

Anesthesia Incident Reporting System (AIRS)

Case 2022-05: First, Do No Harm: But What Harm, and to Whom?

Case 1

A trauma patient from the emergency department showed up as a "surprise" to the operating room. No known history, shot multiple times in the head, chest, and abdomen; emergency thoracotomy in ED after arrest. In the OR, his end-tidal CO2 was 9 mmHg and he had no pulse. The surgeons put a rapid infusion catheter into his femoral vein and we began to resuscitate him. The patient was in and out of cardiac arrest during the entire procedure and required frequent doses of intra-cardiac epinephrine and defibrillation. The blood bank called to say that we had used up almost all of his blood type. Finding a "shredded IVC," the surgeons decided to pack and run to ICU with the rapid infuser running. He ended up receiving another 40 units in the ICU and died 6 hours later.

Case 2

A patient was brought to the operating room for profuse bleeding from everywhere. He had drowned in a lake where he had been submerged for hours before being rescued and resuscitated. Both pupils were fixed and dilated when the patient was brought to the operating room. The patient arrested several times and was declared dead, being in the operating room for about an hour. Nobody was sure why the patient was brought to the OR.

Case 3

We are in the middle of a gang war. Four patients with gunshot wounds showed up to the OR at once in the middle of the night. Fortunately, the OB floor was quiet, so they came over to help. Everybody was taken care of, but we were one emergency away from having to ration care.

hese cases highlight the incredibly difficult ethical dilemmas faced by our anesthesia teams on an ongoing basis and emphasize the timeliness of the recent Monitor articles on "Ethics in Challenging Times" (ASA Monitor 2022;86:24-5; ASA Monitor 2022;86:26; ASA Monitor 2022;86:27-8). While the ASA Guidelines for the Ethical Practice of Anesthesiology contain excellent tenets of professionalism, they do not specifically touch on the ethical dilemmas apparent in these cases (asahq.org/ standards-and-guidelines). The more comprehensive ASA Ethics Handbook, however, does have excellent chapters on specific scenarios such as massive transfusion and withdrawal of life-sustaining therapy and determination of futility, and should be available wherever we practice anesthesia (asahq.org/ about-asa/governance-and-committees/ asa-committees/committee-on-ethics).

Beauchamp and Childress first published their framework for medical ethics in The Principles of Biomedical Ethics in 1979 (The Principles of Biomedical Ethics. 1979). Although there are worthwhile criticisms of these principles, and other schools of thought (casuist, for one), this framework remains dominant in the practice and teaching of medical ethics. Their four core principles of medical ethics, as nicely summarized by Gillon, are autonomy (the right of a patient to determine what will happen to them); beneficence (medical care should provide net benefit); non-maleficence (reflected in the vow of all physicians to do no harm even as they attempt to treat); and justice (perhaps best thought of as fairness) (BMJ 1994;309:184-8).

These four principles are often termed "prima facie," meaning that each is binding unless it conflicts with another principle, in which case a choice has to be made between the conflicting principles. For physicians, the conflict most often arises between beneficence and non-maleficence: more simply, the risk-benefit of every medical treatment or procedure that we do. Gillon and others have indicated that beneficence and non-maleficence represent two sides of a coin and must be considered together. The risk/benefit question for anesthesiologists during routine care is typically simple - the benefit of general anesthesia for hip replacement against the possibility of death from anesthesia (perhaps as low as 1:200,000). Weighing the risk and benefit in the cases above is far more difficult and typically is done in the midst of frantic attempts to save the patient's life. We will return to this later.

There is also the consideration of whether the conflict in principles must be decided for a single individual alone or



whether we must apply them in the larger context of societal benefit. For all three cases, the concern of the reports appears to be whether the hospital had the resources to manage these patients and all of their other patients. Would resuscitation of the first patient empty the blood bank and put a different patient at risk?

During the COVID pandemic, all of us have faced the juxtaposition of individual autonomy and the larger public health framework - the broader right of the community to be healthy and to be safe. In this frame, governments consistently set restrictions on personal autonomy in order to achieve net benefit for the community. It has long been accepted that a patient with active tuberculosis is not permitted to go freely into the public with no regard for the danger to others – personal autonomy does not permit societal maleficence. We accept the fact that we cannot choose to drink and drive. Fortunately, most of the deliberations around COVID restrictions on autonomy are (and have been) done at a governmental level far above us. The difficulty of these decisions is reflected in the significant variation in limitations of personal freedom, with, for instance, New Zealand restricting all travel in and out of the country and mandating masks and shutdowns of restaurants, sporting events, and so on, and Sweden setting no restrictions whatsoever. Again, our focus in this discussion is not on these larger societal questions (mask and vaccine mandates), but on those we face late in the night in a single OR, with little support for what can be agonizing decision-making.

For most of the cases that we face on a day-to-day basis, such as the first two cases, we can come to resolution by focusing on the patient in front of us, and weighing one patient against the next may not be necessary. As noted above, beneficence and non-maleficence form the crux of the

> "risk-benefit" discussion we attempt daily in our informed consent process. Any endeavor to heal carries with it the very real possibility of harm by chance alone (unusual anatomy, equipment failures) or by human error, which catches us all unaware and thus is nearly impossible to discuss a priori with a patient. This ability to provide clear and direct discussion about benefit and risk for an individual patient requires extensive education and training - efforts that are often overlooked in our focus on scientific facts and clinical skills. This conundrum – how to provide appropriate

discussion around risks and benefits - deserves far more discussion and education in the calm setting of elective surgery, and even more practice and consideration in crisis scenarios (Medication Safety during Anesthesia and the Perioperative Period. 2021). And in the first two cases, there is the additional difficulty that there was no opportunity to talk to the patient and to understand any preferences they might have had. While consideration of "net benefit" for the patient should guide the decision-making, it can be difficult to do while still running the rapid infuser.

As Gillon makes clear, to offer net benefit "we must respect the patient's autonomy, for what constitutes benefit for one patient may be harm for another." Thus, for one person, being intubated and ventilated and having several trips to the OR with many blood products in the setting of irreversible neurological injury would constitute harm. The possibility of surviving a drowning to spend the next 10 or 20 years in a vegetive coma with the attendant decubiti and no meaningful interaction with loved ones may be viewed as a nightmare to one, while another patient may cling to the "woman awakens from a 10year coma" possibility. Individual patient and familial preferences may also include significant cultural and religious considerations, such as the Jewish and Muslim prohibition against discontinuing ventilation. Neither of the first two reports mention any discussions with the family about patients' known wishes or a discussion of the probable futility.

As stated above, these two cases, and most cases in the OR, can be approached without invoking societal harm - the focus can be solely on the patient in question, i.e., "is the patient likely to obtain any benefit from further interventions?" If the patient is unlikely to benefit, then continuing treatment begins to represent harm; this seems to be at the heart of the first two cases. Treatment without possibility of benefit runs counter to our vow of "primum non nocere." The problem, of course, is knowing how to and when to ask this question or how to slow surgeons who are continuing what appear to be futile efforts.

Most of us who find ourselves deep into a massive transfusion protocol find it difficult to rationally consider this patient's likelihood of survival (the concept of futility), and it is here that we have work to do. The practicalities of knowing how to call a stop, and who should be involved in that decision, are currently not clear and are rarely discussed. Should we consider that, in one of these difficult scenarios,

there is one senior individual who is assigned to "run the code," who does not check blood, hang saline, or push epinephrine, but who stands back, observes, and who can have the time to consider "net benefit" and when we have reached futility? In the throes of a frantic effort to normalize the TEG, it is very difficult to take the time to determine when futility has been reached. And even if we were to have such a practice (one individual to observe and make decisions), that individual would have little or no guidance or data on which to base such a decision.

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We have detailed decision trees on managing anemia or a difficult airway but very few for difficult ethical choices. In truth, protocols and algorithms do exist in a few cases to guide decision-making by considering futility. The BLS termination of resuscitation (TOR) rule for out-of-hospital non-traumatic cardiac arrest, or the 2010 AHA guidelines that recommend TOR after three full rounds of CPR, are based on extensive data on the likelihood of survivability after cardiac arrest. When the BLS TOR criteria are met, there is a 99.5% likelihood of death. Although it would seem logical to stop when there is less than a one in 100 chance of survival. there remains variability, with some countries (the U.S.) focused on a culture of "survival at all costs."

Not only are there few protocols to guide futility decisions, those that do exist speak primarily to out-of-hospital resuscitation and not to in-hospital decisions. This seems more a matter of choice than need: We have vast troves of data on what variables predict atrial fibrillation after cardiac surgery but few analyses of who lives or dies in massive transfusion. We need to work toward having easily available algorithms that predict futility in massive transfusion cases, in-hospital cardiac arrest, neurological injury, and drowning. Such algorithms could be accessed quickly and discussed with a patient's family, both to guide our teams and to provide better information and comfort to the families. We need to do this work before a crisis, as once we enter the fray, we need solid data to guide us rather than subjective opinions. At the present time, there are few risk calculators that predict survivability for these cases. It would be of great utility to have a risk calculator like the American College of Surgeons' NSQIP (asamonitor.pub/3vCwkQ4). By inputting 15-20 variables, one can generate a patient-specific risk of mortality, the need for transitional care after surgery, and the likelihood of any complication.

It may be possible for individual hospitals to review their own data and make conscientious decisions about futility. Early in the TAVR program, the team at one of the authors' hospitals reviewed their deaths and found they could define what was a survivable complication (embolization of a valve) and what was not (rupture of the aortic annulus), at least in the elderly population of that time. This real data allowed them to have better discussions with patients and families, allowed the freedom to not set up a cardiac surgery back table or pump (all survivable events were hemodynamically stable so OR set-up could be done as needed, while the non-survivors were catastrophically unstable), and offered some comfort to the teams who met one of these complications. We do not have readily accessible data to guide us in emergent situations in the OR, which is when we really need it. Providing some guidance developed in calm and rational times will save agonizing decisions in the OR and save teams the aftermath of questioning their actions.

We should briefly touch on the utility of a hospital medical ethics committee. Medical ethics consults are available in most hospitals, with an ethicist on call. However, this service is frequently available only 8-to-5 on weekdays. And this may be appropriate, for these experts do not make clinical judgements but rather help illuminate the ethical questions for the care team to consider. It always remains to the clinical team, in discussions with the patient or the family, to determine either futility or that the risk of harm exceeds what the patient or their family would have wanted.

In closing, the primary purpose in such discussions has been to advocate for better education and training in ethical dilemmas and for better tools to use in evaluating futility. Training, like simulation of anesthetic crises, can help each of us and our teams develop decision trees or algorithms that can be used in these cases. Much like that found in emergency manuals to facilitate clinical crisis management, we need decision trees that help us define when futility has been reached (asamonitor.pub/3IHJxe2). Multidisciplinary committees at every hospital should meet and provide at least basic guidance as to when further treatment would likely be futile (at 100 units of blood? 200? Difference if patient is 25 or 95?). More empiric data is needed to guide "evidence-based" decision-making. For example, scientists could access and analyze available national data to guide the development of a "futility" calculator. The resources we pour into futile care are enormous and can rarely be justified within the principle of beneficence (JAMA Intern Med 2013;173:1887-94). Spending these resources on a patient unlikely to survive raises the question of justice – we cannot distribute resources fairly if we empty the blood bank for a patient who would survive only with a 'miracle." This question is beyond the scope of this discussion, but it arises frequently.

We need to provide better information for our patients' families, we need to be cognizant of the potential to cause harm to our patient, AND we need to understand how our patient would view that harm. We also need to reduce the amount we spend on futile care, and we need to reassure our teams in the midst of the fray that it was not their failure, that they could not have done more, and that it is ethical to stop when a patient has virtually no chance of survival.

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