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

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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.

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had long been our program’s practice, it was not customary
do so with the arterial line-arterial cannula connection
at the sterile field.
The tubing packs were also modified so that all oxy-
genator/reservoir direct connections were standard tub-
ing 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 car-
diopulmonary 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 sophisti-
cated 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 sup-
port 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 doc-
umenting 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 per-
fusionist’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 con-
sideration 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 opera-
tion: 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 con-
rol 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 find-
ings. 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


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\text{Table 1. NREs by root cause and bypass period.}
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<table>
<thead>
<tr>
<th></th>
<th>Pre-CPB</th>
<th>Bypass</th>
<th>Post-CPB</th>
<th>Type Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technique</td>
<td>8</td>
<td>14</td>
<td>2</td>
<td>24 (35%)</td>
</tr>
<tr>
<td>Equipment</td>
<td>13</td>
<td>29</td>
<td>0</td>
<td>42 (61%)</td>
</tr>
<tr>
<td>Patient-Related</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>3 (4%)</td>
</tr>
<tr>
<td>Bypass Period</td>
<td>23 (33%)</td>
<td>44 (64%)</td>
<td>2 (3%)</td>
<td>n = 69</td>
</tr>
</tbody>
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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...
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.

REFERENCES


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8. The General Laws of Massachusetts. Chapter 111: Section 24A. Reduction of morbidity and mortality; establishment of program; information and reports.