient outcomes. It is also critical that research is focused on determining the impact of the various Medicare MTM programs and/or their components so that best practices for health plans and ultimately standards can be established.

System Coordination and Communication

Stakeholders impacting therapeutic drug management have varying incentives to improve quality. Quality measures, and the reporting of those measures to the public, should promote practices that are known to improve quality regardless of stakeholder incentives. For example, if communication between all providers is a key to improving therapeutic drug management, then a quality measure should be developed and tested that assesses that communication (e.g. medication reconciliation between settings of care or electronic transfer of prescriptions with two-way communication of information). Measuring how information transfers between providers managing drug therapy could decrease communication barriers and increase the quality of medication outcomes.

Most quality measures focus on a specific setting or provider. Measures designed to link multiple care settings should be considered. For example, home health and pharmacy could share responsibility to decrease acute care hospitalization. Physician offices, community pharmacies and hospitals could be held accountable for a single measure of medication reconciliation. Nursing homes, home health agencies, hospitals and physician offices all have

quality measures related to offering, documenting or providing influenza vaccine to specific patient populations. Measures that link quality assessment of therapeutic drug management across care settings would be ideal.

Summary

Medication use impacts the quality of life of patients and the overall health care system. A comprehensive framework and consensus standards are necessary to improve, evaluate, and report the quality of therapeutic drug management. A conceptual quality framework is described that includes five domains where quality can be measured to improve patient outcomes. This framework can be used to develop and promote measures that improve all activities that influence the medication use process. A shared commitment by diverse stakeholders with appropriate incentives is key to using this framework to improve the safe, effective and efficient use of medications.

THE NATIONAL QUALITY FORUM

APPENDIX B

WORKSHOP PROCEEDINGS

"BUILDING A FRAMEWORK FOR MEASURING THERAPEUTIC DRUG MANAGEMENT QUALITY" DECEMBER 12, 2006

INTRODUCTION

Advances in pharmaceutical science and technology are among the most important achievements of modern healthcare. With the widespread use of modern drug treatments, large numbers of patients have improved quality of life, and hundreds of thousands of patients with previously fatal diseases now live with chronic conditions or experience only transient acute illnesses At the same time, there is a growing need to improve the intended outcomes of medications for patients and to minimize harmful effects of inappropriate medication use through improved patient adherence, provider decisionmaking, cost-effectiveness of medication use, medication safety, and system coordination. While effective therapeutic drug management activities addressing these areas exist, more work is needed to identify these activities and standardize their adoption across the continuum of settings involved in the medication use process.

More than 40 percent of Americans take at least one prescription drug, and 16 percent take at least three. Nearly 90 percent of Medicare beneficiaries report taking prescription medicines, and nearly half of those individuals use five or more different medications.[1] With such high prevalence of the population using medications, there are many opportunities for misuse, overuse and underuse of medications, which may either render the medications ineffective or expose patients to increased risk of result in adverse events. Also standardizing systems to integrate medication management has become more critical with so many Americans using prescription medications. Twenty-two percent of hospitalizations have been attributed to patient non-adherence.[2] Studies indicate that between 14 and 23 percent of elderly patients receive inappropriate medications and up to 40 percent of patients do not take their medications as prescribed[3,4,5,6]. Inappropriate and ineffective medication use leads to high rates of

emergency department visits and hospital admissions and is very costly—in 2001 the cost of drug-related morbidity and mortality to the US healthcare system was estimated at $177.4 billion. While interventions exist that are known to improve these rates, adoption and implementation of effective methods has not been standardized.

Additionally, in 2003 there was the advent of a requirement of Medicare prescription drug plans to offer Medication Therapy Management (MTM) services which include an array of pharmacists' and other health practitioners' professional activities and responsibilities This all adds to the urgency for standardization across the continuum of therapeutic drug management. The National Quality Forum (NQF) began an effort in June of 2006 to identify a national framework, preferred practices, and a set of voluntary consensus standards to evaluate and report therapeutic drug management in a project, '*National Voluntary Consensus Standards for the Reporting of Therapeutic Drug Management Quality.*' A background paper was commissioned to propose a comprehensive framework for therapeutic drug management quality standards and to survey the landscape of current standards and identify major research and measure development gaps. Subsequently, a workshop was convened to lay the foundation for the project and provide direction for future efforts.

WORKSHOP OVERVIEW

On December 12, 2006, NQF convened an invitational workshop of stakeholders familiar with and interested in therapeutic drug management quality performance measurement. Participants included representatives from both the public and private sectors; academia and consumer organizations; and provider, health professional, policy, and purchaser groups.

The workshop was to further review and refine the framework for the NQF project, 'National Voluntary Consensus Standards for the Reporting of Therapeutic Drug Management Quality'. Participants reviewed the framework to establish the foundation for identifying and evaluating practices and measures during the Therapeutic Drug Management (TDM) Quality Project. The principle purpose of the workshop was to establish a framework for therapeutic drug management based on the medication use process. The major workshop objectives were to: 1) identify the key elements of a framework for TDM quality; 2) brainstorm around the priority domains of the framework; and 3) explore the status of performance measures for use in TDM quality (including identifying measurement gaps).

The workshop discussion was supported by the commissioned background paper, "A Comprehensive Framework for Measuring the Quality of Therapeutic Drug Management", by JKuhle, KBFarris and LLarson, that proposed a framework based on the medication use process and identified current TDM performance measures and practices.

PREVIOUS NQF WORK RELATED TO THERAPEUTIC DRUG MANAGEMENT

NQF-Endorsed™ Consensus Standards in Therapeutic Drug Management

While this project is the first *comprehensive* effort by the NQF in the area of medication management, several completed NQF projects to date have endorsed related voluntary consensus standards. A summary of NQF work in this area to date is below:

NQF endorsed several ambulatory care standards related to medication use and management in its multi-year, multi-phase project, *Standardizing Ambulatory Care Performance Measures*. Twenty-six standards have been endorsed in ambulatory care in the priority areas of asthma/respiratory illness, bone and joint disease, heart disease, medication management, mental health, and prevention immunization and screening.

NQF has also endorsed several medication management standards related to hospital care. In *National Voluntary Consensus Standards for Hospital Care: An Initial Performance Set,* 14 standards are identified related to therapeutic decisionmaking and medication management in the areas of acute coronary syndrome, heart failure, pediatric conditions, pneumonia, and surgical complications. Six additional measures have also been endorsed in cardiac surgery (*National Voluntary Consensus Standards for Cardiac Surgery)*.

Serious Reportable Events in Healthcare: 2006 Update identifies as a serious adverse event that should be reported by all licensed healthcare facilities 'patient death or serious disability associated with a medication error.' In addition, *Safe Practices for Better Healthcare: 2006 Update* endorsed nine practices related to medication management aimed at reducing the risk of harm resulting from processes, systems, or environments of care.

An *Evaluation of Measures for Childhood Asthma and Medication Management* was conducted for the Centers for Medicare and Medicaid to identify pediatric measures related to these two conditions. The measures did not go through the entire consensus process.

Additional Therapeutic Drug Management Standards

Other performance standards for therapeutic drug management have been identified that

could potentially be considered as candidate standards for the NQF Consensus Development Process (CDP), that may help fill the significant gaps in therapeutic drug management quality performance standards, and address the lack of widespread adoption of current standards. Significant standard development or identification work related to aspects of therapeutic drug management has been completed or is underway by the American Medical Association (AMA), National Committee for Quality Assurance (NCQA), URAC, the Pharmacy Quality Alliance (PQA), the Institute for Healthcare Improvement (IHI), and Assessing Care of Vulnerable Elders (ACOVE).

WORKSHOP DISCUSSION

Definition of Therapeutic Drug Management

Discussion of the definition of Therapeutic Drug Management focused on the definition that was proposed in the commissioned background paper [by authors]:

'Therapeutic Drug Management encompasses the services provided by professionals and the decisions made by patients that influence the likelihood of a positive effect of drug therapy on the length and/or quality of a patient's life. Thus, therapeutic drug management involves the micro level components of the medication use process, yet the micro level components of the medication use process are clearly impacted by macro level components.'[7]

Workshop participants agreed that Therapeutic Drug Management has the same connotation as 'Medication Management.' While 'Medication Therapy Management' can apply to populations and settings other than what is intended by its inclusion in the Medicare Modernization Act (MMA), due to the potential for it to be viewed in the narrow scope of Medicare Prescription drug plans it will only be used in this context for this project. The term 'pharmaceutical care' is an important concept that has emerged in relation to medication management quality improvement efforts. The philosophical tenets of this concept are incorporated into the definition of Therapeutic Drug Management.

The background paper defines a medication as:

"A chemical entity that treats or prevents or alleviates the symptoms of disease."

Workshop participants agreed that the definition of 'medication' used in the commissioned background paper should be used for this project when referring to 'medications' or 'drugs.'

Workshop participants felt that it was important to include 'biologics' in this definition of medications.

Priority domains

Priority domains were selected according to the identified definition of therapeutic drug management and the goals of Therapeutic Drug Management performance quality standardization. Participants agreed upon the five domains proposed by the commissioned background paper, and determined the scope for each of these domains to be used in this project going forward:

1) Therapeutic Decisionmaking

The therapeutic decisionmaking domain encompasses primarily the evidence-based medication therapy decisions related to the assessments, prescribing and monitoring of individual patient medication therapy. This includes appropriateness and optimization of medication selection, regimen, dosage and dosing, as well as the over and under-use of medications.

Examples of activities related to therapeutic decisionmaking identified by workshop participants:

- Patient Medication Review
- Identification of overuse, underuse, and misuse
- Appropriate use of medication samples
- Use of evidence when selecting medications
- Follow-up with other providers, including pharmacists, involved in patient's care

2) Education and Adherence

The education and adherence domain addresses the activities related to the availability, adequacy, use, understanding and documentation of patient education with respect to knowledge about their medications and their medication use behaviors, such as adherence, seeking information and care.

Examples of activities related to patient decisions and behaviors identified by workshop participants:

- Assessment of patient satisfaction with care
- Assessment of patient literacy
- Maintenance of a comprehensive patient medication list
- Patient care seeking behavior
- Patient treatment utilization
- Patient adherence to prescribed medication regime
- Provider empowerment of patient to participate in their care, and understand and evaluate plans and providers.
- Patient reporting of side effects to provider
- Patient identification with a 'medical/pharmacy home'

3) Safety and Safe Medication Use

The safe medication use domain encompasses safe medication use and the prevention/ avoidance of medication errors, adverse drug reactions and drug interactions through safe medication prescribing, dispensing and administration. This domain also includes utilization issues that have safety implications, e.g., overuse, underuse and polypharmacy.

Examples of activities related to safe medication use identified by workshop participants:

- Systems for identification of errors and sharing of information
- Education/training of both existing professionals and medical/pharmacy/other professional students
- Patients on medications 'red-flagged' to be most related to unintended harmful outcomes should be closely monitored
- Use of ER codes to identify adverse drug events

4) Efficiency / Cost-Effectiveness

The cost-effectiveness priority domain is more population-based and includes the issues of cost-effectiveness and value analysis, i.e., the comparison of medication benefits and costs. This domain includes administrative and clinical programs that ultimately affect drug therapy access at the group or population level (e.g., formulary models, benefit designs, and related institutional and organizational policies).

Examples of activities related to cost-effectiveness identified by workshop participants:

- Assessment of medication utilization rates
- Assessment of generic efficiency rates
- Monitoring of cost effectiveness of medication therapy management programs in relation to each other
- Assessment of the effects of health plan design on patient decisions and behaviors.

5) System Coordination and Communication

The system coordination and communication priority domain involves the documentation, reporting, technology, coordination and communication of therapeutic drug management quality activities related to the other domains, but also involves the issues related to the implementation of the quality measures and practices of the other domains.

Examples of activities related to therapeutic decisionmaking identified by workshop participants:

- Patient transfer from one provider to another most important leverage point.
- Consideration of impact of HIPAA on communication
- Equity at a system level
- Medication reconciliation between providers
- Use of information technology in the medication use process

Medication Related Activities not Included in Therapeutic Drug Management

The macro level components of the medication use process do not focus on the individual patient, but involve the activities of drug development and research, drug manufacturing, drug regulations, wholesale distribution, marketing and advertising. These activities will not be directly included in the discussions of therapeutic drug management quality.

Medication Use Process

Workshop participants discussed the appropriateness of the framework based on the medication use process proposed by the commissioned background paper. The framework incorporates the agreed upon definition of therapeutic drug management and activities related to each of the five identified priority domains. The framework illustrates the role various

stakeholders play in the medication use process as well as activities related to therapeutic drug management.

Workshop participants emphasized the need for standardization of performance in therapeutic drug management, but agreed that it is important to employ a 'patient-centered' approach that allows for modification of practices based on individual patient characteristics. Participants agreed that the visual schematic of the medication use process should have the patient at the center, while the role of the provider should also be emphasized.

Participants also felt that an endorsed framework should illustrate the current environment but also allow for emerging issues so that it remains relevant over time. For example, while it is not feasible for information technology to be employed universally at this time, areas of therapeutic drug management that can potentially over time incorporate these technologies should be identified.

Given the complexity of the medication use process diagram, care coordination was deemed to be integral to the model, and that all healthcare professionals involved in the patient's care should communicate and share information, especially at the 'hand-off' or transitions between providers. Participants felt that the role of the pharmacist in patient care has not been emphasized enough in the past. Standards for Therapeutic Drug Management Quality should include pharmacists as well as other providers.

Purpose and timeline of the *'National Voluntary Consensus Standards for the Reporting of Therapeutic Drug Management Quality'* project

The NQF project, *'National Voluntary Consensus Standards for the Reporting of Therapeutic Drug Management Quality'* seeks to gain consensus on preferred practices, measures, and a framework for Therapeutic Drug Management Quality. The project follows the formal consensus development process for identifying voluntary consensus standards as required by the National Technology Transfer Advancement Act.

The Therapeutic Drug Management project began in the summer of 2006. A call for nominations to the project Steering Committee and Technical Advisory Panels was issued in May of 2006. A call for frameworks, measures, and practices was subsequently issued in July of 2006. The first steering committee meeting took place in late January 2007, and Technical Advisory Panels are expected to meet and make initial recommendations to the Steering

Committee on performance standards in May and June 2007. The Technical Advisory Panels will also continue doing work in the Fall of 2007. The project is anticipated to be completed by mid-2008.

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[1] Bedell SE, Jabbour S., Golbert R, et al. Discrepancies in the use of medications. *Arch Int Med:* 2000; 160(14):2129 – 2134.
[2] Stagnitti MN. Trends in outpatient prescription drug utilization and expenditures: *1997 – 2000* – Statistical Brief #1. Rockville, MD: Agency for Healthcare Research and Quality; July 2003.
[3] Aparasu R, Mort J. Inappropriate prescribing for the elderly: Beers criteria-based review. *Ann Pharmacother* 2000; 34:338-46.
[4] Stuck A, Beers M, Steiner A et al. Inappropriate medication use in the community-residing older persons. *Arch Intern Med* 1994;154:2195-2200.
[5] Chrischilles E, Segar E, Wallace R. Self-reported adverse drug reactions and related resource use: A study of community-dwelling person 65 years of age and older. *Ann Intern Med* 1992;117:634-40.
[6] Bond W, Hussar D. Detection methods and strategies for improving medication compliance. *Am J Hosp Pharm* 1991;48:1978-88.
[7] Kuhle J, Farris KB, Larson L. A comprehensive framework for measuring the quality of therapeutic drug management. *NQF Draft*. November 2006.

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APPENDIX E: SELECTED REFERENCES

DECISIONMAKING

American Society of Health-System Pharmacists. ASHP guidelines on preventing medication errors with antineoplastic agents. *Am J Health Syst Pharm* 2002 Sep 1;59(17):1648-68

Arizona Department of Health Services. Psychotropic medication use in children, adolescents, and young adults. 2003.

Baker, D. W., Parker, R. M., Williams, M. V., Pitkin, K., Parikh, N. S., Coates, W. and Imara, M. (1996) The health care experience of patients with low literacy. *Archives of Family Medicine*, 5, 329–334.

California Workgroup on Guidelines for Alzheimer's Disease Management. Guidelines for Alzheimer's disease management. Los Angeles (CA): Alzheimer's Association of Los Angeles, Riverside and San Bernardino Counties; 2002 Jan 1. 52

Council on Scientific Affairs for the American Medical Association (1999) Health literacy: report for the AMA council on scientific affairs. *Journal of the American Medical Association*, 281, 552–557.

Davis, T. C., Williams, M. V., Branch, W. T. and Green, K. (1999) Explaining illness to patients with limited literacy. In Whaley, D. A. (ed.) *Explaining Illness: Research, Theory, and Strategies for Comprehension.* Lawrence Erlbaum, Mahwah, NJ.

Doak, C. C., Doak, L. G. and Root, J. H. (1996) *Teaching Patients with Low Literacy Skills*, second edition. J. B. Lippincott, Philadelphia.

Fulmer T, Foreman MD, Zwicker CD. Medication in older adults. In: Mezey M, Fulmer T, Abraham I, Zwicker DA, editor(s). Geriatric nursing protocols for best practice. 2nd ed. New York (NY): Springer Publishing Company, Inc.; 2003. p. 207-28. [41 references]

Health Care Association of New Jersey (HCANJ). Medication management guideline. Hamilton (NJ): Health CareAssociation of New Jersey (HCANJ); 2006 Apr. 33 p.

Knobel H, Carmona A, Grau S, et al. Adherence and Effectiveness of Highly Active Antiretroviral Therapy. *Archives of Internal Medicine* 1998; 158:1953.

Kripalani S, Yao X, Haynes RB. Interventions to Enhance Medication Adherence in Chronic Medical Conditions. *Archives of Internal Medicine* 2007; 167:540-550.

Mayeaux, E. J. Jr, Murphy, P. W., Arnold, C., Davis, T. C., Jackson, R. H. and Sentell, T. (1996) Improving patient education for patients with low literacy skills. *American Family Physician*, 53, 205–211.

McDonald HP, Garg AX, Haynes RB. Interventions to Enhance Patient Adherence to Medication Prescriptions. *Journal of the American Medical Association* 2002; 288:2868-2879.

Murray MD, Young J, Hoke S, et al. Pharmacist Intervention to Improve Adherence in Heart Failure. *Annals of Internal Medicine* 2007; 146:714-725.

National Council on Patient Information and Education (NCPIE). *The NCPIE Coalition- Working together to promote safe medication use.* Bethesda, MD: NCPIE, 2007.

New York State Department of Health. Adherence to antiretroviral therapy among substance users. New York (NY): New York State Department of Health; 2005 Jun. 11 p.

Osterberg L, Blaschke T. Drug Therapy: Adherence to Medication. *The New England Journal of Medicine* 2005; 353:487-497.

Parker, R. M., Davis, T. C. and Williams, M. V. (1999) Patients with limited health literacy. In Bateman, W. B., Kramer, E. J. and Glassman, K. S. (eds) *Patient and Family Education in Managed Care and Beyond.* Springer, New York, pp. 63–71.

Paterson DL, Swindells S, Mohr J, et al. Adherence to Protease Inhibitor Therapy and Outcomes in Patients with HIV Infection. *Annals of Internal Medicine* 2000; 133:21-30.

Williams, M. V., Baker, D. W., Honig, E. G., Lee, T. M. and Nowlan, A. (1998a) Inadequate literacy is a barrier to asthma knowledge and self-care. *Chest*, 114, 1005–1015.

Williams, M. V., Baker, D. W., Parker, R. M. and Nurss, J. R. (1998b) Relationship of functional health literacy to patients' knowledge of their chronic disease. A study of patients with hypertension and diabetes. *Archives of Internal Medicine*, 158, 166–172.

EDUCATION AND ADHERENCE

Aberg JA, Gallant JE, Anderson J, Oleske JM, Libman H, Currier JS, Stone VE, Kaplan JE. Primary care guidelines for the management of persons infected with human immunodeficiency virus: recommendations of the HIV Medicine Association of the Infectious Diseases Society of America. Clin Infect Dis 2004 Sep 1;39(5):609-29.

Bergman-Evans B. Improving medication management for older adult clients. Iowa City (IA): University of Iowa Gerontological Nursing Interventions Research Center, Research Dissemination Core; 2004 Oct. 55

Claxton AJ, Cramer J, Pierce C. A systematic review of the associations between dose regimens and medication compliance. *Clinical Therapeutics* 2001:23;1296-1310.

Fletcher B, Berra K, Ades P, Braun LT, Burke LE, Durstine JL, Fair JM, Fletcher GF, Goff D, Hayman LL, Hiatt WR, Miller NH, Krauss R, Kris-Etherton P, Stone N, Wilterdink J, Winston M. Managing abnormal blood lipids: a collaborative approach. Circulation 2005 Nov 15;112(20):3184-209.

Hodgson SF, Watts NB, Bilezikian JP, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the prevention and treatment of postmenopausal

osteoporosis: 2001 edition, with selected updates for 2003. Endocr Pract 2003 Nov-Dec;9(6):544-64.

Institute for Clinical Systems Improvement (ICSI). Hypertension diagnosis and treatment. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Oct. 53 p.

Institute for Clinical Systems Improvement (ICSI). Diagnosis and outpatient management of asthma. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2005 Mar.

Institute for Clinical Systems Improvement (ICSI). Major depression in adults in primary care. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 May. 81

Institute for Clinical Systems Improvement (ICSI). Lipid management in adults. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Jun. 76 p.

Joint Task Force on Practice Parameters. Attaining optimal asthma control: a practice parameter. J Allergy Clin Immunol 2005 Nov;116(5):S3-11.

Kaiser Permanente Care Management Institute. Depression clinical practice guidelines. Oakland (CA): Kaiser Permanente Care Management Institute; 2006 Mar.

Kruk ME, Schwalbe N. The relation between intermittent dosing and adherence: Preliminary insights. *Clinical Therapeutics* 2006:28;1989-1995.

New York State Department of Health. Identification and ambulatory care of HIV-exposed and -infected adolescents . New York (NY): New York State Department of Health; 2003. 21

Schedlbauer A, Schroeder K, Peters TJ, et al. Interventions to improve adherence to lipid lowering medication (review). *The Cochrane Library* 2007: Issue 1.

Schroeder K, Fahey T, Ebrahim S. Interventions for improving adherence to treatment in patients with high blood pressure in ambulatory settings (review). *The Cochrane Library* 2007: Issue 1.

Working Group on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the use of antiretroviral agents in pediatric HIV infection. Bethesda (MD): U.S. Department of Health and Human Services; 2006 Oct 26. 120 p

PATIENT SAFETY

ASHP Guidelines on Pharmacist-Conducted Patient Education and Counseling. 1996.

ASHP Guidelines : Minimum Standard for Home Care Pharmacies. 1998.

ASHP Guidelines on Preventing Medication Errors in Hospitals. Approved by the ASHP Board of Directors, June 1993.

Council Recommendations to Enhance Accuracy of Dispensing Medications. National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP).

Egberts TC, Smulders M, et al. Can adverse drug reations be detected earlier? A comparison of reports by patients and professionals. 1996. *BMJ,* 313:530-531.

Gandhi TK, Weingart SN, Borus J, et al. Adverse Drug Events in Ambulatory Care. New Engl J Med. 2003; 348:1556-1564.

Gurwitz JH,Field TS, Harrold LR, at al. Incidence and Preventability of Adverse Drug Events Among Older Persons in the Ambulatory Setting. JAMA. 2003; 289: 1107-1116.

Pharmacy's Framework for Drug Therapy Management in the 21st Century. Academy of Managed Care Pharmacy. 2002.

EFFICIENCY

American Society of Consultant Pharmacists. Guidelines for the Development of Formulary Systems in Nursing Facilities. July 1996.

American Society of Health-System Pharmacists. ASHP Guidelines on Formulary System Management. AM J Hosp Pharm. 1992; 49:648-52.

Fairman, K, Teitelbaum F, Motheral B, et al. Letter to the Editor. Am J Managed Care, 1996; 2:588-592.

Hefner DL.Cost-effectiveness of a restrictive drug formulary: Louisiana vs Texas. Washington, DC: National Pharmaceutical Council; 1980.

Huskamp HA, Deverka PA, Epstein AM, et al.The effect of incentive-based formularies on prescription-drug utilization and spending. N Engl J Med.2003;349:2224-2232.

Kamal-Bahl S, Briesacher B.How do incentive-based formularies influence drug selection and spending for hypertension?Health Affairs.2004;23:227-236.

Kravitz RL, Romano PS.Managed care cost containment and the law of unintended consequences.Am J Managed Care.1996;2:323-324

Lexchin J.Effects of restrictive formularies in the ambulatory care setting.Am J Managed Care.2001;7:69-76.

Mather DB, Sullivan SD, Augenstein D, Fullerton DS, Atherly D. Incorporating clinical outcomes and economical consequences into drug formulary decisions: a practical approach. *Am J Managed Care* 1999 Mar;5(3):277-85.

Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173).

Motheral B, Fairman KA.Effect of a three-tier prescription co-pay on pharmaceutical and other medical utilization.Med Care.2001;39:1293-1304.

Mott DA, Cline RR. Exploring Generic Drug Use Behavior: The Role of Prescribers and Pharmacists in the Opportunity for Generic Drug Use and Generic Substitution. Med Care. 40(8): 662-674, August 2002

National Committee for Quality Assurance. UM 10 procedures for pharmaceutical management. 2000 Standards for Accreditation of MCOs. 1999: 58-60.

Opportunity for Generic Drug Use and Generic Substitution. *Medical Care.* 40(8):662-674, August 2002.

Rector TS, Finch MD, Danzon PM, et al.Effect of tiered prescription co-payments on the use of preferred brand medications.Med Care.2003;41:398-406.

Ross-Degnan D, Soumerai SB.HMO formularies and care costs.Lancet.1996; 347:1264.Joyce GF, Escarce JJ, Solomon MD, et al. Employer drug benefit plans and spending on prescription drugs.JAMA.2002;288:1733-1739.

Sharkey PD, Tracy DM, et al.Intended and unintended consequences of HMO cost-containment strategies: Results from the managed care outcomes project.Am J Managed Care.1996;2:253-264.

Sharkey PD, Philips-Harris C. Formulary limitations and the elderly:Results from the managed care outcomes project. Am J Managed Care.1998;4:1105-1113

SYSTEM COORDINATION AND COMMUNICATION

Academy of Managed Care Pharmacists. Sound Medication Therapy Management Programs. 2006

Academy of Managed Care Pharmacy, The "Framework for Quality Drug Therapy".

American Pharmacists Association., National Association of Chain Drug Stores Foundation. *Medication therapy management in community pharmacy practice: core elements of an MTM service(version 1.0).* J Am Pharm Assoc. 2005.; 45:573-9. Available at http://www.aphanet.org/AM/Template.cfm?Section=Pharmacy_Practice_Resources&Template=/CM/ContentDisplay.cfm&ContentID=3303. Last accessed May 2007.

Blackburn RW, Brown TR, Chen D, Zierler-Brown S. Clinical Documentation for Patient Care: models, concepts, and liability concerns for pharmacists. *American Journal of Health System Pharmacy* 2007; 64: 1851-1858

FDA *Medication Errors* http://www.fda.gov/cder/drug/MedErrors/default.htm Last accessed April 2007

Geoffrey F. Joyce, PhD; José J. Escarce, MD, PhD; Matthew D. Solomon, MA; Dana P. Goldman, PhD. Employer Drug Benefit Plans and Spending on Prescription Drugs. *JAMA.* 2002; 288:1733-1739.

IHI. *Errors from Unreconciled Medications per 100 Admissions.* http://www.ihi.org/IHI/Topics/PatientSafety/MedicationSystems/Measures/Errors+Related+to+Unreconciled+Medications+per+100+Admissions.htm

JCAHO. *National Patient Safety Goals.* Available at http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/07_hap_cah_npsgs.htm. Last accessed May 2007.

JCAHO. *Sentinel Event Alert Issue 23* Available at http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_23.htm. Last accessed May 2007.

Medical News Today. *Benefits of Good Doctor-Patient Communication – Outcomes Improve.* http://www.medicalnewstoday.com/printerfriendlynews.php?newsid=67421

Meredith P. Bioequivalence and other unresolved issues in generic drug substitution. *Clin Ther* 2003 Nov;25(11):2875-90.

Nebeker J, Barach P, Samore M. Clarifying Adverse Drug Events: A Clinician's Guide to Terminology, Documentation, and Reporting. *Annals of Internal Medicine* 2004; 140: 795-801

Pronovost P, Weast B, Schwartz M. et al. Medication reconciliation: a practical tool to reduce the risk of medication errors. Journal of Critical Care 2003 Dec ;18(4):201-5.

Rozich M, Resar R. Medication Safety: One Organization's Approach to the Challenge. Journal of Clinical Outcomes Management Vol 8,No 10 page27-34.

Smith DG. The effects of copayments and generic substitutions on the use and costs of prescription drugs. *Inquiry* 1993 Summer; 30(2): 189-98.

Soto CM, Kleinman KP, et al. Quality and correlates of medical record documentation in the ambulatory care setting. BMC Health Services Research Published online 2002 December 10.