A Pharmacist-Run Oral Chemotherapy Program: An Economic and Clinical Opportunity

Robert Mancini, Pharm.D.
David B. Wilson, R.Ph.
Outline

- Emergence of Oral Chemotherapies
- MSTI Oral Chemotherapy Department
- ONS Standards for Handling Chemotherapy & How it Applies
- Benefits & Risks of Oral Chemotherapy
- Business Model Development
- Economic Outcomes

Emergence of Oral Chemotherapy

- Oral Chemotherapies have been available for decades
  - Chlorambucil, MTX, 6-MP, cyclophosphamide
- New era started with approval of Xeloda in 1998
- Last 6 years have seen an explosion in development
- 25 Million doses annually
- One-Fourth of all new cancer agents are oral
  - Currently 5% of all antineoplastics


1950-1997: 14 Oral Chemo Agents
1998- Present: 19 New Agents

1964- Melphalan
1966- Thioguanine
1967- Hydrea
1969- Procarbazine
2005- Nexavar & Revlimid
2006- Sprycel
Sutent
Zolinza

1953-1997: 14 Oral Chemo Agents
1998- Present: 19 New Agents
Trends in Oral Chemo Prescribing

• Based on Current Trends
  – Now: 7 new, 23 refills per week
  – In 2 years: 14 new, 128 refills per week

• Zytiga as an example
  – 6 prescriptions first day it was available
  – 21 new patients in first month
  – If 25% of newly approved drugs are oral, what is likely to happen?

Prescription Quantities
ONS Guidelines for Chemotherapy Administration Safety

- Documentation Standards
- Ordering Standards
- Preparation Standards
- Administration Standards
- Follow-up/Monitoring Standards

Figure 1. Chemotherapy Administration Flow

Benefits of Oral Chemo

• CONVENIENCE!!!
  – Mostly for the patient, of course
  – Patients prefer oral agents to IV provided efficacy is not compromised
• Less interruption of day to day life

Risks of Oral Chemotherapy

• Adherence/Compliance
  – Complex dosing schedules
  – May only be certain days of the week
  – Weeks on vs. Weeks off
  – Several pills per dose
• Adherence rates average 40-50%
  – With long-term therapy
  – Alters ability to treat disease
• Dr. Tsang ASCO Abstract 2006
  – Only half of patients on Gleevec took as prescribed
Adherence Rates

The problem is grave for cancer patients

Poor medication adherence can lead to:

- unnecessary disease progression
- complications
- reduced functional abilities
- lower QOL
- premature death

Stages of Change (At Best)

- Human beings need time to adapt to change
- The normal stages of change are:
  - Pre-contemplation (getting ready)
  - Contemplation (deciding to act in the future)
  - Preparation (getting ready to act)
  - Action (not a linear process; may include backsliding)
Process of Adaptation
• 10% of people can easily adapt to change
• 60% of people want to change, but experience great difficulty
• 30% lack the capacity or the will to change

Areas Amenable to Change
• Some areas of the adherence dilemma are more amenable to change:
  – Access to medications
  – Regimen complexity
  – Cost related problems
  – Medication beliefs (misinformation, fear, distrust, denial)
  – Depression (Rand Corporation 2009)

Risks of Oral Chemotherapy
• Changes in work flow
  – Moves patients out of infusion centers
  – Decreases income if scripts are sent to outside pharmacies
  • A lot of unreimbursed staff time
    – Education
    – Co-pay & patient assistance
  – Complex reimbursement strategies
  – Difficulty in ensuring adherence
Risks of Oral Chemotherapy

- Accessibility
  - Insurance frequently requires prior auth, inhibiting ease of access
  - Outpatient pharmacies don’t stock these regularly
  - Many require special requirements to dispense

Drug Interactions

- Warfarin (Increased INR)
  - Capecitabine (Xeloda)
  - Erlotinib (Tarceva)
  - Mercaptopurine (6-MP)

- CYP 3A4 Inhibitors & Inducers
  - Lapatinib, Imatinib, Dasatinib, Nilotinib, Sunitinib, Sorafenib & Erlotinib

- Food vs Empty Stomach
- Dasatinib needs acidic environment

Pharmacist Interventions

- Dose Adjustments for Renal & Kidney Function
- Twenty documented interventions
Risks of Oral Chemotherapy

- Costs
  - Some covered under major medical
  - Some covered only under prescription insurance
    - Exorbitant co-pays
    - Lack of coverage


Risks of Oral Chemotherapy

How to Create Your Program
Analyze Current State

- Number of patients seen
- Number or percentage on oral chemo
- What drugs
- Cost and reimbursement of those drugs
- Percentage of referrals expected

Perform Pilot for Proof of Concept

- Implement on a limited basis. Good luck.
- Need a retail pharmacy
- This is NOT something for nothing.
  - 40 hrs/wk x 1 month
  - 20 hrs/wk x 2 more months

Use Pilot results to validate and refine proposal

- Develop workload expectations
- Determine space and equipment needs
- Determine staffing needs
Oral Chemo Break Even Point Analysis

<table>
<thead>
<tr>
<th>Costs</th>
<th>Dollar Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salaries</td>
<td>$170,000</td>
</tr>
<tr>
<td>Non-Salary Overhead</td>
<td>$5,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prescription Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Rx’s</td>
<td>402</td>
</tr>
<tr>
<td>Avg Rx Price</td>
<td>$3,217</td>
</tr>
<tr>
<td>Avg Rx Markup</td>
<td>$1,883</td>
</tr>
<tr>
<td>Bad Debt Percent</td>
<td>3.00%</td>
</tr>
</tbody>
</table>

**Assumptions**
- Pts on Active Tx: 844
- % Pts on Oral Chemo: 25%
- % Referrals to OC: 50%
- Rxs & Rf/pt/yr: 4
- Yearly Rx & Rf for BEP: 82

**Annualized from Pilot**
- Gross Revenue: $1,357,574
- Cost of Goods Sold: $562,948
- Fixed Costs: $175,000
- Bad Debt: $40,727

**Net Revenue**: $619,626

The Mail Order “Issue”

Create a Business Plan

- Numbers
- Resources needed
- Impact on
  - Patient Satisfaction
  - System Improvement (incl MD, RN satisf)
  - Patient Safety
  - Financial Impact
Justify the resources

- 4 items from previous slide
- Less than 1% write offs. Yes. <1%
- Over $1 million in free drug from MFG
- ~$200,000/yr in patient assistance funds
- Adherence… patient don’t get these filled
- Safety
- Outside Audits
- Continual feedback/reporting to Admin

References

- Curtiss FR. Pharmacy Benefit Spending on Oral Chemotherapy Drugs. J Managed Care Pharm. 2006;12(7):570-17
- ASCO Best Practices: Increased Use of Oral Chemotherapy Drugs Sparks Increased Attention to Patient Adherence