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President’s Message

Welcome, 2020!

Every New Year brings an opportunity for a fresh start, and often, resolutions to accomplish the things we haven’t quite conquered yet. This New Year marks the beginning of a new decade, and 2020 evokes images of clear, perfect vision. As you embark upon the New Year, I encourage you to think about your goals. What new challenges do you have for yourself? What steps will you take to advance your career over the next 365 days? How can you improve your risk management program? What new skills would you like to master? What projects would you like to see through to completion?

Big, audacious goals can often seem overwhelming; many times, we give up before we even get started. Being ambitious can seem daunting and maybe even a little scary. To succeed, I challenge you to think about what outcome you desire, but also all the little steps that you need to take to get there. This year, challenge yourself to take those small steps. Identify a mentor and get some advice over coffee. Write that article and submit it to the *Journal of Health Care Risk Management* for publication. Volunteer or run for office at your local risk management chapter. Join Toastmasters and overcome your fear of public speaking, so that you can present at Annual Conference. Make the business case to your supervisor for a raise or promotion (or both!).

Many risk managers hold themselves back from success because they are, by nature, risk averse. Success, however, always involves some measure of risk. If you aren’t a bit uncomfortable, then you probably aren’t growing and learning. So for 2020, I encourage you to take a little risk. Push yourself out of your comfort zone and into that first step on the path toward success as you define it.

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The power of data has long been recognized. The question is how to access it, explore it, and craft solutions that are both effective and efficient. This is a “how-to” article as well as a look at UMass Memorial’s successes. Not everyone has the resources that UMass Memorial has, but everyone can learn from their story.

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A bit about me: Bedside boards to create a culture of patient-centered care in pediatric intensive care units (PICUs)

By Martina Spazzapan, MBBS, BSc, AKC®, Byrave Vijayakumar, MBBS, BSc, and Claire E. Stewart, BSc, MBBS, MRCPCH

Introduction: This project assessed whether the introduction of personalized bedside boards containing nonmedical information about patients in a pediatric intensive care unit (PICU) help provide health care professionals (HCPs) better insight about each child’s personal qualities and preferences and thereby help improve patient-centered care and patient safety.

Methods: Staff and parents of children in a PICU unit completed a questionnaire assessing how well HCPs knew their patients and their design preferences for the board. The questionnaire was completed before and after board introduction, and patient involvement was central to the design of the board.

Results: There was an improvement in all parameters assessed. Significant improvements include the perception of PICU as a welcoming environment, nurses’ understanding about what comforts their patients, and doctors’ ability to recognize their patients outside the hospital. Doctors and nurses felt they knew their patients better. Parents’ views regarding whether HCPs know what comforts their child and would recognize them outside the hospital also improved. Feedback about board aesthetics and usefulness was positive.

Conclusion: Personalized bedside boards significantly improved how well HCPs knew their patients across various elements. Patient-centered care and, in turn, patient safety in PICUs can be promoted by using personalized bedside boards containing nonmedical information to help HCPs understand their patients’ individual needs and tailor their treatment.
INTRODUCTION

Patient-centered human factors

In recent years, significant attention has been given to the role of human factors in improving patient safety. Human factors are defined as “environmental, organisational and job factors, and human and individual characteristics which influence behaviour at work in a way which can affect health and safety.” Specifically, patient-centered human factors have been the focus of such paradigm of risk management in the context of health care systems.

A widely accepted definition of patient-centered human factors is “the application of human factors theories and principles, methods and tools, analyses, and interventions to study and improve work done by patients and families, alone or in concert with healthcare professionals.” This feeds into the wider concept of patient-centered care (PCC), which is widely accepted as a fundamental aspect of the provision of high-quality care. Core recognized elements of PCC include seeing the patient as an individual, providing care that respects and responds to individual patient needs and preferences, and encouraging the active involvement of patients and their families in their care.

The framework of patient- and family-centered care has been recommended by the American College of Critical Care Medicine for the intensive care unit setting and the American Academy of Pediatrics for the pediatric setting. PCC has been shown to improve the level of professional satisfaction, reduce emotional stress, and increase the feeling of achievement in health care professionals. Moreover, PCC has been found to have beneficial implications for key stakeholders of health care, improving not just the patient experience but also clinical outcomes and patient safety. A review of the evidence linking patient experience and clinical safety and effectiveness found that positive associations exist between the two across a variety of settings and population groups, with reports of improved objective health outcomes, self-reported health and well-being, and adherence to treatment; reduced use of health care resources; and fewer adverse events.

Environmental and human factors in pediatric intensive care units

Pediatric intensive care units (PICUs) are responsible for caring for one of the most vulnerable patient populations. The young age, critical condition of patients, and use of sedation and respiratory support can prevent many of the children from expressing their personal preferences and needs to hospital staff. This can make adopting a holistic approach a significant challenge for health care professionals: Patients are often unable to communicate their wishes, and it is frequently difficult to appreciate a patient’s baseline status from direct information. PICU staff is therefore heavily reliant on family members to provide holistic information about patients, including an assessment of their preadmission baseline, indications on their preferences, and generally an idea of what they are like at home.

However, literature has shown that developing a collaborative relationship with parents in the provision of care for their children is challenging for both health care professionals and parents, who often feel excluded from their child’s care. Such challenges can be explained by the emotional and psychological stress associated with the transfer of the caregiving role of critically ill children from parents to the PICU staff. Other contributing factors are intrinsic to an intensive care environment and include measures such as infection control, limited visiting hours and visitors allowed, limited privacy, and time pressures on PICU staff. To address these challenges, PCC methods have been shown to be effective, particularly in improving recognition of patients’ individuality and responding to their needs and preferences. To improve family involvement in the context of PICU, literature encourages a greater focus on family visitation, family-centered rounding, presence during invasive procedures, and family conferences. Improving PCC has become a leading priority in improving quality of health care; therefore, PICU staff are encouraged to look at initiatives that are applicable to the PICU’s unique context.

Strategies for improving PCC

Looking at PCC across patient populations, the literature highlights the presence of effective past and existing interventions used to promote PCC in primary and secondary care. Examples include the “What Matters to Me Today” bedside boards, which allow hospital patients to inform HCPs of personal details and preferences (eg, preferred bedtime); the “This Is Me” form, which allows patients with dementia, delirium, or communication difficulties to inform HCPs about their personal life, preferences, and personality; and the “What Matters to You?” campaign supported by NHS Scotland, encouraging health care staff to have more meaningful conversations with their patients.

Feedback and results from previous projects carried out in the pediatric population, such as “What Matters to Me” and “All About Me,” have highlighted the usefulness of sharing personalized nonmedical information about patients with complex medical needs, a concept that applies to PICU patients. Nevertheless, literature on PCC-focused initiatives in the context of PICU is limited at the time of the writing.

To fill this gap in the literature, we investigated the benefits of introducing personalized bedside boards that focus on nonmedical information in the context of PICU. In this study, we hypothesized that the introduction of such boards would help improve staff’s knowledge of patients as individuals, as well as increase patient and family...
involvement in the provision of humanized care, in turn improving PCC. Our results show that working together with PICU families brings about positive changes in staff and parent attitudes. We anticipate that this will improve clinical outcomes and safety in the longer term; however, this was not researched at this stage.

MATERIALS AND METHODS

Preintervention

The project took place in the 13-bed PICU of St. Mary’s Hospital, London, United Kingdom, over a period of 1 month. Patients’ parents and members of the PICU staff were anonymously surveyed to obtain baseline data about PCC in the unit. A 7-part questionnaire was used to assess quantitatively, on a scale of 1 to 10, how well HCPs on the PICU ward knew the patients.

Different versions of the questionnaire were created for parents and each health care specialty involved in patient care. This included doctors, nurses, physiotherapists, and pharmacists. In order to evaluate HCPs’ knowledge of patients’ personal preferences and baseline, we asked whether staff members felt they knew what comforts their patient, their patient’s favorite toy, and whether they would be able recognize their patient outside the hospital. We then compared their self-evaluation with that provided by parents over the course of a month.

Other items in the questionnaires were used to provide suggestions for the design and content of the bedside boards including color, layout, and section headings. Some parents suggested adding details about their children’s families; likes and dislikes; favorite colour, toy, music, and so on; and a space for artwork. Others suggested limiting the number of headings to let people add their own. At the end of the survey period, it emerged that the preferred format for the board was a yellow A3 sheet, titled “A Bit About Me.”

Preferred section headings included:

- “Please call me ___”
- “Pictures of me”
- “Words to describe me”
- “Important people to me”
- “What makes me feel better when I am upset”
- “Things that you should know about me”

We kept the last heading purposefully vague to give parents the freedom to add information they felt was valuable. Three design options were created from these suggestions, which were circulated to all staff and parents for feedback. Once all comments were collated and following a period of consultation with the PICU ward manager and the head of patient experience, a finalized version was created (Figure 1).

Intervention

Copies of the “A Bit About Me” boards were printed and positioned in each bed space with the help of the ward manager and nursing staff (Figure 2). E-mails and posters in offices and staff rooms were used to inform PICU staff members about the introduction and purpose of the board, encouraging them to use the information provided on the boards to engage the children for whom they care. On admission, nurses were advised to encourage parents of patients to fill in the boards using whiteboard markers. Notice posters were also created for the parents’ room as an additional reminder. The nursing staff was asked to wipe clean the boards upon patients’ discharge from the PICU, so that they could be used for new patients upon admission.

Postintervention

After the introduction of the “A Bit About Me” boards, staff and parents were surveyed again over the course of 3 weeks. Items from the preintervention questionnaire were used after the intervention to measure for changes across the parameters of interest. As the surveys were anonymized, we did not record whether the same individuals had answered both questionnaires. However, it is likely that a percentage of parents were surveyed both times, while others answered only one of the surveys, depending on their child’s length of stay. As we did not record whether respondents of the second survey had answered the first one, however, a two-tailed unpaired Student’s t-test was employed to analyze for changes in perceived PCC.

Feedback from parents and health care staff regarding the personalized bed space boards was also collected using a specific items questionnaire. This allowed us to quantitatively assess on a scale of 1 to 10 the approval of the design, the usefulness of the board, and general awareness about the project. Finally, the questionnaire also provided an opportunity to provide any ideas or suggestions to improve the project.

RESULTS

Thirty-eight questionnaires were collected to obtain baseline data, while 36 were completed after the introduction of the boards (Table 1). All parents surveyed reported that their child was either nonverbal or sedated for respiratory support; hence, patients’ views were not elicited in this study.

An unpaired, two-tailed Student’s t-test was used to analyze and compare the pre- and postintervention results. After intervention, there was an improvement in all
parameters assessing how well HCPs knew their patients, with statistically significant improvement across 5 of the elements assessed.

There was a significant increase in whether nurses felt they knew what comforts their patients and their patients’ favorite toy ($P < .005$). A significant improvement in whether doctors felt they knew their patients well ($P < .5$) and could recognize them outside the hospital ($P < .005$) was also observed (Table 2). Moreover, the perception of the PICU as a welcoming environment improved ($P < .05$); following our intervention, both doctors and parents felt that nurses know their patients well ($P < .05$).

Improvements in all other questionnaire items were also noted; however, these did not demonstrate statistical significance (Table 3).

These results were further supported by improved parents’ views regarding whether HCPs knew what comforts their child (pre, 77%; post, 100%) (Figure 3A and B), their
### Table 2: Statistically Significant Results (Scale 1-10)

<table>
<thead>
<tr>
<th>Item</th>
<th>Before</th>
<th>After</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurses know what comforts their patients</td>
<td>6.06</td>
<td>7.95</td>
<td>.0004</td>
</tr>
<tr>
<td>Nurses know child’s favorite toy</td>
<td>4.00</td>
<td>6.50</td>
<td>.0022</td>
</tr>
<tr>
<td>Doctors would recognize patient on the street</td>
<td>4.33</td>
<td>7.83</td>
<td>.0025</td>
</tr>
<tr>
<td>Nurses feel they know patients well</td>
<td>5.24</td>
<td>7.15</td>
<td>.0018</td>
</tr>
<tr>
<td>Nurses feel doctors know patient well</td>
<td>4.35</td>
<td>6.90</td>
<td>.0002</td>
</tr>
<tr>
<td>PICU is a welcoming environment</td>
<td>6.91</td>
<td>8.08</td>
<td>.0120</td>
</tr>
<tr>
<td>Doctors feel nurses know patients well</td>
<td>4.86</td>
<td>7.14</td>
<td>.0424</td>
</tr>
<tr>
<td>Parents feel nurses know patients well</td>
<td>4.25</td>
<td>7.71</td>
<td>.0194</td>
</tr>
<tr>
<td>Doctors feel they know patients well</td>
<td>3.67</td>
<td>6.29</td>
<td>.0356</td>
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PICU, pediatric intensive care unit.

### Table 3: Remaining questionnaire items (Scale 1-10)

<table>
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<tr>
<th>Item</th>
<th>Before</th>
<th>After</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PICU staff is approachable</td>
<td>8.50</td>
<td>8.94</td>
<td>.1435</td>
</tr>
<tr>
<td>Doctors know what comforts their patients</td>
<td>4.11</td>
<td>5.43</td>
<td>.3892</td>
</tr>
<tr>
<td>Doctors know child’s favorite toy</td>
<td>2.11</td>
<td>4.43</td>
<td>.1134</td>
</tr>
<tr>
<td>Nurses would recognize patient on the street</td>
<td>5.65</td>
<td>6.30</td>
<td>.3194</td>
</tr>
<tr>
<td>Parents feel doctors know patients well</td>
<td>3.88</td>
<td>7.14</td>
<td>.0596</td>
</tr>
</tbody>
</table>

PICU, pediatric intensive care unit.

**DISCUSSION**

This study shows how a simple, cost-effective intervention can be implemented to improve patient centered care in a high-pressure environment such as the PICU. In addition to this short-term benefit, we expect the “A Bit About Me” boards to make information potentially useful to improve patients’ care and safety available to health care staff.

**Patient and parent involvement**

All the patients participating in the study were nonverbal or sedate, thus making it impossible to involve them in first person. However, their parents were an integral part of the study from its very beginning. Parents were surveyed before and after our intervention to assess for any improvement in their perception of patient centered care, as well as being actively involved in the design and content of the “A Bit About Me” boards.

In filling in the boards on behalf of their children, parents had a fundamental role in providing nonmedical information to improve staff’s knowledge of their patients’ traits. For this reason, it is not surprising that feedback on the board utility and appeal was positive. Having an opportunity to paint a picture of what their children are like at home can help parents in a particularly stressful time, bringing them hope. A common understanding of a child’s baseline status and characteristics allows staff and parents to develop a shared goal, working together toward getting the patient back to his or her premorbid status. We hope that parent engagement continues so that all patients have their boards filled in during their stay in the unit.

**Staff attitudes around nonmedical information**

Staff in the PICU are experienced in close patient monitoring and often use personalized medical boards for patient care. However, the wealth of information they interact with daily is purely medical in nature. The presence of a personalized space for nonmedical information was therefore novel for the health care professionals involved and very well received.

Time constraints limit the amount of time that staff can spend getting to know their patients; therefore, the “A Bit About Me” boards provide a concise way to acquire such personal information. This can create opportunities for small talk interactions with parents, and therefore improve rapport and satisfaction from both parties involved.
Improved relationships between staff and parents can foster parents’ engagement in their children’s care, which in turn can lead to improved health literacy, clinical decision making, self-care, and patient safety.\textsuperscript{20}

In addition to being a tool for improving the relationship between staff and parents, the boards can provide guidance for better patient treatment. Particularly for what concerns nursing care, understanding what effective sources of consolation for distressed children are can have tremendous value. The “Things you should know about me” subheading can also add value in improving care and safety, depending on the type of information volunteered in the section.

**Nonmedical information for improved comfort and safety**

Although we did not look specifically at safety outcomes during this study, by observing the information provided in the “Things you should know about me” section we had an opportunity to appreciate how using the boards has the potential to improve patient comfort and safety. One set of parents mentioned that their child preferred a specific barrier cream over other alternatives, which had not been noted in the medical documentation, as it does not constitute an allergy. By having access to this information, nurses were aware of the patient’s preferences and were able to accommodate them, thus improving the quality of their...
I feel that parents are well informed about the board.

I like the board design (8.39 ± 1.54).

I find the board useful (8.70 ± 1.49).

I feel that parents are well informed about the board (6.44 ± 2.65).

**Board Feedback (Scale 1-10)**

**Table 4: Board Feedback After Intervention**

<table>
<thead>
<tr>
<th>Board Feedback (Scale 1-10)</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>I like the board design</td>
<td>8.39</td>
</tr>
<tr>
<td>I find the board useful</td>
<td>8.70</td>
</tr>
<tr>
<td>I feel that parents are well informed about the board</td>
<td>6.44</td>
</tr>
</tbody>
</table>

Other examples include one patient whose parents wrote down they are vegetarian, which provided useful information for the catering staff; others who mentioned they are scared of needles, therefore requiring additional tact and caution during venipuncture; and one child whose parents noted they did not like the cold spray used for cannulation, which meant any staff performing the procedure was able to avoid using it.

These anecdotal examples of information written down by parents show benefits in terms of patient comfort and safety. While the information may appear to be of minor relevance, any expression of patient preference can be useful in situations, as is often the case in the PICU, where patients are unable to communicate predilections or worries directly. We aim to continue auditing the use of the boards in the future, including comfort and safety outcomes in further research.

The literature on the effect of patient involvement in safety matters is limited; however, the emphasis is growing on the promising role of patient participation in error prevention. The World Health Organization’s World Alliance for Patient Safety has established a Patients for Patient Safety component, highlighting how patient perspective can be a significant contributor to improving patient safety when working in partnership with health care staff, although very little relevant research exists to date.

We suggest that future studies focus on whether interventions such as the one discussed in this article can facilitate patient contribution in risk management and whether such contribution leads to error prevention.

**Limitations**

The main limitation of this study is the small sample size, which restricted the power of our statistical analysis. This was secondary to the small dimensions of St. Mary’s PICU (a 13-bed unit) and the complex nature of PICU patients, who often have a prolonged stay. Moreover, the busy nature of the unit meant the time available for staff to complete the questionnaires was limited.

Another limitation was the time frame between pre- and postintroduction surveys. In the immediate aftermath of an introduction of the board, it is not unusual for staff to be engaged, although to assess the sustainability of these results would require further follow-up. We aim to evaluate medium- and long-term outcomes of the initiative by administering questionnaires 6 and 12 months after introduction of the board.

**Sustainability and applicability**

Despite the limitations discussed, preliminary results from our project demonstrate that the implementation of personalized bed space boards for nonmedical information is a simple, cost-effective, and sustainable intervention. From a cost perspective, the boards were designed in house and printing required minimal financing, and because they are wipeable, they are suitable for repeated use.

Due to their simplicity and limited cost, the “A Bit About Me” boards could easily be introduced in further PICUs across the region, and larger-scale implementation could be achievable. However, we believe that staff and parent involvement at an early stage of board design was a crucial aspect of this project. Therefore, we recommend that staff and parent consultations be carried out prior to implementation of personalized boards in other locations, to ensure that agreement on the content and design of the boards is reached by all parties involved.

Scalability of this concept is not limited to other PICUs but can involve other inpatient populations. Examples include adult patients in the intensive care unit, elderly patients suffering from dementia on geriatric wards, and some stroke rehabilitation units. As suggested above, minor adjustments to board content would be required to best adapt PCC to the local population.

**CONCLUSION**

The implementation of “A Bit About Me” boards, focused on nonmedical information, demonstrating a positive impact in improving how well PICU staff felt they knew their patients as individuals. It showed similar improvements on subjective impressions of how well parents felt staff knew their children.

The impact of our project has important benefits for PICU staff including doctors and nurses, parents of patients, and the children. The personal patient information provided by the board can help staff overcome barriers in perceiving and treating patients as individuals, as well as help HCPs provide a more tailored PCC. Working with patients’ families can provide staff with valuable information about their patients as individuals, making patients and parents feel more involved.

We anticipate that the collaboration between staff and parents encouraged by this project improve communication and relationships between the parties involved. This, in turn, can lead to improved patient satisfaction, outcomes, and safety, which we aim to
research further. This quality improvement project also demonstrated how an intervention to improve family experiences of inpatient care can be simple, cost effective, and sustainable. Further research is required to see if this initiative is scalable and whether the results are replicable in other centers.

REFERENCES
ABOUT THE AUTHORS

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Clinical/Patient Safety

A contemporary medicolegal analysis of perioperative vision loss from 2007 to 2016

By Amy Du, MD, MS, Ramsey Saba, MD, Ethan Y. Brovman, MD, Penny Greenberg, RN, MS, and Richard D. Urman, MD, MBA

Introduction: Perioperative vision loss (POVL) is a rare but catastrophic event. Closed claim databases are useful for investigating risk factors of POVL to help guide practices in risk mitigation and risk management strategies.

Methods: We retrospectively analyzed the Controlled Risk Insurance Company (CRICO) Comparative Benchmarking System database for perioperative nerve injuries from when claims were closed between 2007 and 2016. We then extracted, deidentified, and analyzed all the POVL cases.

Results: Of 53 nerve injury claims closed between 2007 and 2016, we found 9 pertaining to POVL. Of these 9 cases, 100% resulted in permanent injury, 76% were associated with spine surgery, 89% of the patients were positioned prone intraoperatively, 67% were noted to have improper or missing documentation, and 56% of the patients claimed they were not informed of the risk of vision loss during preoperative consenting. Four of the 9 cases were settled, with a mean settlement amount of $906,250 (standard deviation, ± $745,647).

Conclusions: POVL often results in permanent injury with costly burden on the health care system. Risk reduction strategies need to be instituted on the provider and system level, involving a multidisciplinary health care team to develop and execute clinical protocols and patient communication strategies that will help prevent POVL.
INTRODUCTION

Since the first reported case of perioperative vision loss (POVL) in nonocular surgery in 1948, reviews of POVL incidences have consistently shown it to be a rare occurrence, resulting in a significant, often permanent patient injury. The American Society of Anesthesiologists (ASA) Task Force on Perioperative Visual Loss defines POVL as visual impairment or complete loss of sight associated with general anesthesia that occurred anytime during the immediate preoperative period until discharge from the acute care unit. Although the ASA Task Force focused its 2019 POVL practice advisory specifically on spine surgery, POVL has been associated with various types of surgery, including cardiac surgeries, laparoscopic prostatectomy and abdominal procedures, obstetric operations, vascular surgeries, and head and neck surgeries.

There are different etiologies of POVL, distinguished by their pathophysiology and clinical presentation, in addition to direct injury to the eye or visual pathway. One cause of POVL is described as central retinal artery occlusion, which occurs due to systemic or local embolization, external pressure on the globe of the eye, and, rarely, vasospasm of the central retinal artery, resulting in ischemia of all or most of the retina. Patients usually present with unilateral painless vision loss with relative afferent pupillary dysfunction and possible periorcular trauma. Ischemic optic neuropathy (ION), another described form of POVL, is seen when ischemic events occur at the short posterior ciliary arteries supplying the head of the optic nerve, resulting in anterior ischemic optic neuropathy (AION) or more proximally along the pial capillary plexus, causing posterior ischemic optic neuropathy (PION). The characteristic funduscopic examination finding in AION is papillary edema with peripapillary hemorrhage, whereas PION presents with bilateral painless vision loss and a normal funduscopic examination. AION is more commonly associated with cardiac surgeries and PION more with spinal, neck, laparoscopic and robotic surgeries. Another etiology for POVL is cortical vision loss, commonly caused by ischemic or embolic strokes. Patients with cortical vision loss present with pupillary defects, a normal funduscopic examination, and higher-order visual dysfunctions.

The incidence of POVL varies widely across types of operations, with the highest reported range from 0.06% to 0.113% in cardiac surgery. Although the incidence of POVL in spine surgery is also notably higher compared to other types of operations, it appears to have declined over the years. Stevens et al reported a POVL incidence of 0.2% (7 in 3450) related to spine surgery across three institutions between 1985 and 1994. However, more recent studies reported POVL incidence associated with spine surgery to be between 1.02 in 10,000 cases and 0.09%. Reasons for this trend are multifactorial, and understanding the risk factors of POVL and changes in clinical and institutional practices may further explain this reduction in the incidence of POVL.

The ASA developed the Perioperative Visual Loss Registry in 1999 to facilitate reporting of POVL cases. Using the data from the registry, the ASA Task Force on Perioperative Visual Loss identified 6 risk factors of POVL in 2006: inadequate patient positioning, male sex, high intraoperative blood loss, obesity, long surgical duration, and high volume of intraoperative colloid administration as a proportion of nonblood fluid management. More studies are needed to further elucidate the reason for the downward trend of POVL in spine surgery and to develop strategies on eliminating POVL altogether.

Although it often leads to permanent, disabling injury, POVL is a relatively uncommon phenomenon, and much of the existing literature on POVL is derived from case reports and case series. Closed claim databases provide a useful source for investigating rare, catastrophic clinical events. Moreover, they provide qualitative medicolegal information to help guide institutional and clinical practices in risk mitigation and risk management after injuries have already occurred. The present investigation is a retrospective analysis of recent closed claim malpractice data over a 10-year period to provide additional contemporary insight into possible contributing factors and risks associated with POVL and ways to preemptively mitigate medicolegal consequences of these injuries.

METHODS

The closed claim data for this study were obtained from the Controlled Risk Insurance Company (CRICO, Boston, MA), which was formed in 1976 by the hospitals in the Harvard Medical School system. CRICO provides both claims management and patient safety innovation. To improve patient care and risk management, CRICO Strategies developed the Comparative Benchmarking System (CBS) database, which contains more than 400,000 malpractice claims from hospitals insured by CRICO and more than 400 additional academic and community institutions. The CBS includes both captive and commercial insurers, and accounts for over 30% of malpractice claims in the United States. Cases reported to the CBS are not reported to the ASA Closed Claims Project.

The CBS database was queried for all perioperative nerve injuries from when the claim was closed between 2007 and 2016. All the cases relating to perioperative vision loss were extracted from the query result; they were all deidentified and then reviewed by the authors. Each claim contained a narrative summary that included patient comorbidities, type of surgery, injury course, the type of vision loss, specific complications, case disposition (settled or dismissed), indemnity amount, and the National Association of Insurance Commissioners (NAIC) severity.
The NAIC scale was developed as a simple method ranking injuries from 1 to 9 for increasing severity (Table 1).\(^\text{19}\) It is common practice to set investigative priorities on newly opened claims by assigning them a NAIC severity code.\(^\text{20}\) NAIC establishes state insurance regulatory standards and best practices and coordinates regulatory oversight.\(^\text{21}\)

One major point of interest found in the CBS claim files was the contributing factors related to each claim. Each claim could have one or more subcategories listed as potential contributing factors. For example, a single claim could have listed both “documentation error/missing” or “technical knowledge/performance” as factors contributing to the claim or injury. The contributing factors were originally coded by claims specialists overseen by a committee of physicians, lawyers, and analysts.\(^\text{18}\) This process was completed prior to the initiation of our study.

The data were organized and summarized into tables using Google Sheets (Google, Mountain View, CA). Means, standard deviations (SDs), and ranges were calculated and reported where appropriate. The pie chart was made using Microsoft Excel (Microsoft Corporation, Redmond, WA). Given the small sample size, subgroup analysis was not statistically feasible.

## RESULTS

### Indemnity payment details

Of 53 perioperative nerve injury claims closed between 2007 and 2016, a total of 9 CRICO cases relating to POVL were identified. Of these cases, 4 were closed, with a mean indemnity payment of $906,250 (SD, $745,647) (Table 2). Based on CRICO’s categorization of

### Table 1: National Association of Insurance Commissioners Severity of Injury Scale (Adapted)\(^\text{19}\)

<table>
<thead>
<tr>
<th>Scale</th>
<th>Severity Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temporary Injuries (Codes 1-4)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Emotional injury</td>
</tr>
<tr>
<td>2</td>
<td>Insignificant</td>
</tr>
<tr>
<td>3</td>
<td>Minor</td>
</tr>
<tr>
<td>4</td>
<td>Major</td>
</tr>
<tr>
<td>Permanent Injuries (Codes 5-9)</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Minor</td>
</tr>
<tr>
<td>6</td>
<td>Significant</td>
</tr>
<tr>
<td>7</td>
<td>Major</td>
</tr>
<tr>
<td>8</td>
<td>Grave</td>
</tr>
<tr>
<td>9</td>
<td>Death</td>
</tr>
</tbody>
</table>

### Table 2: Patient Characteristics and Claims Overview of CRICO Vision Loss Cases, 2007-2016

<table>
<thead>
<tr>
<th>Cases</th>
<th>N (%) or USD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total perioperative nerve injury claims</td>
<td>53</td>
</tr>
<tr>
<td>Total perioperative vision loss claims</td>
<td>9</td>
</tr>
<tr>
<td>Age (y), m = 2</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>53.4</td>
</tr>
<tr>
<td>SD</td>
<td>7</td>
</tr>
<tr>
<td>Range</td>
<td>42-60</td>
</tr>
<tr>
<td>Nonneurologic patient comorbidities</td>
<td></td>
</tr>
<tr>
<td>Obesity</td>
<td>4 (44)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>7 (78)</td>
</tr>
<tr>
<td>Smoker</td>
<td>3 (33)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>2 (22)</td>
</tr>
<tr>
<td>Anemia</td>
<td>1 (11)</td>
</tr>
<tr>
<td>Diabetes mellitus/vascular disease</td>
<td>4 (44)</td>
</tr>
<tr>
<td>NAIC outcome severity</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>4 (44)</td>
</tr>
<tr>
<td>7</td>
<td>5 (56)</td>
</tr>
<tr>
<td>Settled cases</td>
<td>4 (44)</td>
</tr>
<tr>
<td>Payment to patient for settled cases (USD)</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>906,250</td>
</tr>
<tr>
<td>SD</td>
<td>745,647</td>
</tr>
<tr>
<td>Range</td>
<td>375,000-2 million</td>
</tr>
<tr>
<td>Contributing factors</td>
<td></td>
</tr>
<tr>
<td>Technical knowledge/performance</td>
<td>9 (100)</td>
</tr>
<tr>
<td>Nonneurologic patient comorbidities</td>
<td>7 (78)</td>
</tr>
<tr>
<td>Documentation error/missing</td>
<td>6 (67)</td>
</tr>
<tr>
<td>Bleeding/coagulopathy</td>
<td>2 (22)</td>
</tr>
</tbody>
</table>

NAIC Severity of Injury Code: 6 = permanent significant injury; 7 = permanent major injury. 
m = number of missing data points. 
NAIC, National Association of Insurance Commissioners; SD, standard deviation; USD, US dollars.
contributing factors, “technical knowledge/performance” was included as a contributing factor in all 9 cases. “Patient comorbidity (nonneurologic)” and “documentation error/missing” were contributing factors for 78% and 67% of the cases, respectively.

**Patient factors**

Claimants ranged from 42 to 60 years of age with a mean age of 53.4 years (SD, ± 7) (Table 2). The most common nonneurologic comorbidity was hypertension (78%). Forty-four percent of claimants had diabetes mellitus or some form of vascular disease, 44% were obese, and 33% were smokers.

**Surgical and anesthetic factors**

Of the 9 cases, 7 (78%) were orthopedic cases (5 spine cases, one shoulder arthroscopy, and one hip arthroplasty), while the remaining two cases were neurosurgery (lumbar decompression) and chronic pain management (spinal cord stimulator implantation) operations (Figure 1 and Table 3). Six (67%) of the cases were spine surgeries. General anesthesia was administered in 7 (78%) of the cases. In 8 (89%) of the cases, the patient was placed in the prone position. Although the database did not specify patient position in the remaining one case, it is unlikely to

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**Table 3: Surgical and Anesthetic Factors and Nature of Vision Loss of CRICO Cases, 2007-2016**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N (%)</th>
<th>Total N = 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical specialty</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orthopedic</td>
<td>7 (78)</td>
<td></td>
</tr>
<tr>
<td>Neurosurgery</td>
<td>1 (11)</td>
<td></td>
</tr>
<tr>
<td>Chronic pain</td>
<td>1 (11)</td>
<td></td>
</tr>
<tr>
<td>Patient position</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prone</td>
<td>8 (89)</td>
<td></td>
</tr>
<tr>
<td>Not specified</td>
<td>1 (11)</td>
<td></td>
</tr>
<tr>
<td>Spinal surgery</td>
<td>6 (67)</td>
<td></td>
</tr>
<tr>
<td>Surgical time (h), m = 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>6.5</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>3.091347372</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>1–9.7</td>
<td></td>
</tr>
<tr>
<td>Estimated blood loss (mL), m = 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>1225</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>602.0797289</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>400–1800</td>
<td></td>
</tr>
<tr>
<td>Anesthesia type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>General</td>
<td>7 (78)</td>
<td></td>
</tr>
<tr>
<td>MAC</td>
<td>2 (22)</td>
<td></td>
</tr>
<tr>
<td>Laterality, m = 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unilateral</td>
<td>5 (56)</td>
<td></td>
</tr>
<tr>
<td>Bilateral</td>
<td>3 (33)</td>
<td></td>
</tr>
<tr>
<td>Nerve injured</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Optic</td>
<td>9 (100)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>0 (0)</td>
<td></td>
</tr>
<tr>
<td>Onset of symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediate</td>
<td>7 (78)</td>
<td></td>
</tr>
<tr>
<td>Delayed</td>
<td>2 (22)</td>
<td></td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AION</td>
<td>1 (11)</td>
<td></td>
</tr>
<tr>
<td>PION</td>
<td>3 (33)</td>
<td></td>
</tr>
<tr>
<td>Unspecified ION</td>
<td>5 (56)</td>
<td></td>
</tr>
<tr>
<td>Informed about vision loss risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>5 (56)</td>
<td></td>
</tr>
<tr>
<td>Not specified</td>
<td>4 (44)</td>
<td></td>
</tr>
</tbody>
</table>

**Continued**
Table 3: Continued

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N (%), Total N = 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perioperative complications</td>
<td></td>
</tr>
<tr>
<td>Intraoperative hypotension</td>
<td>5 (56)</td>
</tr>
<tr>
<td>Inadequate positioning/padding, or lacking documentation</td>
<td>4 (44)</td>
</tr>
<tr>
<td>Facial edema</td>
<td>3 (33)</td>
</tr>
</tbody>
</table>

m = number of missing data points.
AION, anterior ischemic optic neuropathy; ION, ischemic optic neuropathy; MAC, monitored anesthesia care; PION, posterior ischemic optic neuropathy; SD, standard deviation.

be prone because it was a total hip arthroplasty. The mean surgical time was 6.5 hours (SD, ± 3.09), with a range of 1 to 9.7 hours. The cases had a mean estimated blood loss of 1225 mL; however, only 4 cases included estimated blood loss data. Of the 9 cases, 5 (56%) claimed that patients were not informed of vision loss as a risk of the procedure.

Complication details

The optic nerve was determined to be injured in all 9 cases, with 33% of the cases being PION and 11% AION, while 56% were not specified (Table 3). Immediate postoperative onset of symptoms was seen in 78% of the cases, and 56% of patients experienced unilateral vision loss. All of the injuries (100%) were permanent and classified as major or significant, with an NAIC severity score of 6 (44%) or 7 (56%) (Tables 1 and 2).

Contributing factors for the injury included “technical knowledge/performance” (100%), “patient comorbidity (nonneurologic)” (78%), “documentation error/missing” (67%), and “bleeding/coagulopathy” (22%) (Table 2). Table 4 provides sample narrative summaries of the 4 cases that were settled. Most notably, a $2 million settlement was paid for a patient who suffered PION after an almost 9-hour spinal surgery for severe scoliosis (Table 4).

DISCUSSION

Our analysis of the CRICO data demonstrates that perioperative vision loss (POVL) is an uncommon but catastrophic complication with possible permanent sequelae. Of 53 nerve injury claims closed between 2007 and 2016, only 9 closed claim cases pertaining to POVL were identified. Most of the cases are associated with spine surgeries (76%) and prone positioning (89%). When the cases were ruled in favor of the claimant, the indemnity payment amounts were substantial, with a mean amount of $906,250 and the highest being $2 million due to the permanence and severity of the injuries. Notably, 67% of the cases had a contributing factor of improper or missing documentation, and 56% specified that patients were not informed of vision loss as a risk factor during preoperative consenting.

In a previously published study, Lee et al22 compared trends of perioperative visual complications after spine surgery between 1980-1994 and 1995-2011 using the Closed Claims Project Database. The authors found that optic nerve injuries increased from 5% to 38% over the time periods studied. Furthermore, 71% of the optic nerve injuries they reviewed during 1995-2011 were associated with spine surgeries, which is consistent with 67% of ION associated with spine surgeries found in the current study. However, a larger 2016 study by Rubin et al11 of spinal fusion surgeries noted a significant decrease in ION from 1998 to 2012 with an incidence rate ratio of 0.72 per 3 years (95% confidence interval, 0.58-0.88). Possible explanations for this decline may include changes in clinical practices through complex interactions across various risk factors, such as equipment used for patient positioning during spine surgeries, intraoperative blood transfusion and fluid management practices, and duration of surgery.15 On the other hand, patient characteristics may be less contributory to the decline. Based on trends from the Nationwide Inpatient Sample database, Rubin et al11 found that the number of obese and male patients undergoing spine surgery has not diminished over time. Moreover, the average age of patients undergoing surgery in the United Kingdom increased by more than 14% between 1999 and 2015, and various indicators suggest a similar trend in the United States.11,23

We did not find any POVL associated with cardiac surgery in our investigation. This may be due to the small sample size. Additionally, cardiac surgeries tend to have a complex set of risks associated with the operation itself, particularly in the setting of cardiopulmonary bypass (CPB), so patients may not seek litigation due to the multifactorial etiology of their injuries. Kalyani et al8 conducted a retrospective case-control study in 2004 with subjects matched for age, sex, risk of vascular diseases, and type of cardiac surgery requiring CPB, and found the incidence of perioperative optic neuropathy to be 0.113% (11/9701). A larger, time-matched case-control study at the Mayo Clinic found a POVL incidence of 0.06% (17/27,915) in patients undergoing cardiac surgery requiring CPB between 1976 and 1994.7 The authors found that the presence of clinically significant vascular disease or a requirement for preoperative angiogram were risk factors for ION in this patient population. The risk was found to be further amplified by a postoperative hemoglobin level below 8.5 mg/dL.

In our study, the case with the highest settlement amount ($2 million) involved a patient who underwent a 9-hour corrective spine operation for severe scoliosis. Based on a 2016 retrospective study of the Nationwide Inpatient Sample database, De la Garza-Ramos et al24 noted that the
Table 4: Summary of Settled Cases in Relation to Contributing Factors

<table>
<thead>
<tr>
<th>Contributing Factor(s)</th>
<th>Settlement Amount (USD)</th>
<th>Narrative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical knowledge/performance; nonneurologic patient comorbidities; documentation error/missing</td>
<td>$375,000</td>
<td>A patient with a history of hypertension, smoking, and bipolar disorder underwent an L5-S1 vertebral decompression and fusion. Anesthesia and surgical consent was signed, but risk of ischemic neuropathy was not discussed. Facial padding was not documented. Intraoperative hypotension was corrected with intravenous fluids and blood transfusions. Total estimated blood loss was approximately 2 L, with a total operative time of 9 hours. The patient had postoperative facial edema and reported right eye vision loss, leading to a diagnosis of complete infarction of the optic nerve.</td>
</tr>
<tr>
<td>Technical knowledge/performance; documentation error/missing</td>
<td>$2 million</td>
<td>A patient underwent spinal surgery for scoliosis. No documentation of the risk of blindness was included in the consent process. Intraoperatively, multiple episodes of hypotension were treated with intravenous fluids. Estimated blood loss was 1.5 L, with an operative time of 9 hours. Postoperatively, the patient noted inability to see and was diagnosed with posterior ischemic optic neuropathy.</td>
</tr>
<tr>
<td>Technical knowledge/performance</td>
<td>$750,000</td>
<td>A patient with a history of obesity, hypertension, and smoking underwent lumbar decompression and fusion. Intraoperatively, the patient had several episodes of hypotension (30-50 mm Hg below baseline preoperative blood pressures) associated with decreased urine output. Total operative time was 10 hours. Postoperatively, the patient noted decreased, blurry vision, initially thought to be due to a medication side effect. Following discharge, the patient was evaluated by an ophthalmologist and diagnosed with ischemic optic neuropathy.</td>
</tr>
<tr>
<td>Technical knowledge/performance; documentation error/missing; nonneurologic patient comorbidities</td>
<td>$500,000</td>
<td>A patient with a history of obesity, hypertension, and coronary artery disease underwent spinal cord stimulator implantation for chronic back pain. Consent did not discuss the risk of blindness. The patient was positioned prone under deep sedation. However, a custom prone positioning pillow was not used. Total operative time was 5 hours. Postoperatively, the patient reported vision loss and was diagnosed with posterior ischemic optic neuropathy.</td>
</tr>
</tbody>
</table>

USD = United States Dollars.

incidence of POVL after corrective surgery for pediatric scoliosis was 0.16%. The authors also found that male sex, younger ages, having Medicaid insurance, and operations involving fusion of or more levels were independent risk factors for POVL. A more recent study of ischemic optic neuropathy following spine surgery at the Mayo Clinic also suggested that multilevel fusion spine surgeries, as well as intraoperative hypotension and higher blood loss, were associated with increased risk of ION.25

However, other studies found that older ages are associated with increased risk of POVL in adults undergoing spine surgery.22,26,27 suggesting a bimodal age distribution as a risk factor when taking the study by De la Garza-Ramos et al24 into account. Additional risk factors associated with ION in spine surgery include obesity, male sex, need for an intraoperative blood transfusion, and higher blood loss.22,26 Moreover, the 2012 study by the Postoperative Visual Loss Task Force as part of the ASA Closed Claim Project found that the use of a Wilson frame, longer anesthesia duration, and increased colloid as a percentage of nonblood fluid replacement also contribute to the risk of POVL.26 Although sex information was not presented in the CRICO data, the patient characteristics and operative factors in our study are consistent with existing literature: a mean age of 53.4 years, mean blood loss of 1225 mL, mean surgical time of 6.5 hours, obesity (44% of the patients; eg, hypertension, smoking, diabetes mellitus), and anemia (one patient).

Identifying and mitigating the risks of POVL is an effective risk management strategy and involves a multidisciplinary team approach. The ASA Task Force on Perioperative Visual Loss, in collaboration with the North American Neuro-Ophthalmology Society and the Society

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CONCLUSION

Based on the results of our study and existing literature, risk reduction strategies need to be instituted on the provider and system level and involve a multidisciplinary team of anesthesiologists, surgeons, nurses, and risk managers. Modifiable patient and procedure-specific factors should be considered to help prevent POVL. Strategies may include evidence-based intraoperative management that takes into consideration known risk factors for POVL, informed patient consent addressing risks and benefits, proper perioperative documentation, postoperative monitoring, checklist and clinical protocol development, and ensuring adherence to existing practice guidelines.

REFERENCES


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Richard Urman, MD, MBA, FASA is Associate Professor of Anaesthesia at Brigham and Women's Hospital in Boston, Massachusetts and Director, Center for Perioperative Research.
Harnessing the power of medical malpractice data to improve patient care

By Dana Siegal, RN, CPHRM, CPPS, John Swift, MBA, Janell Forget, RN, BSN, JD, and Tim Slowick, MBA

Intelligence gleaned from medical malpractice cases helps health care institutions analyze their litigation practices, trend financial outcomes, and even identify clinical services needing attention. But when examined more deeply, medical malpractice data can also be a powerful patient safety tool by revealing clinical patterns that contribute to medical errors and by enabling leadership to more accurately plan investments in patient safety and risk management. This case study describes how one organization, UMass Memorial Health Care in Worcester, Massachusetts, harnesses its deeply coded medical malpractice data and benchmarks its performance against national peers to catalyze clinical improvements. This strategy has proven successful in yielding positive change in such areas as emergency department ultrasound coverage, obstetrics communication, and airway management training. UMass Memorial’s ability to embed claims data use into its culture and to share learning across clinical services offers lessons for health care organizations of any size.

INTRODUCTION

When a young male arrives at UMass Memorial Health Care’s emergency department in Worcester, Massachusetts, complaining of pain in his genitals, ultrasound technicians are readily available, no matter the time or day. Ultrasound is critical for diagnosing problems like testicular torsion, an uncommon but serious condition in which a poorly attached testicle gets twisted and loses blood flow. This requires surgery to restore the testicle’s blood supply, when possible, and sometimes to secure the other side to protect fertility. With testicular torsion, seconds count when it comes to diagnosis and treatment; earlier detorsion leads to better outcomes.
UMass Memorial provides full-time, in-house ultrasound services on its University and Memorial campuses to address torsion and many other emergency medical conditions. However, that was not the case until 2015, when hospital leadership replaced its nighttime and weekend on-call ultrasound service with 24/7 onsite technician coverage.

**Medical malpractice lawsuits and data propelled this clinical change**

UMass Memorial’s claims and risk management (RM) staff had noticed a cluster of 4 medical malpractice cases involving teenagers who had lost a functioning testicle from testicular torsion. It appeared that three cases involved patients who had arrived at the ED at a time when ultrasound technicians were not available to provide immediate services. This caused delays in accurate diagnosis and treatment. According to a 2018 article in *Clinical Practice and Cases in Emergency Medicine* from the University of California Irvine Department of Emergency Medicine, testicular torsion occurs in about 4.5 per 100,000 males under age 25, but it is the third most common cause of medical malpractice suits in this demographic.1

An analysis of claims data revealed a disturbing fact: UMass Memorial was an outlier in testicular torsion outcomes, compared to peer academic medical centers across the country. The data were provided through UMass Memorial’s long-standing partnership with Controlled Risk Insurance Company (CRICO) Strategies. CRICO is a Boston-based medical professional liability (MPL) insurance program serving all of the Harvard medical institutions and their affiliates. CRICO Strategies extends CRICO’s data-driven methodologies to a national collaborative of hospitals, health care networks, and insurers who share data and insights to promote patient safety.

With this evidence in hand, chief medical officer and urologist Stephen Tosi, MD, who chairs the hospital’s claim committee, urged the administration to expand its ultrasound technician staffing to full-time coverage. The strategy worked. UMass Memorial has not experienced a similar case since the improvement was made.

This is one of several examples, described in this article, of how UMass Memorial delves deeply into its medical malpractice data to identify practice trends and vulnerabilities and to develop solutions involving a range of clinical services. These and other efforts have helped the organization reduce its risk exposure, improve patient safety, and drive down its volume of claims.

While not every health care organization has the RM and clinical coding resources of an academic medical center like UMass Memorial, the center’s commitment to capturing, learning from, and sharing claims data across clinical services—in other words, its success in embedding data use in its culture and encouraging collaboration—offers lessons for organizations of any size. A small hospital may have only a handful of claims each year. But even a single claim, turned into a compelling story, can become a potent teaching tool to think about malpractice vulnerabilities elsewhere in the institution.

**THE ADDED VALUE OF MEDICAL MALPRACTICE DATA**

Most health care organizations know there is value in studying medical malpractice claims; the data help them manage their litigation practices, evaluate financial outcomes, make underwriting decisions, and even identify high-level clinical services needing attention (see Box 1, p. 29).

However, when studied more closely, malpractice data can also be a powerful patient safety tool. It can reveal specific frontline missteps, clinical voids, and patterns of communication and judgment failure that contributed to a medical error or other cause of harm. Examining this intelligence enables leaders to sharpen their focus and more accurately plan investments in patient safety and risk management.

Sometimes, MPL data yields important surprises. For example, one might hypothesis that the key factor in a series of “surgical claims with complications” is technical failure in the procedure, however deeper analysis uncovers that the real root of the claims is expectation setting in the consent process. Another example is related to radiology issues in diagnostic claims—often thought to be related to

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**Box 1. The Power of Medical Malpractice Data**

- Provides 20/20 insights about the bigger picture, not just the provider at the moment when an error occurred.
- Helps target real problems.
- Supports RM efforts to be organization-wide and proactive.8
- Includes depositions, expert witness reports, and relevant medical records.
- Reveals the many common, human contributing factors and failures that caused the error/mishap, not just the “headline.”
- Represents one of two main strategies (with tort reform) for bringing down health care costs related to errors.9
Box 2. National Academy Recommends Teamwork

The National Academy of Medicine’s 2015 report, Improving Diagnosis in Health Care (Chapter 9), includes this vision for improving diagnosis and reducing diagnostic error:

**Goal 6:** Develop a reporting environment and medical liability system that facilitates improved diagnosis by learning from diagnostic errors and near misses.

**Recommendation 6d:** Professional liability insurance carriers and captive insurers should collaborate with health care professionals on opportunities to improve diagnostic performance through education, training, and practice improvement approaches and increase participation in such programs.

CODING AND BENCHMARKING

The opposite is true for UMass Memorial, the largest health care system in Central Massachusetts and the clinical partner of the University of Massachusetts Medical School. The system includes three hospitals with 1125 beds, 2000 physicians and registered nurses, and 13,000 total employees. The organization has its own captive insurance company and manages its own claims internally. But for the past 20 years, UMass Memorial has worked with CRICO Strategies to reduce its malpractice exposure by subscribing to its clinical coding and benchmarking services.

As part of this relationship, a clinical taxonomy specialist (nurse) from CRICO Strategies reviews and codes the UMass Memorial medical malpractice claims info and relevant medical records—a process that yields roughly 200 data points for each case involving the clinical, cognitive, and system failures that have led to the error, harm, or claim. In addition, UMass Memorial gauges its performance against peers through CRICO Strategies’ Comparative Benchmarking System (CBS), a national database of more than 400,000 MPL cases from more than 550 hospitals and health systems and 180,000 physicians covered by both captive and commercial insurers. Finally, regular conference calls with other CRICO Strategies members around the United States spark ideas for refining UMass Memorial’s patient-safety program and remind its Claims and RM staff that they are not alone.

DECLINING CLAIMS VOLUME

Reflecting a national trend (see Box 3, p. 31), the volume and frequency of malpractice claims at UMass Memorial has declined in recent years (see Figures 1 and 2). Risk and claims management leadership attribute this positive trend to several factors, including patient-safety improvements like expanded ultrasound coverage and enhanced training for clinicians. Many of these changes have been guided by evidence from malpractice cases, near misses, and closed observation cases (adverse events that did not become lawsuits).

UMass Memorial has also reduced its claims and legal expenses by effectively using early intervention and resolution, accomplished by openly acknowledging an error and reaching out to the injured party to discuss fair compensation. Various forms of alternative dispute resolution like this have helped health systems nationally settle disputes in a less costly and adversarial way than traditional litigation. In addition, UMass Memorial has sold or closed some hospitals and physician practices that did not have strong operating margins, and it has brought more physicians on board, requiring a stronger management structure to provide oversight.

Finally, UMass Memorial has lowered its claim volume by restructuring and reenergizing its RM program, which had
Box 3. A Decade of Medical Malpractice in America

In February 2019, CRICO Strategies, a division of CRICO’s Risk Management Foundation of the Harvard Medical Institutions Inc., released its benchmarking report “Medical Malpractice in America,” an analysis of 124,000 medical professional liability cases with claim-made dates or indemnity close dates between 2007 and 2016.6 Among the findings:

- Claims overall are trending down. The rate of MPL cases (paid and unpaid) declined 27%, from 5.1 to 3.7 per 100 physicians, from 2007 to 2016.
- For obstetricians/gynecologists, the risk of having a claim or lawsuit filed against them dropped a dramatic 44%.
- Case management expenses rose faster than consumer and legal inflation.
- The proportion of cases naming multiple defendants is growing based on the 2007–2016 cases reviewed.
- Indemnity payments are trending upward, with more cases paying higher dollars. The average payment grew on average 3% annually, to $360,000 in 2016. The volume of cases closing with $1 million-plus payments rose an average of 4.4% annually, while payments under $1 million fell.
- Average indemnities for high-severity, nondeath injuries to younger people are highest. High-severity injuries are 41% more likely to lead to a payment.
- Surgical treatment remains the most common source of MPL cases.
- The proportion of cases alleging errors in medical treatment (eg, care management) rose over 10 years; the share of diagnosis-related cases declined.
- Breakdowns in clinical judgment are the most common and costly contributing factors in MPL cases.
- Reducing diagnostic errors in ambulatory care requires attention to all phases of the diagnostic process.

been too lean, had significant staff turnover, and had acquired a poor reputation in the organization. To address this, the department increased the size and depth of its staff. It appointed seasoned nurses from UMass Memorial, developed their RM skills, and embedded them in clinical departments as points of contact for providers. This restructuring enabled RM to build relationships and trust throughout the medical center. People no longer run away from the team.

Likewise, risk managers at small hospitals can nurture relationships with nurse and physician leaders to support this work.

TARGETING PROBLEMS AND SOLUTIONS

Here, we describe several examples of how UMass Memorial has strategically harnessed medical malpractice data to reduce its risk and improve patient safety. These stories showcase the critical role that risk and claims managers can play, no matter the size of their organization, in making sure malpractice data are captured and passed along to practitioners. This information should not gather dust in claims files. The stories also show how risk managers can help facilitate cross-department communication about insights gained from malpractice data. There are many opportunities in health care to embrace this concept.

OBSTETRICS COMMUNICATION

A few years ago, it became apparent that communication gaps existed between two disciplines that typically handle births at UMass Memorial: family physicians and obstetricians. The problem had led to some delayed referrals of patients, during obstetric emergencies, from family physicians to their obstetrics counterparts, who typically have more training than family physicians in cesarean delivery and other operative procedures. Data mined from CRICO Strategies’ CBS, which represents 30% of MPL cases filed in the United States, showed that UMass Memorial was an outlier in this area, historically underperforming its national peers. Internal data from malpractice lawsuits and adverse events confirmed this situation.

Our claims and RM departments shared these findings with clinical leaders in family medicine and obstetrics. They, in turn, launched a successful education program in 2016 to strengthen communication among family physicians, obstetricians, and maternity and postpartum nurses—especially during obstetric emergencies. The program was developed by a multidisciplinary team and involves a series of twice-annual workshops on such topics as postpartum hemorrhage, hypertension and preeclampsia, communication and risk, pain management in labor, and shoulder dystocia. Simulation and team-training exercises play an important role in these sessions. RM’s grant program funds the initiative.

Sara Shields, MD, professor of family medicine at UMass Medical School, and Ellen Delpapa, MD, professor and chief of maternal-fetal medicine at UMass Memorial, note that communication-focused workshops with providers in maternity health “is critical to sustaining our overall excellent outcome and to reducing malpractice risk in this
area.” They hope the team-based training will have a lasting impact on preventing failure or delay of patient referral to obstetrics. In addition, “Our claims data demonstrate that investing in risk management in maternity care can potentially save $1000 to $2000 for every dollar invested.” The authors consider this a great success story. (See Figure 3.)

MOBILE SIMULATION

Data obtained from malpractice claims and closed observation cases at UMass Memorial—as well as from national peers—several years ago identified a need to improve responses to airway emergencies, when a patient is struggling to breathe and requires immediate attention. Airway emergencies may occur during elective procedures that require sedation, such as a colonoscopy or cardiac catheterization, or in the intensive care units (ICUs), where severely ill patients may require mechanical ventilation. RM staff worked with interprofessional, multidisciplinary clinical teams to develop corrective action plans to address issues that had been identified as contributing to suboptimal performance.

All clinical staff (about 400 providers) who participate in administering elective sedation for procedures at UMass Memorial now undergo a biannual credentialing process. The course consists of didactic modules, airway management task training, and a high-fidelity simulation scenario to help them remain compliant and proficient in airway management for sedation. The program has now been active for over 4 years.

In the ICU setting, providers managing patient airways were already knowledgeable and skilled. However, an analysis revealed that communication among different clinical specialties and multiple disciplines during emergency situations did not always have the desired outcome. So the idea of using simulation to standardize training expanded to crisis resource management training for the “Code Airway” teams responding to difficult cases in the ICU. The medical center chose a mobile in situ simulation approach. This would allow UMass Memorial to offer multispecialty simulation, which is very difficult to coordinate in a simulation center, and to provide simulation training to off-site locations, including member hospitals and affiliates, that would not normally have access to high-fidelity simulation.

**Figure 1:**
Overall Reduction in Claims, Suits, and Observations. Reduction in volume of open claims, suits, and observations (top) and open claims and suits (bottom) across UMass Memorial Health Care system between 2016 and 2019.
RM provided grant funding to support the development of a state-of-the-art simulation program in airway management to improve team performance and patient outcomes and to reduce our exposure to litigation risk. The funds covered the cost of training several faculty members as simulation instructors and purchasing high-fidelity equipment to record, conduct, and debrief in situ simulation cases. Our goal is to train residents and other clinicians, including ICU nurses, in such departments as anesthesiology, surgery, and emergency medicine. The Code Airway curriculum was developed by a multidisciplinary task force of clinician-educators, called REAcT (Root Cause Analysis Education and Action Team), which aims to capitalize on learning from root cause analysis outcomes and interventions. REAcT plans to continue collaborating with RM to provide the simulation training and to collect quantitative and qualitative data to evaluate its effectiveness.

According to Maksim Zayaruzny, MD, MS-HPED, assistant professor of anesthesiology and perioperative medicine and director of medical simulation in the Department of Anesthesiology, “A mobile simulation program in a large, multisite clinical system like ours builds our capacity to address rare, high-stakes events, such as Code Airway or neonatal resuscitation. It also helps with singular events, such as testing a system before implementation of new patient flows, processes, or standard operating procedures.” He says continued ongoing collaboration between REAcT and RM is crucial to the success of this program.

GRAND ROUNDS AND RISK ROUNDS

Grand rounds, an educational staple throughout health care, offer an excellent platform for using medical malpractice intelligence to advance patient safety.

At UMass Memorial, it is not uncommon for a department chair to request a one-time or annual presentation on the unit’s malpractice risk and possible solutions for improvement. In that case, claims and RM staff typically tease out vulnerabilities and trends in that service by reviewing 10 years’ worth of internal data—from lawsuits, adverse events, and

Figure 2:
Frequency of Claims and Suits. Frequency of professional liability claims and suits at UMass Memorial’s Worcester (main) campuses, showing decline in volume after risk management restructuring in 2015.
Figure 3:
Obstetrics/Gynecology Claims and Suits. Volume of obstetrics/gynecology claims and suits at UMass Memorial’s Worcester (main) campuses between loss years 2004 and 2018, showing significant reduction after training and simulation interventions began in 2012.

Source: UMass Memorial risk management and claims management departments.

observations—along with national comparative data from CRICO Strategies. One helpful resource is CRICO Strategies’ annual benchmarking reports on such topics as medication safety and communication, including the most recent one, “Medical Malpractice in America.” We meet with the department’s leadership to discuss our findings and how best to convey them to their clinicians.

In July 2018, for example, claims and RM presented a grand rounds on anesthesia to roughly 45 attending physicians, residents, and certified registered nurse anesthetists. We described UMass Memorial’s overall experience in anesthesia and compared our performance to academic medical peers across the country. The data revealed several areas of potential vulnerability for the anesthesia team, including:

- Communication among providers
- Patient airway monitoring
- Medication errors
- Monitoring and supervision of residents
- Fluid overload
- Patient consent

The positive feedback and value of sharing this information were clear, and we’ll be leveraging the approach in future educational programs with anesthesia and other clinical departments.

Similarly, our risk and claims management teams delivered a “risk rounds” to a graduating class of nurse practitioner (NP) students at UMass Memorial. The talk presented data from CRICO Strategies national database and from a 2018 study by The Doctors Company (another CBS member) on claims against NPs. The research, which analyzed 67 claims against NPs in family medicine and internal medicine practices between 2011 and 2016, found that malpractice allegations made against NPs were similar to those made against primary care physicians. The eye-opening event reminded the student attendees why it's
so important to begin thinking about risk and liability issues.

BUILDING COMMUNITY

One impetus for this talk was a conversation that Tim Slowick, director of claims management for UMass Memorial Health Care, had with counterparts whose organizations also contract with CRICO Strategies. During a conference call focused on underwriting, the group discussed issues around scope of practice for NPs and physician assistants (PAs), both advanced-practice providers. (While PAs are licensed as part of a physician-PA team, NPs in some states have autonomy to practice independently.) There has been an uptick in using lower-cost “midlevel” providers like these across UMass Memorial, as well as some related claim activity. Claims and RM have informed hospital presidents within the system about potential risks.

The conversation was part of a series of monthly calls that CRICO Strategies convenes, as part of its collaborative learning community, to allow national peers to compare notes on underwriting, patient safety, and claims. Participants share their experiences, challenges, and solutions to problems that others may, or will, also face in their organizations. Someone on the line might say, “We saw that, too, and here’s what we did,” and others can take that learning back to their institutions and explore it. A typical discussion involves 10 to 20 individuals.

A recent conversation by claims managers, for instance, focused on the impact that younger jury pools may have on malpractice awards, given generational differences in attitudes about medicine and retribution; Millennials tend to have high expectations for health care and believe that when it fails, someone is going to pay. Another call addressed how medical practices and providers are dealing with the spread of legalized marijuana, both medical and recreational, when it comes to caring for patients who may be under its influence or seeking marijuana for treatment. And on a recent underwriting call, colleagues discussed the emerging risks around specialty areas such as diagnostic radiology. They considered questions that underwriters might have, including: Who is responsible for making sure that x-ray or magnetic resonance imaging results are communicated to the patient and others who need to know? And from an underwriting perspective, how do we price that risk?

This kind of collaboration transcends competition. The professionals who are involved in this aspect of health care are dedicated to patient safety and to sharing knowledge on how to contribute hope and improvement to the industry and to patient care.

Within their own organizations, risk managers can play an important role in creating an environment where people feel safe to talk about their struggles and empowered to bring about change. Leadership, meanwhile, has a responsibility to ensure that RM is seen as a key partner and advocate for the organization’s safety agenda.

CONCLUSION

In conclusion, UMass Memorial Health Care considers medical malpractice data an invaluable resource to learn from and share. Data use is embedded in the organization’s culture. Risk and claims management teams work together closely, often combining data from the center’s coded MPL claims and uncoded adverse events. Analyzing these data on a deep level allows leadership to not only maximize litigation and underwriting management but to examine clinical priorities and advocate for improvements.

With the testicular torsion case cluster, the evidence provided a compelling rationale that having an in-house ultrasound technician available around the clock to perform those studies was critical, and that having full-time ultrasound coverage for other patients was an added bonus. RM was able to demonstrate that avoiding even one malpractice case would save the medical center almost $14,000 in loss-adjustment expenses, such as attorney and expert fees, and that such costs far outweighed the salary requirements for additional ultrasound technicians. Leadership was also aware that making consistent progress in reducing the indemnity impact of claims would lead to reduced malpractice insurance costs over time. In other words, additional tech staffing would be money well spent and was the right thing to do for the center’s patients, families, and clinicians.

Medical malpractice data are, of course, only one potential factor in influencing decision making. But we know from experience that it is a much more potent tool for advancing safety than many health care leaders realize.

Whether you’re a large academic medical center with access to the resources of a data analytics partner like CRICO Strategies, or a small community hospital with a small RM and claims staff, the bottom line is that you have data available that will allow you to identify issues and trends, educate clinicians, and work together to develop solutions.

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Clinical/Patient Safety

Introduction of enterprise risk management in neonatal intensive care unit to reduce breast milk errors

By Maliha Shareef, MD, MS, FAAP and Barbara J Youngberg, JD, MSW, BSN, FASHRM

Preterm infants born before 34 weeks gestation are unable to feed by mouth. Mothers of these preterm infants are thus asked to pump breast milk to be fed to infants through a nasogastric tube. Each mother’s pumped breast milk must be carefully labelled and stored so that it is not fed to the wrong baby during the infants stay in the neonatal intensive care unit, which can range from days to months. All hospitals have strict policies and procedures in place to ensure infants are fed their mother’s milk but still occasional errors are reported. We looked at the effect of introducing the enterprise risk management method in preventing breast milk errors in our neonatal intensive care unit.

A Level III neonatal intensive care unit (NICU) is a highly specialized area where infants as young as 22 weeks and as small as 500 g are resuscitated. These infants are not neurologically developed to suck and swallow, and can only be fed through a nasogastric tube until they are ready to eat by mouth. Breast milk is considered the “best milk” for these premature infants, as it reduces the risk of necrotizing enterocolitis and late-onset sepsis. An additional benefit of breast milk is increased neonatal neurodevelopmental growth.1–3

The event reporting system at our hospital had recorded an incident in which one mother’s breast milk was given to another mother’s infant. This misadministration incident was reported by the NICU nursing director to the medical director of the NICU. The medical director then informed both families of the error per the hospital’s error management plan. However, both infants had been home for 2 months when the error was realized. This led to further investigations of the question: How did this happen? The NICU has a very robust and safe method of storing breast milk. A root cause analysis was started and the process failure identified and rectified. This incident precipitated an analysis of the whole breast milk handling and storage process from the viewpoint of enterprise risk management (ERM).
ERM is a framework for achieving safe and reliable health care delivery. It includes the processes of identifying, assessing, and managing risk. The essential elements of ERM are comprehensive framework, value protection, value creation, and managing uncertainty. The ERM process creates value and optimizes risk opportunities. The steps in this process are risk and opportunity identification, risk evaluation and assessment, strategic risk response and implementation, review, evaluation, and monitoring. The aim of risk identification is to reduce uncertainties by risk recognition and to clarify the nature and extent of known and potential risks through risk evaluation and assessment. These risks should be reduced and eliminated by the risk responses generated through the ERM process. Health care leaders need to recognize that better management of patient safety risk as well as business risk will increase the value of the organization through increase in reputation and prevention of financial losses that would benefit the organization and the community. Hospital boards that support the ERM framework will be able to create greater value for their organization and serve their stakeholders.4-6

Breastfeeding is an essential part of the birthing process. Mothers are encouraged to breastfeed as soon as their child is born, leading to increased mother-infant bonding. But in the NICU as these infants are born prematurely they are not developmentally ready to breastfeed. Preterm infants cannot breastfeed until they reach the gestational age of 34 weeks. Their mothers are asked to pump 8 to 12 times daily starting after delivery to increase their milk supply. The breast milk is then stored. Preterm delivery with a infant in the NICU is highly stressful to the parents. This stress could lead to a decrease in the milk supply. Breastfeeding education of pregnant women is usually started during pregnancy and continued after birth. The preterm mothers are educated in pumping with an electric pump. Both the nurses and the lactation consultants help and guide the mother in establishing a pumping schedule.7,8

The preterm infants are admitted to the NICU with a prolonged length of stay. The mothers are discharged home a few days after delivery, thus separating the mother from the child. Parents are then instructed in the proper labeling, storage, and transport of milk from home. The guidelines for milk storage after pumping have been established by the American Dietetic Association and the Human Milk Banking Association of North America. These guidelines include storing the milk in sterile or aseptic food-grade plastic or glass containers that are built to withstand long-term freezing. Labels on the bottles should include the infant’s name, date and time of milk expression, and medications or supplements taken by the mother. The milk could be frozen at –4°F for up to 6 months. Frozen milk should be transported to the hospital on ice. Milk in a cooler with ice packs could be used up to 24 hours. Frozen breast milk is warmed to 75°F before feeding the infant. Once warmed, the milk should be used within 4 hours. Excessive heat exposure to breast milk could destroy maternal enzymes and immune factors in the milk such as immunoglobulin A.9,10

Parents can rent electric pumps at home for pumping breast milk. Hospitals are required to provide pumps and a pumping room for mothers who have infants in the NICU. Newer hospitals have a single room for each infant. These rooms are equipped with an electric pump and supplies for pumping and storing breast milk are provided to the mother. The rooms have refrigerators with freezers that can hold the milk. At the time of feeding, the milk can be warmed in special milk-warming machines to the temperature of expressed breast milk (EBM). Hospital policies are in place for infant bottle feeding, breastfeeding, breast milk handling/preparation, and NICU breast milk handling/preparation. The policies are followed by three units in the hospital: Labor and Delivery, the Mother-Baby unit, and the NICU.11,12

Hospitals also have policies to cover misadministration of breast milk. Unfortunately, this continues to be a problem in the nurseries. Hospital such as the Children’s Hospital of California and Pennsylvania hospitals had numerous breast milk administration errors.13,14 These hospitals made changes in their policies and procedures to reduce the identified errors. Children’s Hospital of California decided to centralize its breast milk administration process and introduced bar code scanning. Each infant has a tag with a unique bar code that matches the breast milk labels. The Pennsylvania Patient Safety Reporting System is a confidential statewide system that has filings on medical errors since 2004. Their recommendations include mother and infant identification, labeling breast milk containers, storage and management, dispensing, education, and communication.15-17 In our case, both of the infants were home for 2 months and the mother fed the infant breast milk before discovering that the label had a different infant’s name. This incident was reported in the hospital’s event reporting system, which triggered root cause analysis. During the root cause analysis, we looked at the causes and the contributing factors to identify the vulnerability in our system that led to this incident. The aim was to reduce the risk and decrease the likelihood of recurrence. We also wanted to improve performance and increase sustainability.

The multiple breast milk errors have identified a need for change. Introducing the ERM approach at this point would be a shift from the silo approach in the NICU to a more comprehensive approach. Transparency is a strong element in the culture of our NICU. The parents remain with their infants from birth. The father accompanies the infant to the NICU, while the mother is recovering in the delivery room. All procedure and care management rounds occur in front of the parents. The policies for infant feeding in the NICU are robust and followed strictly to reduce any variability and cultivate safe practices, thus leading to value protection.

Breast milk safety and reduction in the misadministration of the milk would increase our reputation and improve our
patients’ satisfaction. Value creation will occur with improved patient satisfaction scores, increase quality outcome, and increase respect and credibility in our organization. Both our chief executive officer (CEO) and chief medical officer (CMO) will have a competitive edge in the organization. Both our CEO and CMO, in outcome, and increase respect and credibility in our organization. Both our chief executive officer (CEO) and chief medical officer (CMO) will have a competitive edge in the organization.

Implementing ERM requires communication between different hospital departments, learning from the expertise of each member of the team, and providing reports to the CEO, CMO, and the board. To follow the above process, we identified the risk domains in our NICU and analyzed the risk assessment so that we could take action. After we rated the risk drivers and the current risk management activities, we discussed the strategies and solutions and determined the implementation steps for our NICU.18

RISK DOMAINS

Operational

The three units of the hospital—Labor and Delivery, Mother-Baby, and NICU—have robust policies in place for safe handling and storing of the breast milk. The Labor and Delivery unit and the Mother-Baby unit deal with infant feeding, as these infants are full term and can breastfeed. Their policy does not require inclusion of storage guidelines. The NICU with its extremely premature infants has both safe handling and storage policies in place. The most common error that occurs is one mother’s milk being fed to another infant. Labeling has been identified as the breakdown process point, specifically when the label is generated and attached to the bottle before storage. Verification of the infant’s arm band and the label on the bottle could be affected if the infant’s arm band is missing or placed on the chart. Problems with storage organization and management include decreased area in the refrigerator and freezer to store breast milk, lack of specified bins labeled with the individual infant’s name, and lack of appropriate alarm system for controlling the appropriate temperature of the freezer.19

Clinical/patient safety

As breast milk is a body fluid, it can transmit diseases from the mother to the infant. Thus, breastfeeding is contraindicated in HIV-positive mothers. Other diseases such as hepatitis B and C and cytomegalovirus (CMV) can also be transmitted to the infant through breast milk. If an infant has received breast milk, both the source mother and biological mother along with the infant must be tested for the above diseases. Consent must be obtained from both of the mothers to evaluate their medical records for information about HIV and hepatitis status. If a length of time has passed before the error is realized, as in our case, both the mothers and the infant need to have fresh blood drawn for the testing. This leads to increased pain and anxiety in both of the mothers. If the source mother is positive for HIV, then the mother and the receiving infant must be treated by an infectious disease specialist. The infant receives a hepatitis B vaccination after birth and two more doses at 1-month intervals. If the source mother tests positive for hepatitis B, the infant would have to receive immunoglobulins to prevent him/her from getting the disease. The treatment for hepatitis C is very expensive, and the US Food and Drug Administration has recently approved drugs for children 12 to 17 years of age. If milk was expressed when the mother had sore or cracked nipples, there is an increased risk of transmission of hepatitis B and C. As there have been no reported cases of CMV transmission through breast milk, it is not recommended to regularly test for CMV in the mothers or the exposed infant.20

The Centers for Disease Control and Prevention (CDC) states that as the HIV mothers are contraindicated to give breast milk to their infants, they would not be pumping and bringing in any milk. Although there have been no incidences reported of HIV transmission from a single bottle of breast milk, the mothers and infant are still tested for HIV after a breast milk error occurs. Hepatitis B and C will not spread through breast milk unless there is contamination with blood. Infants receive a hepatitis B vaccine shortly after they are born and thus would be protected.21

Financial

Reduction in breastfeeding errors impacts the length of stay in the NICU. The daily cost of a NICU bed is $3,500 to $10,000. A significant reduction in length of stay of these extremely premature infants would have large financial benefit and would lead to increased annual savings. Using software for bar code scanning would decrease labor cost and save nursing time. This would motivate the administration to invest in the equipment, space, and staffing to ensure an ideal feeding process. The cost of all testing for the mothers and the infant is covered by the hospital. Lab tests cost $500 per incidence to test donor mother and recipient infant. Any treatment involved would also increase the financial burden on the hospital. The pain and suffering for the families will also have monetary consequences and decrease the return on investment. Health Insurance Portability and Accountability Act (HIPAA) fines $25,000 per incident, and breast milk errors are considered as a HIPAA breach.21,22

Human capital

Staff education and communication for safe handling and storage of EBM is essential for a reliable system. A study of breast milk management showed that using trained
technicians in the preparation, storage, and delivery of EBM led to reduction in feeding errors. The study also demonstrated a reduction in length of infant stay in the NICU from 10.1 to 7.9 days. The study concluded that trained technicians improve consistency, safety, and accuracy in enteral nutrition preparation, and this leads to decreased feeding errors. Consideration must be given to short staffing in the NICU, as nursing fatigue could lead to increased feeding errors. The NICU’s registered dietitian can collaborate with the nurses and the technicians to reduce errors in feeding.

**Strategic planning**

The NICU can develop a quality initiative plan with a multidisciplinary team that would audit the handling, storage, and distribution of the EBM. Elimination of the feeding errors would be the priority. A specific protocol to minimize EBM feeding errors would become a part of the quality assurance program. The nurses along with the registered dietitian and the trained technicians would collaborate to validate the error prevention process. A protocol would be created to improve the standard of care that the technicians would check to improve detection and correction of feeding errors.

**Technology**

Refrigerators and freezers are provided in each infant’s room for the EBM to be kept in. Mothers are provided with an electric breast pump and sterile bottle to store the milk. Labels are provided for the mother, and she is instructed to write the date and time expressed on each bottle. Milk-warming machines are also in each room to warm the milk to the temperature of EBM. A centralized sterile processing area is supervised by the registered dietitian, where the trained technician prepares the EBM with special fortifier. Alternatively, the nurses add the powdered fortifier in the infant’s room in a sterile method.

**Legal and regulatory**

As hospitals are considered a high-hazard industry, they are highly regulated. As most of the NICU infants are covered under Medicaid insurance, the hospital has increased facility adherence to the Joint Commission and the Centers for Medicare & Medicaid Services regulations as applicable to NICU feeding practices, which is in the best interest of health care systems. A HIPAA violation occurs with breast milk feeding errors as the name of the source mother is on the label, and thus a compliance report must be submitted. The Department of Patient Relations for the hospital must be informed for two reasons; firstly to ensure that mothers are not being charged for the error and the resultant tests, and secondly, to inform the involved families that new protocols have been initiated to ensure this error is not repeated. The risk management team is involved to reduce the financial burden and to deal with any legal outcomes. The Department of Infection Control must be informed of the incident, as there is a possibility of infectious disease transmission. The CEO, CMO, and Chief financial officer, along with the risk officer, are informed.

**Hazard**

To avoid the hazard of flooding and disrupting the electric power to the freezers, the electric appliances in our hospital have been placed on the third floor. Mothers stay on the fifth floor after delivery, which is very close to their infants in the NICU on the fourth floor. After discharge, mothers can stay with their infants in the NICU to continue the bonding that increases breast milk production. Mothers can sleep on an extendable couch available in each infant’s room and are provided food trays while staying with their infants.

**RISK ASSESSMENT SCALES**

The risks identified in the Risk Domains section need to be quantified for the organization to take action. The risk score incorporates two dimensions of risk, likelihood, and impact, and is calculated to show the significance of the risk on the organization. A score between 1 and 5 is given. Each organization defines the descriptors that are meaningful to it. The risk scoring is used by the organization to identify the high-priority risk for immediate intervention. Mislabling of breast milk and wrong milk given to the infant have the highest risk scores, as shown in Table 1.

**STRATEGIES AND SOLUTIONS**

**Implementation steps: planning**

Three teams were formed:

- The first was the Failure Mode Effects and Analysis team lead by the risk manager. The goal was to identify the failure points and their root cause analysis.

- The second team consisted of the Breast Milk team led by the director of lactation consultants, which had a goal of breast milk handling and safe storage. The goal was to identify any failure points and determine a course of action.

- The third team consisted of the information technology project manager, nursing director, and NICU nurses. This team would be responsible for the bar coding and software system.

**Implementation steps: development**

A robust protocol was formed based on the guidelines from the CDC. When an infant is mistakenly fed another child’s bottle of EBM, the following steps are performed:

- The mother whose breast milk was given to another child is informed. Consent for her medical information
Table 1: Risk Assessment Scales

<table>
<thead>
<tr>
<th>Risk</th>
<th>Risk Domains</th>
<th>Impact/Severity</th>
<th>Likelihood</th>
<th>Risk Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mislabeling</td>
<td>Operational</td>
<td>Moderate 3</td>
<td>Potential 3</td>
<td>3 × 3 = 9</td>
</tr>
<tr>
<td>Wrong milk</td>
<td>Legal/Regulatory</td>
<td>Major 4</td>
<td>Likely 4</td>
<td>4 × 4 = 16</td>
</tr>
<tr>
<td>Infection</td>
<td>Clinical/Patient</td>
<td>Low 1</td>
<td>Unlikely 2</td>
<td>1 × 2 = 2</td>
</tr>
<tr>
<td>Expired milk</td>
<td>Clinical/Patient</td>
<td>Low 1</td>
<td>Potential 3</td>
<td>1 × 3 = 3</td>
</tr>
<tr>
<td>HIPAA breach</td>
<td>Financial</td>
<td>Moderate 3</td>
<td>Potential 3</td>
<td>3 × 3 = 9</td>
</tr>
</tbody>
</table>

HIPAA, Health Insurance Portability and Accountability Act.

and chart review is obtained. The mother is encouraged to get tested for HIV and hepatitis B and C.

- The mother whose infant has been exposed, and the infant, would need to be tested for HIV and hepatitis B and C.

- The laboratory is informed not to charge the mothers and the infant for the tests done.

- The Departments of Risk Management, Patient Relations, and Infection Control are sent a compliance report.

Implementation steps: integration

Infant and mother identification:

- Making sure that the bands on the mother and infant match.

- Parents are educated to check the label on the milk bottle and their bands.

Labeling breast milk containers:

- Make sure the label has the name, date, and time of expression of breast milk.

- The labeling should be carefully inspected for the above information before storing.

Storage and management:

- Breast milk kept in the freezer is set at the appropriate temperature.

- The freezer has an alarm for unacceptable temperature change.

Dispensing:

- Verify with the mother that the label matches with the information on the band for the infant and the mother before thawing and warming the breast milk.

Education and communication:

- Provide ongoing educational opportunities for staff to learn and demonstrate safe breast milk handling.

- New staff should undergo training.

- Educate parents in checking labels before feeding the infant.

Implementation steps: monitor/evaluation

- Regularly reinforce and educate to ensure safety and compliance.

- Continue to audit the error reporting system for missed events or near-miss events.

- Continue staff training through online modules.

- Educational material on safe handling and storage (English/Spanish) to be given to the parents.

CONCLUSION

EBM errors are more common than previously believed. Hospitals in California and Pennsylvania have done extensive studies and have recommendations to improve and therefore decrease the number of errors.11,19 In the NICU case presented above, we found out that these two infants had been extremely premature and thus had a prolonged length of stay in the NICU. The freezer/refrigerator in the infant’s room was filled to capacity, so extra breast milk was placed in bins in a common freezer. These bins were full and overflowing. The change was that any extra milk bottles will be given back to the infant’s mother to store at home, and no further bottles will be placed or stored in common freezers, thus eliminating the risk. Introduction of ERM methods in the NICU helped identify the deficiencies and organize the policies and procedures to reduce breast milk errors. These changes increased both patient safety and patient satisfaction scores. Introduction of ERM in the NICU was a successful project and can be utilized in other intensive care units to identify and manage uncertainties, create value, and optimize risk opportunities.
REFERENCES


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INFORMED CONSENT

Delaware law allows emergency hysterectomy without informed consent

FACTS:
Stacia Vick saw Dr. Nasreen Khan for prenatal care starting in December 2014, and ending with the delivery of her child at Kent General Hospital on June 11, 2015. To facilitate the delivery, Dr. Khan felt that it was necessary to perform an episiotomy. However, Ms. Vick developed postpartum hemorrhage on June 12, which required an emergency hysterectomy. Ms. Vick had executed, at some point prior to the delivery, a consent to a hysterectomy if an emergency situation developed. According to Ms. Vick, however, she revoked that consent prior to the performance of the hysterectomy. The hysterectomy was performed, allegedly against Ms. Vick’s will, and without her informed consent.

Ms. Vick brought suit for medical malpractice (alleging that the hysterectomy and the episiotomy were performed negligently), lack of informed consent, assault, false imprisonment, intentional and negligent infliction of emotional distress, negligence, and fraud. She also brought suit against Bayhealth (the parent of Kent General Hospital) for vicarious liability for the allegedly negligent acts of Dr. Khan. However, with the exception of the medical malpractice, lack of informed consent, and vicarious liability claims, all of the claims were barred by the statute of limitations. The defendants filed motions for partial summary judgment on the remaining claims. This is the decision of the Superior Court of Delaware for Kent County on those motions.

ISSUES:
Was Dr. Khan required to obtain Ms. Vick’s informed consent for the emergency hysterectomy? Was Dr. Khan negligent in performing the episiotomy and hysterectomy? Was Bayhealth vicariously liable for Dr. Khan’s actions?

ANALYSIS:
The court noted that the Delaware statute on informed consent provides that:

No recovery of damages based upon a lack of informed consent shall be allowed in any action for medical negligence unless: (1) The injury alleged involved a nonemergency treatment, procedure or surgery; and (2) The injured party proved by a preponderance of evidence that the health-care provider did not supply information regarding such treatment, procedure or surgery to the extent customarily given to patients, or other persons authorized to give consent for patients by other licensed health-care providers in the same or similar field of medicine as the defendant.

18 Del. Code § 6852(a).
The court held that because the hysterectomy was done on an emergency basis, Ms. Vick’s informed consent was not required. The defendants’ motion for summary judgment on this issue was granted.

With regard to the malpractice claim, the court held that “plaintiffs bear the initial burden of presenting expert medical testimony as to (1) the applicable standard of care, (2) the alleged deviation from that standard, and (3) the causal link between that deviation and the alleged injury.” The plaintiff’s expert, Dr. Berry, specifically stated that his only criticism of the hysterectomy and the episiotomy was that the hysterectomy was done without Ms. Vick’s informed consent. He was not critical of the manner or technical performance of the hysterectomy or the episiotomy. Accordingly, Ms. Vick had not shown that the standard of care was breached. The motion for summary judgment on this issue was granted.

It is not entirely clear why the court decided to address the motion for summary judgment on the vicarious liability claim. Since it had already determined that Ms. Vick had not shown that Dr. Khan had been negligent, there was nothing for which Bayhealth could be held vicariously liable. The issue was moot. Nevertheless, the court persisted. The court noted that there are two ways to show that a hospital may be vicariously liable for the actions of a medical staff member: actual control and apparent agency. Although the court never used the term respondeat superior in discussing actual control, it was clear that it was contemplating an employment relationship. It found no evidence that Dr. Khan was employed by Bayhealth or that Bayhealth exerted sufficient control over Dr. Khan to warrant the imposition of vicarious liability.

The test for apparent agency, according to this court, is: “One who represents that another is his servant or agent and thereby causes a third person justifiably to rely upon the care or skill of such apparent agent is subject to liability to the third person for harm caused [by] a lack of care or skill of the one appearing to be a servant or other agent as if he were such.” Thus, there must be a “holding out” of the person as the principal’s agent, and then the patient must reasonably rely on such a representation. The court noted that Ms. Vick selected Dr. Khan to provide her care, she saw Dr. Vick outside the hospital, and the hospital played no role in the formation of this relationship. Accordingly, the court held that Dr. Khan was not an agent of the hospital and granted the motion for summary judgment in its entirety.

**RISK MANAGEMENT CONSIDERATIONS:**

As a practical matter, it is generally true that informed consent is not required in an emergency situation. This is because the patient’s consent is implied. However, this presumes that the patient would consent if she were able to do so. This presumption does not continue to exist if the patient flatly refuses to undergo the emergency procedure. A patient is entitled to refuse even the most necessary of emergency or lifesaving procedures. This is due to the ethical principle of autonomy, which is respected in the law. The court should have allowed the finder of fact to determine whether Ms. Vick had revoked her consent for the hysterectomy.

While it is not clear whether any of the plaintiffs’ claims are still viable, given that the court did not dismiss the entire action, it is clear that this is a rather troubling decision. However, simply because the court held that informed consent (consent after the discussion of risks, benefits, and alternatives) was not required, this is not to say that it held that consent was not required. Under circumstances such as these, the determination of whether the patient consented would be a question for the jury: Was the written consent (in which Ms. Vick consented to a hysterectomy in an emergency) valid, or did Ms. Vick orally revoke it? Unfortunately, the claim for assault (and presumably battery) was barred by the statute of limitations, so this question will never be answered.

Nonetheless, it is not the case that health care providers have free rein to do whatever they feel is necessary in an emergency situation in Delaware because they do not need the patient’s informed consent. They still need consent. Without consent, the providers are potentially liable for medical battery. It is not clear what damages Ms. Vick might have been able to obtain on a battery claim in this case (given that the jury would have to weigh the damages of having undergone a wrongful hysterectomy versus the benefit of not losing her life), but she could have gotten something in the way of damages.

This is the kind of situation in which no health care provider should be placed, but unfortunately they do find themselves in this position. From an ethical or a legal perspective, the provider would be completely justified in honoring the patient’s refusal and not performing the emergency procedure. However, that approach risks serious harm or death to the patient. Consequently, in these situations the courts have been clear: Providers should err on the side of sustaining life.

**EMERGENCY MEDICINE**

**EMTALA imposes continuing obligation to stabilize inpatients in the sixth circuit**

**FACTS:**

On June 2, 2016, Hortense Galuten, then 93 years old, presented to the emergency department (ED) at
Williamson Medical Center. She was diagnosed with (1) severe hypernatremia, (2) decreased oral intake, (3) malnutrition, (4) chronic kidney disease stage IV, (5) leukocytosis, (6) hemocoagulation, (7) hypertension, (8) dementia, and (9) possible Parkinsonism. She was admitted for treatment and remained an inpatient until June 11, 2016, at which time she was transferred to a rehabilitation facility. It was alleged that she was suffering from the following additional conditions on discharge: hypoxia, emesis, and abdominal pain. Additionally, it was alleged that, at the time of transfer, Ms. Galuten was negligently restrained on a gurney, which allowed her to vomit and aspirate the vomitus, thus causing acute respiratory distress. She died the day after she was admitted to the rehabilitation facility.

Suit was filed for violations of the Emergency Medical Treatment and Labor Act, 42 U.S.C. § 1395dd (EMTALA), 42 U.S.C. § 1983 (violation of civil rights under color of state law), and Section 1557 of the Patient Protection and Affordable Care Act (ACA), 42 U.S.C. § 18116. This opinion is the decision of the US District Court for the Middle District of Tennessee on the defendants’ motion to dismiss.

**ISSUES:**

Did Ms. Galuten’s care violate EMTALA? Were her civil rights violated by the hospital’s actions under color of state law? Was she discriminated against on the basis of her age?

**ANALYSIS:**

It has long been the law in the Sixth Circuit (which includes Tennessee) that hospitals have an obligation to continue to provide care to a patient with an emergency medical condition until the condition has been stabilized. See, for example, Moses v. Providence Hospital and Medical Centers, Inc., 561 F.3d 573 (Sixth Cir. 2009); Thornton v. Southwest Detroit Hospital, 895 F.2d 1131 (Sixth Cir. 1990). This is in contravention to the position that the Centers for Medicare & Medicaid Services (CMS) takes on the subject, which is that:

If a hospital has screened an individual … and found the individual to have an emergency medical condition, and admits that individual as an inpatient in good faith in order to stabilize the emergency medical condition, the hospital has satisfied its special responsibilities under this section with respect to that individual.

42 C.F.R. § 489.24(d)(2)(i)

This regulation means that a hospital’s obligations under EMTALA disappear once the patient is admitted, assuming that the hospital intended to attempt to stabilize the emergency medical condition.

The court noted that, on a motion to dismiss, the plaintiff must merely allege that a cause of action exists, without reference to the plaintiff’s ability to prove the truth of his assertions. This must, of course, be more than a mere recitation of the elements of the cause of action. The court held that the plaintiff had sufficiently met his pleading obligation to avoid a motion to dismiss under the law of the Sixth Circuit. The court denied the motion to dismiss as to the EMTALA claim.

The court also analyzed the case under Section 1557 of the ACA (42 U.S.C. § 18116), “which provides that an individual shall not, on the grounds prohibited in, among other things, the Age Discrimination Act of 1975 (42 U.S.C. § 6101, et seq.), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving federal financial assistance.” Unfortunately for the plaintiff in this case, he was required to file a complaint with the Office of Civil Rights (https://www.hhs.gov/civil-rights/filing-a-complaint/complaint-process/index.html) inside the Department of Health & Human Services within 180 days of the alleged violation. This filing is jurisdictional: If the plaintiff has not filed a complaint and exhausted his administrative remedies, the district court cannot hear the claim. The plaintiff had not filed a complaint with the Office of Civil Rights at all. Consequently, the court dismissed this claim under the ACA for failure to exhaust administrative remedies.

Plaintiff conceded that his claims under Section 1983 were barred by the statute of limitations, so these claims were dismissed.

**RISK MANAGEMENT CONSIDERATIONS:**

This case highlights the inherent fallacy in the Sixth Circuit’s requirement that care be given until the patient’s emergency medical condition has been stabilized. While it is not clear whether more could have been done to stabilize Ms. Galuten’s condition, it is clear that she was not going to live forever, or possibly not even much longer, regardless of the level of care provided. Consequently, requiring that a hospital stabilize a patient’s condition when the patient is dying is unrealistic, if not wholly impossible. There are going to be people who present at hospital EDs whose conditions cannot be stabilized. This happens on a daily basis at virtually every hospital in the United States.

Additionally, it is not necessary to impose EMTALA obligations on hospitals to care for their unstabilized inpatients. EMTALA should be viewed as a threshold issue: it requires hospitals to admit patients to their EDs, screen them objectively, and do what they can for them if they determine they have an emergency medical condition. Once patients are admitted, there are two significant changes in the patient’s situation: (1) their care is governed by the CMS Conditions of Participation for Hospitals, and
(2) they have a provider/patient relationship with the hospital, which requires the hospital to act within the standard of care or face malpractice liability. Prior to EMTALA, hospitals could turn away patients with impunity because they did not have a provider/patient relationship with them. That is no longer true because of EMTALA. In short, the Sixth Circuit should overrule its precedent and recognize that a hospital’s obligations under EMTALA cease when the patient is admitted in good faith. If the hospital did, in fact, admit Ms. Galuten in bad faith (solely to avoid EMTALA liability and without any intention of stabilizing her condition), the CMS regulations on the subject would apply, and the plaintiff would still have a cause of action.

The reason this is important is that EMTALA is, essentially, a strict liability cause of action. All that the plaintiff must show is that (1) the hospital violated the statute and (2) the patient was injured as a result of the violation. Under a standard-of-care cause of action, the plaintiff must actually prove that the hospital acted negligently.

Although this case says nothing about the merits of a claim for age discrimination in the provision of health care services, it does make an important point. Section 1557 of the ACA is normally associated with protection against discrimination on the basis of gender identity (which is currently stayed by court order), but it also protects against discrimination if the following statutes are violated: Title VI of the Civil Rights Act of 1964 (prohibits discrimination on the basis of race, color, and national origin in programs and activities receiving federal financial assistance), Title IX of the Education Amendments of 1972 (prohibits discrimination on the basis of sex in any federally funded education program or activity), Section 504 of the Rehabilitation Act of 1973 (prohibits discrimination against people with disabilities in programs that receive federal financial assistance), as well as the Age Discrimination Act of 1975 (prohibits discrimination on the basis of age in programs that receive federal financial assistance). The requirement that a plaintiff must exhaust his administrative remedies before filing suit in court may take some of the sting out of Section 1557, but this is still a matter of concern.

Galuten v. Williamson Medical Center, No. 3:18-cv-00519 (M.D. Tenn. April 9, 2019)

EXPERT TESTIMONY/VICARIOUS LIABILITY

Expert testimony must have a foundation in scientific literature

FACTS:

Linda Wendt was admitted to MidMichigan Medical Center–Midland (MMCM), where she underwent a left total knee arthroplasty (TKA). Ms. Wendt was morbidly obese (body mass index = 50) and suffered from type 2 diabetes. It appears that no problems resulted from the TKA itself, and the orthopedic surgeon was not involved in this case. Dr. Jill Bowerman provided anesthesia care for the TKA. Dr. Bowerman provided two doses of fentanyl and administered both a sciatic nerve block and a femoral nerve block. Ms. Wendt allegedly suffered permanent nerve damage in her left leg as a result of the nerve blocks.

Ms. Wendt sued Dr. Bowerman for medical malpractice and sued MMCM for vicarious liability for Dr. Bowerman’s actions as its ostensible agent. MMCM moved for summary disposition on the vicarious liability claim, which was granted by the trial court. Dr. Bowerman moved for summary disposition on the grounds that the testimony of plaintiff’s expert witness, Dr. Rein, was unreliable and should be excluded. The trial court convened a hearing on the matter and reviewed scientific literature presented by the parties. The trial court then granted the motion for summary disposition and excluded Dr. Rein’s testimony. This appeal to the Michigan court of appeals was taken.

ISSUES:

Should Dr. Rein’s expert testimony have been excluded because it was unreliable? Was Dr. Bowerman acting as MMCM’s apparent agent for the purposes of vicarious liability?

ANALYSIS:

An appellate court will only overturn a trial court’s decision to admit or exclude testimony if the trial court abused its discretion in doing so. The test for the reliability of expert testimony in Michigan is:

(a) Whether the opinion and its basis have been subjected to scientific testing and replication.
(b) Whether the opinion and its basis have been subjected to peer review publication.
(c) The existence and maintenance of generally accepted standards governing the application and interpretation of a methodology or technique and whether the opinion and its basis are consistent with those standards.
(d) The known or potential error rate of the opinion and its basis.
(e) The degree to which the opinion and its basis are generally accepted within the relevant expert community. As used in this subdivision, “relevant expert community” means individuals who are knowledgeable in the field of study and are gainfully employed applying that knowledge on the free market.
The court of appeals noted that the scientific evidence put forth to support Dr. Rein’s opinion did not, in fact, support his position. Rather, it supported Dr. Bowerman’s position. It also noted that the materials on which he relied had not been subjected to scientific testing and replication (Dr. Rein’s positions were based primarily on his experience). Additionally, Dr. Rein based some of his opinions on misinterpretations of the medical record. The court of appeals found that Dr. Rein’s testimony was unreliable and affirmed the judgment of the trial court.

The court then turned to the issue of MMCM’s vicarious liability for the actions of Dr. Bowerman. The Michigan Supreme Court first recognized that hospitals can be liable for the actions of their independent medical staff members in *Grewe v. Mt. Clemens General Hospital*, 273 NW 2d 429, 404 Mich. 240 (Mich. 1978). In *Grewe*, the court held that the hospital could be liable if the patient looked to the hospital to provide care, as opposed to physicians with whom the patient already had a relationship. The test at the present time is: “(1) the person dealing with the agent must do so with belief in the agent’s authority and this belief must be a reasonable one, (2) the belief must be generated by some act or neglect on the part of the principal sought to be charged, and (3) the person relying on the agent’s authority must not be guilty of negligence.”

The court of appeals noted several factors in deciding that Dr. Bowerman was not MMCM’s ostensible agent. First, Ms. Wendt signed a consent form on admission that specified that some of the doctors who would care for her were not employees or agents of the hospital. Second, she testified that, at the time of the surgery, she did not know who Dr. Bowerman was, so she could not have reasonably relied on Dr. Bowerman’s authority to act on behalf of MMCM. Third, and most importantly, MMCM did not do anything to hold Dr. Bowerman out as its agent. Accordingly, the court affirmed summary disposition for the hospital on this count.

**RISK MANAGEMENT CONSIDERATIONS:**

The issue of the reliability of expert testimony is a perennial problem. This writer has seen his share of expert witnesses who will testify to whatever the plaintiff (to be fair, and sometimes the defendant) will pay him or her to say. There are also judges who, possibly in the interest of not being reversed or wanting the plaintiff to have her day in court, will allow the testimony. Judges rarely have a scientific background and, even if they do have a scientific background, they should not substitute their opinions for those of the experts. In the interest of professional ethics, parties should refrain from putting forth experts whose testimony is unreliable and refutable.

Risk managers may wish to obtain a copy of the plaintiff’s expert’s deposition to review before trial. Many risk managers have an informal bank of experts with whom they can consult to test the validity of the expert’s positions. Care must be taken, of course, to avoid disseminating adverse information, whether true or fabricated by the expert, about the care provided to the patient.

It is unclear why the court took up the issue of the hospital’s vicarious liability, unless it was merely to ensure that it addressed all of the issues. The affirmance of the motion for summary judgment against Dr. Bowerman caused the issue of vicarious liability to be moot, because there was nothing for which the hospital could be vicariously liable. Nonetheless, intermediate courts of appeal sometimes elect to decide all issues before them on the chance that there may be further appeal.

The court’s decision on MMCM’s vicarious liability shows how many of these cases depend upon the opinions of the judges, rather than strict adherence to precedent. The court held that Ms. Wendt did not look to the hospital for anesthesia care, when she obviously did. If she had not looked to the hospital, she would have come to the hospital with an agreement with her own anesthesiologist to provide care, which no patient does. The court held that the hospital did not do anything to hold Dr. Bowerman out as its agent, when it obviously assigned Dr. Bowerman to the case. The only factor that was correct was that Ms. Wendt did not rely on the appearance of agency because she testified that she did not remember meeting Dr. Bowerman.

This latter fact is also a matter of concern. While it is possible that Ms. Wendt was not paying attention, or that she had postanesthesia amnesia, if Dr. Bowerman did not meet with Ms. Wendt in the preoperative phase, that is a problem. The anesthesiologist should do the preoperative assessment of the patient, which includes talking to the patient about her condition. The anesthesiologist should also obtain the patient’s informed consent for anesthesia, which involves discussing the risks and benefits of, as well as alternatives to, the proposed anesthesia plan. It is improper for the anesthesiologist to simply come into the operating room, push fentanyl, and then administer nerve blocks because that is what she always does for TKAs. If the anesthesiologist has these discussions with the patient, it may preclude future litigation over an adverse outcome. Had Ms. Wendt been informed of the risk of residual
nerve pain after the procedure, and had she consented to the anesthesia approach that was contemplated, this lawsuit might never have happened.


**MEDICAL MARIJUANA**

**The employment of a medical marijuana user in Michigan is not protected**

**FACTS:**

Angela Eplee interviewed for a position with the Lansing Board of Water and Light (BWL), a department of the city of Lansing. At the conclusion of the interview, she was given a conditional offer of employment. This offer was conditioned on the passage of a urine drug screen. She immediately told the interviewer that she was a registered user of medical marijuana and produced documentation to that effect. Nonetheless, when the results of the drug screen showed tetrahydrocannabinol (THC) in her urine, the offer of employment was withdrawn.

Ms. Eplee sued for violation of the Michigan Medical Marijuana Act (MMMA), Mich. Comp. Laws § 333.26421, and for breach of contract in the withdrawal of the offer of employment. The trial court held a hearing on the BWL’s motion for summary disposition and dismissed the action. Ms. Eplee appealed that decision to the Michigan Court of Appeals.

**ISSUES:**

Did BWL violate the MMMA when it rescinded its offer of employment due to Ms. Eplee’s use of medical marijuana? Did BWL breach its contract with Ms. Eplee when it rescinded its conditional offer of employment due to Ms. Eplee’s use of medical marijuana?

**ANALYSIS:**

As a starting point, the court noted that the relevant portion of the MMMA reads as follows:

A qualifying patient who has been issued and possesses a registry identification card is not subject to arrest, prosecution, or penalty in any manner, or denied any right or privilege, including, but not limited to, civil penalty or disciplinary action by a business or occupational or professional licensing board or bureau, for the medical use of marijuana in accordance with this act …


The court noted a number of factors in the MMMA. These include that it does not provide for a private cause of action for its violation; that it is an immunity statute that provides immunity from arrest, prosecution or penalty; and that it protects from the denial of any right or privilege. The court held that Ms. Eplee could not show that she had a private cause of action. She was not arrested, prosecuted, or penalized. Finally, she could not show that she had a right or privilege to at-will employment by the BWL. Accordingly, the court found that she had no right to bring an action under the MMMA.

The court also noted that one does not have a contractual right to employment in Michigan absent an express or implied contract, or a promise of continued employment that can be terminated only for just cause. The court noted that Ms. Eplee was unable to demonstrate that the conditional offer of employment was for anything other than at-will employment, which could be terminated at any time for no reason, so there was no contract to be breached.

Consequently, the court of appeals affirmed the grant of summary disposition for the defendants.

**RISK MANAGEMENT CONSIDERATIONS:**

This decision adds to the confusion that surrounds the jurisprudence of medical marijuana use, and particularly the use of medical marijuana in Michigan. In essence, this decision gives people in Michigan a choice: refrain from using medical marijuana, which may alleviate the symptoms of their condition, and be employed; or use medical marijuana as their doctor has recommended and be unemployable (unless they can find a job that does not require a drug screen). This decision states succinctly that it is legal for employers in Michigan to discriminate against someone for using medical marijuana. If that is the case, why did the state legalize it?

One of the interesting points in this decision is the court’s complete willingness to overlook one part of the statute: “including, but not limited to, civil penalty or disciplinary action by a business.” The revocation of a conditional offer of employment can be considered a “disciplinary action.”

This column recently reviewed the case of *Wild v. Carriage Funeral Holdings, Inc.*, No. A-3072-1713 (N.J. Super. Ct., App. Div. March 27, 2019), in which the Court of Appeals of New Jersey, in a factually similar case, held that it makes no sense to legalize medical marijuana if a qualified registered user can be discriminated against for using it. The relevant statute in New Jersey had no protections built into it, so the court created them. What good is a right if one is penalized for exercising it?

The problem is complicated. Marijuana, whether medical or recreational, is illegal at the federal level, but the federal
government is precluded from spending money to prosecute people in the medical marijuana industry or users, as long as they are complying with state law. United States v. McIntosh, 833 F.3d 1163 (Ninth Cir. 2016). Both medical and recreational use is legal in a handful of states. The majority of states have legalized the use of medical marijuana. Still more have legalized the use of cannabidiol products.


**NEGLIGENT INFILCTION OF EMOTIONAL DISTRESS**

Mother in waiting area when daughter died may have cause of action in Alaska

**FACTS:**

Nixola Jean Doan accompanied her adult daughter, Tristana, to the ED at Fairbanks Memorial Hospital in March 2011, because Tristana was coughing and having difficulty breathing, but the decision does not list any medical diagnoses made during the visit. (One of the defendants, however, was the Interior AIDS Association/Project Special Delivery.) Ms. Doan stayed at the hospital with Tristana until her condition worsened at approximately 7:00 p.m. Ms. Doan was asked to leave the room at that time and Tristana was intubated. Ms. Doan did not see her daughter again until approximately 11:41 p.m., which was shortly after she died.

Ms. Doan brought suit on behalf of Tristana’s estate for medical malpractice and wrongful death. She also brought suit on her own behalf for negligent infliction of emotional distress (NIED). The defendants filed a motion for summary judgment on the NIED claim on the grounds that Ms. Doan did not have “a contemporaneous understanding of the cause of Tristana’s death” (emphasis in original). The motion on the NIED claim was granted by the trial court. Ms. Doan took this appeal on that issue to the Supreme Court of Alaska.

**ISSUE:**

Is it necessary, in Alaska, for a plaintiff to demonstrate that she had a contemporaneous understanding that the event giving rise to her emotional distress was caused by someone’s negligence?

**ANALYSIS:**

The court undertook a thorough analysis of the tort of NIED starting with the seminal case of *Dillon v. Legg*, 68 Cal. 2d 728, 69 Cal. Rptr. 72, 441 P.2d 912 (Cal. 1968) handed down by the Supreme Court of California. The test in that case was: “(1) Whether plaintiff was located near the scene of the accident as contrasted with one who was a distance away from it; (2) Whether the shock resulted from a direct emotional impact upon plaintiff from the sensory and contemporaneous observance of the accident, as contrasted with learning of the accident from others after its occurrence; and (3) Whether plaintiff and the victim were closely related, as contrasted with an absence of any relationship or the presence of only a distant relationship.” The Alaska Supreme Court modified this test when it declined, however, to interpret Dillon as imposing a “rigid requirement of sensory and contemporaneous observance of the accident,” instead requiring only “the reasonable foreseeability that the plaintiff-witness would suffer emotional harm.” *Kavorkian v. Tommy’s Elbow Room, Inc.*, 727 P.2d 1038 (Alaska 1986).

The court noted that a requirement that the plaintiff who suffered the emotional distress recognize that the conduct giving rise to the distress was negligent would impose too heavy a burden on the plaintiff. For example, a plaintiff who was a physician might recognize that the conduct was tortious, but a layperson might not. The court focused, instead, on the immediacy of the recognition that an injury had occurred. It noted that a plaintiff who is some distance away when she heard of the event may have time to “steel” herself against the distress that witnessing the event might cause, whereas someone nearby would not have that luxury. The test boiled down to the foreseeability of the distress.

The court held that Ms. Doan was proximate to her daughter’s location and whether she suffered distress at seeing her daughter’s body was an issue for the jury to decide. The Supreme Court reversed the grant of summary judgment and sent the case back for further consideration.

**RISK MANAGEMENT CONSIDERATIONS:**

The Supreme Court of Alaska has taken an expansive view of the tort of NIED, but it has not opened the floodgates of litigation in this area. When the court held that the plaintiff need not recognize that the conduct was negligent at the time of the event, it may have clouded the issue of what conduct can give rise to a claim for NIED. This case does not stand for the proposition that any family member, upon viewing the remains of a recently deceased family member, will have an independent claim for NIED. The underlying conduct that caused the death must have been negligent. This court has simply held that the plaintiff did not need to recognize that the conduct was negligent at the time it occurred. In this context, a claim for NIED in Alaska may simply be an add-on to a claim for medical malpractice or wrongful death, much the same
way that a claim for loss of consortium may be brought in one of these cases.

The foregoing may be scant consolation to a hospital or provider faced with an NIED claim filed by a truly distraught plaintiff. It gives the jury an additional mechanism to reach into the pockets of the defendant(s). There may, unfortunately, be little that a provider can do to fend off such a claim.

One approach is the tried-and-true formula of talking to the family. The family should be apprised of the patient’s condition in a frank and forthright manner. The family should not be left in the waiting area wondering when they can go back and talk to their loved one, only to be suddenly told that their loved one has died. Counseling needs to be immediately available. As the court in this case noted, if the family members have time to “steel” themselves against the awful eventuality, the shock may not be as pronounced. The facility and the providers should adopt an attitude of “no surprises” to the maximum extent possible.


**ABOUT THE AUTHOR**

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