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Enhancing the Pharmacist's Professional Status through Collaborative Prescribing : US and Japanese Perspectives

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The objective of this mini-review is to examine collaborative prescribing between pharmacists and physicians as a means of enhancing the professional status of pharmacists. It considers the history of such collaboration, the current status of healthcare and the pharmacists' impact on patients' health, defines collaborative drug therapy management (CDTM), discusses the legal considerations in CDTM and the requirements for CDTM, and gives a Japanese perspective. We found that many pharmacists in the United States have concluded collaborative practice agreements with physicians under a written legal protocol regarding the selection, adoption and monitoring of new dosage forms and types of medications, management of routine follow-up with patients, and refill medications. Through collaborative drug therapy management, pharmacists can contribute to increasing compliance with drug therapy regimens and reducing the rate of adverse drug events.

However, pharmacists in the United States and Japan face several obstacles in becoming fully successful in their efforts in these regards. Among them are gaining physicians' support and current regulations that prevent pharmacists from prescribing in many areas. In Japan, the prohibition of pharmacists having physical contact with the patients by law is another obstacle. These obstacles can be overcome by documenting the benefits for costs and clinical outcomes arising from allowing pharmacists to play a greater role in the medical literature.

Key words —— collaborative drug therapy management, prescribing practice, professional status, pharmaceutical care, legal issue

Introduction

In recent years, an increasing number of pharmacists in the United States are involved in such activities as clinical pharmacy services, pharmaceutical care, and collaborative drug therapy management. All of these activities will enhance the status of the pharmacy profession. Among them, collaborative drug therapy management is one of the most promising areas for the pharmacist to pursue as a health care professional. The traditional system , by which only certain health professionals, namely physicians, are authorized to initiate or prescribe, is criticized for contributing to the growing rate of healthcare costs and medication errors[1]. The processes of drug prescribing, dispensing, administering, monitoring, and adjusting doses whenever necessary, as practiced in the traditional system, occur in a separate fashion that frequently results in otherwise avoidable drug-related problems that contribute significantly to poor patient outcomes and increased medical costs[2]. Ernst and colleagues showed that drug-related problems in the United States exceeds $177 billion dollars annually and is the cause of numerous unnecessary hospitalizations and deaths each year[3]. In nursing homes, medication-related errors or adverse reactions cost $1.33 for every $1 spent on the medications[4]. Although medication error rates are not routinely tracked among many institutions in Japan, data from a medication error reporting program at a university hospital detected nearly two medication errors per day which were voluntarily reported by hospital staff or patients within a 2-year period[5].

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Shimp and colleagues found that the strongest predictor of potential drug-related problems is the number of prescription medications a patient is receiving[6]. In order to minimize the frequency of avoidable drug-induced problems and enhance patients' health-related quality of life, an interdisciplinary approach to patient care through collaborative drug therapy management is emerging[1].

History

Throughout history, pharmacists had always been allowed to "prescribe," or recommend medications for patients who came into the pharmacy. Frequently, pharmacists prepared their own "concoctions" or remedies for patients with their own secret formulas[7]. However, in 1938, the United States enacted the Federal Food, Drug, and Cosmetic (FDC) Act to protect the safety of patients against misbranded prescriptions that were inadequately labeled with instructions for use or possible adverse effects that may occur with use[1]. In 1951, the Durham-Humphrey Amendment resulted in the legal separation of prescribing by physicians and dispensing of drugs by pharmacists[8]. It was thought that these restrictions were in the best interest of patients and the health care system, particularly in regard to safety. However, with the dramatic increase in the number of complex medications developed by pharmaceutical manufacturers since the "golden age of drug discovery" following World War II, it has become difficult for physicians to keep abreast of technological advances in both the medical and pharmaceutical fields[9]. While only 650 medications were available for use in the 1960's, more than 10,000 different medications on the market within the United States today (Pharmacists for Quality Patient Care, Alliance for Pharmaceutical Care, Partners to Improve Health Outcomes URL http://www.accp.com/position/paper 11.pdf (accessed 2004 Nov 4)). Since reports on medication errors and drug-related morbidity and mortality have also received increased attention in the medical literature in recent years, many have called into question this complete separation of prescribing and dispensing[10, 11].

Current Status of Healthcare

The economic and social influences on health care have driven the mission towards a new approach to pharmacists' roles in the care of patients. In the United States, the "baby boomer" population will reach retirement age around the year 2010[12]. This dramatic increase in the age of the population, many of whom are receiving multiple medications for various chronic medical conditions, is driving healthcare expenditures upward at a rapid pace. In an effort to control costs of hospitalization, Medicare and many other private insurance companies have implemented prospective "diagnosis-related-group" or DRG prospective payment systems. Hospitals receive a fixed reimbursement for the primary diagnosis a patient has during hospital admission, even if the hospital spends more or less money treating the patient[12]. In Japan, a similar rise in the elderly population has boosted medical expenditures at an alarming rate. Under proposed reforms within the national health insurance system, a similar diagnosis-related group payment system is undergoing pilot testing to eliminate the expensive fee-for-service system that currently exists[13, 14].

In both the United States and Japan, society is undergoing an "information revolution." With electronic transmission of prescriptions to pharmacies and the computerization of hospital medical records, more pharmacists are privy to patient information that was not previously available before the technology age[12, 15].

Due to the philosophical changes in pharmaceutical education which have taken place in the past 25 years in the United States[16], the field of pharmacy has undergone a "re-professionalization"[12]. It was in 1973 that the Indian Health Service (IHS) piloted the Pharmacist Practitioner Training Program (PPTP), whereby pharmacists could provide collaborative drug therapy management for patients following completion of an intensive training program supervised by physicians[17, 18]. It was found in an assessment of this program that the quality of care provided by pharmacists, as judged by auditors, was similar to physician-provided care. Questionnaires rating physician and patient satisfaction with the program indicated that both groups had favorable opinions of the PPTP and the care that pharmacists provided[18].

In 1987, the American Association of Colleges of Pharmacy (AACP) approved a mandatory 6-year doctor of pharmacy degree program with heightened emphasis on providing pharmaceutical care to patients[19]. By embracing pharmaceutical care, pharmacists can focus on optimizing patients' medication regimens and preventing adverse drug reactions and drug-drug interactions, instead of simply providing a prescription or over-the-counter medication to a patient with some patient education materials[20]. Optimal drug therapy outcomes are achieved through selecting rational, cost-effective drug therapy and preventive identification and correction of adverse drug reactions and drug-related problems, including supra- or subtherapeutic doses of medications, untreated indications, unnecessary medications, duplicate drug therapy, inappropriate drug or dose of therapy, or the need for pharmacokinetic therapeutic drug monitoring (TDM) to attain an adequate dose of medication for the patient to achieve the desired response[20, 21].

Evidence of Impact of Pharmacists on Patient's Health

In recent years, the development, promotion, and publication of pharmacists' clinical activities in managing patients within the United States has driven support for the continued expansion of collaborative roles in caring for patients. Since the early papers detailing the success of clinical pharmacy services were published in the 1970's, numerous peer-reviewed publications in the medical literature have documented the positive impact of pharmacists' new clinical

roles on economic and therapeutic outcomes[22]. These publications have caught the attention of the public eye, and the United States government, as it seeks new ways to reduce the costs associated with the growing elderly population. The most profound evidence showing the impact of pharmacists on patient care is from pharmacists practicing collaboratively with physicians in the hospital setting. Bond and colleagues have shown a 65% reduction in medication errors in hospitals with a high number of clinical pharmacists providing pharmaceutical care to patients compared to those hospitals with minimal or no clinical pharmacy staff. Lower rates of medication errors were also correlated with pharmacist-provided adverse drug reaction management, drug protocol management, drug information services, and admission histories[23]. Pharmacists attending rounds with physicians in the intensive care units similarly decreased the rate of adverse drug events by 66% and nearly 90% of the 400 interventions made over a 6-month period of time were to correct or prevent potential medication errors. The cost avoidance estimates of this clinical pharmacy service provided annually is nearly $ 270,000 in savings[24].

Definition of Collaborative Drug Therapy Management

Collaborative drug therapy management (CDTM) can exist between one or more physicians and pharmacists in the hospital or community setting. Collaborating pharmacists and physicians work together to develop a written drug therapy management protocol, or agreement for the scope of patient management activities a pharmacist is permitted to perform in order to improve patient care outcomes[18]. Many protocols incorporate evidence-based clinical practice guidelines or goals for disease state outcomes developed by national agencies in order to guide pharmacists' decision-making processes (American Society of Consultant Pharmacists, ASCP Policy Statement, Statement on collaborative practice, URL http : //www.ascp.com/public/pr/policy/collaborative.shtml (accessed 7 Oct 2004)). Under such a protocol, a qualified pharmacist is granted legal authority to provide services such as physical or health assessments, ordering medication-related laboratory tests, administering certain drugs, or selecting, initiating, monitoring, continuing, and modifying medication regimens[18]. (American Society of Consultant Pharmacists, ASCP Policy Statement, Statement on Collaborative Practice, URL http : //www.ascp.com/public/pr/policy/collaborative.shtml (accessed 7 Oct 2004)). Documentation of the protocol agreement and pharmacist's recommendations are placed in the patient's permanent medical record to allow other health care professionals caring for the patient to see the pharmacist's interactions with the patient and plans for the drug therapy regimen[18].

Legal Considerations Involved with CDTM

Since the Durham-Humphrey act was passed in 1951 separating physician prescribing and pharmacist dispensing of prescription medications, pharmacists have not routinely been recognized as healthcare providers. However, many states have overcome this barrier by implementing legal amendments to the state's pharmacy practice act or governmental insurance plan. Other states have pursued waivers from the federal government's Centers for Medicare and Medicaid Services (CMS) to receive pharmacist provider status and reimbursement for providing clinical services through collaborative drug therapy management[25]. Although many states have been successful in gaining legal authority for pharmacists to create collaborative drug therapy management protocols with physicians[26], receiving payment for such services by the federal government Medicare program or by private insurance companies has been virtually nonexistent to date.

However, legislation is currently being considered which may eliminate this barrier. The Medicare Prescription Drug Bill of 2003 is the first piece of legislation that has granted prescription drug coverage to elderly patients insured under the federal government Medicare program (American College of Clinical Pharmacy, ACCP Position Statement : a Medicare outpatient pharmacy benefit, URL http : //www.accp.com/medrxben.pdf (accessed 15 Oct 2004)). Previously, only the federal Medicaid indigent care programs and private health insurance providers offered prescription drug benefits for patients. A fundamental cost-savings element incorporated into this bill authorizes pharmacists to provide collaborative drug therapy management services (MTMS) to high-risk Medicare patients. The Medication Therapy Management Act of 2003 is another important related bill which would amend the Social Security Act to allow pharmacists to have provider status in collaboration with physicians for managing patients taking numerous medications and patients with chronic disease states such as asthma, diabetes, chronic heart failure, hypertension, and hyperlipidemia[26]. (American College of Clinical Pharmacy, Medication therapy management services definition and program criteria, URL http : //www.accp.org/Docs/MainNavigation/Resources/6308_MTM Services Definition and Program Criteria 27-Jul-04.pdf (accessed 15 Oct 2004)). Provider status for pharmacists would grant monetary reimbursement for clinical services provided to these patients.

In July 2004, 11 national pharmacy organizations uniformly agreed to a scope of practice for pharmacists to provide "Medication Therapy Management Services" for Medicare patients. Under this defined scope of practice, pharmacists would be able to obtain records of or perform a patient's health assessment, develop a medication treatment regimen to treat the patient's diagnosed disease states by either selecting new medications or altering the patient's current medication regimen, monitoring the efficacy and safety of medications prescribed for each patient, evaluating the patient for potential drug-drug interactions or adverse drug reactions, and administering medications in specific situations. Pharmacists would also be able to educate pa-

tients about their medications and coordinate their medication therapy plan with other health services the patient is receiving. For the first time in the United States, pharmacists would receive governmental payment for clinical services provided to all of the patients they manage who are insured through governmental healthcare. Patients specifically targeted by this plan include those that are receiving at least four prescriptions, spending over $250 in medications per month or over $650 in medications per quarter, and patients who are seeing multiple physicians.

Requirements for Collaborative Drug Therapy Management

It is important to note that several requirements must be met in order for pharmacists to participate productively in collaborative drug therapy management. These considerations include an environment suitable for collaborative practice, access to patients and their medical records, competent pharmacists with specialized knowledge, skills, and abilities in the given disease area, written documentation of pharmacist's activities, and monetary compensation for services performed[1, 18].

1. Collaborative practice environment

Pharmacists need to identify a physician or provider group that is willing to collaborate with a pharmacist. The physician or health system will then identify patient populations, disease states, specific drugs, and certain drug-related issues in which health professionals wish to manage collaboratively with pharmacists[25]. Zillich and colleagues found that the most influential factors in developing a collaborative relationship between pharmacist and physician are role specification, trustworthiness, and relationship initiation[27]. Pharmacists must work with physicians to establish which roles the pharmacist and physician will take in sharing the responsibility for patient care. Outlining the professional duties and general areas of responsibility will become the approved scope of practice for that pharmacist[18]. Pharmacists should be visible to physicians and provide more than what is expected when a physician asks for information from the pharmacist. If the physicians continuously receive more than they expect to receive from pharmacists, it makes a good impression, and an atmosphere of trust is established. Additionally, pharmacists must be present in the clinics for a consistent amount of time each day or week, so the physicians can ensure the pharmacists are reliable, dedicated members of the healthcare team[25].

2. Access to patients and medical records

Accomplishing collaborative drug therapy management relies on developing a trustworthy relationship not only with physicians, but also with patients. Pharmacists should clearly communicate their role in caring for patients to them. It is also imperative to gain shared access to patient's medical records either electronically or through another mechanism so that pharmacist's recommendations and implemented changes can be made available to all providers caring for the patient[18].

In the United States, pharmacists participating in the Asheville Project targeted the city government of Asheville, North Carolina for a collaborative drug therapy management program. The city of Asheville provides medical insurance to employees who often have low-paying jobs. Overall healthcare costs, hemoglobin A1c levels, and cholesterol levels were significantly reduced during the two-year period, and employees increased their attendance at work[28]. Since many pharmacies are open for extended hours, and later than physician's offices and are typically more conveniently located in major shopping areas, it is often more suitable for patients to receive follow-up care at pharmacies than scheduling an appointment with a physician (Asheville Project Update : Results Continue to Exceed ADA Goals, NCCPC Pharmaceutical Care—Asheville Project, URL http : //www.ncpharmacists.org/nccpc/asheville.html (accessed 13 Oct 2004)).

3. Education, postgraduate training, and credentialing

In the United States, the current 6-year doctor of pharmacy education has provided pharmacy students with more focused training in drug therapy than any other group of healthcare professionals[1]. The clinical degree programs also have extended education in communication skills and teamwork to allow pharmacists to develop more interpersonal skills for effective communication with both patients and healthcare professionals[4].

Point-of-care testing is an example of a new technology available on-site in pharmacies that has enabled pharmacists to expand patient care roles. Point-of-care testing utilizes portable screening devices for checking patients' blood glucose, hemoglobin A1c, cholesterol levels, prothrombin time, international normalized ratio, and bone mineral density screening, amongst others. While the cost of the testing devices and testing strips are not inconsequential, they have been shown to have significant impact on patient outcomes when utilized in pharmacist-driven disease management programs[29]. In addition, the Board of Pharmaceutical Specialties offers board certification for the following pharmacy specialties : pharmacotherapy, nutrition support, oncology, psychiatric pharmacy, and nuclear pharmacy (Board of Pharmaceutical Specialties, Recognized specialties, URL http : //www.bpsweb.org (accessed 18 Oct 2004)). Numerous certificate and credentialing programs also exist which allow pharmacists to demonstrate additional clinical competency in drug therapy management of specific disease processes : anticoagulation, diabetes, men's health, lipids, asthma, geriatrics, and in providing immunizations[4] (American Society of Health-System Pharmacists, Grants and traineeships from the ASHP research and education foundation, URL http : //www.ashp.org/foundation (accessed 18 Oct 2004), American Pharmaceutical Association, Pharmacy-based immunization delivery, http : //www.aphanet.org/education/ctp/delivery.html (accessed 18 Oct 2004)).

4. Documentation of activities and quality assessment

It is essential that pharmacists participating in CDTM document all clinical pharmacy activities in the patient's medical chart. Additionally, in order to demonstrate the quality and value of services provided, to win the trust of physician and patient collaborators, and to be able to expand the scope of pharmacist practice in the future, it is essential that pharmacists track the clinical outcomes achieved with patients that are managed closely by the pharmacist under CDTM[18, 25]. In a publication by Rupp et al., community pharmacists who managed asthma patients decreased hospital admissions by 77% and emergency department visits by 78%[30]. Munroe and colleagues showed that pharmacists who provided disease state management services in their community pharmacies saved an average of $2700 per patient annually in medical costs[31]. Pharmacists who managed high-risk patients receiving numerous medications under collaborative practice were able to decrease the number of medications received and to save nearly $600 per patient annually in drug therapy costs[32]. Pharmacist participation in collaborative practice agreements under the Mississippi Medicaid disease management program were responsible for decreased visits to the emergency department in asthmatic patients and a significant lowering of mean hemoglobin A1c values in diabetic patients managed[33].

5. Payment for services

Any type of practitioner must be able to generate revenue sufficient to support the direct and indirect costs of their practice activities, including CDTM. While certain CDTM protocols do establish payment of physicians for their time in reviewing pharmacists' pharmaceutical care activities, there is not a uniform system to compensate physicians under CDTM with pharmacists in the United States[19]. Additionally, with the exception of certain model demonstration programs, *to date*, pharmacists in the United States cannot yet routinely receive reimbursement from the government for care of Medicare or Medicaid patients or patients covered by third party health insurance programs, which, in total, make up 76% of patients receiving medical care in the United States[34]. Therefore, many pharmacists are reliant on patients to pay out-of-pocket for their drug management services. Although prices for different services vary, most pharmacists receive between $20 to $40 per patient for screening and other health management services[33, 35].

6. Organization and systematic approach

Kuo and colleagues recommend a 10-step approach to establishing a collaborative drug therapy management practice with physicians based on their own experiences in a family medicine clinic[26], and we modified the list (**Table 1**). Developing a solid working relationship with physician colleagues and an environment in which pharmacists can be relied upon to provide care is the first step in creating a collaborative medication therapy management program. Global screening initiatives to identify patients at high risk for drug therapy-related problems or adverse drug reactions can also prove successful in developing a role for pharmaceutical care. Next, pharmacists and physicians must work together to create evidence-based protocols, guidelines, and services to be performed by pharmacists[25]. These protocols should be approved by the appropriate legal authorities for ensuring patient safety, possibly including licensing boards or governmental agencies. Pharmacists must receive permission by their employers and possibly undergo a credentialing process to ensure they are qualified to perform the duties outlined within the collaborative practice protocol. Information required for billing records should be sought in advance of seeing patients, so that pharmacists can include these specific details within medical chart progress notes in order to receive reimbursement promptly. Pharmacists should design a template for writing medical progress notes in patients' charts so that they can be consistent and efficient in documenting patient interactions and recommendations for medication changes. A budget should be developed to determine start-up expenses required for purchasing point-of-care or other patient monitoring and physical assessment equipment, reference books, computers, or for reorganizing workspace in order to see patients. Finally, pharmacists should document the outcomes of all interventions made on patients seen through collaborative practice agreements so that the quality of care can be evaluated[26].

Status of Collaborative Drug Therapy Management in the United States in 2004

As of January 2004, 40 states in the United States have established statutes or regulations for CDTM by pharmacists and 3 states have pending CDTM legislation. **Table 2** shows CDTM authorization by state as of March 2004[26].

Table 3 summarizes the advantages and disadvantages to initiating and maintaining a successful CDTM practice[36]. While clinical pharmacists in the United States have been successful in gaining physician approval to provide cognitive services, until recently, they have been largely unsuccessful in being awarded payments for these activities by governmental agencies or insurance companies. Many pharmacies rely on retail sales of non-prescription items or the nominal dispensing fees charged when prescriptions are filled to finance such efforts by pharmacists. In addition, many pharmacies charge the patients a fee for these services, and they have a fee structure equivalent to the technical difficulty of the service provided. In some practices, a billing system has been established. Billing for pharmacist-physician collaborative drug therapy management services requires the use of the physician's unique provider identification number and CPT (current procedural terminology) evaluation and management code. **Table 4** shows CPT codes and its billing requirements based on the level of service provided, and **Table 5** shows an example of CDTM protocol for hyperlipidemia.

The Prescription Drug and Medicare Modernization Act

Table 1. Eleven Prototype Steps for the Initiation and Maintenance of Collaborative Drug Therapy Management Services by Pharmacists. Adapted from Reference 25).

1. Develop a favorable working relationship with physician colleagues for a possible establishment of medication therapy management service (MTMS) and gather support from your employer
2. Assess the needs of your patients, patient population, or employer by evaluating trends in disease states in the community (example: is there a large asthma patient population in your community?) or evaluating compliance with targeting goals on guidelines (example: how many patients in your community have controlled diabetes based on hemoglobin A1c or fasting blood glucose levels?)
3. Draft evidence-based MTMS collaborative protocols and agreements in cooperation with your physician colleagues
4. Apply for credentialing status within your health organization or through your employer
5. Consult the billing office staff for billing procedure and requirement within your health organization or governmental agency
6. Design a clinic-encounter form or progress note template for inclusion into the patient's medical record (should include medical history of the patient, history of the presenting problem, physical examination data, medical decision-making regarding drug therapy changes, drug counseling provided, time spent with the patient)
7. Prepare a comprehensive and complete MTMS policies and procedures manual to follow in order to pursue professionally-oriented MTMS practice
8. Identify and train support staff in order to carry out MTMS efficiently
9. Allocate resources for start-up, maintenance expenses, and medical equipment necessary to practice MTMS
10. Advertise the MTMS to patients and other healthcare providers
11. Document outcomes from the patients seen under the collaborative practice agreement (example: percentage of patients controlled to a hemoglobin A1c less than 7%), evaluate, and improve your service

Table 2. The 40 United States in which Collaborative Drug Therapy Management (CDTM) is Legally Authorized[33].

Alabama (pending)[a]	Nebraska
Alaska	New Jersey
Arizona	New Mexico
Arkansas	New York (pending)[a]
California	Nevada
Connecticut	North Carolina
Florida	North Dakota
Georgia	Ohio
Hawaii	Oregon
Idaho	Pennsylvania
Illinois	Rhode Island
Indiana	South Carolina
Iowa	South Dakota
Kansas	Tennessee
Kentucky	Texas
Louisiana	Utah
Maryland	Vermont
Massachusetts (pending)[a]	Virginia
Michigan	Washington
Minnesota	Wisconsin
Mississippi	Wyoming
Montana	

[a] There are 3 additional states with pending collaborative practice agreements

of 2003 was passed in Congress and now the government is working on the operational details in time for a January 2006 start date. One of the essential aspects of this bill was the definition of pharmacist provider activities which can be billed for under a collaborative practice agreement with another healthcare provider (**Table 6**).

Japan Perspective

Japan has decided to launch a 6-year pharmacy education system beginning in the year 2006. This means that medical schools and pharmacy schools now have the same duration of professional training in schools. With the added clinical therapeutics focus in the two-year curriculum addition, pharmacists will be competent in all aspects of selecting and managing drug therapy for a given patient scenario once a diagnosis has been determined. Pharmacists who productively demonstrate this extra knowledge and expertise in choosing specialized drug therapy regimens for individual patients can protect the well-being of patients. Since pharmacists are drug experts, and receive more training about drug therapy than any of the medical professions, it is imperative to establish Japanese-style CDTM for the benefits of patients and the health care system in Japan. The CDTM system within the United States, particularly the systematic approach proposed by Kuo and colleagues[25], is a good example to utilize in order to develop a similar collaborative practice between pharmacists and physicians in Japan.

Table 3. Advantages and Disadvantages of Collaborative Practice.

Advantages	Disadvantages
Team exceeds the sum of the parts	Overlapping responsibilities
Elimination of hierarchies	Disagreement of care
Greater retention of staff	Multiple billing for services
Innovative and creative practices that are unique marketing tools	Pharmacists viewed as budget holders or cost controllers
Improved patient outcomes	Can extend decision-making process. Thus, more time is needed for patient care
Distribution of resources and enhanced efficiency	Lack of time for seeing patients and filling required prescriptions
Holistic care emphasized rather than curative	Billing and documentation procedures take time away from other activities
Avoidance of fragmented and individualistic practices	Reimbursement for services provided sometimes not cost-justifiable for time spent
Little to no competition for resources	
Can share knowledge and experience to achieve better patient care	
Incentive to improve practice and knowledge	

Note: The table was cited from reference 36), and modified by the authors.

With regard to the practical steps for launching CDTM, it is logical for the CDTM to be initiated by the prefecture or locally. The prefecture or local group of pharmacists must make a positive impact on physicians by demonstrating the competency of the pharmacists' drug therapy knowledge. Pharmacists practicing within a university setting are another source for program development. Clinical faculty members, whose number will increase as 6-year programs launch in 2006, should take the initiative to establish CDTM as part of their clinical practice. Professional pharmaceutical societies and licensure authorities can play a key role in developing sample drug therapy management protocols that could easily be manipulated for a given clinic or hospital scenario (Louisiana State Board of Nursing, Sample collaborative practice agreement, URL http : //www.lsbn.state.la.us/documents/Forms/collab.pdf (accessed 20 Oct 2004)).

Once CDTM is established between a pharmacist and physician, the next step is for CDTM to be recognized within the health insurance system so that the pharmacists can be reimbursed for the CDTM services they provide. It will become possible for the CDTM to be included in the national health insurance system once pharmacist's involvement in CDTM proves to be beneficial for patients and economical for the health care system as a whole. Subsequently, pharmacists can market the cost-effective and safe services they provide to the healthcare system.

In addition to utilizing a step by step approach for launching CDTM, it is important for pharmacists to demonstrate competence in professional knowledge and superb interpersonal communication skills when interacting with physicians, patients, and administrators. By communicating effectively, both patients and physicians will easily see the benefits a pharmacist can provide to patients under a CDTM arrangement.

Conclusion

Collaborative drug therapy management is a positive approach to guide the profession of pharmacy into a more patient-oriented focus. Many pharmacists in the United

Table 4. Current Billing Procedures Used for Collaborative Drug Therapy Management Services[25)a].

CPT Code	Examination	Medical Decision-Making	Problem Severity	Example Service by Pharmacist[b]	Time (min)
99211	Problem-focused	Physician presence not required	Minimal	Routine laboratory follow-up (check INR on warfarin)	5
99212	Problem-focused	Uncomplicated	Minor to moderate	Follow-up for therapeutic efficacy after medication initiation or dosage change (blood pressure evaluation after ACE inhibitor initiation)	10
99213	Expanded problem-focused	Low complexity	Minor to moderate	Initiation of a new medication (beta-blocker for heart failure)	15
99214	Detailed	Moderate complexity	Moderate to high	New patient; evaluation of reason for referral (diabetes medication and dietary counseling; physical assessment for neuropathy)	25
99215	Comprehensive	High complexity	Moderate to high	New patient; evaluation for potential polypharmacy	45

[a]CPT = Current Procedural Terminology. For established patients, two of the three major key components (history, examination, and medical decision-making) are required to select the appropriate CPT billing code. Counseling and coordination of care were consistent with patient's needs and problems.

[b]INR=international normalized ratio; ACE=angiotensin converting enzyme

Table 5. Example Collaborative Drug Therapy Management Protocol for Hyperlipidemia.

Collaborative Drug Therapy Management Protocol for Hyperlipidemia

— Clinical Pharmacist —

1. This collaborative practice agreement is created to comply with the pharmacy and medical practice acts regarding collaborative drug therapy management (CDTM) under a written protocol of a physician. The documents herein are guidelines for practice and allow for professional discretion and deviation if necessary when it is for the benefit of the patient.
2. The collaborating professional authorized to prescribe medications and who are responsible for delegation of CDTM is _____ MD with the Department of _____ at _____ (employer); responsibilities include being available for consultation during business hours, reviewing selected patient progress notes weekly, and providing coverage for patients after hours.
3. The clinical pharmacist authorized to prescribe medications under the CDTM written protocol and who will carry out the CDTM is _____ PharmD with the Department of _____ at _____ (employer); responsibilities are to see patients in a timely manner and complete documentation within 48 hours.
4. In accordance with the clinical practice guidelines for hyperlipidemia, the clinical pharmacist may provide care for patients under the direction of the collaborating physician by performing the following:
   A. Assesses patients needs as dictated by physician consultation. Related disease states include but are not limited to smoking cessation, coronary heart disease, obesity, and hypertension.
   B. Evaluates pharmacologic and non-pharmacologic therapies taken by the patient, including nonprescription and herbal remedies.
   C. Orders, interprets, and conducts pertinent laboratory studies.
   D. Initiates and adjusts medications in accordance with the prescribing privileges defined.
   E. Provides patient education in verbal and written form on the patient's disease states, pharmacologic, and non-pharmacologic therapies.
   F. Documents activities within the patient's visit, treatment decisions made, and laboratory tests ordered, and provides the physician with a copy of the documentation.
   G. Consults with referring physician and other members of the healthcare team as

States have implemented collaborative practice agreements with physician partners to manage routine follow-ups by patients, refill medications, and select, initiate, and monitor new doses or types of medications under written legal protocol with physician supervision. Through collaborative management of patients, pharmacists can work to increase compliance with drug therapy regimens and reduce the rate of adverse drug events with drug therapies. Under these col-

(Table 5. のつづき)

appropriate (dietician, social worker). Other subspecialty consultations will be made by the overseeing physician.

H. Obtains authorization by the overseeing physician for any deviations from the protocol or treatment guidelines and documents the reason for deviation in the medical record

I. This protocol does not allow the pharmacist to diagnose medical diseases.

J. The clinical pharmacist may use the clinical practice guidelines for hyperlipidemia and coronary artery disease risk factor reduction cited below for treatment decisions:

- Executive Summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). JAMA 2001; 285: 2486-2497.
- Grundy, Scott, Cleeman, J., Merz, C., et al. Implications of Recent Clinical Trials for the National Cholesterol Education Program Adult Treatment Panel III Guidelines. JACC 2004; 44: 720-32.
- Gibbons RJ, Abrams J, Chatterjee K, et al. ACC/AHA 2002 guideline update for the management of patients with chronic stable angina: a report of the ACC/AHA task force on practice guidelines. 2002. Available at: www.acc.org/clinical/guidelines/stable/stable.pdf

This collaborative drug therapy management protocol was formulated and approved by:

_____ _____

Physician signature and date Director of pharmacy signature and date

Requesting practitioner:

_____

Clinical pharmacist signature and date

laborative agreements, pharmacists in the US have gained the trust of many physicians and have freed physicians' time to worry with the more complex issues of diagnosis and therapy, thus allowing more time to evaluate new and more complex patients. Collaborative management of patients can save money by decreasing the frequency of physicians' office visits and aides in making changes to medication therapy in a timely manner.

With the financial support of a socialistic government-financed healthcare system within Japan, pharmacists are afforded the luxury of receiving payment or reimbursement for interacting with patients and physicians in a clinical manner. With the additional training, pharmacists will be more prepared to take over such unique and evolving roles with the healthcare system of Japan.

However, pharmacists do have several obstacles to overcome in order to be completely successful in their efforts. One of these obstacles is the inability by law to have physical contact with the patients. Without this ability, it is difficult to expand the variety of clinical services to screening activities like blood pressure monitoring or checking cholesterol or blood glucose levels. Another potential obstacle is physician support. Pharmacists in the United States have faced and overcome this problem by avoiding the territory of diagnosis, and referring the patient for further medical care and diagnosis by a physician, upon finding a potential

Table 6. Design of the Prescription Drug and Medicare Modernization Act of 2003.

Starting date	January 2006
Monthly premium	$37 (¥4070)
Deductible	$250 (¥27,500)
Benefit	• Covers 75% of each prescription up to $2,250 (¥247,500) in spending • If spend more than $3,600 (¥396,000) in prescriptions in one year, Medicare will cover 95% of prescription costs thereafter
Individuals making less than $14,355 a year	• Copayment is reduced to $3 (¥330) per prescription • No monthly premium or deductible
Qualifications for Medication Therapy Management (MTM) by pharmacist providers	• Pharmacy providers develop program in collaboration with physicians • Patient eligibility o Referred for MTM by another healthcare provider o Prescribed medications from more than 1 prescriber o Receiving more than 4 chronic medications o Has at least 1 chronic disease (heart failure, diabetes, asthma, osteoporosis, hypertension, hyperlipidemia, depression, osteoarthritis, chronic obstructive pulmonary disease) o Has laboratory values outside of the normal range that can be treated with drug therapy o Has documented nonadherence to medication therapy for more than 3 months o Has decreased health literacy or language barriers due to cultural differences requiring intensive counseling o Monthly medication costs exceed $200 (¥220,000) o Recently discharged from hospital or skilled nursing facility in the past 14 days and receiving new medications

Adapted from *Medicare Prescription Drug Basics,* URL http://www.cms.hhs.gov/medicarereform/drug%20coverage%205-31.pdf, Accessed 8/24/05, *Medication Therapy Management in a Community Pharmacy Practice: Core Elements of an MTM Service—Version 1.0,* URL http://www.aphanet.org/AM/Template.cfm?Template=/CM/ContentDisplay.cfm&ContentID=3303, Accessed 8/24/05, and *Housing Assistance from the Department of Housing and Urban Development*, URL http://www.cms.hhs.gov/medicarereform/hud.pdf, Accessed 8/24/05.

problem during the screening process. Additionally, pharmacists involved in CDTM have been very active in documenting the positive cost impact and clinical outcomes associated with their services within the medical literature. The peer-reviewed written word is the only long-lasting method to make potential collaborators aware of the true benefits of pharmacists' impact on patient care. Communication skills are also essential in promoting the new clinical services pharmacists can provide with the training received under 6-year clinical pharmacy programs. If pharmacists in Japan are able to remove these potential barriers to true pharmaceutical care, they will enjoy an enhanced professional status and some of the most advanced pharmacy-initiated patient care practices in the world.

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