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Expert Report Grace Schara Case

My name is Gilbert G. Berdine, MD. My undergraduate education was at the Massachusetts Institute of Technology (MIT) from 1971-1974. I graduated from MIT in 1974 with a B.S. degree in Chemistry and a second B.S. degree in Life Sciences. My medical school education was at the Harvard University School of Medicine from 1974-1978. I graduated from Harvard in 1978 with an M.D. degree. My post graduate training in Internal Medicine and in Pulmonary Diseases was at the Peter Bent Brigham Hospital in Boston, Massachusetts (now called Brigham and Women's Hospital) from 1978-1983. I completed post graduate training in Internal Medicine and in Pulmonary Diseases in 1983. I am Board certified by the American Board of Internal Medicine in both Internal Medicine and in Pulmonary Diseases. My Pulmonary Diseases board certification predates the existence of Critical Care as a subspecialty and the existence of Sleep Medicine as a subspecialty, so I have grandfather certification in Critical Care and in Sleep Medicine. I was a member of the faculty at the University of Texas Health Science Center in San Antonio from 1983-1989. I was in private practice of Pulmonary Diseases, Critical Care, and Sleep Medicine from 1989-2009. I joined the faculty at the Texas Tech University Health Sciences Center (TTUHSC) in Lubbock, Texas in 2009 and have been a member of the faculty at TTUHSC since 2009.

My duties at TTUHSC have included care of inpatients at University Medical Center on the General Medicine service and on the Pulmonary Consult Service. I have cared for many patients with Acute Respiratory Distress Syndrome (ARDS) including many patients who developed ARDS from COVID-19. My duties at TTUHSC also include care of outpatients in Pulmonary Specialty Clinic. I have many patients in my outpatient practice who have survived hospitalization due to ARDS from COVID-19. My duties have included the supervision of post graduate trainees on the General Medicine inpatient service, the Pulmonary Consult Service and in Pulmonary Fellow Clinic. My duties include the regular interpretation of all forms of chest imaging including chest radiographs, CT scans of the chest, MRI images of the chest, and PET scans of the chest. I have cared for many patients who have required all forms of respiratory support including supplemental oxygen, continuous positive airway pressure (CPAP), bi-level positive airway pressure (BiPAP), average volume assured pressure support (AVAPS), and all forms of invasive mechanical ventilator support. I have cared for many patients requiring respiratory support who were cognitively impaired including many patients with Down's Syndrome. I teach medical students each year in respiratory physiology and respiratory pathophysiology and am very familiar with the entire spectrum of respiratory physiology and respiratory pathophysiology. My teaching includes lectures and interactive sessions on the causes of hypoxemia and how to distinguish between these causes. My duties at TTUHSC include the teaching of medical ethics to medical students and post graduate residents in training. I have been recognized by the Dean of TTUHSC on multiple occasions for my promotion of medical ethics at TTUHSC. I teach the principles of informed consent to medical students and post graduate residents in training.

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The following portion of the report is based on my review of records relevant to this case. These records include medical records and transcripts of depositions. I have also reviewed Wisconsin Legislature: 448.30. This report is a complete revision of the original report due to new information learned by me from the new material made available to me.

On or about October 1, 2021, the patient was diagnosed with COVID on the basis of an at-home positive PCR test. The patient was 19 years of age. The patient was born with Down Syndrome. The patient was cognitively impaired since birth. The father and the mother were the main caregivers of the patient and medical power of attorney for the patient. Grace had a diagnosis of obstructive sleep apnea (OSA) and was treated at home with CPAP using a mask. At the time of the patient's hospitalization, the father assumed the role of primary decision-maker.

As a result of the positive PCR test, the father made use of a pulse oximeter to monitor the patient's oxygen saturation (SpO2).

It is necessary at this point to make general statements about the medical standard of care regarding informed consent. The medical standard of care requires: the recommended therapy, test, or procedure must be explained in language understandable by the patient or the medical advocate; the benefits of the proposed therapy, test, or procedure must be given with reasonable expectations about the probability of achieving desired goals; the possible harms of the proposed therapy, test, or procedure must be given with reasonable expectations about the probability of occurrence; possible alternatives to the proposed therapy, test, or procedure to achievement of the desired goals must be offered to the patient or medical advocate. All these elements of informed consent must be documented in the medical record.

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Predictive Value of d-dimer in PE

	Negative d-dimer	Positive d-dimer
Low Clinical Prob	High Predictive Value Negative for PE No Further Testing	Low Predictive Value Indeterminate for PE ? Alternative Diagnosis
High Clinical Prob	Low Predictive Value Indeterminate for PE ? Alternative Diagnosis	Low Predictive Value Indeterminate for PE ? Alternative Diagnosis

Figure 1: Predictive Value of d-dimer

On October 6, SpO2 was running between 80-89, which is low, so the father brought the patient to urgent care. The father sought prescription for supplemental O2 at home that would be used in conjunction with Grace's CPAP mask. A d-dimer test was performed. The result was elevated, so the patient was advised by the urgent care staff to go to the emergency room (ER) to exclude pulmonary embolism (PE) via a computed tomography (CT) scan. This recommendation was an error (see Figure 1), but not a breach of the standard of care since the majority of urgent care physicians and ER physicians make the same mistake repeatedly. The d-dimer test has low predictive value in a case of hypoxemia where COVID pneumonia is suspected; however, there is a financial incentive for physicians to order unnecessary CT scans. Due to this policy, at my own institution, approximately 30 CT scans are ordered for every PE discovered when the ratio should be more like 3:1. This error is an example of a class of errors where information that should only be applied to very specific circumstances is extrapolated as a general principle in order to generate more tests and procedures. Although the error deviates from best care practice, the error becomes a standard of care less than best practice when "everybody does it." This class of error is widespread in the healthcare industry. I see examples of it on a regular basis at my own institution. This example of this class of error is important to understand what will happen later in the case. Rather than address the patient complaint, the complaint was deflected to another problem leading to more tests and procedures. It must be noted that had the urgent care providers addressed the patient complaint, prescribed supplemental O2 for Grace, and ensured the prompt delivery of the

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supplemental O2 to Grace's residence, then Grace would more likely than not have recovered from this illness at home without any visit to the Emergency Room (ER) or admission to a hospital.

Although a plain chest radiograph (CXR) would have been sufficient to make the diagnosis of COVID pneumonia, the CT scan led to the same conclusion. The CT report indicated extensive infiltrates with areas of consolidation in both lungs; likely related to pneumonia. The CT images are consistent with this report.

At this point some general comments about the care of patients receiving intensive monitored care are necessary. The ABCDEF bundle has been developed to improve outcomes in patients receiving intensive care.[1] The principles of ABCDEF apply to intensive unit (ICU) care as well as care in monitored patients receiving frequent nursing attention in step down units or emergency rooms (ER). The principles of ABCDEF applied to the care of Grace Schara once she entered the ER. "The ABCDEF bundle includes: Assess, Prevent, and Manage Pain (A), Both Spontaneous Awakening Trials (SAT) and Spontaneous Breathing Trials (SBT) (B), Choice of analgesia and sedation (C), Delirium: Assess, Prevent, and Manage (D), Early mobility and Exercise (E), and Family engagement and empowerment (F)."[1] This bundle has become the medical standard of care. Failure to employ **ALL** elements of the ABCDEF bundle was a breach of the medical standard of care. The subsequent care of Grace would fail to properly employ the (B), (D), and (F) elements of ABCDEF on multiple occasions. Each failure to properly employ elements D and F would be a breach of the medical standard of care.

On October 6, following the CT report, the ER staff recommended admission to the hospital. The ER reports indicate a complaint of shortness of breath. The patient did not complain of shortness of breath. This error of recording as fact statements that were not true would be repeated during this case. This error calls into question the validity of **EVERY** future statement in the medical record about shortness of breath. I cannot determine from the record whether future claims of shortness of breath are true, figments of imagination, delusions, or assumptions. This error was the first demonstration of the inability of the providers to effectively communicate with the patient. Although this particular failure to effectively communicate with and misinterpret communication from Grace was not a breach of the standard of care, the failure to recognize the problem with effective communication and effectively solve the problem by taking advantage of the father as an interpreter was a breach of the medical standard of care. The medical standard of care required the providers to properly employ the Family engagement and empowerment (F) element of the ABCDEF bundle to correct the demonstrated problem with communication between Grace and the providers. This particular failure to properly employ element F of the ABCDEF bundle in the ER was a breach of the medical standard of care by the hospital. Subsequently up until the time of Grace's death, **ALL** the physicians named as defendants in this case would fail to properly use the father or family representative to effectively communicate with Grace and breach the medical standard of care. This failure would be directly responsible for incorrect diagnoses, incorrect recommendations, and incorrect therapy directly leading to the death of Grace on October 13. The medical standard of care required the providers to make the father or family representative an integral member of the health care team, include the father or family representative in **ALL** decision making

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regarding the management of Grace, and carefully consider **ALL** input from the father or family representative about problems with the management of Grace. Subsequently up until the time of Grace's death, **ALL** the physicians named as defendants in the case failed to include the father or family representative in **ALL** decision making regarding the management of Grace thereby breaching the medical standard of care. Subsequently up until the time of Grace's death, **ALL** the physicians named as defendants failed to carefully consider **ALL** input from the father or family representative about problems with the management of Grace thereby breaching the medical standard of care. These failures would be directly responsible for incorrect diagnoses, incorrect recommendations, and incorrect therapies leading to the death of Grace on October 13.

In addition to properly employing the F element of ABCDEF, inclusion of the father or family representative was required by the medical standard of care since the father or family representative was the medical advocate for Grace who was a cognitively impaired patient. During the subsequent events in the hospital up until the time of Grace's death, **ALL** the physicians named as defendants in this case would breach the standard of care by failing to properly obtain informed consent from the father or the family representative for Grace's plan of care. The above mentioned breaches of the medical standard of care would become catastrophic and lead to Grace's death when the father was evicted from the hospital on October 10.

The father was told that he could not be in the room with the patient due to the patient's COVID-19 diagnosis. The father replied that in that case, the patient would be taken home. The hospital decided that the father could stay with the patient as long as he did not leave the room. The father agreed to this condition. The father was never given a written copy of the policy in question. The father was never informed about additional requirements to remain in the hospital. Had the father been informed that he would be evicted from the hospital by a security guard if he developed signs and symptoms of COVID, more likely than not he would not have accepted admission of Grace to the hospital, taken Grace home, found a way to obtain supplemental O2 for Grace, and Grace would have recovered from her illness at home. This failure of proper informed consent to hospital admission was a breach of the medical standard of care, would eventually lead to a catastrophic breach of the medical standard of care when the father was evicted from the hospital on October 10, and would eventually lead to the direct cause of death of Grace on October 13.

While still in the ER, supplemental O2 via nasal cannula, despite the difficulties with the nasal cannula, led to improvement of SpO2 from 88% to 96-98%. The ER note indicates that on 10/06/2021 at 14:16 the SpO2 was "97% on 3 lpm NC." **None** of the physicians named as defendants in this case recognized that the modest O2 supplement of 3 lpm NC, which can easily be delivered by home equipment, was adequate for Grace when she was calm and tended to by her father. The father was seeking supplemental O2. If the hospital had assisted the father in obtaining home O2, like he wanted, more likely than not Grace would have survived the illness at home. Instead, the hospital admitted Grace without proper informed consent. At the time of admission, the father was told, "What they told me in the ER was that we recommend we admit Grace to the hospital for three, four days, we'll put her on

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oxygen and a steroid and she'll be fine." The father was promised more than could be delivered. This promise without mention of reasonable expectations was a breach of the medical standard of care for informed consent. There was no mention that if Grace's condition deteriorated, Grace would be sedated, restrained, and eventually die. There was no mention that if Grace did not comply with the providers' expectations of "calmness" then she would be sedated with a continuous infusion of Precedex for a period of time exceeding the manufacturer's recommendation. There was no mention that if Grace failed to comply with the providers' expectations of "calmness" that sedatives would be escalated to the point of cardiovascular collapse. There was no mention that if an overdosage of Precedex failed to treat agitation, the providers would repeat the overdosage with an even higher dose. There was no mention that if the father developed signs and symptoms of COVID he would be evicted by a security guard without any possibility of appeal. The failure to mention these possible negative outcomes was a breach of the medical standard of care for informed consent. There was no discussion of alternative options. If the providers had offered to obtain home supplemental O2 as required by the medical standard of care for informed consent, more likely than not the father would have accepted the option of home O2 and all of the subsequent tragic events would have been avoided. The failure to discuss alternative therapy was a breach of the medical standard of care for informed consent.

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Normal Distribution

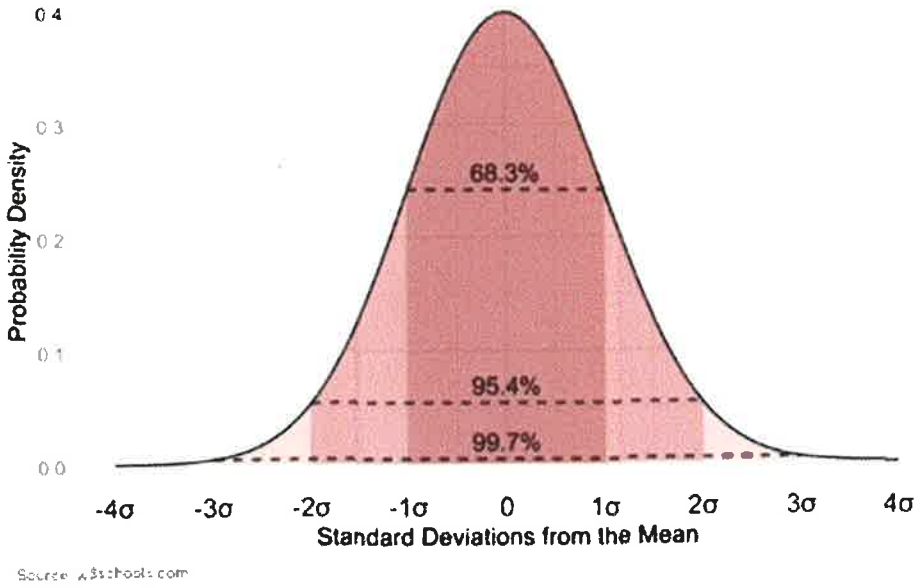

Figure 2: Normal Distribution

A general discussion of the concepts of normal, average, protocol, and outliers is necessary. Figure 2 illustrates the normal distribution. Many attributes, such as height, follow this distribution. The attribute has an average value. The mean, median, and mode averages are all equal for a normally distributed attribute. In Figure 2, the average value has the greatest probability density. Attributes less than or greater than the average have lower probability density than the average. As the deviation from the average value is greater in both directions, the probability density decreases. These are called the left hand tail and right hand tail of the distribution. Individuals outside any arbitrary deviation from average are called outliers. Protocols are designed to be successful at treating the average case. As an individual case deviates further and further from average, the protocol becomes less and less appropriate. **EVERY** protocol will fail at some deviation from average. The medical standard of care requires recognition when a protocol fails in an **INDIVIDUAL** patient. **ALL** the physicians named as defendants in this case failed to recognize when hospital protocols failed in Grace Schara. The medical standard of care requires providers to consider alternative plans when protocols fail in individual patients. **All** the physicians named as defendants in this case failed to consider alternative plans of care in Grace Schara.

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While still in the ER, the medical record indicates that Grace was pulling off her O2. The father indicates that was not true, but rather the O2 supply line to the nasal cannula was falling off of Grace's droopy ears. This is one of many indications where the providers demonstrate their inexperience with dealing with outlier patients like Grace. Although it is noted in multiple locations in the medical record that Grace had obstructive sleep apnea (OSA) and was treated with CPAP at home, **NO** provider ever suggested that the problems Grace had with using hospital O2 equipment might be remedied by using Grace's own mask to deliver O2. This failure was a breach of the medical standard of care. The medical standard of care required that the providers recognize their inability to effectively communicate with Grace. Had the providers asked the father about the experience at home with the CPAP mask, more likely than not the father would have agreed to bring in Grace's own CPAP mask to use with the supplemental O2 system. Had this step been taken, more likely than not, the O2 delivery method would not have required further escalation and Grace would have eventually recovered from the illness using supplemental O2 with her own CPAP mask. The medical standard of care required that the providers enlist the father as an essential member of the health care team and include the father's input to improve Grace's care. This failure to use the father as part of the team would escalate until the catastrophic breach of the medical standard of care on October 10 when the father was evicted from the hospital.

Some time later on October 7, the nasal canula oxygen was transitioned to high flow vapotherm. This higher O2 flow rate was not necessary as the SpO2 was consistently 96-98% with the nasal cannula until the hoses fell off the ears. The simplest solution to the O2 problem would have been to use the patient's own CPAP mask with O2 bled into the mask. This mask was what Grace was used to and comfortable with at home. The failure to recognize the logically correct solution to this problem, rather than blindly following corporate protocol, was a breach of the medical standard of care. It subsequently became apparent that Grace did not tolerate the vapotherm delivery because of the loud noise made by the machine. **NONE** of the physicians named as defendants in the case recognized that the BiPAP was used **ONLY** because Grace did not tolerate other methods of O2 delivery. Nasal cannula O2 was adequate for Grace, but the hoses fell off her droopy ears. The vapotherm O2 was adequate for Grace, but she did not tolerate the noise. Subsequent statements by **ALL** the physicians named as defendants in this case that Grace required BiPAP or mechanical ventilation for adequate oxygenation were incorrect and breaches of the medical standard of care. **NONE** of the physicians named as defendants in this case **EVER** demonstrated that O2 delivery by Grace's own CPAP mask would be inadequate to meet Grace's O2 requirements. **ALL** the physicians named as defendants in this case would breach the medical standard of care by failing to mention the alternatives of supplying O2 with Grace's own CPAP mask.

The next source of friction between the father and the providers was about interruptions of Grace's sleep by alarms and frequent vital signs. The father raised a generally accepted criticism of intensive care practices. "The only strategy strongly recommended in the PAD Guidelines, to reduce the incidence and duration of ICU delirium and to improve functional outcomes, is promoting sleep hygiene to prevent sleep disruption and the use of early and progressive mobilization in these patients."[1] Multiple sources in the literature note that well over 90% of alarms in intensive care settings are clinically irrelevant. The

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conclusion of one study was: "Over 94% of alarm soundings in a pediatric ICU may not be clinically important. Present monitoring systems are poor predictors of untoward events."[2] Although the cited study was in a pediatric ICU, the observations and conclusions have been generally recognized in adult intensive care settings. The medical standard of care required that the providers listen to the father's concerns about alarms, no matter how they were expressed, include the father in a discussion with the lead doctor, the lead nurse, or both to identify the scope of the problem, and discuss possible solutions with the father to the unnecessary disruption of sleep and find solutions satisfactory to everyone. The failure to have this discussion about the interruption of Grace's sleep was a breach of the medical standard of care. More likely than not, the failure to address the concerns raised by the father about Grace's sleep led to delirium in Grace which would be interpreted by the providers as "agitation" to be treated by physical and chemical restraint. **NONE** of the physicians named as defendants in this case properly assessed Grace for delirium, mentioned delirium as a diagnosis in Grace, considered sleep deprivation as the cause of delirium in Grace, or worked in cooperation with the father to eliminate or decrease the causes of sleep deprivation and delirium in Grace. These failures by **ALL** the physicians named as defendants in this case were breaches of the medical standard of care. The only solution recommended by **ANY** of the physicians named as defendants in this case for observed agitation in Grace was chemical sedation starting with Precedex.

Some explanation of gas exchange is necessary here. There were significant misunderstandings on the part of **ALL** the physicians named as defendants in this case. The most important value of O2 in the body, is not the SpO2, nor the PaO2, nor the mixed venous O2; it is the partial pressure of O2 in the mitochondria of cells. It is this level that determines organ function. Without an adequate partial pressure of O2 in the mitochondria of cells organs fail and patients die. The usual partial pressure of O2 in cellular mitochondria in normal humans at rest is less than 5 torr and may be less than 1 torr in healthy subjects. The value is so low that it is often approximated as zero to simplify calculations of O2 transport. We cannot easily measure mitochondrial O2, so we use proxies that are easily measured. SpO2 is one such proxy. Higher is better, but there is no critical value if organ function is preserved. Obsessing over SpO2 is a mistake whenever the obsession leads to more important problems.

Under what circumstances do we ignore low values of SpO2? Whenever the measures necessary to increase the SpO2 above 90 (or some other arbitrary number) interfere with more important goals. During bronchoscopies, when we obtain samples by lavage, or brush, or biopsy, we frequently encounter a low SpO2. We do not terminate the procedure due to the low SpO2. We minimize the time necessary to complete a step, pause to let the patient recover, and speed up the recovery by increasing ventilation.

How much O2 is necessary? The answer is enough to keep mitochondrial production of ATP going. We cannot easily measure mitochondrial O2, so we use proxies including SpO2. How much SpO2 is necessary? This depends on the individual situation. People live in the mountains with SpO2 less than 88% without any deleterious effects. Again, higher SpO2 is better, but the goal of higher SpO2 does not justify **ANY** means to achieve it. For patients on mechanical ventilation, too high an inspired O2

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concentration is toxic and causes additional lung injury. When we reach generally acceptable limits, we compromise the SpO2 to prevent further lung injury.

The partial pressure of O2 in the alveoli, or in the arterial blood, or the SpO2, is a balance between two opposing transport processes. Ventilation delivers O2 to the alveolar gas. An increase in ventilation, all other things being equal, increases SpO2. O2 is consumed in the cellular mitochondria to generate the ATP necessary for all cellular functions. The higher the rate of O2 consumption in the cellular mitochondria, all other things being equal, leads to a decrease in SpO2. Hyperventilation increases SpO2, all other things being equal, so hyperventilation is helpful in some situations. The earliest adaptation to altitude in healthy subjects is hyperventilation. A secondary benefit of hyperventilation is the increase in pH which shifts the oxygen-hemoglobin dissociation curve to the left and increases the SpO2 for all values of partial pressure of O2 in the pulmonary capillaries. However, if the O2 consumption by the respiratory muscles to achieve the hyperventilation is greater than these benefits, SpO2 will decrease, so hyperventilation can be harmful in some situations. The adverse effects of increases in pH may cause symptoms that are of greater concern than SpO2.

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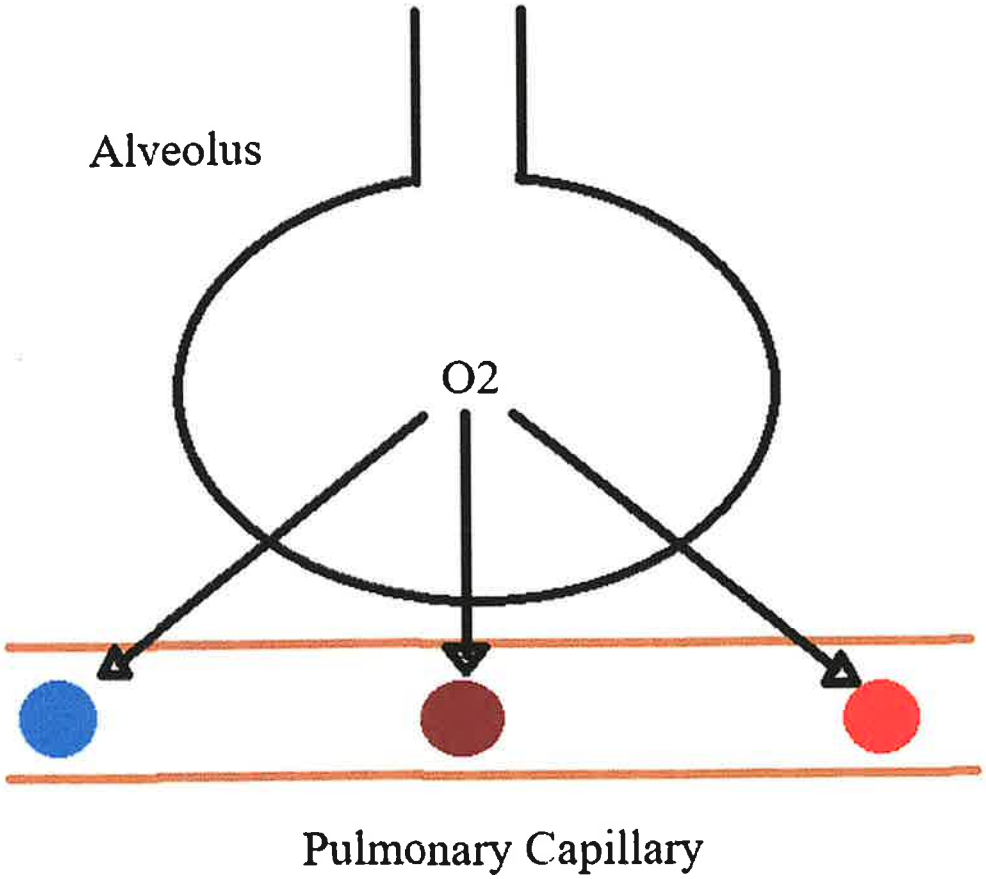

Figure 3: RBC transit through pulmonary capillary

Figure 3 illustrates the transport of oxygen by diffusion from alveolar gas to the red blood cells (RBC). RBC enter a pulmonary capillary at the left. The partial pressure of O2 (pO2) and the saturation of hemoglobin in the RBC is that of mixed venous blood. The usual value of pO2 in mixed venous blood for normal healthy humans at rest is a pO2 of about 40. The RBC in mixed venous blood is represented as blue. The diffusion of O2 from the alveolus to the RBC is a continuous process as the RBC travels from the entrance of the capillary to the exit of the capillary. The rate of diffusion is proportional to the difference in the partial pressure of O2 in the alveolar gas and the partial pressure of O2 in the RBC. As the partial pressure of O2 in the RBC asymptotically approaches the partial pressure of O2 in the alveolar gas, the rate of diffusion decreases. In normal healthy adults at rest, the capillary transit time is about 0.75 seconds. In normal healthy adults, diffusion of O2 from alveolar gas to RBC is essentially complete in 0.25 seconds. In normal healthy adults at rest, the transport of O2 from alveolar gas to RBC is limited by cardiac output rather than the diffusion of O2.

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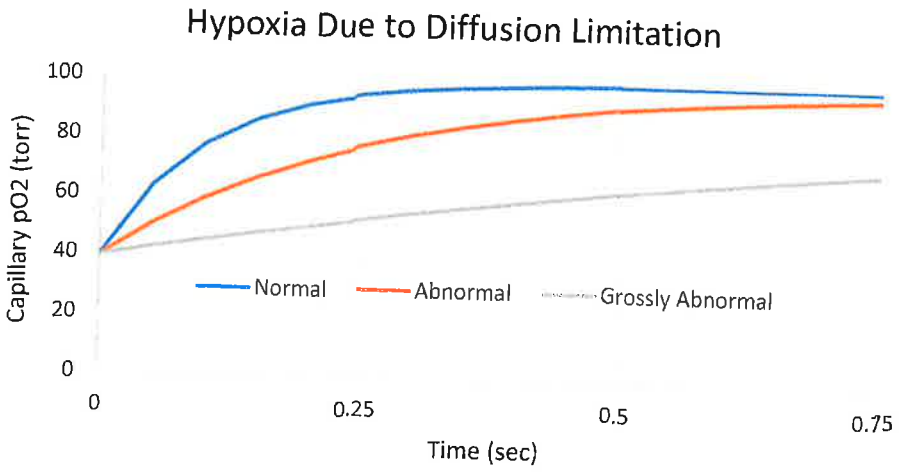

Figure 4: Diffusion Limitation and Effect of Activity

The above discussion of SpO2 is true for normal healthy adults. There is a second mechanism by which physical activity and emotional stress decrease SpO2 that does not occur in normal healthy people but becomes a very important factor in patients with diseased lungs, especially ARDS (see Figure 4). As RBC transit the pulmonary capillaries from the pulmonary arterial side entrance to the pulmonary venous side exit, oxygen diffuses from alveoli to the RBC. The RBC is in the capillary for a limited amount of time. This limited amount of time is called the capillary transit time and is inversely proportional to cardiac output. The greater the cardiac output, the shorter the capillary transit time. In normal healthy people at rest, diffusion is complete after the RBC has spent 1/3 of the total transit time. The normal healthy person, therefore, can accommodate a 3-fold increase in cardiac output without recruiting more capillaries or demonstrating diffusion limitation. By recruiting additional capillaries, normal healthy adults can accommodate an additional 3-fold increase in cardiac output without demonstrating diffusion limitation. So, a normal healthy adult can increase cardiac output 9-fold without causing a decrease in SpO2 due to diffusion limitation. A patient with COVID pneumonia (or acute lung injury of any cause), however, has few open capillaries, so transit time is decreased for the same cardiac output compared to a normal subject. These patients may have no capillaries available for recruitment. Furthermore, interstitial edema increases the distance for diffusion, so more time is required for diffusion to be complete in any given capillary. Some patients have just barely adequate time for diffusion to complete at rest while calm. Some patients (Abnormal curve in Figure 4) will have normal SpO2 at rest but will show very large decreases in SpO2 with **ANY** cause of increased cardiac output. Patients like Grace (Grossly abnormal curve in Figure 4) have reduced SpO2 at rest and require supplemental O2 to increase SpO2 to 90% or higher. These patients will demonstrate repeated decreases in SpO2 with **EVERY** act that increases cardiac output by even minute amounts followed by recovery at rest. The greater the decrease in SpO2, the longer the recovery time. Agitation causes the same decrease in SpO2 that occurs with minimal physical activity.

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The preferred solution to agitation when it results in hypoxia is to identify the cause of the agitation and either eliminate the cause or provide emotional comfort to the patient to ameliorate the effect of the agitation on SpO2. As mentioned above, one of the most important causes of agitation is delirium caused by sleep deprivation. **None** of the providers mention delirium caused by sleep deprivation as a cause of agitation in Grace. The failure to recognize delirium caused by sleep deprivation by **ALL** the providers was a breach of the medical standard of care. **None** of the providers considered the father's concern about unnecessary alarms and too frequent vital signs as the cause of the delirium in Grace. The failure to link the father's concern about unnecessary alarms and too frequent vital signs to the delirium in Grace by **ALL** the providers was a breach of the medical standard of care. Another cause of delirium in Grace was discomfort with the O2 apparatus. As mentioned above the medical standard of care required attempts to solve these problems. Even after the father requested the use of the home CPAP system, **NONE** of the providers considered the use of Grace's own CPAP mask to solve the O2 problems due to Grace's droopy ears. **ALL** the physicians named as defendants in this case misdiagnosed the problems of SpO2 as caused by progression of COVID rather than poor toleration by Grace of the hospital standard operating procedure O2 delivery methods. The failure to recommend the logically correct use of Grace's own CPAP mask with supplemental O2 by **ALL** the physicians named as defendants in this case was a breach of the medical standard of care.

At the time Grace was moved from the ER to the hospital, there were several salient facts. The medical record did **NOT** correctly indicate the chief complaint. Grace was hypoxic in the absence of supplemental O2. Low flow nasal cannula O2 @ 3 l/min was adequate to meet Grace's requirements at rest in a calm state. The nasal cannula delivery system fell off Grace's droopy ears. There was **NO** requirement for an escalation in O2. The best solution to the O2 delivery problem would have been a trial of Grace's own CPAP mask with supplemental O2. More likely than not, the combination of Grace's own CPAP mask supplemental O2 would have been adequate to supply O2 to Grace. If the combination of Grace's own CPAP mask and supplemental **FAILED** to deliver adequate O2 supply, then **AND ONLY** then would it have been accurate to claim that Grace an escalation to some form of high flow O2. Even in the unlikely event that the combination of Grace's own CPAP mask and supplemental O2 was **DEMONSTRATED** to be inadequate to meet Grace's O2 requirements, the next escalation of O2 therapy would be a combination of Grace's own CPAP mask with Grace's own CPAP equipment.

Dr. Beck admitted Grace to the hospital on 10/07/2021 around 0333. The note incorrectly states the chief complaint: "who was brought into the hospital by her family secondary to shortness of breath." Dr. Beck copied forward the error in the ER notes. This was a breach in the medical standard of care. Dr. Beck failed to correctly determine the chief complaint. This failure was a breach of the medical standard of care. Dr. Beck failed to mention that O2 was adequate on 3 l/min nasal cannula and the BiPAP was being used due to difficulties with Grace's droopy ears. This failure was a breach of the medical standard of care. Dr. Beck failed to provide the father with a written copy of the "visitation policy." Dr. Beck failed to inform the father that he would be evicted from the hospital if he developed signs and symptoms of COVID. These failures were breaches of the medical standard of care.

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Dr. Baum visited with Grace and her father on 10/07/2021 around 0817. The note states, "She does use CPAP at home." The note further states, "Her father was in the room with her and he is going to be staying in the hospital." Under ASESSMENT AND PLAN, the note states, "I told the patient we will use the BiPAP overnight." The father is described as an ornament rather than as a necessary member of the team. The medical standard of care required Dr. Baum to explain to the father how his observations and reports on Grace's condition would improve care. Dr. Baum failed to meet the medical standard of care on this point. Had Dr. Baum met the medical standard of care, he would have listened to the father's concerns about interruptions to sleep caused by unnecessary alarms, and Dr. Baum would have considered these concerns to be legitimate warnings about the development of delirium. Had these concerns been adequately addressed, more likely than not delirium would not have developed over the next day. The medical standard of care required Dr. Baum to advise the father on how his comfort toward Grace would be necessary to avoid delirium. Dr. Baum failed to meet the medical standard of care on this point. The medical standard of care required Dr. Baum to listen to the father's request for a trial of Grace's own CPAP mask with Grace's home CPAP machine and negotiate a plan with the father. Instead, Dr. Baum gave an order: "I told the patient we will use BiPAP overnight." These failures were a breach of the medical standard of care. These failures would lead to the unnecessary development of delirium over the next day which would trigger an order for Precedex. Dr. Baum had an opportunity to provide the father with a written copy of the "visitation policy." Dr. Baum had an opportunity to inform the father that he would be evicted if he developed signs and symptoms of COVID. Dr. Baum's failures on these points were breaches of the medical standard of care. These breaches of the medical standard of care would eventually lead to three overdosages with Precedex. These breaches of the medical standard of care would eventually lead to Grace's death on October 13.

Sometime on October 7, around 1930, Dr. Beck ordered lorazepam on a PRN basis every 6 hours as needed for anxiety or agitation. The father **NEVER** consented to PRN use of lorazepam. Lorazepam was administered around 1954; it did not produce the desired result. There would be 4 additional doses of lorazepam subsequently given prior to Grace's death based on this order without informed consent. None of these doses had the desired effect. The use of lorazepam without informed consent was a breach of the medical standard of care. The failure to obtain informed consent for additional doses of lorazepam would be repeated with a failure to obtain inform consent for Precedex. Three overdosages of Precedex would eventually occur without informed consent for Precedex. The third overdosage with Precedex would become fatal for Grace on October 13 when lorazepam and morphine were administered in combination with an overdosage of Precedex.

Sometime on October 7, around 2200 an order under Dr. Marada's name for Precedex was entered into the medical record. Incredibly, Dr. Marada in his deposition denies responsibility for this order. There are four explanations for Dr. Marada being the ordering physician in the medical record. First, Dr. Marada entered the order. Second, a verbal order was entered in Dr. Marada's name which Dr. Marada later signed off on. Third, Dr. Marada signed off on the order by a process called medication reconciliation. Fourth, Dr. Marada left his workstation with his EMR account open, somebody else entered the order, or signed off on the verbal order, or signed off on the medication reconciliation, and the EMR system

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assigned Dr. Marda's name to the order. Whichever explanation is the truth, Dr. Marada was responsible for the order. The Precedex was ordered without informed consent by the father. The failure to obtain informed consent for Precedex from the father was a breach of the medical standard of care by Dr. Marada.

This order for Precedex was for a continuous infusion, so there were multiple parameters for the order. Sometimes, Precedex is ordered with a bolus, but not in this instance. There is an **INITIAL** infusion rate. The usual practice for this parameter is about 0.1 microgram/kg/hr. This particular Precedex order was for an **INITIAL** infusion rate of 1.0 microgram/kg/hr. If there was a compelling reason for this unusually high **INITIAL** infusion rate, the medical standard of care required the reason to be documented in the medical record by the ordering physician. No such documentation can be found in the medical record. The failure to document the compelling reason for an **INITIAL** infusion rate of 1.0 was a breach of the medical standard of care by Dr. Marada. Within 20 minutes of the start of the infusion, the nurse noted oversedation and sudden drop in blood pressure. Both adverse events are known complications of Precedex. The nurse, in his words, "aggressively" decreased the infusion rate to 0.7 which is the upper limit of usual starting doses for Precedex. The oversedation and hypotension corrected without further intervention. The medical standard of care required that the ordering physician of record, regardless of how the physician became the ordering physician of record, to have reviewed the nurse's documentation of this adverse event, make changes to the order to prevent a repeat of this adverse event, and inform the father of the adverse event. The medical standard of care required **EACH** physician that visited with the patient following this overdosage with Precedex to inform the father about the overdosage. Furthermore, the medical standard of care required **EACH** physician that visited the patient to include the father in a discussion of how to treat the delirium in Grace **WITHOUT** repeating the overdosage with Precedex. The failure by **ANY** physician to review the documentation by the nurse, make changes to the order for Precedex to prevent repeat occurrences of the adverse event, and informing the father of the adverse event was a breach of the medical standard of care. When **EVERY** physician named as a defendant in this case failed to meet the standard of care as indicated above, the final responsibility for meeting the standard of care fell to Dr. Mirada as the author of record for the order of Precedex.

Precedex was **NOT** safe for Grace Schara at an infusion rate greater than 0.7 micrograms/kg/hr. It does not matter what the prior experience of **ANYONE** has been in **OTHER** patients. The medical record documents that a Precedex infusion rate greater than 0.7 micrograms/kg/hr would predictably lead to bradycardia, hypotension, and respiratory depression. **ANY** subsequent use of Precedex at an infusion rate greater than 0.7 would require documentation of a compelling reason to do so. Failure to document a compelling reason for administering Precedex at an infusion rate greater than 0.7 would be a deliberate overdosage of Precedex.

On October 8, around 0400 Precedex was increased to 0.8 microgram/kg/hr. It was previously established that a dose greater than 0.7 would lead to adverse effects including hypotension. The medical standard of care required that either the order be changed with a maximum dose of 0.7, or that informed consent to increase the Precedex above 0.7 be obtained from the father. There is **NO** documentation in the medical record that informed consent for **ANY** dose of Precedex was **EVER** obtained from the father. The use of Precedex without informed consent was a breach of the medical

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standard of care. The increase of the dose from 0.7 to 0.8 without informed consent was a breach of the medical standard of care. Even if informed consent for Precedex had been obtained from the father, **AND** informed consent to increase the dose of Precedex to 0.8 had been obtained from the father, the increase in dose of Precedex to 0.8 without documentation in the medical record of the compelling reason to use a dose of Precedex previously demonstrated to have adverse effects on Grace was a breach of the medical standard of care. The adverse effects of this deliberate overdosage with Precedex would not take long to appear.

On October 8 around 0930 Dr. Baum visited with Grace and the father. The medical record indicates that Dr. Baum was aware that Grace was receiving Precedex. There is no evidence that the father was informed that Precedex was being administered. There is no evidence that the father was informed that Precedex had previously caused a life-threatening adverse event in Grace. There is no evidence that Dr. Baum explained to the father the compelling reason to increase the Precedex dose to a level that would predictably lead to another life-threatening adverse event. These failures of informed consent were all breaches of the medical standard of care by Dr. Baum. Dr. Baum notes, "Her father had questions today about getting BiPAP at home." There is no evidence that Dr. Baum gave a satisfactory answer to those questions. Had Dr. Baum arranged for home BiPAP with Grace's own CPAP mask, more likely than not, Grace would have recovered from her illness at home. Instead of answering the father's legitimate questions, Dr. Baum pressed the father to "agree to intubation. I discussed that with him today and I told him we need to discuss and he needs to make a decision in case things would worsen suddenly." There is no evidence that Dr. Baum informed the father that the cause of things worsening suddenly would be the second overdosage of Precedex that was currently underway during this visit. Dr. Baum notes that the blood pressure was 84/52. The evidence for the second adverse event due to Precedex was already apparent.

On October 8, around 1008 the Precedex was increased from 0.8 to 0.9. Given the previous adverse event caused by Precedex and the recent blood pressure of 84/52, the medical standard of care required documentation in the medical record of a compelling reason to make this increase, and for this compelling reason to be explained to the father, and for the father to grant informed consent for the increase. There is no evidence that any of these requirements were met, so this increase in Precedex to 0.9 was another breach of the medical standard of care by Dr. Baum and Dr. Mirada. As a result of these breaches of the medical standard of care, Grace would have a life-threatening event due to this second and deliberate overdosage with Precedex.

On October 8, around 1200 the nurse notes in the medical record that the father is asking questions that the nurse cannot answer. The father seems to be the only person aware that a catastrophe is imminent. On October 8, around 1220, the nurse updates Dr. Mirada about bradycardia. More likely than not, this update led to a request for a PICC line.

On October 8, around 1320 the Precedex was decreased from 0.6 to 0.5. There is no documentation in the medical record for how the Precedex was decreased from 0.9 to 0.6. The failure to properly document **ALL** the changes in Precedex dosage was a breach of the medical standard of care. On October 8, around 1453 a radiograph was taken to verify placement of a PICC line. It is clear from subsequent

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events that the PICC line was necessary to administer norepinephrine and dopamine. The administration of norepinephrine and dopamine was ordered by Dr. Mirada. The administration of norepinephrine and dopamine was necessary to resuscitate Grace from the predictable adverse event caused by deliberate overdosage of Precedex. Norepinephrine would be started around 1542. Around 1601 the medical record indicates a blood pressure of 66/39 and a heart rate of 39. The vital signs are recorded in the medical record roughly hourly, so I cannot tell how much lower the blood pressure and heart rate fell. Atropine would be administered around 1610. The Precedex would be turned off around 1611. Dopamine would be started around 1708. The resuscitation would continue until October 9, around 0100. The resuscitation for the predictable adverse event from a deliberate overdosage of Precedex would continue for around 8 hours. The administration of Precedex without informed consent was a breach of the medical standard of care by **EVERY** physician named as a defendant in this case. The increase in Precedex from 0.7 to 0.8 on October 8, around 0400 without documentation of a compelling reason for deliberate overdosage was a breach of the medical standard of care by Dr. Baum and Dr. Marada. The deliberate overdosage with Precedex without informed consent was a breach of the medical standard of care by Dr. Baum and Dr. Marada.

On October 8, around 2125 Dr. Marada visited with Grace and the father to perform an ICU consultation. This consultation took place during the resuscitation with norepinephrine, dopamine, and atropine from the predictable adverse event caused by the deliberate overdosage with Precedex. Dr. Marada notes, "She is on Precedex drip." Dr. Marada further notes, "The patient is lethargic mostly because of Precedex." This consultation took place about 6 hours after Precedex had been turned off. Incredibly, Dr. Marada, in his deposition claimed the elimination half-life of Precedex was about 6 minutes. The actual elimination half-life of Precedex is about 2 hours. Incredibly, Dr. Marada, in his deposition claimed that he had no concerns about Precedex in this case. The facts, however, are that Grace required about 8 hours of resuscitation with norepinephrine and dopamine to prevent her from dying following a deliberate overdosage with Precedex. The resuscitation was taking place during his consultation, yet Dr. Marada failed to inform the father that Grace was being resuscitated with norepinephrine and dopamine – on his order – for a deliberate overdosage with Precedex. The medical standard of care required Dr. Marada to adjust the order for Precedex to prevent a recurrence of this adverse side effect of Precedex. This requirement was irrespective of who ordered the Precedex. This failure was a breach of the medical standard of care. This breach of the medical standard of care was a proximate cause of the death of Grace on October 13. This failure to inform the medical advocate about the current condition of the patient was a breach of the medical standard of care by Dr. Marada. The Precedex and both overdosages with Precedex were administered on Dr. Marada's order, yet Dr. Marada failed to inform the medical advocate about the use of Precedex, and both overdosages. These failures were breaches of the medical standard of care by Dr. Marada. The Precedex was administered on his order, without proper informed consent. This failure was a breach of the medical standard of care by Dr. Mirada. Dr. Mirada failed to document a compelling reason for a very unusual starting infusion rate of 1.0 microgram/kg/hr for Precedex which was responsible for the first overdosage with Precedex. This failure was a breach of the medical standard of care. Dr. Mirada failed to document a compelling reason for increasing the Precedex infusion rate from 0.7 to 0.8 with further increase to 0.9 on his order when this increase would predictably lead to a second Precedex overdosage – an overdosage that would require about 8 hours of

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resuscitation with norepinephrine and dopamine to correct. This failure was a breach of the medical standard of care. The statement by Dr. Mirada, in his deposition, that he had no concerns about Precedex on October 8 in this case demonstrated a reckless disregard for the well-being of Grace Schara. These actions by Dr. Marada eventually would lead to the death of Grace on October 13.

On October 9, around 0208 the Precedex was resumed. Incredibly, despite two adverse events with Precedex overdosage, there had been no change in the order. As best as I can tell from the medical record, the maximum dose of Precedex on the order is 1.5 micrograms/kg/hr. Given that there have been two adverse events with Precedex dose greater than 0.7, the failure to modify the Precedex order by limiting the maximum dose to 0.7 was a breach of the medical standard of care by Dr. Baum and Dr. Leonard. The failure to modify the Precedex dose would directly cause the death of Grace on October 13.

On October 9, around 1009 Dr. Leonard visited with Grace and the father. The documentation of the visit does not mention Precedex which has been resumed. Dr. Leonard did not inform the father that Grace was receiving Precedex. Dr. Leonard did not obtain informed consent for Precedex. Dr. Leonard did not inform the father that the cause of the difficulties on October 8 was an overdosage of Precedex. Dr. Leonard did not engage the father in a discussion of how to avoid another overdosage of Precedex in the future. Each of these failures was a breach of the medical standard of care by Dr. Leonard. These breaches directly and proximately caused the death of Grace on October 13. Dr. Leonard had an opportunity to provide the father with a written copy of the "visitation policy." Dr. Leonard had an opportunity to inform the father that he would be evicted from the hospital if he developed signs and symptoms of COVID. Dr. Leonard failed on both points. These failures were breaches of the medical standard of care by Dr. Leonard. These breaches of the medical standard of care by Dr. Leonard would eventually cause the death of Grace on October 13.

On October 9, around 1330 Dr. Baum visited with Grace and the father. Dr. Baum notes the patient is on Precedex. Dr. Baum notes the patient is on a low dose of norepinephrine to support blood pressure. Dr. Baum failed to obtain informed consent for Precedex from the father. Dr. Baum failed to inform the father how Precedex caused the problems on October 8. Each of the failures was a breach of the medical standard of care by Dr. Baum. These breaches of the medical standard of care by Dr. Baum would directly cause the death of Grace on October 13.

As mentioned above, the "ABCDEF" bundle is an established standard of care for critically ill patients.[1] The "F" stands for Family Engagement and Empowerment and is part of the bundle for good reasons. "The ABCDE bundle has evolved to include Family Engagement, as no ICU treatment plan is complete without incorporation of the family's wishes, concerns, questions, and participation. Family members and surrogate decision makers must become active partners in multi-professional decision-making and treatment planning. Through this partnership, patients' preferences can be identified, the anxiety of families can be lessened, and physicians can have appropriate input into decisions." The word appropriate in this last sentence means consistent with the medical standard of care for informed consent.

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On October 10, around 0830 Alison Barkholtz, RN, accompanied by a security guard, informed the father that he was being evicted from the building. "First and foremost, the reason that I was entering this room of the patient was to speak with both the individual that was in the room, which was the patient's father, because he was exhibiting signs and symptoms of COVID, which at the time we did not allow any visitors into the hospital that had signs or symptoms of COVID,..." The father was never provided a copy of the "policy" in question. Plaintiff attorney has requested a copy of the "policy" in question, but he has never received a copy. As best as I can tell, the above quote from the deposition of Alison Barkholtz, RN is the only record of this "policy." The policy, as stated by Alison Barkholtz, applied to visitors wanting to enter the hospital. This "policy" would not have applied to the father as he was already in the hospital. The entry into the hospital by the father was a negotiated waiver of another policy which did not allow patients with COVID (Grace) to have visitors in the room. The only restriction on the father was that he had to remain in the room. The rationale that the visitor be required to remain in the room is based on quarantine. It is expected that the visitor will be exposed to COVID and eventually develop signs and symptoms of COVID. The requirement that the visitor **REMAIN** in the room quarantines the visitor from the population outside of the room. There is no indication in the record that the father did not remain in the room until he was evicted by Alison Barkholtz, RN. The eviction of the father improperly broke this quarantine and unnecessarily exposed other people – including the security guard – to COVID. The eviction of the father on the basis of a policy that did not apply to the father was a breach of the medical standard of care by Alison Barkholtz and the hospital. The unnecessary exposure of people in the hospital to the father by his eviction, thereby **INCREASING** the risk of COVID spread, was a breach of the medical standard of care by Alison Barkholtz and the hospital. These breaches of the medical standard of care were catastrophic and eventually – after the accumulated effect of many errors that would never have occurred had the father remained in the room as advocate and interpreter for the patient -- led to the death of Grace. Prior to the eviction of the father, there were multiple complaints against the father for asking too many questions and turning alarms off. The eviction of the father turned off the most important alarm in Grace's room. The father was the best instrument for monitoring Grace's mental status. The father was the best instrument in the room for monitoring Grace's brain function. The father was the best tool for keeping Grace calm and minimizing O2 consumption. Without the father, the only tool to keep Grace calm would be sedatives including Precedex which had previously failed to achieve the goals of therapy despite overdosage leading to life threatening effects. The eviction of the father would guarantee the worsening in delirium in Grace. The worsening delirium in Grace would guarantee an increase in O2 consumption and decrease in SpO2. The worsening delirium in Grace would lead to the third, and this time fatal, overdosage of Precedex. The eviction of the father from the hospital was a death sentence for Grace.

The eviction of the father by Alison Barkholtz and the hospital deprived a cognitively impaired patient of access to the medical advocate. This was an extraordinary act by Alison Barkholtz and the hospital. The medical standard of care and norms of due process required adequate documentation of the process leading up to the eviction. The medical standard of care required a discussion with **ALL** the physicians providing care to Grace to determine whether the eviction would interfere with the care of Grace and present a danger to Grace's life. The medical standard of care required that such discussions be documented in the medical record and that the father be given a written copy of statements by each

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physician in such discussion. There is no evidence in the medical record that such a discussion occurred with **ANY** physician providing care to Grace. If **ANY** such discussion occurred, there is **NO** documentation of such discussion in the medical record. If **ANY** such discussion occurred, the father was **NOT** given a written copy of statements by the physicians. These failures were breaches of the medical standard of care by Alison Barkholtz and the hospital. These failures would eventually cause the death of Grace on October 13.

On October 10, around 2000 the Precedex was resumed at a dose of 0.2 micrograms/kg/hr. Informed consent for the administration of Precedex was **NEVER** obtained. The use of Precedex without informed consent was a breach of the medical standard of care. Based on subsequent events, there were no changes to the Precedex order capping the dose at 0.7. The failure to limit the maximum dose of Precedex to 0.7 – despite two previous overdosages -- was a breach of the medical standard of care by Dr. Gandev, Dr. Baum, and Dr. Shokar. The inappropriate use of Precedex would lead to Grace's death on October 13.

On October 11, around 1056 Dr. Gandev took over care of Grace from Dr. Leonard. This is called a handoff. The medical record documents that Dr. Gandev was aware the Precedex was being administered. The medical standard of care required a thorough review of medications including informed consent, appropriateness of orders, and whether the clinical history required changes to medications. Dr. Gandev failed in all these responsibilities. Dr. Gandev failed to obtain informed consent for Precedex. This was a breach of the medical standard of care by Dr. Gandev. Dr. Gandev failed to inform the father or another family representative of the previous overdosages with Precedex and the consequences of the overdosages to Grace. The was a breach of the medical standard of care by Dr. Gandev. Dr. Gandev had the opportunity to make appropriate changes to the maximum infusion rate of Precedex and Dr. Gandev failed to do so. This was a breach of the medical standard of care by Dr. Gandev. These breaches directly and proximately caused the death of Grace on October 13.

The use of Precedex was continuous – without interruption – from October 10, around 2000 to October 13, around 1837 when the Precedex was held by Dr. Shokar. The manufacturer of Precedex states that Precedex should not be administered continuously for more than 24 hours.[3] The administration of Precedex by the providers to Grace exceeded the manufacturer's recommendation. Element 'B' of the ABCDEF bundle is: Both spontaneous Awakening Trials (SAT) and Spontaneous Breathing Trials (SBT).[1] Best medical practice employs daily SAT with Precedex. Precedex was approved by the FDA in 1999. The article cited explaining ABCDEF was written in 2017 – no exception was made for SAT when using Precedex despite 18 years of use. The package insert available at the time of these events indicates that during the Phase III trials of Precedex adverse events included respiratory depression (36.8%), hypoxia (2.2%), and bradypnea (1.6%).[3] The package insert available at the time of these events indicates that adverse events reported during post-approval use include: apnea, bronchial obstruction, dyspnea, hypercapnia, hypoventilation, hypoxia, respiratory depression, and respiratory insufficiency. An adverse respiratory event had already been documented for Grace by nurse Haines. Claims that Precedex does not cause adverse respiratory events are not true. Any such claims that Precedex does not cause adverse respiratory events are easily disproved by counterexample.

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On October 13, around 0000 the Precedex was increased to 0.8 microgram/kg/hr. This was a deliberate overdosage. The predictable result of this dose change would be cardiovascular collapse. The only question would be how long it would take for the overdosage to become fatal. On October 13, around 0602 the Precedex was increased to 0.9. On October 13, around 0700 the Precedex was increased to 1.0. On October 13, around 0730 the Precedex was increased to 1.1. On October 13, around 0754 the Precedex was increased to 1.2. The documentation for the increase in Precedex to 1.3 is missing from the medical record. On October 13, around 1048, the Precedex was increased to 1.4. The ordering physician for the Precedex changed to Dr. Leonard. There are four explanations for Dr. Leonard's name being attached to the order for Precedex. First, Dr. Leonard made the order. Second, someone entered a verbal order and Dr. Leonard signed off on it. Third, Dr. Leonard signed off on the order by the process of medication reconciliation. Fourth, Dr. Leonard entered the EMR with his account, left the work station without locking the computer, and someone else used Dr. Leonard's account to order the Precedex, or sign off on a verbal order, or sign off on a medication reconciliation. Irrespective of which explanation is the truth, Dr. Leonard was responsible for the order. The order of Precedex without informed consent was a breach of the medical standard of care by Dr. Leonard. The continued use of Precedex when it never produced the desired result was a breach of the medical standard of care by Dr. Leonard. The continuous use of Precedex for more than 24 hours violated warnings by the manufacturer. The FDA has never approved Precedex for continuous use for more than 24 hours. Continuous use of Precedex for more than 24 hours was off-label use. The medical standard of care required documentation of a compelling reason for off-label use. The failure to document a compelling reason for continuous use of Precedex was a breach of the medical standard of care by Dr. Leonard. The use of Precedex at a dose exceeding the dose that had previously caused two adverse events without documentation of a compelling reason was a breach of the medical standard of care by Dr. Leonard. The failure to inform the father or family representative of continued use of a medication that was responsible for two life-threatening adverse events was a breach of the medical standard of care by Dr. Leonard. The failure to appropriately change the order for Precedex or discontinue the order for Precedex was a breach of the medical standard. These breaches of the medical standard of care by Dr. Leonard directly and proximately caused the death of Grace on October 13.

Dr. Gandev and Dr. Shokar provided care to Grace subsequent to October 13, around 0000 when the Precedex was increased to an overdosage. Dr. Gandev and Dr. Shokar were required by the medical standard of care to decrease or discontinue the Precedex, irrespective of who the ordering physician was. Dr. Gandev and Dr. Shokar failed to decrease or discontinue the Precedex. This failure was a breach of the medical standard of care. This breach of the medical standard of care directly caused the death of Grace.

On October 13, around 1125, lorazepam 0.5mg IV was administered on top of the Precedex overdosage. On October 13, around 1134 a feeding tube was placed in the left nare. SpO2 decreased to 61% during the placement. On October 13, around 1241 Dr. Gandev noted, "After a long discussion, family opted for DNR and DNI status." Dr. Gandev **NEVER** discussed DNR or DNI with the patient or family. The medical power of attorney **NEVER** agreed to DNR. This misrepresentation of code status was a breach of the medical standard of care by Dr. Gandev. On October 13, around 1257 Dr. Shokar noted, "Code status was

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reviewed with family and she is a DNR/DNI." The medical power of attorney **NEVER** agreed to DNR. This misrepresentation of code status was a breach of the medical standard of care by Dr. Shokar. It must be noted that the only reason for the misunderstanding of code status was that the father was evicted from the hospital. Had the father remained in the room, there would have been no misunderstanding. The hospital created this problem when the hospital unnecessarily evicted the father. The misrepresentation of the patient's code status was a breach of the medical standard of care by Dr. Gandev and Dr. Shokar. This breach of the medical standard of care directly caused the death of Grace.

On October 13, around 1600 the RASS was -1 which corresponds to drowsy. On October 13, around 1700, the medical record indicates Grace was somnolent. On October 13, around 1730, Grace remains somnolent with "min/no response." The physicians named as defendants in this case stated that the purpose of the Precedex was to treat agitation. The continuation of Precedex at a rate of 1.4 micrograms/kg/hr when the patient had been somnolent for more than 30 minutes was a breach of the medical standard of care. The continuation of Precedex at a rate of 1.4 when the patient was unresponsive was a breach of the medical standard of care. Incredibly, on October 13, around 1746 with the patient somnolent for more than 45 minutes and currently unresponsive, lorazepam 0.5mg IV was administered. This gets repeated 3 minutes later. Sister Jessica, who was in the room with Grace, noted in her deposition, "So the hospital monitor, the big machine said 44 percent oxygen, and then our finger monitor that I have -- or had said 93 percent oxygen, and then they brought in another monitor, a higher end monitor that said 69 percent oxygen. And so all of a sudden, we have three different numbers all at the same time." More likely than not, the different readings were signaling problems with circulation to the different probes, most likely due to impending cardiovascular collapse. Jessica further noted, [Shokar]: "if she can take these nice deep breaths, really letting the oxygen deep into her lungs, that that will benefit Grace." This is an incredible misunderstanding of gas exchange and narcotics. Narcotics **DECREASE** alveolar ventilation by a decrease in tidal volume, rate, or both. One would **NEVER** use morphine to increase tidal volume. So, Dr. Shokar orders morphine 2mg IV at 1815 and repeats 2mg IV at 1830. The cause of Grace's agitation, more likely than not, was the absence of the father and the feeding tube. Despite repeated failure to control agitation with an overdosage of Precedex, the sedative overdosage was compounded by adding lorazepam and morphine to the mix. Rather than getting the desired result of "nice deep breaths" Jessica noted around 1815, "all of a sudden, you know, her numbers are dropping. Like I said, the hospital monitors must have been beeping because I – I sensed something, and then I checked for a pulse and I could not find a pulse. And then I lift Grace's eyelid up, and her eyes were rolling to the back of her head." The deliberate overdosage with Precedex became an execution by sedatives including Precedex, lorazepam, and morphine. The change in Grace's code status to DNR without informed consent was a breach of the medical standard of care by Dr. Shokar. The addition of lorazepam to the sedation when the patient was somnolent and unresponsive was a breach of the medical standard of care by Dr. Shokar. The misrepresentation to the family representative of the effects of morphine was a breach of the medical standard of care by Dr. Shokar. The addition of morphine to the sedative mix at a time when the patient was somnolent and unresponsive was a breach of the medical standard of care by Dr. Shokar. These breaches of the medical standard of care by Dr. Shokar were the direct and proximate cause of the death of Grace.

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Grace died on October 13, around 1927. To a reasonable degree of medical certainty, more likely than not, the cause of death was a sedative overdosage. The use of Precedex without informed consent was a breach of the medical standard of care. **EVERY** time the dose of Precedex was increased above 0.7 micrograms/kg/hr, the result was hypotension, bradycardia, and respiratory depression. The repeated use of Precedex at doses above 0.7 was a breach of the medical standard of care by **EVERY** physician named as a defendant in this case. The escalation of sedation on October 13 with the addition of lorazepam and morphine to a somnolent patient was a breach of the medical standard of care by Dr. Shokar. Shortly after the addition of morphine, Grace died. When, as Jessica put it, "all of a sudden her numbers are dropping" the medical standard of care required, at a minimum, stopping the Precedex, reversal of morphine with naloxone, reversal of the lorazepam, and cardiovascular support with norepinephrine, dopamine, and atropine. Dr. Shokar failed to take these measures, thereby breaching the medical standard of care. This breach of the medical standard of care by Dr. Shokar contributed to the death of Grace. Had Dr. Shokar met the medical standard of care and reversed the narcotic with naloxone, reversed the lorazepam, and provided pharmaceutical resuscitation with norepinephrine, dopamine, and atropine, more likely than not Grace would have survived this deliberate overdosage with Precedex. Following the previous deliberate overdosage with Precedex, it took 8 hours of resuscitation with norepinephrine and dopamine to stabilize Grace. Following this deliberate overdosage with Precedex, lorazepam, and morphine, the providers stood around and did **NOTHING**.

Summary:

At the time of admission to the hospital October 6-7, the defendants failed to properly obtain informed consent for admission of Grace to the hospital. The defendants promised results that could not be delivered. When the hospital restriction on visitation was waived to allow the father to accompany Grace in the hospital room, the defendants failed to provide a written notice of additional and unstated conditions. The defendants failed to inform the father that should he develop signs and symptoms of COVID that he would be evicted from the hospital by a security guard. This failure was a breach of the medical standard of care. The defendants in this case had opportunities to correct this breach of the medical standard of care by providing a written copy of the "visitation policy" to the father. Had the defendants properly informed the father prior to eviction from the hospital of the unstated restriction on his presence to remain COVID free, the patient would have been taken home, received superior care in the home compared to the hospital by virtue of family interaction, and would have more likely than not survived the illness. Failure by defendants to provide the father with a written copy of the "visitation policy" was a breach of the medical standard of care.

Defendants followed a plan of care based on average expectations for an average patient with COVID. Grace was not an average patient. Grace was a cognitively impaired patient with Down Syndrome. In the ER, Grace had adequate SpO2 on low flow O2 via nasal cannula. However, her ears had peculiar anatomic features that caused the O2 lines to fall off her ears. Defendants misinterpreted this problem as a requirement for high flow O2 by Vapotherm. The Vapotherm delivered adequate O2, but Grace could not tolerate the noise of the machine. Defendants misinterpreted this problem as a requirement for BiPAP. A requirement for BiPAP would be copied forward by **ALL** the defendant physicians in their notes. This would be misinterpreted as progression of COVID illness which would require intubation and

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mechanical ventilation. Rather than try other options, such as Grace's own CPAP mask with Grace's own CPAP machine and supplemental O2 bled in, defendants attempted to force BiPAP to deliver the desired results. When alarms and the difficulties with the hospital BiPAP mask and machine led to delirium manifested as agitation with decreases in SpO2 due to increases in O2 consumption, the defendants misinterpreted the decrease in SpO2 as a progression of COVID.

There was no metric for COVID severity at the time of these events. There remains no metric for COVID severity today. The metric used by defendants – decrease in SpO2 or O2 delivery requirement to maintain SpO2 greater than 90% – has many causes. The defendants repeatedly failed to consider **OTHER** causes for problems with SpO2. The defendants blamed every failure of their treatment plan on progression of COVID. The defendants failed to recognize that their treatment plan was a failure for an patient such as Grace. The father repeatedly made reasonable suggestions for better results in treatment in Grace. Rather than properly implementing element F of ABCDEF, the father was ignored, argued with, complained against, and eventually evicted from the hospital. The failures mentioned above were breaches of the medical standard of care. The failures mentioned above contributed to delirium in Grace. The failures mentioned above directly led to the death of Grace.

Rather than correct the causes of the delirium, defendants tried to force Grace to be calm with Precedex. This would be trying to pound a square peg into a round hole. Defendants **NEVER** obtained informed consent for the use of Precedex. This was a breach of the medical standard of care. The Precedex was started with an unusually high maintenance dose of 1.0 microgram/kg/hr. The usual starting dose for Precedex was 0.1. Very quickly Grace suffered the adverse consequences of respiratory depression and hypotension from the Precedex dose of 1.0. The nurse "aggressively" decreased the Precedex dose to 0.7. Although the lower dose of Precedex solved the problems of respiratory depression and hypotension, it failed to deliver the desired result of calmness. Defendants **NEVER** informed the father of the life-threatening complications caused by Precedex. This was a breach of the medical standard of care. The first overdosage with Precedex should have been a warning that led to a better treatment plan. The failure to heed that warning, properly employ element F of ABCDEF, and cooperate with the father to develop a better treatment plan for Grace was a breach of the medical standard of care. If anything, Grace became more agitated on Precedex. **ALL** the physicians named as defendants in this case had opportunities to change the Precedex order capping the maximum dose at 0.7 micrograms/kg/hr. **NONE** of the physicians named as defendants changed the order. This was a breach of the medical standard of care by **ALL** the physicians named as defendants in this case.

Every time the use of Precedex by defendants failed to achieve the desired result and caused life threatening complications, the defendants got a bigger hammer by raising the Precedex dose. Precedex was resumed. There was still no informed consent for Precedex. The father was **NEVER** informed of the adverse consequences of the first Precedex overdosage. **ALL** the physicians named as defendants had opportunities to obtain informed consent for Precedex following the first overdosage of Precedex. **ALL** the physicians failed to obtain informed consent for Precedex following the first overdosage of Precedex. **ALL** the physicians failed to inform the father of the adverse consequences to Grace during the first overdosage with Precedex. These failures were breaches of the medical standard of care by **ALL** the physicians named as defendants in this case. The Precedex dose was increased above the 0.7 dose

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previously demonstrated to be the maximum safe dose in Grace. The second overdosage was deliberate. **ALL** the defendants failed to obtain informed consent for a deliberate overdosage with Precedex. Predictably, this second and deliberate overdosage with Precedex led to adverse consequences of hypotension and bradycardia. This time, the adverse consequences could not be solved simply by decreasing the Precedex dose. This second and deliberate overdosage of Precedex required 8 hours of resuscitation with norepinephrine, dopamine, and atropine to prevent the death of Grace. Again, defendants failed to obtain informed consent for the use of Precedex. Again, defendants failed to inform the father of the life-threatening complications of Precedex (not theoretical, but actual). Again, defendants failed to properly employ element F of ABCDEF and cooperate with the father to develop a better treatment plan for Grace. These failures were all breaches of the medical standard of care. **ALL** the physicians named as defendants in this case had an opportunity to change the Precedex order following this second and deliberate overdosage. **ALL** the physicians named as defendants in this case failed to change the Precedex order following this second and deliberate overdosage. This failure was a breach of the medical standard of care by **ALL** the physicians named as defendants in this case.

Rather than consider alternative solutions to the problem of delirium in Grace, the defendants continued to try to pound a square peg into a round hole; they just got a bigger hammer. Precedex was resumed. Again, the defendants failed to obtain informed consent for the use of Precedex. Again, the defendants failed to inform the father of the life-threatening complications following the previous uses of Precedex. Rather than properly employing element F of ABCDEF by listening to the reasonable suggestions of the father to improve the care of Grace, defendants forcibly evicted the father from the hospital. Eventually, the dose of Precedex would be increased to 1.4, far higher than the previously demonstrated safe dose of 0.7, and kept there for a prolonged period of time exceeding the manufacturer's recommendations. Predictably, this third overdosage would have adverse consequences directly causing the death of Grace.

When the defendants forcibly evicted the father from the hospital, the defendants deprived the patient of immediate access to her father who was medical advocate and medical power of attorney. The process by which the medical power of attorney of a cognitively impaired patient was forcibly removed from the hospital was a breach of the medical standard of care, a violation of the cognitively impaired patient's autonomy, and a violation of normal standards of due process.

Prior to the eviction of the father from the hospital on October 10, 2021, the defendants breached the medical standard of care for family engagement and empowerment. This breach of the medical standard of care led to delirium which presented as agitation and decrease in SpO2. This breach of the medical standard of care was made worse by the eviction of the father from the hospital. The delirium caused by these breaches of the standard of care were inappropriately treated with a third and deliberate overdosage of Precedex rather than addressing the root causes of the delirium.

This forcible eviction of the father by the defendants based on a policy that did not apply to the father was a breach of the medical standard of care. This eviction started a chain of events leading to the death of the patient. The patient was agitated, in part, due to lack of access to family members. Without the comfort of the father, the agitation was worse than it otherwise would have been. The agitation caused oxygen consumption to increase and SpO2 to decrease. Without the comfort of the father, the decrease

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in SpO2 was worse than it otherwise would have been. The decrease in oxygen saturation was misinterpreted as progression of COVID.

The entire purpose of seeking a DNR order was to give medical staff direction in the event that the father could not be reached. The only reason that there was a possibility that the father could not be reached was that the father had been forcibly evicted from the room by the defendants and was no longer immediately available for instructions on the boundaries of care.

The defendants failed to properly obtain consent for a DNR order. The medical power of attorney agreed to no CPR in the hypothetical event of cardiac arrest and failed resuscitation efforts, and the hypothetical situation that the medical power of attorney could not be reached for further instructions; but he did **NOT** consent to an overdose of sedatives or to comfort care. A change in status to DNR was made on October 13 at 10:56 without **ANY** consent. This change in status was likely responsible for the addition of lorazepam and morphine to the existing overdosage of Precedex administered following the order.

The patient had been doing reasonably well on October 13 at 9:00 AM. CXR on the morning of death showed no significant progression of pulmonary disease. It is my opinion, to a reasonable degree of medical certainty, that the deterioration in clinical status after this time, and subsequent death of the patient, was more likely than not caused by the third and deliberate overdosage of Precedex compounded by too rapid administration of lorazepam, and morphine. When presented with a rapid deterioration of clinical status, Dr. Shokar failed to reverse the effects of the morphine, failed to reverse the effects of the lorazepam, and failed to attempt any pharmaceutical resuscitation with norepinephrine, dopamine, and atropine that had worked previously following the second and deliberate overdosage with Precedex. These failures by Dr. Shokar were a breach of the medical standard of care and were the actual and proximate cause of the patient's death.

The above report reflects my knowledge of the case at the time of writing. Should new information become available, I reserve the right to amend this report.

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X _____

Gilbert Berdine
M.D.

12/06/2024

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