Pharmacists, Patient Drug Use and Misuse, and Necessary Evolving Professional Roles

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Each of the health professions in the United States and beyond has undergone dramatic changes in the recent past and will continue to evolve substantially in the future. Although most of the changes affecting the US health care system in the last century have been suggested to be incremental in nature, those providing care within the health care system have seen unprecedented impact on their roles. Pharmacy as a profession has seen significant changes in the scope and range of professional responsibilities and opportunities in the past several decades. These changes relate to perceptions both internal and external to the profession. There are elements resistant to change within the pharmacy profession that have not embraced an expanded and altered role different from previous expectations, but many pharmacists have been empowered by the change and challenges and have thrived. Society deserves and demands no less than a safe and appropriate medication use system. Yet there are fundamental flaws in the drug use process in the US. Medication compliance hovers around 50%, prescription drug misuse is rampant, over-the-counter (OTC) medications are misused, adverse drug events occur (many of which are preventable), antibiotic misuse has led to drug resistant strains of many bacteria, and, despite recent changes to Medicare, many patients remained uninsured with respect to prescription medications. Pharmacy needs to embrace new proactive roles for these and other medication-related errors to decline in occurrence and severity.

The Complexity of Drug Use, Influence of Self-Medication, and Impact of Insurance Coverage

The use of drugs as a form of medical treatment in the US constitutes an enormously complex process. Individuals can purchase medications through numerous outlets. OTC medications can be purchased in pharmacies, grocery stores, supermarkets, convenience stores, via the Internet, and through any number of additional venues. Prescriptions can be purchased through traditional channels (community chain and independent pharmacies,}

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food market pharmacies), from mail service pharmacies, through the Internet, from physicians, from health care institutions, and elsewhere. Because of this proliferation of outlets for drug acquisition, the monitoring of the positive and negative outcomes of the use of these drugs, both prescription and OTC, can be disjointed and incomplete. With the advent of new, sophisticated information technologies (IT), pharmacists should be able to harness IT and computer technology so as to better monitor drug use and the drug use process regardless of patient access to medications.

Reasons for the Increase in Self-Medication. Self-medication can be broadly defined as a decision made by a patient to consume a drug without the explicit approval or direction of a health professional. The self-medication activities of patients increased dramatically in the late 20th century. Many contemporary developments have continued to fuel this increase. There are ever increasing locations from which to purchase OTC medications. There have been many medications switched to OTC classification from prescription only classification in the last 50 years. In addition, patients are increasingly becoming comfortable with self-diagnosis and self-selection of OTC remedies. These changes may, in part, be fueled by direct marketing to consumers. Direct-to-consumer advertising for prescription drugs has doubled in the recent past, from $1.1 billion in 1997 to $2.7 billion in 2001. As drugs have been switched from prescription to OTC status, the advertising and promotion of these drugs increase as well.

Where Consumers Obtain Medications. Although pharmacists are seen as the gatekeepers for patients to obtain prescription drugs, patients can also obtain prescription medications from other pharmacies and/or from dispensing physicians. Patients may also borrow from friends, relatives, or even casual acquaintances. In addition, patients obtain OTC medications from physicians through prescriptions, on advice from pharmacists, through self-selection, or through the recommendations of friends or acquaintances. Through all of this, it must be recognized that both formal (structural) and informal (pervasive) system components are at play. Pharmacists or physicians may or may not be consulted regarding the use of medications. But, in some cases, health professionals are unaware of the drugs patients are taking. In addition, herbal remedies or health supplements may be taken without the knowledge or input of a health professional.

As an example, consider the patient medication profiling capability of most pharmacists. Computerization of patient medication records is commonplace in pharmacy. This computerization allows for:

- Ease in billing third-party prescription programs
- Maintenance of drug allergy information
- Drug use review
- Notification of drug interactions
- Aid in meeting the OBRA '90 (Omnibus Budget Reconciliation Act of 1990) requirements for patient counseling, drug use review, and estimation of appropriateness of therapy

This computerization permits drug-related information to be easily entered, retained, and retrieved. However, OTC medications are rarely entered into such records (one exception may be OTC drugs prescribed by physicians and dispensed through a prescription by pharmacists). This exclusion of a whole class of drugs from the monitoring programs of pharmacy may have a profound effect upon the ability of pharmacists to monitor the drug
therapies of their patients. If the patient purchases the OTC medication in the pharmacy, the pharmacist may have an idea of the drugs consumed. However, if OTC drugs are purchased in a non-pharmacy outlet, the pharmacist is completely unaware of many drugs a patient may be taking. Another factor adding to the complexity of the problem is the fact that a patient may also utilize numerous pharmacies for varying prescription products. Thus there is no one record repository for all medications a patient may be taking.

The Impact of Insurance Coverage. External variables may greatly influence patients and their drug-taking behaviors. Coverage for prescribed drugs allows those with coverage to obtain medications with varying cost-sharing requirements. However, many do not have insurance coverage for drugs or other health-related needs. It has been estimated that in 2004 14.7% of Americans, approximately 42 million people, lacked health insurance for all or part of the year.3 Certainly, these considerations have huge ramifications for how and when consumers obtain prescribed and OTC medications. Those that do have health insurance have seen premiums rise drastically in the recent past, 8.4% in 2000 and 11% in 2001.4 Miller notes that in some cases employees are not just being asked to pay more for health insurance but to pay for it all.4

Harnessing Information Technology to Enhance the Patient Drug Use Process

The lack of adequate information that patients receive concerning the drugs they take has prompted the US federal government to become involved in mandating the provision of information to patients. The OBRA ’90 guidelines stipulate, among other tenets, that certain information be offered to patients. Some pharmacists go above and beyond the minimum requirements specified in these guidelines. Others simply follow the basic letter of the law.

These governmental efforts are based upon the acknowledgement that patients simply do not understand enough about the drugs they take. Efforts to institute mandated patient package inserts (PPIs) in the 1970s and 1980s were aimed at the lack of patient drug knowledge and receipt of such from health professionals.

Information Technology. Currently, we live in an age when information technology is eclipsing our ability to properly monitor what is being transmitted and to whom. Unless safeguards are enacted, this transfer of information can have a negative impact in addition to the intended positive effects. Computerization of medical and pharmacy records affords providers and institutions unique ways to store voluminous amounts of health data without the expansive storage that was necessary in the past. Compliance interventions can be developed with technology available; however, important safeguards need to be in place to ensure that only those who should see health data are the ones doing so.

e-prescribing. Automatic prescription order entry, also termed e-prescribing (electronic prescribing), occurs when the physician enters prescription information electronically, which is then automatically transmitted to the pharmacy for dispensing. There is nothing that the patient needs to do other than simply go to the pharmacy to pick up the medication. This has the potential to decrease errors in prescribing and dispensing and make it easier for the patient to comply. The Medicare Modernization Act of 2003 includes e-prescribing as a compo-
How Medication Noncompliance Adversely Affects Patients

Preventable problems with drug misuse in the US include overuse and underuse on the part of patients, adverse drug reactions, and frank errors on the part of providers or dispensers. Overuse can include intended patient compliance that exceeds prescribed amounts or purposeful drug abuse. Underuse includes noncompliance with initial prescribed drugs or partial compliance with prescribed therapies.

Patient compliance with medication regimens is an integral part of the process of drug use by patients. Patient compliance and the interconnectedness of subtypes are depicted in Figure 1. Initial compliance refers to patients initially filling prescriptions authorized by prescribers. Estimates of initial noncompliance range from 3% to 20% of all new prescriptions written in the US. Partial compliance entails taking some prescribed drugs, but not all as prescribed. Estimates of partial noncompliance in the US range from 50% to 80%. Complete compliance is being adherent 100% of the time with prescribed regimens. Finally, hypercompliance occurs when patients consume amounts over and above that which has been prescribed. The line between initial compliance and partial compliance is a one-way vector, whereas the lines between partial, complete, and hypercompliance are bidirectional. This diagram of compliant behavior can be replicated for each and all medications patients take. The complexity of compliance is readily apparent.

The prescribed drugs that patients take can be a small part of total drug use by patients. Other drugs taken may include OTC drugs, herbal supplements, vitamins, nutritional supplements, and perhaps drugs borrowed from other friends, family members, or strangers.

Pharmacists can significantly influence patient compliance, but it is not possible to entirely control the usage of drugs on the part of patients. Since drugs can be obtained from such varied sources, the pharmacist is often unable to know all the locations from which a patient obtains medications. However, pharmacists can play a major, active role in ensuring proper patient compliance. Therapeutic benefits to patients, more appropriate usage of health resources and economic rewards to pharmacists will all be enhanced through appropriate patient compliance monitoring by pharmacists.

How Significant is Noncompliance?

Various authors have estimated, in passing, the rate of compliance to be between 30% and 80%. Rates for estimated compliance vary considerably based on the samples studied and the therapeutic focus of interest in the study designs. Investigators from fifty years ago narrowed their investigations of noncompliance to specific diseases treated by very narrow ranges of drug therapies.

Both self-medication and patient compliance behaviors are exceedingly complex. McDonald and colleagues point out that patient interventions attempting to influence compliance are complex, labor intensive, and not particularly effective. They further suggest that more convenient care, reminders, self-monitoring by patients, reinforcement, family therapy, and additional attention may need to be in play for compliance improvement to oc-
Haynes and colleagues call for better approaches to enhance compliance that are more efficient and more effective.\(^5\)

**Drugs Prices, New Insurance Plans, and Impact upon Patients and Drug Use.** Significant issues related to pharmaceutical manufacturers include high profitability and patients’ noncompliance due to inability to pay. Ethics here relate to how manufacturers’ profit-driven ethos is causing patients to be noncompliant due to the high cost of pharmacotherapy. Medications for chronic conditions such as hypertension or dyslipidemia may be under-complied with due to the high cost of therapies.\(^7\) Although it is accepted that the elderly use three times as many drugs as younger patients, this number may actually be understated in seniors due to their financial inability to comply.\(^8\) Seniors face difficulty with economic compliance for several reasons. A recent Henry J. Kaiser Family Foundation publication\(^9\) examining drugs use and the elderly determined:

- 73% of seniors take 5 or more prescription medications
- 57% take more than one type of prescription
- 67% use more than one prescribing physician
- 41% use more than one pharmacy

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**Figure 1. Inter-Relatedness of Compliance Behaviors**

\(^1\) Fincham: Pharmacists, Patients, and Professional Roles
**Health Highlights**

- 52% of seniors with 3 or more chronic conditions are noncompliant.
- To reduce the costs of medications, seniors with 3 or more chronic conditions skipped or reduced the dosage mediation (35%) or did not even fill the initial prescription (19%)

This is a crucial issue for seniors. The Medicare Part D prescription drug benefit, although projected to help some seniors, will not address the issue of drug company charges for prescription drugs. The enabling legislation was passed with the provision that CMS personnel could not negotiate prices with the pharmaceutical manufacturers.

**Medicare Part D Outpatient Drug Therapy Coverage.** Beginning in 2006, Medicare through Part D began payment for outpatient drug therapies for Medicare recipients who signed up for coverage. This important and revolutionary change in payment for outpatient drug therapies for seniors will be interesting to observe, monitor, and assess for the near and long-term future. After a deductible amount is reached for most individuals, patients will receive benefits up to a certain level and then have a period of non-coverage through Part D. For the majority of patients spending $2,250-$5,100, there will be no coverage in 2006. After $5,100 is spent, a 5% co-payment is required.

How this plan will affect patient compliance will be individual and variable. Many seniors struggle as it is with compliance, and the variable cost of drugs may impact many patients in a negative manner relative to compliance. The copayment, coinsurance, and deductible amounts will increase rather steadily over the next decade. This increase, coupled with increasing monthly premiums, will tax many seniors and again variously impact their drug taking compliance behavior. Cubanski et al.\(^\text{10}\) recently reported the negative impact on compliance of the increasing numbers of drugs and variable payment mechanisms excluding coverage. Regardless, the outcomes and behaviors (both patient and provider) will be fertile, empirical areas for drug related research in the future.

**What are the Economic Consequences of Noncompliance?**

Compliance is often thought of (as it should be) in terms of therapeutic success or failure. If patients can reach a certain level of compliance, improvement in symptom occurrence, a lessening of disease morbidity, and/or the achieving of a total cure are all possible. Conversely, if noncompliance occurs, predictable continuation of symptoms, worsening of disease, or death may occur depending upon the condition being considered. Problems with patient compliance are similar across diseases, regimens, and age groups.\(^\text{6}\) Compliance and the lack thereof are equal opportunity problems.

Patient noncompliance can have significant economic ramifications as well. It is known is that a small segment of our population (5%) accounts for 49% of overall cost expenditures in the US health care system.\(^\text{11}\) Some of these expenditures are no doubt attributable to non-compliance with drug therapies and ramifications related to patient behaviors. What follows below is what we know about the economic consequences of noncompliance.

The ramifications of noncompliance and commentary on such are not new. The issue of noncompliance with therapies dates back centuries and includes concerns about vaccina-
tions for smallpox. A decade ago, Feldman and DeTullio noted in general terms the economic ramifications of noncompliance, and Scott, more specifically, indicated that the costs of compliance amounted to billions annually and would be a target of health plans so as to reduce downstream costs. The economics of noncompliance upon downstream health care expenditures are significant predictors of health care costs.

The accelerating and unabated increase in the costs of drugs leads to a certain amount of noncompliance which no doubt can lead to further costs. Kennedy et al. note that a significant number of adults with disabilities are noncompliant, and half of these individuals report negative health consequences as a result. For example, the authors of an Australian study note that one-fourth of drug related admissions to a hospital were attributed to noncompliance on the part of patients.

Admissions to emergency departments have also been tied to patient noncompliance. Dennehy et al. determined in one large scale study that 58% of drug related illnesses were tied to patient noncompliance across many disease states.

Expanding Vital Sign Measurements to Include Compliance Estimates

With the elderly, it is not age per se that makes the issue of noncompliance so crucial; instead, it is the multiple morbidities that become critical with seniors. Complex drug therapies serve to enable noncompliant behavior. Noncompliance respects no age, but the characteristics of the elderly place them at risk.

Compliance estimates on behalf of patients should be considered for inclusion in “vital signs” sections of medical records, electronic or otherwise. These compliance estimates can be viewed as just as important as the other crucial measures that are included in assessing patients. Blood pressure measurements are merely isolated determinations if no concomitant assessments and recordings of adherence to treatment regimens to treat hypertension are also made. Pulse values for a congestive heart failure patient are of little use if compliance with treatments is not also assessed at the same time. One cannot hide values for weight, height, temperature, blood pressure and or pulse readings when having vital signs evaluated and recorded. In the same vein, patients need to feel comfortable having compliance estimates gleaned and recorded in patient medical records. This may take multiple entries for multiple drugs consumed and be time consuming. But, it would appear to be a very good use of time and energy. Assuming patients are compliant when they actually are not and therefore failing to provide additional, individualized compliance aids or further pharmacotherapy that might be easier complied with are ultimately more time consuming and vastly more costly for all involved.

Concordance as a New Approach to Compliance and Empowerment of Patients

The issue of changing the medication taking paradigm from one of paternalistic control, suggestion, or admonishment to one of a shared process of communicating and agreeing on therapeutic options is an important goal in the process of empowering patients to be better compliers.

A working party in the U.K. was assigned the task of examining patient compliance and improving aspects of medication taking by the
Royal Pharmaceutical Society of Great Britain in 1995. The task force completed its work with the issuing of a report, *From Compliance to Concordance*.22 Elwyn et al.23 note that there is little evidence at present indicating concordance leads to better outcomes, but the concordance approach suggests that the involvement of patients in discussions of beliefs about medications, side effects, harms, and benefits will lead to better and safer care.

Key tenets in the concordance model include: empowerment of patients, investment of time, assistance by caregivers, a sense of involvement on the part of patients, shared and informed decision-making, feedback, and restructuring input and use of medications over time. A crucial component of concordance is the placing of patients’ health beliefs center stage in the joint decision making approach used by patients and physicians and other health providers.23 Tones24 suggests that health promotion and focusing on the patient proactively averts the “blame the victim” approach so common in the past when examining patient adherence.

Key questions regarding any model of compliance enhancement, including concordance, need exploring. Has the patient “bought into” the need for the new drug (i.e. use of concordance)? Is the dynamic relationship between physicians and patients such that the patient is encouraged and empowered to move from a passive to an active role with respect to his or her care? Is there a linguistic mismatch between patient and provider? Is the patient sufficiently health literate to understand and assimilate the physician-directed questions, instructions, and/or treatment plan?

The concordance model is a method that can be emulated to improve the dynamic between patient and physician. Simply stated, the patient needs to participate in the decision-making process concerning the drugs prescribed. We need to move away from therapy “silos” which isolate the physician and patient during the design of therapeutic interventions. There is a need to adequately interact to ensure patient buy-in and tie-in. Personal health records and health information technology advancements need to incorporate patient accessibility and input into future system architecture.

**The Influence of Pharmacists on Patient Noncompliance**

In the vast majority of dispensing situations, pharmacists oversee medication dispensing, and the potential for impact by the pharmacist may be one untapped answer for many of the problems of medication noncompliance. Where does the pharmacist enter the compliance matrix? The potential for pharmacists to avert medication noncompliance is both enormous and rewarding. The pharmacist is the focal professional with regard to patient medication consumption. The convergence of the marketing, prescribing, acquisition, and provision of drug products centers around pharmacists. This convergence applies in all health care settings, whether ambulatory or institutional. The provision of pharmaceutical care entails the dispensing of the knowledge that accompanies the provision of actual drug products. Proper use of a drug may not occur without proper delivery of drug knowledge to the patient.

There is no professional in a better position to first detect, as well as inform others, of the noncompliant patient. Often, the pharmacist has a special relationship with both physician and patient. Because of this relationship, the pharmacist may bridge the gap between the
recommendations of the physician and the special problems and/or concerns of the patient. Considering the role of the pharmacist in the provision of pharmaceuticals to patients, the pharmacist also may be a crucial professional with regard to strategic, mechanical, or behavioral attempts to impact the noncompliant patient.

The Need for Primary Care Pharmacy to Enhance Outcomes

Pharmacists have been shown in the US to make a dramatic difference in drug misuse. For example, a study conducted in Boston's Brigham and Women's Hospital found that pharmacist participation in patient rounds with the ICU team dramatically reduced the adverse drug event rate in an ICU from 33.0 per 1,000 patient days to 11.6 per 1,000 patient days.

Recently in the UK, “primary care pharmacy” has established roots. The concept of pharmacists working alongside physicians and others is not new, but the innovative structure of this movement in the UK is novel. There, pharmacists provide enhanced services in the ambulatory care setting that include needle exchange and methadone administration, smoking cessation and blood pressure monitoring services, sexual health services (e.g. emergency contraception), disposal of outdated and unwanted medications, and therapeutic drug monitoring. These services may be provided in the US, but not with the same range of services and degree of acceptance. Pharmacy in the US will need to move to such models of practice in order to survive as well as optimally thrive in the near and long term future. These collaborative models of practice incorporating multidisciplinary teams, each with specific skill sets and abilities, will require each involved health profession to evolve and accept the necessary accommodating changes in order to enhance patient care.

It is necessary to examine drug use in many groups of patients, including the elderly, so as to exclude drug use that increases costs, causes adverse effects, and is inappropriate and/or damaging. Pharmacists have templates from which to work to solve drug related problems. The updated Beers criteria for identifying inappropriate drug use in the elderly provides such documentation. In this comprehensive analysis, drugs that should not be used in the elderly are presented. Long-term care patients exposed to inappropriate drugs for the elderly and misprescribing are susceptible to the same adverse effects as ambulatory patients. However, costs due to inappropriate drugs use can be more pronounced for elderly long-term care patients.

What Else Do Pharmacists Need to Do?

Pharmacists need to play a much larger public health role in the US. Pharmacists are the most accessible and computer-adapted profession. As such, pharmacists have a responsibility to capitalize on these attributes. The primary care pharmacy model presented earlier in this paper is an estimable goal for which to aim. Preventive needs begging for interventions in collaboration with sister health professions include:

- smoking cessation counseling and referral
- sexually transmitted disease education and awareness campaigns (including the delivery of emergency contraception when required
and appropriate)
• counseling on the epidemic of alcohol over-
use and binge drinking
• nutrition counseling

Such collaborations have been explored and
inaugurated elsewhere as well. Pharmacists
working with physicians, nurses, allied health
professionals, social workers, dieticians, pa-
tients, caregivers, and others on common and
overlapping goals can enhance patient care and
outcomes.

Provision of pharmacy care services individ-
ually and on a larger scale can enhance popula-
tion health by utilizing the available technol-
ogy and data being collected on a daily basis.
Managed care, the Utilization Review Program
within Medicaid and Medicare programs, and
further data mining opportunities can allow
pharmacists to provide population-based phar-
macy care to thousands of patients.

Summary

In summary, patient compliance with med-
ical regimens is a complex health care concern
which involves ethical, economic and social is-
issues. Nonetheless, it is vital that all involved
with drug taking and compliance issues real-
ize that we as a society must institute proac-
tive measures to initiate collaboration amongst
health care providers, pharmacists and patients
to ensure that patient care is enhanced and that
the potential of each relevant stakeholder is re-
alized.

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