Category: Cross-cutting Innovation and Collaboration – Work in Progress

Clinical Research Inpatient Nursing Optimization – Post Trial Activation

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1. Background

Moffitt Cancer Center's inpatient nursing units integrate clinical trial procedures with routine patient care. As oncology trials grow, inconsistencies in communication, documentation, and workflow coordination have led to inefficiencies. The Clinical Trials Office (CTO) collaborated with inpatient nursing leadership and the Process Excellence (PEx) Department to identify workflow gaps, standardize processes, and improve research integration, aiming to enhance efficiency, patient safety, protocol compliance, and interdisciplinary collaboration.

2. Goals

- Standardize inpatient workflows to integrate clinical trial activities with standard patient care.
- Enhance coordination between nursing and research teams to ensure protocol compliance and quality care.
- Develop structured communication and documentation to reduce redundancy and improve transparency.
- Measure and analyze protocol deviations to identify inefficiencies and implement corrective actions.

3. Solutions and Methods

- A Kaizen event was conducted with CTO, inpatient nursing leaders, and process improvement specialists to map current workflows and develop standardization strategies using lean tools. The baseline identified 264 protocol adherence deviations, with a goal to reduce them by 10 percent. Clear roles and responsibilities were established across research and inpatient teams to ensure smooth handoffs and accountability, improving efficiencies and decreasing deviations. Focus areas included:
- Standardization of Communication and Documentation: An Inpatient (IP) Checklist was developed to facilitate clear and structured handoffs between Clinical Research Coordinator (CRC) and clinical teams. Tools were designed to reduce variability in submission and reporting requirements. A SharePoint site was created for centralized access to trial protocols, patient care checklists, and training materials.
- Standardization of Research Kit and Medication Handling: Improved Research kit management and storage protocols to ensure accessibility, compliance, and staff training. Secured cabinet storage for investigational products and research-related materials was established in inpatient units.
- Deviation Tracking and Process Monitoring: A dashboard was developed to track research deviations and improve real-time monitoring of inpatient clinical trial processes.

4. Outcomes

- A unified inpatient nursing workflow was implemented to minimize variations in trial-related procedures, and the CRC/IP checklist enhanced coordination between inpatient and research teams, reducing miscommunication.

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- Standardized CTO email templates minimized documentation redundancies, and the centralized SharePoint site offered real-time access to trial protocols and patient care workflows.
- Enhanced deviation tracking and standardized safety reporting have enabled quicker identification and resolution of compliance issues. These improvements have significantly boosted research compliance and efficiency.
- Standardized research kit handling ensured that investigational products were properly stored and accessible.
- A pilot program was launched in February 2025 with Blood Marrow & Transplant, Hematology, and Immune-Cell Therapies CTO. Over the next few months, the pilot will be monitored to ensure it has improved communication and documentation between CRCs and the Clinical Team.

5. Learned and Future Directions

- Creating standardized processes helped reduce inefficiencies.
- Clear, real-time communication improved research conduct. The checklists, standardized templates, and SharePoint site improved accessibility to critical research documents.
- Continuous education and reinforcement of research procedures were crucial for adoption across inpatient nursing units.

Future Enhancements:

- Expand the standardized inpatient workflow model to surgical inpatient trials and nursing.
- Utilize deviation reporting dashboard to establish target thresholds on a per program basis to create robust CAPA's.