Nurses' Attitudes Toward Clinical Research: Experience of the Therapeutic Hypothermia After Pediatric Cardiac Arrest Trials

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Objectives: To understand factors affecting nurses' attitudes toward the Therapeutic Hypothermia After Pediatric Cardiac Arrest trials and association with approach/consent rates.

Design: Cross-sectional survey of pediatric/cardiac intensive care nurses' perceptions of the trials.

Setting: Study was conducted at 16 of 38 self-selected study sites.

Subjects: Pediatric and cardiac intensive care nurses.

Measurements and Main Results: The primary outcome was the proportion of nurses with positive perceptions, as defined by agree or strongly agree with the statement "I am happy to take care of a Therapeutic Hypothermia after Pediatric Cardiac Arrest patient". Associations between perceptions and study approach/consent rates were also explored. Of 2,241 nurses invited, 1,387 (62%) completed the survey and 77% reported positive perceptions of the trials. Nurses, who felt positively about the scientific question, the study team, and training received, were more likely to have positive

perceptions of the trials ($p < 0.001$). Nurses who had previously cared for a research patient had significantly more positive perceptions of Therapeutic Hypothermia After Pediatric Cardiac Arrest compared with those who had not (79% vs 54%; $p < 0.001$). Of the 754 nurses who cared for a Therapeutic Hypothermia After Pediatric Cardiac Arrest patient, 82% had positive perceptions, despite 86% reporting it required more work. Sixty-nine percent believed that hypothermia reduces brain injury and mortality; sites had lower consent rates when their nurses believed that hypothermia was beneficial. Institution-specific approach rates were positively correlated with nurses' perceptions of institutional support for the trial ($r = 0.54$; $p = 0.04$), ICU support ($r = 0.61$; $p = 0.02$), and the importance of conducting the trial in children ($r = 0.61$; $p = 0.01$).

Conclusions: The majority of nurses had positive perceptions of the Therapeutic Hypothermia After Pediatric Cardiac Arrest trials. Institutional, colleague, and study team support and training were contributing factors. Despite increased work, nurses remained enthusiastic demonstrating that studies with intensive bedside nursing procedures are feasible. Institutions whose nurses believed hypothermia was beneficial had lower consent rates, suggesting that educating nurses on study rationale and equipoise may enhance study participation. (*Pediatr Crit Care Med* 2016; 17:e121–e129)

Key Words: heart arrest; nurses; pediatrics; perceptions; research

Families, healthcare providers, and researchers may be reluctant to enroll critically ill children into a research study. Parents agree that pediatric research advances treatment of pediatric diseases (1–4) but express concerns that research in an emergency setting might delay critical medical care or that adhering to a research protocol might be detrimental to their child (4).

Pediatricians agree that research is essential to improving children's health, and primary care physician support is a key factor in parental willingness to participate in research. However, pediatricians are often reluctant to refer their patients for research studies (5, 6) due to potential risks from treatment side effects, patient inconvenience, lack of physician time/resources, and risk to the doctor-patient relationship (7–9).

Little is known about nurses' perceptions of clinical research, another potentially important factor in patient or parental willingness to join a trial (10). Nurses, like pediatricians, view pediatric research as integral to enhancing health outcomes with concomitant reluctance to encourage patient participation (9, 11).

The Therapeutic Hypothermia After Pediatric Cardiac Arrest (THAPCA) trials are multicenter investigations of active temperature control after pediatric cardiac arrest. Children are enrolled into one of two parallel trials, depending on whether arrest occurred out-of-hospital or in-hospital. Subjects are randomized within 6 hours of return of circulation to either therapeutic hypothermia (body cooling at 32–34°C) or therapeutic normothermia (normal body temperature maintenance at 36–37.5°C). The primary outcome is survival with good functional outcome. These critically ill children are managed within a PICU or cardiac ICU (CICU). Detailed study designs have been published (12).

Since nurses are patient advocates who provide emotional and informational support to parents, we proposed to assess the perceptions of nurses involved in the THAPCA trials (13–17). Our primary perception outcome measure was self-reported happiness to care for a THAPCA patient. We evaluated association of the measure with nurse characteristics (demographics, education, and participation in past research activities), self-reported confidence in research skills, perceived study team support, training and work burden, and the importance of the THAPCA research hypothesis. We also investigated the associations between nurses' attitudes and THAPCA trial performance with respect to rates of approach and consent at each center.

MATERIALS AND METHODS

A cross-sectional survey (**eSurvey**, Supplemental Digital Content 1, http://links.lww.com/PCC/A219) exploring nurses' attitudes about the THAPCA trials was conducted. All 38 THAPCA sites were invited to participate, with 16 expressing interest and providing study staffing. All participating sites obtained institutional review board approval before initiating the survey.

Study Survey

The survey was developed through a series of discussions with the THAPCA Data Coordinating Center (DCC) and THAPCA nurse coordinators. The group generated the survey questions based on experience with the THAPCA trials and extensive literature review on the subject of nurses' perceptions of research and job satisfaction. The survey questions were tested for comprehension, readability, and relevance to the study objective by statisticians and survey design experts at the DCC. Although there are additional survey design methods used to develop surveys, we felt that our methodology was sufficient to gather and begin to understand nurses' perceptions of the THAPCA trials.

Thirty questions, predominantly Likert items, explored nurses' perceptions of the THAPCA trials. The primary outcome was the proportion of nurses with positive perceptions of the THAPCA trials, as defined by nurse agreement (agree or strongly agree) with the statement "I am happy to take care of a THAPCA patient." Demographics, views on the scientific importance of the trials, relationships with the study team, and training regarding study procedures and patient care in the THAPCA trials were assessed. All PICU/CICU nurses employed at a site were eligible to participate even if they had never cared for a THAPCA subject. Additional questions were posed to nurses who had cared for a THAPCA patient. The survey was conducted between September 2012 and May 2013 during which time both trials were actively recruiting.

Participating sites forwarded PICU/CICU nurses' e-mail addresses to the DCC. An initial e-mail invited nurses to access the secure anonymous web-based survey, followed by weekly reminders for 3 months until each nurse completed the survey, opted out, or did not respond. Survey data were collected electronically in Checkbox Survey Software (Watertown, MA) and stored at the DCC for analysis. Surveys with over 90% of questions answered were considered complete and included in the analysis.

Statistical Analysis

Responses of "agree" and "strongly agree" were combined in the analysis, as were responses of "disagree" and "strongly disagree." "Neutral" responses were grouped with "disagree" and "strongly disagree" for primary aim analyses (positive perceptions of the THAPCA trials) but reported and analyzed separately otherwise. Analyses included descriptive statistics of respondent demographics, perceptions of the scientific importance of the trials, relationship with the study team, perceptions of training on study procedures, and patient care related to the THAPCA trials. Chi-square tests were used to compare the categorical variables between various nurse subgroups. Site-specific approach (proportion of eligible patients approached) and consent (proportion of approached patients who consented) rates were calculated using enrollment data through May 2013 to correspond with survey timing. Pearson correlations were calculated between average institution-wide responses to each Likert item question and site approach and consent rates. Data analysis was performed with SAS version 9.3 (SAS Institute, Cary, NC).

RESULTS

Demographics

Of the 2,241 nurses at 16 THAPCA sites who received an e-mail invitation, 1,387 (62%) completed the survey. Demographics (**Table 1**) show that the majority of nurses were female and less than 35 years old with less than 6 years of experience as a PICU/CICU nurse. Although 93% had previously cared for a patient on a clinical research study, only 13% reported previous participation in research activities such as developing/evaluating protocols, conducting a research study, or authoring a research article or abstract/poster. Slightly over half (55%) had cared for a THAPCA patient.

Nurses' Perceptions of the THAPCA Trials

Seventy-seven percent reported positive perceptions of the THAPCA trials, with comparable rates by gender, age, and education level (**Table 2**). Nurses with at least 3 years of PICU/CICU experience were more likely to have positive perceptions of the trials than those with less experience (79% vs 73%; $p = 0.005$). Perceptions were significantly more positive for nurses who had previously cared for a patient in any research study compared with those who had not (79% vs 54%; $p < 0.001$) and for those who had cared for a THAPCA patient in particular versus those who had not (82% vs 72%; $p < 0.001$). When nurses felt positively about the scientific importance of THAPCA, the study team, and training they received on study procedures, they were more likely to have positive perceptions of the THAPCA trials ($p < 0.001$ for each). Nurses were significantly less positive about the THAPCA trials when they felt that taking care of THAPCA patients required more work than other PICU/CICU patients although positive perceptions remained high (80% vs 93%; $p = 0.001$).

TABLE 1. Characteristics and Research Experience of Respondents[a]

Respondent Characteristic	Overall ($n = 1,387$), n (%)
Gender (female)	1,272 (92)
Age, yr	
18–24	130 (9)
25–34	704 (51)
35–44	306 (22)
45–54	174 (13)
55–64	70 (5)
65+	2 (0)
Years of experience as nurse in PICU/cardiac ICU, yr	
1–2	423 (31)
3–5	342 (25)
6–10	248 (18)
10–15	174 (13)
≥ 16	196 (14)
Highest level of nursing education	
Nursing diploma	43 (3)
Associate's degree	206 (15)
Bachelor's degree	1,029 (74)
Master's degree	103 (7)
Doctoral degree	4 (0)
Cared for a patient on a clinical research study	1,283 (93)
Participated in research activities such as developing or evaluating protocols, conducting a research study, or authoring a study article, abstract, or poster	185 (13)
Cared for a patient who was enrolled in the Therapeutic Hypothermia After Pediatric Cardiac Arrest trials	754 (55)

[a]Percentages are out of responses with available data.

Scientific Importance and Equipoise

Most nurses (88%) agreed that the THAPCA trials are scientifically important, and 90% thought that the studies should be conducted in children despite efficacy in adults after cardiac arrest (**Table 3**).

A majority of nurses (69%) felt that hypothermia reduces brain injury and mortality, whereas 27% were neutral on this question. When asked whether normothermia reduces brain injury and mortality, 23% agreed while 59% were neutral. Nearly three quarters (71%) agreed that fevers after pediatric cardiac arrest increase brain injury and mortality. Most nurses (88%) wanted to know the results of the THAPCA trials.

TABLE 2. Positive Perceptions of Participating in the Therapeutic Hypothermia After Pediatric Cardiac Arrest Trials

Respondent Characteristic	Positive Perception of THAPCA Trials[a] (%)	*p*[b]
Overall	1,073/1,387 (77)	
Gender		0.27
Male	79/108 (73)	
Female	989/1,272 (78)	
Age, yr		0.69
18–34	642/834 (77)	
35+	430/552 (78)	
Highest level of nursing education		0.76
Nursing diploma/associates degree	195/249 (78)	
Bachelor's degree	796/1,029 (77)	
Master's/doctoral degree	80/107 (75)	
Years of experience working as a nurse in PICU/CICU		0.005
1–2	307/423 (73)	
≥ 3	762/960 (79)	
Cared for a patient on any clinical research study		< 0.001
Yes	1,017/1,283 (79)	
No	56/104 (54)	
Directly cared for a patient who was enrolled in the THAPCA trials		< 0.001
Yes	620/754 (82)	
No	450/629 (72)	
Believe that the THAPCA trials are scientifically important		< 0.001
Strongly agree/agree	1,012/1,216 (83)	
Neutral/disagree/strongly disagree	58/166 (35)	
The THAPCA study team is responsive to the bedside nurse's needs when they are caring for a THAPCA patient		< 0.001
Strongly agree/agree	806/928 (87)	
Neutral/disagree/strongly disagree	260/452 (58)	
Feel that I have been adequately trained to care for a THAPCA patient		< 0.001
Strongly agree/agree	573/617 (93)	
Neutral/disagree/strongly disagree	498/768 (65)	
Compared with a regular PICU/CICU patient, taking care of a THAPCA patient requires		0.001
Much more/a little more work	520/648 (80)	
Neither more nor less/a little less/a lot less work	99/106 (93)	

THAPCA = Therapeutic Hypothermia After Pediatric Cardiac Arrest, CICU = cardiac ICU.

[a]Positive perception of the THAPCA trials was defined by nurse agreement (agree or strongly agree), with the statement "I am happy to take care of a THAPCA patient."

[b]*p* values reflect the chi-square test.

TABLE 3. Responses to Key Survey Questions Regarding Clinical Research and the Therapeutic Hypothermia After Pediatric Cardiac Arrest Trials

Survey Questions	Agree/Strongly Agree, *n* (%)[a]	Neutral, *n* (%)[a]	Disagree/Strongly Disagree, *n* (%)[a]
I believe that the THAPCA trials are scientifically important	1,216 (88)	115 (8)	51 (4)
Even though cooling has been shown to improve the survival in adults after cardiac arrest, the THAPCA trials should be done to know how to treat children after cardiac arrest	1,235 (90)	85 (6)	59 (4)
Hypothermia after pediatric cardiac arrest reduces brain injury and mortality	960 (69)	372 (27)	50 (4)
Normothermia after pediatric cardiac arrest reduces brain injury and mortality	322 (23)	808 (59)	251 (18)
Fevers after pediatric cardiac arrest increase brain injury and mortality	980 (71)	275 (20)	131 (9)
I would like to know the results of the THAPCA trials	1,212 (88)	111 (8)	57 (4)
Research is an important component of patient care in the PICU/CICU	1,272 (92)	49 (4)	63 (5)
My institution values clinical research and makes it easy to participate in research	1,197 (87)	109 (8)	77 (6)
My PICU/CICU supports the THAPCA trials	1,209 (87)	109 (8)	65 (5)
I derive professional satisfaction from taking care of a THAPCA patient	477 (63)	242 (32)	34 (5)
When I am caring for a THAPCA patient, I can count on my nursing colleagues on the unit to support me in completing the research and standard-of-care procedures for the patient	598 (79)	115 (15)	43 (6)

THAPCA = Therapeutic Hypothermia After Pediatric Cardiac Arrest, CICU = cardiac ICU.
[a]Percentages are out of responses with available data.

Relationships With the Study and Clinical Care Teams

Respondents agreed that research is a key component of care in the PICU/CICU (92%). The majority felt that their institutions valued research, making it easy to participate (87%) and that their PICU/CICU supported the trials (87%). Nurses who had cared for a THAPCA patient stated that they felt professionally satisfied (63%) and could count on support from their nursing colleagues (79%) when caring for a THAPCA patient (Table 3).

Among all respondents, 70% felt that PICU/CICU nurses were regarded as members of the THAPCA research team and 81% of nurses who had cared for a THAPCA trials patient agreed. When asked whether the THAPCA study team was responsive to bedside nurses' needs when caring for a THAPCA trials patient, 67% agreed, and 76% felt that the study team was knowledgeable about the study protocol and interventions (**Table 4**).

Training

Sixty-one percent of nurses who cared for a THAPCA patient agreed that they had been adequately trained on study procedures; this proportion was only 25% among nurses who had not cared for a THAPCA patient (Table 4). When asked whether they wanted more training on study procedures, 57% of nurses who had cared for a THAPCA patient, and 67% of nurses who had not, agreed that additional training was desirable.

Perceptions and Approach/Consent Rates

Higher site-specific subject approach rates were positively correlated with nurses' perceptions that their institution values research ($r = 0.54$; $p = 0.04$), that their PICU/CICU supports the THAPCA trials ($r = 0.61$; $p = 0.02$), and that the trials should be done in children despite data demonstrating hypothermia benefit in adults ($r = 0.61$: $p = 0.01$) (**Table 5**). Higher approach rates did not translate into higher consent rates among those approached. Sites had lower consent rates when their nurses believed that hypothermia was beneficial ($r = –0.55$; $p = 0.03$). However, there was no association when nurses believed that normothermia worked ($r = 0.12$, $p = 0.68$). We also observed a negative correlation between consent rates and nurses' perceptions of THAPCA's scientific importance ($r = –0.56$; $p = 0.03$) and colleague support ($r = –0.55$; $p = 0.03$).

DISCUSSION

Our study of over 1,300 nurses engaged in a labor-intensive trial of critically ill children at 16 sites provides valuable insight into nurses' perceptions of research and their influence on approach and consent rates. Limited research has shown that nurses generally have positive attitudes toward pediatric research but are reticent to recommend participation to their patients, due to a lack of understanding about clinical research, lack of familiarity with a specific trial, or disapproval of the research question (9, 11, 18). Our findings may help other study teams understand the potential impact of bedside nurses' attitudes on the planning and execution of complex multi-institutional studies.

We found that nurses overwhelmingly believed that it was scientifically important to assess hypothermia in children, despite existing literature demonstrating efficacy in adults after cardiac arrest (19, 20). This supports the importance of testing

TABLE 4. Perceptions of the Therapeutic Hypothermia After Pediatric Cardiac Arrest Site Study Team and Study Training

Response to Survey Question	Overall ($n = 1,387$), n (%)	Nurses Who Have Directly Cared for a THAPCA Patient ($n = 754$), n (%)	Nurses Who Have Not Directly Cared for a THAPCA Patient ($n = 629$), n (%)	p[b]
I feel like the PICU/cardiac ICU bedside nurses are involved members of the study team when they care for a THAPCA patient				< 0.001
Agree/strongly agree	968 (70)	608 (81)	360 (58)	
Neutral	317 (23)	96 (13)	221 (35)	
Disagree/strongly disagree	94 (7)	50 (7)	44 (7)	
The THAPCA study team is responsive to the bedside nurse's needs when they are caring for a THAPCA patient				< 0.001
Agree/strongly agree	925 (67)	596 (79)	329 (53)	
Neutral	377 (27)	105 (14)	272 (44)	
Disagree/strongly disagree	74 (5)	51 (7)	23 (4)	
The study team is knowledgeable about the THAPCA study protocol and study interventions				< 0.001
Agree/strongly agree	1,047 (76)	666 (89)	381 (61)	
Neutral	276 (20)	55 (7)	221 (35)	
Disagree/strongly disagree	54 (4)	31 (4)	23 (4)	
I feel I have been adequately trained to care for a THAPCA patient				< 0.001
Agree/strongly agree	615 (45)	458 (61)	157 (25)	
Neutral	410 (30)	180 (24)	230 (37)	
Disagree/strongly disagree	356 (26)	114 (15)	242 (38)	
I would like to have more training on the THAPCA trials				< 0.001
Agree/strongly agree	849 (62)	430 (57)	419 (67)	
Neutral	358 (26)	211 (28)	147 (24)	
Disagree/strongly disagree	166 (12)	109 (15)	57 (9)	
I would like to have more input about how the work is organized for the THAPCA patients				0.009
Agree/strongly agree	578 (42)	324 (43)	254 (41)	
Neutral	647 (47)	331 (44)	316 (51)	
Disagree/strongly disagree	154 (11)	99 (13)	55 (9)	

THAPCA = Therapeutic Hypothermia After Pediatric Cardiac Arrest.

[a]Percentages are out of responses with available data.

[b]p values reflect the chi-square test.

interventions in children and not adopting a "one-size fits all" approach by extrapolating results from adult studies to the pediatric population. Our findings suggest that as with pediatricians, scientific merit is an important contributor to nurses' attitudes about a study (6). The majority were interested to know the results of the THAPCA trials, indicating a level of engagement beyond simply completing study procedures as part of their patient care duties. Presenting study results to clinical caregivers may ensure that these important research partners feel informed and valued, fostering interest in future research participation.

TABLE 5. Correlation Between Survey Questions and Site Approach and Consent Rates

Survey Questions	Approach Rate Correlation (*p*)	Consent Rate Correlation (*p*)
Research is an important component of patient care in the PICU	0.48 (0.07)	−0.38 (0.16)
My institution values clinical research and makes it easy to participate in research	0.54 (0.04)	−0.29 (0.30)
My PICU/CICU supports the THAPCA trials	0.61 (0.02)	−0.28 (0.31)
I believe that the THAPCA trials are scientifically important	0.45 (0.10)	−0.56 (0.03)
Even though cooling has been shown to improve survival in adults after cardiac arrest, the THAPCA trials should be done to know how to treat children after cardiac arrest	0.61 (0.01)	−0.36 (0.19)
Hypothermia after pediatric cardiac arrest reduces brain injury and mortality	0.30 (0.27)	−0.55 (0.03)
Normothermia after pediatric cardiac arrest reduces brain injury and mortality	−0.32 (0.24)	0.12 (0.68)
Fevers after pediatric cardiac arrest increases brain injury and mortality	0.42 (0.12)	−0.01 (0.96)
I feel like the PICU/CICU bedside nurses are involved members of the study team when they care for a THAPCA patient	0.25 (0.37)	−0.19 (0.49)
The THAPCA study team is responsive to the bedside nurse's needs when they are caring for a THAPCA patient	0.30 (0.27)	−0.09 (0.75)
The study team is knowledgeable about the THAPCA study protocol and study interventions	0.36 (0.19)	−0.28 (0.32)
I would like to have more input about how the work is organized for the THAPCA patients	−0.01 (0.96)	0.22 (0.44)
I feel I have been adequately trained to care for a THAPCA patient	−0.18 (0.51)	−0.10 (0.73)
I would like to have more training on the THAPCA trials	0.19 (0.50)	0.37 (0.17)
I would like to know the results of the THAPCA trials	0.49 (0.06)	0.17 (0.54)
I perceive the THAPCA trials to be a well-organized study	0.20 (0.48)	−0.32 (0.24)
I am happy to take care of a THAPCA patient	0.08 (0.78)	−0.37 (0.18)
Taking care of a THAPCA patient requires (more work)	−0.02 (0.95)	−0.07 (0.81)
When I am caring for a THAPCA patient, I can count on my nursing colleagues on the unit to support me in completing the research and standard-of-care procedures for the patient	0.34 (0.21)	−0.55 (0.03)
I derive professional satisfaction from taking care of a THAPCA patient	0.35 (0.20)	−0.26 (0.35)

CICU = cardiac ICU, THAPCA = Therapeutic Hypothermia After Pediatric Cardiac Arrest.

Nurses' beliefs about the effectiveness of the study interventions raised questions about lack of equipoise. Over two thirds of nurses believed that hypothermia reduced brain injury and mortality, whereas a majority were neutral or disagreed that normothermia provided benefit. Perhaps, this difference should not have been surprising, since hypothermia is the standard of care for birth-asphyxiated newborns and implemented during pediatric cardiac surgery (21, 22). Media reports of children surviving drowning in icy ponds may strengthen beliefs that hypothermia is beneficial. In addition, lack of equipoise by clinical care physicians may have reinforced nurses' perceptions of hypothermia's benefit. A majority of our sample was neutral on whether normothermia provided benefit, which we would like to attribute to equipoise, but suspect that it might result from unfamiliarity with this treatment. Few pivotal hypothermia studies have included a normothermia arm (23, 24). Although THAPCA training focused on ensuring that the study teams (investigators, consulting subspecialties, and research coordinators) had equipoise between the interventions, the large numbers of nurses rotating care for these children did not receive such training.

An intriguing finding was that sites whose nurses believed that hypothermia was beneficial had lower consent rates. Bedside nurses were immersed in the immediate intensive care of their patients and typically did not have direct influence on the consent process. Since decision making could be influenced given the high-value families place on nurses' opinions, it may be prudent for study teams to involve bedside nurses in educational efforts about research protocols.

Nurses overwhelmingly agreed that caring for a THAPCA patient required more work than other PICU/CICU patients, yet the majority derived professional satisfaction from doing so. Critically ill children in the THAPCA trials require significant nursing support. PICU/CICU nurses must oversee many study procedures including managing the temperature control

equipment, recording frequent vital signs, procuring recurrent laboratory tests, and reporting adverse events. Our results suggest that support from colleagues, confidence in study training, and assistance from the study team contributed to nurses' positive views despite demanding study procedures. Although clinical trial designs should be simplified as much as possible, our data indicate that researchers should not be dissuaded from considering studies requiring intensive bedside nursing procedures.

Of nurses surveyed, 93% had previously cared for a patient enrolled in a research study. Nurses with such previous experience viewed THAPCA more positively than those who had never cared for a research subject. By active participation in research, nurses may attain a level of confidence in their ability to carry out research procedures, fostering positive views of trials, the study team, and future research.

Nurses, particularly those who had not cared for a THAPCA patient, wanted more training on study procedures. Although THAPCA study personnel training was quite extensive and central, training for bedside nurses was site specific. Research teams should note that nurses who felt sufficiently trained on the study intervention, and that the study team was responsive to their needs, were significantly more positive about the trials.

Finally, nurses at institutions with higher overall approach rates for the THAPCA trials were more likely to feel that their institution valued research and that their PICU/CICU supported the trials and made it easy for them to participate. They were also more likely to agree that the trials should be done in children despite benefit in adults. These perceptions may reflect an overall culture of research at the participating THAPCA sites, where support for clinical research activities is expected. Also, physicians and investigators may be more likely to approach parents about study involvement when nurses support their efforts. For investigators planning a trial, nurses' perceptions of research support within their institutions and units could serve as a marker for evaluating potential success of a candidate institution. Although this positive association was encouraging, higher approach rates did not lead to higher consent rates.

The observed negative correlation between consent rates and nurses' perceptions of scientific importance and colleague support is challenging to explain. Targeted research should further explore the impact of nursing perceptions on study consent and enrollment.

Study Limitations

We note here several limitations. Only a subset of THAPCA sites agreed to participate. Since this study relied on coordinator volunteerism, sites with strong research support may have preferentially chosen to participate, biasing findings. However, the 16 participating sites are diverse with respect to geography and patient volume, increasing confidence in the generalizability of results to a broad range of institutions. Although all nurses at each participating site were invited to participate, a larger proportion of nurses who felt positively about research or the THAPCA trials may have responded, limiting generalizability to all PICU/CICU nurses. We cannot determine whether caring for a study patient made nurses feel more positive or if nurses with more positive perceptions of research volunteered to care for a THAPCA patient. Finally, this study was considered to be exploratory, with reported significance levels unadjusted for multiple comparisons.

CONCLUSIONS

Most nurses we surveyed had positive perceptions of the THAPCA trials. Positive views of institutional, colleague, and study team support as well as study training appear to be contributing factors. Nurses felt that the scientific question posed by the THAPCA trials was important and wanted to know the results of the study, indicating a high level of engagement. Despite the increased work burden, nurses remained enthusiastic about the trials, demonstrating that studies with intensive bedside nursing procedures are feasible. As nurses with previous experience caring for a research patient (including a THAPCA patient) were more likely to view THAPCA positively, research teams should find creative ways to expose nurses to research opportunities. Although there was no association between consent rates and perceived normothermia benefit, institutions whose nurses believed hypothermia was beneficial had lower consent rates, suggesting that educating nurses on study rationale and equipoise may enhance study participation.

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