Implementing and Expanding Clinical Pharmacy Services

Douglas Scheckelhoff, MS, FASHP
Vice President
Practice Advancement
Objectives

• Describe the historical evolution of pharmacy services in the U.S. and outline the current state of clinical pharmacy practice

• Review training and credentialing models for pharmacists and the importance of training in advancing practice

• Describe strategies for implementing and expanding clinical services
Overarching goal of the Hospital Pharmacy: safe and effective use of medication

How do we accomplish this goal? Adopt a practice model that:

• Places pharmacists in roles where they use their drug knowledge to achieve the best medication-related outcomes and safe medication use

• Utilizes pharmacy technicians to perform technical tasks associated with product preparation and handling

• Optimizes the use of automation and technology in every step of the medication use process to improve safety and efficiency

• Follows other established, evidence based safe practices.
Evolution of clinical pharmacy practice in the United States
Historical Evolution of Hospital Pharmacy Practice in the U.S.

• Major improvements in drug distribution systems, birth of clinical pharmacy, and residency training and accreditation (1960s)
• Growth and focus on clinical services (1970-80s)
• Major expansion and acceptance of clinical services and growth of specialization (1980-90s)
• Key direction setting conferences:
  o Hilton Head – “Directions for Clinical Practice in Pharmacy” (1985)
  o Pharmacy Practice Model Initiative (PPMI) (2011)
  o Ambulatory Care Summit (2014)
Evolution of Clinical Pharmacy Services

1960s - 1970s
- Improvements in drug distribution systems to enhance safety and control costs
- Development of formularies to influence prescribing and utilization
- Central vs Decentralized Pharmacists
  - Pharmacists based in patient-care areas, e.g. ICUs, patient care units
  - Establishment of basic clinical services and involvement with other providers
  - Establishment of satellite pharmacies

1970s - 1980s
- Clinical Pharmacist practice focus areas
  - Nutrition support, pharmacokinetics, drug information, cost effectiveness
  - Pharmacists in patient care areas without dispensing responsibilities
  - Inter-professional relationship building
  - Beginnings of clinical specialization
  - Increasing number of full time pharmacists on patient care units
  - Beginnings of drug utilisation review
Evolution of Clinical Pharmacy Services

1980s - 1990s

• Board Certification of Pharmacists begins with Pharmacotherapy credential offered by BPS
• Degree change to entry-level all Pharm.D.
• “General” and “Clinical Pharmacy” residency standards merged to form “Pharmacy Practice” standard
• Greatly increased presence of clinical pharmacists on patient care units
  ▪ Complete therapeutic drug monitoring
  ▪ Rounding with medical teams
  ▪ Target drug programs focusing on cost effectiveness
  ▪ Education of physicians and nurses
  ▪ Participation in quality initiatives
  ▪ Extension of drug utilization review to medication use evaluation
• Many new pharmacy specialty practices emerging
Current Hospital & Clinic Practice in the U.S.

- Team-Based “Interprofessional” Pharmaceutical Care
- Responsibility for therapeutic outcomes given to and accepted by pharmacists
- Specialized Training: Pharmacy Generalists and Specialists
- Automation and Advanced Clinical Information Systems
- Evidence-Based Drug Therapy
- Outcomes Driven, Cost Effective
Current Hospital & Clinic-Based Practice

• Extensive use of automation, robotics, smart infusion devices, computerized prescriber order entry (CPOE), bar coding & clinical decision support

• Pharmacists provide hospital-wide clinical services:
  
  o Design drug therapy
  
  o Monitor for desired outcomes & adjust therapy
  
  o Ensure adherence
Current Hospital & Clinic-Based Practice

• Medication-use evaluation:
  o Transformed into population-based care
    ▪ Drug policy and protocol design
    ▪ Rational drug use across populations
    ▪ Focus on outcomes

• Ambulatory clinics:
  o More pharmacists work in clinics
    ▪ Primary Care Clinics
    ▪ Specialty Clinics
    ▪ Work across acute and ambulatory care
      – Enhance continuity of care
      – Manage transitions of care
Focus on Practice Model

What is a Practice Model?

• Defines important types and levels of patient care services

• Allows for:
  o Application of best practices
  o Standardization of care
  o Judgment of pharmacist and individual patient needs
What is a Practice Model?

- Incorporates roles of pharmacists, technicians, and other support personnel into the provision of interprofessional care

- Encompasses patient care activities that span across all sites of care

- Optimizes technology and information systems to enhance care
Focus on Practice Model

Imperatives for Practice Model Change

• Our Patients
  o Medication use and its outcomes are far from optimal in the U.S.
  o Admissions and readmissions to hospitals due to medication therapy are too high
  o Provision of primary care and management of chronic disease is inadequate to meet the nation’s needs
  o Wellness and prevention do not receive adequate attention
Focus on Practice Model

Imperatives for Practice Model Evaluation

• Pharmacists are the:
  o Most accessible healthcare professionals
  o Specifically and intensively educated and trained in drug therapy

• Maximizing pharmacists integration into health care teams will improve:
  o Quality
  o Safety
  o Patient Satisfaction
  o Financial Performance
Evolution of Clinical Pharmacy Services

% Hospitals

Pharmacist on Rounds
Patient monitoring
Pharmacokinetic Consults


American Society of Health-System Pharmacists®
Pharmacists Involvement in Therapeutic Drug Monitoring for Inpatients

![Bar chart showing percentage of hospitals with involvement in therapeutic drug monitoring over time.](chart)

- **Monitor**
  - 2000: 76%
  - 2003: 92%
  - 2006: 95%
  - 2009: 95%
  - 2012: 95%

- **Authority To Order an Initial Serum Medication Level**
  - 2000: 63%
  - 2003: 69%
  - 2006: 80%
  - 2009: 85%
  - 2012: 85%

- **Authority To Adjust a Dosage for a Routinely Monitored Medication**
  - 2000: 79%
  - 2003: 73%
  - 2006: 79%
  - 2009: 83%
  - 2012: 83%
Pharmacists assigned to most patients 8 hours/day, 5 days/week or more

2013 data

American Society of Health-System Pharmacists®
## Pharmacists in patient care areas

<table>
<thead>
<tr>
<th>Area / Patients</th>
<th>All Hospitals</th>
<th>Large Hospitals*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical care unit</td>
<td>38%</td>
<td>86%</td>
</tr>
<tr>
<td>Inpatient medical-surgical</td>
<td>36%</td>
<td>86%</td>
</tr>
<tr>
<td>Oncology unit</td>
<td>36%</td>
<td>82%</td>
</tr>
<tr>
<td>Cardiology unit</td>
<td>27%</td>
<td>84%</td>
</tr>
<tr>
<td>Pediatric unit</td>
<td>17%</td>
<td>84%</td>
</tr>
<tr>
<td>Anticoagulation service</td>
<td>21%</td>
<td>67%</td>
</tr>
<tr>
<td>Neonatal</td>
<td>21%</td>
<td>73%</td>
</tr>
<tr>
<td>Emergency Department</td>
<td>16%</td>
<td>77%</td>
</tr>
<tr>
<td>Infectious disease service</td>
<td>21%</td>
<td>77%</td>
</tr>
</tbody>
</table>

2013 data

* Large hospitals defined as 600 or more beds.
Pharmacists involvement in patient care

How Pharmacists Are Authorized to Write Orders

- **Prescribe**: 9%
- **Modify/Initiate by protocol**: 91%

| Authority to write medication orders | 87% |
| Authority to order serum concentrations/other lab tests | 84% |
| Documents recommendations in permanent med record | 62% |

* Includes selection, initiation, monitoring and adjustment of medication therapy pursuant to diagnosis of a medical disease or condition.
Medication Therapies Pharmacists have Responsibility for Ordering, Dosing, and Monitoring Outcomes

- Vancomycin: 89%
- Aminoglycosides: 80%
- Renally Dosed Antibiotics: 80%
- Anticoagulation: 63%
- Nutrition: 43%
- Antibiotic Selection: 21%
- Pain Management: 12%
Antimicrobial Stewardship

- 63% have a program (up from 44% in 2012)
- 29% of hospitals use clinical surveillance software

### Strategies Used

- Daily review and feedback to prescribers: 79%
- Guideline dissemination, …: 74%
- Formulary / restriction: 71%
- Clinical decision support: 31%
- Antimicrobial cycling: 8%

### How Assess Impact of Program

- Antibiotic utilization: 84%
- Bacterial resistance and infection control: 67%
- Reduced expenditures and costs: 59%
- Patient outcomes: 45%
Anticoagulation Management

<table>
<thead>
<tr>
<th>Year</th>
<th>Warfarin</th>
<th>LMWH</th>
<th>Heparin</th>
<th>Pt. Education</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>34.6</td>
<td>35.7</td>
<td>32.3</td>
<td>21.8</td>
</tr>
<tr>
<td>2013</td>
<td>36.1</td>
<td>36.4</td>
<td>35.0</td>
<td>30.9</td>
</tr>
</tbody>
</table>

- **Not at all**
- **On request**
- **Routinely**
Type of Data Used to Demonstrate Value of Pharmacist Interventions
(84% of Hospitals Collect Data)

- Frequency (Qty&Type): 92%
- Time: 51%
- Cost Savings: 50%
- Outcomes: 32%
- HCAHPS Scores: 25%
- Patient Satisfaction: 22%
- Readmission Rates: 19%
- Decreased LOS: 10%
Impact of Strategies to Improve the Appropriateness of Drug Use

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Hospitals</th>
<th>Low/no</th>
<th>Moderate</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Guidelines</td>
<td>64%</td>
<td>64%</td>
<td>32%</td>
<td>5%</td>
</tr>
<tr>
<td>RPh Intervention</td>
<td>59%</td>
<td>34%</td>
<td>38%</td>
<td>9%</td>
</tr>
<tr>
<td>P&amp;T Policy</td>
<td>54%</td>
<td>38%</td>
<td>34%</td>
<td>8%</td>
</tr>
<tr>
<td>Formulary</td>
<td>50%</td>
<td>42%</td>
<td>34%</td>
<td>9%</td>
</tr>
</tbody>
</table>

- Low/no
- Moderate
- High
Pharmacists Working in Ambulatory Clinics

Most common clinics
- Anticoagulation
- Oncology
- General MTMS
- Diabetes
- Other
- Family medicine
- HIV/AIDS
- Lipid Control
- Pain Management
- Cardiac-hypertension

<table>
<thead>
<tr>
<th># of Staffed Beds</th>
<th>% of Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td>200-299</td>
<td>28.6%</td>
</tr>
<tr>
<td>300-399</td>
<td>41.2%</td>
</tr>
<tr>
<td>400-599</td>
<td>56.5%</td>
</tr>
<tr>
<td>&gt;=600</td>
<td>67.3%</td>
</tr>
</tbody>
</table>

Source: ASHP National Survey
Collaborative Pharmacy Practice

- 47 out of 50 states have Collaborative Drug Therapy Management (CDTM) in which pharmacists:
  - Initiate, modify & discontinue therapy based on protocols (form of dependent prescribing)
  - Order lab tests, conduct physical assessments & perform therapeutic substitution
- Current efforts around “provider status” at federal level
- Current efforts around “provider status” at state level
Transforming how pharmacists care for patients

PPMI is a profession-led initiative that is empowering the pharmacy team to take responsibility for patient outcomes.

<table>
<thead>
<tr>
<th>Care Team Integration</th>
<th>Leveraging Pharmacy Technicians</th>
<th>Pharmacist Credentialing &amp; Training</th>
<th>Technology</th>
<th>Leadership in Medication Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Promotes a team-based approach to health care</td>
<td>- Empowers the pharmacy team to ensure that pharmacy technicians perform all traditional preparation and distribution activities</td>
<td>- Elevates the reputation of the pharmacy team</td>
<td>- Evaluates the available technologies to support patient safety and quality of care</td>
<td>- Empowers pharmacists to take responsibility for patient outcomes</td>
</tr>
<tr>
<td>- Shifts the roles of the health care team to enable pharmacists to optimize their time with patients across the continuum of care</td>
<td>- Urges technicians to handle non-traditional and advanced responsibilities and activities to allow pharmacists to take greater responsibility for direct patient care</td>
<td>- Ensures pharmacists, residents, and students have training and credentials for activities performed within their scope of practice now and in the future</td>
<td>- Encourages use of available automation and technology to improve patient safety, quality and efficiency, while also reducing costs</td>
<td>- Positions pharmacists to promote health and wellness, optimize therapeutic outcomes, and prevent adverse medication events</td>
</tr>
<tr>
<td>- Enhances the relationship between pharmacists and patients by positioning pharmacists as providers</td>
<td>- Promotes technician training and certification requirements, such as the need for uniform standards for advanced technician roles</td>
<td>- Promotes the use of credentials to provide services at the top of the scope of practice</td>
<td>- Identifies emerging technologies to improve pharmacy practice</td>
<td>- Emphasizes that given their extensive education and training, pharmacists are integral in helping achieve the best outcomes</td>
</tr>
</tbody>
</table>
Future of Pharmacy Practice in the U.S.

- Pharmacist is essential member of every healthcare team
- Focus on complete spectrum of acute and chronic therapy in and across all sites of care
- Outcomes driven and cost effective drug therapy
- Sophisticated automation and advanced clinical information systems
- Majority of all pharmacist time spent in direct patient care
- Expanding roles for pharmacists: prescribing, health and wellness
Training and credentialing models for pharmacists
U.S. Model for Training Pharmacists in Hospitals

- Entry level Doctor of Pharmacy Degree
- PGY1 training for generalists
- PGY2 training for specialists
- Maintaining competence
- Board Certification, credentialing and privileging
Current model for developing and maintaining pharmacist competency

Pharmacy Education

Pharmacist Licensure

PGY1 Residency

PGY2 Residency

Graduate School
- MS, MBA, MPH
- Management
- Informatics

Pharmacy Practice

Board Certification – Pharmacist specific
(eg. Oncology, Amb Care, Pharmacotherapy, Nutrition, Psychiatric)

Board Certification – Multidisciplinary or disease management
(eg. HIV, Pain and Palliative, Diabetes)

Continuing Pharmacy Education

Continuing Professional Development

Certificate Programs, Traineeships

Exit
Current Status of Pharmacy Education (U.S.)

• Previously had 5-year baccalaureate degree
  o Few experiential rotations; Heavy in basic sciences
  o Some completed post-baccalaureate doctor of pharmacy (Pharm.D.) degree

• 6-year doctor of pharmacy (Pharm.D.) degree
  o 2-year pre-pharmacy
  o 4-year Pharm.D. curriculum
  o Internship requirements (degree and practice)
  o Many schools require B.S. degree prior to entering professional sequence

• Clinical experiences required throughout the professional curriculum
  o Introductory Pharmacy Practice Experiences (IPPEs)
  o Advanced Pharmacy Practice Experiences (APPEs)
Post-Graduate Training (U.S.)

• Postgraduate Year One (PGY1) Residency
  o builds upon knowledge, skills, attitudes, and abilities gained from professional pharmacy degree program
  o enhances general competencies in managing medication-use systems
  o supports optimal medication therapy outcomes for patients with a broad range of disease states

• Postgraduate Year Two (PGY2) Residency
  o builds upon the competencies established in PGY1 year
  o focused in a specific area of practice
  o increases the resident’s depth of knowledge, skills, attitudes, and abilities
  o develops expertise in medication therapy management and clinical leadership in the area of focus
  o where board certification exists, graduates are prepared to pursue such certification
Residency Training

PGY1 Required educational outcomes:

Upon completion, residents must be able to:

• *Manage and improve the medication-use process.*
• *Provide evidence-based, patient-centered medication therapy management with interdisciplinary teams.*
• *Exercise leadership and practice management skills.*
• *Demonstrate project management skills.*
• *Provide medication and practice-related education/training.*
• *Utilize medical informatics.*
Specialty Residency programs currently accredited and offered in the U.S.

- Critical Care Pharmacy
- Oncology Pharmacy
- Ambulatory Pharmacy
- Infectious Diseases
- Pediatric Pharmacy
- Administration
- Administration/M.S.
- Internal Medicine Phmcy
- Psychiatric Pharmacy
- Cardiology Pharmacy
- Solid Organ Transplant
- Pharmacotherapy
- Geriatric Pharmacy
- Emergency Medicine Pharmacy
- Drug Information
- Pharmacy Informatics
- Medication Use Safety
- Palliative Care/Pain Management
- HIV Pharmacy
- Nutrition Support Pharmacy
- Managed Care Pharmacy Systems
- Pharmacogenetics/Biologics
- Nephrology Pharmacy
- Nuclear Pharmacy
- Pharmacoeconomics/Outcomes
Increased Demand by Employers for Residency:

By 2020 residency training should be required for new graduates going into practice (% agree):

- Entering faculty position: 87% (Participants), 90% (RPDs)
- Entering ambulatory care position: 80% (Participants), 85% (RPDs)
- Entering hospital position: 76% (Participants), 80% (RPDs)
- Entering managed care position: 59% (Participants), 54% (RPDs)
- Entering community pharmacy position: 24% (Participants), 11% (RPDs)

Source: January 2011 Residency Capacity Survey: Participants of Conference & Residency Program Directors
Board of Pharmaceutical Specialties (BPS)

• Four primary responsibilities
  o Identifies and recognizes critical specialty practice areas;
  o Sets standards for the certification and recertification of pharmacy specialists;
  o Objectively evaluates individuals seeking certification and recertification;
  o Serves as information resource and coordinating agency for pharmacy specialties.

• Certifies specialists in:
  o Pharmacotherapy (BCPS)
  o Oncology (BCOP)
  o Nuclear Pharmacy (BCNP)
  o Nutrition Support (BCNSP)
  o Psychiatry (BCPP)
  o Ambulatory Care (BCAPP)
Growth of Board-Certified Specialists
2003-2012

Source: Board of Pharmacy Specialties
ASHP Vision for the Pharmacy Workforce

• Vision for Pharmacist Responsibilities
  o Pharmacist recognized as the drug therapy expert
  o Majority of pharmacist time spent providing care on interprofessional teams.
  o Pharmacists take responsibility for the entire medication use process
  o Pharmacists become part of every patient care team
  o Expanded roles for pharmacy technicians and automation to allow pharmacists to accomplish the items above

• Credentials
  o All entry level pharmacists will have completed a PGY1 residency
  o PGY2 residency training will be required for specialized care
  o BPS board certification will grow
Evidence supporting clinical pharmacist value
Clinical Pharmacists Affect Mortality

- Review of Medicare patient data base for nearly 3 million patients at 885 hospitals from 1989 – 1998..
- Compared hospitals with 14 different pharmacy clinical services to those without.
- Seven services associated with reduced mortality rate:
  - Drug Use evaluation
  - Patient Education
  - ADR Management
  - Pharmacy Protocol Management
  - Code Team Participation
  - Admission Drug Histories
  - Participation on Rounds

Evidence supporting clinical pharmacist value

• Report to U.S. Surgeon General in 2011

• Cited 153 articles, highlighting evidence of improvements in:
  o quality of care and patient outcomes
  o disease prevention and management
  o cost effectiveness and cost containment
  o primary care
  o access to care
Evidence supporting clinical pharmacist value

- Effect of Pharmacists on Patient Care
- Systematic review of 298 articles, evaluating pharmacist impact on:
  - Therapeutic outcomes
  - Safety outcomes
  - Humanistic outcomes
- Review showed pharmacist involvement improved dosing, mortality, length of stay, adherence, knowledge, quality of life
- Therapeutic outcomes improved in blood pressure, hemoglobin A1c, cholesterol with pharmacist involvement
Evidence supporting clinical pharmacist value

Recommendations from the Institute of Medicine:

- Pharmacists should be available on nursing units and on rounds to improve access to medication information.
- Health care settings, particularly inpatient, should ensure pharmaceutical decision support is available.
- Pharmacists should be involved in medication management in nursing homes and ambulatory care settings.
- Increase consumer awareness of the right to pharmacist counseling on medications.
- Implement a team-based (including pharmacist) approach to medication reconciliation.
- Generally increase availability of and access to medication management services provided by pharmacists.
- Pharmacists should serve as active participants in the medication use process.
Key Strategies for Developing Clinical Pharmacy Services

• Strengthen drug distribution system
• Enhance education and training for new graduates and existing practitioners
• Collect and evaluate data on medication use in hospitals and clinics
• Develop a trusting relationship between clinical pharmacists, physicians, and nurses by placing the pharmacist on the care unit
Key Strategies for Developing Clinical Pharmacy Services

• Utilize existing literature and experiences of others
• Collect outcomes data
• Cost justify activities of pharmacists
• Develop and utilize physician and nursing champions
• Decentralize pharmacists in all possible ways
Questions?
Greenville Hospital System
Greenville, SC
686 beds
Developing all staff pharmacists to take on direct patient care
Focus on integrated practice
Pharmacist involvement with med histories, reconciliation
BCMA, CPOE, HER
Advice: Staff buy-in was key; developed staff and proactively sought ways to help them with change
Advice: Start with a gap analysis
Practice Spotlights

- Banner Good Samaritan Medical Ctr
- Phoenix, AZ
- 638 beds
- Focus on involving pharmacist in team based care
- Pharmacist involved from admission to discharge
- Pharmacy Techs take med history
- Pharmacists manage therapy based on protocols with medical staff
- Advice: Change to new model focused on collaboration and improving patient outcomes
- Advice: Collect baseline data to show impact on outcomes.
Baystate Medical Center
Springfield, MA
653 beds
Department focuses on clinical and cost-effective pharmacotherapy using lean principles
Efficiencies gained through Lean have provided for expanded clinical services
EHR, CPOE, ADC
Struggled for years to “get out of the basement”
3 critical success factors: collaboration, engagement, communication
Practice Spotlight:

- Providence St. Peter Hospital
- Olympia, WA
- 337 beds
- Transitioned from “product” to “patient” centered model
- Developed a three year strategic plan to centralize operations and decentralize pharmacists to patient care units

Advice:
- 1) involve staff in strategic planning,
- 2) assure staff have the clinical skills needed to do the job,
- 3) individual and system accountability is essential
Practice Spotlights

- Martha Jefferson Hospital
- Charlottesville, VA
- 149 beds (102 ADC)
- Focused on balance of what pharmacists do, what technicians do, and how technology used
- Started residency program and has helped support changes
- All pharmacists rotate through all areas of practice
- Bar coded dispensing technology was a key success factor
- Staff happier with their new roles
- Advice: communication is key; staff need to know the vision, plans
Practice Spotlights

- Fauquier Health
- Warrenton, VA
- 92 beds
- Clinical services include pharmacokinetic dosing, TPN, antimicrobial stewardship, consults, rounding
- Developed active mentoring program.
- Big change in behavior of introverted pharmacists
- Advice: Gaining support from senior staff was critical – tailored to meet unique needs of each staff member
- Took time to win over medical staff – cost/outcomes data is what worked