

Engaging Community Pharmacists in HIV Adherence through MTM Re-Imbursement:

An AETC Research Initiative on Improving Adherence Outcomes in New Jersey

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Session Learning Objectives

At the end of this 90-minute session, participants will:

- Understand the rationale for including community pharmacists among the targeted clinical groups eligible for HIV medication adherence intervention training by the AETC and MTM compensation by medication insurers
- Assess regional strengths and barriers within existing AETC pharmacy training programs in other regions for building HIV medication adherence counseling competencies
- Know how to engage regional AETCs to take the lead role in the development of multi-state, cross-discipline collaborative training projects aimed at addressing and/or resolving barriers to HIV patient care

Overview

- **Project Background**
- **Study Description**
- **AETC Training Curriculum**
- **Lessons Learned and Recommendations**

Medication Therapy Management

- Consensus Definition of MTM (4/27/05):
A broad range of services (activities and responsibilities) within a pharmacist's scope of practice that are provided to patients to optimize therapeutic outcomes
- MTM services:
 - are distinct from medication dispensing and applicable to all patients in need of pharmacist-level interventions to improve care
 - are patient-centered so as to empower patients to successfully self-manage their medications
 - require collaborative engagement of other health care providers to facilitate continuity of care

Key MTM Model Concepts

- **Core Elements**
 - Medication Therapy Review (MTR)
 - Annual and Targeted
 - Personal Medication Record (PMR)
 - Medication Action Plan (MAP)
 - Intervention and/or referral
 - Documentation and follow-up

Keys to Successful MTM Delivery

- Pharmacists given dedicated time during workday to provide MTM services
- Pharmacists allowed to bill for MTM service delivery
- Significant outreach to educate patients and physicians about the value of MTM services
- Risk stratification models used to identify patients who might benefit most from MTM services
- MTM services are documented in a consistent and efficient format useful for reimbursement
- Outcome measures designed to analyze MTM service impact by both health and cost factors

“Staying on Track”

- Adherence counseling study funded by Abbott Laboratories via the Health Federation of Philadelphia (HFP), a local performance site of the PA/Mid-Atlantic AETC.
- Initially designed to examine the impact of nurses and social workers serving as adherence counselors
- Poor results led investigators to engage a different intervention population.
- ID Pharmacist serving as AETC faculty identified PharmD residents from her hospital-based HIV clinic as good match for providing study interventions.
- Study results were far more successful when outcomes relied on provision of adherence counseling by pharmacists

NY/NJ AETC HIV Pharmacy Preceptorship

- Clinic-based Preceptorship
 - Designed and implemented by UMDNJ, a local performance site of the NY/NJ AETC, with curriculum co-written by Rutgers faculty pharmacists and ID physicians
 - Pharmacists observe how the participation of an infectious disease pharmacist within a hospital-based HIV clinic care team can impact HIV+ patient health
 - Sites include: Jersey Shore University Medical Center (Neptune, NJ), St. Michael's Medical Center (Newark, NJ) & Hackensack University Medical Center (Hackensack, NJ)
 - Since 2002, 58 community pharmacists have received this training

NY/NJ AETC HIV Pharmacy Preceptorship

- Community Pharmacy-based Preceptorship
 - Designed and implemented by UMDNJ with curriculum written collaboratively by Rutgers faculty pharmacists and community practice (retail) pharmacists
 - Pharmacists observe the delivery of community practice-based medication adherence counseling of HIV+ customers and discuss methods for overcoming potential barriers to collaborative practice with clinic providers
 - Sites include: Newport Pharmacy (Jersey City, NJ), Bell Pharmacy (Edison, NJ), Giannotto's Pharmacy (Newark, NJ) & Woodruff Drugs (Bridgeton, NJ)
 - Since 2004, 44 community pharmacists have received this training

NY/NJ AETC HIV Pharmacy Preceptorship

- Family-Centered HIV Pharmacy Preceptorship
 - Designed and implemented by UMDNJ with curriculum written collaboratively by a Rutgers faculty pharmacist, a community practice pharmacist & a pediatric ID physician
 - Pharmacists observe the delivery of family-centered HIV care within a Part-D funded clinic and discuss HIV medication use during pregnancy/L&D and with pediatric patients, family-focused adherence counseling strategies, and the use of compounding for pediatric formulations
 - Single site at the Robert Wood Johnson AIDS Program at UMDNJ-RWJ Medical School (New Brunswick, NJ)
 - Since May of 2008, 2 community pharmacists have received this training

HIV Pharmacy Preceptorship Evaluation

- RPh participant responses indicate:
 - desire to adopt med counseling as standard HIV practice
 - barriers to RPh clinical behavior change include:
 - time, logistical and financial constraints
 - discomfort in providing HIV pts medication counseling
- Barrier analysis from two pharmacist focus groups conducted by NY/NJ AETC in 2007:
 - Most RPhs lack enough education/training to provide effective HIV medication counseling to customers
 - Most RPhs do not receive financial compensation from third-party payers for time spent delivering MTM to HIV+ customers instead of dispensing pills

Project Background

- Addressing barriers:
 - UMDNJ approached several New Jersey pharmacists to discuss whether it was possible to compensate pharmacists for providing retail-based adherence counseling interventions
 - RPh from Abbott Laboratories suggested linkage with HFC and Philadelphia-area pharmacists to explore possibilities of tapping Ryan White CARE Act funds
 - Working group of AETC players, Pharmacy School faculty, retail RPhs and Abbott Laboratories players charged with examining existing MTM programs and research projects on HIV pharmacist interventions

Kaiser Data

(Horberg, et al. *J. Acquired Immune Deficiency Syndrome*. 2007)

OBJECTIVE

- To determine the association of clinical pharmacists with health outcomes and utilization measures among HIV-infected patients

METHODS

- Observational study of 1571 HIV-infected patients prescribed their initial highly active antiretroviral therapy (HAART)
 - 733 at sites with an HIV-trained pharmacist
 - 838 at sites without an HIV-trained pharmacist
- Outcomes analyzed included
 - Changes in plasma HIV RNA level, CD4 T-cell counts, service utilization (hospital days, emergency department visits, and office visits) over 24 months

Kaiser Data

(Horberg, et al. *J. Acquired Immune Deficiency Syndrome*. 2007)

RESULTS

- Patients exposed to a clinical pharmacist were more likely to achieve an HIV RNA level <500 copies/mL at 12 mo.
- At 24 mo., however, results depended on the provider panel size, where large HIV practices (>50 pts) were less impacted by clinical pharmacist presence than small HIV practices (≤ 50 pts)
- CD4 T-cell counts were modestly but non-significantly higher for the patients exposed to a clinical pharmacist

CONCLUSIONS

- Positive association between exposure to clinical pharmacist and plasma HIV RNA control
- Decline in office visits at 12 months

Kaiser Data: Limitations

- Retrospective study that did not document whether patients actually saw a pharmacist (i.e. received MTM services) – just whether a pharmacist was available to be seen at site
- Did not analyze impact of MTM to health care costs
- Did not examine whether community pharmacists could also play a role in improving health outcomes through delivery of MTM services

Project Initiation

- NJ Department of Health and Senior Services-
Division of HIV/AIDS Services (NJDHSS-DHAS):
 - Progressive state entity with interests in quality management projects and clinician training
 - Effective manager of ADAP funds (expansive yet cost-containing formulary)
 - Good working relationship with NJ Medicaid
- Working Group Goal:
 - Convince NJDHSS-DHAS to fund innovative study to examine whether training and compensating retail RPhs for MTM improves adherence and health outcomes and provides a cost-saving benefit to NJ's HIV care system

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Project Description

- In NJ, AIDS Drug Assistance Program (ADAP) subscribers ordinarily use one pharmacy for prescription fills
- Participant pharmacy selection is based upon usage patterns of ADAP patients from 7 HIV clinics currently engaged in Quality Management projects currently being funded by the NJDHSS-DHAS and the Newark EMA
- The project was designed with four overlapping phases:
 - Enrollment
 - Training
 - Intervention
 - Evaluation
- During Intervention Phase, pharmacies will be reimbursed for providing adherence counseling to study patients at a rate of \$1.20 per minute, an innovative incentive that no pharmacy adherence projects have previously examined

Patient Exclusion Criteria

- Self-report of active illicit drug use or intake of more than three alcoholic beverages/day
 - It would be desirable to exclude active drug users or alcoholics, since there is much evidence-based research suggesting that active drug/alcohol abuse decreases medication compliance among HIV patients
 - Methadone or other legal drug treatment process would NOT be used as an exclusion criterion
- Patients receiving investigational medications (including Expanded Access Program medications)
- Patients using more than one pharmacy (including mail-order) for their OTC and prescription medications
 - Potential study participants would be asked to sign a non-binding agreement to get Rx and OTCs filled only at the study pharmacy for the duration of the study. Those refusing would be excluded.
- Patients currently enrolled in another adherence counseling program and/or study

Data Collection

- Data will be collected using standard forms across all sites and later entered into a database to facilitate analysis
 - Data will be entered directly into a secure web-based database during the intervention with the patient; this web-based tool is being funded, in part, by a data management SPNS grant project currently being administered by the City of Paterson for RW-funded agencies within the Bergen-Passaic TGA
 - Outcomes data will be evaluated based on whether or not the patient received the intervention or not, statistics analysis, etc

Potential Outcomes

- Changes in expenditures related to in patient hospital care for patients
- Changes in adherence through self-report and pharmacy records
- Changes in antiretroviral regimens and potential cost savings associated with reducing the amount of unused medications
- Reduction in resistance test ordering
- Reduction in prescribing of medication for OIs

Potential Outcomes

- Rates of medication dispensing errors
- Rates of prescribing interacting drugs
- Changes in viral loads, including the percentage of patients with undetectable viral loads
- Changes in CD4 counts
- Evaluate characteristics of successful pharmacies/pharmacists involved in the project from both the control and the intervention group

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AETC Curriculum

- 40 hours of intense HIV training is being provided free through the NY/NJ AIDS Education and Training Center (AETC) and the PA/Mid-Atlantic AETC
 - Didactic lectures
 - Internet-based and print self-study activities
 - Case discussion
 - Clinical preceptorships
 - Pre and Post Examinations
 - Trainings are ACPE accredited via UMDNJ

Curriculum – Part 1

■ Self-Study: Enduring Material

- Level I training (didactic learning modality)
- 3 hours of CE content
 - Print Monograph developed by Albany Medical Center entitled "HIV and the Role of the Pharmacist"
- Monograph hand-outs will be given to participants upon enrollment in the project with a completion date set a few days prior to the first live training session

Curriculum – Part 2

■ Live Session: Group Program

- Level I Training (Didactic learning modalities)
- 7 hours of CE content
- Topics to Include:
 - HIV Overview
 - Epidemiology in NJ
 - HIV Parthenogenesis
 - Understanding Resistance and Adherence
 - Pharmacology
 - Lab values
 - HIV Medications
 - Drug classes, profiles, doses and side effects
 - Tx guidelines and acceptable combination therapies

Curriculum – Part 2

- Co-morbidities and Opportunistic Infections
 - medications commonly used
 - medication profiles, doses and side effects
- Drug interactions
 - Prescription ARV medications
 - Prescription non-ARV medications
 - OTC products
- Side Effects Management
 - Etiology
 - Prescription medications
 - OTC products
- Introduction to the HIV Patient
 - Cultural Competency
 - Patient Counseling Strategies through MTM

Curriculum – Part 3

■ Self-Study: Enduring Materials

- Level I Training: didactic learning modality
- 2 hours of CE content accessible through the UMDNJ-CCOE HIV clinical training website
 - Web-based article on HIV medication use during pregnancy, labor and delivery from *NJ AIDSLine* CE magazine (1 hr)
 - Web-based article on addiction, HIV and identification of drug-seeking customers from *NJ AIDSLine* CE magazine (1 hr)
- Participants will be asked to complete both web activities before attending next group session

Curriculum – Part 4

■ Live Program: HIV Pharmacy Preceptorships

- Level III Training (Patient Observation Programs)
- 17 hours of CE content in total, provided as three separate and individually arranged trainings
- HIV Clinical Pharmacy Preceptorship (6 hrs)
 - Focus is on role of pharmacist within an interdisciplinary HIV care team at an out-patient clinic
 - Sites will be at HIV clinics in Hackensack, Newark, Neptune and Philadelphia
 - Learning focus is on patient observation in the clinic from ARV medications selection process to the physical conditions related to a patient's HIV disease progression

Curriculum – Part 4

■ HIV Community Pharmacy Preceptorship (5 hrs)

- Focus is on role of the community practice (retail) pharmacist in providing MTM with HIV patients to improve patient adherence to ARV and in managing side effects and reducing drug errors
- Sites will be at independent pharmacy stores located in Jersey City, Newark, Edison and Bridgeton
- Learning focus is on the observation of MTM being provided to HIV+ patients within a community pharmacy store setting and addresses adherence counseling strategies, avoidance of drug errors and side effects management using OTC products and/or prescription products

Curriculum – Part 4

- **HIV Family-Centered Pharmacy Preceptorship (6 hrs)**
 - Focus is on the role of the pharmacist in managing the administration of correctly formulated and dosed HIV-related medications to pregnant women, children and adolescents utilizing family-centered approaches to clinical care
 - One site, located in New Brunswick at UMDNJ-Robert Wood Johnson AIDS Program
 - Learning focus is on pharmacological and adherence considerations of perinatal and pediatric patients through patient observation at a Part-D funded HIV clinic and through observation and review of compounding techniques for pediatric med formulations

Curriculum – Part 5

- **Live Program: Group Program**
 - Level IV training (MTM Case Discussion)
 - 4 hours of CE content
 - Participants are required to write up a difficult MTM case from their practice to present to the group for discussion
 - Each participant will have up to 30 minutes to present their case to the group and lead a case discussion, with assistance from the AETC faculty trainer, if needed

Curriculum – Part 6

- **Live Session: Group Program**
 - Level II training (skills building exercises)
 - 7 hours of CE content: MTM Counseling in Practice
 - Each participant will have 45 minutes to conduct an initial MTM assessment on a standardized patient in front of the group and develop an adherence care plan. Each participant will then receive 15 minutes of feedback from both the group and the interviewed patient, as moderated by the faculty trainer

Additional AETC Training

- Individual Clinical Consultation (Level IV) opportunities with AETC faculty will be provided to study participants, via phone or e-mail, on an as-needed basis throughout the Project Implementation period
- At least once during the Project period, a case discussion training (Level IV) will be held so the study participants can discuss, as a group, any difficult cases from within their enrolled patient cohort
- Additional reading materials may be provided to study participants throughout the Project period, as determined by AETC faculty

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What Would This Study Add to Kaiser Data?

- Utilizes a prospective data set
 - Kaiser was retrospective and observational
- MTM interventions controlled across sites via 35-hr required AETC training curriculum
- May provide expanded demographic analysis
 - Over 50% of Kaiser pts were white males
- Documenting of adherence via pharmacy refills
- Examine costs of MTM vs. medication waste, clinic visit frequency, hospitalizations and other health cost variables

What Would This Study Add?

- Patients in Kaiser study may not have actually visited with the pharmacist
 - Our study proposal would do this systematically
 - Patients would be randomized to getting the intervention or not getting the intervention
 - Education would be consistent across sites, same program for each pharmacist to hopefully control differences in pharmacist education
 - Our study would examine impact of outpatient pharmacies (i.e. retail settings) for addressing adherence and patient health outcomes

Lessons Learned:

- Lack of training and compensation for MTM are barriers to implementing adherence interventions in retail pharmacies.
- AETCs are well equipped to assist community RPhs in acquiring the skills needed for providing effective MTM adherence interventions in retail settings
- Regional Partnerships essential for engaging ADAP and Medicaid in MTM compensation dialogues

Recommendations:

- If the project shows a benefit:
 - Extend existing study to 18-24 months to determine if impacts continue over time
 - Expand the program within New Jersey to set up second pilot that would examine whether similar impacts occur with other insurance subscribers lacking a “lock-in” option (e.g. Medicaid subscribers)
 - Engage with ADAP systems in NY and PA to assess their interest in piloting initial project in their respective states

Recommendations:

- To assess strengths of pharmacy practice and pharmacy training system in your region:
 - Engage local AETC to explore how pharmacy services are delivered to HIV patients within your region and how training is offered to pharmacists
 - What is the role of independent, chain and mail order pharmacies in your area?
 - Are ID pharmacists employed at HIV medical sites?
 - Are pharmacies co-located at medical sites or off-site?
 - Are pharmacists routinely targeted for AETC trainings?
 - How are trainings being offered (level, freq, etc.)?
 - Is the AETC open to developing new trainings or changing pharmacy training plans?

Recommendations:

- To assess strengths of pharmacy practice and pharmacy training system in your region:
 - Hold focus groups with consumers to discuss their perceptions of pharmacy delivery and pharmacist knowledge within your region
 - Contact local Pharmacy School(s) to determine if ID Pharmacist Faculty provide co-management services in HIV clinics as a clinical rotation site for PharmD students; if so, they may be suitable for building a Clinic-based or Part-D based Pharmacy Preceptorship site with local AETC

Recommendations:

- To assess strengths of pharmacy practice and pharmacy training system in your region:
 - Ask large HIV medical provider practices which community pharmacies routinely work with them to provide above standard pharmacy care to shared patients; contact those pharmacies about participating with local AETC program
 - Engage local Pharmacy Association to assess interest among community practice pharmacists for strengthening HIV care services at stores

Recommendations:

- Tips for building a dedicated Pharmacy Training program within the AETC:
 - AETC National Resource Center is developing a pharmacy-specific program coordinators handbook to assist coordinators in strengthening pharmacist trainings which will be available on the NRC website fall, 2008: www.aids-ed.org
 - Assemble focus group of AETC faculty, Pharmacy School faculty and community practice pharmacists to discuss assessment outcomes and develop comprehensive regional plan for enhancing local HIV pharmacy practice

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