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Evolution of Clinical Pharmacy in the US and Future Directions for Patient Care

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Abstract

This paper describes key events in pharmaceutical education, training, practice and research that have occurred over the past 55 years. Some of these events included the development of the doctor of pharmacy degree, residency training and co-location of clinical pharmacists in patient care areas. These changes not only necessitated more specialized training but then led to board certification to ensure quality patient care. Specific examples of the research that has supported the involvement of clinical pharmacists in direct patient care will be discussed.

Keywords

clinical pharmacy; history and development; interdisciplinary care; ageing of the population

1.0 INTRODUCTION

The role of pharmacists in direct patient care is increasing especially as the population ages. The role of clinical pharmacists underwent important changes from the 1960s through 1990s as their participation in direct patient care increased. Understanding the development of clinical pharmacy helps to establish new models of team-based care, particularly for older populations suffering from many co-morbidities and who receive numerous medications.

This article discusses the history of clinical pharmacy in the United States (U.S) and estimates future trends in hospital and ambulatory care. The role clinical research has played in the development of clinical pharmacy services, direct patient care and rational pharmacotherapy will be highlighted in this paper.

The objectives of this article are to:

- Discuss the key education and training experiences that helped set the stage for new clinical pharmacy services.

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This article was written as a contribution to the Special Issue on Clinical Pharmacy that was developed following my presentation at the 42nd Annual Symposium of the ESCP in Prague, the Czech Republic, in October 16-18, 2013.

- Describe the pivotal developments in clinical pharmacy that have shaped the current practice environment in the U.S.
- Discuss the concept of direct patient care and the education and training requirements to provide clinical pharmacy services to complex patients.

The literature on the history and development of clinical pharmacy is extensive so I will focus on a few key developments that have helped shape clinical pharmacy in the U.S. Clinical pharmacy started in the U.S. and it has evolved differently in other countries.

I have been lecturing to our students at the University of Iowa on the history of clinical pharmacy since 2007. In addition to the literature, I have found two books particularly useful sources for this topic. The first is *The Practice of Pharmacy: Institutional and ambulatory pharmaceutical services* by McLeod and Miller (1981)¹ and the second is *Clinical Pharmacy in the United States: Transformation of a Profession* by Elenbaas and Worthen (2009).² Both books are excellent references for those interested in tracing the history of clinical pharmacy in the U.S.

2.0 Education

The issue of the proper degree in pharmacy had been debated in the U.S. since at least the 1930s. There were two early developments that shaped clinical pharmacy including the formation of doctor of pharmacy degree (Pharm.D.) programs and residencies in clinical pharmacy (see below). While there were earlier attempts to provide the Pharm.D. degree, it was first formally recommended in 1950. However, only the University of Southern California implemented the Pharm.D. in 1950 and then the University of California San Francisco followed in 1955.² A few other colleges of pharmacy adopted the degree in the late 1960s.

In the early 1970s, federal funding assisted with greatly expanding clinical pharmacy faculty in Colleges of Pharmacy. Pharmacy education debated where clinical pharmacy fit within pharmacy training. The American Association of Colleges of Pharmacy (AACP) spearheaded an effort to examine this issue. Dr. John Millis was asked to chair a commission to study pharmacy and the “Millis Commission” released their report in 1975 when I was in my second year of pharmacy school. Their landmark report on the *Pharmacists of the Future* had numerous recommendations including that pharmacy, in essence, is a clinical profession. The report indicated that pharmacists should be trained to provide direct patient care to improve public health. This report and other efforts continued to spur the expansion of clinical pharmacy within colleges of pharmacy often in collaboration with hospitals and ambulatory clinics into the next decade.

There debate about whether the Pharm.D. degree should be the sole professional degree was contentious in our country for many years. Finally, in 1992 the AACP House of Delegates voted to approve the Pharm.D. degree as the only professional degree in pharmacy, doing away with the Bachelor of Science in Pharmacy.³ The American Council on Pharmaceutical Education (ACPE) is the body that sets educational standards and accredits colleges of pharmacy. In 1997, ACPE decreed that they would no longer accredit Bachelor of Science

programs effective in 2000 and all colleges of pharmacy had to convert to the Pharm.D. as the sole professional degree.

ACPE has revised the standards for colleges and schools of pharmacy several times since 2000. ACPE Standards 2016 go into effect July 1, 2016.⁴ The new standards are designed to ensure that graduating pharmacy (Pharm.D.) students are ready to practice in teams and prepared to directly contribute to patient-centered care, work in inter-professional teams, use evidence-based practice, apply quality improvement and utilize informatics. The desire to meet these standards are an effort to ensure our students can meet the practice demands described below.

3.0 Advances in Residency Training and Practice

The educational developments discussed above were occurring in parallel to advances in postgraduate residency training and clinical pharmacy practice. There were many key developments in the 1960's, but I will cover just a few.⁵ The first hospital pharmacy residency was established in 1962 and residency standards were published by the American Society of Hospital Pharmacists (ASHP) in 1963. These residencies were not clinical residencies but, instead, focused on developing leadership skills in pharmacy administration and traditional pharmacy operations. The development of these important services cannot be examined alone. Rather, the political context in which pharmacy was operating is also important. During this same period the number of medications on the market expanded rapidly. Medicare and Medicaid legislation was enacted to cover healthcare for the elderly and the poor, respectively, which greatly increased the access of healthcare for large numbers of patients. Additionally, the large number of veterans from World War II were now in their 40's to 50's and began receiving more extensive care in veteran's hospitals and clinics. These changes in healthcare provided opportunities for pharmacists to assist with the care of these larger patient populations.

Hospital pharmacy leaders like Paul Parker at the University of Kentucky and pioneers at other academic centers were promoting the decentralization of pharmacists. Pharmacist rounding with inpatient hospital services has been traced to the University of Kentucky in 1957. Drug therapy was becoming much more complex. Hospitals began to develop specific drug information centers to assist physicians and other providers with evaluating the medical literature.⁶ The first drug information center run by pharmacists was established by Paul Parker and Dr. David Burkholder at the University of Kentucky in 1962.² These centers began to expand at other large U.S. hospitals. It became apparent that the volume of literature was a challenge to rapid retrieval to answer questions. The Iowa Drug Information Service was developed by William Tester at the University of Iowa in 1965. This service took original articles and placed them on microfiche and quickly became one of the major sources of drug information for pharmacists. This service allowed drug information pharmacists and other clinical pharmacists to search the literature much more rapidly compared to other strategies. Such services further helped to solidify pharmacists as the members of the healthcare team who provided drug information. However, the Iowa Drug Information Service closed in December 2014 and the Drug Information Center at the University of Kentucky closed earlier. Drug information centers in other institutions have

also closed. These changes are not because drug information is not important. Drug information used to be provided from a defined room with many files of articles where physicians made telephone calls and waited for responses to their questions. However, providers now obtain their drug information free on their smartphone or desktop. We now have clinical pharmacy specialists in the medical office or hospital who are the drug information experts but they now have important answers at their fingertips without the need for a physical drug information center.

Another important development that placed clinical pharmacists near patients and physicians in hospitals was unit dose services designed to improve patient safety. The first program was developed and tested at the University of Iowa, again by William Tester and Jerry Black in 1964.⁷ These services expanded to other hospitals and allowed pharmacists to become decentralized on the patient floors very near the physicians and nurses. This proximity also increased opportunities for pharmacists to round with the medical services. The landmark 9th Floor Pharmaceutical Service project occurred at Moffitt Hospital at the University of California, San Francisco (UCSF) in 1966.⁸ Many future clinical pharmacy faculty were trained at UCSF and went on to help establish new clinical pharmacy educational programs at other Colleges of Pharmacy in the U.S.

It is important to note, however, that these “experiments” were really only occurring at a few large academic centers in the 1960s. These services expanded to other academic centers and veterans hospitals in the 1970s but would still be rare or nonexistent in small or medium-sized hospitals until much later.

There were numerous developments in ambulatory care in hospital outpatient clinics and other centers and I will discuss some examples.⁹⁻¹² In addition to papers describing these services, research studies subsequently found that prescribing and patient care could be improved when clinical pharmacists assisted with patient management.¹³⁻¹⁵ To my knowledge, the first paper to describe improved outcomes with clinical pharmacy services for any chronic condition was published in the cardiology journal *Circulation* in 1973.¹⁴ Dr. James McKenney studied clinical pharmacy services provided from a community pharmacy for patients with hypertension. The pharmacist worked with two physicians from a distant community health center and went to their office to review medical records and make recommendations. Patients in the pharmacist-managed group had significantly better blood pressure (BP) control than a control group.

Another unique ambulatory care service was when the University of Iowa College of Pharmacy placed a clinical pharmacist in the office of a family physician at the Pioneer Medical Center in the small town of Mechanicsville.^{16,17} This office had one physician, one nurse and the clinical pharmacist. The physician did not write prescriptions. Rather, the clinical pharmacist discussed the patient with the physician and then used the medical record to fill the prescription. The clinical pharmacist frequently selected the drug or dose and the documentation was in the record rather than a separate prescription copy. These models were expanded by Dr. Dennis Helling at the University of Iowa in the 1970's to become the largest network of clinical pharmacists in family medicine.^{10,11,18-20} I was extremely fortunate to have been able to train in two of these offices when I was a pharmacy student in

the bachelor of pharmacy program. Helling and colleagues found that patients who had one encounter with a clinical pharmacist in a family physician's office had much greater satisfaction with their overall care.¹⁸ We later found that family practice offices with clinical pharmacists had significantly more appropriate prescribing than offices that did not have clinical pharmacists.¹³

One of the first anticoagulation clinics run by clinical pharmacists was described by Dr. Thomas Reinders at the Medical College of Virginia (MCV) in 1979.²¹ These clinical pharmacists had complete responsibility for adjusting warfarin doses and ordering laboratory values which was a fairly radical practice for that time period. Additionally, Dr. McKenney became a faculty member at MCV and established the pharmacy services clinic where physicians referred patients to the clinical pharmacist for disease management.²² I was again very fortunate as a Pharm.D. student to have the opportunity to train in both of these clinics. Over the next 20 years both anticoagulation services and pharmacist –run ambulatory clinics became standard in many U.S. hospitals.^{10,11} Investigators found such services reduced bleeding and recurrent thromboembolic events and they were cost effective.²³

The year 1979 was a pivotal year in international clinical pharmacy. That year, both the American College of Clinical Pharmacy (ACCP) and the European Society of Clinical Pharmacy (ESCP) were formed. These organizations were created by pioneering clinical pharmacists who were disappointed with the pace of clinical pharmacy development and support at the national level. These early leaders desired societies that specifically represented and promoted clinical pharmacy. We can now say their “experiment” was a huge success as was evidenced also in this 42nd ESCP Symposium in Prague in 2013 and the scope of influence of ACCP and ESCP.

The early 1980s heralded additional major events. ASHP rolled out new residency accreditation standards in 1980.² These standards were divided into accreditation for clinical pharmacy practice and specialty pharmacy practice which began the first formal accreditation of unique practice areas in pharmacy. These specialty areas included internal medicine, critical care, infectious diseases, primary care and many others.

In February 1985, ASHP convened an invitational conference in Hilton Head South Carolina. The attendees provided a broad representation in pharmacy and they articulated that pharmacy was a clinical profession.²⁴ This and other important pharmacy leadership conferences energized the profession of pharmacy to further spark the growth of clinical pharmacy in the U.S.

During the 1980s, literally hundreds of papers and studies appeared in the literature that documented the value of clinical pharmacy services in hospitals and ambulatory settings.^{2,10,11} Many clinical pharmacists were beginning to focus their practices and specialize in unique areas such as cardiology, emergency medicine, oncology, infectious diseases, critical care, primary care and many others.^{25–28} These developments necessitated specialty training and many papers were describing the new areas of specialty forming in pharmacy.

Some criticized clinical pharmacy as a service that was provided much of the time directly to physicians with less focus on patients. These criticisms led to important concepts when, in 1988, Dr. Douglas Hepler further crystallized the concept of Pharmaceutical Care previously coined by Dr. Donald Brodie.^{2,29} Hepler and Dr. Linda Strand further expanded this concept by describing a covenantal relationship between the pharmacist and the patient in which the pharmacist's primary responsibility was to identify, prevent and resolve drug-related problems.³⁰ This concept articulated the responsibility of the pharmacist to work directly with the patient to optimize drug therapy. Pharmaceutical care was eventually adopted around the world.

Community pharmacy residency programs were slow to develop in the U.S. but they expanded in the early 1990s. ASHP and the American Pharmacists Association partnered to conduct accreditation of community pharmacy residencies in 1999. The University of Iowa was the first program to receive accreditation that offered community pharmacy residencies at multiple unique pharmacies. Community pharmacy residencies are now well established in the U.S. and are training leaders who are developing unique patient care services in community pharmacies.

4.0 Role of research in development of clinical pharmacy services

Clinical pharmacy research can be traced back to studies from the early 1970s including studies on aspirin conducted by Gerhard Levy.^{31,32} Many of these early studies involved pharmacokinetic studies or dosing nomograms.^{33,34} Such studies are understandable as the discipline of clinical pharmacy in those days often involved pharmacokinetic consult services.

As clinical pharmacy became more established, research expanded into many specialty areas of pharmacy.¹ However, it was not until the 1980s when research that evaluated whether clinical pharmacy services improved health outcomes began to increase substantially.¹¹

An area that has become much more common in the U.S. is collaborative practice or team-based care in which pharmacists work with physicians to help manage chronic conditions.³⁵⁻⁴¹ Our research projects were based on direct patient care involving clinical pharmacists in practical research. They further helped to shape development of clinical pharmacy services.

In order to clarify how clinical pharmacy research may contribute to development and implementation of clinical pharmacy services, I will briefly describe selected examples of our research projects based on collaborative practice of clinical pharmacists who were embedded within the office of physicians.

We recently conducted two trials of physician-pharmacist collaboration to improve BP control funded by the U.S. National Institutes of Health.^{36,42} Our goal was to conduct cluster, randomized trials that used intention-to-treat analyses and also were controlled for many critical covariates that can influence BP.^{43,44} We found that the intervention significantly improved BP control and resulted in approximately an 8 mm Hg better mean systolic BP compared to usual care. We also found that 24-hour BP control was much better

in the intervention groups compared to the control groups.^{45,46} It appears the major reason for the better BP in the intervention group was because of more aggressive titration of BP medications.⁴⁷

These studies led us to ask the question whether this clinical pharmacist intervention model could be scaled up in a large number of medical offices with very diverse operations and minority populations. There is little evidence concerning whether a pharmacist intervention was also effective for African Americans⁴⁸ or Hispanics. For this reason we designed the Collaboration Among Pharmacists and physicians To Improve Outcomes Now (CAPTION) trial to determine if the physician/pharmacist collaborative intervention for BP would be implemented in diverse medical offices with high minority populations.⁴¹ This study was designed to evaluate whether the standardized intervention provided by clinical pharmacists 1) would be implemented in a large number of medical offices with diverse operations, 2) had a sustained effect once the clinical pharmacy service was discontinued, and 3) was effective not only in White patients, but also in under-represented minorities (primarily Blacks and Hispanics).

The CAPTION trial was a prospective, cluster-randomized multi-center clinical trial in 32 medical offices from 15 states in the US.^{49,50} All medical offices employed faculty-level clinical pharmacists (mean 1.9 per office) who primarily provided education for physicians and patient care and none of the intervention pharmacists dispensed medications.⁵¹ Offices were then randomized to a: 1) 9-month physician-pharmacist collaborative intervention (brief intervention or BI), 2) 24-month physician-pharmacist collaborative intervention (sustained intervention or SI), or 3) control group. Clinical pharmacists in offices randomized to the 9-month intervention arm were instructed to discontinue the intervention at that time. Clinical pharmacists randomized to the 24-month arm were instructed to continue the above frequency and scope of the intervention for a full two years. The control group received usual care.

At baseline, the suggested model was for the clinical pharmacist to review the medical record and perform a structured interview with the patient, including: 1) a detailed medication history; 2) an assessment of patient knowledge of BP medications, purpose of each medication, goals of therapy, medication dosages and timing, and potential medication side effects; 3) potential contraindications to specific BP medications; and 3) expectations for future dosage changes, monitoring and issues that may become future. The clinical pharmacist then made recommendations to change drug therapy to the physician. In some offices, the clinical pharmacists had authority to add medications or adjust doses on their own.

The results of this study were recently published.⁴¹ The study involved 625 subjects with uncontrolled hypertension, 377 (60.3%) females, 337 (53.9%) from racial or ethnic minorities, and the mean age was 60.3 ± 12.8 years. The majority of minorities (328/337, 97.3%) were African American (n=239) or Hispanic (n=89).

At 9 months, systolic BP was 6.1 mm Hg lower in intervention subjects compared to usual care (p=0.002). The adjusted difference in mean systolic BP between the intervention and

control groups for subjects from racial or ethnic minorities at 9 months was -6.4 mm Hg ($p=0.009$).

Mean BP was also significantly improved in subjects from racial minorities in intervention offices at 18 and 24 months compared to control group offices ($p < 0.001$). This study found that the pharmacist intervention could be implemented in a large number of diverse primary care offices and that the intervention was effective in under-represented minorities and patients from low socioeconomic groups.

5.0 Future directions of clinical pharmacy in hospital and ambulatory care

It is becoming clear that some types of clinical pharmacy practices see very complex patients.⁵² Pharmacists who provide direct patient care need to have specific credentials to practice in these complex areas. It is important to recognize that traditional pharmacy services such as counseling, immunizations, health screening or medication reconciliation provide value to the healthcare system. However, these examples are not what we mean when we use the term direct patient care. Direct patient care has been defined by the Council on Credentialing in Pharmacy (CCP) as:

- Direct patient care practice involves the pharmacist's direct observation of the patient and his or her [i.e., the pharmacist's] contributions to the selection, modification, and monitoring of patient-specific drug therapy. This is often accomplished within an inter-professional team or through collaborative practice with another healthcare provider.⁵³

When I was president of ACCP in 2001, the ACCP Board of Regents articulated the strategic goal to have all pharmacy graduates complete a residency by the year 2020. We felt this was important because of the complexity of pharmacy practice that require a high level of skills and training. ACCP has stated that direct patient care will require not only residency training, but also board certification in the proper specialty area.^{52,54,55} However, one of our biggest challenges in the U.S. is that we do not have enough residencies to fulfill these needs. Most residencies are funded by hospitals, clinics or community pharmacies and funding makes it difficult to sufficiently expand these residencies.

There were nearly 4,000 board certified specialists in clinical pharmacy in 2003. By 2014, these numbers had increased to almost 22,000. Table 1 displays the various clinical pharmacy specialties in the U.S., the year the specialty was approved by the Board of Pharmaceutical Specialties and the number of individuals certified in each specialty in 2012 and 2014. These dramatic increases in highly trained specialists have positioned the profession of pharmacy extremely well for the major changes that have occurred in healthcare reform in the U.S. I expect the rapid rise in board certified clinical pharmacy specialists will continue for at least the next decade.

The Affordable Care Act (ACA) was signed into U.S. Law in 2010. This act resulted in 16.4 million uninsured Americans gaining health insurance and another 12.3 million enrolled in Medicaid that covers the poor and disabled.⁵⁶ Even before the ACA was enacted, there were serious concerns about a shortage of primary care physicians and other healthcare providers.

Leaders have promoted more effective implementation of non-physician providers, including pharmacists, to address these care gaps.^{57,58} This and other legislation has established Accountable Care Organizations (ACOs) that are groups of physicians, hospitals, and other health care providers, who form an entity that provides coordinated high quality care to their Medicare patients.⁵⁹ The goal of ACOs is to coordinate care to ensure that patients with chronic conditions get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors. The hope is that ACOs will also save money. Smith et.al. discussed the need to include pharmacists in ACOs and integrated care teams.⁵⁸ Pharmacists have also become important members of care teams in Federally Qualified Health Centers which also serve the poor.

ACOs and other insurers are supporting the use of the patient-centered medical home (PCMH) to minimize episodic care, improve continuity and provide more comprehensive management of chronic illness and preventive care.⁶⁰ The PCMH was developed and endorsed by the American Academy of Family Physicians, American Academy Pediatrics, and the American College of Physicians.⁶¹⁻⁶³ The National Committee on Quality Assurance (NCQA) has developed standards and provided formal recognition of health plans and individual providers for many years.⁶⁴ While previous standards supported team-based care, the 2014 standards made team-care an essential component of the PCMH by including it as one of the six key standards. Health systems that want to achieve the highest level (3) of the PCMH must have well-functioning healthcare teams since this component is responsible for 20% of the total score. In addition, care management, medication management, care coordination and coordination of care transitions are all functions typically performed by non-physicians and make up another 14% of the score. All of the educational, residency and certification developments that have occurred in the U.S. have prepared pharmacists to fill these requirements. Many health systems are now adding clinical pharmacists to meet these standards and these numbers will increase rapidly in the next several years.

The PCMH emphasizes that care be organized around the needs of the patient, their relationship with their physician, and that healthcare teams assist with care of the patient.^{61,65} The standards do not state who should be on the team or how the team functions. However, the highest performing health systems have pharmacists on these teams.⁶⁶ The physician delegates responsibility to pharmacists to perform a medication history, identify problems and barriers to achieving disease control, perform medication counseling and adjust medication and dosages. There is some evidence that the PCMH improves outcomes, increases physician satisfaction, and decreases costs of care.^{67,68}

The challenges of managing chronic conditions have led to strategies to provide care management, previously termed disease-state management. These programs usually focused on a given condition, such as diabetes. The PCMH demands more comprehensive programs that manage multiple conditions such as diabetes, dyslipidemia, hypertension, pain management and psychosocial issues.^{69,70}

These trends demonstrate that clinical pharmacy services continue to expand in U.S. hospitals and involve a wide range of specialty areas. More hospitals and health systems are requiring residency training, or more to be qualified for higher level clinical pharmacy

positions. I predict we will continue to see more clinical pharmacists hired in private physician offices. This trend is being driven by new healthcare reforms and the requirements that physicians demonstrate good outcomes in order to receive full payment. The first few years of the U.S. healthcare reform were traumatic for our health system (and politicians!!). However, clinical pharmacy is well positioned for this expansion, primarily because of the changes in education, residency training and board certification that have developed over the last 40 years.

Clinical pharmacy services and direct patient care have a promising future in many countries. Clinical pharmacists are now more specialized for specific services or complex care. Recent advances in education and clinical pharmacy research enabled development of clinical pharmacy services in many countries all over the world. The large increase in complex older patient populations suggests that the involvement of clinical pharmacists in interdisciplinary care will become more important to improve medication safety, efficacy and effectiveness.

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7.0 References

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KEY MESSAGES

- Clinical Pharmacy services were developed in the United States in the 1960's and expanded rapidly in subsequent decades.
- Studies have found that clinical pharmacy services can improve medication use in hospitals and ambulatory care settings and improve patient outcomes.
- Future clinical pharmacy services in the U.S. will continue to expand and will require evidence of qualifications including board certification to provide advanced services.

Table 1Board Certified Specialties in clinical pharmacy in the U.S.⁷¹

Specialty Area	Name	Initials	Year Approved	Number Certified as of 2012	Number Certified as of 2014
Pharmacotherapy	Board Certified Pharmacotherapy Specialist	BCPS	1988	11,608	15,897
Oncology Pharmacy	Board Certified Oncology Pharmacist	BCOP	1996	1421	1773
Ambulatory Care Pharmacy	Board Certified Ambulatory Care Pharmacist	BCACP	2009	1000	1956
Psychiatric Pharmacy	Board Certified Psychiatric Pharmacist	BCPP	1992	758	845
Nuclear Pharmacy	Board Certified Nuclear Pharmacist	BCNP	1978	552	533
Nutrition Support Pharmacy	Board Certified Nutrition Support Pharmacist	BCNSP	1988	523	556
Total Certified				15,862	21,560