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 90% 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 market by the FDA.

- Suggests published estimates are now outdated.
- Greater than ever safety concern for dispensing orally administered therapies in the oncology population.

The American Society of Health-System Pharmacists (ASHP) guidelines on preventing medication errors with chemotherapy and biotherapy:

- **Administration (56%) and ordering (36%) were the most common phases of the medication use process where errors occur.[5]**
- A questionnaire of National Cancer Institute cancer centers identified a **lack of standardization** due to a lack of compulsory requirements.[4]

There remains neither consensus nor best practice statement for the safe practice of oral oncolytic therapies in the United States

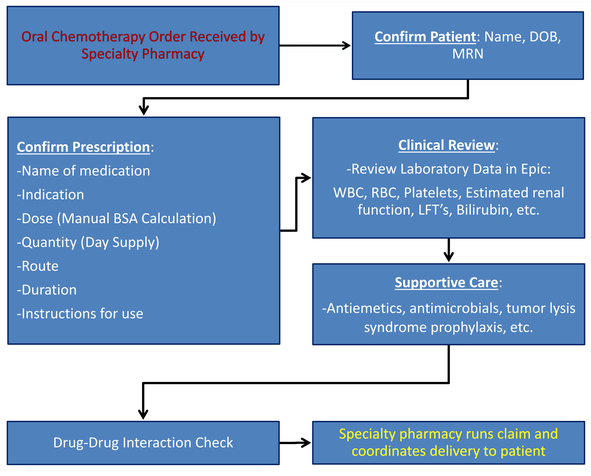
Objectives

1. Create a standardized check process for oral oncolytics
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 oncolytic 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
  - Capecitabine and temozolomide
- Process implemented in December 2016
  - 22 months of specialty pharmacist i-vent documentation in the electronic medical record, Epic, were evaluated and quantified

Specialty Pharmacist Check Process



Specialty Pharmacist Documentation SmartPhrase

Prescriber: ***

Oral Chemotherapy Regimen: ***

Indication for oral chemotherapy: ***

BSA: ***

Dose verified within the limits of regimen/protocol: {yes / no:107576:::1} ***

Appropriate Day Supply/Refills: {yes / no:107576:::1} ***

Lab values appropriate for treatment: {yes / no:107576:::1} ***

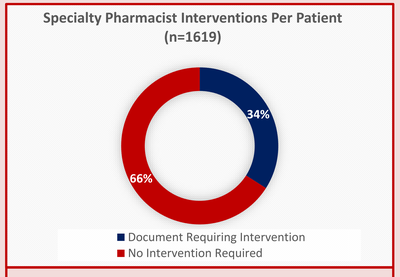
Allergy Evaluation: {yes / no:107576:::1} ***

Drug Interactions: {yes / no:107576:::1} ***

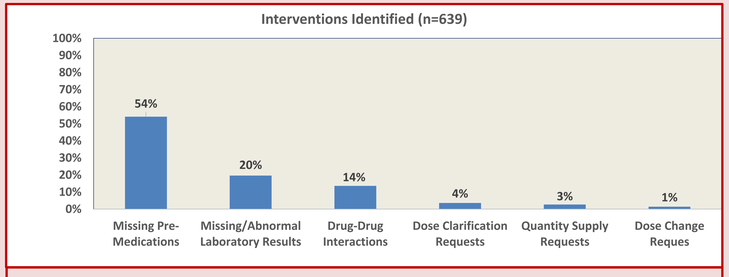
Appropriate pre-medications ordered: {yes / no:107576:::1} ***

Comments/ Notes regarding orders: ***

Results



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

Discussion

- Oral oncolytic therapy is exponentially growing and possess 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 oncolytics 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 oncolytics.
  - This single center analysis of 2 BSA dosed oral oncolytics showed 34% of interventions required pharmacist intervention.
  - Missing pre-medications were most commonly needed clarification prior to oral oncolytic script fill.
  - Laboratory results requiring clarification to continue filling prescription and drug-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.

Conclusions

- Implementation of an internal checking tool of oral oncolytics creates a standardized safety check and promotes active communication with oncology care teams.
- Oral oncolytic 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 all oral oncolytic agents is ongoing; however, requires resources to allow for pharmacist dedicated time to provide clinical checks outside normal operation workflow.

References

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