Evaluation of the impact of implementing an Investigational Drug Service in a Community Health System: A Best Practice Analysis

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**Background:** Investigational Drug Services (IDS) is a pharmacy driven program that manages medications used in clinical trials. In 2014, the Hematology/Oncology Pharmacy Association (HOPA) released 40 best practice standards for IDS, the standards provide guidance in medication management, regulatory compliance, medication safety, protocol development/order set development, education, and increasing expanded access to investigational medications. On January 2020, Novant Health (NH) established a system-wide IDS. Since the implementation of this service, a formal review highlighting improvement of IDS has not been completed. The purpose of this study is to evaluate the impact of formal implementation of NH Investigational Drug Services by determining compliance to HOPA’s best practices before and after the 2020 implementation.

**Objective:** The primary objective is to evaluate the impact of formal implementation of NH IDS on regulatory compliance, medication management, and pharmacist and technician’s responsibilities, by utilizing the 2014 HOPA Investigational Drug Service Best Practice Standards. Secondary objectives include evaluating compliance in the following HOPA Best Practice subcategories to determine areas of improvement in the post implementation period: general best practices, best practices for prescribing investigational medications, best practices for dispensing investigational medications, best practices for administering investigational medication, pharmacist best practices for protocol development, best practices for patient counseling and monitoring.

**Methods:** This This study is a retrospective cohort study evaluating best practices pre and post-implementation of IDS. Out of the 40 best practices, 30 were analyzed as nominal data points, while 10 were analyzed as continuous data points. The pre-intervention group was defined as the time before the formal implementation of IDS while the post-intervention group was defined as the time after the formal implementation of IDS. Data points were analyzed either by a paired t-test or a Chi-square test. The Social Science Statistics Program was utilized to conduct statistical analysis.

**Results:**. Overall, there was a statistically significant increase in compliance metrics in the post-implementation period. The pre-intervention phase had 20 best practices defined as Y, while the post-intervention group had 28 best practices defined as Y (p =0.009823). Regarding best practices assigned continuous end points, there was an overall average increase in compliance by 23.3% in the post-intervention group (p = 0.03). The best practice area “Investigational Drug Service Responsibilities-IDS general best practice” was the main driver of the primary outcome with an increase to 13 compliant best practices in the post-implementation period compared to 6 in the pre-implementation period (p = <0.005). Non-compliant areas included best practices regarding IDS pharmacy representation in the IRB, patient counseling, and assessment of medication adherence.

**Conclusion:** The formalization of the IDS system has increased compliance to the HOPA Best Practice standards providing benefits in enhancing the way research protocols are currently managed regarding policy development, medication management, study coordination, and development of medication information.