CASES

FOR THE

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Case 1:

One major difference between an acute care hospital and an acute inpatient rehabilitation (AIR) facility is the level of treatment available to patients. Like an acute care hospital, an AIR is staffed by physicians (called physiatrists), nurses, and other health care professionals. Yet, as one physiatrist wrote, "some of us treat patients in free-standing rehabilitation hospitals where not all medical interventions can be performed safely as a result of the unavailability of certain medical supplies or medications, lack of specialized training of staff, a low staff to patient ratio, and, in some circumstances, insufficient physician training and experience with specific medical interventions"[1].

At one freestanding AIR, potential medical emergencies are handled by paging an on-call team of a resident physician, nursing team, and respiratory therapist. Given the limits of treatment noted above, if deemed necessary by the resident physician due to a patient's deteriorating status, an ambulance is called to transport the patient to an emergency department for more intensive medical care.

Mrs. Mayberry is a 78-year old woman who was admitted to the AIR for physical therapy and speech therapy following a stroke. The stroke has resulted in an expressive aphasia, which in this case means that Mrs. Mayberry is largely unable to produce the words she is searching for, though neurological testing suggests that her comprehension remains intact. Upon admission, a do not attempt resuscitation order was discussed with Mrs. Mayberry and her daughter, who was at the bedside. When the physiatrist asked Mrs. Mayberry if she wanted resuscitation attempted in case of cardiopulmonary arrest, she nodded her head "Yes." Her daughter, in affirmation, said "Mom always said she wanted to live until she was 100, so I can see why she would want this." Furthermore, Mrs. Mayberry's daughter presented a Power of Attorney for Health Care that Mrs. Mayberry completed a few years prior, stating that in regard to life-sustaining treatment, she would want her life prolonged as much as possible, regardless of her condition.

A week later, Mrs. Mayberry was participating in physical therapy when her breathing became labored. The physical therapist called the on-call team, who took Mrs. Mayberry's vital signs. Of note, her blood pressure had dropped dangerously low. A common treatment to correct this would be the administration of drugs called vasopressors, which would require transferring Mrs. Mayberry to the emergency department. When informed she needed to be transferred, Mrs. Mayberry vehemently shook her head "No." Even as the physiatrist explained to Mrs. Mayberry that if her blood pressure continued to drop, her heart could stop, she continued to shake her head, seemingly refusing the transfer. However, due to her aphasia, Mrs. Mayberry is unable to explain why she is refusing.

<u>Questions:</u>

1. Should the physiatrist transfer Mrs. Mayberry to the ED in spite of her refusal? Why or why not?

2. Suppose that Mrs. Mayberry continues to refuse the transfer, up until the point that she loses consciousness, at which point she can no longer refuse transfer (or anything else, for that matter). What should the physiatrist do at that point?

3. When, if ever, should past wishes override present expressions of preferences?

References:

1. Sawicki NN, Brenner JM, Kessler A, Tarsney PS, Mukherjee D. 2016. "Ethical, Legal, and Medical Challenges When a Patient Refuses a Transfer From Rehabilitation to Acute Medical Services." *PM&R: The journal of injury, function and rehabilitation* 8(7): 690-7.

Case 2:

In some states, including Utah, if a person lacks the capacity to make decisions about her medical care *and* declined to appoint a power of attorney for health care before losing capacity for decision making, then state law appoints a surrogate decision maker for that patient. The surrogate decision maker is appointed using a rank order of priority, as determined by the state legislature. In Utah, for example, the order is: spouse, children, parents, siblings, grandchildren, grandparents. Interestingly, even if a person lacks the capacity to name a power of attorney, state law still allows her to disqualify a surrogate decision maker.

Robert Denby is a 29-year old man who was in a car accident approximately six weeks ago. Of note, he suffered extensive injuries to the right side of his body, and also received a mild brain injury. After spending a few weeks in the hospital to stabilize his injuries, Robert was transferred to an acute inpatient rehabilitation (AIR) hospital for continued medical care while he worked on physical, occupational, and speech therapies. Though it is clear that Robert is a willing participant in his admission to and therapies at the AIR, and is able to converse with others, the medical team does not believe that Robert fully understands his medical condition. For example, even after being told about his injuries, Robert will still attempt to get up out of his wheelchair by himself and place weight on his right leg. Though his brain injury will probably improve, the team does not think Robert currently has capacity for making complex medical decisions.

Robert's parents have been a constant presence at the AIR since he was admitted. Both Robert and his parents have acknowledged to the team that they have not been close—barely spoken to each other, even—for the better part of a decade. But while in the AIR, they have been attentive to Robert's needs, and have been trained by the staff on many aspects of how to safely care for him, like how to transfer him from bed to wheelchair. Robert and his parents seem to be getting along well enough, and Robert has never said anything to the team about not wanting his parents at the AIR.

One of Robert's other visitors, Ben, comes to the AIR infrequently, and doesn't stay very long if Robert's parents are around. Robert has confided with the team that Ben is actually his long-time partner, but has never told his parents. Robert believes that his parents would not approve of the relationship, which is the main reason he cut off contact with them almost ten years ago, and also is why Robert and Ben haven't gotten married.

It is nearing Robert's planned discharge date, and the team needs to figure out where Robert is going after the AIR. Ben wants Robert to return to their home, stating that a comfortable and familiar environment would help Robert recover, and privately Robert agrees that he would prefer this plan. Robert's parents, however, expect that Robert will discharge to their home, and Robert doesn't raise objections when they talk in terms of that discharge plan. Given that his parents have been trained in how to care for Robert, and can provide more constant supervision (they are retired while Ben works), the team feels that this is the safest discharge plan. But Ben knows Robert best, and has been by his side for the past decade, not his parents. His parents, however, are Robert's surrogate decision makers under the law. Though Robert is unable to make this complex medical decision for himself, the team thinks he has the capacity to name a

power of attorney for health care, and could name Ben, who then could decide the discharge plan. When asked if he wants to do that, however, Robert shakes his head and says, “I can’t do that to my parents. I might need them.”

Questions:

1. Where should Robert discharge to? Why?

2. What features of this case are most ethically relevant to its resolution? Are any features ethically irrelevant?

3. Does the medical team have a responsibility to disclose to Robert’s parents what he has said he prefers? Why or why not?

References:

http://le.utah.gov/xcode/Title75/Chapter2A/75-2a-S108.html

Case 3:

According to 45 CFR 46.116, which requires a researcher to obtain the informed consent of any research participant or his or her legally authorized representative, "information given to the subject shall be in language which is understandable to the subject.…" For individuals who are not native speakers of English, and therefore might be at risk for exploitation in research, the U.S. Office of Human Research Protections (OHRP) permits informed consent to be obtained by oral presentation and use of a short written consent form in the native language of a potential research participant.

By government mandate, the Institutional Review Board (IRB) is responsible for providing continual oversight for the protection of human participants in research, ensuring compliance with applicable regulations, laws, and policies. An IRB may additionally stipulate that informed consent materials be given to research participants in their native language "when the information would meaningfully add to the protection of the rights and welfare of participants."

The patient population at an academic medical center is approximately 20% Spanish-speaking. Leadership is contemplating whether to make it policy that some or all studies should be required to have the capacity to enroll participants whose primary language is Spanish. This would ensure that all patients have access to potentially beneficial experimental treatments. However, leadership anticipates some pushback from investigators due to the extra time and resources it will take to prepare Spanish-language informed consent materials and data collection instruments.

Questions:

1. What are the arguments for and against requiring investigators to have the appropriate materials and staff to enroll Spanish speaking participants?

2. What criteria should guide the IRB in determining which studies must have the capacity to enroll Spanish-speaking participants?

3. Morally speaking, under what circumstances may informed consent be obtained by oral presentation?

References:

OHRP. Informed consent of subjects who do not speak English, 1995. Available at: http://www.hhs.gov/ohrp/regulations-and-policy/guidance/obtaining-and-documenting-infomed-consent-non-english-speakers/index.htm

Mastroianni A, Kahn J. Swinging the pendulum. Shifting views of justice in human subjects research. Hastings Cent Rep, 2001;31:21–8.

Code of Federal Regulations. 45 CFR 46, Subpart A. Basic HHS Policy for Protection of Human Research Subjects.
http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

Case 4:

Phase I clinical trials are research studies that evaluate new drugs for safety in healthy human volunteers. All trial phases are required in the process of getting a drug to market.

The typical research subject is male, and there is evidence to suggest that many individuals who participate in Phase I trials lack regular employment and that many participate in multiple sequential studies. Often, volunteers are exposed to substances for which the side effects have yet to be ascertained. They undergo constant monitoring of body function, may be subjected to extreme diets and/or activity regimens, and may develop potentially adverse or even, in rare cases, fatal complications from a protocol regimen. Frequently, Phase I volunteers are required to reside in a clinical research center (on the campus of a pharmaceutical company or university) over the entire course of a study. Payment for such studies varies, depending upon the number of visits and whether or not participants are required to stay on site. For example, a six-week blood pressure medication study can pay $500-1000. Meanwhile, a six-month diabetes control medication study can pay up to $10,000.

Many people, thinking idealistically, consider such participation in Phase I trials to be a noble act. However, the ethical justification of enrolling healthy human volunteers in these clinical trials is still being debated. At best, appeals to autonomy are complicated by the fact that, while participants in Phase I studies are *volitionally* consenting, these studies may require them to ingest substances that are potentially toxic and may ultimately be fatal to them.

There has been much debate in the bioethics literature regarding appropriate payment models and amounts for healthy volunteers. Three potential models of payment are the market model, the wage-payment model, and the reimbursement model. The market model operates according to the principle of supply and demand. In this model, the market regulates if and how much subjects should be paid for participating in a specific study. Meanwhile, the egalitarian wage-payment model works according to the premise that participation in research requires minimal skill. Yet, because research participation requires time, effort, and enduring uncomfortable or undesirable procedures, this model suggests that participants who perform similar functions should be paid similar wages to unskilled laborers (for example, minimum wage). Finally, the reimbursement model articulates another distinct form of egalitarianism. It is based on the position that research participation requires only minimal skill and therefore participants should only be reimbursed for expenses incurred, not for inconvenience, pain, or suffering.

Some have argued for classifying Phase I research study participation as a job; however, this poses a dilemma. While the Social Security Administration (SSA) classifies compensated participation in a research study as a job (that is, as taxable income), this potentially excludes participants from being eligible for various social benefits should their annual income exceed a certain amount. Furthermore, FICA deductions are not withheld from research payments and

thus, healthy research participants in Phase I trials do not earn credits toward disability and retirement benefits on their SSA work records. Indeed, participants are not able to claim disability benefits in the event of serious adverse effects because SSA does not consider such effects as work-related disability.

There is currently vigorous debate about whether labor protections should be afforded to healthy research volunteers in Phase I trials. According to one analysis, if human research volunteers were to be considered as workers, they would have rights to be paid at least minimum wage for a 40-hour work week, FICA deductions, overtime and holiday pay, guaranteed safety in the workplace, workers' compensation for work-related injuries, and organization into a unionized workforce.

Questions:

1. What (if any) is the ethical justification for using healthy volunteers as research participants?

2. Discuss various ways to prevent exploitation in healthy research volunteers. Should they be classified and treated as unionized employees with all incumbent rights and benefits appertaining? Why or why not?

3. What is the morally appropriate payment model for healthy volunteers?

References:

Dickert N, Grady C. What's the price of a research subject? Approaches to payment for research participation. N Engl J Med. 1999 Jul 15;341(3):198-203.

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Case 5:

A medium-sized for-profit hospital considers purchasing a life support machine for its intensive care unit. Extracorporeal life support (ECLS) externally provides both cardiac and respiratory support to maintain an adequate amount of exchange of oxygen and carbon dioxide to sustain life. ECLS works by intravenously removing blood from the patient and artificially removing the carbon dioxide and oxygenating red blood cells. Generally, it is used solely as a life-sustaining intervention for patients with heart and lung failure.

Hospitals face pressure to purchase and maintain such machines in order to keep up with the state of the art in medicine and compete in the marketplace. Administrators implicitly and in some cases explicitly pressure clinicians to diagnose and treat patients in ways that ensure the hospital optimizes the cost-benefit trade-off that is associated with such expensive machine**s**.

Hospitals have to justify costs and expenditures incurred with such equipment, preferably by offsetting revenues. These costs include initial purchase and installation, operations, maintenance, upkeep, and so forth. In addition, there are direct and indirect costs associated with maintaining patients on such machines. These costs are often difficult to justify, even if government funding for prolonged care is available. Such prolonging of biological life is often considered as futile care. Recent high profile cases poignantly illustrate these problems.

Questions:

1. How should a hospital balance obligations to patient care against the need to remain financially solvent and viable?

2. When might it be ethically justified to keep a patient on a machine that maintains heart and lung function after they have been declared brain dead? Why?

3. Who should bear the burden of costs for very expensive hospital machinery, assuming that the costs exceed what nearly all of the people who utilize it can afford?

References:

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effectively expands the donor pool. The Journal of Trauma, 2005; 58(6):1095–1101.

Case 6:

Alissa Bowden calls me from her car, driving into work after her early morning OB appointment. She is six months pregnant with her first child, and six weeks into her position as the newest palliative care physician at the hospital. I've only had one brief conversation with her before – a "drive-by" ethics question about surrogate hierarchies – so we don't really know each other yet. Alissa's phone call, from her morning commute, is not a drive-by.

"Hi, I'm not sure if you remember me. I'm Alissa, the new palliative care doctor. Oh, you do remember! Great! Sorry to call so early…Julia, our social worker, gave me your cell phone and said you might be able to help."

"We have this patient that our team just picked up yesterday – Ms. Elliott, up in the Neuro-ICU. We got consulted for transition to in-patient hospice and symptom management – the son, Bill, her surrogate, has decided to withdraw life support because it wouldn't be acceptable to her. She's a Christian Scientist, which I don't know much about except that they avoid medical care and rely on faith for healing. So, I'm not worried about the withdrawal – I mean, it makes sense: she had an anoxic brain injury after a cardiac arrest at home. She was on the phone with a friend late at night and stopped talking and the friend called 911, so she was coded in the field and intubated and brought here – after being down about 25 minutes, from what I was told. They cooled her and rewarmed her, but she's been in *status epilepticus* with no neurologic recovery for the past two weeks, so the son is saying she wouldn't want life support, that it's against her religion. And he wants it done today. What I'm having a hard time with is that he's saying he not only wants the ventilator removed, but he wants all medications stopped and nothing else given because medications are also not allowed in their religion. She's on four anti-epileptics and I'm afraid her seizures will be even worse if I stop them; and though she's not on any pain meds, she's been intubated for two weeks, so I'm worried about secretions and dyspnea after we extubate her. Oh, and he also wants to take her out of here immediately after extubation – he wants her to go to a Christian Science healing center and wants to know if I will *allow* him to take her by non-medical transport -- I don't even know what that means! She's been vent dependent for two weeks, and seizing. How are they going to sit her up in a car? I don't even know if that's legal or if he'd have to go against medical advice, or what. Anyway, I'm just really uncomfortable with the idea of stopping all medications and extubating her and then not being able to provide comfort measures. I mean, I know a surrogate can refuse any medical interventions for a patient, but professionally, especially working in palliative care, I have a really hard time with this because I'm afraid she's going to suffer and I won't be able to do anything. So, I just don't know what to do and I'm hoping you can help."

<u>Questions:</u>

1.As the clinical ethics consultant in this case, talking to Dr. Bowden during her morning commute, how do you respond to her request for help?

2. What stands out as needing attention, and why?

3. What questions do you need to pursue, and with whom, as you respond to Dr. Bowden?

Case 7:

It's Friday afternoon when I almost run him down, coming off the elevator in the critical care tower, with my face glued to my phone. I feel terrible for a moment, until I realize he'd been walking-while-texting as well, and is equally embarrassed. In the awkwardly overlapping apologies and reassurances, we recognize each other as colleagues, rather than strangers, which only makes the near-collision slightly less ridiculous.

"Hey Andrew! I've been meaning to run into you, just not literally. How are things going with Mr. Kuznetsov and his family? I saw he finally got the PEG tube placed on Wednesday – that the family consented, after all those delays and postponements. And today's the last day of antibiotics, right?"

Andrew Darby is teaching faculty in internal medicine, and we've developed a good rapport over the years from when he and his ward teams have made consultation requests. Andrew's team had requested an ethics consultation earlier this week regarding Mr. Kuznetsov, an 83-year-old man with advanced dementia and multiple medical problems, who has had a long and complicated hospital course. The team requested Ethics "to assist the team in dealing with Mr. Kuznetsov's family," who were simultaneously "refusing" and "dictating" care.

Per the team's account, the family has refused to accept the diagnosis of advanced dementia and they insist that Mr. Kuznetsov's altered mental status (AMS) is due to meningitis, for which they have demanded high-potency antibiotics (despite a clean lumbar puncture from when he first arrived, almost a month ago). Since admission, his already altered mental status worsened dramatically when he had a PEA arrest on the wards, with a complicated intubation and likely anoxic injury. The team explains that after two and a half weeks in the ICU, Mr. Kuznetsov has returned to the wards with a tracheostomy for airway protection. He has been minimally responsive for almost a month now, and is in need of a PEG for long-term nutrition. On Monday, the team had wanted to place the PEG, because the NG-tube had been in for 21 days, which they felt was too long and far outside the standard of care. Plus, they couldn't transfer Mr. Kuznetsov to a skilled nursing facility or sub-acute facility until he had a PEG. The team also had wanted to stop the antibiotics they believe are no longer indicated (and to do so despite the family protests), or at least get another lumbar puncture to prove Mr. Kuznetsov's AMS was not from meningitis (and to gather more evidence for stopping the antibiotics in the face of family protest).

I had asked questions and talked strategy with Andrew and his residents, and Andrew decided he and his senior resident, along with the Infectious Disease consultant, would "take one more crack at talking with the surrogate before we have to get some big family meeting together." By the end of that afternoon, the chart showed a plan reflecting the conversation with the three physicians and Mr. Kuznetsov's son and daughter. Mr. Kuznetsov would have a PEG tube placed the following day, and the team would continue antibiotics for another 3 days – until Friday – at which point Mr. Kuznetsov would have completed a 14 day course of vancomycin and cefipeme, the standard of care for meningitis (though, as was clear in the team's notes, they did not have solid evidence of meningitis). The plan appeared to be the result of a negotiation, with the team temporarily ceding ground on what they felt was the less critical issue of

inappropriate antibiotics in their effort to have the PEG placed.

Between Tuesday and today, I had watched the chart and noted that Mr. Kuznetsov did get his PEG placed with no complications, and that the residents' notes were counting down until the last day of antibiotics, so I was a bit surprised when my question to Andrew yielded a grimace of annoyance and sheepishness, and a burst of impassioned speech:

"Yeah. I guess. I mean, I'm kind of in a quandary about that. Of course, the plan is to stop today. But the family cornered my resident this morning and is continuing to insist that Mr. K still needs the antibiotics, that it's too early to stop because he's still having slight fevers and he's still non-responsive. They told the resident this was our fault he was like this after the arrest and we couldn't just stop treating him. That's totally not true, but now I have to go back and talk with them and decide if it's worth the fight or not. Am I going to discontinue the antibiotics, which *are not indicated – there is NO evidence* of infection at this time… *but* he's got the PEG, he's going to be discharged in, like, three days, and is it *really* worth it to fight with these people? I mean, I know it's not like the antibiotics are benign – we know there are risks to him! Not to mention the global issue of resistant organisms! But are they *really* going to cause that much harm over the next three days? I'm not really looking for an answer from Ethics – I mean I know what the right answer is, kind of. But then there's the medico-legal concerns – I mean this is the kind of family that *will* sue – probably will no matter what we do, but still! I don't want to have to deal with that. Oh, and of course it's a long weekend, so my colleague Jim is covering – and you know what he's like. As much as I'm dreading fighting with the family, if I don't stop the antibiotics like we said we would, then I have to explain to Jim that I'm leaving him with a plan for a totally unnecessary intervention and a demanding, outrageous family who thinks they can get whatever they demand, and I can just imagine the look he's going to give me. And then there's the worry – ok, say I let them get away with this demand – like they've been able to get their way with so many already – but what if something happens and he gets worse and isn't getting discharged in three days? Have I set myself or my team up for an even worse fight if he crumps in the next 72 hours? It's just a mess. Anyway, I'm not looking for Ethics to do anything– I'm just venting. I know there's not a right or a wrong thing to do here…"

<u>Questions:</u>

1. As the Clinical Ethics Consultant who has been following this situation for almost a week, how do you respond to what Andrew is now sharing?

2. What issues emerge out of his complex report that need to be addressed, in what ways might you do so, and why do you chose these methods of addressing them?

3. What is the morally appropriate thing for Andrew to do?

Case 8:

A 32-year-old male is admitted to the hospital with pneumonia. Upon further investigation, the patient is diagnosed with HIV. He has never been diagnosed with HIV before. He is predicted to have a good chance of managing and living with his HIV infection if he continues to get regular medical treatment.

Each day the patient's wife visits the patient, and offers her support. As far as she knows, the patient is only being treated for pneumonia; she is unaware that the patient has been diagnosed with HIV. The patient and his wife do not have any children.

Several days into the patient's hospital admission, the patient's attending physician asks him if he is going to tell his wife about his HIV infection. The patient simply says "No!" without further explanation, and will not provide any more explanation upon additional questioning.

The physician is deeply distressed by the patient's refusal to notify his spouse about his HIV infection, and uncertain about what to do next.

This particular physician is especially struggling with what to do because a year ago, in a similar situation, she chose to notify a patient's sexual partner about the patient's HIV infection without the patient's permission. A few days after the patient was discharged from the hospital, the physician learned from a medical colleague that the patient's sexual partner had subsequently physically beaten the patient and left her seriously injured and alone. The physician remains haunted by that case and the consequences that resulted from her actions.

Questions:

1. If the physician cannot persuade the patient to voluntarily disclose his HIV status, should the physician disclose the patient's HIV status to the patient's wife without the patient's permission?

2. The hospital would like to develop a general policy about disclosure of HIV status to a patient's sexual partner(s) in order to better address situations like this case in the future. What position and approach to disclosure should the hospital take in the policy? What is your rationale?

3. If the physician chooses to disclose the patient's HIV status to the patient's wife without the patient's permission, what advice and recommendations would you give to the physician about how to engage in a good disclosure process? What is your justification for your various recommendations?

Case 9:

Mr. Blue is a 48-year-old person without reliable shelter. He largely keeps to himself; sometimes he stays at local homeless shelters, and other times he sleeps in a local park. He is a familiar face to the local hospital emergency department staff. Sometimes Mr. Blue is in the Emergency Department for some form of basic medical treatment every other week.

One day, Mr. Blue is found unconscious in the local park and rushed to the hospital, where he is found to have suffered a severe stroke. Mr. Blue is emergently intubated and placed on a ventilator in the hospital Intensive Care Unit (ICU). A hospital social worker is tasked with locating family members of Mr. Blue to serve as his surrogate decision-maker while he is unable to make decisions for himself.

Seven days pass, during which time Mr. Blue remains unconscious. The consulting neurologist estimates that Mr. Blue has a 40% chance of surviving to discharge from the hospital. If Mr. Blue survives, he will likely have severe cognitive, language, and motor impairments, and may require ongoing ventilator support for an indefinite period of time. Mr. Blue will likely have little or no ability to interact with other persons.

In the meantime, the hospital social worker has mobilized considerable resources to locate family members of Mr. Blue, including hiring a private investigator, but these efforts have been unsuccessful. Even efforts to locate friends of Mr. Blue have been unsuccessful, and Mr. Blue does not appear to have ever completed a health care advance directive. Mr. Blue is without any living family members or friends to serve as his surrogate decision-maker.

By Day 13, the attending physician is not optimistic that Mr. Blue will be able to be extubated anytime soon, and she would like to proceed with a tracheostomy to better meet the patient's long-term ventilator needs and to avoid complications that can result from prolonged endotracheal intubation. This is not an emergency procedure, but there is some urgency in order to avoid complications that can arise from prolonged endotracheal intubation. As a result, the tracheostomy procedure requires consent from either the patient or a surrogate decision maker. However, Mr. Blue remains unconscious, and no surrogate decision maker has been located for him. Additionally, due to various obstacles with local government agencies, it will be at least one month, and potentially longer, before the hospital can obtain a guardian for Mr. Blue, who could then serve as Mr. Blue's surrogate decision-maker. Also, the local laws are silent about how to address issues of medical consent and decision-making for patients that lack a surrogate decision-maker.

On Day 15, no decision has been made yet about the tracheostomy procedure. Additionally, the patient shows some signs of heart failure, and the patient is now at increased risk of suffering a cardiac arrest. Typically, at this point, the attending physician would discuss the patient's code status with the patient or a surrogate decision-maker, and consider whether to implement a Do Not Attempt Resuscitation Order (DNAR). However, there is no one available to consent to a DNAR order for Mr. Blue.

The next day, two Emergency Department nurses (Nurse Green and Nurse Red) are transferred and join the ICU medical team on a permanent basis. Upon seeing Mr. Blue in the ICU, each nurse remembers him from his frequent visits to the Emergency Department. Nurse Red remarked to the patient's attending physician that she once heard Mr. Blue comment that he (Mr. Blue) would never want to be on a ventilator for a long period of time, and he would prefer that he be allowed to die if things came to that. Later that day, Nurse Green remarked to the patient's attending that she once heard Mr. Blue say that life is an amazing gift, and he (Mr. Blue) would do whatever it takes to fight to stay alive.

As the medical team struggles to figure out how best to make decisions for this patient, one member of the medical team observes that the hospital does have a full time clinical ethicist and also an ethics committee.

Questions:

1. Who should make health care decisions for Mr. Blue? What is your justification?

2. How should different types of decisions about medical treatment (e.g. about a tracheostomy, or a DNAR order, or withdrawing life-sustaining treatment) be addressed when there is no available surrogate decision-maker? Explain your reasoning.

3. In order to better address situations like this in the future, the hospital would like to develop a general policy about decision-making for patients who lack surrogate decision-makers. What approach to this issue should the hospital take? What is your rationale?

Case 10:

In October 2016, the organization Doctors Without Borders turned down donation from Pfizer of one million doses of PCV13, marketed as Prevnar 13. This vaccine innoculates against a normally fatal pneumonia. Worldwide, 1.4 million children a year die from this disease.

Prevnar 13 has been available since 2009. Pfizer has copyrights on the vaccine, as well as several on the processes used to produce the vaccine. Currently, only two companies manufacture the vaccine, Pfizer and GlaxoSmithKline (GSK). Doctors Without Borders has been interested in the vaccine since its release, but the price of the vaccine has always been too high to acquire the vaccine without donation.

The decision to turn down the vaccine did not come easy, according to Jason Cone, the Executive Director of Doctors Without Borders in the United States. While the donated vaccines would be useful, Cone explains that these are, "often used as a way to make others 'pay up.' By giving the pneumonia vaccine away for free, pharmaceutical corporations can use this as justification for why prices remain high for others, including other humanitarian organizations and developing countries that also can't afford the vaccine." In a blog post, Cone explained that companies that donate vaccines restrict how the vaccines may be used. Moreover, the continued donation of vaccines crucial to the on-going success of governmental and non-governmental vaccination programs depends entirely on companies offering donations. Cone writes of the crisis being faced in Uganda currently. Despite Pfizer's commitment to the donation of Diflucan to Uganda, the nation is experiencing a shortage of the vaccine. This vaccine prevents against cryptococcal meningitis, which causes 625,000 deaths a year worldwide.

Instead of free Prevnar 13, Doctors Without Borders wants Pfizer to reduce the price of the vaccine so that they may purchase the vaccine when it is needed. A similar request and months of petitioning led GSK to lower the cost of the 3 shot series to less than $10 for humanitarian organizations. While Pfizer has publically committed to give up to 740 million of the vaccines at a discounted rate to Global Alliance for Vaccines and Immunization (GAVI) through 2025, it has refused to offer lower pricing to NGOs.

This might make good business sense, however, and this business sense might ultimately be a boon for vaccine production and creation.. Vaccine development is expensive and historically the profit margin on vaccines has been quite low. Several decades ago, many pharmaceutical companies abandoned their vaccine divisions because there was not much profit to be made and many were losing money. The increase in the cost of vaccines over the past few years has brought an increase in profits for pharmaceutical companies, but it has also brought with it more investment in vaccine development. Moreover, even though profits have gone up, vaccine sales still only account for 2-3% of pharmaceutical company profits. Some economists argue that even with vaccines produced by pharmaceutical companies who have managed to make vaccine production profitable, lower prices on these vaccines have caused shortages in the US market.

<u>Questions:</u>

1. Is Doctors Without Borders morally justified in refusing the vaccines?

2. Is Pfizer acting morally commendably by offering this donation? What information is necessary to make that judgment?

3. How far do the social responsibilities of a business extend? Are a drug company's responsibilities different than another type of business' responsibilities?

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Case 11:

Americans have what many medical professionals would consider a weight problem. According to the National Institute of Diabetes and Digestive and Kidney Diseases, more than two in three American adults are overweight or obese, and over one in three is obese. Given these statistics, it would seem that discussion of weight related issues with patients should be a priority for doctors.

Some doctors, however, reject this as a priority. Dr. Elisabeth Poorman, a primary care physician in Massachusetts, explains that she has stopped telling her patients to lose weight. Poorman based her decision on her experience with a patient who she told to lose weight and sent to a nutritionist. Months later, the patient came back having lost a small amount of weight, but complaining of being dizzy and having a racing heart. The patient admitted to using weight loss drugs. "Since then, I have worried that telling patients to lose weight is harming them. These conversations fail to acknowledge how rare weight-loss success is..." Even for those who do lose weight, Poorman continues, "my five minutes of counseling are no match for the toxic culture of weight loss, a culture so desperate that people spend billions of dollars on supplements that may contain speed."

Yet some studies indicate that conversations with doctors can have an impact on patient attempts at weight loss. A study presented in *Obesity Research & Clinical Practice* provides evidence that overweight or obese patients whose doctors explained to them that they were overweight or obese were, "significantly more likely to report a 5% weight loss in the past year." Another study conducted by researchers at Johns Hopkins indicates an obese person is likely to lose twice as much weight when they report feeling that their health care provider was "particularly supportive" of their weight loss goals.

While both of these studies indicate the importance of a doctor's role in a patient's initial weight loss, there remains a question of the viability of long term maintenance of weight loss. A review of 31 long-term studies involving tens of thousands of dieters indicated that within two years, over 80% of dieters had regained all of the weight they had lost. Some studies indicate that only 5% of people who lose weight will keep it off long term. Because of the unlikelihood of the long-term success of weight loss efforts, Dr. Arya Sharma, the chair of Obesity Research and Management at the University of Alberta, argues that doctors should be wary of advising their patients to lose weight. "A lot of our weight-loss recommendations are unethical because we shouldn't be saying lose weight when there is no chance people will keep it off." Moreover, there is conflicting evidence of the relationship about the relationship between health outcomes and being overweight or even mildly obese. Studies indicate lower mortality rates for those who are overweight and even mildly obese.

<u>Questions:</u>

1. Are Poorman and Sharma morally justified in their decisions not to talk with their patients about weight loss? Are they morally obligated to disclose that decision to their patients?

2. Are physicians morally obligated to talk with patients about health concerns in cases where the research on the issue is inconclusive?

3. Are physicians morally obligated to talk with patients about health concerns patients have very little chance of successfully addressing?

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Case 12:

A 14-year-old boy is being treated at a hospital for acute lymphoblastic leukemia. His treatment requires chemotherapy, as well as blood and platelet transfusions. Due to their drug abuse, his parents no longer have custody of him, so his aunt, a Jehovah's Witness, is his legal guardian. This boy shares his aunt's religious beliefs, which include a strict objection to receiving blood transfusions. His disease has progressed to the point that he is anemic and doctors fear he will die unless he receives a transfusion. His parents want him to receive the life-saving treatment, while his aunt does not. The state in which the hospital is located has mature minor laws, so a judge is called into the hospital to assess whether the boy is lucid enough to make decisions about his own medical care.

Questions:

1. What should the judge decide, and why?

2. Is the law the best channel for obtaining a decision in this instance?

3. Assuming the boy is lucid, should his medical decisions be left up to him? Why or why not?

Case 13:

In Afghanistan, the market for marijuana production is underdeveloped and has great potential to bring economic benefits to the country. In countries around the world, there is a legal market for marijuana, both as a recreational drug and for medical purposes. Afghanistan currently produces and exports enough opium to account for about a quarter of its GDP, according a recent United Nations (UN) report. By replacing opium with marijuana, the Afghan economy could improve significantly and export a far less harmful drug. However, if this change were to be made, the Afghani farmers would need outside support, most likely from the UN. This necessitates that the UN condone marijuana production and sales, which, although better than supplying materials for creating heroin, still has serious public health implications.

Questions:

1. Should the UN encourage the production, commercial sale, and exportation of Afghani marijuana?

2. Should the UN help fund the effort to have Afghani farmers switch from producing opium to producing marijuana?

3. Given the role that production of opium plays in Afghanistan's overall economy, is there anything morally objectionable about Afghani farmers producing opium?

Case 14:

In the year 2018, the H5N1 strain of flu, often known as avian influenza, undergoes a mutation so that it can pass readily from one human to another. This flu originates in a developing country where many people begin to fall ill very rapidly. Soon the World Health Organization (WHO) and health organizations across the globe are involved in controlling the outbreak and in attempting to understand the mechanics of the new virus and how to create a vaccine against it. However, the country in which the flu originates will not provide samples of the virus because they have not been guaranteed any sort of benefit sharing after they release this information. If a vaccine is formed, history has shown that only developed countries have been able to produce and purchase it in amounts sufficient to help their populations.

Questions:

1. Should the WHO force a developing country to share it's virus samples, even though that country will probably not have access to the vaccines that result?

2. Is there a way for pharmaceutical companies and research institutions in the developed world to patent discoveries related to the flu so that they can help people around the world, but still maintain benefits for themselves?

3. If the WHO forces developing countries to share their virus samples, is it obligated to ensure that these countries get a share in the benefits? Do such benefits include ensuring that citizens of such countries have affordable access to the vaccines created from the samples?

Case 15:

An American-based global health organization founded a campaign to combat malaria in a small Sub-Saharan African country. They found that the easiest way to effectively prevent their target populations from being exposed to the disease was by providing them with mosquito nets. To distribute the nets more easily and quickly, the organization provided teams that were already stationed in the country with enough nets to give their patient populations a few nets per family. Since these teams were already distributing medications and healthcare to their patients, the nets were distributed for free and as an addition to the regular packages of basic health supplies that the teams give out at their clinics. The organization conducted a study a year after the nets were distributed and found that compliance with using them was very low and thus malaria infection rates were hardly impacted. After some additional analysis of the data, they determined the most probable cause for people not using the nets was the fact that they were free. Since the people receiving the nets did not have to pay for them, they valued them less and thus were less likely to use them. The organization then decided to charge a small fee for nets at their clinics during the following year. There was outcry among humanitarian organizations in the United States because such a fundamental health necessity was now only available at a price. This hurt the organization's public image and caused many of their supporters to question their actions.

Questions:

1. Is it ethically acceptable to charge money for mosquito netting when dealing with a poor target population if it will increase effectiveness in combating malaria?

2. Who, if anyone, is morally responsible for the failure of people to utilize the nets?

3. What is the morally correct way to deal with the issue, and why?