Development of Monitoring Tools and Interventions to Increase Staff and Faculty Consent Success Rates

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Background

Like many institutions, there has been a decrease in informed consent success rate since the COVID pandemic at the University of Illinois Cancer Center. The Clinical Research Coordinator (CRC)/physician relationship is crucial to a successful and effective informed consent process. The physician discussion with a patient sets the tone of a consent discussion and communication from physician to CRC enables a link so that when the CRC completes the consent process, the whole care team is aware and is able to ensure the best experience for our patients. In order to maximize enrollment to treatment clinical trials at UICC, a report was development to monitor informed consent success rates across staff and faculty involved in the informed consent process. This report identified some significant variability in informed consent success rates. Interventions were then developed to address this variability and attempt to increase informed consent success rates to a consistent rate and increase treatment trial accrual.

Objective

Have all CRCs and MDs meet a standard level informed consent success rate of 65% or higher.

Methods

In December 2023, a report was designed including the number of patients approached to consent, the number of patients consented, the informed consent rate, and the recruitment rate per CRC and clinician. The report revealed that 5/9 CRCs and 12/19 physicians met the greater than 65% informed consent success rate goal. Range of informed consent success rates was broad indicating a high degree of variability (46.15%-89.29% for CRCs and 17%-100% for clinicians).

It was determined the reasons for lower informed consent success rates were highly individualized and included poor communication between the CRC and clinician, CRC confidence, physician discussion quality, and consenting methods. Some variability in consent success rates were due to situational issues, such as study complexity, mismatch of clinician demographics with patient population, or systemic disease group dynamics that required change beyond the scope of this project. Interventions to address the remaining variables were identified, developed, and implemented.

Results

For CRCs showing poor confidence, consent training was implemented. The training included mock consenting with a senior coordinator with feedback, a senior coordinator in the room observing the consent process, and group discussion with the clinical operations team to create process training.

Clinicians with low consent rates were discussed with UICC clinical research leadership and individual and personalized discussions held. Additionally, the Heme/Onc division began providing effort based upon the number of clinical trial participants enrolled by each clinician to further incentivize faculty clinical trial participation.

In February 2025, a comparative report was generated to observe outcomes for interventions developed. The report revealed that 10/11 CRCs and 16/17 physicians met the greater than 65% informed consent success rate goal, an increase of 63.8% for CRCs and 49.1% for physicians. The range of informed consent rate improved dramatically in the physician cohort with the least successful having a consent rate of 64% in 2024 versus 5 physicians at or below 50% in 2024. In the CRC cohort, the only CRC not meeting criteria was our Phase 1 CRC which has the hardest trials to accrue due to their complexity.

Conclusions

This analysis led to creation of successful interventions to address suboptimal consent success rates. All physicians and CRCs receiving tailored consent and research training have shown benefits both to the consenter and the patient being consented. The additional training and support was welcomed by both physicians and CRCs, and the combination of interventions was extremely successful in addressing effective informed consent in our diverse patient population. In future, we will continue monitoring informed consent metrics and utilize the consent training interventions developed and the faculty clinical trial effort policy is planned to continue indefinitely.

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