Curricular Track II—Pearls from Innovative Practice Models
Activity No. 0217-0000-11-106-L04-P (Knowledge-Based Activity)

Wednesday, October 19
10:15 a.m.–11:45 a.m.
Convention Center: Rooms 302 & 303

This session is available for elective credit for the ACCP Career Advancement Certificate Program. For more information, visit the ACCP Web site at www.accp.com/academy.

Moderator: Alissa Segal, Pharm.D.
Associate Professor of Pharmacy Practice Massachusetts College of Pharmacy & Health Sciences and Joslin Diabetes Center, Boston, Massachusetts

Agenda

10:15 a.m. Pearls from Innovative Practice Models: Pharmacy Practice in an Obstetric Care Clinic
Denise D. Ragland, Pharm.D., CDE
Associate Professor of Pharmacy Practice, College of Pharmacy
University of Arkansas for Medical Sciences, Little Rock, Arkansas

10:35 a.m. Pearls from Innovative Practice Models: Pharmacist-Managed Latent Tuberculosis Infection Clinic
Julie P. Last, Pharm.D.
Clinical Pharmacist and Ambulatory Clinic Coordinator, Hospital of Saint Raphael, New Haven, Connecticut

10:55 a.m. Pearls from Innovative Practice Models: Local and National Programs Integrating Comprehensive Pharmacy Services into Medical Homes
Steven W. Chen, Pharm.D., FASHP
Associate Professor, Department of Clinical Pharmacy & Pharmaceutical Economics and Policy; Hygeia Centennial Chair in Clinical Pharmacy; Director, Pharmacy Practice Residency in Primary Care; Distinguished Faculty Fellow, Center for Excellence in Teaching University of Southern California; Co-Chair Emeritus, HRSA Patient Safety & Clinical Pharmacy Services Collaborative; University of Southern California, Los Angeles, California

11:15 a.m. Panel Discussion
Steven W. Chen, Pharm.D., FASHP
Julie P. Last, Pharm.D.
Denise D. Ragland, Pharm.D., CDE
Faculty Conflict of Interest Disclosures

Steven W. Chen: no conflicts to disclose.
Julie P. Last: no conflicts to disclose.
Denise D. Ragland: no conflicts to disclose.

Learning Objectives

1. Recognize potential practice sites or patient populations in need of pharmacy services.
2. Identify common challenges that threaten the development of an innovative practice, including health care reform.
3. Identify key steps in building a successful and innovative practice.

Self-Assessment Questions

Self-assessment questions are available online at www.accp.com/am
Pearls from Innovative Practice Models

Pharmacy Practice in an Obstetric Care Clinic

October 19, 2011

Denise D. Ragland, Pharm.D., CDE

Associate Professor of Pharmacy Practice, College of Pharmacy University of Arkansas for Medical Sciences, Little Rock, Arkansas
Conflicts of Interest

- No conflicts to disclose.
Objectives

1. Recognize potential practice sites or patient populations in need of pharmacy services.
2. Identify common challenges that threaten the development of an innovative practice.
3. Identify key steps in building a successful and innovative practice.
That which is newly introduced: a change
Hired to work with Palliative Care Team
Campus-wide meeting announced

UAMS to apply for Women’s Health Center of Excellence
UWC receives state-wide referrals

Overcrowded
Understaffed
“Why do we need a pharmacist if the clinic doesn’t have a pharmacy?”
Why?

- Drug in pregnancy info
- Drug in lactation info
- Medication histories
- New Rx counseling
- Depression screening
- Immunizations
- Contraception counseling
- Telemed consults
- Medication assistance

- Diabetes education
  - Causes of GDM
  - Medical nutrition therapy
  - Glucometer training
  - Injection teaching
  - BG log review
  - Hypoglycemia instruction
  - Insulin dosing
  - Postpartum evaluation
  - Access to DM supplies
Diabetes education cannot be done in five minutes or less

Observation leads to opportunities
Observation

- UWC nurses trained needle-phobic patients by “sticking” pillows

Opportunity

- Pharmacist, CDE has time to provide proper training
- Student pharmacists have opportunities to practice skills
Observation

- Overwhelmed patients are noncompliant with diabetes self-management

Opportunity

- Screenings to rule out depression
What percent of women will experience a depressive disorder while pregnant?

A. 1-4%
B. 5-8%
C. 9-13%
D. 14-23%

Obstetrics & Gynecology 2009, 14(3):703-713
Only 17% of patients with severe depression symptoms received tx

- 200 pts surveyed with Beck-Depression Inventory-II
  - 100 w/ diabetes: 19 T1DM, 41 T2DM, 40 GDM
  - 100 without diabetes
- Pts were referred for mental health consults
- Research opportunity for students
Evaluate
Collaborate
Disseminate
Prevalence of comorbid depression in women with diabetes during pregnancy
  5th International Symposium of Diabetes in Pregnancy

Depression and diabetes: establishing the pharmacist’s role in detecting comorbidity in pregnant women

Presence of depression symptoms in pregnant women with and without diabetes
  J Reprod Health. Currently in review
Why do contraception counseling in an OB clinic?
What percent of U.S. pregnancies were reported as unintended in 2001?

A. 23%
B. 34%
C. 49%
D. 86%

*Perspectives on Sexual & Reproductive Health* 2006, 38(2):90-92
Observation
- Overcrowded teen pregnancy clinic
- Few patients had received reproductive health education

Opportunity
- Contraception counseling by student pharmacists

Arkansas Times
Retrospective study at UWC
269 patients surveyed & counseled on contraception
86% unintended pregnancy rate
54.6% (n=147) unaware of EC
68% (n=100) willing to use or would consider using EC in the future

To assess impact of counseling on patient knowledge of EC

- 12 question survey pre- & post-test
- 10 min counseling session with flipchart

EC counseling: an opportunity for pharmacists.
J Am Pharm Assoc. Accepted Feb 2011
Results

Max score = 13

- Pre-test: 5.4
- Post-test: 10.7
- Follow-up: 10.3

1-5 months post
Which is true regarding levonorgestrel emergency contraception?

A. It is contraindicated in pts with h/o DVT.
B. It is not available without a prescription.
C. It works by disrupting an implanted ovum.
D. It may be effective taken 5 days after unprotected intercourse.

ACOG Position Statement No. 69, 2005
Fluzone® is a live influenza vaccine that should NOT be administered during pregnancy.

A. True
B. False
Observation

- 2005: Severe shortage of flu vaccine
- One-half of all vaccines ordered for UWC go unused

Opportunity

- 2006: AR Board of Pharmacy allows immunization-certified students to administer if directly supervised by preceptor
2007-2008
Number of vaccines administered at UWC triples!

- Protected patients
- Relieved nurses
- Empowered student pharmacists
Persistence pays off
What are the key steps in building an innovative practice?

- Observation leads to opportunity
- Innovate, collaborate, evaluate, disseminate
- Persistence pays off
On-going Projects

- Association of mid-trimester serum vitamin D level & depression during pregnancy and the puerperium
- Clinical usefulness and patient acceptance of continuous glucose monitoring in pregnancy
- Patterns of contraception use in women receiving prenatal care at an academic health care center
Obstetrical Opportunities: Will Pharmacy Ever Realize Them?


Currently in review
Pearls from Innovative Practice Models:
Latent Tuberculosis Infection Clinic

Julie P. Last, Pharm.D.
Hospital of Saint Raphael
New Haven, CT
October 19, 2011
Conflicts of Interest

- No conflicts to disclose
Hospital of Saint Raphael

- 511-bed community, teaching hospital, New Haven, CT
- Leader in Cardiac, Cancer, Stroke, and Joint Replacement Services
- Affiliated with University of Connecticut School of Pharmacy and Yale University School of Medicine
- Pharmacy Services 24/7, five pharmacy satellites, and computerized physician order entry (CPOE), profiled automated dispensing cabinets (ADC)
Learning Objectives

- Recognize potential sites or patient populations
- Identify key elements in creating a successful practice
- Identify common challenges in development of a new program
Definitions

Latent Tuberculosis Infection (LTBI) – An infection in which an individual has dormant Mycobacterium tuberculosis organisms but is asymptomatic.

Active tuberculosis disease – Progression from the latent TB infection to active TB disease caused by Mycobacterium tuberculosis overcoming the defenses of the immune system and beginning to multiply, causing the patient to experience signs and symptoms associated with tuberculosis.

Centers for Disease Control. 2005. The difference between latent TB infection and active disease. TB Elimination. Document # 250101
Epidemiology

**Worldwide** – Approximately 1.7 billion people worldwide are considered to be infected with *Mycobacterium tuberculosis*

- On average, 10% of LTBI patients progress to active disease
- Overall risk of developing active disease ranges from 5% to 15% annually
- HIV patients – lifetime risk is 50%
- Countries with low TB incidence – active disease comes mainly from reactivated LTBI

Ahmad, S. Pathogenesis, Immunology, and Diagnosis of Latent Mycobacterium tuberculosis Infection: Review Article. *Clinical and Developmental Immunology* 2011; 17 pages
Epidemiology

**United States** – National public health concern

- 14,871 cases reported nationwide in 2003
- Approximately 5.1 cases/100,000

**Prevalence is due to:**

- Increased immigration
- HIV epidemic
- Low socioeconomic status
- Insufficient public health infrastructure for the control of LTBI


Ioachimescu, O., Tomford, J.W. Tuberculosis. The Cleveland Clinic. [Online]. 2004; 1-15
Adherence

Risk of progression from latent infection to active disease

- Approximately 5 to 15% total LTBI patients are at risk of converting to active tuberculosis

- Non-adherence to LTBI therapy can reach up to 50%
  - Urban areas are on the high end of the spectrum

- Once active, patients become infectious

- Risk increases if LTBI therapy is not completed
  - Development of drug resistance
Adherence (cont.)

Demographic and epidemiologic factors for non-compliance

- Male gender
- Homelessness
- Alcohol abuse
- Residence in urban areas
- Low socioeconomic status
- Adverse drug reactions and drug interactions
- Asymptomatic nature of infection

Connecticut

- Requires all patients with a positive tuberculosis test to be reported to the Department of Public Health (DPH)
- Responsible for any patients lost to follow-up from tuberculosis clinics
- Concerned with controlling possible outbreaks by tracking patients diagnosed with LTBI
Potential patient population

Urban vs. suburban
- Different pharmacy services may be required based on setting
  - In-patient protocols vs. ambulatory programs
- Different incidence for various disease states
- Insured vs. uninsured
  - Reimbursement rate
    - State vs. private insurance
    - Private insurance reimbursement rate is generally higher than state or federal coverage
  - Different socioeconomic status
LTBI Clinic – Patient population

**Urban setting**
- Low socioeconomic status
- High immigration rate – third world countries
- Many non-English speaking patients

**Mostly Medicaid/Medicare patients**
- LTBI treatment covered by state TB program
  - Visit reimbursement
  - Free medication
  - State does not pay for liver function tests ---- have to charge patient’s insurance

**Some uninsured patients**
- Patients have to pay for labs out of pocket
Pharmacy Practice Setting

Retail vs. hospital vs. long-term care facilities
- Different settings have different requirements
- Different patient population
  - Age, comorbidities, concomitant medications

Similar practice setting in close proximity
- May provide analogous services
- May create competition
- May decrease reimbursement/revenue from your services
LTBI Clinic – Pharmacy Practice

Hospital setting
- Referrals from outpatient primary care clinics only
- Patients’ PCP is a medical resident overseen by an attending physicians

Another large hospital
- Yale-New Haven Hospital within 1 mile radius
- Offers many comparable services

Needed a form of service that would distinguish us
Key elements in creating a successful practice

1. Overview
2. Description of Pharmaceutical Services
3. Duties and Responsibilities
4. Return on Investment (ROI)
5. Summary
6. References
Key elements (cont.)

1. Overview:
   - Identify a sense of urgency for the project
   - Present data supporting the statement of urgency
   - Describe an example of your project from others’ experience
## LTBI Clinic – Overview

<table>
<thead>
<tr>
<th>Pre-Clinic Data - 2004</th>
<th>Pre-Clinic Data - 2005</th>
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</thead>
<tbody>
<tr>
<td>69 patients total</td>
<td>66 patients total</td>
</tr>
<tr>
<td>32 adults</td>
<td>27 adults</td>
</tr>
<tr>
<td>37 children</td>
<td>39 children</td>
</tr>
<tr>
<td>16 patients completed therapy</td>
<td>19 patients completed therapy</td>
</tr>
<tr>
<td>2 adults</td>
<td>5 adults</td>
</tr>
<tr>
<td>14 children</td>
<td>14 children</td>
</tr>
<tr>
<td>23% completion rate</td>
<td>28% completion rate</td>
</tr>
<tr>
<td>77% lost to follow-up</td>
<td>72% lost to follow-up</td>
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</tbody>
</table>
2. Description of Pharmaceutical Services:
   - Identify role of the pharmacist
   - Explain how the role of the pharmacist will improve pharmaceutical care
   - Determine scope of practice for the pharmacist
     - Protocol based
     - Collaborative practice
LTBI Clinic – Description of Pharmaceutical Services

**Pharmacist’s role**
- Pharmacist managed tuberculosis clinic has been shown to improve therapy completion rate (Tavitian, 2003).
- Educate patients on the importance of adherence, safety, and efficacy of the medication

**Scope of practice for the pharmacist**
- Physician-directed treatment Protocol
3. Duties and responsibilities:
   - Develop a job description
   - Develop competency based evaluation tool
   - Assess additional educational material
     - Certifications
     - Self-study modules
     - Patient education materials
LTBI Clinic – Duties and Responsibilities

1. Implementation of a computerized patient tracking system for those lost to follow-up

2. Patient education
   a. Pathology of LTBI
   b. LTBI treatment
   c. Importance of compliance

3. Monitoring for hepatotoxicity
   a. Liver function tests – AST and ALT
   b. Jaundice – yellowing of the skin and eyes
   c. Nausea/vomitting; abdominal pain; diarrhea
   d. Fatigue/Weakness
   e. Loss of appetite
LTBI – Duties and Responsibilities (cont.)

4. Refer patient to PCP if
   a. Liver function tests are abnormal
   b. Patient experiences adverse drug reactions
      i. Peripheral Neurotoxicity – tingling sensation
      ii. Hepatotoxicity

5. Process all required documentation
   a. Connecticut’s Department of Public Health TB form 32
   b. Document all appropriate information in medical chart

6. Establishment of proper reimbursement procedures
   a. Incident to physician billing
Key elements (cont.)

4. **Return on Investment Opportunity:**
   - **Costs**
     - The total spent for goods or services including money, time and labor.
   - **Revenue**
     - The entire amount of income before any deductions are made.
   - **Profit**
     - The excess of revenues over outlays in a given period of time (including depreciation and other non-cash expenses).
LTBI Clinic – Return on Investment

Costs – Total: $27,580

- Labor
  - Salary of the pharmacy staff (4 hours) – $16,640
  - Benefits – $4,160
  - Non-productive time – $2,496
- Space requirements
  - Office rental space and office equipment – None
- Miscellaneous
  - Laboratory tests – $4,284
LTBI Clinic – Return on Investment (cont.)

Revenue – Total: $44,321

- Visits
  - $39,780

- Miscellaneous – Reimbursement for any laboratory tests required for therapy monitoring
  - $4,541
LTBI Clinic – Return on Investment (cont.)

Net Profit: $16,741

- Revenue minus cost

- $44,321 - $27,580 = $16,741

- Pharmaceutical services – cost justified
## LTBI Clinic – Return on Investment (cont.)

<table>
<thead>
<tr>
<th>Costs</th>
<th>Hours/Week</th>
<th>Annual Expenses</th>
<th>Revenue</th>
<th>Visits/Year</th>
<th>Annual Revenue</th>
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</thead>
<tbody>
<tr>
<td><strong>Labor</strong></td>
<td>4</td>
<td><strong>Salary $16,640</strong></td>
<td><strong>Visits</strong></td>
<td>612</td>
<td><strong>$39,780</strong></td>
</tr>
<tr>
<td>Clinical Pharmacist, PharmD</td>
<td></td>
<td><strong>Benefits $4,160</strong></td>
<td>• 68 patients – 9 monthly visits</td>
<td></td>
<td></td>
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<tr>
<td>• 1 Pharmacist</td>
<td></td>
<td><strong>Non Prod. $2,496</strong></td>
<td>• $65/visit</td>
<td></td>
<td></td>
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<tr>
<td>• Tuesdays – 8am to 12pm</td>
<td></td>
<td><strong>Total $23,296</strong></td>
<td></td>
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<tr>
<td><strong>Non Labor</strong></td>
<td></td>
<td><strong>None $3,276</strong></td>
<td><strong>Liver Function Tests</strong></td>
<td>612</td>
<td><strong>$4,541</strong></td>
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<tr>
<td>Space Requirements</td>
<td></td>
<td><strong>Total $4,284</strong></td>
<td>• 68 patients – 9 visits</td>
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<tr>
<td>Liver Function Tests</td>
<td></td>
<td><strong>Total revenue $44,321</strong></td>
<td>• $7 for hospital to perform the test</td>
<td></td>
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<tr>
<td>Total Cost</td>
<td></td>
<td><strong>$27,580</strong></td>
<td><strong>Net Profit $16,741</strong></td>
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</table>
Key elements (cont.)

5. **Summary:**
   - Recap the overview
   - Reiterate the description of the pharmaceutical services
   - Review pharmacist’s responsibilities
   - Summarize cost justification requirements
LTBI Clinic - Summary

- Pre-Clinic data for two years (2004 and 2005):
  - Therapy completion rate – 26%
  - Loss to follow-up rate – 74%

- Clinic opened in October 2006
  - Has been open for 5 years

- After two years (October 2006 – October 2008):
  - Therapy completion rate – 74%
  - Loss to follow-up rate – 26%
Key elements (cont.)

6. References:
   - Essential for evidence-based medicine
   - Justifies statements that are made
   - Gives verifiable facts instead of an opinion
Limitations/Difficulties

Lack of Project Champion
- May be more difficult to sell to specialty areas,
  - such as Infectious Disease and HIV Clinics

Limited resources
- Are there other costs associated with services (i.e. rent)?

Prevalence of disease state
- Are there enough cases in the demographic area to support the services provided?

Non-adherence
- No patients, no services, no reimbursement
Limitations/Difficulties (cont.)

Potential lack of reimbursement

- No profit, no services
- Private insurance vs. state coverage
  - Different coverage
  - Not all ICD-9 codes reimbursed
    - Example: smocking cessation is not covered by the state of Connecticut
LTBI Clinic - Limitations

Lack of retrospective data
- Data from previous years is not very well documented
  - Discrepancies between hospital and state records
- Difficult to assess

Patients’ non-compliance
- Due to asymptomatic nature of infection and potential adverse reactions of the medication

Patients visit covered by state
- Do not bill patient’s insurance
- Does not cover lab costs
  - Private insurance
  - Patients out of pocket
Patient Protection and Affordable Care Act

- **Grant Programs**
  - Grant programs for collaborations between physician and pharmacists

- **Integrated Care Models**
  - Pharmacists involved in medical homes, accountable care organizations, communities, and home based programs

- **Transitional Care Activities**
  - Pharmacists involved in medication reconciliation, discharge planning when patient’s care gets transferred

- **Medicare Advantage Plan Incentive**
  - Pharmacist involved in care for chronically ill, high-cost patients
    - Polypharmacy in ambulatory setting
Conclusion

- **Patient population required for the new service**
  - Urban vs. suburban --- low income vs. moderate to high income
  - Is the practice setting appropriate for the program planned

- **Identify key elements**
  - What constituents are required for the new program
    - Sense of urgency, description of the services, duties and responsibilities, ROI, summary and references

- **Be cognizant of all possible challenges when creating a new practice model**
  - Any resistance from other health care professionals
  - Potential lack of reimbursement
References

References (cont.)


Questions?
Pearls from Innovative Practice Models:

Local and National Programs Integrating Comprehensive Pharmacy Services into Safety Net Medical Homes

Steven W. Chen Pharm.D., FASHP, FCSHP
Hygeia Centennial Chair in Clinical Pharmacy
Associate Professor, USC School of Pharmacy
Director, Pharmacy Practice Residency in Primary Care
Distinguished Faculty Fellow, Center for Excellence in Teaching
Co-Chair Emeritus, HRSA Patient Safety & Clinical Pharmacy Services Collaborative
chens@usc.edu (323) 442-1556
Intent of this session

To discuss local and national models of pharmacist-managed patient care for underserved populations
Questions to run on…

- How can you identify a potential safety net site and a population of focus in need of pharmacy services?
- What are the challenges / barriers to developing a pharmacy service in the safety net setting, and how does healthcare reform fit?
- What are key steps in building a successful pharmacy program in the safety net setting?
Outline

- What is the safety net?
- Key steps for developing a safety net pharmacy program
- Barriers, challenges, and healthcare reform
Safety Net Clinic

- "Those providers / entities that organize and deliver a significant level of health care and other health-related services to uninsured, Medicaid, and other vulnerable patients."

- Providers of healthcare regardless of ability to pay

- Rural safety net: 20% of Americans, 11% of physicians

- “If you’ve seen one safety net clinic, you’ve seen one safety net clinic.”
## Initial USC School of Pharmacy Safety Net Partners

<table>
<thead>
<tr>
<th>Demographic Characteristics</th>
<th>T.H.E. Clinic&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Weingart Medical Clinic&lt;sup&gt;b&lt;/sup&gt;</th>
<th>South Central Family Health Center&lt;sup&gt;c&lt;/sup&gt;</th>
<th>QueensCare Clinics&lt;sup&gt;d&lt;/sup&gt;</th>
<th>LA County&lt;sup&gt;e&lt;/sup&gt;</th>
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<td><strong>Education and Income:</strong></td>
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<td>&lt;12 years education (%)</td>
<td>56</td>
<td>70</td>
<td>25</td>
<td>23</td>
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<td>Median Family income</td>
<td>$21,038</td>
<td>$2,500</td>
<td>$23,554</td>
<td>$34,267</td>
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<td>Unemployment rate (%)</td>
<td>12</td>
<td>96</td>
<td>7</td>
<td>5</td>
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<tr>
<td>&lt;100% of Federal poverty level (%)</td>
<td>75</td>
<td>100</td>
<td>92</td>
<td>29</td>
<td>24</td>
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<tr>
<td>Receiving Public assistance (%)</td>
<td>25</td>
<td>100</td>
<td>18</td>
<td>na</td>
<td>7</td>
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</table>
Uninsured in the U.S.

- 49.9 million Americans
- Ethnic minorities (L,B, others), 41% < HS education
- Limited healthcare providers available
- Wide range of support staff competency
- Fragmented medication lists, greater risk for med safety problems
- Needs:
  - More healthcare professionals, subspecialties
  - Better disease management and prevention
  - Focus on medications (1\textsuperscript{st}-line for \textasciitilde90\% of chronic illnesses)

Covertheuninsured.org, RWJ Foundation; U.S. Census Bureau, Sept 2011
$1 of every $5 spent on healthcare goes to diabetes care.

**Comprehensive Diabetes Care**

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<td>2008</td>
<td>63.4</td>
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<tr>
<td>2007</td>
<td>32.1</td>
<td>31.7</td>
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<td>60.5</td>
<td>59.8</td>
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<tr>
<td>2008</td>
<td>65.6</td>
<td>59.5</td>
<td>56.9</td>
</tr>
<tr>
<td>2007</td>
<td>63.9</td>
<td>58.9</td>
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<tbody>
<tr>
<td>2009</td>
<td>47.0</td>
<td>50.0</td>
<td>33.5</td>
</tr>
<tr>
<td>2008</td>
<td>45.5</td>
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<tr>
<td>2007</td>
<td>43.8</td>
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<td>2006</td>
<td>43.0</td>
<td>46.9</td>
<td>30.6</td>
</tr>
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<td>2005</td>
<td>43.8</td>
<td>50.0</td>
<td>32.7</td>
</tr>
<tr>
<td>2004</td>
<td>40.2</td>
<td>47.6</td>
<td>30.6</td>
</tr>
</tbody>
</table>

2010 State of Healthcare Quality Report
Outline

- What is the safety net?
- Key steps for developing a safety net pharmacy program
6-Step Process for Establishing a Safety Net Pharmacy Program in Safety Net Clinics

1. Find a clinic, form your team
2. Identify services and population of focus
3. Develop a proposal & protocol
4. Establish key measures of success
5. Pilot service, collect measure day 1
6. Share results with stakeholders for sustainment and spread
1. Find a Clinic, Form a Team

- Potential clinic partners
  - Local primary care associations
  - Health profession schools
  - Consultants
  - HRSA Patient Safety & Clinical Pharmacy Services Collaborative

- Forming your team
  - Pharmacy expertise: Safety net laws / regulations, ambulatory care clinicians, grant / data managers, public health
  - Physician champion / advocate
2. Identify Services and Population of Focus

- Refine formulary (PAP, 340B)
- Pharmacy vs. Dispensary vs. Contract with retail pharmacy
- Provide disease state / medication therapy management (DSM, MTM) to high-risk patients
- Improve medication safety
- Align with clinic’s quality improvement efforts (Medical Home, Meaningful Use, etc.)
2. Identify Services and Population of Focus

- Patients with chronic illnesses known to be poorly managed according to national measures (e.g., NCQA SOHC, HRSA PSPC)
- Review available quality / utilization reports (e.g., registries, UR, P&T)
- What are perceived to be the most significant disease / medication-related problems?
- Take opportunity you’re given (e.g., refills, reconcile meds, anticoagulation)
3. Develop Proposal and Protocol

Differs from state to state; flow chart recommended

- **Physician / PA / NP appointment**

  Drug-related problem(s)¹ and/or poor chronic disease control?

  - Yes
  - **Schedule CPS appointment**
  - **PHYSICIAN / NP / PA**
  - **CLINICAL PHARMACIST**

  - **Pharmacist evaluation¹**, screen for drug-related problems

  - Drug-related problem(s)¹ identified?
    - Yes
    - **Modify drug therapy per approved protocols, follow-up²**
    - Drug-related problem(s) resolved?
      - Yes
      - **END**
      - No
      - **continue usual care**
    - No
  - No

  - **END**
4. Establish Key Measures of Success

- Establish measures immediately
- Align with national standards (National Quality Forum, NCQA, Medical Home, Meaningful Use, etc.) for relevance, benchmarking

**Quality of life survey**

- Treatment targets, appropriate selection of drugs, medication safety
- Satisfaction survey

**Resource utilization** (e.g., drug expenses, PharmD vs. PCP visits, hospitalizations, urgent care)

*The Joint Commission Journal on Quality Improvement* 1996;22(4)
Grants for Program Initiation or Expansion

http://www.foundationcenter.org/findfunders/

- HRSA: $140,000 grant (2003)
- Community Pharmacy Foundation: $50,000 (2004)
- QueensCare Foundation:
  - $300,000 for 3 years (2004)
  - $1,100,000 for 3 years (2006)
- UniHealth:
  - $405,000 for 3 years (2004)
  - $405,000 for 3 years (2005)
  - $350,000 (2010)
  - $300,000 (2011, in submission)
Practice-Based Research: Return on Investment

- **Medication cost savings** (1 FTE pharmacist serving 3 clinics)
  - ↑ PAP utilization + 340B purchasing
  - > $700,000 in annual medication costs saved
  - Access to critical medications previously thought to be unattainable

- **Extension of pharmacy services with the help of students**
  - Student assistance in dispensary → 10-20 additional hours of disease state management time

- **Physician time saved**
  - Access, complex patients, not needed to dispense meds, etc.
# Practice-Based Research

**Disease Management / Medication Therapy Management**

**Patient Visits, 10/04-9/08**

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient Referrals</strong></td>
<td>2,779</td>
</tr>
<tr>
<td><strong>Unique Patients Seen</strong></td>
<td>2,235</td>
</tr>
<tr>
<td><strong>Patient Visits</strong></td>
<td>15,904</td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td>13,267</td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td>9,452</td>
</tr>
<tr>
<td><strong>Dyslipidemia</strong></td>
<td>8,720</td>
</tr>
<tr>
<td><strong>Asthma</strong></td>
<td>975</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>1,403</td>
</tr>
</tbody>
</table>
Blood Pressure Management (n=242)

Majority of patients with DM (BP goal < 130/80)

Baseline

Baseline

Post-enrollment

-26 mmHg SBP

-12 mmHg DBP

6-Step Process for Developing Clinical Pharmacy Services in Safety Net Clinics
RESEARCH REPORTS

Diabetes

The Impact of Clinical Pharmacy Services Integrated into Medical Homes on Diabetes-Related Clinical Outcomes

Kathleen A Johnson, Steven Chen, I-Ning Cheng, Mimi Lou, Paul Gregerson, Carla Blieden, Mel Baron, and Jeffrey McCombs
Overall Impact of Pharmacist Intervention on Individuals with Diabetes (N=484)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Change in A1C Adj.R² = 0.4093</th>
<th>Likelihood of Achieving A1C &lt; 7</th>
<th>Likelihood of Achieving A1C &lt; 8</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Estimated Effect (% A1C)</td>
<td>p-Value</td>
<td>Estimate Effect (Odds Ratio)</td>
</tr>
<tr>
<td>Intercept</td>
<td>7.760</td>
<td>&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>Intervention group</td>
<td>-1.38</td>
<td>&lt;0.0001</td>
<td>4.037</td>
</tr>
<tr>
<td>Gender (male)</td>
<td>0.292</td>
<td>0.0770</td>
<td>0.586</td>
</tr>
<tr>
<td>Age (in years)</td>
<td>-0.025</td>
<td>0.0018</td>
<td>0.986</td>
</tr>
<tr>
<td>Insured (1=MediCal + other)</td>
<td>0.358</td>
<td>0.2719</td>
<td>-</td>
</tr>
<tr>
<td>Hispanic (1 = Black + other)</td>
<td>0.403</td>
<td>0.0717</td>
<td>0.819</td>
</tr>
<tr>
<td>Smoker (1=yes)</td>
<td>0.080</td>
<td>0.8783</td>
<td>1.622</td>
</tr>
<tr>
<td>Baseline A1C level</td>
<td>-0.721</td>
<td>&lt;0.0001</td>
<td>0.874</td>
</tr>
<tr>
<td>Days between first /last A1C test</td>
<td>-0.0002</td>
<td>0.5708</td>
<td>1.000</td>
</tr>
</tbody>
</table>
### USC Pharmacist Documentation Form

#### PATIENT INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
<th>Site</th>
<th>MRN</th>
<th>DOB</th>
<th>Gender</th>
<th>Insurance</th>
<th>Ethnicity &amp; Language</th>
<th>Point of Care</th>
<th>Initials</th>
<th>Entered in computer database</th>
</tr>
</thead>
<tbody>
<tr>
<td>/ /</td>
<td></td>
<td>/ /</td>
<td></td>
<td>M/F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### INTERVENTION: Each row is for an individual intervention (i.e., one MRP per row)

<table>
<thead>
<tr>
<th>Drug(s) involved</th>
<th>Indication</th>
<th>Intervention Codes (see table below):</th>
<th>Follow-up Visit Date (optional)</th>
<th>Resolved? (optional)</th>
<th>Description of event MUST complete for Severity II or III pADEs and all ADEs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>I**</td>
<td>II***</td>
<td>III***</td>
<td></td>
</tr>
</tbody>
</table>

1. A E | i | 101 | 108 | / / | Y | N | FTR |

2. A E | i | 101 | 108 | / / | Y | N | FTR |

3. A E | i | 101 | 108 | / / | Y | N | FTR |

#### I. MEDICATION-RELATED PROBLEM (MRP)
- Appropriateness and effectiveness
- Untreated medical problem
- Drug(s) dosing inadequate for treatment goals (dose, interval, duration)
- Treatment not optimal or not necessary based on evidence or guidelines
- Monitoring standards not being followed

#### II. pADE / ADE CLASSIFICATION:
- Potential Adverse Drug Event (pADE)
  - A. No med error / event, but potential for pADE identified
  - B. Med error / event did NOT reach patient
  - C. Med error / event reached patient, but no harm
  - D. Med error / event reached patient, monitoring or intervention required to confirm no harm

#### III. ADE SEVERITY RATING:
- I. Potential for minimal harm (would require patient self-management) or no harm
- II. Potential for moderate harm (would require healthcare professional intervention or hospitalization to resolve)
- III. Potential for severe harm (permanent disability or death)

#### IV. ACTION / INTERVENTION:
- 101. DC drug(s)
- 102. Substitute drug(s)
- 103. Add drug(s)
- 104. Change dose / dose interval
- 105. Change schedule to PRN
- 108. Order lab / dx / test
- 109. Educate patient
- 110. Refer to other service
- 111. Clarify Rx
- 112. Substitute dosage form
- 113. Make appt w / provider
- 114. Provide Rx compliance box
- 115. Other

*Select 1 code if possible, 2 max.  
**Circle 1 only  
***Circle all that apply

Adapted From:  
1. From Patient-Centered Primary Care Collaborative (http://www.ocpcc.org/files/medmanagempub.pdf);  
2. From NCCMERP (http://www.nccmerp.org/medErrorCptIndex.html);  

Steven Chen, PharmD, University of Southern California School of Pharmacy
# 27 Problem Categories

## 1. MEDICATION-RELATED PROBLEM (MRP)\(^1\)

### Appropriateness and Effectiveness
1. Untreated medical problem
2. Drug dosing not adequate for treatment goals (dose, interval, or duration)
3. Treatment not optimal or not necessary based on current evidence / guidelines
4. Monitoring standards not being followed

### Safety (pADE / ADE)
5. Drug dosing excessive for treatment goals (dose, interval, or duration)
6. Incomplete / improper directions
7. No indication for medication prescribed
8. Polypharmacy / duplication
9. Contraindication
10. Adverse drug reaction (ADR)
11. Allergy
12. Drug interaction
13. Lab/diagnostic test indicated, not ordered

## 14. Abnormal lab result not addressed
15. Pharmacy / dispensing error
16. Medication overuse or misuse
17. Dose discrepancy between patient use & prescribed therapy

### Nonadherence and Patient Variables
18. Medication underuse / poor adherence
19. Dosage form is not reasonable for patient
20. Inadequate patient self-management of lifestyle and other non-drug variables
21. Patient dissatisfied or refuses treatment, no rational reason given

### Miscellaneous
22. Drug not available in prescribed strength
23. Inadequate refills between scheduled visits
24. Nonformulary / not cost effective drug choice
25. Illegible prescription
26. No follow-up appointment with PCP
27. Other

---

**Adverse Drug Event (ADE)**
- E. Event occurred, resulting in temporary harm and requiring intervention
- F. Event occurred, resulting in temporary harm and requiring hospitalization
- G. Event occurred, resulting in permanent harm / disability
- H. Event occurred, life-threatening
- I. Event occurred, resulted in death

**Miscellaneous**
- 20. Patient dissatisfied, or refuses treatment, no rational reason given

---

*Adapted from: (1) From Patient-Centered Primary Care Collaborative (http://www.nccpc.org/patientcenteredprimarycare.pdf); (2) From NCCMERP (http://www.nccmerp.org/medErrClass/index.html); (3) From Medicare Nursing Home level of harm categories, http://www.medicare.gov/NIC/Compare/related/incomeexerofharm.asp?language=English&version=default*
II. ADE / pADE CLASSIFICATION

Potential Adverse Drug Event (pADE)
A. No med error / event, but potential for ADE identified
B. Med error/event DID NOT reach patient
C. Med error/event reached patient, but no harm
D. Med error/event reached patient, monitoring or intervention required to confirm no harm

Adverse Drug Event (ADE)
E. Event occurred, resulting in temporary harm and requiring intervention
F. Event occurred, resulting in temporary harm and requiring hospitalization
G. Event occurred, resulted in permanent harm / disability
H. Event occurred, life-threatening
I. Event occurred, resulted in death

---

*Select 1 code if possible. 2 max.  **Circle 1 only  ***Circle all that apply

Adapted From: (1) From Patient-Centered Primary Care Collaborative (http://www.pcpcc.net/files/medmanagem.pdf); (2) From NCCMERP (http://www.nccmerp.org/medErrorCatIndex.html); (3) From Medicare Nursing Home level of harm categories, http://www.medicare.gov/NHPCompareStates/related/in/drawlevelofharm.asp?language=english&state=CA
3 Severity Rating Categories for ADE/pADE

**III. pADE SEVERITY RATING**

i. Potential for minimal (would require patient self-management) or no harm

ii. Potential for moderate harm (would require healthcare professional intervention or hospitalization to resolve)

iii. Potential for severe harm (permanent disability or death)
15 Pharmacist Intervention Categories

IV. ACTION / INTERVENTION
101. DC drug(s)
102. Substitute drug(s)
103. Add drug(s)
104. Change dose/dose interval
105. Change duration of tx / qty
106. Change PRN to schedule
107. Change schedule to PRN
108. Order lab / dx'tic test
109. Educate patient
110. Refer to other service
111. Clarify Rx
112. Substitute dosage form
113. Make appt w/ provider
114. Provide Rx compliance box
115. Other
Problems identified by category
(N=2,085, 9.4 medication-related problems per patient)

- Quality of Care (1657) [80%]
- Medication Safety (301) [14%]
- Legal/Dispensing (4) [<1%]
- Cost (123) [6%]

CPS / MTM at local, state, and national levels
Most Common Quality of Care Problems (N = 1,657)

80% of Problems

- Drug therapy not adequate for treatment goals: 984 (60%)
- Poor Adherence: 253 (15%)
- New or Untreated Medical Problem: 213 (13%)
- Treatment not optimal based on the literature: 166 (10%)
- Other: 41 (3%)

6-Step Process for Developing Clinical Pharmacy Services in Safety Net Clinics
### Interventions Provided by Pharmacists

(N = 2,480, 11.1 per patient)

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Interventions (#)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change Dose or Drug Interval</td>
<td>765</td>
</tr>
<tr>
<td>Add New Medication</td>
<td>757</td>
</tr>
<tr>
<td>Provide Education</td>
<td>305</td>
</tr>
<tr>
<td>Substitute Medication</td>
<td>274</td>
</tr>
<tr>
<td>Discontinue Medication</td>
<td>245</td>
</tr>
<tr>
<td>Order lab or Diagnostic test</td>
<td>52</td>
</tr>
<tr>
<td>Provide Adherence Aid</td>
<td>51</td>
</tr>
<tr>
<td>Other</td>
<td>31</td>
</tr>
</tbody>
</table>

6-Step Process for Developing Clinical Pharmacy Services in Safety Net Clinics
5. Pilot service, collect measures day 1
   - Start small, pilot with a single physician if possible

6. Share results with stakeholders for sustainment and spread
   - Payers / Health plans
   - Administrators / Senior leaders
   - Medical team
   - Patients
   - Community (public, legislators)
USC School of Pharmacy Affiliated Safety Net Clinics (3 to 12 sites in 7 years)

Clinicas Del Camino Real

QueensCare

MCA “a family clinic”

JWCH Institute, Inc.

SCHFC

LACHC

CHOC Breathmobile
Teaching / Service Opportunities
SHARE Community Education / Service

Patient Education Classes
- Counseling
- Medication Reconciliation
- Translation
- Data Collection
- Immunizations

Health Fairs

6-Step Process for Developing Clinical Pharmacy Services in Safety Net Clinics
Examples of Patient Self-Management Tools

<table>
<thead>
<tr>
<th>Medication Name and Dose</th>
<th>Purpose</th>
<th>How to take it:</th>
<th>When to Take it</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochlorothiazide 25mg tablets</td>
<td>To lower your blood pressure</td>
<td>Take 1 tablet every day</td>
<td>1</td>
</tr>
<tr>
<td>Benazepril (Lozengin) 20mg tablets</td>
<td>To lower your blood pressure</td>
<td>Take 1 tablet every day</td>
<td>1</td>
</tr>
<tr>
<td>Lovastatin (Moxaon) 20mg tablets</td>
<td>To lower your cholesterol</td>
<td>Take 1 tablet every evening with dinner</td>
<td>1</td>
</tr>
<tr>
<td>Enteric-coated aspirin 81mg tablets</td>
<td>To decrease your chance of having a heart attack or stroke</td>
<td>Take 1 tablet every day with food</td>
<td>1</td>
</tr>
<tr>
<td>Advair 250/50 Diskus inhaler</td>
<td>To CONTROL your asthma</td>
<td>Take 1 inhalation twice a day</td>
<td>1</td>
</tr>
<tr>
<td>Albuterol inhaler</td>
<td>RESCUE inhaler, to be used for an asthma attack</td>
<td>Take only when needed according to asthma action plan</td>
<td></td>
</tr>
</tbody>
</table>

Doe, John (1234567)
"The USC Pharmacists provide our patients and clinic a comprehensive package of health education, drug information, disease management and dispensing assistance."

"We are able to provide a wider range of services to a greater number of patients due to the PAP software and assistance that the USC School of Pharmacy has provided."

"Our disease management indicators have improved dramatically as a result of the assistance we have received from the USC Pharmacy clinicians."

"Patient satisfaction has never been better thanks to the USC School of Pharmacy."

"Our patients have consistently provided positive feedback about how the pharmacy services have increased the quality of care at the clinic and made their healthcare experience more satisfying."
6-Step Process for Developing Clinical Pharmacy Services in Safety Net Clinics
Scholarship and Public Relations
Legislative/Policy Agenda

Visits to Congressional Offices
In Washington DC to discuss value of supporting clinical pharmacy service integration in safety net clinics

Representative Lucille Roybal-Allard

Sacramento
State Legislature
Recognition

6-Step Process for Developing Clinical Pharmacy Services in Safety Net Clinics
Outline

- What is the safety net?
- Key steps for developing a safety net pharmacy program
- Barriers, challenges, and healthcare reform
What we have supporting the spread of clinical pharmacy services....

- Published evidence clarifying the value of CPS
- Pharmacist support
- Allied health profession support
- Government support
- Tremendous needs among the underserved with few answers
- Alignment with healthcare reform (PCMH, ACO)
What we need…

More…
- Evidence of CPS value published in medical journals
- Pharmacy professional organization unity
- Interprofessional education
- Postgraduate training
- Collaboration, external endorsement
- Tuition repayment
- Establish our domain, clarify our product, and create demand for clinical pharmacy services among the public

Changes in…
- Reimbursement limitations for clinical pharmacy services
- The perception of community pharmacy
Aim of HRSA’s Patient Safety & Clinical Pharmacy Collaborative

“Committed to saving and enhancing thousands of lives a year by achieving optimal health outcomes and eliminating adverse drug events through increased clinical pharmacy services for the patients we serve.”
Vision for Results Generated by PSPC Teams

- Integrated CPS
- Health Status
- Adverse Drug Events
<table>
<thead>
<tr>
<th>Eligible Organizations</th>
<th>Consolidated Health Centers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comprehensive hemophilia diagnostic treatment centers</td>
<td>Federally Qualified Health Center, or FQHC look-alikes</td>
</tr>
<tr>
<td>Native Hawaiian health centers</td>
<td>Family planning (Title X)</td>
</tr>
<tr>
<td>Urban Indian organizations</td>
<td>Ryan White Care Act (Parts A, B, C, D) grantees</td>
</tr>
<tr>
<td>Certified tuberculosis clinics</td>
<td>Black lung clinics</td>
</tr>
<tr>
<td>Certain disproportionate share hospitals (&gt;11.75%)</td>
<td>Healthcare reform additions:</td>
</tr>
<tr>
<td>Certified sexually transmitted disease clinics</td>
<td>Sole community and critical access hospitals, rural referral centers, and free standing cancer centers</td>
</tr>
<tr>
<td>Children’s Hospitals</td>
<td></td>
</tr>
</tbody>
</table>
PSPC 2.0 Teams - Where are They?

~ 70 Safety Net Clinics in Year 1
~ 120 Clinics in Year 2
Patients with Health Status Under Control vs. Out of Control, September 2009 (Baseline)
Patients with Health Status
"Under Control" vs. "Out of Control"
through August 2010

Number of Patients

Teams

Under Control
Out of Control
Teams are working to drive rates of potential adverse drug events (pADEs) and adverse drug events (ADEs) to zero.

Average team improvement after 11 months:

- pADE rates ↓ 60% (0.86/patient to 0.34/patient)
- ADE rates ↓ 49% (0.12/patient to 0.06/patient)
## PSPC Spread

<table>
<thead>
<tr>
<th></th>
<th>PSPC 1.0</th>
<th>PSPC 2.0</th>
<th>PSPC 3.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organizations</td>
<td>209</td>
<td>350</td>
<td>445</td>
</tr>
<tr>
<td>Teams</td>
<td>68</td>
<td>110</td>
<td>135</td>
</tr>
<tr>
<td>CHCs</td>
<td>57</td>
<td>79</td>
<td>118</td>
</tr>
<tr>
<td>Hospitals</td>
<td>30</td>
<td>43</td>
<td>43</td>
</tr>
<tr>
<td>Schools of Pharmacy</td>
<td>24</td>
<td>53</td>
<td>98</td>
</tr>
</tbody>
</table>
Additional Support for the Spread of Integrated Clinical Pharmacy Services

- FDA: Funding, use of broadcast headquarters
- CDC, AHRQ: volunteer faculty
- CMS: State Quality Improvement Organizations (QIOs) must engage 5-10 new teams into PSPC, minimum 100 Medicare / dual eligibles each
- Affordable Care Act
  - Expanding Authority to Bundle Payments (1/13)
  - The Community Based Care Transitions Program (CCTP): Goal of reducing hospital readmissions, testing sustainable funding streams for care transition services, maintaining or improving quality of care, and documenting measureable savings to the Medicare program.

For more information: http://www.hrsa.gov/patientsafety/
Multidisciplinary IPE Program at California Hospital Medical Center and LAC-USC

Brian Prestwich, MD
Zain Al-Shamiyeh (Pharm Student)
Hillel Bocian (Med Student)

Barriers, Challenges, and Healthcare Reform
New Health Initiative Focuses on Immigrants

By Amy Hamaker on September 6, 2011 10:04 AM

A diverse panel of experts from eight USC schools, led by Lihua Liu, assistant professor in the Department of Preventive Medicine at the Keck School of Medicine of USC, recently formed a new public health initiative to focus on the health of immigrants in the United States.

The Immigrant Health Initiative (iHi), which received a $25,000 grant per year for up to three years from the USC Collaboration Fund, will engage students and faculty in exploring why the positive health characteristics of many immigrants to the United States deteriorate soon after their arrival and what can be done to stop and reverse such a trend. The panel included experts in communications, law, cinema, social work, medicine and urban planning.

Among the research and educational opportunities planned are class projects, student grants, junior faculty mentoring opportunities, community-based outreach programs and research proposals for federal or private funding sources.

The initiative’s first seminar, “Health Disparities and the Immigrant Health Initiative” presented by Provost Professor William Vega, executive director of the USC Edward R. Roybal Institute on Aging.
Barriers, Challenges, and Healthcare Reform