The Evolving Role of the Pharmacist in Clinical Care

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Objectives

• Describe the evolving landscape of oncology care and the role of the oncology pharmacist within clinical care areas with focus on potential impact on patient outcomes.

• Recognize opportunities for clinical oncology pharmacists to add value through activities such as post-chemotherapy follow-up visits, medication reconciliation, oral chemotherapy outpatient programs, and supportive care/palliative care management.

• Identify success and challenges with collaborative practice agreements (CPAs) in oncology pharmacy.
Patient Centered Care

• Interdisciplinary Team
  – Oncologist
  – Nurse Practitioner
  – Nurse Coordinator
  – Medical Assistants
  – Social Worker
  – Psychiatrist
  – **Pharmacist**
  – Others
New Roles for Oncology Pharmacists

• Historically…
History of Hem/Onc Drug Approvals

Oncology Pharmacy

- Increasing complexity of regimens
- Increase in drug approvals (oral, IV, etc.)
  - First in class
- Growing list of adverse effects
- Drug interactions
- Extensive monitoring protocols
Oral and Infusion Therapies: Annual Costs*

* If a patient pays cash price
“As the care of patients with cancer continues to be challenged with high-cost therapies, medication shortages, regulatory requirements, and dwindling reimbursement, the oncology pharmacist is heavily relied on to provide support for the clinical team to improve overall cancer care and patient quality of life.”

Oncology Pharmacist Training

<table>
<thead>
<tr>
<th><strong>Oncology Pharmacists</strong></th>
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<tbody>
<tr>
<td><strong>Training</strong></td>
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<tr>
<td>All licensed pharmacists possess degree in pharmacy (bachelor or doctorate), have passed national board and drug law examinations, and have completed at least 1,740 hours of practice experience.</td>
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Postgraduate training for specialization in oncology pharmacy includes:

<table>
<thead>
<tr>
<th><strong>Path 1</strong> (most common)</th>
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<tbody>
<tr>
<td>PGY1* and PGY2† residencies</td>
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<tr>
<td>≥ 1 year of work experience with ≥ 50% of time spent in oncology pharmacy</td>
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<tr>
<td>Successful completion of BCOP examination</td>
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<th><strong>Path 2</strong></th>
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<tr>
<td>Combination of postgraduate and/or on-job training specific to oncology pharmacy</td>
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<td>May lead to BCOP certification</td>
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Pharmacist Roles

• Optimal position to provide evidence-based care:
  – Initial treatment decisions
  – Subsequent therapeutics management
  – Supportive care/Palliative care
  – Survivorship
  – Education
New drug development …
New patient challenges
Drug Development

• 771 medicines and vaccines for cancer are in clinical trials or awaiting review by the FDA
  – 73 for breast cancer
  – 46 for colorectal cancer
  – 98 for lung cancer
  – 45 for prostate cancer
  – 78 for lymphoma
Drugs in Development

• Approximately 80% of investigational agents for cancer in the pipeline are potentially first-in-class treatments
  – Drug – drug interactions
  – First in human studies
  – New adverse reactions
Oral Chemotherapy

• Shift from IV anticancer therapy to oral therapy

Advantages:
• Avoids long infusion administration time
• Timed on patient’s schedule
• Advantageous for patients living far from an infusion center
Oral Chemotherapy

Disadvantages:

• Patient adherence and persistence
  • Average nonadherence rate to oral chemotherapy is estimated at 21%

• Erratic absorption

• Drug monitoring availability
Documented Problems with Adherence

**CALGB 49907 Adherence Companion Study**
- Adjuvant oral chemotherapy with Breast Cancer
- Adherence: microelectronic monitoring systems (MEMS)
- 83% persisted with capecitabine to protocol completion
- 25% took fewer than 80% of expected doses

**CML patients on imatinib for median of 59.7 months**
- 26.4 % had adherence rate ≤ 90% with 14% of these ≤ 80%
- Adherence had a strong correlation with response criteria
- In a multivariate analysis, adherence was the only independent predictor for CMR
# Barriers to Adherence

<table>
<thead>
<tr>
<th>Patient-specific Factors</th>
<th>Provider-related Factors</th>
<th>Treatment-related Factors</th>
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<tbody>
<tr>
<td>Health beliefs</td>
<td>Relationships</td>
<td>Complexity of regimen</td>
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<tr>
<td>Patient history</td>
<td>Satisfaction with care</td>
<td>Behavioral changes required for treatment</td>
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<tr>
<td>Social support</td>
<td>Insurance coverage</td>
<td>Cost</td>
</tr>
<tr>
<td>Socioeconomic status</td>
<td>Convenience of care</td>
<td>Duration of therapy</td>
</tr>
<tr>
<td>Age</td>
<td>Continuity of care</td>
<td>Adverse effects</td>
</tr>
<tr>
<td>Comorbid conditions and polypharmacy</td>
<td></td>
<td>Immediacy and evidence of benefit</td>
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</tbody>
</table>
Enhance Adherence

• Multidisciplinary programs for managing oral chemotherapy
One Method

- Prescription written by MD
- Routed to pharmacist for review & insurance check
- Oral chemotherapy teaching
- 48-72 hour follow-up phone call
  - Was the script filled & medication started
  - Adherence assessed
- 7-10 day follow-up phone call
  - Identify adverse drug effects
  - Assess administration, handling & safety
- Cycle completion - refill status checked
Pharmacist Review

• Medication Reconciliation
  – Prior to start of new treatment
  – Throughout treatment course
• Contraindications for Therapy Reviewed
• Prior adverse effects assessed
Ceritinib (Zykadia™) New Start

• Considerations:
  – Dosing: 750 mg (5 capsules) orally once daily on an empty stomach
  – Dose Adjustments:
    • Renal/hepatic (mild): no adjustment
    • Hold for elevated LFTs, ILD/pneumonitis, prolonged QTc, severe/intolerable N/V, persistent hyperglycemia, symptomatic bradycardia, uncontrolled BP, prior surgery, proteinuria
  – Pharmacokinetics: metabolized by CYP3A4
    • Drug-drug interactions:
      – CYP3A4/P-gp strong inhibitors: avoid or reduce ceritinib dose by 1/3 dose
      – CYP3A4/P-gp inducers: avoid
      – CYP3A4 and CYP2C9 substrates with narrow TI: consider dose reduction of substrate(s)
Patient Education

• Most common adverse effects (≥ 25%):
  – Diarrhea
  – Nausea
  – Transaminitis
  – Vomiting
  – Abdominal pain
  – Fatigue
  – Decreased appetite

• Most common Grade 3/4 adverse reactions (>5%):
  – Diarrhea
  – Fatigue
  – Transaminitis
  – Hyperglycemia
  – Hypophosphatemia
  – Increased lipase levels
  – Anemia
Tips

Counseling

- Take on an empty stomach
- May cause: nausea/vomiting, liver injury, interstitial lung disease, cardiac abnormalities, hyperglycemia
- Yellowing of the skin/eyes, dark urine

Monitoring

- Liver function tests (monthly)
- EKGs and electrolytes to monitor QTc-prolongation
- Blood glucose
- Heart rate and blood pressure
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48-72 Hour Follow-up

• Confirm date of starting medication
  – Delays with new access to therapy
    • Specialty Pharmacy Requirements
    • Patient Assistance

• Confirm appropriate method of taking therapy
  – Empty stomach (2 hours before or after meals)
  – Low Fat meal
7-10 day Follow-Up

• Start of adverse effects (outside of N/V)
  – Role for Collaborative Practice Agreement
  – Management of initial adverse effects

• Re-assess adherence, handling, and administration
Symptom Management Algorithms

- Anorexia
- Bleeding or Bruising
- Constipation
- Fatigue
- Fever and/or Chills
- Nausea/Vomiting
- Rash: EGFR
- Rash: non-EGFR
- Hypertension
- Hand-Foot Syndrome
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• **Cycle completion - refill status checked**
Cycle Completion

• Confirm manageable adverse effects
• Continue to assess adherence
• Monitor new medications started/stopped outside of oncology area
Symptom Management…
Opportunities for Growth
Evolving Landscape for Pharmacy

• Collaborative Practice Agreements (CPAs)
  – Arrangement between one or more physicians and pharmacists that permits the pharmacist to assume professional responsibility for performing patient assessments:
    • Drug therapy laboratory testing
    • Selecting/initiating/monitoring, continuing and adjusting drug regimens under a defined protocol
Collaborative Practice Agreements

• Many variations

• Different from Clinical Pharmacist Practitioner (CPP)
  – Can function as a physician assistant (PA) or nurse practitioner (NP)
    • North Carolina
    • Veterans Affairs (VA)
Missouri’s Medication Therapy Services (MTS)

• Missouri’s Rule (20 CSR 2220.6.060(1)(F))
  – Defines MTS:
    • “the designing, initiating, implementing, or monitoring of a plan to monitor the medication therapy or device usage of a specific patient, or to enhance medication therapeutic outcomes of a specific patient, by a pharmacist who has authority to initiate or implement a modification of the patient’s medication therapy pursuant to a medication therapy protocol.”
“Typical” Oncology CPA

• Patients & Diseases
• Diagnosis or Diagnoses/Drug Therapies/Monitoring
  – Prescriptive authority (Not in Missouri Law)
  – Guideline driven
  – Laboratory tests
• Plan for emergencies
  – Toxicity
  – On Call physician
Credentialing

• Additional education/certificate programs
  – Anticoagulation certificate
  – Diabetes certificate
  – CME/CE in specialty areas
  – Specialty Meeting Attendance

• Residency/Specialty Training(experience)
  – PGY2 Pharmacy Residency in Oncology

• Board of Pharmaceutical Specialties Certification in Oncology Pharmacy (BCOP)
Relationships

• The MOST important element!!!!
  – Regular interaction
  – Protocol review
  – Improvement strategies
  – Emergency plan
  – Patient notification
  – Termination provision
Legislative Requirements

• Licensure
• State to State interpretation of CPA
• Board Review
  – Pharmacy Board
  – Medical Board
• Other Issues
CPA Components

• Overview
  – Identify patients and disease state
  – Diagnosis or diagnoses

• Scope of Practice

• Physician Availability

• Focused and ongoing professional practice evaluation
  – Case based review
  – Recommendations for improvement and plan

• Procedures and prescribing authority

• Summary
Check List

• Check State Board of Pharmacy Practice Act
• Identify physician
• Develop CPA (MTS)
  – Duties and responsibilities
    • Focused - antiemetics protocol
    • Broad – patient assessment, prescribing
• Plan for ongoing review of care and quality improvement
Evolving Landscape

• Medication Therapy Management (MTM) programs
  – Medication therapy review
  – Pharmacotherapy management
  – Disease management
  – Pharmacogenomics
  – Medication safety
Patient Factors…
Changing oncology
Changing Landscape

• Oral Therapies
• Targeted Therapies
• Personalized Therapies
Tumor Genomics

• Patient referral
• Turn around time
  – Biopsy
  – Sequencing Time?
• Feeding into targeted clinical trials, Phase 1
• Commercially available targeted agents
Complex Process

- Patient consultation
  - Informed consent

- Medical staff
  - Collective decision
  - Biopsy

- Clinical data
- Biological material

- Biobank

- High-throughput platform
  - Microarray
  - NGS

- Low-throughput platform
  - IHC biomarkers

- Data pre-processing

- Bioinformatics platform
  - Storage and integration of heterogeneous data (clinical data, high-flow throughput data)
  - Extraction of new biological knowledge with analysis pipelines
  - Generation of reports with synthetic information for the therapeutic decision

- Biomedical staff
  - Results interpretation
  - Therapeutic decision

- EHR
  - Data record

- IT support
  - Data storage
  - High performance computing

- Bioinformatics pipelines
  - Data analysis

- Information system
  - Data integration
  - Knowledge and data sharing

- EHR
  - Data record

- Actor
  - Clinicians
  - Specialists
  - Surgeons

  - Anatomopathologists
  - Bioinformaticians
  - Biostatisticians
  - Data managers
  - Laboratory technicians
  - System administrators

  - Biologists
  - Clinicians
  - Pharmacists
Barriers to Clinic Implementation

• Molecular Diagnostics
  – Cost
  – Tissue quality
  – Tumor content
  – Turnaround

• Clinical Implementation
  – Tumor heterogeneity
  – Expert interpretation
  – Drug availability
  – Trial design and endpoints
  – Clinical validity and utility
Team Approach

• Tumor Genomics Board
• Patient Assistance
• Compassionate Use
• Drug to Target Selection
  – Multi-kinase inhibitors
  – Chemotherapy + tyrosine kinase inhibitor
Palliative Care/Supportive Care

• Evaluation of therapeutic options given patient specific factors

• Areas for Pharmacists:
  – Pain management
  – Nausea/Vomiting management
  – Anticoagulation management
  – Unique tyrosine kinase inhibitor adverse effects
Training the Future
Oncology Education

• Pharmacy School curriculum evaluation of oncology emphasis

• Exposure
  – Pharmacy Residency
  – Advanced Pharmacy Practice Education (APPE)
  – Introduction Pharmacy Practice Education (IPPE)

• Interprofessional opportunities
Future Directions
Historical Perspective: Justifying Pharmacy Clinical Services

– Cognitive services

– Value tied to the product
  • Cost avoidance or Cost savings
  • Examples:
    – Decreasing drug costs per hospital admissions
    – Managing high-cost drugs on formulary
    – Addressing duplicate therapies
    – Switching routes of administration
Continuing to show VALUE

• “Scope of Hematology/Oncology Pharmacy Practice”
  – Framework for oncology pharmacists to follow both inpatient and outpatient
• Billing for services
• Research
Clinical Trials

• Increasing demand for oncology pharmacists to be co-investigators or principal investigators in clinical trials

• Positions on IRB

• Protocol Review Process
Continuous Quality Improvement (CQI)

• Pharmacovigilance
  – Enhancing data driven analytic methods commonly used in practice

• Medication Safety
“Oncology pharmacists are viewed as cancer medication experts based on their training, expertise, and knowledge, and they function best in a collaborative environment with other health care professionals whose expertise complements their own.”

Citations

• Chen B, Harvey RD, Liewer S, Valgus J. *ASCO expert corner:* the role of an oncology pharmacist. Cancer.net


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