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51 Enrolling Heart Failure Patients for the Mighty Heart Study: Challenges and Solutions During COVID-19 Pandemic



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Study Objectives: Mobile Integrated Health (MIH) programs combine community paramedicine and telemedicine to deliver urgent medical care in patient homes. During the COVID-19 pandemic, MIH has significant potential to mitigate concerns about COVID-19 infection from seeking urgent care in health care settings. The MIGHTY Heart (“Using Mobile Integrated Health and Telehealth to Support Transitions of Care among Heart Failure Patients”) study is a comparative effectiveness pragmatic trial comparing a transitions of care coordinator to MIH. Recruitment began in January 2021, 10 months into the pandemic. Existing challenges to patient engagement in research have become more pronounced during the pandemic; studies show that pre-COVID-19, less than 50% of trials met proposed timelines for recruitment, and early evidence suggests this number has dropped during the pandemic. Here we report on the challenges and solutions for recruiting patients in emergency medicine-focused programs during the COVID-19 pandemic in the first 5 months of recruitment.

Methods: We convened a Stakeholder Engagement Board (SEB) including nurses, patients, community paramedics, and case managers. We conducted a descriptive, thematic synthesis of the SEB discussions to address the challenges. We implemented strategies for increased enrollment generated by the SEB two months into the MIGHTY Heart study and evaluated changes in the proportion of patients enrolled among those who were eligible for the study before and after implementation of these strategies.

Results: We identified 4 significant COVID-related challenges to recruitment into the MIGHTY-Heart study. COVID-19 patients excluded from inpatient recruitment: 18% of screened patients (n=287) were COVID-19 positive while inpatient, and hospital policy prevented the team from approaching them in contact isolation. Limited family presence: the hospital visitor policy restricts visiting hours to 4 hours and 1 family member. Patients are more likely to participate if the decision is made with a family member. Due to COVID-19, patients are more reticent to allow any health care providers in their homes out of concern for possibly infecting other family members with COVID-19. Mandatory mask wearing in the hospital has posed barriers to communication, especially for some of the elderly patients, who may rely on visual and auditory cues for verbal communication. From the SEB, we identified 3 strategies to support patient engagement. Virtual recruitment: after discharge, patients who were COVID-19 positive were contacted by phone or email. Patients were emailed the informed consent and study materials and mailed gift cards. Family engagement: per patient request, the research assistants would call patient’s family members if they were not at the bedside at the time of recruitment to explain the study and answer any questions that family members might have. Study materials were left at the patient’s bedside for patients to read and share with family members in advance of deciding to enroll in the study. The proportion of eligible patients who enrolled in MIGHTY Heart increased from 28-32% before these strategies were implemented to 46-52% in the months after implementation (Figure 1).

Conclusion: The novel solutions developed by the SEB and study team increased enrollment in the MIH program. These strategies may be useful for others facing challenges to recruitment in emergency medicine-related programs during the COVID-19 pandemic.

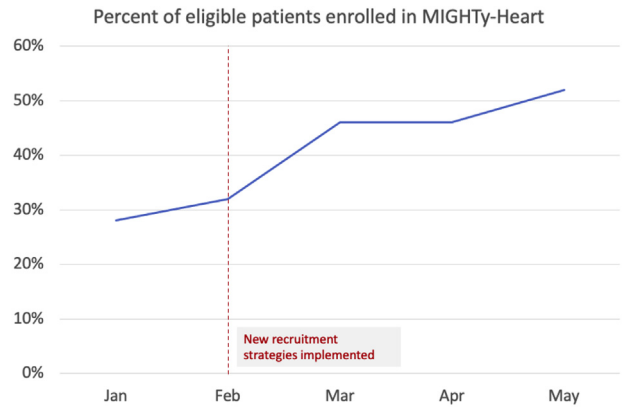


Figure 1: Percent of eligible patients enrolled in MIGHTY Heart before and after implementing new recruitment strategies

52 Rapid Antibody Testing For SARS-CoV-2 Vaccine Response Among Pediatric Health Care Workers



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Study Objectives: SARS-CoV-2 has infected more than 150 million and caused over 3 million deaths. While development of vaccines will likely temper the associated morbidity and mortality, the long-term durability of the immune response to these vaccines remains unknown. Our objective was to evaluate the use of a rapid IgM/IgG SARS-CoV-2 antibody detection kit as a screening tool for humoral immune response to COVID-19 vaccination and to assess neutralizing and nucleocapsid antibodies via ELISA.

Methods: We conducted a cross-sectional study of pediatric health care workers (PHCW), with no history of SARS-CoV-2 infection who received 2 doses of BNT162b2 (n=113) or mRNA-1273 (n=12), at a pediatric quaternary care institution. Participants were tested for IgM/IgG antibodies to the SARS-CoV-2 spike protein receptor-binding domain with the Hangzhou Biotest Biotech RightSign COVID-19 IgG/IgM Rapid Test Cassette. ELISAs were subsequently run to detect the presence of anti-spike IgG/neutralization effect and IgM/IgG SARS-CoV-2 anti-nucleocapsid antibodies. The mean number of days post 2nd dose was 22, the range was 17-36.

Results: 98.4% received positive rapid IgG results; 0.8% were IgM+. Of those with rapid IgG+ results, 100% were anti-spike protein IgG+ on ELISA; none who tested IgG negative via the rapid test demonstrated positive anti-spike protein IgG on ELISA. All those with positive rapid tests demonstrated neutralizing capability via ELISA. With respect to anti-nucleocapsid antibodies, only 1.6% were IgM+ and 5.6% were IgG+.

Conclusion: Anti-spike serology was consistent with previous studies. In many countries, HCWs were among the first to be vaccinated and several larger studies have explored the vaccine-mediated antibody responses in this population. However, to our knowledge there have been no studies examining PHCW. This population is unique in that due to their work with children, they are likely more frequently exposed to coronaviruses than the general population. Both the spike protein and the nucleocapsid protein appear somewhat conserved across coronaviruses, and children with no exposure to/history of SARS-CoV-2 infection have been shown to have detectable levels of IgG antibodies reactive to the SARS-CoV-2 spike protein. However, very few participants in our study were anti-nucleocapsid IgM+/IgG+; the significance is as yet undetermined. Although the generalizability of our results may be limited due to the limited number who received mRNA-1273, the strong correlation between the rapid results and confirmatory ELISA testing suggests this test may be used to assess for positive and neutralizing antibody response to BNT162b2. This may allow for rapid and relatively inexpensive documentation and monitoring of individual immune response, including evaluating the need for booster vaccination, as well as aiding in large-scale immune surveillance.