Communication Is Key

In the practice of pediatric medicine, physicians care for arguably the most innocent and vulnerable subset of our population, children. When a child suffers an adverse outcome while under the care of a physician and other caregivers, it has a profound effect on the family, the medical providers, and, often, the entire local community. This edition of Closed Claim Review is about a young child who was a healthy, vibrant toddler thought to be suffering from a common childhood ailment. The outcome, however, can be described as nothing less than tragic.

Jessie Givens[1] was an 18-month-old female, who presented with her grandmother to her usual pediatric group. She was seen on that day by Nurse Practitioner, Susan Owens. Jessie had vomited twice earlier in the day but had a normal appetite, normal fluid intake, and no fever. She was negative for abdominal pain, did not have a sore throat, and was voiding regularly. Some coughing had been noted for about a day but no gagging or difficulty swallowing. At that time, labs were drawn. Ms. Owens diagnosed Jessie with acute gastroenteritis and sent her home.

The next day, during a follow-up call from the practice, Jessie's grandmother stated that Jessie did not have a fever and had experienced less gagging, was happy and playful, still voiding regularly, was drinking liquids, and was able to eat crackers and toast.

On day three, the pediatric group called to report that the labs previously taken were all normal. Later that evening, the grandmother called the after-hours line to report that Jessie had vomited again. She stated that after Jessie vomited, then started playing like nothing was wrong.

The next day (day four), the mother called the practice and reported that Jessie had vomited again. A prescription for Zantac was written at that time. As of day five, it was reported that Jessie had not vomited, and her diet was improving.

Two days passed, and the grandmother called the pediatric group expressing concern that Jessie's condition had taken a turn for the worse. At this point, Jessie had been ill for seven days. During this call, the grandmother stated that Jessie woke in the morning with stomach pain. She conveyed during the call that when she tries to eat, "food gets stuck in her throat and she tries to spit it out." She was instructed to take Jessie to the hospital.

It is noteworthy at this point, that throughout the course of treatment, different family members either presented with Jessie or made calls on her behalf to the pediatric practice. Similarly, differing staff members at the practice had taken calls from the family regarding these issues, which ultimately effected the consistency of communications.

Jessie and her mother presented to the local emergency department later that day. She was seen by Dr. Martha Whitaker. The history & physical noted that Jessie was spitting food out of her mouth but was occasionally drinking liquids. Jessie presented with a mild fever. She was examined, including her neck, throat, and abdomen. The emergency department's records from this encounter noted that Jessie had been vomiting intermittently for several days, but the report from her mother was that the vomiting at times was more like "spitting-up." There was no mention of choking or gagging, but Dr. Whitaker was told that Jessie was not tolerating solid foods.

Dr. Whitaker examined Jessie, noting that the child was not in distress, and her breathing was normal. She ordered another round of labs. During this encounter, Dr. Whitaker took the unusual step of calling the pediatric practice where Jessie was seen during the prior week. Her reason for making this call was to be certain that she knew Jessie's entire history. During her call to the practice, she was informed by a nurse of Jessie's general condition. The nurse, however, did not read the call slip where the practice was told by the grandmother that "food gets stuck in her throat, and she tries to spit it out." Jessie's mother also did not communicate this vital information to Dr. Whitaker or anyone else during this ED encounter. Based on the child's symptoms, Dr. Whitaker diagnosed Jessie with viral syndrome and GERD, prescribing acetaminophen for the fever. Instructions were given to watch the child closely for any continued vomiting, blood, or inability to keep down fluids. Dr. Whitaker directed the family member to follow-up at the pediatric practice the next day and indicated that a consult by a gastroenterologist may be necessary. Jessie was then

discharged home.

Early the next morning, Jessie was found unresponsive in her crib. She was rushed to the local emergency department, but it was too late. Jessie had passed away. An autopsy revealed that a coin was found lodged in Jessie's esophagus.

A lawsuit was filed by Jessie's parents alleging the wrongful death of their child. Dr. Whitaker and Susan Owens, N.P. were named as individual defendants in the suit. The pediatric practice and the hospital where Jessie was seen in the emergency department were named as defendants based on the theory of vicarious liability for the individually-named defendants. The primary allegations against each defendant were failure to properly assess and examine the patient, failure to obtain an adequate history from the family due to the child's inability to communicate, and failure to order an x-ray. Because this was a wrongful death claim, the applicable statute provided certain damages measured by the injuries to the decedent but also allowed for an award of damages for injuries to the beneficiaries as well. The amount of damages that a jury could potentially award in this case was a concern given the facts and the child's age.

The plaintiff's expert opined that the symptoms with which the child presented were typical of a history of foreign body in the esophagus, which an x-ray would have detected. Consequently, in the expert's opinion, Susan Owens, N.P. and Dr. Whitaker deviated from the standard of care by not ordering an x-ray.

The defense theme was that the child did not present with symptoms that would warrant an x-ray. Counsel for the defendants produced several experts to support this theme.

Was an x-ray warranted given the child's symptoms? An x-ray is an accepted means to detect the presence of a radiopaque object like a coin.[2] Coins are the most common object swallowed by children in the United States.[3] An estimated forty percent of foreign body ingestions in children are not witnessed, which was the case here.[4] But, Jessie's symptoms were relayed by differing family members, at different times and places, sometimes in person and sometimes over the phone. This information was received and charted by various healthcare providers at the pediatric practice's office and then at the hospital's emergency department.

A pediatric surgeon opined specifically pertaining to the disease process. This expert opined that the cause of death was due to mediastinitis caused by the coin, as opposed to death from a foreign body. This is an important distinction because this particular disease process was known to rapidly progress. The surgeon pointed out that the patient's white blood count while at the emergency department was normal, which indicated that the disease process had not yet started. This expert believed that what the family described to Susan Owens, N.P. was more in line with a description of a viral ailment and not a foreign body obstruction.

Another pediatrician was offered as a defense expert. This expert also was of the opinion that based on the symptoms conveyed by the family, there was nothing suggestive of the

presence of a foreign body. Further, it would be irresponsible to x-ray every child that presented with the symptoms described by the family. Given the circumstances, the standard of care did not require an x-ray.

Yet another pediatric expert disputed the plaintiff's expert's conclusion that an x-ray was warranted. This expert performed a "blind review" without the benefit of knowing the outcome of the case and reported that a foreign body obstruction was never a consideration.

Applying hindsight, it may seem to some that a foreign body was evident. The medical experts retained by each side could not agree on whether the child's symptoms indicated the presence of a foreign body. A major issue in this case was that the number of people involved in the communication process proved to be a complicating factor.

What can be learned from this tragedy? As a reminder, some symptoms of a foreign body obstruction are refusing to eat, vomiting, gagging, choking, neck or throat pain, and drooling.[5] With very young children who are unable to effectively communicate, clear and consistent communication between a patient's healthcare team and the family is imperative to properly diagnose and treat a child's illness. If presented with a similar scenario, where multiple people have called multiple times on behalf of a patient, the provider should consider asking the caregiver to bring the patient back in to obtain an accurate clinical picture. This could potentially reconcile any prior inconsistent communications between the caregivers and the provider. Foreign body obstructions are extremely difficult to diagnose without clear information from the family or an obvious symptom. Past retrospective studies have indicated that most children with confirmed foreign body ingestions were asymptomatic.[6] Be certain all encounters are charted in the same place, so that these notes can easily be located for future reference during treatment. Lastly, do not hesitate to make follow-up inquiries by phone or otherwise with the child's parent or primary caregiver to be certain that a thorough history is obtained.

Given the nature of this case, all parties agreed to mediate the matter. Ultimately, it settled without the necessity of trial.

1 Names and identifying details have been changed for confidentiality.

2 Tintinalli, J. Swallowed Foreign Bodies. Tintinalli's Emergency Medicine – A Comprehensive Study Guide. 7th Ed. 2011; p. 552.

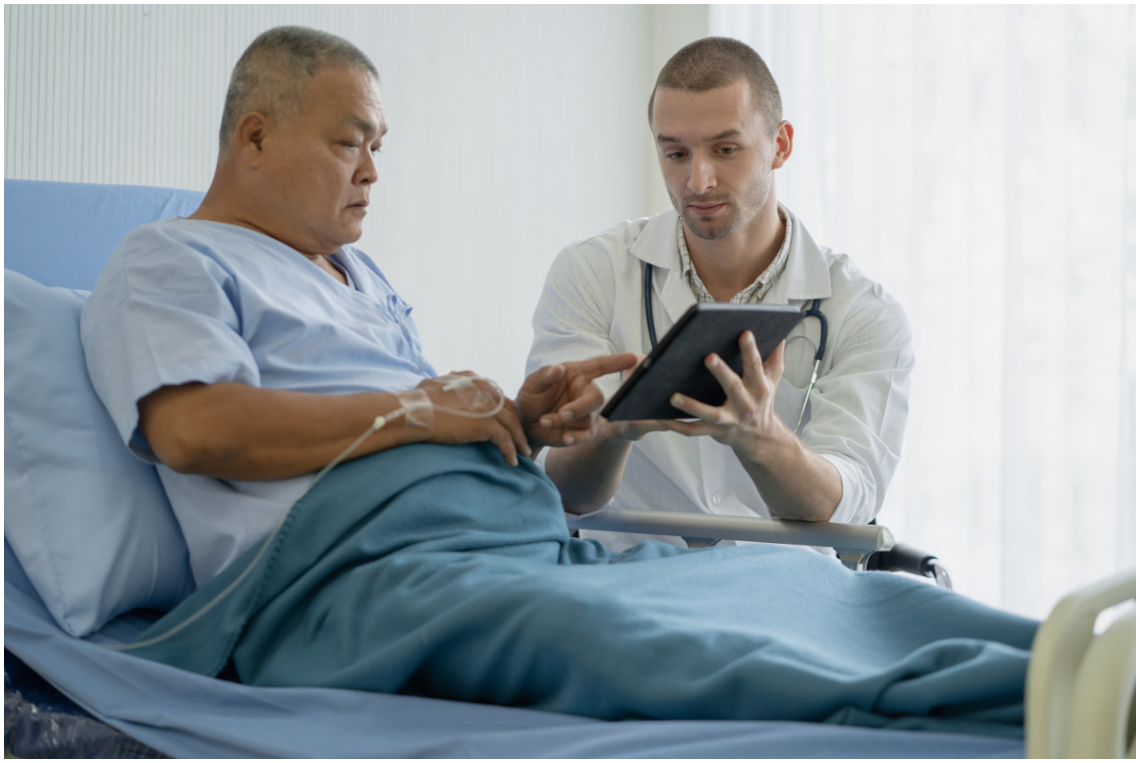
3 Uyemura, M.D., M., Foreign Body Ingestion in Children. American Family Physician. 2005, July 15, 72(2); 290.

4 *Id.* at 287.

5 Tintinalli, J. Swallowed Foreign Bodies. Tintinalli's Emergency Medicine – A Comprehensive Study Guide. 7th Ed. 2011; p. 552.

6 Id. at 287.

Informed Consent: Best Practices



This article is the second in a series of two; the first appeared last month and can be accessed here. In the previous article, we discussed important concepts of the informed consent process, including the need to document the discussion.

What are best practices when documenting consent? Documentation of the informed consent process should occur contemporaneously with the discussion and prior to the performance of a procedure. The practice of documenting the consent process **after** the fact (e.g. in an operative note) could be viewed as self-serving if there is an adverse event.

The most thorough informed consent process may be negated if there is no contemporaneous documentation to evidence that such a process took place. Poor or absent documentation forces a physician to testify from memory about an event which probably occurred several years earlier and negatively impacts his/her credibility as a result. Furthermore, poor or absent documentation may be a significant factor in the decision of a patient's attorney to pursue legal action in the first place. On the flip side, a well-documented and thorough informed consent may be the deciding factor for a plaintiff's attorney not to pursue litigation at all.

Ideally, the informed consent discussion should be documented in both the patient's chart and in a separate consent form that is signed by the patient/representative. (If this discussion takes place in the office setting, it should be included within the office record.) Avoid generic forms. As an example – a hospital's boilerplate consent form typically does not include the risks unique to the patient and may not accurately reflect your discussion with the patient. In many cases we reviewed, the only documentation associated with the consent process was a boilerplate hospital surgical consent form, which did not reflect the details of the discussion during which surgeons outlined the risks. This made it difficult for the defense to argue that the particular surgical complication had been explained to, and was understood by, the patient prior to the procedure. Remember, it is the *discussion* that takes place between the physician and the patient (or patient's legal representative) that constitutes the basis for the consent to be informed. The consent form that is signed by the patient or representative is merely evidence memorializing that the discussion took place and the patient/representative understood the information discussed.

Some specialists do not always have the benefit of access to the patient's entire chart to document the informed consent discussion for their respective care, but, for example, in anesthesia, the content discussion should be documented in the pre-anesthesia record.

Since lack of informed consent is often an allegation in a malpractice lawsuit, let's review the specific documentation requirements of informed consent.

In order to ensure that the patient has been given sufficient information with which to make an informed decision as to the course of his/her medical treatment, the following should generally be discussed and documented in the medical record:

- Details of the nature of the patient's illness and diagnosis
- Indications for the proposed treatment plan, procedure, or medication, as well as the anticipated prognosis
- A description of the proposed treatment or procedure, including medication that will be prescribed, and its purpose
- The probable outcome, particularly if it is difficult to predict, and the patient's expected post-procedure/treatment course
- Potential modifications or extensions of the treatment or procedure
- The possible benefits of having the procedure
- The most likely and severe risks and side effects of the procedure and treatment or medication, preceded by a general inclusive statement, such as "including but not limited to"
- A statement about unexpected complications/additional medical procedures
- Reasonable alternative methods of treatment or no treatment, including the risks, benefits, and the prognosis associated with each alternative or with no treatment
- Notification of experimental or investigational procedures

For additional specifics to include, SVMIC policyholders and staff with a Vantage account may refer the following document: Sample Informed Consent Form.

Regardless of whether the office uses a paper-based medical record or an electronic health record (EHR), the informed consent process should be documented either through a consent form or through a detailed note in the medical record. Both forms of documentation should reflect all of the pertinent information given to the patient, specify what supplemental information was given, and indicate that the patient was given the opportunity to ask questions and have them answered. The name of a witness (if any) to the consent process should also be recorded on the consent form or in the medical record, and written documentation should be made as soon as possible after verbal consent is given. It is a good idea to have a place on the consent form for the patient to sign, preceded by a statement that he/she understands the information given, has been given the opportunity to ask questions and has had all questions answered, and consents to the medical intervention. Documentation of the consent process in the medical record should be noted by the practitioner as well. In an electronic system, this may require that the forms be printed and then scanned after signing, or that the system allow for an electronic authentication process to be employed by the patient.

Avoid the use of summary statements such as “The patient was advised of the potential risks/complications of the operation and alternatives.” Instead, note at least some of the actual risks, complications, and alternatives discussed with the patient. For example, a better entry would state that “information regarding the risks, complications and alternatives was discussed with the patient and/or family, including but not limited to…”, followed by the specific information discussed and any questions asked by the patient.

While the most serious risks for a procedure may be rare, it’s important to include those in your discussion and documentation as well. Juries may factor in the patient’s willingness to undergo surgery, which could potentially result in infection, bleeding, injuries to adjacent organs, and death when weighing the patient’s allegation that they would not have undergone a procedure if they had known about the complication of something more minor.

If using an EHR, the use of automated reminders or prompts might be employed so that when a procedure is scheduled, the practitioner is alerted to complete an informed consent discussion and the appropriate resources are made available for printing at that time. In addition, the prompt could include electronic links to the educational material that may be given to the patient as well as the appropriate consent form. Some EHRs may also include a pre-programmed default, which would document that the material was given to the patient, that a full discussion of the potential risks, benefits, and alternatives of the proposed medications or treatment took place, and that the patient gave full consent. However, if this default language does not include the details of the conversation, such as the specific risks and benefits that were discussed, the physician may need to add this information to the documentation.

Informed Refusal

The concept of informed refusal is the flip side of informed consent. Informed refusal acknowledges that every competent patient has the right to refuse a recommended test, procedure or treatment but requires the physician or healthcare provider to inform the

patient of the risks of that refusal.

While most people are more familiar with the concept of informed consent, informed refusal is not an unusual allegation in medical malpractice litigation. In order to successfully defend against an allegation of informed refusal, there should be documented evidence that the patient was provided sufficient information regarding the risks of forgoing treatment. Both informed consent and informed refusal are predicated upon the notion that a patient is entitled to all information necessary to make an informed choice. Patients benefit from these discussions by becoming more knowledgeable about the recommended treatment and more vested in his or her own healthcare. Physicians benefit because informed patients tend to have more realistic expectations and are less likely to sue for malpractice even when faced with a less than optimal outcome.

If a provider encounters a competent patient who refuses recommended testing or treatment, rather than simply noting the patient's refusal, try the following steps:

- Ask about the reasons for refusal
- If it appears the refusal is due to a lack of understanding, re-explain the rationale for the procedure or treatment in lay terms, emphasizing the probable consequences of refusal.
- Document the patient's refusal and reasons for such; emphasize that the patient understood the risks of refusing the recommended care
- Try also to obtain the patient's signature on an "informed refusal" form (SVMIC policyholders and staff with a Vantage account may download a sample of a general informed refusal form here: **Sample Informed Refusal Form**). By using a refusal form, the patient may better appreciate the potentially serious consequences of his or her decision. If the patient refuses to sign the form, the documentation in the record regarding any discussion(s) with the patient, his or her reasons for refusing the care and his or her refusal to sign the form will suffice.
- If the patient was referred to the physician as a consult, the physician must be sure to document the previously-listed information in a letter to the referring physician

Thorough documentation of the informed consent/informed refusal discussion may very well prove to be the defining factor of a successful defense. Certainly, anytime there is an invasive procedure, anesthesia/sedation, treatment, testing, medication or injection that presents a risk of bleeding, infection, burns, fainting, severe adverse reaction, damage to adjacent structures/tissue, blindness, paralysis, loss of organ or death, informed consent should be obtained and documented. This is best done by providing the appropriate information for the patient or representative to make an informed decision, thoroughly documenting that discussion in the chart and, if possible, having a procedure-specific written consent form signed.

Primary Care First: Applications Now Being Accepted

Primary care physicians in Arkansas, Tennessee, Virginia, and 23 other states are invited to apply for Primary Care First, the latest payment model by the Centers for Medicare & Medicaid Services (CMS). Applications are accepted from practices that meet certain basic criteria, like having an electronic health record. Not only are the conditions standard, but the patient count need only be a minimum of 125 Medicare beneficiaries. Patients can voluntarily select you in MyMedicare.gov; in addition, CMS uses claims-based data to determine beneficiary attribution. The program is open to physicians in internal medicine, general medicine, geriatric medicine, family medicine, and/or hospice and palliative medicine.

The payment is provided on a “per patient-per month” (PMPM) basis, in addition to a flat primary care visit fee of $50. The PMPM payments fall into five tiers based on acuity, ranging from $24 to $175 per month. These fees are *in addition* to the visit fee, although it is notable that CMS is placing a small portion – 10% - of the payment at risk. For the first

year, the adjustment is made based on hospital utilization. Thereafter, there are five "Quality Gateway" measures for comparison; these include a standard patient experience survey, A1c, controlling high blood pressure, advance care plan, and colorectal cancer screening. Although 10% is at risk, there is a 50% *upward* "continuous improvement" adjustment should performance be favorable. Dubbed the "Seriously Ill Population," there is special consideration for Medicare beneficiaries in hospice and palliative care, with $275 allocated for the monthly payment, in addition to an initial fee of $325.

The application process, which opened on October 24, closes on January 22, 2020. The application may be found here.

Physician Fee Schedule Final Rule

What's Ahead for 2020?

On November 1, the Centers for Medicare & Medicaid Services (CMS) released the highly anticipated Final Rule for the 2020 Physician Fee Schedule (PFS). Although the PFS is specific to Medicare reimbursement, CMS' dictums have significant influence over all insurers. Perhaps the most significant changes – those made to evaluation and management (E/M) codes – will wait until next year, as the implementation date is January 1, 2021. However, the 2,475-page rule will certainly impact the coming year. The following highlights the impacts.

> Slight boosts in the unit valuation of services typically performed by clinical social workers, podiatry, urology, and obstetrics/gynecology, thus increasing the overall reimbursement for those specialties. Ophthalmology and optometry, as well as vascular surgery and neurology, got hit with small decreases due to the re-valuing of the units associated with commonly used codes. Most specialties are projected to experience no change in the coming year.

A new Principal Care Management (PCM) code that mirrors the current Chronic Care Management (CCM) coding and reimbursement scheme, albeit requiring only a single serious, high-risk illness to use. CMS is reporting that the agency expects this code will be used by medical specialists "who are focused on managing patients with a single complex chronic condition requiring substantial care management." "We anticipate," reveals CMS, "that …PCM services will be billed when a single condition is of such complexity that it cannot be managed as effectively in the primary care setting, and instead requires management by another, more specialized, practitioner."

CCM codes will get a boost in payment, to include a new add-on code for additional time spent beyond the 20-minute monthly minimum requirement. Further, the definition of a care plan in the Complex CCM code set was relaxed: the plan can be "established, implemented, revised, or monitored."

Increased reimbursement for Transitional Care Management (TCM) codes 99495 and 99496, used for the services provided on a patient following a discharge.

Provision for a single, annual patient consent for communication technology-based services (CTBS) and inter-professional consultations.

Coverage for a multitude of opioid treatment services – to include those provided via telehealth.

Confirmation regarding the supervision requirements for physician assistants, which are being relaxed but only in the absence of state law. If state law does not otherwise dictate the requirements of supervision, CMS advises "documentation at the practice which demonstrates the working relationship that PAs have with physicians in furnishing their professional services." State-based requirements will continue to trump these new, more lenient rules if such exist.

The Quality Payment Program, which requires participation from approximately half of the country's physicians and advanced practice providers, imposes a penalty for non-compliance. The program, commonly referred to as the name of one its participation pathways – the Merit-based Incentive Payment (MIPS) System – will experience little change in the coming year. The cost category, one of four in MIPS, was supposed to rise to 20% of the weight but will remain at 15% with quality at 45%; CMS increased the exceptional performance threshold to 85 points, up from the proposed 80; and finalized new episode-based measures in the cost performance category. CMS further expressed its intention to move to MIPS Value Pathways, although the agency is still working on the details.

Last, but certainly not least, CMS backed off from its proposal to collapse payment for E/M levels two through four. Instead, the agency opted to adopt the American Medical Association's (AMA) new guidance for E/M coding. There will no longer be a level one, new patient code (99201), although it was rarely, if ever, used. The more significant change is the fact that the performance of a history and/or exam is required only as

medically appropriate and need not be incorporated as it relates to the choice of the code level. Per the AMA, “the code descriptors…state providers should perform a ‘medically appropriate history and/or examination.’” Furthermore, providers can choose the E/M level based on either medical decision making or time. It is vital for all providers to become familiar with the AMA’s changes as these will impact the E/M codes, which are relevant to all patients, not just Medicare beneficiaries.

In addition to these changes to the codes, office/outpatient E/M codes will get a significant boost in payment due to a revision to the relative value units that provide the foundation for payment. CMS has introduced payment for a new “prolonged services” CPT code 99XXX, for each 15 additional minutes above and beyond the highest-level E/M codes. (This new code will replace 99358-99359.) Primary care and medical specialists will get an additional payment bump by using a new, Medicare-only add-on code – GPC1X - to describe the work associated with ongoing care, although the (positive) reverberations of these alterations will have to wait for another year.

The E/M changes are being executed in 2021, but CMS proceeds in clarifying its modified documentation policy so that physicians and advanced practice providers can simply “review and verify (sign and date), rather than re-documenting, notes made in the medical record by other physicians, residents, medical, physician assistant and APRN students, nurses or other members of the clinical team.”

Those highlights pale in comparison to the paltry nickel increase to the overall payment rate – after accounting for these changes and the required budget neutrality, CMS announced the payment conversion factor to be $36.09, just pennies over the current $36.04.

The quotes are extracted from CMS’ Final Rule, which is on display at this link: https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-24086.pdf.
