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Research Brief

Nurse-Driven Simulations to Prepare and Educate for a Clinical Trial

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KEYWORDS

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Abstract

Background: To date, there is limited literature exploring the effectiveness of training staff for a clinical trial via high-fidelity simulations. This study was conducted to explore this educational modality for an emergency department (ED)—based clinical trial.

Methods: ED nurse educator—driven simulations were deployed for a clinical trial to train diverse ED staff and were described. An anonymous survey was then conducted to assess staff knowledge regarding the clinical trial and participation in trial simulations.

Results: Over 21 months, 13 seizure simulations were run with 97 participants. ED staff who attended a simulation were ~3 times more likely to correctly answer survey questions about the clinical trial. The vast majority of simulation participants (95.8%) found them to be helpful.

Conclusion: Simulations provided lessons to improve the knowledge and operations of a clinical trial. Nursing staff was instrumental during simulations and in the development of site-specific processes. Future clinical trials that involve multidisciplinary groups and time-sensitive actions may benefit from this approach.

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Background

High-fidelity simulations are emerging as a valuable educational tool for emergency department (ED) staff (Sauter et al., 2016). Simulating high-risk, low-frequency events can enhance confidence and competence in individual roles during critical situations in the ED (Burke et al., 2017). Simulations are helpful to strengthen teams that may have infrequent

opportunities to collectively practice high-stress, low-frequency scenarios (Burke et al., 2017; Petrosoniak, Auerbach, Wong, & Hicks, 2017; Spurr, Gatward, Joshi, & Carley, 2016). Although studies support the use of high-fidelity simulations to train ED staff regarding emergency patient care, there are limited data on its use to train a multidisciplinary ED staff for a clinical trial. This study used the Established Status Epilepticus Treatment Trial (ESETT), a part of the Neurological Emergencies Treatment Trials (NETT) (NETT: Neurological Emergencies Treatment Trials, 2018) which has 16 participating sites across the United States in the Pediatric Emergency Care Applied Research Network (PECARN) (Pediatric Emergency Care Applied Research Network, 2018). The objective of

Key Points

- Simulation attendees were more knowledgeable of the clinical trial.
- Conducting nurse-driven high-fidelity simulation training with a multidisciplinary emergency department team for a clinical trial is feasible and likely enhances collaboration and communication.

ESETT is to determine the best second-line drug for prolonged seizures. All disciplines participated in the simulations. Nursing education was emphasized given the pivotal role nurses assume during ED critical care, such as trauma (Garvey, Liddil, Eley, & Winfield, 2016), and correspondingly an ED-based clinical trial for status epilepticus. Our work aims (1) to describe the use of and (2) to examine potential benefits of nurse-educator co-led high-fidelity simulations to train ED staff for a clinical trial.

Methods

Sample: Context and Setting

The simulation training was conducted at Nationwide Children's, a 468-bed, free-standing pediatric tertiary care hospital serving Central Ohio. The Nationwide Children's Emergency Department is a 62-bed American College of Surgeons—certified pediatric level 1 trauma center with 86,994 ED visits in 2017. At the time of this study, the multidisciplinary ED team consisted of 173 nurses, 73 physicians, and 6 research coordinators, as well as 46 pharmacists and 28 respiratory therapists who may respond to a critical ED patient. The study was deemed exempt as a Quality Improvement project by the Nationwide Children's Institutional Review Board.

Simulations

ED nurse educators and research coordinators co-led high-fidelity simulations to educate ED staff on the ESETT

clinical trial and practice enrollment scenarios. These insitu simulations allowed staff to practice research functions in their usual clinical roles and settings before enrolling live patients (Petrosoniak et al., 2017; Spurr et al., 2016). Simulations were run using a pediatric, one-year old, high-fidelity simulator. The simulations were not pre-planned with ED staff. Instead, simulations were initiated by broadcasting a “mock-seizure alert” over badge communication devices to all on-shift ED staff. All available personnel were called to a designated trauma room to participate in the simulation. Simulations were run before the initiation of and during the clinical trial to troubleshoot the protocol and educate the staff. In addition, simulations were varied in complexity and repeated to reinforce learning, as well as to prevent a decline in skills (Spurr et al., 2016). Study-specific details such as inclusion/exclusion criteria and treatment end points informed the scenarios. Participants were encouraged to work in real time with limited interruptions and used a timer to practice protocol adherence. Simulations were scheduled to capture all shifts. Participation was voluntary and recorded on a sign-in sheet. A short debriefing was completed after each simulation. Finally, a follow-up e-mail was sent to all attendees to thank them for their participation as well as to highlight key points and important discoveries.

Survey

An anonymous, 11-question survey developed using RED-Cap™ (Harris et al., 2009) was given to assess staff knowledge of ESETT and gauge the effectiveness of the simulations. All ED staff were surveyed, as all participants are vital to each enrollment. Given the pivotal role of the nursing staff in ED resuscitations, this group was subanalyzed. Demographic variables of respondents included role, length of employment in the ED, and attendance at an ESETT simulation. Three staff knowledge questions assessed comprehension of the trial, with an open text field available to capture additional lessons learned from simulations. Each ED staff member was provided an opportunity to respond to the survey by varied methods (e-mail, paper, and tablet device), instructed to complete once, and sent periodic reminders via e-mail to maximize participation. The survey was available for four months. Descriptive and summary statistics were collated using Stata 14.0 (StataCorp, 2015).

Results

Simulations

In total, 13 in situ high-fidelity simulations were run between October 12, 2015 and July 24, 2017. Six simulations were held before initiation of the ESETT

Table 1 All ED Staff Responses, n = 159/326 (48.7%)

Staff Survey Responses	Total	Simulation	No Simulation	Odds Ratio (95% CI)
Correctly identified goals of ESETT	125/159 (78.6%)	43/48 (89.6%)	82/111 (73.9%)	3.04 (1.05, 10.72)
Correctly named the drugs being trialed	43/159 (27.0%)	20/48 (41.7%)	23/111 (20.7%)	2.73 (1.22, 6.06)
Knew the location of the enrollment cards	83/159 (52.2%)	36/48 (75.0%)	47/111 (42.3%)	4.09 (1.83, 9.51)

Note. CI = confidence interval; ED = emergency department; ESETT = Established Status Epilepticus Treatment Trial.

clinical trial in preparation for the trial. Seven simulations were held intermittently after the trial had begun to maintain staff knowledge. Importantly, the simulations did not delay the start of the clinical trial, and no issues were raised during any simulation that paused trial enrollment. A total of 97 ED staff members attended the simulations, with nurses comprising 43 (44.3%) attendees. As multidisciplinary education and collaboration were primary objectives, simulations allowed the research team and staff to refine the vital role of each participant during an enrollment. For example, before clinical trial initiation, we discovered that nurses would assist with blood draws and administer the clinical trial drug by using a specific medication pump and that pharmacists would help review inclusion/exclusion criteria for an enrollment. Anecdotally, as a result of the simulations, the research team noticed an increase in calls to the team from the ED staff regarding potentially eligible patients and perceived improved collaboration among the staff during actual ESETT enrollments.

Surveys

Surveys were available to ED staff between September 18, 2017 and January 12, 2018. The overall ED staff response rate was 159/326 (48.7%). The nursing response rate was 109/159 (68.6%). The response rate for other ED staff combined was 50/153 (32.7%) and by discipline was research coordinators 6/6 (100%); physicians 27/73 (36.9%); pharmacists 11/46 (23.9%); and respiratory therapists 6/28 (21.4%). Of all survey respondents, 48 (30.2%) reported that they had attended an ESETT simulation.

Regarding the three main survey questions, the ED staff were most knowledgeable of: “What is the goal of the ESETT trial?” 125/159 (78.6%); followed by “What is the location of the enrollment cards?” 83/159 (52.2%); and

least knowledgeable of “What drugs are being trialed?” 43/159 (27.0%) (Tables 1-3). This ranking of correct responses remained the same for all ED staff, whether nurses or other staff, whether or not they attended a simulation (Tables 1-3). Staff who attended a simulation were more likely to correctly respond to each question, to know the goals of ESETT (odds ratio [OR] = 3.04; 95% confidence interval [CI] = 1.05, 10.72), drugs being trialed (OR = 2.73; 95% CI = 1.22, 6.06), and location of the enrollment cards (OR = 4.09; 95% CI = 1.83, 9.51) (Tables 1-3). For the subset of nurses, simulation increased, with significant improvement, knowledge in one core question (Tables 1-3). Of the staff who attended a simulation, the vast majority, 46/48 (95.8%), reported them to be helpful. Nineteen of these 48 staff members participated in an ESETT enrollment and responded that they applied something learned in a simulation during an enrollment. Specific lessons learned that were reported included (1) how to manually program the medication pump to administer the ESETT trial drug; (2) how to use the trial-designated portable media player; and (3) the timing of events during an enrollment.

Conclusions

To our knowledge, this is the first study to describe use of high-fidelity simulations to train multidisciplinary ED staff for a clinical trial. Studies have shown that high-fidelity simulations are useful in training ED staff for high-risk, low-frequency events (Burke et al., 2017; Garvey et al., 2016; Sauter et al., 2016; Spurr et al., 2016). Simulations have been used to teach specialized groups in the ED in sedation procedures (Sauter et al., 2016) and resuscitation (Burke et al., 2017), showing a

Table 2 Nurse Survey Responses, n = 109/159 (68.6%)

Staff Survey Responses	Total	Simulation	No Simulation	Odds Ratio (CI)
Correctly identified goals of ESETT	82/109 (75.2%)	25/29 (86.2%)	57/80 (71.3%)	2.52 (0.74, 10.99)
Correctly named the drugs being trialed	14/109 (12.8%)	4/29 (13.8%)	10/80 (12.5%)	1.12 (0.23, 4.34)
Knew the location of the enrollment cards	50/109 (45.9%)	19/29 (65.5%)	31/80 (38.8%)	3.00 (1.14, 8.17)

Note. CI = confidence interval; ESETT = Established Status Epilepticus Treatment Trial.

Table 3 Other Staff Survey Responses, n = 50/153 (32.7%)

Staff Survey Responses	Total	Simulation	No Simulation	Odds Ratio (CI)
Correctly identified goals of ESETT	43/50 (86.0%)	18/19 (94.7%)	25/31 (80.7%)	4.32 (0.45, 209.52)
Correctly named the drugs being trialed	29/50 (58.0%)	16/19 (84.2%)	13/31 (41.9%)	7.39 (1.57, 45.79)
Knew the location of the enrollment cards	33/50 (66.0%)	17/19 (89.5%)	16/31 (51.6%)	7.97 (1.49, 79.61)

Note. CI = confidence interval; ESETT = Established Status Epilepticus Treatment Trial.

precedence for training multidisciplinary groups for a specific purpose. Attendance at a simulation was associated with increased staff knowledge of and improved awareness of the ESETT trial. The vast majority (95.8%) of simulation attendees found them to be valuable. Nurses assume a critical role during a trauma (Garvey et al., 2016), and subsequently nurses were invaluable during trial simulations and enrollments. Owing to their involved role, nurses also created a bridge between all disciplines in the room by relaying valuable patient information. Discussions between nursing and research staff during simulations helped to shape the trial workflow, reinforced role responsibilities, and led to the creation of cards to guide staff during an enrollment. Lessons learned in regards to running simulations in preparation for a clinical trial include the necessity for flexibility in scheduling and the need to include a pre/post survey to better gauge staff knowledge of the trial. Logically, education and improvement in the setting of an ED clinical trial is a natural next step. This single-center study has limitations. While the pivotal target group of ED nurses had a 68.6% response rate, overall staff response rates were relatively low. Some staff who attended a simulation likely did not complete a survey. As with any survey, a response bias may have altered results.

In summary, the use of high-fidelity simulations to train a multidisciplinary ED staff for clinical trial enrollments is supported by this study. ED nurse co-led high-fidelity simulations were successfully implemented for the trial, improving protocol embracement and staff knowledge. Nursing staff was particularly valuable during simulations and subsequent enrollments. Further research is needed to confirm if high-fidelity simulations are useful for training staff for other clinical trials. Future projects could include (1) a multicenter study in which all sites participate in the

clinical trial along with trial-specific simulation training to gauge efficacy across hospital sites and (2) creation of a validated tool to measure high-fidelity simulation training for clinical trials.

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