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Technique Article

The Children's Hospital Boston Non-Routine Event Reporting Program

Gregory S. Matte, BS, CCP, LP; Daniel Riley, BS, CCP, LP; Robert LaPierre, BS, CCP, LP; Robert Howe, BS, CCP, LP; Mark Anderson, MS, CCP, LP; Sharon Boyle, BSN, RN, CCP, LP; Linda Durham, BS, CCP, LP; William Regan, BA; Frank Pigula, MD

Children's Hospital Boston, Department of Cardiovascular Surgery, Boston, Massachusetts

Abstract: Several authors have described methods to track perfusion and cardiac surgical morbidity and mortality as well as perfusion accidents. There is currently not a standard definition of a perfusion accident nor is there a standard reporting threshold for events which do not directly cause known morbidity. We propose the term non-routine events (NREs) instead of accidents, and provide a working definition and reporting threshold for such. This paper describes the program which we developed to track perfusion NREs within the Cardiovascular Program at Children's Hospital, Boston. NREs are categorized by type (technique, equipment, or patient-related) and bypass period (pre-cardiopulmonary bypass, bypass, or post-cardiopulmonary). NRE outcomes are also classified by the level of discussion or change in perfusion practice after multidisciplinary review. We have documented during a 44 month interval that 42% (29/69) of reported NREs occur during the bypass period and are equipment related and thus, efforts to improve practice should focus there. We have also seen a generally decreasing incidence of NREs requiring either a change in perfusion practice or a new protocol during this time period. We believe that our regular multidisciplinary meetings to discuss NREs have increased awareness among the entire team about potential problems in the program and that intuitively, it has improved patient safety.
Keywords: cardiopulmonary bypass, perfusion morbidity and mortality, prospective database, non-routine events. *JECT. 2010;42:158–162*

Charriere et al. defined a permanent injury or death incidence of 1:3220 cardiopulmonary bypass procedures in France for 2005 (1). Kurusz et al.'s perfusion accident survey for the United States concluded a permanent injury or death rate of 1:1000 cardiopulmonary bypass procedures (2). Stoney et al. reported the same incidence of 1:1000 for permanent injury or death and added a perfusion accident occurrence of 1:300 (3). These studies did not address differences between adult and pediatric populations. Given the wide variety of technical procedures and considerations in congenital heart surgery, we contend that this field may be at even higher risk. In fact, Stammers and Mejak reported in their 2000 perfusion safety study that centers only performing pediatric cardiopulmonary bypass procedures had a serious patient injury incident rate of 1.4–2.7 times higher than centers performing adult or combined adult/pediatric perfusion (4). Furthermore, this higher incidence rate was apparent even though pediatric-only centers were more likely to use two perfusionists per case. Others have described common problems, fixes, and prevention strategies to deal with perfusion related bypass problems (5). The purpose of this paper is to describe the process instituted at Children's Hospital Boston for defining, documenting, and discussing bypass related non-routine events (NREs).

In 2005, our institution switched all perfusion custom tubing packs to include phosphorylcholine coated tubing. In the ensuing months, we had multiple instances of tubing disconnect either before or during cardiopulmonary bypass. A multidisciplinary group consisting of surgery, perfusion, anesthesia, and nursing was convened. The problem was identified (tubing disconnect), analyzed (connection slippage), and a remedy was implemented. This included tie banding all high pressure connections at the field with sterile tie bands and a sterile banding gun. While tie banding all high pressure connections in the perfusion circuit

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Address correspondence to: Gregory S. Matte, BS, CCP, LP, Children's Hospital Boston, 300 Longwood Avenue, FA-144, Boston, MA 02115. E-mail: Gregory.matte@cardio.chboston.org
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had long been our program's practice, it was not customary to do so with the arterial line-arterial cannula connection at the sterile field.

The tubing packs were also modified so that all oxygenator/reservoir direct connections were standard tubing instead of phosphorylcholine coated tubing. As a result of this experience we conceived and implemented the NRE Reporting Program. The NRE Reporting Program is now our structured approach to the documentation, and reporting of problems, or potential problems, during cardiopulmonary bypass for congenital heart disease patients. An NRE is defined as that which is out of the ordinary that affects, or potentially affects, patient safety and/or surgical progress during, or around the cardiopulmonary bypass period. This broad definition was intentionally chosen. It has been observed in other studies of sophisticated technical endeavors that seemingly unrelated events may share a root cause or initiate a sequence of events that result in process failure. Svenmarker and Appelblad noted that minor mishaps or incidents should be viewed with increased diligence as there is emerging data to support correlation with postoperative complications (6). De Leval et al. concluded in their arterial switch operation study that minor incidents correlate with postoperative complications and mortality (7). Since defining the level which an incident is significant enough to report is difficult, we recommend over reporting as more ideal than under reporting. Our broad definition of an NRE takes this into consideration by allowing the perfusionist to report any event as long as it meets the minimum subjective threshold of potentially affecting patient safety.

DESCRIPTION

The Cardiovascular Program at Children's Hospital, Boston staffs three operating rooms with six surgeons, seven perfusionists, eleven anesthesiologists, and 16 members of the nursing staff. In December 2005, we implemented the NRE Reporting Program and began prospectively documenting all perfusion-related events for bypass cases which were deemed non-routine. As defined, the event must be related to the conduct of perfusion and to the perfusionist's responsibilities and/or the bypass circuit. The occurrence of a non-routine event triggers documentation by the perfusionist on the hospital network using a Non-Routine Event Reporting Form (Figure 1). Next, this form is printed and placed in the NRE Binder along with a copy of the case's perfusion record. The binder is securely stored in the perfusion staff room according to Health Insurance Portability and Accountability Act (HIPAA) guidelines. Internally, this data provides the opportunity for perfusion staff discussions exploring scenarios, treatment options, and the ever-popular, "What I would have done", in an informal setting before the more formal multidisciplinary meeting. Quarterly meetings then allow for collective consideration of NREs. This multidisciplinary meeting is well represented by the cardiovascular program. A perfusionist presents a brief clinical abstract of the patient and the NRE is discussed. Specifics of the case and event are reported but the staff involved remain anonymous. The conclusions from each case are recorded and then entered into the online NRE database. The NRE binder is then updated for future reference.

There have been 2694 bypass cases at our institution from December 2005 through July 2009. Perfusion NREs were relegated to one of three periods within the operation: prebypass, bypass, and postbypass, and also relegated to technique, equipment, and patient factors (Table 1). We have documented 69 NREs in 67 patients during this 44-month interval giving an incidence rate of 2.6% or one in 39 procedures. The majority of NREs (64%, 44/69) occurred during the bypass period with the balance occurring in the prebypass period (33%, 23/69) and postbypass period (3%, 2/69) (Table 1). When NREs are examined as a function of root cause (technique, equipment, patient related), the results again significantly favored one category. Most NREs were related to equipment (61%, 42/69), whereas technique (35%, 24/69) and patient factors (4%, 3/69) made up the balance. Moreover, analyzed collectively for timing and root cause, 42% (29/69) of the NREs are equipment related issues that occur during the bypass period.

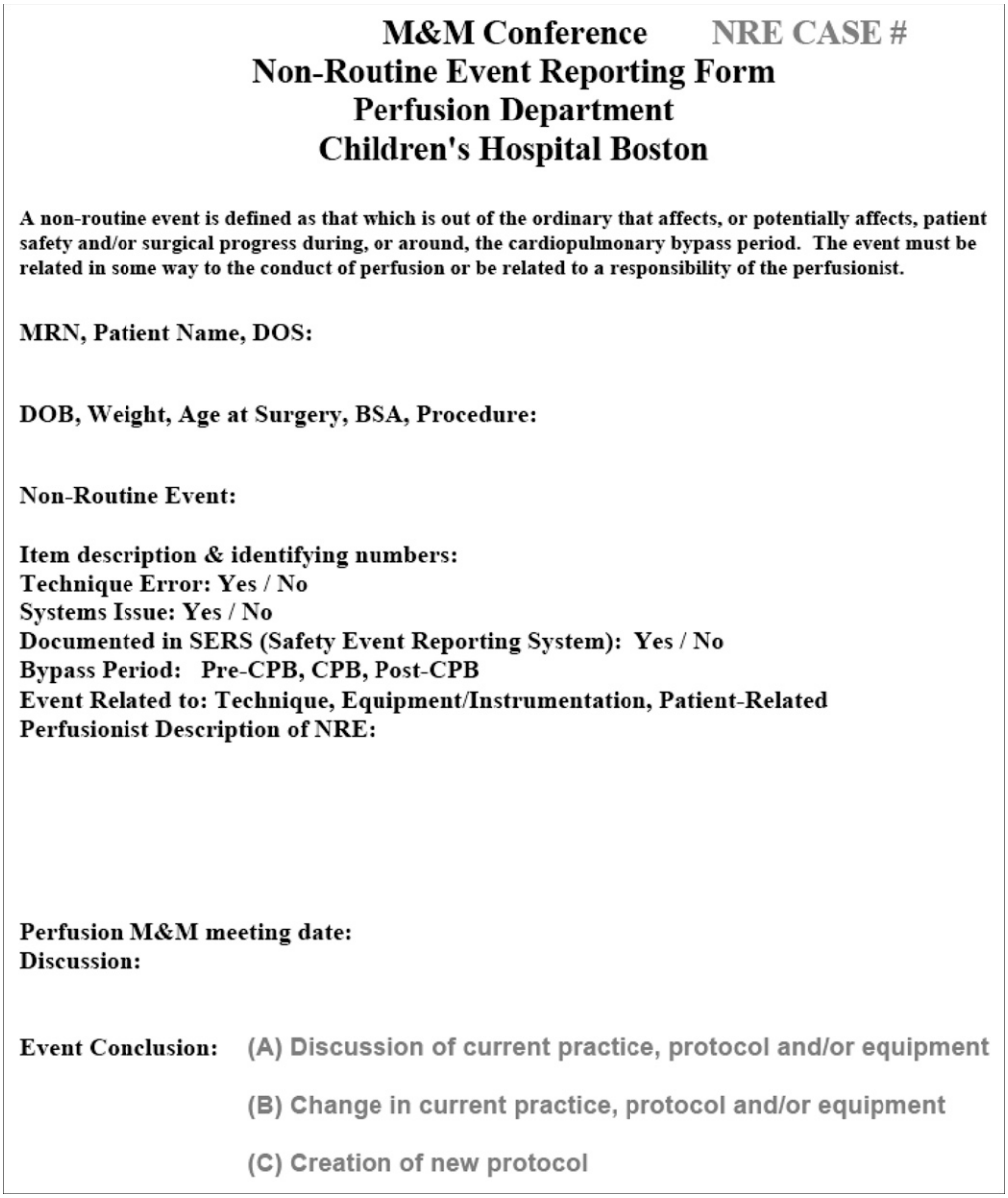
DISCUSSION

We have developed and implemented a quality control measure in the Cardiac Surgery Department that focuses on cardiopulmonary bypass support for congenital heart surgery at Children's Hospital Boston. This review describes the definitions and the processes that we have found useful and that we believe contribute to improved patient safety during a highly vulnerable period of their care, the operation itself.

Examination of this data reveals several important findings. Equipment issues account for the majority of NREs we observed at 61%. This is perhaps understandable given the complexity of current cardiopulmonary bypass (CPB) technology. When an analysis of cause and time period is reviewed, equipment related NREs during CPB accounted

Table 1. NREs by root cause and bypass period.

	Pre-CPB	Bypass	Post-CPB	Type Totals
Technique	8	14	2	24 (35%)
Equipment	13	29	0	42 (61%)
Patient-Related	2	1	0	3 (4%)
Bypass Period Totals	23 (33%)	44 (64%)	2 (3%)	$n = 69$



M&M Conference NRE CASE #
Non-Routine Event Reporting Form
Perfusion Department
Children's Hospital Boston

A non-routine event is defined as that which is out of the ordinary that affects, or potentially affects, patient safety and/or surgical progress during, or around, the cardiopulmonary bypass period. The event must be related in some way to the conduct of perfusion or be related to a responsibility of the perfusionist.

MRN, Patient Name, DOS:

DOB, Weight, Age at Surgery, BSA, Procedure:

Non-Routine Event:

Item description & identifying numbers:
Technique Error: Yes / No
Systems Issue: Yes / No
Documented in SERS (Safety Event Reporting System): Yes / No
Bypass Period: Pre-CPB, CPB, Post-CPB
Event Related to: Technique, Equipment/Instrumentation, Patient-Related
Perfusionist Description of NRE:

Perfusion M&M meeting date:
Discussion:

Event Conclusion: (A) Discussion of current practice, protocol and/or equipment

(B) Change in current practice, protocol and/or equipment

(C) Creation of new protocol

Figure 1. The NRE Reporting Form collects pertinent event data along with patient identifiers for future referencing in various hospital databases. A hardcopy of this form is filed in the NRE binder in the pumproom and an electronic copy is stored on the hospital network.

for 42% of all NREs observed. For example, six oxygenator-related NREs were documented in our 44-month reporting period. All units were sent back to their manufacturer. Two of the units were reported to have defects according to the manufacturer whereas the other four did not. The NRE program gave the team a well documented history of each event and outcome which may be referenced by any team member if there are oxygenator issues in the future.

It is important to note that the primary cause of an NRE is not always apparent. There were several events related to hyper/hypocapnia during cardiopulmonary bypass. These events are difficult to categorize because they can be related to equipment (oxygenator performance), patient factors (depth of anesthesia), or technique (incorrect sweep gas source). Although oxygenator function would be a primary focal point for the hypercapnia cases, we also evaluated our gas delivery system in the new cardiac operating rooms. We found the carbogen gas delivery system which we use for pH-stat blood gas management contained defective one-way control valves. This potentially allowed for the improper mixing of carbogen gases, leading to the observed hypercapnia and hypocapnia. Since the one way control valves have been replaced, no similar NRE has been reported.

Not all NREs require changes in policies or procedures (Table 2). In fact, most do not. In nearly 4 years of our NRE Reporting Program, 77% of reported NREs have resulted

Table 2. NRE outcomes were relegated to one of three categories.

	December 2005	2006	2007	2008	Through July 2009	Outcome Totals
A. Discussion of current practice, protocol, and/or equipment	2	4	8	28	11	53 (77%)
B. Change in practice, protocol, and/or equipment	0	9	1	2	2	14 (20%)
C. Creation of a new protocol	0	2	0	0	0	2 (3%)
Annual Totals	2	15	9	30	13	$n = 69$

It is important to note that annual totals may have been influenced by the evolution of our definition of an NRE during the program's development. Note the generally decreasing incidence of outcomes B and C.

in the team simply discussing current practices and protocols whereas 20% resulted in a change in practice or protocol. Our group has only had to implement two new protocols representing 3% of reported NREs. These were in the first 12 months of the program. We expect that over time, this trend will continue whereby changes in practice and protocols are rare.

It is important to reiterate that the NREs reported in this series occurred among the various permutations of staff on the team. In the past, there was not a structured system to inform all members of the team as to the specifics of each event and the rate of occurrence. The implementation of the NRE reporting process allows for tracking of events, documentation of case specifics, and a record of subsequent discussions and outcomes. These regular multidisciplinary meetings, which we term "Perfusion Morbidity and Mortality" (M&M), allow for a collective education of NREs, and leverages the group's experience and expertise unavailable to any individual discipline. The meetings are particularly useful in a large cardiovascular program like ours that has many staffing combinations. We have found them to be the most efficient and effective way to disseminate important knowledge about perfusion NREs and perfusion practice in general. It is important for individuals and institutions to recognize that the materials and discussions related to morbidity and mortality meetings are generally protected under individual state law and are not subject to subpoena (8).

Finally, it is important to note where the NRE Reporting Program has led to changes in our written Policy and Procedures. In the instance when the "aortic cannula dislodged," we developed a protocol entitled, "Critical Language during Cardiopulmonary Bypass." The protocol established at our institution is that the phrase, "stop the pump" should prompt the perfusionist to also clamp the venous line along with the arterial. This prevents exsanguination and aids in recannulation of the aorta while minimizing communication between the surgeon and perfusionists so that each may concentrate on their respective tasks at hand. The other policy which was created was titled, "PA Pressure Testing Circuit Modification." It was important to document the specifics for this technique since only one surgeon was using it at the time and not all perfusionists and staff had seen the procedure in the operating room. In this instance, the NRE was a new procedure and the outcome was the dissemination of information regarding a new perfusion practice. The Perfusion M&M meeting proved an excellent forum for the cardiovascular team to understand the technique and its advantages and potential pitfalls.

CONCLUSION

Our cardiovascular surgery program has developed and implemented a perfusion non-routine event reporting system along with an independent Perfusion M&M meeting. This prospective method of documentation is useful for incident monitoring and safety improvement at centers performing cardiopulmonary bypass on patients with congenital heart disease. This program has increased awareness among the cardiac surgery team in regards to specific NREs and we believe intuitively that patient safety has been improved by periodic multidisciplinary review. Although we have not collected data to prove scientifically that patient safety has improved, it can be presumed that two outcomes generally lead to such. First, we have experienced a decrease in the number of new protocols required to cover our perfusion practice. Second, we have had a decrease in the number of NREs which require changes in perfusion policy or practice. The Swedish Perfusion Incident survey, which spanned 15 years, reported a decreasing perfusion incident rate at centers which use a prospective database (6). Although it is difficult to show correlation of incident rates and reporting styles, our institution supports a prospective reporting system. The Australia and New Zealand College of Perfusion currently has an online perfusion incident reporting system (9).

Worthy of consideration is the eventual formation of an online registry for reporting perfusion non-routine events in the United States. Standardized definitions for each, along with uniform reporting thresholds, would add more power to the database and benefit the entire field of perfusion and cardiac surgery.

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