

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 developed 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 70-75% or higher.

Methods

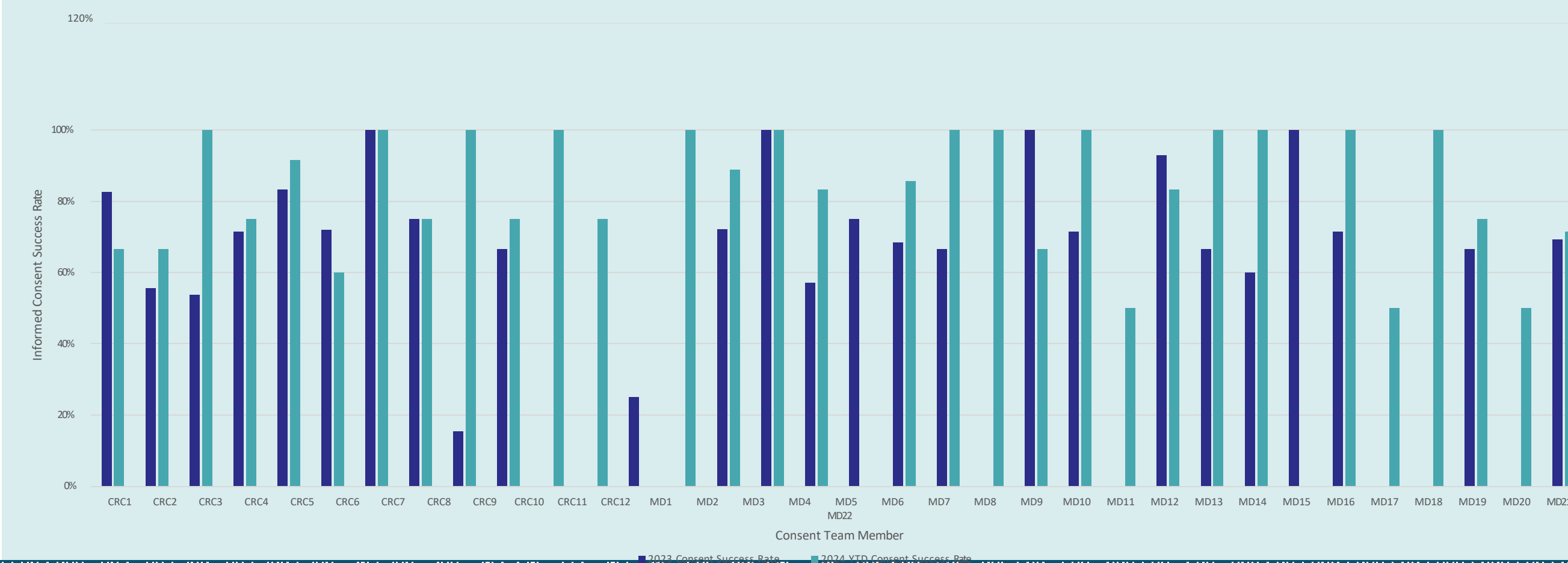
Each clinical treatment trial patient discussion and the outcome of that discussion is tracked and documented. At UICC, a faculty member initiates informed consent discussions and the CRC follows up with the patient and completes the consent process and documentation. A report was designed by the UICC Clinical Trials Office (CTO) Associate Director of Clinical Research Operations showing the number of patients approached to consent, the number of patients consented, the informed consent rate, and the recruitment rate per CRC and clinician.

Results

Analysis of data for 2023 revealed that 6/10 CRCs and 8/20 MDs met the 70% or higher informed consent success rate goal. Range of informed consent success rates was broad indicating a high degree of variability (15%-100% for CRCs and 0%-100% for clinicians, see Figure 1). CRCs with low success rates were observed consenting and issues identified.

These included poor communication between the CRC and clinician, confidence level of the CRC during the consent process, effectiveness of the presentation of the study to the patient by the clinician, and the method used for reviewing the informed consent form with the patient such as reading the consent form verbatim. Some issues identified, such as complexity of the study, mismatch of clinician demographics with patient population, or systemic disease group dynamics required changes beyond the scope of this project. The analysis was repeated 4/25/24 to determine the affects of interventions to date. Post intervention consent rates success rates improved (9/12 CRCs and 15/22 MDs meeting goal).

Figure 1: Informed Consent Success Rate Analysis



Conclusions

This analysis led to creation of interventions to address suboptimal consent success rates. CRCs showing lack of consenting confidence or reading the consent form were provided with tailored consenting training including mock consenting with a senior coordinator multiple times with feedback, a senior coordinator observing the consent process, and peer group discussion about process improvement and additional needs for informed consent process training. Clinicians identified with poor informed consent success rates and the reasons for their low rates were discussed with UICC clinical research leadership and leaders are intervening individually to address underlying causes for the low consent success rates. Post intervention analysis results are preliminary, but appear to support success of the interventions developed.

Acknowledgements

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