Category: Clinical Trial Operations – Completed Project

The Dog Ate My Pill Diary and Other Stories From the Frontlines of Drug Accountability

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1. Background

Karmanos Cancer Institute is an NCI designated Comprehensive Cancer Center and a Quality Oncology Practice Initiative (QOPI) certified site. In preparation for our QOPI re-certification we recognized we could apply those standards to enhance documentation and communication of drug accountability for our research patients. There was a need for more robust, real time documentation of drug compliance that could be standard for all clinical trial patients. We created and implemented the Management of Oral Investigational Drug (OID) policy, workflow, and nursing documentation aid that met the needs of the hospital requirements and research standards. This included compliance, patient education, return visit instructions, clinic contact, and specific dosing instructions.

2. Goals

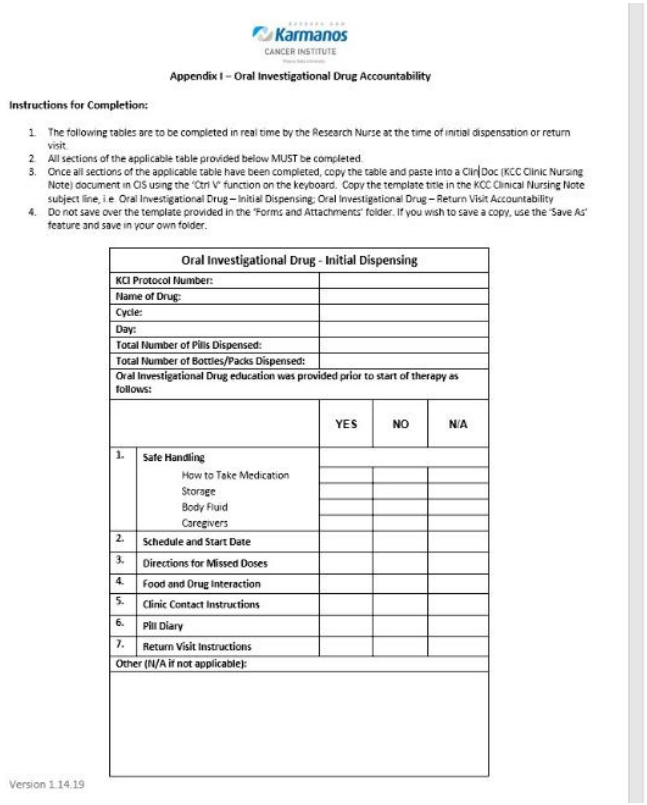
Primary goals in order to meet QOPI standards and research objectives:

- Monitor patient adherence to OID administered outside of the health care setting at clinically meaningful intervals
- Ensure documentation of dosing, education, and compliance is available in the electronic health record (EHR)
- Standardization of OID accountability across all Multidisciplinary Team (MDT) services
- Address and limit discrepancies between OID dispensed and OID returned to improve data accuracy

3. Solutions and Methods

Methods:

- Developed a working group consisting of Research Nurses (RN) and Study Coordinators (SC) to ensure the process met all needs
- Institutional standards, QOPI, and research requirements were utilized when creating the policy and workflow
- Accountability is performed at every study visit, uploaded in the EHR using the nursing documentation aid, and is completed independent of sponsor requirements
- Standardized pill diary templates were created for use when not provided by the sponsor
- New process was piloted for one month (approximately 100 patient visits) to identify potential issues
- Process was amended based on pilot experience, finalized, and formally implemented across all MDTs



Karmanos CANCER INSTITUTE

Appendix I – Oral Investigational Drug Accountability

Instructions for Completion:

1. The following tables are to be completed in real time by the Research Nurse at the time of initial dispensation or return visit.
2. All sections of the applicable table provided below MUST be completed.
3. Once all sections of the applicable table have been completed, copy the table and paste into a ClinDoc (KCC Clinic Nursing Note) document in CIS using the 'Ctrl V' function on the keyboard. Copy the template title in the KCC Clinical Nursing Note subject line, i.e. Oral Investigational Drug – Initial Dispensing; Oral Investigational Drug – Return Visit Accountability
4. Do not save over the template provided in the 'Forms and Attachments' folder. If you wish to save a copy, use the 'Save As' feature and save in your own folder.

Oral Investigational Drug - Initial Dispensing				
KCI Protocol Number:				
Name of Drug:				
Cycle:				
Day:				
Total Number of Pills Dispensed:				
Total Number of Bottles/Packs Dispensed:				
Oral Investigational Drug education was provided prior to start of therapy as follows:				
		YES	NO	N/A
1.	Safe Handling			
	How to Take Medication			
	Storage			
	Body Fluid			
	Caregivers			
2.	Schedule and Start Date			
3.	Directions for Missed Doses			
4.	Food and Drug Interaction			
5.	Clinic Contact Instructions			
6.	Pill Diary			
7.	Return Visit Instructions			
Other (N/A if not applicable):				

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Oral Investigational Drug – Return Visit Accountability			
KCI Protocol Number:			
Name of Drug:			
Cycle:			
Day:			
Total Number of Pills Returned/Remaining:			
Total Number of Pills that Should be Returned/Remaining:			
Number of Bottles/Packs Returned to Pharmacy:			
		YES	NO*
1.	Diary Reviewed for Completeness		
2.	Taking Oral Investigational Drug (including all required doses) per Protocol Requirements		
3.	Discrepancies Reviewed with the Treating Physician		
* 'No' responses require explanation below. Document strategies to improve compliance, if applicable.			
		YES	NO*
Is dosing continuing for this participant?			
* Document rationale for participant not continuing oral investigational drug (e.g., dose held, discontinuing, end of treatment, etc.)			
Total Number of Pills Dispensed:			
Total Number of Bottles/Packs Dispensed:			
Today's Dose from:		Remaining Supply	New Supply
		YES	NO*
1.	New Pill Diary Provided		
2.	Return Visit Instructions Provided		
* 'No' responses require explanation below.			

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4. Outcomes

Standardizing this process among patients receiving OID has created a notable positive effect on the patient experience, compliance, data quality, and documentation. This policy and workflow guide the RN in a conversation with the patient and clinician to review compliance and enhance patient safety. It enables the RN to clarify discrepancies between the diary and pill count and identify patient dosing errors contemporaneously. OID dosing is documented more frequently and enables timely data entry and query resolution. The development of the OID policy, workflow, and nursing documentation aid ensures consistency across all MDTs. Availability of the documentation in the EHR improves communication among all clinical and research staff.

5. Lessons Learned

We have observed an improvement in patient compliance and expectation when patients are mindful that their dosing will be reviewed at every study visit. In turn, patients are empowered to become active participants in their own care. This frequent interaction has strengthened the rapport between patient and staff. The future direction of our institution is to utilize a comprehensive electronic medical record (EMR). This process can be easily modified and incorporated into the EMR.

We may not be able to stop the dog from eating the pill diary, but this process has provided us with documentation of compliance that we otherwise would not have.