Implementation of Specialty Pharmacy in Conjunction with an Oral Chemotherapy Counseling Clinic

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Pharmacist Objectives
• Review the operational processes of a Specialty Pharmacy that supports oral chemotherapy
• Describe the Specialty Pharmacy team’s interactions with care teams and patients to improve adherence
• Understand key components in the implementation of an oral chemotherapy counseling clinic
• Describe the pharmacist’s role in managing an oral chemotherapy clinic
• Describe tips to help counsel oncology patients to overcome barriers with oral chemotherapy

Disclosure
I do not have (nor does any immediate family member have) a vested interest in or affiliation with any corporate organization offering financial support or grant monies for this continuing education activity, or any affiliation with any organization whose philosophy could potentially bias my presentation.

Technician Objectives
• Review technician workflow in a specialty pharmacy
• Identify opportunities for technicians in an oral chemotherapy counseling clinic

Specialty Pharmacy

- HIV
- Cancer
- Infertility
- Hepatitis
- Rheumatoid Arthritis
- Transplant

- Requires special handling and/or delivery
- May have requirements that must be met to dispense
- Utilized for a complex disease
- Potential for significant waste
Specialty Pharmacy Defined

- Designed to deliver medications with special handling, storage and distribution
- Designed to improve clinical outcomes
- Ongoing clinical support for patients
  - Promote adherence and avoid unnecessary costs
  - Integration with clinicians, manufacturers, financial assistance

Growth of Specialty Pharmacy

- Specialty drug spending in 2012 - $87 billion
  - ~25% of total drug spending
  - ~3.1% of national health spending
  - Estimated to quadruple by 2020 - $400 billion

Share of specialty drug spending by disease state for UnitedHealthcare fully insured commercial plans, 2012

- Oncology: 28%
- Transplant: 3%
- Cardiovascular: 3%
- Growth Hormone: 2%
- Hepatitis C: 2%
- Hemophilia: 2%
- IVIG: 4%
- Multiple Sclerosis: 12%
- Pain Management: 6%
- Other: 19%

Specialty Pharmacy Accrediting Bodies

- Utilization Review Accreditation Commission (URAC)
- Accreditation Commission for Health Care (ACHC)
- The Joint Commission (TJC)
- Center for Pharmacy Practice Accreditation (CPPA)

Specialty Pharmacy Accrediting Bodies

- Organization and Administration
- Pharmacy Operations
- Clinical Management
- Quality Reporting and Improvement
**About SPCB**

- Accredited by the National Commission for Certifying Agencies
- Positions pharmacist to better serve the physician & payer
- Elevates status of the specialty pharmacy professional

**Exam Qualifications**

- BSPharm or PharmD
- Current, active pharmacy license in the US or Canada
- 30 hours of Specialty Pharmacy CE in the past 2 years
- 3000 hours of Specialty Pharmacy practice in the past 4 years

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**Specialty Pharmacy Workflow**

1. **New patient:** Call Center receives referral along with patient demographic, 3rd party information.
2. **Product distribution limitation identified.**
3. **Data entry into pharmacy operating system.**
4. **RX preview.**
5. **Third party out of network identified.**
6. **Transfer referral to a manufacturer in-network pharmacy.**
7. **MSRX able to fill and dispense specialty medication.**
8. **PA resolved.**
9. ** Appeals issues resolved.**
10. **Follow up in 48 hours.**
11. **Refill patient:**
    - Patient is cycled for refill one week prior to due date.
    - Pharmacist clinical review of EMR.
    - Reassessment is completed.
    - Patient contacted to schedule delivery.
    - Resolve PA or copay issues.
12. **Pharmacist will complete initial assessment:**
    - Clinical review of the prescription, patient medical history, allergies, concurrent therapies.
    - Counsel patient on administration guidelines, administration training, adverse reactions, warnings.
    - Review with patient adherence and compliance support they will receive from pharmacy.
13. **Medication is ordered.**
14. **Tech Fill, RPH Verification and POS check out.**
15. **Pack specialty medication and ship via national courier or a local courier service.**
16. **Shipped order is scheduled for timing of next fill to initiate refill and adherence reminder to patient or doctor’s office.**

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**Staff Requirements**

- Pharmacists
  - Front end
  - Back end
- Technicians
  - Front end
  - Back end
  - Filler
  - Packier
  - Shiffer
- Buyer
- Reimbursement Specialists (R.S.)
- Call center

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**Referrals**

- Pharmacy reimbursement specialists located in physician office.

**Prescription processing initiated**

- Demographic information entered
- Pharmacist initial review of prescription
- Oral oncology prescriptions clarified with clinical specialist as needed.

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** Memorial Specialty Pharmacy**

![Diagram of Memorial Specialty Pharmacy workflow]

**Data entry into pharmacy operating system.**

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**Specialty Pharmacy Workflow**

- Referrals
  - Pharmacy reimbursement specialists located in physician office.
- Prescriptions processing initiated
  - Demographic information entered
  - Pharmacist initial review of prescription
  - Oral oncology prescriptions clarified with clinical specialist as needed.

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![Image of Specialty Pharmacy Workflow diagram]
Specialty Pharmacy Workflow

- Medicated
- Patient laboratory results are met
- PPI resolved
- COP received
- PPI resolved
- Transfer referral to specialist in network pharmacy
- Follow-up in 48 hours
- Review PA resolution

Pharmacist, Technician, Buyer, R.S.

PA: Prior authorization

Benefits of a Health System Specialty Pharmacy

- Access to EMR
- Up to date laboratory values
- Access to pathology
- EPIC in-basket messaging to the physician and other members of the healthcare team
- Consultation and prescription reviews by an oncology trained pharmacist
- Located within the clinic with direct access to the physician
- Potentially faster turn around time

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Oral Chemotherapy

Advantages

- Increased control and convenience for the patient
- Potential increase in the quality of life
- Sustained medication exposure
- Potential reduction in travel costs and use of health care resources

Disadvantages

- More likely susceptible to errors
- Nonadherence
- Increased adverse effects

Oral chemotherapy

- Chemotherapy defined:
  - "All antineoplastic agents used to treat cancer, given through oral and parenteral routes or other routes as specified in the standard. Types include targeted agents, alkylating agents, antimetabolites, plant alkaloids and terpenoids, topoisomerase inhibitors, antitumor antibiotics, monoclonal antibodies, and biologics and related agents. Hormonal therapies are not included in the definition for the standards."

Shift in Responsibility of Cancer Care

- The rise of oral oncolytics places patients more in control of their care
- Adherence
- Toxicities
- Importance of the pharmacist role studied in a variety of settings
- Patient follow-up and monitoring is important for improved outcomes and tolerability

American Society of Clinical Oncology (ASCO) & Oncology Nursing Society (ONS) Safety Standards

- "Before initiation of an oral chemotherapy regimen, assessment of the patient’s ability to obtain the drug …"
- "All patients prescribed oral chemotherapy are provided written or electronic patient education materials…"
- Storage, handling, preparation, administration, and disposal
- Concurrent cancer treatment and supportive care medications/measures (when applicable)
- Possible drug/drug and drug/food interactions
- Plan for missed doses
- "Institution maintains a written policy and/or procedure to complete an initial assessment of patients' adherence… plan for clinical staff to address."
- Confirmation the prescription was filled
- Inquire about treatment costs
- Verify patient understands how to take and what to do for missed dose

Quality Oncology Practice Initiative

- ASCO QOPI Certification Program
  - Review an institution’s compliance with quality standards
  - Three-year certification
  - "Demonstrates to patients, payers, as well as the medical community, a practice’s commitment to quality"
- Maintain a plan for ongoing assessment of oral chemotherapy adherence and toxicity

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Memorial Cancer Institute Oral Chemotherapy Clinic

- Development of treatment plans for oral chemotherapy
- Standard documentation and education
- Medication specific guidelines for monitoring
- Development of workflow and staff training

Oral Chemotherapy Treatment Plans

- Initiation of treatment plan for oral chemotherapy
- Medical doctor orders oral chemo
- In-basket message sent to pharmacist
- RX reviewed: New remains on list for consult
- Patient work-up & assessment of start date

Provider

- Initiates treatment plan for oral chemotherapy
- Orders as a prescription if there is no plan created
- If provider initiates "consult to pharmacy"
- Initial introduction is made
- Education usually not provided at this time
- Length of time until prescription received
- Full work-up needed
- Prescription given to Pharmacy Reimbursement Specialist

Pharmacist

- Methods of Oral Chemotherapy Prescription notification
  - In-basket notification
  - Specialty Pharmacy Consult
  - Physician
  - Reimbursement Specialist
- Prescription assessment
  - Established therapy: Review prescriptions, labs and drug interactions
  - No further action
  - New therapy
    - Patient work-up
    - Physician contacted if needed
    - Specialty pharmacy contacted if needed

Pharmacy Reimbursement Specialist

- Introduction to patient
  - Role with prescription co-pay assistance
  - Specialty Pharmacy
  - Clinical Specialist consult
- Prescription is sent to Memorial Specialty Pharmacy
- Documentation into EMR

Oral Chemotherapy Workflow Overview

- MD orders oral chemo
- In-basket message sent to pharmacist
- RX reviewed: New remains on list for consult
- Patient work-up & assessment of start date

Drug order placed
- Documentation
- F/u scheduled
- Ongoing f/u until completion of treatment
Patient Education

- Status of prescription delivery assessed
  - Unless requested earlier by the patient, education provided within one week of delivery
- Consult via telephone or in-person
- Introduction of service
- Assessment of patient's current understanding of therapy
  - “What questions do you have about your new medication?”
  - “What side effects are you aware of”
- Provide education in the order of note template
- Perform medication reconciliation

Patient Education

- If possible provide medication calendar
- Use open-ended questions when assessing adherence and side effects
  - If medication is cycled, verify when week off/on occurred
  - Probe for side effects
    - Patients may associate diarrhea with poor food choices
    - Patients with preexisting hypertension may not associate an increase in blood pressure with their oral chemotherapy
- Utilize teach-back method for key counseling points
- Medication schedules may be complex; provide an example of what a typical week would look like
Guidelines and Resources
- Evaluation of therapy
  - National Comprehensive Cancer Network Guidelines
  - Primary literature
  - American Society of Clinical Oncology
- Drug specific
  - UpToDate
  - Micromedex
- Patient information
  - Chemocare.com
  - Manufacture website
  - Calendars

Tools and Resources
- Oncology Nursing Society (ONS) toolkit
- MASCC Teaching Tool for Patients Receiving Oral Agents for Cancer
- Assessment Questions
- Patient Education
- Drug specific education
- Evaluation

Safe Handling of Oral Chemotherapy
- Manufacturer and distributor
- Packaging and segregation
- Health care providers
  - Training and competencies
  - Not to be dispensed in automatic counting machines
  - Any compounding, crushing or cutting should be done in a biological safety cabinet with personal protective equipment
- Patients and caregivers
  - Use gloves if possible
  - Minimize contact

Summary
- Growth of specialty medication spending is expected to quadruple
- Specialty pharmacies function to improve outcomes and eliminate waste
- Oral chemotherapy education is key to increasing adherence, minimizing toxicities as well as improving outcomes
- Pharmacy technicians have an important role within Specialty Pharmacy as well as in an Oral Chemotherapy Counseling Clinic

References
8. Corticosteroids conversion calculator (hydrocortisone, dexamethasone, prednisone, methylprednisolone, betamethasone) http://www.globalrph.com/corticocalc.htm

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