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A Vulnerable Population: Ethical Enrollment of Acute Myocardial Infarction Patients

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Introduction

- It has been suggested in literature that patients in emergent situations, such as those suffering from an acute myocardial infarction, may meet the definition of a vulnerable population due to the life-threatening nature of the condition
- Key strategies were employed to ensure safe, ethical enrollment of this patient population by addressing concerns that arose.
- Interventions were implemented at all stages of study procedures.

Ethical Concerns

- The study team's ability to perform research activities without hindering the clinical care of the patient
- Time-sensitive nature of obtaining consent and treatment
- The patient's ability to understand consent and study requirements
- Avoiding a sense of coercion for the patient due to the fast-paced clinical care algorithms in place

Key Strategy #1

Care Team Frontloading

Before the study was even open for enrollment, the research team reached out to physicians and staff in affected departments. This proved to be integral to enrollment success. The outreach went above and beyond a brief in-service or presentation.

The research team met with Emergency Department and Cardiac Catheterization Lab staff and physicians for an in-depth discussion regarding logistics of study implementation. Specific questions were addressed at this time.

- **What is the workflow in each department and how will the study affect each process?**
- **How can the study be integrated as seamlessly as possible?**
- **Can each team identify potential barriers and how they can be overcome?**
- **What are the main concerns of the clinical care areas regarding the study?**
- **How can the study team help address all of these items?**

Takeaway: By implementing the frontloading process, the clinical areas were able to voice concerns and have an active, collaborative role in working through study logistics. Before the study began, all of the affected clinical areas were "on the same page," and anticipating the research team's involvement in upcoming cases. This helped to address the ethical concern regarding hindrance of the patient's clinical care.

Key Strategy #2

Informed Consent Division of Labor

- The clinical research coordinators (CRCs) worked with physician investigators to refine an informed consent strategy to ensure all study elements were adequately explained to study subjects in this acute situation.
- It was decided that the physician investigator would initially present the study to the patient, with a brief overview and focus on the procedural and scientific aspects of the study.
- If the patient indicated interest in participating, the CRC would approach the patient to provide the informed consent document for the patient to review, and offer continued explanation of study procedures, commitments, and HIPAA language. The CRC would obtain the patient's signature.
- The physician was close by in the event the patient had additional questions, but this allowed the physician to continue in clinical decision making and directing of patient care during the consent process.

Takeaway: The "Division of Labor" process proved to be the most efficient use of the physician and study team's time, and allowed for the most comprehensive explanation for the patient, for informed consent.

Key Strategy #3

Not Every Candidate Is a Candidate

Before a patient was approached, the study team confirmed that not only did the patient meet inclusion criteria for the trial, but that they were able to participate in the consenting process. No legally authorized representatives (LARs) were used.

If, in the CRC's or physician's opinion, the patient was not suitable for consent EVEN if study criteria were met, the patient was not approached.

- **Reasons why patients were not approached:**
 - Heavily medicated in the field
 - High anxiety/tearfulness
 - Verbalized reluctance to make decisions without significant other/child/parent present
 - Did not appear able to comprehend study or consent explanation (possible historical dementia, poor understanding of English language, etc.)

Takeaway: The "unwritten exclusions" were mutually agreed upon by the study team, and also shared with clinical departments

- CRC's and study physicians supported decisions not to approach certain patients.

Follow-up

- CRC's and physician investigators "debriefed" after the first few study participants were enrolled to discuss informed consent and enrollment for each case in order to improve upon processes.
- CRC's visited patients after their procedures (several hours later or next day) to once again review the consent form and answer any additional patient questions in a more relaxed environment.

Conclusion

- Although ethical concerns are inherent in all clinical trials, especially with emergent patients, conscientious enrollment strategies allow for those concerns to be addressed.
- Communication, collaboration, and follow-up between the study team, clinical teams, and investigators are key components to success.

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