The Experience of Conducting Mortality and Morbidity Reviews in a Pediatric Interventional Radiology Service.

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1. Purpose

Specific Aims

The purpose of this project is to review the experience of conducting morbidity and mortality reviews (M&Ms) in a pediatric interventional radiology (IR) setting and to examine the type and range of issues encountered, the lessons learned and the implementation of any recommendations.

Goal

The goal of M&M reviews (as per hospital policy) is to

1. determine appropriateness and timeliness of the care provided,
2. provide educational value for participants,
3. develop new knowledge
4. further improve upon systems and care provided and
5. emphasize learning and prevention of similar occurrences [1].

There are few studies examining the practice of M&M reviews and the published literature is predominantly in the surgical/anesthetic specialties with little in the radiology literature [2-9]. There is evidence in the QA literature that promotion of a voluntary reporting system, a 'no blame' environment and culture of safety promotes recognition of error and interventions to correct the system and focuses on safety improvements and change of practice [10-11]. Otherwise, studies on the M&M review process as an instrument of quality assurance are uncommon [12-16]. In general, little is known about whether these reviews meet their intended goals. While M&M reviews take place in many clinical settings, it is not a widespread practice in many IR services and the efficacy of the practice is unclear [3,7,15,17].

Practice of M&Ms

Pediatric IR is a relatively new subspecialty and is practiced in only a few centers worldwide. The Hospital for Sick Children is a busy tertiary referral pediatric center which has had an active IR service for many years. Interventional M&Ms have been held for the past 10 years on a monthly basis. The M&Ms were attended by any/all members of the IR team (RNs, MRTs, physicians, pediatricians) and invited guests from other divisions. Cases were collected (initially word of mouth, later on a white board, and more recently electronically) on a voluntary reporting basis from many sources and from any IR team member. All cases were prepared and their brief clinical and imaging details presented. Short literature reviews were presented on relevant topics when appropriate by a staff member or fellow. Minutes were written and submitted to the central M&M Committee of the hospital.

Minutes of M&Ms

The minutes of these review meetings recorded the clinical details of the cases discussed, the teaching/learning points highlighted and the recommendations made. Within these minutes is a wealth of information regarding the types of issues faced, the inherent risks of some of the procedures and the complications seen, including review of any deaths. Recommendations made ranged from small practical tips that are procedure-related, to changes in processes, to more
far-reaching changes in clinical practice, referral, indications and post-procedural care. Given the limited experience with pediatric intervention and that IR M&M reviews are not universally practiced, there is a unique opportunity and indeed responsibility to examine the practice of M&Ms in this type of pediatric clinical service.

2. Material and methods

The IR service has a sophisticated dedicated database (Esh-IGT) in which all procedures are entered. A recently developed limb of this database pertains to the M&M reviews. The minutes of the M&M reviews dating back to 1996 were retrospectively entered into the database to facilitate their analysis. The patients' demographics were reviewed, in addition to ASA level (see Table I), use of nurse administered sedation or anesthesia administered sedation/GA, and procedure(s) undertaken.

Categories

The problem/complication/issue that was discussed was categorized using the definitions seen in Table II. A particular complication/issue could be assigned to more than one category as follows:

1. Device-related
2. Ethics-related
3. Management/education/compliance-related
4. Medication-related
5. Near-miss/good catch
6. Patient-related
7. Procedure-related
8. Process-related
9. Sedation/anesthesia-related
10. Other

Severity

1. Minor A, B
2. Major C, D, E, F (including death), (see definitions in Table III).

As no formal hospital-wide definitions exist, further classification was undertaken as per Dindo et al [19], who created a classification system of surgical complications that may represent a useful and reliable tool for quality assessment worldwide (see Table IV).

1. Grade I
2. Grade II
3. Grade III a, b
4. Grade IV a, b
5. Grade V

In addition, any M&M cases that were categorized as a critical occurrence by the hospital were identified and recorded. A
critical occurrence is defined as "any occurrence that results in an actual or potential serious, undesirable, and unexpected patient or staff outcome including death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition" [20].

Recommendations

Discussions at M&M reviews frequently resulted in decisions or recommendations to change practice or take steps to improve the standard of provision of care. Any recommendations documented were categorized as either:

1. Discussion
2. Educational
3. Manufacturer
4. Process
5. Technical
6. Other

Further descriptions can be found in Table V. The recommendations were also examined as to whether they were implemented or not (yes, no or partial) in an attempt to assess the impact of the M&M process itself. Only descriptive statistics were required.

The complication/issue was categorized in accordance with SIR guidelines as:

3. Results

516 M&M occurrences out of a total of 31,716 patients were discussed at M&M reviews from November 1996 to April 2006, representing 1.6% of all cases. A further 12 cases were listed for M&Ms but were deferred and never discussed. The age of patients varied from premature to 24 years, with the largest proportion (22%) under the age of one (see Figure I). The male to female ratio was 1.3:1. The distribution of ages is similar to that of the general pediatric IR case population. In addition, the weight of the patients brought to discussion at M&Ms ranged from 0.4 kg to 105 kg.

Categories

Each M&M occurrence was assigned to at least one category of issue (see Figure II):

- 305 were assigned to 1 category = 305
- 173 were assigned to 2 categories = 346
- 32 were assigned to 3 categories = 96
- 5 were assigned to 4 categories = 20
- 1 was assigned to 5 categories = 5
- Total = 772

Issues were:

- Procedure-related in 34%
- Patient-related in 20%
- Process-related in 15%
- Device-related in 10%
- Management/education/compliance-related in 8%
- Sedation/anesthesia-related in 4%
- Medication-related in 2%
- Ethics-related in 1%
- Near-misses/good catches in 1%, and
- Other 5% (see Figure III).

**Severity**

The distribution of cases according to the SIR Grading were:

- 292 (57%) Minor: A = 202, B = 90
- 224 (43%) Major: C = 42, D = 151, E = 6, F = 27

The distribution of cases according to the surgical classification were:

- 298 (58%) Minor: I = 232, II = 64, II-d = 2
- 218 (43%) Major: IIIa = 42, IIIa-d = 1, IIIb = 125, IIIb-d = 2, IVa = 15, IVa-d = 3, IVb = 5, V = 27

Distributions are shown in Figures IV and V.

**ASA**

ASA scores are assigned prospectively by an anesthetist doing a case, and were therefore routinely available only for those patients who were managed by an anesthetist. For those in the M&M population without an ASA score, ASA scores were retrospectively assigned to all the cases, based on their clinical history and assessments at the time. The distribution of ASA scores among M&M cases was as follows:

- ASA 1 = 13, 1E = 1, total ASA 1 = 14
- ASA 2 = 151, 2E = 1, total ASA 2 = 152
- ASA 3 = 255, 3E = 7, total ASA 3 = 262
- ASA 4 = 75, 4E = 12, total ASA 4 = 87
- ASA 5E = 1, total ASA 5 = 1

Of the total case population from the same time period (31,716 patients), ASA scores were not available in 29,596 cases (remembering many cases are not assessed by an anesthetist and therefore have no ASA score assigned). The ASA distribution was similar but it appears that proportionately fewer patients with an ASA score of 1 were brought to M&M than those with higher ASA scores (see Figure VI). Given the large number of patients whose score is unknown, one cannot interpret this further.

**Mortality**
27 deaths (IR and non-IR related) were reviewed. Of these, most were related to the procedure (32%) but patient-comorbidity (20%) and errors in process issues (20%) were also major factors involved (see Figure VII). Three of these deaths were managed as critical occurrences. These cases were investigated promptly and consistently by the hospital using a "systems" approach that focuses on identifying opportunities for improvement and changes to the healthcare system to prevent a recurrence of the event [20].

**Procedures**

Collation of the results permitted analysis of the data into groups of procedures. This permits some insights into relative complexity of the procedures, medical fragility of the patients, and their co-morbidity, inherent risks of the procedure, or skill and familiarity of the interventionalists. Examples of groups of procedures examined in this way included biopsies, enterostomy access, and venous access (see Table VI).

**Recommendations**

Following the discussions regarding the 516 M&M occurrences at M&M reviews there was a total of 397 recommendations made in all.

- 241 occurrences = no recommendation
- 194 occurrences = 1 recommendation
- 63 occurrences = 2 recommendations
- 11 occurrences = 3 recommendations
- 3 occurrences = 4 recommendations
- 1 occurrence = 5, 6, 8, 13 recommendations

Of these,

- 80% were implemented
- 11% were partially implemented, and
- 9% were not implemented

Recommendations were:

- Process-related in 49%
- Technical in 20%
- Discussion-related in 15%
- Education-related in 9%
- Manufacturer-related in 6%, and
- Other in 1% (see Figure VIII).

Since cases with similar occurrences were on occasion grouped together for discussion, several of the recommendations applied to a further 12 patients, as the cases had been discussed together and recommendations were made as a whole.
Teaching Points

Reviewing the M&M minutes/records, 516 items in the discussions were identified and classified as teaching points. These were useful tips for team members, either stressed by those with more experience to trainees, or visiting attendees from other disciplines.

4. Conclusion

Discussion

M&M Reviews have appeared to be a useful tool for improving quality assurance in an interventional radiology service. Both minor and major complications were discussed equally and both the classifications defined by the SIR [18] and Dindo et al. [19] prove to be useful tools as both systems yielded results that correlated with each other (similar proportions of major and minor complications). The majority of complications were rated Minor A (38%) and Major D (30%), and similarly under the surgical classification system, Grade I (43%) and Grade IIIb (25%). However, the disproportionate number of major complications (Major D and Grade IIIb) reflects the fact that inherent in a pediatric IR service, children require sedation/GA more often for procedures that could otherwise be done under local anesthetic in adults. Therefore, patients who required another procedure, albeit a minor one with little or no ill effects, were classified as Major because they needed anesthesia or increased level of care. Thus, these classifications could be further refined to accommodate pediatric care.

Morbidities and mortalities were most often related to the procedure undertaken and it is important that a cause is identified so that changes in technique can be identified to improve outcomes. The second most important factor was related to patient-comorbidity, which unfortunately is a factor that cannot be avoided all together, but can be optimized. It is interesting to note that both patient-related and process-related causes of morbidity presented in equal proportion in both minor and major complications, so no one factor seemed to be responsible for major difficulties encountered (see Figure IX).

Of the recommendations made, a majority were process-related, encouraging practical changes in protocol and organization. The highest proportion of recommendations that were only partially implemented were also process-related, which may reflect the length of time that is needed to change protocol in a hospital. In addition, the highest proportion of recommendations that were not implemented was related to contacting manufacturers and requesting changes in equipment or device design. These suggestions tend to fall out of the domain of the IR service and thus it cannot be guaranteed that requested manufacturer changes are realized. However, almost every technical recommendation was implemented, which clearly promotes change in practice for better patient outcomes. Furthermore, if ideas for multidisciplinary discussions or research and educational topics were suggested, it was almost always undertaken.

The results of this project certainly appear to validate the M&M process and its essential role for quality assurance in interventional radiology. This project attempted to quantitatively assess the efficacy of M&M Reviews in a pediatric interventional radiology service and its positive impact on patient care.

Why should a pediatric IR centre conduct M&M Reviews?

- Increased knowledge – for example, statistical analyses can show which procedures are associated with a higher risk to patients and conversely, which patient characteristics (such as age, ASA) can increase procedure risk. A benefit that arose from
undertaking this project included the generation of a list of reasons/categories why cases were brought to M&M. 19 categories, 5 sub-categories and 206 terms were created to identify possible morbidities that could arise in a pediatric IR service. These keywords may prove useful for tracking trends and future data analysis.

- Better patient care – through M&M discussions there is opportunity to formulate simple and practical recommendations that can be easily implemented; in addition, all members of the team are more conscious of and alert to inherent risks, because they are often highlighted in discussions. As well, by sharing tips and solutions to problems during discussions, more uniform practice is promoted, leading to standardization of procedures and greater efficiency.
- Enhanced communication – M&Ms provide a forum for multidisciplinary participation and discussion, thus preventing the pediatric IR service from being too insular and providing learning opportunities from other disciplines.
- To promote change in practice – this project has found that the nature of discussion at M&Ms has evolved over ten years, including its format, reflecting improvements made to the process itself, most recently with the development of the M&M limb of the database.
- To maintain the standard in practice - M&Ms aim to sustain good patient care and recognize good practice.
- To promote team building - M&Ms encourage all members of the IR team (RNs, MRTs, pediatricians, manager, educators, fellows and staff physicians) to meet together on a regular basis, with input from all members welcomed.

Limitations of M&M Reviews:

- Current classification systems of complications are not ideally suited for a pediatric practice.
- Every complication is not (and can not) be brought to M&M for discussion.
- Items brought to discussion at M&M are not necessarily related to morbidity.
- Format of the reviews themselves evolved over the years and likely varied in detail and rigor.
- On occasion, a case flagged for discussion at M&M can be overlooked. This reflects the fact that no process can be perfect and perhaps an electronic system for flagging cases for review at M&M will reduce the number of missed cases. The new limb of the database dedicated to the M&Ms, which was developed during the completion of this project, we hope will help overcome this limitation.

From the experience at the Hospital for Sick Children, incorporation of these elements has shown to improve efficacy at M&Ms:

- Group patients with similar complications/issues for discussion at a single M&M.
- Inviting guest speakers to M&Ms to discuss special educational topics.
- Encouraging multidisciplinary discussion and participation by inviting relevant persons to attend.
- Having all members of the IR team attend M&Ms.
- At the conclusion of each case, focusing the discussions into ‘take-home points’, (Recommendations and Teaching points), and recording both in the database.

Development of an M&M limb of an electronic database will:

- Track trends, type, groups and prevalence of complications over time.
- Track recommendations to ensure implementation.
- Provide capabilities to gather, analyze and publish further reports on M&Ms.
- Facilitate understanding of the causes, factors, and aspects of M&M issues.
- Provide versatile search capabilities of many aspects of M&M reviews.
- Enable the M&M discussion, outcome, recommendations and teaching points to be linked to the case, for future review electronically by any member of the IR team, as the need arises.
- Enable the relative risks of different variables to be examined (e.g. age, prematurity, ASA score, procedure type, physician, etc.).

5. References

6. Mediafiles:

Figure I. Age range of patients discussed at M&M.

![Age range of patients discussed at M&M.](image)

Figure II. Distribution of number of categories assigned for each case brought to M&M.

![Distribution of number of categories assigned for each case brought to M&M.](image)
Figure III. Distribution of classified issues discussed at M&M.

Figure IV. Distribution of complications classified according to SIR guidelines.
Figure IX. Distribution of categories for each SIR classification of M&M issues.

Figure V. Distribution of complications classified according to Dindo et al.
Figure VI. Distribution of ASA scores.

Figure VII. Distribution of categories among deaths reviewed at M&M.
Table I. ASA Physical Status Classification System

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A normal healthy patient.</td>
</tr>
<tr>
<td>2</td>
<td>A patient with mild systemic disease.</td>
</tr>
<tr>
<td>3</td>
<td>A patient with severe systemic disease.</td>
</tr>
<tr>
<td>4</td>
<td>A patient with severe systemic disease that is a constant threat to life.</td>
</tr>
<tr>
<td>5</td>
<td>A moribund patient who is not expected to survive without the operation.</td>
</tr>
<tr>
<td>6</td>
<td>A declared brain-dead patient whose organs are being removed for donor purposes.</td>
</tr>
<tr>
<td>&quot;E&quot;</td>
<td>Emergency case.</td>
</tr>
</tbody>
</table>
Table II. Categories used to classify the complication/issue discussed at M&M review.

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device-related</td>
<td>The complication/issue is due to a device or equipment malfunction or flaw in design.</td>
</tr>
<tr>
<td>Ethics-related</td>
<td>The complication/issue is due to a philosophical, moral or ethical concern, including consent issues.</td>
</tr>
<tr>
<td>Management/education/compliance-related</td>
<td>The complication/issue is due to a lack of education, understanding or management on the part of parents, caregivers, staff or the patient regarding care.</td>
</tr>
<tr>
<td>Medication-related</td>
<td>The complication/issue is due to a side effect or deviation from the normal response to a medication.</td>
</tr>
<tr>
<td>Near-miss/catch</td>
<td>A possible complication/issue was recognized and prevented, thus avoiding morbidity.</td>
</tr>
<tr>
<td>Other</td>
<td>The complication/issue arose from a procedure or protocol handled in another department.</td>
</tr>
<tr>
<td>Patient-related</td>
<td>The complication/issue is attributable to the patient's underlying disease, condition or comorbidity.</td>
</tr>
<tr>
<td>Procedure-related</td>
<td>The complication/issue is due to technical difficulty, deviation from the normal course, omission or error during the procedure.</td>
</tr>
<tr>
<td>Process-related</td>
<td>The complication/issue is due to a problem in organization, infrastructure or protocol.</td>
</tr>
<tr>
<td>Sedation/anesthesia-related</td>
<td>The complication/issue relates to any deviation from the normal course during sedation or anesthetic care.</td>
</tr>
</tbody>
</table>

Table III. SIR Standards of Practice Committee classification of complications by outcome [18].

<table>
<thead>
<tr>
<th>Classification</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor A</td>
<td>No therapy, no consequence.</td>
</tr>
<tr>
<td>Minor B</td>
<td>Nominal therapy, no consequence; includes overnight admission for observation only.</td>
</tr>
<tr>
<td>Major C</td>
<td>Require therapy, minor hospitalization (&lt;48 h).</td>
</tr>
<tr>
<td>Major D</td>
<td>Require major therapy, unplanned increase in level of care, prolonged hospitalization (&gt;48 h).</td>
</tr>
<tr>
<td>Major E</td>
<td>Have permanent adverse sequelae.</td>
</tr>
<tr>
<td>Major F</td>
<td>Result in death.</td>
</tr>
</tbody>
</table>
Table IV. Classification of surgical complications according to Dindo et al. [19].

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade I</td>
<td>Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside.</td>
</tr>
<tr>
<td>Grade II</td>
<td>Requiring pharmacological treatment with drugs other than such allowed for grade I complications.</td>
</tr>
<tr>
<td>Grade IIa</td>
<td>Requiring surgical, endoscopic or radiological intervention not under general anesthesia.</td>
</tr>
<tr>
<td>Grade IIb</td>
<td>Requiring surgical, endoscopic or radiological intervention under general anesthesia.</td>
</tr>
<tr>
<td>Grade IIIa</td>
<td>Life-threatening complications (including CNS complications) requiring ICU/ICU management – single organ dysfunction (including dialysis).</td>
</tr>
<tr>
<td>Grade IIIb</td>
<td>Life-threatening complications (including CNS complications) requiring ICU/ICU management – multiorgan dysfunction.</td>
</tr>
<tr>
<td>Grade IV</td>
<td>Death of a patient</td>
</tr>
<tr>
<td>Suffix “d”</td>
<td>If the patient suffers from a complication at the time of discharge, the suffix “d” (for disability) is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.</td>
</tr>
</tbody>
</table>

*Brain hemorrhage, ischemic stroke, subarachnoid bleeding, but excluding transient ischemic attacks. CNS, central nervous system; ICU, intensive care unit.

Table V. Categories used to classify recommendations made at M&M reviews.

<table>
<thead>
<tr>
<th>Recommendation Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discussion</td>
<td>The recommendation involves discussions with the IGT team or other departments involved in patient care.</td>
</tr>
<tr>
<td>Educational</td>
<td>The recommendation involves a learning opportunity for parents, caregivers, staff or patients, including research.</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>The recommendation involves device or equipment used in interventions and can be intended for the manufacturer or medical engineering.</td>
</tr>
<tr>
<td>Process</td>
<td>The recommendation involves a change in protocol or organization.</td>
</tr>
<tr>
<td>Technical</td>
<td>The recommendation involves a change in technique.</td>
</tr>
<tr>
<td>Other</td>
<td>The recommendation involves another department.</td>
</tr>
</tbody>
</table>
Table VI. Interventional Procedures and occurrences at M&M Review

<table>
<thead>
<tr>
<th>Procedure Type</th>
<th>Procedure</th>
<th>M/MNs # / Total #</th>
<th>% of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biopsy</td>
<td>Mediastinum</td>
<td>3/47</td>
<td>6.38%</td>
</tr>
<tr>
<td></td>
<td>Liver Tranjugular</td>
<td>6/97</td>
<td>6.15%</td>
</tr>
<tr>
<td></td>
<td>Abdominal Mass</td>
<td>2/28</td>
<td>5.26%</td>
</tr>
<tr>
<td></td>
<td>Adrenal Mass</td>
<td>4/91</td>
<td>4.90%</td>
</tr>
<tr>
<td></td>
<td>Liver Mass</td>
<td>2/48</td>
<td>4.17%</td>
</tr>
<tr>
<td></td>
<td>Kidney Mass</td>
<td>1/31</td>
<td>3.23%</td>
</tr>
<tr>
<td></td>
<td>Lung</td>
<td>3/93</td>
<td>3.20%</td>
</tr>
<tr>
<td></td>
<td>Liver</td>
<td>22/978</td>
<td>21.51%</td>
</tr>
<tr>
<td></td>
<td>Bone</td>
<td>2/130</td>
<td>1.27%</td>
</tr>
<tr>
<td></td>
<td>Liver Transplant</td>
<td>3/277</td>
<td>1.09%</td>
</tr>
<tr>
<td></td>
<td>Kidney</td>
<td>4/508</td>
<td>0.56%</td>
</tr>
<tr>
<td>Enterostomy Access</td>
<td>C tube insertion</td>
<td>13/269</td>
<td>6.49%</td>
</tr>
<tr>
<td></td>
<td>GJ tube insertion</td>
<td>9/155</td>
<td>5.61%</td>
</tr>
<tr>
<td></td>
<td>G tube insertion</td>
<td>55/1228</td>
<td>4.72%</td>
</tr>
<tr>
<td>Venous Access</td>
<td>CVL insertion</td>
<td>40/1183</td>
<td>3.40%</td>
</tr>
<tr>
<td></td>
<td>PORT insertion</td>
<td>20/815</td>
<td>2.30%</td>
</tr>
<tr>
<td></td>
<td>PICC insertion</td>
<td>70/2931</td>
<td>2.48%</td>
</tr>
</tbody>
</table>
Hi Betty & Ziv

Congratulations to you both for all the hard work you put into the M&M poster. I was delighted to see that it got a merit certificate / award.

Well done!

Our next step is to get it ready for the publishers, I am very sure that JVIR will accept it, given the funding and the award!

Bairbre