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SPECIAL ARTICLE

HIV clinical pharmacists – the US perspective

J.D. Scott[a,*], K.A. Abernathy[b], M. Diaz-Linares[c], K.K. Graham[d,e] and J.C. Lee[f,g]

[a]*Pharmacy Practice and Administration, Western University of Health Sciences College of Pharmacy, Pomona, USA*
[b]*Infectious Diseases, Orlando VA Medical Center, Orlando, FL, USA*
[c]*Bristol-Myers Squibb, Virology, Chicago, IL, USA*
[d]*Children's Diagnostic & Treatment Center, Ft. Lauderdale, FL, USA*
[e]*Pharmacy Practice, Nova Southeastern University, Ft. Lauderdale, FL, USA*
[f]*HIV Medicine & Clinical Research Coordinator, Special Immunology Services, Saint Mary's Health Care, Grand Rapids, MI, USA*
[g]*Clinical Pharmacy, College of Pharmacy, Ferris State University, Big Rapids, MI, USA*

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Abstract
Clinical pharmacists have been involved in treating people with HIV and AIDS since the epidemic began. Their roles have evolved from inpatient infectious diseases training clinical pharmacists offering treatment regimens for the serious opportunistic infections seen in the hospital, to clinical pharmacists who received specialized training in the treatment of people with HIV in the ambulatory care setting. Their roles and benefits have been documented in the literature, but not to a large extent. Improvements in adherence and cost savings have been seen, but significant improvements in clinical outcomes (changes in viral load and CD4 cell counts) are quite complex and often difficult to identify in the small studies that have been published. This manuscript will review the published data on this topic, and provide examples of clinically trained pharmacists in the US who focus on the treatment of people with HIV infection. The pharmacists discussed here practice in a variety of settings (privately managed free-clinics and government managed clinics), take care of a variety of types of patients (children, adults, military veterans, lower socio-economic groups, etc.), and are employed by a variety of institutions (academic, pharmaceutical company, large healthcare systems and small healthcare systems). These pharmacists were chosen to be representative of the wide variety of individuals, positions and roles of clinical pharmacists involved in the treatment of HIV in the US.

*Corresponding author.
E-mail address: jdscott@westernu.edu (J.D. Scott).

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Los farmacéuticos clínicos especialistas en VIH: la situación en los Estados Unidos

Resumen
Los farmacéuticos clínicos se han involucrado en el tratamiento de los pacientes con VIH y sida desde el comienzo de la epidemia. Sus papeles han evolucionado desde farmacéuticos con formación en enfermedades infecciosas que requieren hospitalización, aquellos que ofrecen regímenes de tratamiento para las infecciones oportunistas graves que aparecen en el hospital, hasta farmacéuticos con formación especializada para el tratamiento ambulatorio de pacientes con VIH. Sus funciones y beneficios se han documentado en la literatura, pero no de forma exhaustiva. Asimismo, se han demostrado las mejoras en la adherencia al tratamiento y el ahorro en costes, sin embargo las mejoras significativas en los resultados clínicos (cambios en la carga viral y recuentos celulares CD4) son muy complejas y a menudo difíciles de identificar en los escasos estudios publicados. En este documento se revisarán los datos publicados sobre este tema, y se mostrarán ejemplos de farmacéuticos con formación clínica en los Estados Unidos especializados en el tratamiento de personas infectadas con VIH. Además, los farmacéuticos incluidos ejercen en diferentes entornos (clínicas privadas y clínicas públicas), asisten a distintos tipos de pacientes (niños, adultos, veteranos de guerra, grupos de orígenes humildes, etc.), y pertenecen a diferentes instituciones (académicas, farmacéuticas, sistemas sanitarios de gran envergadura y de pequeña envergadura). Estos farmacéuticos se han elegido como representantes de una gran variedad de individuos, puestos y funciones que conforma el grupo de farmacéuticos clínicos involucrados en el tratamiento del VIH en los Estados Unidos.

It took 6 years (from 1981, when HIV was first reported, until 1987, when zidovudine was approved by the US Food and Drug Administration [FDA]) for the first medication to become available to treat HIV infection. Prior to 1987 (and even continuing into the 1990s), healthcare workers worked hard to keep their patients alive by treating a wide array of infections they read about, but had never seen. They tried to help patients fight their diarrhea, and retain their muscle and body weight. However, the lack of knowledge about HIV and the limited options available to treat opportunistic infections frustrated all attempts of providers trying to care for these patients.

During this same time, the idea of clinical pharmacists began to grow in the US. The American College of Clinical Pharmacy had been established in 1979, and the post-baccalaureate Doctor of Pharmacy degrees were becoming more sought after. Infectious diseases-trained (ID) specialty pharmacists were already assisting infectious diseases-trained physicians on hospital wards in the treatment of patients with almost any type of infection. These ID pharmacists continued to work with physicians as the hospital wards began to fill with patients with HIV and opportunistic infections.

As treatment and prophylaxis for opportunistic infections improved, and as antiretroviral agents became available in the US, the treatment of patients with HIV started to transition into the outpatient ambulatory care clinics. There, ambulatory care trained clinical pharmacists picked up the torch and assisted in the care of these patients.

However, it was not until about late 1995 that a significant need developed for clinically trained pharmacists to assist in the treatment of patients with HIV infection. As combination therapy was introduced, regimens became more complex. The new classes of antiretrovirals that were becoming available (non-nucleoside reverse transcriptase inhibitors, NNRTI, and protease inhibitors, PI) were often poorly tolerated and most had the potential for drug interactions with each other, with the agents used to treat or prevent opportunistic infections, and/or with medications used to treat other diseases the patients were battling. Clinical pharmacists were becoming more utilized by physicians, nurse practitioners and physician assistants to assist in the care and management of these complicated patients with complicated therapies. Additionally, as new data on the new antiretroviral agents became available, it became obvious that these combination regimens were very effective, when the patients took them properly. When they did not take them properly, the virus would become resistant to the medications, limiting future treatment options at a time when new treatment options were slow to become available. It became apparent that there was a need to promote and maximize adherence to therapy. This role often fell into the hands of pharmacists, primarily because pharmacists could work with patients on optimizing medication taking behavior given their expertise, accessibility to patients and ability to resolve medication related concerns of the patients. Since this time (around 1997 or 1998), pharmacists have been seen as a resource that every large HIV clinic should have.

One of the problems was that the tasks which clinical pharmacists were doing in some areas were tasks that the prescribing healthcare providers could do themselves, thereby avoiding the additional cost of a pharmacist. Some clinics were either avoiding hiring clinical pharmacists, or requiring the clinical pharmacists to prove their worth as part of the healthcare team. Thus, it became necessary for clinical pharmacists to document their activities and often prove their impact on effectiveness and cost savings in the treatment of patients with HIV, as had been done previously in patients with other disease states.

Early reports of clinical pharmacist activity included non-medication counseling, such as HIV risk reduction and condom use.[1] Weingarten and Freeland[2] discussed their program which involved a variety of pharmacists in different specialties working with multidisciplinary teams to improve care and outcomes in HIV patients prior to Highly Active Anti-Retroviral Therapy (HAART). Patients with HIV have preferred and even expected a higher level of service from their pharmacists. Marshall et al.[3] showed that HIV positive men reported that they needed pharmacists with knowledge of HIV and alternative therapies, and expected written, oral, or a combination of knowledge resources to be provided to them. In 2000, pharmacist clinicians from Chicago, IL, wrote about the HIV care at their institution, and reported that they performed 68 interventions within a 5 month period. These interventions included drug interactions (27%), incorrect dosing (25%), omission of a portion of the patient's regular therapy (17%), and other miscellaneous problems (14%). The authors alluded to potential cost savings, but did not extrapolate these cost savings to their program.[4] Cantwell-McNelis and James[5] also published a report providing a descriptive summary of the role of clinical pharmacists in the care of their HIV patients.

In 2003, the American Society of Health-Systems Pharmacists issued a statement in support of pharmacists playing an active role in the care of patients with HIV infection.[6] Interestingly, this seems to be when clinical pharmacy activity in the HIV field had peaked, and the statement was not echoed by the professional societies of other healthcare fields.

In general, most of the published reports of clinical pharmacists' activities were descriptive in nature. This yields interesting information, but is not backed by evidence from data on improvements in clinical outcomes. The first reports of clinical outcomes following clinical pharmacist interventions started showing up in the published literature in 2007. Horberg and colleagues published data looking at the impact of clinical pharmacists in a comprehensive healthcare system (Kaiser Permanente) in Northern California. In this observational trial, about 47% of the 1571 patients reviewed had received care from a clinical pharmacist. Patients who saw a clinical pharmacist had statistically significantly greater decreases in log viral load at 12 months (0.73 log greater decrease, $p<0.001$) and 24 months (0.33 log greater decrease, $p=0.005$) compared to those who did not. There were no differences between the clinical pharmacist group and control in achieving an undetectable viral load or in CD4 count increases at any time point. Patients in the clinical pharmacist group had more hospital days (1.57 days more, $p<0.001$), but fewer doctor office visits (0.88 fewer, $p<0.001$). Overall, while the data was mixed in outcomes, care from clinical pharmacists did show some benefits.[7]

Another group from Chicago[8] showed that implementation of clinical pharmacy services resulted in 2.42 interventions per admission during a 6 month prospective period, contributing to a 38% decrease in readmissions within 1 month of discharge when compared to the same amount of time prior to implementation of their services. Heelon et al.[9] reported that pharmacist review of therapy in their hospital resulted in a shorter time to resolution of antiretroviral related medication errors compared to no pharmacist review (15.5 h vs. 84 h, $p<0.0001$). March et al.[10] reviewed the data from their prospective observational study of a pharmacist managed drug optimization clinic. They made 253 interventions in 34 patients in an urban, publicly funded HIV clinic during an 11-month period. CD4 cells increase significantly from baseline, and viral loads decreased significantly; however, there was no control group. The largest study published involved patients who were recipients of publicly funded healthcare in the state of California (Medi-Cal) during 2004. They compared 5665 patients with HIV who went to standard pharmacies to 1353 patients who went to pharmacies offering a pilot "Medication Therapy Management" program (MTM), where state funds were used to provide supplemental income to pharmacies offering clinical services in addition to dispensing medications. Patients receiving care and medications from the MTM pharmacies had fewer contraindicated regimens (11.6% vs. 16.6%, $p<0.001$), fewer excess medication fills (19.7% vs. 44.8%, $p<0.001$), had higher healthcare costs ($40,596 vs. $36,937, $p=0.001$) and no difference in the rate of opportunistic infections. The increased costs were primarily driven by non-antiretroviral medications and mental health services. Other clinical outcome data, such as CD4 counts and viral loads, were not available. This pilot program is ongoing and future data are expected.[11] This study was potentially biased, as the pharmacies who participated as pilot MTM programs were pharmacies who had received much of their pre-study income from patients with HIV. They were more likely to be more familiar with the treatment of HIV, and may have had stronger relationships with patients and prescribers.

The following is a summary of the background and current practices of five clinically trained, HIV specialty pharmacists in the US. These professionals represent a variety of roles of clinical pharmacists in the US, including university faculty, clinicians in busy free community HIV clinics, a practitioner in an HIV clinic in the US Veterans Affairs program, and a pharmacist who left clinical practice after 14 years to join with a pharmaceutical company. Several are also accredited by the American Academy of HIV Medicine as HIV Experts (AAHIVE). This is a new designation (since January 2009) offered to pharmacists who meet the credentialing requirements (including an examination).

Karen A. Abernathy, PharmD, AAHIVE, is a Clinical Specialist in Infectious Disease and is a pharmacist with the Orlando Veterans Affairs Medical Center (VAMC).

Clinical pharmacists within the VAMC system have the opportunity to practice as mid-level providers, helping physicians attain specific disease state goals. Patients are referred to clinical pharmacy clinics by their medical providers in order to assist with attaining specific disease-related goals in such areas as hypertension, diabetes, lipids, and anticoagulation. After evaluating the patient's drug regimen, therapeutic endpoints, and non-pharmacologic factors, the clinical pharmacists adjust the medication regimen as indicated and schedule medical and laboratory follow-up. All interventions are documented in the patient chart to maintain communication with the primary providers and other members of the healthcare team.

In the case of the HIV clinic, patients are scheduled with the clinical pharmacist to ensure timely care, given the schedule limitations of our clinic's only infectious disease provider and the unexpected patient or medical factors that

may intervene. Patients newly diagnosed with HIV meet the pharmacist to receive education related to the antiretrovirals they are being prescribed. Follow-up is scheduled in two weeks in order for the pharmacist to assess medication adherence, tolerability, and to address any patient concerns.

The HIV clinic includes a nurse who monitors the patients' vital signs, weight, and health risk factors such as physical or emotional abuse, neglect, suicidal ideation, alcohol use, and safe sex practices. These parameters are obtained with every visit prior to the patient seeing the pharmacist or physician. After this screening is complete, the patient's most recent CD4 count and HIV viral load results are reviewed with the patient. To help assess compliance, patients are given a color pictorial of the various HIV formulations in order to identify their medications. Patients are asked to state the number of tablets or capsules they take, the frequency, and whether they take these with or without food. This method allows for clarification of any deviations from the patient's prescribed regimen. Given the significant potential for drug resistance, patients are also asked about the number of missed doses since the previous visit. Potential side effects and health complaints are also elicited. To ensure completeness, over the counter medications, herbal preparations, and medications attained from outside the VAMC system are documented in medical record. Throughout the interview, patients are re-educated about adherence, viral resistance, ways of alleviating common side effects, and specific drugs to avoid. As a mid-level provider, the pharmacist prescribes the HIV medications, schedules appropriate follow up, orders HIV labs to be completed prior to the next visit, completes encounter information for billing, and documents this information in the patient chart.

The HIV clinical pharmacist also provides consultation regarding drug information, drug interactions, and dosing for renal and/or hepatic impairment. Given the terminal nature of untreated HIV disease, the significant morbidity and mortality with inappropriate use of HIV medications, the high cost of antiretrovirals, the importance of adherence, frequency of side effects, potential for drug interactions, and the rapidly evolving information in this field, there are certain pharmacoeconomic and quality of life justification points for a clinical pharmacist in this area.

Mariela Diaz-Linares, PharmD, is a Medical Science Liaison in the Virology US Pharmaceuticals Medical Affairs division of Bristol-Myers Squibb Co.

Dr. Diaz-Linares is currently the medical science liaison (MSL) responsible for provision of HIV disease information, and information about the use of BMS HIV products, to healthcare providers across several states in the Midwest US territory. Her primary responsibility is to support the safe and appropriate use of BMS antiretroviral agents through scientific discussions with healthcare providers. Although in this role she does not have direct patient contact many of the activities are focused on educating healthcare providers on the HIV disease state and clinical data on BMS antiretroviral medicines to support patients living with HIV/AIDS. Within BMS, MSLs are aligned with Medical Affairs.

In her role as an MSL, Dr. Diaz-Linares typically has face-to-face meetings with healthcare providers in her assigned territory. These interactions include on-label, product specific discussions of BMS antiretroviral products, and responses to unsolicited questions related to clarification of specific patient populations, appropriate dosing, safety and drug–drug interactions questions and issues around the appropriate on-label use of a BMS antiretroviral medication. In addition, she may have disease area discussions focused on treatment trends, specific gaps in knowledge, and unmet medical needs that healthcare providers feel impact patient care. Through these interactions scientific information is communicated to providers and insights about unmet medical needs are provided back to the Medical Department ''at headquarters''. In addition to interactions with providers, Dr. Diaz-Linares delivers BMS antiretroviral product presentations in response to requests by formulary committees and other bodies involved in formulary access decisions. She also participates in product and disease state training of employees and independent contractors, from a medical perspective. Dr. Diaz-Linares also supports BMS clinical research activities.

Kathleen K. Graham, PharmD, is a HIV Clinical Research Pharmacist with the Children's Diagnostic & Treatment Center and a Clinical Associate Professor of Pharmacy Practice with Nova Southeastern University in Ft. Lauderdale, Florida.

Dr. Graham is currently with the Children's Diagnostic & Treatment Center in Ft. Lauderdale, Florida. The center cares for approximately 1200 underserved HIV-infected children and adolescents, as well as their adult care-givers and other family members through a Ryan White Comprehensive Family AIDS program grant. The center is also NIH-funded through the International Maternal, Pediatric, and Adolescent AIDS Clinical Trials (IMPAACT) network and the Adolescent Trials Network (ATN). Dr. Graham serves as the research pharmacist of record, provides medication adherence education to the children, adolescents and adults, and continues to precept two advanced pharmacy students per month.

All patients are referred to the Pharmacist-based adherence program when they are starting or changing an antiretroviral regimen. She meets with each person to discuss, identify, and help overcome barriers to adherence. Next, general counseling and education is provided regarding HIV, goals of therapy, and the options and benefits of antiretroviral therapy. With antiretroviral experienced patients, Dr. Graham reviews the resistance test information and together with the patient and provider, constructs an optimal regimen for viral suppression. Dr. Graham also performs a complete pharmacotherapeutic evaluation on all patients for drug interactions, weight-based and renal dosing (which is especially challenging in her pediatric and geriatric populations), side effect monitoring, the need to add/delete prophylaxis for opportunistic infection, and the management of concomitant disease states.

Adherence is a challenge at any age, but pediatric and adolescent populations bring some unique challenges, and Dr. Graham works to provide individualized adherence strategies for all of her patients, regardless of age. A typical clinical appointment lasts 30–60 min. Dr. Graham allows plenty of time for discussion and for patients to ask questions. She then orders follow-up lab test to track outcomes for both efficacy and toxicity. Patients are followed by Dr. Graham until they reach viral suppression successfully as well as their goals for

concomitant disease states. At that point Dr. Graham gives them the option of signing-off of medication counseling and continuing with their provider, or to continue follow-up visits every 3 months with Dr. Graham and their provider. Dr. Graham's practice demonstrates how the HIV Clinical pharmacist plays an important role in patient care by working together with patients and providers to assure optimal pharmacotherapy, adherence, and successful outcomes.

Jean C. Lee, PharmD, BCPS, AAHIVE, is a Clinical Pharmacist in HIV Medicine & Clinical Research Coordinator with Saint Mary's Health Care, Grand Rapids, MI, and an Adjunct Assistant Professor of Clinical Pharmacy at Ferris State University, Big Rapids, MI, USA.

The Special Immunology Services is the second largest HIV clinic in Michigan, treating over 700 patients. It receives a federal grant from the Ryan White Care Act HIV/AIDS Program to provide both medical care as well as case management services. Other specialties within the clinic include a dermatologist and a dietitian. There is an outpatient pharmacy located within the same building where the majority of patients receive their antiretrovirals.

The clinical pharmacist position originated in 1997, due to a request from an infectious disease physician, who found the multiple drug interactions with antiretrovirals unmanageable. It has now grown to a practice where all patients initiating or switching antiretrovirals are to be seen by the clinical pharmacist. Patients are scheduled in a 60-min block of time to receive education about their new antiretrovirals. A typical session includes basic terminology, HIV life cycle, how antiretrovirals aid in suppressing HIV, regimen characteristics (dose, frequency, etc.), and storage of medications. Potential side effects and their management, the importance of adherence, how it affects the development of resistance and the impact of drug interactions are also discussed. A brief discussion of safe sex practices to prevent the spread or acquisition of resistant virus is also conducted. The clinical pharmacist is also responsible for initial side effect management, interpretation of resistance testing providing HAART options and provision of drug information to the clinical staff.

Dr. Lee also serves as a preceptor for a PGY-1 Pharmacy residents and PharmD candidates for a one month rotation in HIV Medicine. Her position is now divided 75% with service in the clinic and 25% as a consultant with service to the state government (Michigan Department of Community Health, HIV Continuum of Care Division). This consultant position includes working with the Michigan AIDS Drug Assistance Program (ADAP) and in training case managers throughout the state in enhancing their knowledge and skills with aiding their clients with medication adherence. Dr. Lee also serves on the Michigan HIV/AIDS Council, which aids in the direction of the state government's efforts in care and prevention services for a patient living with HIV/AIDS.

As the clinical research coordinator, Dr. Lee has received training through Barnett International on conducting clinical research mainly with industry-sponsored studies. Her experience is with investigator-initiated, as well as industry sponsored, Phase III, Phase IV, and Expanded Access research programs.

Jim Scott, PharmD, MEd, AAHIVE, is an Associate Professor of Pharmacy Practice and Administration at Western University of Health Sciences in Pomona, CA and the Clinical Research Scientist at the Jeffrey Goodman Clinic, Los Angeles, CA.

Dr. Scott is currently a tenured Associate Professor at his institution. His time is split (approximately equally) between university and clinic responsibilities. His classroom activities are split amongst several infectious diseases-related topics, and a case-based curricular review course. He is allotted 24–30 h in the curriculum to teach HIV-related concepts. Lectures are divided into 6 topics: pathophysiology, pharmacology, treatment, adherence, resistance, and psychological issues in HIV. Additionally, there is ample time for students to work on HIV-related cases to reinforce the content, and assist them in applying the information in clinical scenarios. Lastly, 2–3 patients with HIV are brought into the classroom to discuss how they became infected and how they have dealt with their HIV infection.

The clinic setting where Dr. Scott practices is supported by both public and private funds, and serves mostly low income men who have had sex with men (MSM). The clinic cares for approximately 2100 patients, all of whom have HIV. An affiliated pharmacy is located in the same building and is staffed by three full-time pharmacists, and a team of technicians, clerks, and students. His team typically includes a specialty pharmacy resident (a one-year post-doctoral training program for pharmacists interested in specializing in HIV treatment), and two advanced pharmacy students (who are in the clinical training portion of their PharmD program). The clinical interventions provided include general counseling and education regarding HIV and antiretrovirals, acting as liaison between the patient and medical provider to select the optional antiretroviral regimen (for patients starting treatment for the first time, for patients with advanced disease, and anywhere between these two), assess adherence issues and assist in overcoming these issues, counsel patients who are co-infected with HIV and Hepatitis C and are preparing to start treatment for the hepatitis, and provide information on a variety of clinically oriented questions that patients present with. Drug information services are provided by the clinical pharmacy team for the medical providers. Dr. Scott is also active in research, and has been involved in numerous studies (including retrospective reviews, prospective clinical trials, and pharmacokinetic studies) as an investigator, primary site investigator, and Principal Investigator.

A typical clinical appointment lasts 30–60 min and involves an assessment of the chief or current complaint, an assessment of known or potential barriers to adherence, and (typically) a discussion of safe sex practices.

In summary, clinical pharmacists have been involved with the care of people infected with HIV since the disease first became known. While there are many HIV specialty clinical pharmacists in the US, there is mostly qualitative data in the published literature. There are several potential reasons for this occurrence. One is that not all clinical pharmacists are trained to objectively analyze the clinical work that they perform. Another potential reason is that clinical pharmacists feel they are too busy to study and write about the work that they do. Lastly, there are many possible confounders, making quantitative data hard to interpret. While a pharmacist may spend several hours over multiple counseling sessions with a patient who is addicted to illicit drugs, the impact of that pharmacist will be dampened by

the patient's drug use. Whatever the reason, more clinical pharmacists need to assess the important work that they do and publish more quantitative data on the impact of their work, in addition to profiling their activities.

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