Implementation of an Internal Check of Oral Oncolytics: A Single-Center, Specialty Pharmacy Safety Initiative

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Introduction
In 2008, the National Cancer Institute estimated 25% of cancer care occurs in the ambulatory setting.1
• Over 25 million oral doses of oral oncolytic therapy administered annually.2
• An error rate of 8.1 per 100 clinic visits has been estimated in published literature.3
A 2005 survey of US cancer centers observed:
• Few centers have standard safeguards for oral oncolytic therapies.
• Most institutions have minimal infrastructure to support adherence.
• On-site pharmacies and consultations with pharmacists are underutilized.4
Between 2014 and 2018, there were over 30 new oral oncolytic medications added to the market by the FDA.
• Suggests published estimates are now outdated.

Discussion
• Oral oncolytic therapy is exponentially growing and poses unique challenges due to the risks associated.
• There is currently no consensus for the safe practice of oral oncolytics.
• Standardization is desperately needed to promote a consistent practice amongst the health care profession.
• Roles of the pharmacist include: a higher vigilance towards ensuring patient centered counseling, toxicity management, adherence monitoring, and financial assessment.
• Implementing an internal checking tool of oral oncyltics creates a standardized safety check and promotes active communication with oncology care teams.
• A double check process is standard for intravenous therapies, yet is not required for oral oncyltics.
• This single center analysis of 2 BSA-dosed oral oncyltics showed 34% of interventions required pharmacist intervention.
• Missing pre-medications were most commonly needed clarification prior to oral oncyltics script fill.
• Laboratory results requiring clarification to continue filling prescription and drug interaction clarifications were other common reasons for intervention.
• Access to pharmacists in clinic with providers minimized the need for the specialty pharmacy to directly receive clarification from providers.

Objectives
1. Create a standardized check process for oral oncyltics
2. Obtain prescription clarification in the beginning of the fill process
3. Create a form of communication between the care team and specialty pharmacy
4. Review quality metrics of implementation of an oral oncyltic check process for a hybrid specialty and ambulatory model to enhance medication safety and improve vigilance.

Methods
• Single academic medical center quality improvement study
• Standardized pharmacist check process and documentation of BSA Dosed Medications
  • Expectation and tolerization
  • Process implemented in December 2016
• 22 months of specialty pharmacy i-vent documentation in the electronic medical record, Epic, were evaluated and quantified

<table>
<thead>
<tr>
<th>Interventions Identified (n=630)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Missing Pre-Medications: 16%</td>
</tr>
<tr>
<td>Missing/Incorrect Laboratory Results: 28%</td>
</tr>
<tr>
<td>Drug-Dose Interaction: 14%</td>
</tr>
<tr>
<td>Dose Clarification: 8%</td>
</tr>
<tr>
<td>Quantity Supply Requests: 4%</td>
</tr>
<tr>
<td>Drug Change Requests: 2%</td>
</tr>
<tr>
<td>No Intervention Required: 100%</td>
</tr>
</tbody>
</table>

The average time required for a specialty pharmacist to review and document encounter per intervention was 12.1 minutes (Range: 10-45 minutes).

A specialty pharmacist referred to a clinical pharmacist directly working with the interdisciplinary team in 22.2% of cases
A specialty pharmacist referred to a provider directly 3.7% of cases

References

Results

Specialty Pharmacist Interventions Per Patient (n=1619)

<table>
<thead>
<tr>
<th>Intervention Category</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug-Drug Interactions</td>
<td>54%</td>
</tr>
<tr>
<td>Dose Clarification</td>
<td>16%</td>
</tr>
<tr>
<td>Quantity Supply Requests</td>
<td>4%</td>
</tr>
<tr>
<td>Drug Change Requests</td>
<td>2%</td>
</tr>
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<td>No Intervention Required</td>
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</tr>
</tbody>
</table>

Conclusions
• Implementation of an internal checking tool of oral oncyltics creates a standardized safety check and promotes active communication with oncology care teams.
• Oral oncylotic therapy pose high risk to patient safety and an increase of standardized checking is required to minimize errors.
• Expanding the double check process to include oral oncyltics is ongoing; however, requires resources to allow pharmacist dedicated time to complete checks outside normal operation workflow.

Specialty Pharmacist Check Process

<table>
<thead>
<tr>
<th>Specialty Pharmacist Documentation SmartPhrase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confirm Prescription: Name of medication, route, dose (Manual BSA Calculation)</td>
</tr>
<tr>
<td>Confirm Patient: Name, DOB, ID, phone</td>
</tr>
<tr>
<td>Clinical Review: Review Laboratory Data in Epic: ANC, WBC, platelets, Estimated Renal Function, LFT, Albumin, etc.</td>
</tr>
<tr>
<td>Supportive Care: Antimicrobials, tumor lysis syndrome prophylaxis, etc.</td>
</tr>
</tbody>
</table>

Specialty pharmacy can confirm and coordinate delivery to patient.