Redefining the Practice Model: Where have we been, where do we go?

Building the Future for Health System Pharmacy Practice

Daniel Ashby, M.S.
Senior Director of Pharmacy
The Johns Hopkins Hospital
Program Overview

- Developing Practice Models – Successes, Challenges, and Lessons Learned
- Patient Outcomes and the Societal Value of Pharmacists
- ASHP Member Facilitated Discussions on Expectations of the Future
- Town Hall on the Future of Hospital and Health-System Pharmacy Practice
Preparing for the Future

- A strategic responsibility of ASHP and its leaders
- Strength of a diverse and well informed membership
- Identify and responding to key trends
- Positioned to act
Historical Perspective

- Hilton Head – “Directions for Clinical Practice in Pharmacy” (1985)

“We must become the change we want to see.”
Mahatma Gandhi
Hilton Head 1985– ASHP

- 120 principal pharmacy practitioners and educators selected by independent panel as invitees (150 total participants)
  - Pharmacy as a clinical profession
  - Extent pharmacy profession had established goals for clinical practice
  - Assess current status of clinical practice of pharmacy
  - How clinical pharmacy faculty can help to improve quality of clinical pharmacy services
  - Identify practical ways to advance clinical practice
  - Barriers to clinical practice encountered by pharmacists
  - Use of pharmacy staff more effectively in clinical education.
  - Relationship that pharmacy should seek with medicine, nursing, hospital administration and the public

- 17 national pharmacy organizations and FDA, 108 participants
  - To continue to examine major issues that will confront the profession during the next 15-20 years
  - Opportunities and responsibilities in pharmaceutical care
  - Societal and public policy trends into the 21st century
  - Emerging trends in biotech on the practice of pharmacy in 2000
  - Technological challenges in information transfer
  - Shifting trends in health care economics
  - Trends in health care systems delivery

- 200 participants commemoration of ASHP’s 50th anniversary
  - Critical skills needed to provide pharmaceutical care
  - Department strategic planning articulating plan for Rx care
  - Personal commitment on behalf of all pharmacy staff
  - Working with Boards of Rx to enable pharmacists and technicians to provide Rx care
  - Expand beyond pilot programs
  - Develop documentation methods for Rx Care that are practical and easy for pharmacists and other health care professionals
  - Acquire technology and human resources to streamline drug distribution systems to increase time available
Wave of Change

First Professional Degrees Conferred 1980 - 2008 (projected)

Source: AACP Profile of Pharmacy Students

* 2004/05 - 2007/08 projections based on fall 2004 enrollments by expected graduation year

ASHP Accredited Pharmacy Residency Program Growth (1964-2008)
ASHP Leadership Agenda 2008-2009

Foster optimal models for the deployment of pharmacy resources in hospitals and health systems

- **Tactic 1:** Encourage hospital and health-system pharmacy departments to evaluate and optimize their practice models (deployment of resources, including how pharmacists and technicians spend their time), and provide information and advice on how to conduct such assessments.

- **Tactic 2:** Encourage research on optimal pharmacy practice models in various types of hospital and health-system settings.

- **Tactic 3:** Improve public awareness of the patient-care capabilities of pharmacists among health professionals, health executives, public policy makers, and the general public.

- **Tactic 4:** Assertively advocate for equitable pharmacy reimbursement, a competitive marketplace for pharmaceuticals, and expansion of third-party payment for pharmacist drug therapy management services.
Vision

- The initiative and summit will create passion, commitment, and action among hospital and health-system pharmacy practice leaders to significantly advance the health and well-being of patients by optimizing the role of pharmacists in providing direct patient care. By describing patient care services and activities that support the safe and effective use of medications, corresponding models can be adopted that optimize the full potential of pharmacist, technician, and technology resources.
PPMI Initiative & Summit

• **Raise awareness** on the imperative to address the future of the pharmacy practice model in hospitals and health systems.

• **Optimize the role** of the pharmacist.

• **Conduct a PPMI Summit** to fully develop the vision and address the five focus areas identified by the PPMI Advisory Committee.

• **Establish a social marketing campaign**

• **Provide grants**, through the ASHP Research and Education Foundation, for demonstration projects.

Supported by grants from

![McKesson](image1.png)  ![Omnicell](image2.png)
Some of the Issues Identified

- Capabilities of pharmacists are not optimized in the management of patients medication therapies.
- Expectations of profession: demand by practitioners versus supply of opportunities.
- Does HS pharmacy have a consistent practice model?
- Information technology revolution and ‘beyond the brick and mortar’ patient care.
- Decreasing health care reimbursement, specifically on drugs.
- Clear vision of what the balance of drug management versus direct patient care should be.
- Pharmacists are among one of the most highly compensated health care professionals.
- Regulations and laws do not permit pharmacists to reach full potential.
- Science is transforming the way medicine will be practiced.
Lessons Learned From Past

1. Philosophy and idealism hold appeal.
2. Begin with the end in mind – we must have a clear vision.
3. Change will require “diffusion of innovation” – today’s leaders will need to discover themselves the wisdom of change and instill the values in those they lead.
4. The profession needs to be ready for change – through ASHP leaders this urgency is being conveyed.
Expectation for Leadership

- Striving for the highest level of safety and well-being of patients
- Role of ASHP, our Leaders, and our Members
- Legacy of stimulating change
- Creating opportunities for HS Pharmacy

“The price of greatness is responsibility.”
Winston Churchill
Developing Practice Models in the 70’s

William E. Smith, PharmD, MPH, PhD, FASHP
Professor and Executive Associate Dean
School of Pharmacy
Virginia Commonwealth University
Primary Goals

- Safer Medication Systems
- Pharmacist clinical practice
- Education
  - Pharmacy student
  - Residencies
Environment – External to Pharmacy

- Medication errors
- Patient drug therapy issues
  - ADR’s and increase in LOS
  - Drug causes for hospitalization
  - Drug information needs of MD
  - Drug interactions – drugs, lab tests
  - Drug induced diseases
Environment – External to Pharmacy (cont)

- Medicare and Medicaid – 1965
- Before DRG and PPS
- Pharmacy – viewed as a revenue department
- Automation – none to very limited
- Nursing time – too much in med activities
- Management views toward pharmacy
Desire for pharmacist clinical practice
- What is clinical practice?
- Inter-professional relationships: RX and MD, RX and RN

PharmD degree – started in the ‘50s, expansion in the ‘60s and ‘70s

Pharmacy facilities – constraints (central, decentral)
Environment – Internal to Pharmacy (cont)

- Programs to accomplish Goals
  - University of Kentucky
  - University of Arkansas
  - The Ohio State University
  - University of Iowa
  - University of California, San Francisco
  - Long Beach Memorial Hospital
  - Others – Texas, SC, NC
Summary – 70’s

- Pharmacist clinical practice
  - Implemented successfully
  - Supported by MD and RN
- Pharmacist increased control of med systems – unit dose, IV admixture
- Outcomes – positive for patient care, but inadequate assessment
Summary – 70’s (cont)

- Increased costs vs decreased costs – not resolved

- Pharmacy technicians
  - Roles defined – not clearly
  - Education and training – not defined
  - Recognition - not resolved

- Pharmacy facilities – central vs decentral
Summary ‘70s

- Goals accomplished
  - Safer medication systems – Yes
  - Pharmacist clinical practice – established
  - Pharmacy education
    - Student and residencies – more clinical

- Final comments – decade of innovation and accomplishments
Developing Practice Models in the 80’s

Burnis D. Breland, M.S., Pharm.D., FASHP
Director of Pharmacy
The Medical Center, Inc.
Columbus, Georgia
The Environment

- DRGs: reimbursement changes
- Managed care: negotiated, capitated
- Reduced reimbursement
  - Decreased admissions, patient days and LOS; shift to outpatient care, home health, urgent care centers, ambulatory surgery centers; strong competition & marketing; diversification, expanded service lines
- Shifted to cost focus
- Consultants: benchmarking, 25th percentile; negative impact on clinical services
Pharmacy Changes

- Medication delivery: unit dose systems & IV admixture became standard of practice
- Satellites and mobile carts became alternatives to central pharmacy dispensing
- Pharmacy computer systems appeared
- Purchasing: prime vendor
- GPOs emerged
Practice Changes

- Clinical practice focus
  - Nutrition support, pharmacokinetics, DI
- Location of practice: decentralized shift
  - Satellites with and without drugs, patient care area based practice roles
- Dispensing & clinical pharmacists taught each other; integrated pharmacy services
- Expanded use of technicians
- Interprofessional relationships: nursing & physicians
Challenges

- Shifting from product focus to clinical, patient care focus
- Few clinically trained pharmacists
- Severe pharmacist shortage
  - Satellites closed, lack of staff
- Lack of clear direction, consensus on role of pharmacists
- What should we do? Anything that advanced clinical practice.
Milestone: The Hilton Head Conference

Directions for clinical practice in pharmacy
- February 10-13, 1985; Hilton Head, SC
- AJHP 1985; 42: 1287-342

Objectives
- Examine the extent to which the profession of pharmacy has established goals with respect to clinical practice
- To assess the current status of the clinical practice of pharmacy and pharmacy education
- To identify practical ways for advancing clinical practice
Opportunities

- Pharmacokinetic dosing
  - Aminoglycosides, theophylline, vancomycin, digoxin and phenytoin
  - Serum drug monitoring
- Parenteral nutrition
- Created demand for clinical pharmacy services; improved patient care; supported medical staff; increased number of clinical pharmacists
Lessons Learned

- Satellites placed pharmacists in the patient care areas; were labor intensive; expanded inventory
- Clinical pharmacists lacked product knowledge; staff pharmacists lacked clinical knowledge; merged knowledge
- Decentralized pharmacists promoted collaborative practice
Lessons Learned

- Needed more general clinical pharmacists, well rounded knowledge base
- Pharmacists “accepted” as clinical team members
- Expanded roles of technicians
- Drug dispensing and distribution systems needed new technology, automation
Successes and Pivotal Events

- Clinical pharmacy became mainstream; de-central pharmacists implemented
- Collaborative practice advanced
- Pharmacy education and residency training expanded
- Pharmacy expanded its role in drug therapy management
- “Pharmaceutical care” introduced as a philosophy of practice (1989-90)
Developing Practice Models in the 90’s

Mark Woods, Pharm.D., FASHP, BCPS
Clinical Coordinator and Residency Program Director
Saint Luke’s Hospital
Kansas City, Missouri
Saint Luke’s Hospital
Circa 1990 – The Environment

AJHP 1990;47:2665

- Unit dose drug distribution system (89%)
- Decentralized pharmacists with medication carts (27%)
- IV admixture program limited in ICU’s (69%)
- Mainframe legacy computer system (64%)
- Staff credentials: predominantly B.S. with some Pharm.D. and few residency-trained
- Precepting pharmacy students since 1988
- P&T Committee focused on formulary/DUE
Pivotal Hospital Pharmacy Events in the 1990’s

- **1988** – Pharmacotherapy credential offered by BPS
- **1990** – AACP mandates Pharm.D. degree would be sole entry-level degree
- **1990** – Profession performs “gender flip”
- **1992** – Implementing Pharmaceutical Care Conference – San Antonio
- **1993** – “General” and “Clinical Pharmacy” Residency standards merged to form Pharmacy Practice Residency standard
- **1995** – PTCB formed
- **1999** – IOM report “To Err is Human” issued
Saint Luke’s Hospital

Operational Opportunities Realized in 1990’s

- Advent of automated dispensing technology
  - Invention of matrix drawer “shopping”
  - Elimination of decentralized carts

- Maturation of computer systems
  - From purchasing/billing/profiles to MAR’s/early decision support
  - Mainframes to PC’s

- Early generation scanning technology

- Consultants
  - “Clinical” consultants
  - Work redesign/organizational flattening consultants
Saint Luke’s Hospital
Clinical Opportunities Realized in the 1990’s

- Development of more formal clinical services/minimum daily expectations
  - Pharmacokinetic monitoring
  - Nutritional monitoring
  - IV-to-PO
  - Patient teaching
  - Rounding on selected services
  - Immunization screening
Saint Luke’s Hospital
Clinical Opportunities Realized in the 1990’s

- Development of integrated practice model
- Improved human resource management
  - Performance management planning
  - Clinical Ladder/Career Development Plan
  - Recruiting/retaining more credentialed staff
    - More Pharm.D./residency trained pharmacists
    - Encouraging/supporting technician certification
  - Staff-directed scheduling (Scheduling Committee)
- Expanded clinical rotations for students
- Developed pharmacy practice residency program
- Pharmacists take a leadership role in hospital quality initiatives
  - Surgical prophylaxis
  - Immunizations/Community-acquired pneumonia
## Growth of Core Services in the 1990’s

As reported in ASHP National Surveys

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<tr>
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<td>67%</td>
<td>81%</td>
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<tr>
<td>Decentralized</td>
<td>27%</td>
<td>27%</td>
<td>29%</td>
<td>34%</td>
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<td>29%</td>
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<td>(75%)</td>
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<tr>
<td>Therapeutic Interchange</td>
<td>49%</td>
<td>69%</td>
<td>68%</td>
<td>75%</td>
<td>81%</td>
<td>--</td>
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<tr>
<td>Pharmacokinetics</td>
<td>57%</td>
<td>65%</td>
<td>75%</td>
<td>81%</td>
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<tr>
<td>TPN program</td>
<td>n/a</td>
<td>37%</td>
<td>35%</td>
<td>48%</td>
<td>53%</td>
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Matching numbers for Accredited Pharmacy Practice (PGY1) Programs

1990 - 2008

More Applicants than Positions

Source: ASHP Accreditation Services
Successes, Pivotal Events and Lessons Learned from the 1990’s

- Increased use of automation yielded mixed results:
  - Early automation did not necessarily make care safer or save time/resources
    - Matrix drawers reduced medication use control
    - Poor quality scanning increased potential for error
    - Did not reduce staffing requirements
  - Automation did free pharmacists from some drug distribution activities leading to the expansion of clinical services

- Computer systems expanded, matured and helped improve operational and clinical functions
Successes, Pivotal Events and Lessons Learned from the 1990’s

- Decisions made regarding the education and training of pharmacy staff contributed to:
  - Improvement in the caliber of our current pharmacy staff
    - More highly trained technicians
    - More Pharm.D., residency-trained and Board Certified staff
  - Our ability to recruit and retain highly qualified staff
  - Organizational “flattening” recommended by consultants and changes in training contributed to many of our current leadership challenges
Successes, Pivotal Events and Lessons Learned from the 1990’s

- Good human resource management became a required leadership competency
  - Insuring rapidly growing clinical services were in alignment with organizational priorities consistent and high quality
  - Need to develop career development plans to reward and recognize achievement-driven staff
  - Gender flip and generational differences caused us to address to life-work balance issues
Pharmacy in 21st Century

Steve Pickette, B.S. Pharm., BCPS
Errors in Health Care: A Leading Cause of Death and Injury

- 44,000 to 98,000 die due to preventable adverse events related to medical errors
- Cost between $17 to $29 billion
- Medication related errors 1.81 per 1,000 orders adult, 4.5 per 1,000 peds

Linda T. Kohn, Janet M. Corrigan, Molla S. Donaldson
Committee on Quality of Health Care in America
Institute of Medicine
National Academy Press
Washington, D.C.
Impact of IOM Report

- Public awareness of impatient medication safety issues
- Organizational emphasis on quality and safety
- Focus on medication safety technology – bar coding, CPOE, automated dispensing
- Increase in medication related regulatory requirements
- Increased expectations from pharmacy
CMS Core Measures

- Pilot project at 11 hospitals 2000-2001
- AMI, CHF, CAP – Initial Implementation 7/1/2002
- Pay-for-performance
- Add SCIP, VTE – total 25 measures
- Public Access to Results – Benchmarking
Welcome to Hospital Compare. In this tool you will find information on how well hospitals care for patients with certain medical conditions or surgical procedures, and results from a survey of patients about the quality of care they received during a recent hospital stay. This information will help you compare the quality of care hospitals provide. Talk to your doctor about this information to help you, your family and your friends make your best hospital care decisions.

Hospital Compare was created through the efforts of the Centers for Medicare & Medicaid Services (CMS), the Department of Health and Human Services, and other members of the Hospital Quality Alliance Improving Care Through Information (HQA). The information on this website comes from hospitals that have agreed to submit quality information for Hospital Compare to make public.

Find and Compare Hospitals

Learn More

- Hospital Process of Care Measures
- Hospital Outcome of Care Measures
- Survey of Patients’ Hospital Experiences
- Medicare Payment and Volume
- Information for Professionals

Page Last Updated: October 5, 2009
Clinical Pharmacist Affect Mortality

- Review of patient data base for nearly 3 million patients at 885 hospitals.
- 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.

Pharmacotherapy 2007;27(4):481-493
Clinical Pharmacy Services and Mortality Rates

Relationship between clinical pharmacist staffing and deaths/1000 admissions

Pharmacotherapy 2007;27(4):481-493
Role of the Pharmacist in Hospitals

- Reviewing individual patients’ medication orders for safety and effectiveness and taking corrective action as indicated.
- Collaboratively managing medication therapy for individual patients.
- Educating patients and caregivers about medications and their use.
- Leading continuous improvements in the medication use process.
- Leading the interdisciplinary and collaborative development of medication use policies and procedures.
How Common Are these Services?

- Only 38% of hospitals overall have service specific pharmacists review therapy.
  - 72% at hospitals greater than 400 beds
  - 26% at hospitals 200 beds or less
- Only 24% of hospitals have pharmacists reviewing medication therapy for 75% or more of patients.
Economic Environment

- Pharmacist Shortage → Salary ↑
- Decreased Medicare Payments, e.g. Readmission, HAI
- Global Recession
- Health Care Reform
CONCLUSIONS

● “Do More With Less”
  ▪ Dispense using technicians/technology
  ▪ Utilize clinical decision support tools
● Pharmacist focus on medication therapy.
● Demonstrate the impact of the pharmacist on financial and quality measures.
Benchmark Comparison of Clinical Services Between PH&S Hospitals

$ Saved per CMI Adj PT Day vs. CMI Adj Pt per Clin FTE
THANK YOU!
Demonstrating Pharmacists’ Impact

Marie Chisholm-Burns, PharmD, MPH, FCCP, FASHP
Professor and Head, Department of Pharmacy Practice and Science
The University of Arizona College of Pharmacy
Introduction

Review of 4 decades of pharmacy practice models reveals expanding practices, challenges, and opportunities.
Pharmacists

- The responsibilities of pharmacists in the U.S. have expanded over time beyond traditional medication dispensing.

- Pharmacists can help fill the gap in health care, as they are trained to monitor medication therapy to optimize desired therapeutic effects and minimize ADEs.

- Synthesis of available evidence can help solidify the effects of pharmacists on direct patient care.
Systematic Reviews

- Given the volume of available pharmacy literature, systematic reviews and meta-analyses are useful tools to study pharmacists’ impact as patient care providers.

- Benefits of systematic reviews and meta-analyses include:
  - Provides a synthesis of data
  - Increased generalizability of findings
  - Identification of consistencies and inconsistencies across populations, settings, disease states, etc.
  - Improved statistical power
  - Increased accuracy of effect size estimates
Objective

- **Objective:** To conduct a comprehensive systematic review of evidence examining the effects of pharmacists’ direct patient care interventions and services on health outcomes (specifically, therapeutic, safety, humanistic, and economic) in the U.S., supplemented with focused meta-analyses.

- **Specific questions addressed:**

  1. What is the evidence of pharmacists’ direct patient care impact on *therapeutic outcomes* among patients across practice settings in the U.S.?

  2. What are the contributions of pharmacists’ services to improving *medication safety* in direct patient care arenas in the U.S.?

  3. What are the effects of pharmacists’ direct patient care interventions on health-related *humanistic outcomes* in the U.S. patient population?

  4. What is the *economic benefit* of pharmacist-provided direct care services?
Outcomes Defined

- **Therapeutic**: A therapeutic (clinical) effect resulting from intervention(s)
  - Examples – surrogate markers (e.g., blood pressure, LDL cholesterol), morbidities, mortality

- **Safety**: Prevention of medication harm or error
  - Examples – adverse drug reactions, adverse drug events, sentinel drug events, medication errors
Outcomes Defined

- **Humanistic**: Psycho-socio-behavioral effects of treatments/interventions
  - Includes – patient functional status, quality of life, treatment adherence, patient knowledge, patient satisfaction

- **Economic**: Costs (e.g., direct, indirect) related to interventions
  - Includes – cost minimization analysis, cost effectiveness analysis, cost utility analysis, cost benefit analysis
Methods

- Step 1. Comprehensive Literature Search (beginning of databases-February 2009)

- NLM/PubMed
- Ovid/MEDLINE
- ABI/INFORM
- Health Business Fulltext Elite
- Academic Search Complete
- International Pharmaceutical Abstracts (IPA)
- PsycINFO
- Cochrane Database of Systematic Reviews
- National Guideline Clearinghouse
- Database of Abstracts of Reviews of Effects (DARE)
- ClinicalTrials.gov
- LexisNexis® Academic Universe
- Google Scholar
Methods

Step 2. Inclusion/Exclusion Assessment

To be included in the systematic review, the following criteria had to be met:

- Evidence of pharmacist involvement in direct patient care (able to discern pharmacist contribution)

- Intervenational and analytical (statistical evaluation of pharmacist-provided direct patient care intervention/service)

- Comparison group present (examples include RCTs, comparison group studies, pre-post studies, before and after studies)

- Objective patient-related outcomes reported (outcomes must be therapeutic, safety, humanistic, and/or economic)
Methods

- Step 3. Data Extraction of Included Studies

  - Extracted data included study characteristics (e.g., design), pharmacists’ interventions/services and activities, patient characteristics, and study outcomes (therapeutic, safety, humanistic, and/or economic).

  - Data concerning outcomes were collected for each study in the four outcome areas using the categories:

    - **Favorable** – \( p<0.05 \) indicating significant improvement as a result of pharmacist provided care\(^1\)

    - **Not Favorable** – \( p<0.05 \) indicating significant improvement in non-pharmacist provided care\(^1\)

    - **Mixed** – Favorable results on one measurement of study variable, but not favorable or no effect on another

    - **No Effect** - No significant differences between pharmacist intervention/service and comparison

    - **Unclear** – Unable to determine outcome based on data presented

\(^1\)In absence of \( p \)-value, based on author conclusions.
### Methods

#### Step 3. Data Extraction of Included Studies

- Level of evidence and level of study outcome also assessed

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<th>Outcomes Criteria</th>
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<td>Randomized controlled trials (RCTs)</td>
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<td>Clinical outcomes – morbidity, mortality, adverse events</td>
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<td>3</td>
<td>Other measurable variables with an indirect or un-established connection to the target outcome, e.g., pre-test/post-test after educational intervention</td>
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Data Analysis

- Summary statistics (frequencies) reported for all included studies on study characteristics.

- Studies also grouped by outcome area (therapeutic, safety, humanistic, and economic), and summary statistics for each area were calculated.
Inclusion criteria for meta-analyses:

- Data extracted from RCTs that: (1) were randomized at the individual patient level; (2) reported the number of individuals in the intervention group and control group; and (3) reported outcomes as means and standard deviations or as proportions.

- Within each outcome area, meta-analyses were conducted for select outcomes (e.g., hemoglobin A1c) for which there were at least four studies reporting similar outcomes.

- An odds ratio or standardized mean difference was calculated as the effect size for each meta-analysis.

Meta-analyses were conducted for each outcome area except economic for the following reasons: (a) limited number of studies; (b) varying study endpoints; and (c) many studies did not sufficiently address cost issues.
Results – Inclusion/Exclusion

Titles/Abstracts identified in literature searches (n=56,573)

Excluded Titles/Abstracts (n=53,002)
- Outcomes not pharmacy-related (n=28,190)
- Foreign articles (n=18,650)
- Meeting abstracts (n=2,845)
- Duplicates (n=1,787)
- Case Studies (n=654)
- Letters/Editorials (n=648)
- Other (n=170)
- Books/Chapters/Book Reviews (n=58)
  (Leaving 3,571)

3,571 Abstracts/full text were subjected to inclusion/exclusion assessment

Excluded Abstracts/Full-text (n=3,236)
- No evidence of pharmacists’ involvement in service or intervention
- Not analytical and interventional in nature
- No comparison group present
- No objective patient-related outcomes reported

Included full text = 335
Results – Included Studies

- 335 studies included in the systematic review.
- 76 of 335 (22.7%) studies rated as having Level 1 design (RCT).
- 165 of 335 (49.3%) studies rated as having Level 1 outcomes.

<table>
<thead>
<tr>
<th>Most frequently reported pharmacists’ direct patient care interventions/services</th>
<th>Most frequently reported disease states</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication understanding education (n=167)</td>
<td>Hypertension (n=71)</td>
</tr>
<tr>
<td>Prospective or retrospective drug utilization reviews (n=126)</td>
<td>Dyslipidemia (n=62)</td>
</tr>
<tr>
<td>Disease understanding education (n=115)</td>
<td>Diabetes (n=53)</td>
</tr>
<tr>
<td>Adherence education (n=111)</td>
<td>Asthma/COPD (n=31)</td>
</tr>
<tr>
<td>Chronic disease management (n=91)</td>
<td>Infection (n=31)</td>
</tr>
<tr>
<td>Weight management/physical education-exercise/diet and nutrition (n=51)</td>
<td>Anticoagulation (n=29)</td>
</tr>
<tr>
<td>Medication therapy management (n=48)</td>
<td>Psychiatric conditions (n=18)</td>
</tr>
</tbody>
</table>
Results – Characteristics of Included Studies (n=335)

<table>
<thead>
<tr>
<th>Study Characteristics</th>
<th>n ( % )</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hierarchy of Study Designs</strong></td>
<td></td>
</tr>
<tr>
<td>Level 1 (RCT)</td>
<td>76 (22.7%)</td>
</tr>
<tr>
<td>Level 2 (Comparison, cohort)</td>
<td>113 (33.7%)</td>
</tr>
<tr>
<td>Level 3 (Pre-post)</td>
<td>86 (25.7%)</td>
</tr>
<tr>
<td>Level 4 (Before and after)</td>
<td>60 (17.9%)</td>
</tr>
<tr>
<td><strong>Hierarchy of Study Outcomes</strong></td>
<td></td>
</tr>
<tr>
<td>Level 1 (e.g., mortality, adverse events, quality of life)</td>
<td>165 (49.3%)</td>
</tr>
<tr>
<td>Level 2 (e.g., surrogate markers)</td>
<td>90 (26.9%)</td>
</tr>
<tr>
<td>Level 3 (e.g., adherence, knowledge, medication use)</td>
<td>75 (22.4%)</td>
</tr>
<tr>
<td>Level 4 (e.g., projected adverse events, satisfaction)</td>
<td>5 (1.5%)</td>
</tr>
<tr>
<td><strong>Study Setting</strong></td>
<td></td>
</tr>
<tr>
<td>Inpatient/Institutional</td>
<td>101 (30.1%)</td>
</tr>
<tr>
<td>Outpatient/Ambulatory Care/Retail/Community</td>
<td>218 (65.1%)</td>
</tr>
<tr>
<td>Emergency Department/Urgent Care</td>
<td>4 (1.2%)</td>
</tr>
<tr>
<td>Home</td>
<td>13 (3.9%)</td>
</tr>
<tr>
<td>Other</td>
<td>14 (4.2%)</td>
</tr>
<tr>
<td><strong>Pharmacists’ Interventions</strong></td>
<td></td>
</tr>
<tr>
<td>Behavioral</td>
<td>1 (0.3%)</td>
</tr>
<tr>
<td>Educational</td>
<td>41 (12.2%)</td>
</tr>
<tr>
<td>Technical</td>
<td>88 (26.3%)</td>
</tr>
<tr>
<td>Combination/Multimodal</td>
<td>205 (61.2%)</td>
</tr>
<tr>
<td><strong>Patients’ Health Care Coverage</strong></td>
<td></td>
</tr>
<tr>
<td>Medicaid</td>
<td>23 (6.9%)</td>
</tr>
<tr>
<td>Medicare</td>
<td>16 (4.8%)</td>
</tr>
<tr>
<td>Veterans Administration/Department of Defense</td>
<td>51 (15.2%)</td>
</tr>
<tr>
<td>Managed Care/Health Maintenance Organization</td>
<td>33 (9.9%)</td>
</tr>
<tr>
<td>Private</td>
<td>19 (5.7%)</td>
</tr>
<tr>
<td>Self-insured</td>
<td>8 (2.4%)</td>
</tr>
<tr>
<td>Uninsured</td>
<td>17 (5.1%)</td>
</tr>
<tr>
<td>Not reported</td>
<td>182 (54.3%)</td>
</tr>
</tbody>
</table>
Results – Therapeutic Findings

- 224 of 335 (66.9%) studies reported therapeutic outcomes.

- 45 of 224 (20.1%) studies rated as having Level 1 design.

- 132 of 224 (58.9%) studies rated as having Level 1 outcomes (e.g., mortality, morbidity, hospitalization).

- 67 of 224 (29.9%) studies were conducted in inpatient settings, 151 of 224 (67.4%) studies were conducted in outpatient settings, and 19 of 224 (8.5%) studies were conducted in other settings.

- Favorable results were found in 51.4% (hospitalization/readmission) to 100% (eye exam visits) of studies.

- The following most frequently reported therapeutic outcomes were selected to undergo meta-analyses: (1) blood pressure; (2) LDL cholesterol; and (3) hemoglobin A1c.
Systolic and Diastolic Blood Pressure

Favors pharmacist interventions/services. Systolic (standardized mean diff. = 0.5) and diastolic (standardized mean diff. = 0.3) were significant (p<0.01). The mean difference between the pharmacist intervention group and the control group in systolic blood pressure reduction was -7.8 mmHg (SD=1.5; 95% CI -9.7 to -5.8). The mean difference between the groups in diastolic blood pressure reduction was -2.9 mmHg (SD=0.7; 95% CI -3.8 to -2.0) versus. Total sample size: systolic=9,357; diastolic=9,208.
Favors pharmacist interventions/services. Standardized mean diff. = 0.3; \( p=0.006 \). The mean difference between the pharmacist intervention group and the control group in LDL cholesterol reduction was -6.3 mg/dL (SD=0.12; 95\% CI -6.5 to -6.0). Total sample size: 745.
Hemoglobin A1c

Favors pharmacist interventions/services. Standardized mean diff. = 0.6; \( p = 0.005 \). The mean difference between the pharmacist intervention group and the control group in hemoglobin A1c reduction was -1.8\% (SD=0.5; 95\% CI -2.7 to -0.9). Total sample size: 550.
Results – Safety Findings

- 73 of 335 (21.8%) studies focused on safety outcomes.
- 12 of 73 (16.4%) studies rated as having Level 1 design.
- 55 of 73 (75.3%) studies rated as having Level 1 outcomes (e.g., adverse drug events, adverse drug reactions).
- 25 of 73 (34.2%) studies were conducted in inpatient settings, 44 of 73 (60.3%) settings were conducted in outpatient settings, and 7 of 73 (9.6%) studies were conducted in other settings.
- Favorable results were found in 60% (adverse drug reactions) to 81.8% (medication errors) of studies.
- Meta-analysis conducted on ADEs as the only safety outcome reported in more than 4 RCTs and meeting other criteria for meta-analysis.
Adverse Drug Events

<table>
<thead>
<tr>
<th>Study name</th>
<th>Odds ratio</th>
<th>Lower limit</th>
<th>Upper limit</th>
<th>Z-Value</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hanlon et al, 1996</td>
<td>0.657</td>
<td>0.347</td>
<td>1.241</td>
<td>-1.296</td>
<td>0.195</td>
</tr>
<tr>
<td>Schnipper et al, 2006</td>
<td>0.121</td>
<td>0.015</td>
<td>1.004</td>
<td>-1.956</td>
<td>0.050</td>
</tr>
<tr>
<td>Jameson, 2001</td>
<td>0.593</td>
<td>0.341</td>
<td>1.030</td>
<td>-1.856</td>
<td>0.063</td>
</tr>
<tr>
<td>Murray, 2007</td>
<td>0.666</td>
<td>0.414</td>
<td>1.072</td>
<td>-1.674</td>
<td>0.094</td>
</tr>
<tr>
<td>Powers, 1983</td>
<td>0.090</td>
<td>0.015</td>
<td>0.525</td>
<td>-2.676</td>
<td>0.007</td>
</tr>
<tr>
<td></td>
<td>0.529</td>
<td>0.335</td>
<td>0.835</td>
<td>-2.734</td>
<td>0.006</td>
</tr>
</tbody>
</table>

Favors pharmacist interventions/services. There was a substantial effect as the odds ratio was 0.53, which represents a significant reduction in the odds of adverse drug events of 47% ($p=0.006$). Total sample size: 937.
Results – Humanistic Findings

- 120 of 335 (35.8%) studies reported humanistic outcomes.
- 50 of 120 (41.7%) studies rated as having Level 1 design.
- 59 of 120 (49.2%) studies rated as having Level 1 outcomes (e.g., quality of life [QoL]).
- 13 of 120 (10.8%) studies were conducted in inpatient settings, 97 of 120 (80.8%) settings were conducted in outpatient settings, and 17 of 120 (14.2%) studies were conducted in other settings.
- Favorable results were found in 12.9% (quality of life [QoL]) to 57.1% (patient knowledge) of studies.
- Meta-analyses performed on medication adherence, patient satisfaction, patient knowledge, QoL-general health, QoL-physical functioning, and QoL-mental health.
Favors pharmacist interventions/services. Standardized mean diff. = 0.6; \( p=0.001 \). Total sample size: 1,720.
Patient Satisfaction

No statistically significant difference ($p=0.18$). Total sample size: 1,326.

<table>
<thead>
<tr>
<th>Study Name</th>
<th>Std diff in Mean</th>
<th>Standard error</th>
<th>Variance</th>
<th>Lower limit</th>
<th>Upper limit</th>
<th>Z-Value</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Byxum, 2001</td>
<td>-0.629</td>
<td>0.344</td>
<td>0.118</td>
<td>-1.283</td>
<td>0.144</td>
<td>-1.540</td>
<td>0.124</td>
</tr>
<tr>
<td>Ebert, 1994</td>
<td>-0.590</td>
<td>0.253</td>
<td>0.064</td>
<td>-1.087</td>
<td>-0.093</td>
<td>-2.328</td>
<td>0.020</td>
</tr>
<tr>
<td>Mcclellan, 2003</td>
<td>-0.161</td>
<td>0.281</td>
<td>0.079</td>
<td>-0.711</td>
<td>0.389</td>
<td>-0.573</td>
<td>0.567</td>
</tr>
<tr>
<td>Mcclellan, 2003</td>
<td>-0.129</td>
<td>0.036</td>
<td>0.107</td>
<td>-2.184</td>
<td>-2.073</td>
<td>-2.228</td>
<td>0.026</td>
</tr>
<tr>
<td>Barree et al., 2000</td>
<td>0.109</td>
<td>0.137</td>
<td>0.019</td>
<td>-0.378</td>
<td>0.160</td>
<td>-0.193</td>
<td>0.428</td>
</tr>
<tr>
<td>Barree et al., 2000</td>
<td>0.100</td>
<td>0.136</td>
<td>0.018</td>
<td>-0.266</td>
<td>0.266</td>
<td>0.000</td>
<td>1.000</td>
</tr>
<tr>
<td>Hawkins, 1996</td>
<td>-0.125</td>
<td>0.139</td>
<td>0.019</td>
<td>-0.397</td>
<td>0.147</td>
<td>-0.099</td>
<td>0.369</td>
</tr>
<tr>
<td>Gain-mannel, 2000</td>
<td>-0.160</td>
<td>0.233</td>
<td>0.054</td>
<td>-0.617</td>
<td>0.296</td>
<td>-0.688</td>
<td>0.492</td>
</tr>
<tr>
<td>Finley, 2003</td>
<td>-0.407</td>
<td>0.219</td>
<td>0.148</td>
<td>-0.8518</td>
<td>0.023</td>
<td>-1.857</td>
<td>0.063</td>
</tr>
<tr>
<td>Schueller, 2006</td>
<td>-0.147</td>
<td>0.216</td>
<td>0.076</td>
<td>-0.688</td>
<td>0.350</td>
<td>-0.594</td>
<td>0.530</td>
</tr>
<tr>
<td>Capoccia, 2004</td>
<td>0.153</td>
<td>0.312</td>
<td>0.097</td>
<td>-0.458</td>
<td>0.765</td>
<td>0.491</td>
<td>0.624</td>
</tr>
<tr>
<td>Deitel, 2001</td>
<td>0.786</td>
<td>0.229</td>
<td>0.050</td>
<td>-0.306</td>
<td>1.204</td>
<td>3.290</td>
<td>0.001</td>
</tr>
</tbody>
</table>
Patient Knowledge

Favors pharmacist interventions/services. Standardized mean diff. = 1.14; \( p=0.001 \). Total sample size: 429.
QoL – General Health

Favors pharmacist interventions/services. Standardized mean diff. = 0.1; $p=0.003$. Total sample size: 2,070.
QoL-Physical Functioning

No statistically significant difference ($p=0.064$). Total sample size: 2,123.
QoL-Mental Health

No statistically significant difference ($p=0.362$). Total sample size: 2,123.
Results – Economic Findings

- 126 of 335 (37.6%) studies reported economic outcomes.

- 15 of 126 (11.9%) studies were rated as having Level 1 design.

- 81 of 126 (64.3%) studies rated as having Level 1 outcomes.

- 59 of 126 (46.8%) studies were conducted in inpatient settings, 62 of 126 (49.2%) settings were conducted in outpatient settings, and 6 of 126 (4.8%) studies were conducted in other settings.

- The economic review team found favorable results in 15.9% (n=20) of studies.

- No meta-analysis conducted for the following reasons: (a) limited number of studies; (b) varying study endpoints; and (c) many studies did not sufficiently address cost issues.
## Results – Economic Findings (n=126)

<table>
<thead>
<tr>
<th>Economic Results</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Favorable</td>
<td>20 (15.9%)</td>
</tr>
<tr>
<td>Not Favorable</td>
<td>0</td>
</tr>
<tr>
<td>Mixed</td>
<td>53 (42.1%)</td>
</tr>
<tr>
<td>No Effect</td>
<td>6 (4.8%)</td>
</tr>
<tr>
<td>Unclear</td>
<td>47 (37.3%)</td>
</tr>
</tbody>
</table>
Study Limitations

- Possibility of publication bias.

- Majority of studies did not report power/sample size analysis, and may not have been powered sufficiently to detect statistically significant differences.

- “Clinical/practical” significance may occur in the absence of statistical significance.

- As with any meta-analysis, when synthesizing the results of similar but independent studies, the impact of interventions may vary.
### Gaps and Suggested Steps

<table>
<thead>
<tr>
<th>Gaps in the Literature</th>
<th>Suggested Steps for Future Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limited number of therapeutic studies examining Level 1 outcomes</td>
<td>Increased examination of Level 1 outcomes</td>
</tr>
<tr>
<td>Many studies did not discern specific impact of pharmacists on patient care</td>
<td>Studies that include pharmacist contributions should be designed to explicate the duties and impact of pharmacist</td>
</tr>
<tr>
<td>Consideration of complexity of humanistic outcomes (e.g., multiple domains, multiple measures, confounding factors)</td>
<td>Narrow study focus to conceptualization of outcome most relevant to study purpose</td>
</tr>
<tr>
<td></td>
<td>Utilize both general and disease-specific measures</td>
</tr>
<tr>
<td></td>
<td>Give due consideration to influence of confounding factors</td>
</tr>
<tr>
<td>Lack of methodologically sound economic studies (e.g., lack of comprehensive measures of cost, do not include costs of intervention, lack of control groups)</td>
<td>Utilize control groups and appropriate statistical analyses</td>
</tr>
<tr>
<td></td>
<td>Include costs of interventions/services, etc., in analyses</td>
</tr>
<tr>
<td></td>
<td>Consider costs/benefits from multiple perspectives: societal, institutional, payer</td>
</tr>
</tbody>
</table>
Through the Years

- Earlier studies were more descriptive in nature regarding outcomes, but have progressed to greater utilization of statistical analysis to determine significance of outcomes.

- Earlier economic studies largely focused on drug costs, whereas more recent studies have improved by including other costs (e.g., interventions, health care utilizations).

- Some earlier studies lacked quality study design which has improved over the years with the incorporation of randomization and control groups.

- Increased examination of higher level outcomes over the years.
Summary

- Pharmacist-provided direct patient care interventions/services have a favorable impact across various patient outcomes (particularly therapeutic and safety), populations, and settings.

- Although gaps exist in the literature and there are numerous avenues for future research, the literature demonstrates favorable impact of pharmacists in improving care.

- Utilizing pharmacists in direct patient care offers a feasible strategy to combat health care quality challenges.

- There are opportunities and challenges.
Acknowledgement

Research supported by the ASHP Foundation
Team Members

Ivo Abraham, PhD, RN
Clara Ehrman, BS
Joshua Graff Zivin, PhD
Elizabeth Hall-Lipsy, JD, MPH
Richard Herrier, PharmD
Lisa Hymson, MPH
Sandra Kramer, MA
Jeannie Kim Lee, PharmD
Jennifer Martin, MA
John Palmer, MD, PhD
Marion Slack, RPh, PhD
Christina Spivey, PhD, LMSW
Tim Wunz, PhD
Never Doubt That A Small Group Of Thoughtful, Committed People Can Change The World. Indeed, It Is The Only Thing That Ever Has.