Category: Trial Start-up and Activation – Completed Project

Evaluation of a Prioritization Matrix for Electronic Order Build in an Investigational Drug Service

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1. Background

Investigational drug services (IDS) play an important role in safely and efficiently managing agents in clinical studies. However, in institutions with large research portfolios, it can be challenging to prioritize which studies to initiate and how to focus effort given finite resources. The implementation of drug orders in the electronic health record system was identified as a time-intensive process that could benefit from a prioritization schema. Currently, a comprehensive build involving physician and nursing communications, hold parameters, supportive care orders, and investigational drug orders is prepared before enrollment begins for all studies requiring on-site administration.

2. Goals

We sought to create standardized criteria for prioritizing studies that had the potential to justify abbreviated order builds. As a test of concept, the matrix was applied to a sample of recently initiated studies by the Michigan Medicine Research Pharmacy.

3. Solutions and Methods

A 2x2 matrix with study complexity on one axis and safety risk level on another was developed by the authors. The matrix sorted studies into three priority groups based on study characteristics. Each priority corresponded to the degree of order build that would be required prior to enrollment of the first subject. Priority 1 (high complexity, high safety risks) would require a comprehensive build; Priority 2 (mixed degrees of complexity and safety) would involve only a drug orderable; and Priority 3 (low complexity, low safety risks) would use a generic editable drug order template.

4. Outcomes

Twenty studies were included in the analysis (10 hematology/oncology and 10 non-hematology/oncology studies). Six studies were deemed to be Priority 1 and would have required a comprehensive build; of these, 4 were non-hematology/oncology protocols. Thirteen studies were categorized as Priority 2; of these, 8 were hematology/oncology studies and involved ISMP High-Alert Medications. Indeed, among the Priority 2 studies, high safety risks were more commonly the reason for an elevated priority than high study complexity. There was 1 study (a non-hematology/oncology protocol) that was scored as Priority 3.

5. Lessons Learned and Future Directions

Nearly all studies would require a degree of order build prior to first patient enrollment. Relying on just-in-time orders to reduce workload does not appear tenable given the low number of Priority 3 studies. Further, the downstream implications of creating an abbreviated build versus a comprehensive build must be considered (e.g., impact on nursing staff).