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Therapeutic Hypothermia, False Hope in Cooling

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Therapeutic Hypothermia Benchmark Study

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by

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Contents

Acknowledgements

Executive Summary

Implementation and Benchmark Project

1. Rationale for the Project
2. Literature Synthesis
3. Project Stakeholders
4. Implementation Plan
5. Timetable/Flowchart
6. Data Collection Methods
7. Cost/Benefit Discussion
8. Discussion of Results

Conclusions/Recommendations

References

Appendix

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Executive Summary

Post-cardiac arrest is a critical time for both the patients and those involved in their treatment. Many factors can contribute to a patient experiencing cardiac arrest, such as a history of arrythmias, septic shock and various comorbidities. Guidelines can change rapidly, and the efficacy of treatments can be difficult to ascertain due to the inability to separate the effects of the multitude of intra-code and post-code interventions. However, as resuscitation science gathers more data, the medical community must adapt to the new information and implement those changes that have been shown to be beneficial while discontinuing treatments that have no proven effect. In post-cardiac arrest patients, maintaining a normal body temperature or treating fever has been shown to be more beneficial than implementing therapeutic hypothermia in preserving neurological function and reducing mortality.

Following the 2015 American Heart Association guidelines post cardiac arrest, many hospitals have spent large amounts of money and time to acquire the equipment and train the staff in the performance of post-arrest targeted temperature management. Targeted temperature management, or therapeutic hypothermia is performed in order to improve neurological outcomes for the patient. However, despite this intervention, many patients though successfully resuscitated from cardiac arrest, either die during or shortly after the hospital stay or are persistently neurologically disabled. Many others suffer hospital acquired infections. Subsequent to the recommendation of the AHA to use TH post resuscitation, more data has been gathered and analyzed which supports normothermia in place of cooling.

Therapeutic Hypothermia Benchmark Study

1. Rationale for the Project

Currently, in this organization, there is no systematic method for examining outcomes in patients who undergo therapeutic hypothermia or who are managed without TH post-ROSC. Because this is a smaller Intensive Care Unit, with only 24 beds, and the process of cooling and rewarming takes several days, most nurses are aware of when a TH patient is admitted and what the outcome after rewarming is, however, no formal process exists to determine if this intervention results in any noticeable benefit to the patients. This year, only 2 patients have undergone TH. Both showed significant neurological deficits several days after rewarming and the families elected to withdraw care.

Families show significant distress while waiting for the patient to go through TH and rewarming with the hopes of waking up. These patients and families are experiencing a very vulnerable and chaotic event with an uncertain outcome. The vulnerability of this patient population and the risks that are already faced of poor neurological outcome as well as the continued risk of death suggests that we should not expose them to greater potential for harm.

Therefore, to preserve both life and functionality of this population, providers must continually receive the latest evidence-based education on interventions showing the greatest benefit and lowest risk to the patient. In post cardiac arrest patients (P), what is the effect of therapeutic hypothermia (I) compared to maintaining normal body temperature (C) on patient neurologic outcomes and mortality (O) over 90 days post arrest (T)?

2. Literature Synthesis

Cardiac arrest is often a multifactorial problem, originating from an individual's underlying comorbidities and aggravated by additional circumstances to culminate in an event. To standardize resuscitation attempts, the American Heart Association creates and routinely updates algorithms to maximize the potential for return of spontaneous circulation or ROSC. The AHA recommends the use of Targeted Temperature Management, or Therapeutic Hypothermia, TH, for patients that remain comatose post-ROSC (Eken, 2015). Despite this, few survive cardiac arrest and even when ROSC is achieved, the individual is vulnerable to poor neurological outcome and has a continued risk of morbidity.

Initial studies that may have prompted these guidelines had small study sizes. Thus, when larger populations were studied, hypothermia showed no benefit over normothermia for survival to hospital discharge or neurological outcomes (Eken, 2015). Both TH and Mild Therapeutic Hypothermia, MTH, have been compared to determine efficacy and shown that neither produced improved outcomes. However, the management of the patient's core temperature to prevent hyperthermia remains a strong recommendation (Ramakrishna et al., 2016). Survival to hospital discharge is improved when strict normothermia is utilized (Casamento et al., 2016) (Chan, Berg, Tang, Curtis & Spertus, 2016). The possibility exists that with the advances in resuscitation science the effectiveness of TH as a post cardiac arrest intervention was initially overstated due to the inability to fully separate factors of the resuscitation attempt or post arrest care (Temperikidis & Manolis, 2015).

Due to the variety of reasons that cardiac arrest can occur and the differing patient populations that experience it from pediatrics to the elderly, several factors have been independently studied to determine if patients benefited from cooling. Shock is one potential

cause of cardiac arrest where TTM conveys no benefit (Annborn et al., 2014). Expert review of evidence states that patients in cardiogenic shock should not be cooled and those in septic shock should only have hyperthermia treated (Cariou, 2017). Individual case study reports have shown that TH can lead to QT prolongation in patients with no prior history of arrhythmias and highlights the potential for fatal arrhythmias (Moeller & Webber, 2017). Furthermore, implementing TH in the post arrest plan of care is shown to increase the risk of pneumonia and other hospital acquired infections (Bhattacharjee, Baidya & Maitra, 2015) (Hakim, Ammar & Reyad, 2018).

Pediatrics and geriatrics must be examined apart from the adult population. Both groups have differences in organ function and often have several comorbidities that lead to cardiac arrest. In the pediatric population, no benefit exists in functionality or survival to one year (Moler et al., 2017). When examining the elderly, age was found to be a predictor of poor neurological outcomes, in that, for every 10 years younger, the patient was more likely to retain good function independent of cooling (Oh et al., 2017). Therefore, TH failed to prove a benefit in the elderly population. The individual examination of these factors as well as different attributes of the critically ill population post-ROSC, demonstrate that TH is not supported by the evidence as an intervention post-ROSC.

3. Project Stakeholders

Because this is a corporate hospital, there are immediate stakeholders at the facility who bring issues to the corporate stakeholders. Some of these stakeholders include the ER medical director, ICU medical director and the physicians who practice in these areas. Additional stakeholders include the nursing staff, facility education department, unit educators and unit

directors. Once the policy change to normothermia passed the immediate stakeholders, it could be sent as a policy change to corporate. This facility has been chosen to lead several initiatives, such as the creation of an in-house dialysis team to support the facilities' needs: therefore, trialing an initiative in within the facility's purview.

Broadly, the American Heart Association is affected by withdrawing TH in favor of normothermia. Not following a guideline of the AHA could be seen as a rejection of their guidelines for resuscitation. Hospitals and many facilities require Basic or Advanced Cardiac Life Support classes that are available only through the AHA. Therefore, all the staff involved in this decision have been exposed to the 2015 guidelines and might have an expectation that any policy change is below the standard of care if they are not familiar with the evidence.

With any change that affects patient care, the patient and their family members are the ultimate stakeholder. Because this is a specialty intervention after a specific event, the majority of families will not be familiar with the intervention. However, aspects of the treatment plan should always be discussed with the patient or designated decision maker and consent obtained where applicable.

4. Implementation Plan

The change to maintenance of normothermia in place of TH will take place primarily in the Emergency Department and the Intensive Care Unit. Although patients on in-patient floors might experience cardiac arrest with resuscitation, the nurses on those floors would not be implementing TH, nor would the physicians order it without an immediate transfer to Intensive Care. In this facility, the Intensivist takes over care from the hospitalist upon transfer. The data needed to make the change are the studies showing the ineffectiveness of TH. Additional data can be presented regarding cost savings in training, personnel, and equipment. The stakeholders

impacted by this change are the emergency and critical care providers implementing a post resuscitation care plan. Critical care and emergency nurses are also impacted due to the practice change. The policy change gives an opportunity to support evidence-based change in critical care and inter-unit cooperation to support vulnerable patients. Furthermore, the change begins the opportunity to develop clinical practice guidelines for Intensive Care Unit patients and specifically for patients post resuscitation (Melnyk, Grinspun & Fineout-Overholt, 2015, p. 182). Permission will be needed from the medical director of both units and the nursing director should be notified. Allies in the organization can potentially be identified in the educators for both departments as well as the education department. These allies will be selected to form a task force for the implementation of this change. The task force of best practice champions (Melnyk, Grinspun & Fineout-Overholt, 2015, p. 195) would help to disseminate information about the change and support change on the unit. Potential barriers include the challenging of the status quo and holdouts in the change process that want to see every possible intervention done to maximize the chances of retained neurological function, though no proven benefit exists. Training should be performed to enact the change. Each unit should have a brief update done during routine staff meeting and an interdisciplinary meeting would ideally be scheduled to discuss interventions best supported by the evidence in post-CA patients. No additional supplies should be utilized. The unit educator for the critical care department and task force members could perform audits on post-CA patients to determine which interventions are being utilized. Maintaining normothermia post ROSC will result in cost savings to the organization. The period of cooling, maintenance and rewarming require one on one nursing from a nurse trained on the equipment. The change will decrease personnel costs as well as the additional in-service and orientation hours needed to train individuals on the equipment. The existing equipment will not

need to be replaced, a savings of roughly $25,000 per machine, plus the associated one-time use items such as cooling pads and annual and periodic maintenance for the equipment

There are three phases of the implementation plan. First, educational meetings will be scheduled to inform members of the organization of the change. During these meetings, individuals can be identified to help the units process the change or self-select to be involved in the task force. Then, the change will "go live" on a set day, giving the providers a chance to receive the disseminated information of the change. Thirty days after the educational meetings are scheduled and carried out would be the scheduled go live day. Routine evaluations would be performed in the post-implementation phase to determine what orders are implemented post resuscitation. Audits will be performed by the task force members. Additionally, to show the benefit of the change, patients should be scored to determine level of neurological function post ROSC and followed up to determine if alive at 90 days post event.

5. Timetable/Flowchart

Timeline of events over 90 days

Day 1-30

Informational meetings carried out in Critical Care areas

EBP champions identified (self or via selection)

Day 31

"Go live" day, change is implemented

Day 31-90+

Chart audits of successfully resuscitated patients performed

Follow up at 90 days post code for final neurological outcome scale

6. Data Collection Methods

The evaluation will be retrospective and prospective. The retrospective data will look at all the patients who have undergone therapeutic hypothermia in the last two years. Analysis will be performed to determine if patient survived to hospital discharge, was diagnosed with a hospital acquired infection and the neurological outcome (where able to be analyzed). The neurological outcome will be the hardest to determine because there has been no standardized way to rate the outcomes prior to this point. The physical and occupational therapy assessments and physician notes will be used to determine where on the neurological outcome scale the patient falls. The scale selected is the Glasgow Outcome Scale- extended (Hahn, Souza, Haak & Heiney, 2019). It rates the patient with an easy to use scale from 1-Death to 8 Upper Good Recovery. Good neurological outcome will be either a 7 or 8 on the scale. An infection will be counted as hospital acquired per the current policy as a culture (blood, sputum or otherwise) obtained more than 24 hours post admission that tests positive for bacteria and it is not explicitly stated by the attending physician as contaminate (Longview Regional Medical Center, 2019).

The hospital currently records information on all codes by placing a procedural code for CPR. This will also serve to flag the charts of all cardiac arrest patients for further review. The patients who have been treated by therapeutic hypothermia can further be narrowed down due to the use of a specific order set and by vital sign logging. Alternative methods of determining where therapeutic hypothermia was used is auditing the use of certain charge codes generated by labels on the equipment. This will provide actual comparison data. Code sheets will be obtained from the House Supervisor who attends all codes and in conjunction with the ICU/ ER Charge Nurse, fills a code sheet out. Evaluation after therapeutic hypothermia is initiated will include

data on time until ROSC (in minutes), neurological status pre and post event, age and whether a hospital acquired infection developed during hospitalization. The information on infections will either be yes or no, as it will be clear from the date and time a culture was collected whether it was 24 hours post arrival to the hospital. This will likely show a decrease in hospital acquired infections in patients not treated with therapeutic hypothermia. Neurological outcome (pre) will be subtracted from the outcome. This number is used to demonstrate differences in neurological function after resuscitation. The neurological deficit, if any, will be compared to the therapeutic hypothermia neurological deficit, calculated on the pre-intervention data obtained in the last two years. All this data will be recorded in the spreadsheet to follow. This is a simple way of having verifiable and reproducible data. Patients who expire during the hospitalization will not be included. Though the Glasgow extended scale does account for death, it cannot account for the families that elect to withdraw care.

The difference in pre and post neurological function will be compared via independent t tests to determine if there is a statistically significant difference (Independent t-test for two samples, n.d.). The significance is set at $p=0.05$. Additionally, median time to ROSC with interquartile ranges will be set. The data set will be divided between patients with a favorable neurological outcome and unfavorable outcome. This can be helpful in determining the success of future resuscitation attempts after certain periods of time have elapsed. Simple percentages will be used to determine how many patients in the therapeutic hypothermia and how many in the normothermia group develop an infection.

7. Cost/Benefit Discussion

With the use of normothermia as opposed to Therapeutic Hypothermia, there are few, if any additional costs. Patients will be managed to keep their body temperature 36 to 38 degrees Celsius (96.8 to 100.4 degrees Fahrenheit). This will be accomplished using acetaminophen for the treatment of hyperthermia as well as cooling blankets, or warm blankets and Bair huggers for hypothermic patients. All of these items are already present in Intensive Care Units, thus yielding not additional cost. The cost of acetaminophen is negligible during an Intensive Care Unit stay.

Some of the data to evaluate the change will be qualitative to examine what orders are being implemented in post cardiac arrest patients. Additional data will examine the actual temperature control of patients. A neurological assessment tool shall be performed prior to discharge and patients will be followed up with to determine a final disposition at 90 days post event. Upon looking at both the materials and staffing spending, there should be decreases in both categories owing to the elimination of the expenses to train personnel, repair and acquire special machines for the purpose of TH.

If the change cannot be enacted at the original go live date, then the contacts can be used to create a greater interdepartmental cooperation. This cooperation and the contacts in each department can be utilized to implement other evidence-based change and work back up to the elimination of therapeutic hypothermia and implementation of normothermia, or prevention of hyperthermia in post cardiac arrest patients. Alternately, if resistance is met, encouraging the aggressive treatment of fever can be a starting point and is supported by the evidence

8. Discussion of Results

One way to evaluate if this plan is successful is to compare the two sets of data to look at the neurological outcome and mortality. If we cannot show the benefits of normothermia, then the physicians will continue to order hypothermia.

The primary way to determine if the plan was a success is to investigate the care on patient's post-ROSC to determine whether or not therapeutic hypothermia is being ordered or not and by whom. If you have one provider who is holding out on the change, it may be possible to revisit the issue once other providers have made the change and have data from the patients involved. If a multitude of providers are not following the change, then the core efforts have failed and the implementation of the change itself must be revisited.

As far as patient outcomes, there should be no change when maintaining normothermia is utilized over therapeutic hypothermia. However, a decrease in pneumonia in the post-ROSC population should be notable.

9.Conclusions/Recommendations

Evidence-based practice is a cornerstone of nursing practice; however, nothing that happens in the nurse-patient interaction happens in a bubble. Because we are working with human beings who have opinions, feelings and desires related to their health care, patient preference must be accounted for. Patients can research different treatment options online and might encounter data from an unreliable source or rely on old data when looking up different treatments or medications. Not every article on the internet comes from a reliable source and not every patient or family member will have the ability to discern which articles are superior and

can hold up to scrutiny. Previous experience can often be counted as evidence (English Long, Gallagher-Ford &Fineout-Overholt, 2010).

Additionally, as an intervention might be proved as unreliable, patients or their families might still perceive it as the standard of care. This could be the case with therapeutic hypothermia. As the American Heart Association still recommends targeted temperature management post resuscitation for a shockable arrest, families who have experienced cardiac arrest or with family members in health care could be aware of these guidelines (Scirica, Scirica & Levine Cardiac Intensive Care Unit, 2013). Failure to communicate the up to date research and rationale behind a decision could lead to families with the belief that not everything is being done to save their loved one or with the perception that workers do not value their family member's life. Additionally, stakeholders in the organization might be more apt to follow the American Heart Association, because it is a large organization and has brand recognition and therefore perceived credibility.

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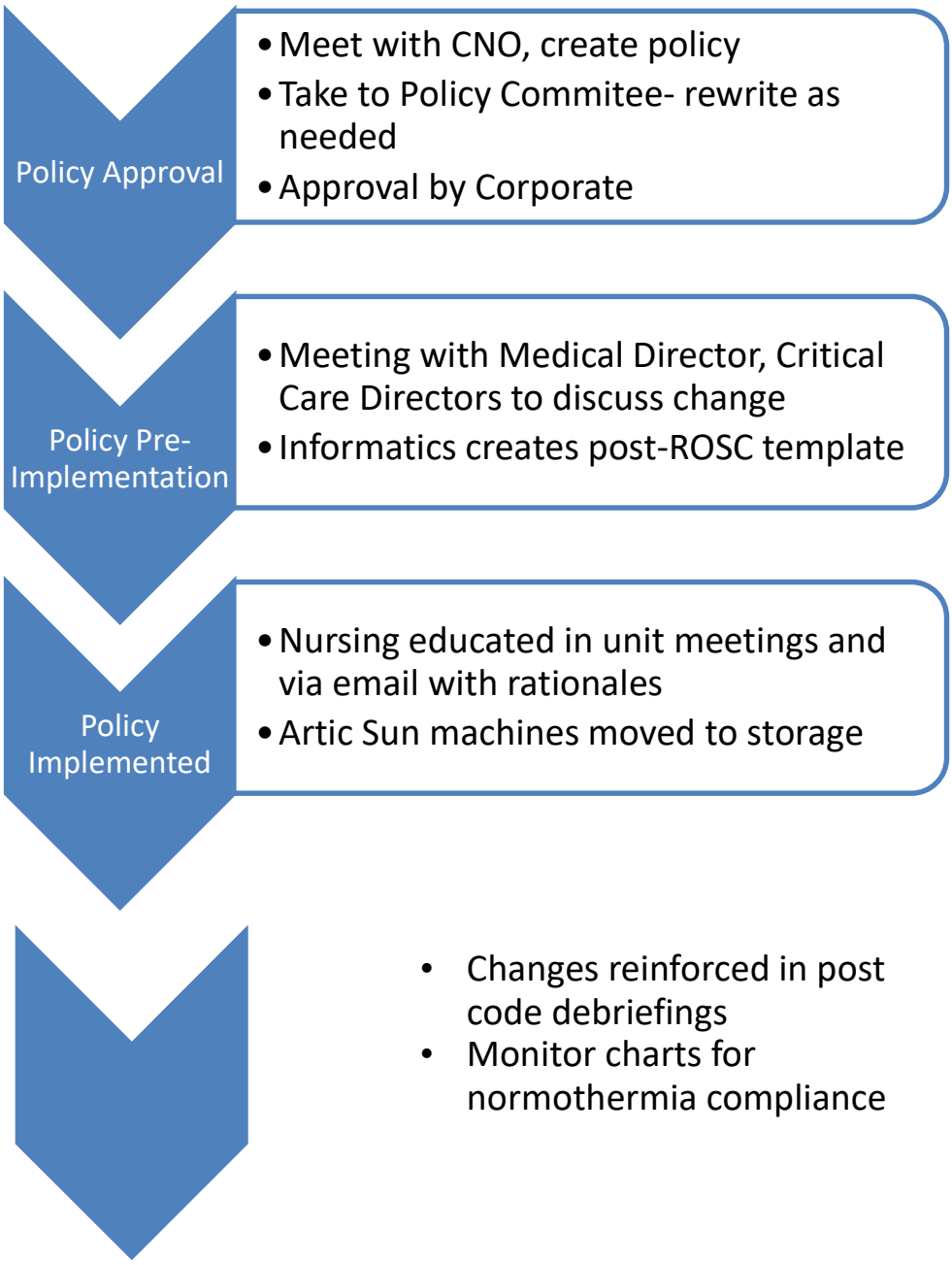
Appendix A

Synthesis Table

	Encounter # xxxxxxx	Age (years)	Time to ROSC (min)	Survival to Discharge	Neuro Scale PRE if available	Neuro Scale Post	Infection	TH	NT
example	9001234	67	32 min	yes	7	2	yes	yes	no
post intervention	9006543	54	41 min	no	8	1	n/a	no	yes

Appendix B

Flowchart



Appendix C

Instrument

Evaluation Tool

1. The teaching/learning resource(s) were adequate.

   Not at all
   Somewhat
   Almost Completely
   Completely

2. The content was relevant to the learning outcome.
   Not at all
   Somewhat
   Almost Completely
   Completely

3. The learning objectives were clearly stated.

   Not at all
   Somewhat
   Almost Completely
   Completely

   Review the literature showing no benefit in therapeutic hypothermia
   Not at all
   Somewhat
   Almost Completely
   Completely

   Describe the promotion of normothermia as an alternative treatment.

   Not at all
   Somewhat
   Almost Completely
   Completely

   Describe the implementation and evaluation of the change from TH to normothermia.

Not at all
Somewhat
Almost Completely
Completely

4. The length of the program was adequate.

Not at all
Somewhat
Almost Completely
Completely

5. The overall program was satisfactory.

Not at all
Somewhat
Almost Completely
Completely