THE ROLE OF THE CLINICAL RESEARCH NURSE IN EXPEDITED RESEARCH DURING COVID

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Background

Purpose: How does the Clinical Research Unit function in expedited research related to COVID?

Significance: During the pandemic, the Clinical Research Unit (CRU) has been involved in a number of trials related to COVID, including the monoclonal antibody infusion trial with Eli Lilly. We initially started this infusion trial in June 2020 and continued through October 2020. The infusion was intended for COVID positive patients at high risk for hospitalization. This infusion, Bamlanivimab, was approved for emergency use authorization (EUA) by the FDA in November 2020. The CRU was the initial site for these infusions due to our experience in the clinical trial phase of this medication. The CRU nurses were instrumental in not only the care and education for patients who participated in the clinical trial, but also in the training of other NMH nurses who cared for these patients.

Objectives:
Primary: Expedite the approval of the monoclonal antibody clinical trial and educate CRU nurses in safe administration, within a 4 week timeframe.
Secondary: Transition the monoclonal antibody infusion from research to standard of care after EUA approval. Train infusions nurses for the care of these patients.
Tertiary: Support the transition of this infusion to FMOU.

Design: Level III: Non-experimental: Descriptive, comparative, correlational, survey, or use of secondary data, or qualitative.

Methods

Primary: CRNC team worked with study team to review and approve the protocol within a 4 week timeframe. Education was provided to staff regarding protocol and proper PPE usage. Developed a workflow with infection prevention for bringing COIVD patients to our clinic space, and EVS for the cleaning of rooms and bathrooms. Worked with Investigational Pharmacy to establish a workflow around ordering and receiving Bamlanivimab infusions.
Secondary: Worked with a variety of interdisciplinary teams for EUA. Worked with NUCATS to modify lease agreement in order to care for standard of care patients, partnered with central scheduling and our administrators for appointment coordination, educated float nurses for caring for infusion patients, CRU CC/EC ensured patients were appropriate for infusion, and were primarily responsible for patient education as there were not physicians on site. Also worked with hospital leadership to have daily huddles and work through issues that came up.
Tertiary: CRU RNs trained FMOU nurses on how to properly care for these patients and document their care in EPIC, which was a new workflow for them.

Analysis

It is important to note the standard time for a clinical trial from start to market is 6-7 years. For Bamlanivimab, it took 5 months to get approval for EUA.

Clinical Trial protocols related to drugs for COVID were also written differently in that they allowed for the investigators to modify the plan quickly and easily. The IRB also adjusted their process to expedite the approval of COVID related protocols.

Results

Findings and Implications: The CRU successfully cared for 23 patients during the Eli Lilly phase II clinical trial, and 136 patients for the EUA of Bamlanivimab on Galter 15.

Limitations included staffing, space, and scheduling constraints.

For future state, we have a workflow for accommodating COVID and non-COVID patients in a safe environment for both patients and staff. We created an orientation for our unit to provide non-research nurses with the skills needed to successfully care for patients in outpatient units. Guidelines for studies eligible for expedited review were established.

Conclusions

There were several groups that were essential to the initiation of this research and EUA. The CRNC team worked with Northwestern University Clinical and Translational Sciences (NUCATS) team and created an expedited review of the Eli Lilly Protocol so we could see patients as soon as possible. When Bamlanivimab was approved for EUA by the FDA, a monoclonal antibody administration team consisting of leadership from a variety of departments was assembled to create a workflow in order to continue seeing these patients in the CRU, as well as train other NMH infusion nurses in caring for these patients. Lastly, the expertise of the clinical research nurse in the CRU was instrumental in executing the clinical trial and caring for these patients with COVID, as well as training other NMH infusion nurses.

Reference

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